Commission Regulation (EU) 2019/1338 of 8 August 2019 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) 2019/1338

of 8 August 2019

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 points (a), (d), (e), and (i) of Article 5(1), Article 11(3) and Article 12(3) and (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 the manufacture of 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 a scientific opinion on the permitted uses of an already authorised substance that may be used in food contact materials ('FCM'). 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 substance poly((*R*)-3-hydroxybutyrate-co-(*R*)-3-hydroxyhexanoate) (FCM substance No 1059, CAS number 147398-31-0) has been authorised by Commission Regulation (EU) 2019/37[(3)] to be used either alone or blended with other polymers in contact with dry or solid foods for which food simulant E is assigned in Table 2 of Annex III to Regulation (EU) No 10/2011 on the basis of two scientific opinions[(4)(5)] published by the Authority. The Authority has adopted a new favourable scientific opinion[(6)] extending the use of this substance alone or blended with other polymers in the manufacture of plastics intended to come into contact with all foods. In the later opinion, the Authority concluded that this substance is not of a safety concern for the consumer if it is used either alone or blended with other polymers in contact with all foods under contact conditions of 6 months or more at room temperature or below, including hot fill or short heating-up phases, provided that the migration of all oligomers with a molecular weight below 1 000 Da does not exceed 5,0 mg/kg food or food simulant. The Authority's conclusion is based on the worst-case migration testing conditions set out in point 2.1.4 of Chapter 2 of Annex V to Regulation (EU) No 10/2011

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2019/1338. (See end of Document for details)*

for long term contact conditions (6 months or more) with food at room temperature or below. In accordance with the provisions of point 2.1.5 of Chapter 2, of Annex V to that Regulation, these worst-case migration testing conditions also address contact conditions of less than 6 months at room temperature or below. Therefore, the use of this substance alone or blended with other polymers in the manufacture of plastics intended to come into contact with all foods under contact conditions of less than 6 months at room temperature or below, including hot fill or short heating-up phases will also be of no safety concern, provided that the migration of all oligomers with a molecular weight below 1 000 Da does not exceed 5,0 mg/kg food or food simulant. In addition, the Authority also confirmed in this opinion that the specific migration limit of 0,05 mg/kg food set for the degradation product crotonic acid in the previous authorisation of FCM substance No 1059, should also apply under this extended use. The entry for this substance in Table 1 of point 1 of Annex I to Regulation (EU) No 10/2011 should therefore include the uses of this substance with all foods and in all conditions, in column 10 of that Table.

(4) The authorisation of the FCM substance No 1059 provided for in this Regulation, requires that the total migration of all oligomers with a molecular weight below 1 000 Da does not exceed 5,0 mg/kg food or food simulant. As analytical methods to determine the migration of these oligomers are complex, a description of those methods is not necessarily available to competent authorities. Without that description, it is not possible for the competent authority to verify that the migration of oligomers from the material or article complies with the migration limit for these oligomers. Therefore, business operators placing on the market the final article or material containing that substance should be required to include in the supporting documentation referred to in Article 16 of Regulation (EU) No 10/2011 a description of the method and a calibration sample if required by the method.

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

(6) 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 intended to come into contact with food complying with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation may be placed on the market until 29 August 2020 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, 8 August 2019.

For the Commission

The President

Jean-Claude JUNCKER