Commission Regulation (EU) 2016/1244 of 28 July 2016 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances from a group related with an alpha beta unsaturation structure (Text with EEA relevance)

COMMISSION REGULATION (EU) 2016/1244

of 28 July 2016

amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances from a group related with an alpha beta unsaturation structure

(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(5) 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 Union list of flavourings and source materials contains a number of substances for which the European Food Safety Authority ('the Authority') has requested additional scientific data to be provided for completion of the evaluation before specific deadlines established in the Annex I Part A to Regulation (EC) No 1334/2008.

(5) In the case of the five following substances belonging to the Flavouring Group Evaluation FGE 208rev.1: *p*-mentha-1,8-dien-7-ol (FL No 02.060), myrtenol (FL No 02.091), myrtenal (FL No 05.106), *p*-mentha-1,8-dien-7-yl acetate (FL No 09.278) and

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myrtenyl acetate (FL No 09.302), the deadline of 31 December 2012 was established in the Union list for the submission of requested additional scientific data. Such data has been submitted by the applicant.

(6) That chemical group includes substance *p*-mentha-1,8-dien-7-al (FL No 05.117) which was used as a representative substance for the group and for which the toxicity data were submitted.

(7) The Authority has evaluated the submitted data and concluded in its scientific opinion of 24 June 2015[(4)] that the substance *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. That substance has already been removed from the Union list by Commission Regulation (EU) 2015/1760[(5)].

(8) In that opinion, the Authority also concluded that since *p*-mentha-1,8-dien-7-al (FL No 05.117) is a representative for the group, there is a potential safety concern for the other substances in that group.

(9) In order to further evaluate the safety of those five substances, the supporting parties concerned were formally requested to provide additional toxicity studies by 30 April 2016 to enable EFSA to finalise their assessment.

(10) The supporting parties concerned submitted the requested new studies before 30 April 2016.

(11) It is also appropriate, pending the evaluation by EFSA of the new scientific data, the eventual full evaluation of these substances according to the EFSA CEF panel procedure if appropriate and the completion of the subsequent regulatory process, to amend the conditions of use of those five substances to better reflect the current real uses of those substances.

(12) Due to technical reasons, transitional periods should be laid down to cover food to which any of the five flavouring substances have been added, which has been placed on the market or dispatched from third countries for the Union, before the entry into force of this Regulation.

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

(14) 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 any of the five flavouring substances have been added: *p*-mentha-1,8-dien-7-ol (FL No 02.060), myrtenol (FL No 02.091), myrtenal (FL No 05.106), *p*-mentha-1,8-

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dien-7-yl acetate (FL No 09.278) and myrtenyl acetate (FL No 09.302) which do not comply with the conditions set out in the Annex to this Regulation and were lawfully placed on the market before the 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 any of the flavouring substances referred to in paragraph 1 have been added and which do not comply with the conditions set out in the Annex to this Regulation may be marketed until their date of minimum durability or use by date where the importer of such foods can demonstrate that they were dispatched from the third country concerned and were en route to the Union before the entry into force of this Regulation.

3 The transitional periods provided in paragraphs 1 and 2 shall not apply to mixtures of flavourings.

Article 3

This Regulation shall enter into force 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, 28 July 2016.

For the Commission

The President

Jean-Claude JUNCKER