Commission Regulation (EU) 2018/831 of 5 June 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) 2018/831

of 5 June 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) Annex I to Commission Regulation (EU) No 10/2011[(2)] 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 Regulation (EU) No 10/2011 reflects the most recent findings of the Authority, that Regulation should be amended.

(3) The Authority has adopted opinions re-evaluating perchlorate contamination in foods and human dietary exposure to perchlorate[(3)(4)]. The substance perchloric acid, salts (perchlorate) (FCM No 822) is included as an additive or polymer production aid in Table 1 of Annex I to Regulation (EU) No 10/2011. A specific migration limit (SML) of 0,05 mg/kg applies to that substance on the basis of the conventional dietary exposure assumption from food contact materials that 1 kg of food is consumed daily by a person of 60 kg body weight. In re-evaluations of perchlorate, the Authority established a Tolerable Daily Intake (TDI) of 0,3 μg/kg body weight per day and noted that both the short and long term exposure to perchlorate of young population groups from all food sources exceeded the TDI whereas the short and long term exposure of the adult population was at the level of the TDI. To account for this, the SML should be calculated on the basis of the TDI and a conventional allocation factor of 10 % of the TDI from FCM should be applied. Consequently, the SML of 0,05 mg/kg for perchlorate should

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/831. (See end of Document for details)*

be lowered to 0,002 mg/kg to ensure that migration of perchlorate from plastic FCM does not endanger human health.

(4) The Authority adopted a favourable scientific opinion[5] on the use of the substance phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters (FCM substance No 974 and CAS No 939402-02-5). This substance is authorised with a migration limit of 5 mg/kg food. On the basis of new scientific evidence the Authority concluded that this substance is not of a safety concern for the consumer if its specific migration limit is increased from 5 to 10 mg/kg food, where the other existing restrictions are still met. Therefore the migration limit of this substance should be increased from 5 to 10 mg/kg, provided the other restrictions are retained.

(5) The Authority adopted a favourable scientific opinion[6] on the use of the substance 1,2,3,4-tetrahydronaphthalene-2,6-dicarboxylic acid, dimethyl ester (FCM substance No 1066 and CAS No 23985-75-3). The Authority concluded that the substance is not of a safety concern for the consumer if used as a co-monomer for the manufacture of a polyester layer intended to be used as an inner layer in a plastic multilayer material intended for contact with foods for which food simulants A, B, C and/or D1 are assigned in Table 2 of Annex III to Regulation (EU) No 10/2011. The migration of the sum of the substance and its dimers (cyclic and open chain) should not exceed 0,05 mg/kg food. That monomer should therefore be included in the Union list of authorised substances with the restriction that these specifications should be met.

(6) The Authority adopted a favourable scientific opinion[7] on the use of the substance [3-(2,3-epoxypropoxy)propyl]trimethoxy silane (FCM substance No 1068, CAS No 2530-83-8). The Authority concluded that although the substance has genotoxic potential, it is not of safety concern due to its low exposure, if any, when used as a component of sizing agents to treat glass fibres imbedded in low diffusivity plastics such as in polyethylene terephthalate (PET), polycarbonate (PC), polybutylene terephthalate (PBTP), thermoset polyesters, and epoxy bisphenol vinyl ester intended for single and repeated use with long-term storage at room temperature, short-term repeated contact at increased or high temperature and for all foods. As some of the reaction products of the substance containing the epoxy function may also have a genotoxic potential, the residues of the substance and of each of the reaction products in the treated glass fibres should not be detectable at 10 μg/kg for the substance and 60 μg/kg for each of the reaction products (hydrolysed monomers and epoxy-containing cyclic dimer, trimer and tetramer).

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

(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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2018/831. (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 26 June 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, 5 June 2018.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/831. (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 entries concerning FCM substances No 822 and No 974 are replaced by the following:

822	71938		Perchloric acid, salts	yes	no	no	0,002		(4)
‘974	74050	939402-02-5	Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters	no	yes	10		SML expressed as the sum of the phosphite and phosphate forms of the substance, 4-tert-amylphenol and 2,4-di-tert-amylphenol. The migration of 2,4-di-tert-amylphenol shall not exceed 1 mg/kg food.’	

(b) the following entries are added in numerical order of the FCM substance numbers: