Commission Regulation (EU) 2018/79 of 18 January 2018 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance)

COMMISSION REGULATION (EU) 2018/79

of 18 January 2018

amending 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 Article 5(1)(a), (d), (e), (h) and (i), Article 11(3) and Article 12(6) thereof,

Whereas:

(1) Commission Regulation (EU) No 10/2011[(2)] ('the Regulation') establishes a Union list of authorised substances which may be used in plastic materials and articles intended to come into contact with food.

(2) Since the last amendment to Regulation (EU) No 10/2011, 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 permitted use of already authorised substances. In order to ensure that the Regulation (EU) No 10/2011 reflects the most recent findings of the Authority, that Regulation should be amended.

(3) The Authority adopted a favourable scientific opinion[(3)] on the use of the substance (butadiene, styrene, methyl methacrylate, butyl acrylate) copolymer cross-linked with divinylbenzene or 1,3-butanediol dimethacrylate (FCM substance No 856 and CAS No 25101-28-4). The Authority concluded that the substance is not of 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 current authorisation of this substance should be extended to include that use, provided that those specifications are met.

(4) The Authority adopted a favourable scientific opinion[(4)] on the use of the monomer 2,4,4′-trifluorobenzophenone (FCM substance No 1061 and CAS No 80512-44-3). The Authority concluded that this substance is not of a safety concern for the consumer if

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/79. (See end of Document for details)*

used as co-monomer up to 0,3 % w/w based on the final material in the manufacture of polyether ether ketone plastics. That monomer should 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 opinion[5] on the use of the monomer 2,3,3,4,4,5,5-heptafluoro-1-pentene (FCM substance No 1063 and CAS No 1547-26-8). The Authority concluded that the substance is not of a safety concern for the consumer if used as co-monomer together with tetrafluoroethylene and/or ethylene co-monomers 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 mass fraction below 1 500 Da in the fluorocopolymer should be no greater than 30 mg/kg. That 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[6] on the use of the substance tungsten oxide (WO_n (n = 2,72-2,90)) (FCM substance No 1064 and CAS No 39318-18-8). The Authority concluded that the substance is not of a safety concern for the consumer if the additive is used as a reheat agent in polyethylene terephthalate (PET). The Authority 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. For other technical functions or for use in other polymers, the Authority concluded that the migration should not exceed 0,05 mg/kg (expressed as tungsten). That substance should be included in the Union list of authorised substances with the restriction that those specifications should be met.

(7) The Authority adopted a favourable scientific opinion[7] on the use of the mixture of methyl-branched and linear C_{14}-C_{18} alkanamides, derived from fatty acids (FCM substance No 1065 and CAS No 85711-28-0). The Authority concluded that the substance is not of 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. That mixture should therefore be included in the Union list of authorised substances with the restriction that these specifications should be met.

(8) Annex I to Regulation (EU) No 10/2011 should therefore be amended accordingly.

(9) 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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2018/79. (See end of Document for details)*

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 8 February 2019 and may remain on the market until 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, 18 January 2018.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/79. (See end of Document for details)*

ANNEX

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

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

(a) the entry concerning FCM substance No 856 is replaced by the following:

856	40563	25101-28-4	(butadiene, styrene, methyl methacrylate, butyl acrylate) copolymer cross-linked with divinylbenzene or 1,3-butanediol dimethacrylate	no	no			Only to be used in: — rigid poly(vinyl chloride) (PVC) at a maximum level of 12 % at room temperature or below; or — at up to 40 % w/w in blends of styrene acrylonitrile copolymer (SAN)/ poly(methyl methacrylate) (PMMA) repeat-use articles at room temperature or below, and when either	