Commission Regulation (EU) 2015/1760 of 1 October 2015 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 p-mentha-1,8-dien-7-al (Text with EEA relevance)

COMMISSION REGULATION (EU) 2015/1760

of 1 October 2015

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 *p*-mentha-1,8-dien-7-al

(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) That list 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 *p*-mentha-1,8-dien-7-al (FL-no 05.117) is included in the list as a flavouring substance under evaluation for which additional scientific data must be submitted. 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 24 June 2015[(4)] that *p*-mentha-1,8-dien-7-al (FL-no 05.117) is genotoxic *in vivo* and therefore its use as a flavouring substance raises a safety concern.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2015/1760. (See end of Document for details)*

(6) The substance *p*-mentha-1,8-dien-7-al (FL-no 05.117) occurs naturally in the peel of fruits from some plants from the genera *Perilla, Citrus* and others.

(7) Accordingly the use of *p*-mentha-1,8-dien-7-al (FL-no 05.117) 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.

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

(9) Due to low use levels and the low total amount that *p*-mentha-1,8-dien-7-al (FL-no 05.117) has been added to foods in the Union, the presence of that substance in food does not raise immediate safety concerns. Therefore, taking into account also technical reasons, transitional periods should be laid down to cover food containing the flavouring substance *p*-mentha-1,8-dien-7-al (FL-no 05.117), which has been placed on the market or dispatched from third countries for the Union, before the date of entry into force of this Regulation.

(10) Part A of Annex I to Regulation (EC) No 1334/2008 should therefore be amended accordingly.

(11) 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

1 Foods to which the flavouring substance *p*-mentha-1,8-dien-7-al (FL-no 05.117) has been added which were lawfully placed on the market before the date of entry into force of this Regulation may be marketed until their date of minimum durability or use by date.

2 Foods imported into the Union to which the flavouring substance *p*-mentha-1,8-dien-7-al (FL-no 05.117) has been added may be marketed until their date of minimum durability or use by date where the importer of such food can demonstrate that they were dispatched from the third country concerned and were en route to the Union before the date of entry into force of this Regulation.

Article 3

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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2015/1760. (See end of Document for details)*

Done at Brussels, 1 October 2015.

For the Commission

The President

Jean-Claude JUNCKER