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Delegations will find attached document D041268/02.

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COMMISSION REGULATION (EU) .../...

of **XXX**

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) .../...

of **XXX**

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 2000/13¹, 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 flavourings², 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 872/2012³ 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.

¹ OJ L 354, 31.12.2008, p. 34.

² OJ L 354, 31.12.2008, p. 1.

³ Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC (OJ L 267, 2.10.2012, p. 1).

- (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 2015⁴ 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.
- (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

⁴ Scientific Opinion on Flavouring Group Evaluation 208 Revision 1 (FGE.208Rev1): Consideration of genotoxicity data on representatives for 10 alicyclic aldehydes with the α,β -unsaturation in ring / side-chain and precursors from chemical subgroup 2.2 of FGE.19. EFSA Journal 2015;13(7):4173, 28 pp. doi:10.2903/j.efsa.2015.4173 Available online: www.efsa.europa.eu/efsajournal

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.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER