Commission Regulation (EU) 2016/637 of 22 April 2016 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 certain flavouring substances (Text with EEA relevance)

COMMISSION REGULATION (EU) 2016/637

of 22 April 2016

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 certain flavouring substances

(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 Articles 11(3) and 25(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(4) 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 the 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 ('Authority') has requested additional scientific data to be provided for completion of the evaluation before specific deadlines established in Part A of Annex I to Regulation (EC) No 1334/2008.

(5) In case of the following four substances belonging to chemical subgroup 2.2 of FGE.19: 2,6,6-trimethyl-1-cyclohexen-1-carboxaldehyde (FL No 05.121), myrtenyl formate (FL No 09.272), myrtenyl-2-methylbutyrate (FL No 09.899), and myrtenyl-3-methylbutyrate (FL No 09.900), the deadline of 31 December 2012 was established in

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2016/637. (See end of Document for details)*

the Union list for the submission of requested additional scientific data. Such data has been submitted by the applicant.

(6) This chemical group includes also the substance *p*-mentha-1,8-dien-7-al (FL No 05.117) which was used as 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 representative for the substances in this group, there is a potential safety concern for such substances.

(9) Therefore, 2,6,6-trimethyl-1-cyclohexen-1-carboxaldehyde (FL No 05.121), myrtenyl formate (FL No 09.272), myrtenyl-2-methylbutyrate (FL No 09.899), and myrtenyl-3-methylbutyrate (FL No 09.900) should be removed from the Union list.

(10) Taking into account technical reasons, transitional periods should be laid down to cover food to which one of the four flavouring substances has been added, 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.

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

(12) 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 one of the flavouring substances listed in the Annex to this Regulation has been added and were lawfully placed on the market before the date of entry into force of this Regulation, excluding mixtures of flavourings, may be marketed until their date of minimum durability or use by date.

2 Foods imported into the Union to which one of the flavouring substances listed in the Annex to this Regulation has been added, excluding mixtures of flavourings, 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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2016/637. (See end of Document for details)*

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, 22 April 2016.

For the Commission

The President

Jean-Claude JUNCKER