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COMMISSION REGULATION (EU) .../...

of **XXX**

amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food [as regards...]

(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/EEC¹, and in particular Article 5(1)(a), (d), (e), (h), and (i), and Article 11(3),

Whereas:

- (1) Commission Regulation (EU) No 10/2011² ('the Regulation') lays down specific rules as regards plastic materials and articles intended to come into contact with foods.
- (2) Since the last amendment to the Regulation, the European Food Safety Authority ('the Authority') has published further reports on particular substances that may be used in food contact materials as well as on the permitted use of already authorised substances. In order to ensure that the Regulation reflects the most recent findings of the Authority, the Regulation should be amended.
- (3) The Authority adopted a favourable scientific opinion³ on the use of the substance (butadiene, styrene, methyl methacrylate, butyl acrylate) copolymer cross-linked with divinylbenzene or 1,3-butanediol dimethacrylate, with the FCM substance No 856, and with the CAS number 25101-28-4. The Authority concluded that the substance is not a safety concern for the consumer if used as a polymeric additive at up to 40% w/w in blends of styrene acrylonitrile copolymer (SAN) / poly(methyl methacrylate) (PMMA) repeat-use articles intended for contact at room temperature with aqueous, acidic and/or low alcoholic (< 20%) foodstuffs for less than 1 day and with dry foodstuffs for any duration of contact including long-term storage. The present authorisation of this additive should be extended to include this use, provided that those specifications are met.
- (4) The Authority adopted a favourable scientific opinion⁴ on the use of the monomer 2,4,40-trifluorobenzophenone with the CAS No 80512-44-3, and with the FCM substance No 1061. The Authority concluded that this substance is not a safety concern for the consumer if used as co-monomer up to 0.3% w/w based on the final material in the manufacture of polyether ether ketone plastics. This monomer should

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 2016;14(11):4637.

⁴ EFSA Journal 2016;14(7):4532

therefore be included in the Union list of authorised substances with the restriction that this specification should be met.

- (5) The Authority adopted a favourable scientific opinion⁵ on the use of the monomer 2,3,3,4,4,5,5-heptafluoro-1-pentene with the CAS No 1547-26-8, and with the FCM substance No 1063. The Authority concluded that this substance is not a safety concern for the consumer if used as comonomer together with tetrafluoroethylene and/or ethylene comonomers to manufacture fluorocopolymers that are only intended to be applied as polymer processing aids at up to 0.2% w/w of the FCM. For this application, the low molecular weight fraction below 1,500 Da in the fluorocopolymer should be no greater than 30 mg/kg. This monomer should be included in the Union list of authorised substances with the restriction that those specifications should be met.
- (6) The Authority adopted a favourable scientific opinion on the use of the substance tungsten oxide, WO_n, with n = 2.72–2.9, with the FCM substance No 1064, and with the CAS number 39318-18-8. The Authority concluded that the substance is not a safety concern for the consumer if the additive is used as a reheat agent in PET. The Panel considered that due to the insolubility of the substance, low migration is expected for any foreseeable use as a reheat additive in PET. Therefore, verification of the migration limit is not necessary in such a case. For other technical functions or for use in other polymers, the panel concluded that the migration should not exceed 0.050 mg/kg (expressed as tungsten). The present authorisation of this additive should be extended to include this use, provided that those specifications are met.
- (7) The Authority adopted a favourable scientific opinion⁶ on the use of the mixture of methyl-branched and linear C₁₄-C₁₈ alkanamides, derived from fatty acids with the FCM substance number No 1065. The Authority concluded that the substance is not a safety concern for the consumer if used in the manufacture of polyolefin articles intended for contact with all foodstuffs other than fatty foods (as defined by simulant D2) and when its migration does not exceed 5 mg/kg food. This mixture should therefore be included in the Union list of authorised substances with the restriction that this specification should be met. As N-stearamide may be part of this mixture but is included in the authorisation of stearamide with FCM No 306 for which no migration limit is assigned, the migration limit for the mixture should not apply to the migration of this substance.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

⁵ EFSA Journal 2016;14(10):4582.

⁶ EFSA Journal 2017;15(2):4724.

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
Jean-Claude JUNCKER