Commission Regulation (EU) 2018/678 of 3 May 2018 amending and correcting 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) 2018/678

of 3 May 2018

amending and correcting 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 for use in food and their conditions of use.

(2) Commission Implementing Regulation (EU) No 872/2012[(3)] adopted the list of flavouring substances and introduced it as Part A of Annex I to Regulation (EC) No 1334/2008.

(3) 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 on the that list.

(4) The European Food Safety Authority ('the Authority') has completed the assessment of the substances included in the Union list with the following FL numbers: 09.931, 13.058, 15.004, 15.057, 15.079, 15.109, 15.113, 16.090 and 16.111. Those substances were listed as flavouring substances under evaluation in 2012. They have now been assessed by the Authority in the following flavouring group evaluations: evaluation FGE.72rev1[(4)] (substance with FL-No 09.931), evaluation FGE.21rev4[(5)] (substances with FL-Nos 15.057 and 15.079), evaluation FGE.76rev1[(6)] (substances with FL-Nos 15.004, 15.109 and 15.113), evaluations FGE.94[(7)] and FGE.94rev.2[(8)] (substance with FL-No 16.090), evaluations FGE.94rev.1[(9)] and FGE94rev.2[(10)] (substance with FL-No 16.111), and evaluation FGE.67rev2[(11)] (substance with FL-No 13.058). The Authority

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concluded that those flavouring substances do not give rise to safety concerns at the estimated levels of dietary intakes.

(5) Therefore, those flavouring substances should be listed as evaluated substances and the footnote references 1 to 4 should be deleted from the entries concerned.

(6) In addition, two errors have been identified in the Union list as regards the name of the substance with FL-No 12.054 and the identification numbers of the substance with FL-No 17.038. Those errors should be corrected.

(7) Part A of Annex I to Regulation (EC) No 1334/2008 should be amended and corrected accordingly.

(8) 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, 3 May 2018.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX

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

(1) The entry concerning FL-No 09.931 is replaced by the following:

09.931	2,6-Dimethyl-2,5,7-octatriene-1-ol acetate	999999-91-2	12226					EFSA

(2) The entry concerning FL-No 12.054 is replaced by the following:

12.054	2-Ethylthiophenol	4500-58-7	13329	11666				JECFA

(3) The entry concerning FL-No 13.058 is replaced by the following:

13.058	3-(5-Methyl-2-furyl) butanal	31704-80-6	15500	10355				EFSA

(4) The entry concerning FL-No 15.004 is replaced by the following:

15.004	5-Methyl-2-thiophenecarbaldehyde	13679-70-4	14050	2203				EFSA

(5) The entry concerning FL-No 15.057 is replaced by the following:

15.057	4,6-Dimethyl-2-(1-methylethyl)dihydro-1,3,5-dithiazine	104691-40-9			At least 44 % isopropyl-4,6-dimethyl and 27 % 4-isopropyl-2,6-dimethyl; secondary components at least 24 % 2,4,6-trimethyldihydro-1,3,5-dithiazine; 6-methyl-2,4-diisopropyl-1,3,5-dithiazine; 4-			EFSA

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					methyl-2,6-diisopropyl-1,3,5-dithiazine; 2,4,6-triisopropyl-dihydro-1,3,5-dithiazine			

(6) The entry concerning FL-No 15.079 is replaced by the following:

15.079	2-Isobutyldihydro-4,6-dimethyl-1,3,5-dithiazine	101517-87-7			At least 64 % 2-isobutyl-4,6-dimethyl and 18 % 4-isobutyl-2,6-dimethyl; secondary components at least 13 % 2,4,6-trimethyl-1,3,5-dithiazine; 2,4-diisobutyl-6-methyl-1,3,5-dithiazine; 2,6-dimethyl-4-butyldihydro-1,3,5-dithiazine; substituted 1,3,5-thiadiazine			EFSA

(7) The entry concerning FL-No 15.109 is replaced by the following:

15.109	2,4,6-Trimethyldihydro-1,3,5(4H)-dithiazine	638-17-5	1049	11649				EFSA

(8) The entry concerning FL-No 15.113 is replaced by the following:

15.113	5,6-Dihydro-2,4,6-tris(2-methylpropyl)4H-1,3,5-dithiazine	74595-94-1	1048					EFSA