

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 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.

⁽¹⁾ OJL 354, 31.12.2008, p. 34.

⁽²⁾ OJL 354, 31.12.2008, p. 1.

⁽³⁾ 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 (OJL 267, 2.10.2012, p. 1).

⁽⁴⁾ *EFSA Journal* 2013;11(10):3392

⁽⁵⁾ *EFSA Journal* 2013;11(11):3451

⁽⁶⁾ *EFSA Journal* 2013;11(11):3455

⁽⁷⁾ *EFSA Journal* 2010; 8(5):1338

⁽⁸⁾ *EFSA Journal* 2014;12(4):3622

⁽⁹⁾ *EFSA Journal* 2012;10(6):2747

⁽¹⁰⁾ *EFSA Journal* 2014;12(4):3622

⁽¹¹⁾ *EFSA Journal* 2015; 13(5):4115

- (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

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 | 999999-91-4 | 1226 | | | | | EFSA' |
|---------|--|-------------|------|--|--|--|--|-------|

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

| | | | | | | | | |
|---------|-------------------|-----------|-----|-------|--|--|--|--------|
| '12.054 | 2-Ethylthiophenol | 4500-58-7 | 529 | 11666 | | | | JECFA' |
|---------|-------------------|-----------|-----|-------|--|--|--|--------|

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

| | | | | | | | | |
|---------|------------------------------|------------|------|-------|--|--|--|-------|
| '13.058 | 3-(5-Methyl-2-furyl) butanal | 31704-80-0 | 1500 | 10355 | | | | EFSA' |
|---------|------------------------------|------------|------|-------|--|--|--|-------|

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

| | | | | | | | | |
|---------|----------------------------------|------------|------|------|--|--|--|-------|
| '15.004 | 5-Methyl-2-thiophenecarbaldehyde | 13679-70-4 | 1050 | 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-methyl-2,6-diisopropyl-1,3,5-dithiazine; 2,4,6-triisopropyl-dihydro-1,3,5-dithiazine | | | EFSA' |
|---------|--|-------------|--|--|---|--|--|-------|

(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' |
|---------|--|------------|------|--|--|--|--|-------|

(9) The entry concerning FL-No 16.090 is replaced by the following:

| | | | | | | | | |
|---------|---|------------|------|--|--|--|--|-------|
| '16.090 | 3-(3,4-Dimethoxyphenyl)-N-[2-(3,4-dimethoxyphenyl)-ethyl]- acrylamide | 69444-90-2 | 1777 | | | | | EFSA' |
|---------|---|------------|------|--|--|--|--|-------|

(10) The entry concerning FL-No 16.111 is replaced by the following:

| | | | | | | | | |
|---------|---|------------|------|--|--|--|--|-------|
| '16.111 | Glycine, N- [[(1R,2S,5R)-5-methyl- 2-(1-methylethyl)cyclohexyl]carbonyl]-, ethyl ester. | 68489-14-5 | 1776 | | | | | EFSA' |
|---------|---|------------|------|--|--|--|--|-------|

(11) The entry concerning FL-No 17.038 is replaced by the following:

| | | | | | | | | |
|---------|------------------------------|------------|------|--|---|---|--|-------|
| '17.038 | gamma-Glutamyl-valyl-glycine | 38837-70-6 | 2123 | | 5-oxo-L-prolyl-L-valyl-glycine (PCA-Val-Gly) and L-alpha-glutamyl-L-valyl-glycine less than 0,7 %, L-gamma-glutamyl-L-valyl-L-valyl-glycine less than 2,0 %, Toluene not detectable (l.o.d. 10 mg/kg) | Restrictions for use as a flavouring substance: In category 1 — not more than 50 mg/kg In categories 2 and 5 — not more than 60 mg/kg In category 6.3, breakfast cereals — not more than 160 mg/kg In category 7.2 — not more than 60 mg/kg In category 8 — not more than 45 mg/kg In category 12 — not more than 160 mg/kg | | EFSA' |
|---------|------------------------------|------------|------|--|---|---|--|-------|

| | | | | | | | | |
|--|--|--|--|--|--|---|--|--|
| | | | | | | In category 14.1 — not more than 15 mg/kg In category 15 — not more than 160 mg/kg | | |
|--|--|--|--|--|--|---|--|--|