Commission Regulation (EU) 2017/1250 of 11 July 2017 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of the flavouring substance 4,5-epoxydec-2(trans)-enal (Text with EEA relevance)

COMMISSION REGULATION (EU) 2017/1250

of 11 July 2017

amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of the flavouring substance 4,5-epoxydec-2(trans)-enal

(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 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC[(1)], and in particular Article 11(3) thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings[(2)], and in particular Article 7(6) thereof,

Whereas:

(1) Annex I to Regulation (EC) No 1334/2008 lays down a Union list of flavourings and source materials approved for use in and on foods and their conditions of use.

(2) Commission Implementing Regulation (EU) No 872/2012[(3)] adopted a list of flavouring substances and introduced that list in Part A of Annex I to Regulation (EC) No 1334/2008.

(3) Part A of Annex I to Regulation (EC) No 1334/2008 may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application submitted by a Member State or by an interested party.

(4) The flavouring substance 4,5-epoxydec-2(trans)-enal (Fl No: 16.071) is included in Annex I to Regulation (EC) No 1334/2008 as a flavouring substance under evaluation and for which additional scientific data was requested by the Authority. Such data has been submitted by the applicant.

(5) The European Food Safety Authority evaluated the submitted data and concluded in its scientific opinion of 4 May 2017[(4)] that 4,5-epoxydec-2(trans)-enal (Fl No: 16.071)

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2017/1250. (See end of Document for details)*

raises a safety concern with respect to genotoxicity as there is a genotoxic effect observed in the liver of rats in the *in vivo* assay submitted.

(6) Accordingly, the use of 4,5-epoxydec-2(trans)-enal (Fl No: 16.071) does not comply with the general conditions of use for flavourings set out in Article 4(a) of Regulation (EC) No 1334/2008. Consequently, that substance should be removed from the list without delay in order to protect human health.

(7) Therefore, the Commission should use the urgency procedure for the removal of a substance which raises a safety concern from the Union list.

(8) Part A of Annex I to Regulation (EC) No 1334/2008 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

Part A of Annex I to Regulation (EC) No 1334/2008 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 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, 11 July 2017.

For the Commission

The President

Jean-Claude JUNCKER