

**COMMISSION REGULATION (EU) 2016/55**  
**of 19 January 2016**  
**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 <sup>(1)</sup>, 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 <sup>(2)</sup>, 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 for use in food and their conditions of use.
- (2) Commission Implementing Regulation (EU) No 872/2012 <sup>(3)</sup> 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) Part A of the Union list contains both evaluated flavouring substances, which are assigned no footnotes, and flavouring substances under evaluation, which are identified by footnote references 1 to 4 in that list.
- (5) The European Food Safety Authority (EFSA) has completed the assessment of 5 substances which are currently listed as flavouring substances under evaluation. Those flavouring substances were assessed by EFSA in the following flavouring group evaluations: evaluation FGE.12rev5 <sup>(4)</sup> (substances FL-nos. 07.041 and 07.224), FGE.63rev2 <sup>(5)</sup> (substances FL-nos. 07.099 and 07.101), and evaluation FGE.312 <sup>(6)</sup> (substance FL-no 16.126). EFSA concluded that these flavouring substances do not give rise to safety concerns at the estimated levels of dietary intake.
- (6) As part of its evaluation, EFSA has made comments on the specifications of certain of those substances. The comments are related to names, purity or composition of the substances FL-nos: 07.041, 07.224 and 07.099. Those comments should be introduced in the list.
- (7) The Union list referred to in Regulation (EC) No 1334/2008 is intended to regulate only the use of flavouring substances which are added to food in order to impart or modify odour and/or taste. Substance FL-no 16.126 could also be added to food for other purposes than flavouring and such uses remain subject to other rules. This Regulation lays down conditions of use which relate solely to its use as a flavouring substance.

<sup>(1)</sup> OJ L 354, 31.12.2008, p. 34.

<sup>(2)</sup> OJ L 354, 31.12.2008, p. 1.

<sup>(3)</sup> 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).

<sup>(4)</sup> EFSA Journal 2014; 11(12):3911.

<sup>(5)</sup> EFSA Journal 2014; 11(4):3188.

<sup>(6)</sup> EFSA Journal 2013; 11(10):3404.

- (8) The flavouring substances assessed in those evaluations should be listed as evaluated substances by deleting footnote references 1 and 2 in the relevant entries of the Union list.
- (9) Part A of Annex I to Regulation (EC) No 1334/2008 should therefore be amended accordingly.
- (10) 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*

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, 19 January 2016.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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## ANNEX

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

(1) The entry concerning FL-no 07.041 is replaced by the following:

'07.041	beta-Isomethylionone	79-89-0		650	Mixture of E/Z isomers (50-70 % (E) and 30-50 % (Z))		EFSA'
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(2) The entry concerning FL-no 07.099 is replaced by the following:

'07.099	6-Methylhepta-3,5-dien-2-one	1604-28-0	1134	11143	Mixture of E/Z stereoisomers: 60-90 % (E)		EFSA'
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(3) The entry concerning FL-no 07.101 is replaced by the following:

'07.101	4-Methylpent-3-en-2-one	141-79-7	1131	11853			EFSA'
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(4) The entry concerning FL-no 07.224 is replaced by the following:

'07.224	trans-1-(2,6,6-Trimethyl-1-cyclohexen-1-yl)but-2-en-1-one	23726-91-2			At least 90 %; secondary components 2-4 % alpha-damascone and 2-4 % delta-damascone		EFSA'
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(5) The entry concerning FL-no 16.126 is replaced by the following:

'16.126	3-[(4-amino-2,2-dioxido-1H-2,1,3-benzothiadiazin-5-yl)oxy]-2,2-dimethyl-N-propylpropanamide	1093200-92-0	2082			Restrictions for use as a flavouring substance: In category 1 — not more than 3 mg/kg. In category 3 — not more than 5 mg/kg. In category 5 — not more than 15 mg/kg. In category 5.3 — not more than 30 mg/kg. In category 5.4 — not more than 10 mg/kg. In category 6.3 — not more than 15 mg/kg. In category 7 — not more than 10 mg/kg. In category 12 — not more than 10 mg/kg. In category 14.1 — not more than 5 mg/kg. In category 16, excluding products covered in categories 1, 3 and 4 — not more than 5 mg/kg.	EFSA'
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