Commission Regulation (EU) 2017/378 of 3 March 2017 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances (Text with EEA relevance)

COMMISSION REGULATION (EU) 2017/378

of 3 March 2017

amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards 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 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 the deadlines established in Part A of Annex I to Regulation (EC) No 1334/2008.

(5) In the case of the substances belonging to the Flavouring Group Evaluation ('FGE 203') rev.1: the deadline of 31 December 2012 was established in the Union list for the submission of requested additional scientific data. The substances belonging to this FGE203 rev.1 are: deca-2,4-dien-1-ol (FL No 02.139), hepta-2,4-dien-1-ol (FL No 02.153), hexa-2,4-dien-1-ol (FL No 02.162),

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2017/378. (See end of Document for details)*

nona-2,4-dien-1-ol (FL No 02.188), hexa-2(trans),4(trans)-dienal (FL No 05.057), trideca-2(trans),4(cis),7(cis)-trienal (FL No 05.064), nona-2,4-dienal (FL No 05.071), 2,4-decadienal (FL No 05.081), hepta-2,4-dienal (FL No 05.084), penta-2,4-dienal (FL No 05.101), undeca-2,4-dienal (FL No 05.108), dodeca-2,4-dienal (FL No 05.125), octa-2(trans),4(trans)-dienal (FL No 05.127), deca-2(trans),4(trans)-dienal (FL No 05.140), deca-2,4,7-trienal (FL No 05.141), nona-2,4,6-trienal (FL No 05.173), 2,4-octadienal (FL No 05.186), tr-2,tr-4-nonadienal (FL No 05.194), tr-2,tr-4-undecadienal (FL No 05.196), and hexa-2,4-dienyl acetate (FL No 09.573). Such data has been submitted by the applicant.

(6) That chemical group includes hexa-2(trans),4(trans)-dienal (FL No 05.057) and deca-2(trans),4(trans)-dienal (FL No 05.140) which were used as representative substances for the group and for which toxicity data were submitted.

(7) The Authority has evaluated the genotoxicity of these two representative substances in its scientific opinion of 26 March 2014[(4)].

(8) For hexa-2(trans),4(trans)-dienal (FL No 05.057) it confirmed safety concerns based on the evidence from publications reporting the induction of DNA adducts in different systems *in vitro* and *in vivo*, the IARC classification as possible carcinogen to humans, considering the conclusion drawn by IARC that mechanistic data provide additional support for the relevance of the animal carcinogenicity data to humans and that there is a moderate evidence that tumour induction occurs via a genotoxic mechanism.

(9) For deca-2(trans),4(trans)-dienal (FL No 05.140) it came to the conclusion that a non-threshold mechanism of genotoxicity cannot be excluded on the basis that there is some indication for genotoxicity *in vivo* and considering the evidence from *in vitro* studies for the induction of different types of DNA damage (oxidised DNA bases and bulky adducts).

(10) Overall, the Authority concluded that the safety concern regarding genotoxicity cannot be ruled out for both representative substances of the group and that this conclusion is likewise applicable to the other substances of the FGE group 203.

(11) The parties concerned have indicated that they are undertaking a variety of toxicity studies on the substances in FGE group 203 responding to the concerns expressed by the Authority. In addition, the Commission has requested further information in order to fully evaluate the safety of those substances.

(12) The supporting parties submitted the studies and information on 26 September 2016.

(13) Pending the evaluation by the Authority of the substances in group FGE, the eventual full evaluation of these substances according to the EFSA CEF panel procedure and the completion of the subsequent regulatory process, it is appropriate to limit the conditions of use of those substances to their current use.

(14) Due to technical reasons, transitional periods should be laid down to cover food not complying with the conditions set out in the Annex, which has been placed on the Union market or dispatched from third countries for the Union before the entry into force of this Regulation.

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

(16) 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 flavouring substances listed in the Annex to this Regulation have been added which do not comply with the conditions set out in that Annex and which have been 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 to which any of the flavouring substances listed in the Annex to this Regulation have been added, and which do not comply with the conditions set out in that Annex and which have been imported into the Union from a third country 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 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, 3 March 2017.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2017/378. (See end of Document for details)*

ANNEX

Table 1 of Section 2 of Part A of Annex I to Regulation (EC) No 1334/2008 is amended as follows:

(a) the entry for FL No 02.139 is replaced by the following:

02.139	Deca-2,4-dien-1-ol	18409-21-7	11789	11748		Restrictions of use as a flavouring substance:	In category 2 — not more than 1,5 mg/kg, in category 3 — not more than 5 mg/kg, in category 5 — not more than 9 mg/kg, in category 7 — not more than 15 mg/kg, in category 8 — not more	EFSA

							than 5 mg/kg, in category 12 — not more than 3 mg/kg, in category 14.1 — not more than 2 mg/kg, in category 14.2 — not more than 1 mg/kg, in category 16 — not more than 2 mg/kg.	

(b) the entry for FL No 02.153 is replaced by the following:

02.153	Hepta-2,4-dien-1-ol	33467-79-1	71784			Restrictions of use as a flavouring substance:	In category 1 — not more	EFSA