

## Union List of Flavouring Substances

### Amendment to the Union List Part A (Annex I to Flavouring Regulation)

**Commission Regulation (EU) 2016/55, adopted on 19 January and published on 20 January 2016, amends the List of flavouring substances.**

**It relates to the removal of footnotes (evaluation completed), corrections of names and specifications for certain substances and establishment of restrictions of use for one substance.**

#### Background

This Information Letter informs about the adoption and publication of **Commission Regulation (EU) 2016/55** amending the list of flavouring substances (Annex I Part A to Regulation (EC) No 1334/2008).

This Regulation aims at updating and correcting the list regarding different aspects:

- Removal of footnotes for five flavouring substances. It means that the evaluation by EFSA has been finalised for those substances.
- Modification of names, purity and composition of three substances.
- Establishment of restrictions of use for one substance.

#### Removal of footnotes

The presence of footnotes mentioned in column 8 of the UL indicates that the evaluation of the flavouring substance by EFSA is ongoing.

Regulation (EU) 2016/55 removes footnotes for five flavouring substances (see Table below), covered by 3 FGE's. EFSA has completed the evaluation of these substances and concluded that they would not present rise to safety concerns at the estimated levels of dietary intake.

FGE	FL-no	Chemical Name	CAS-no	JECFA-no	CoE-no
FGE.12rev5	07.041	beta-Isomethylionone	79-89-0		
FGE.12rev5	07.224	trans-1-(2,6,6-Trimethyl-1-cyclohexen-1-yl)but-2-en-1-one	23726-91-2		
FGE.63rev2	07.099	6-Methylhepta-3,5-dien-2-one	1604-28-0	1134	11143
FGE.63rev2	07.101	4-Methylpent-3-en-2-one	141-79-7	1131	11853
FGE.312	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	

Please, note that the evaluation by EFSA is a continuous process. Even if footnotes in the UL are being updated, as it is the case with Regulation (EU) 2016/55, they cannot reflect the real and current situation of the completion of safety evaluations by EFSA. Other substances may have meanwhile been fully assessed by EFSA.

## Correction of names and specifications

In its opinions, EFSA made comments on the name and specifications of three substances (on the 5 mentioned previously). Regulation (EU) 2016/55 takes into account these comments as follows:

07.041 Introduction of particular specifications + slight modification of the name		
	<i>Previous :</i> [empty]	<i>New:</i> Mixture of E/Z isomers (50-70 % (E) and 30-50 % (Z))
	<i>Previous:</i> beta-Isomethyl ionone	<i>New:</i> beta-Isomethylionone
07.224 Slight modification of the name of the substance		
	<i>Previous :</i> tr-1-(2,6,6-Trimethyl-1-cyclohexen-1-yl)but-2-en-1-one	<i>New:</i> trans-1-(2,6,6-Trimethyl-1-cyclohexen-1-yl)but-2-en-1-one
07.099 Introduction of particular specifications		
	<i>Previous :</i> [empty]	<i>New:</i> Mixture of E/Z stereoisomers: 60-90 % (E)

## Restriction of use

The flavouring substance FL-no: 16.126 can be used for other purposes than flavouring. In order to better separate the functions, the legislator decided to set restrictions for the use as flavouring substance.

Food categories in which FL-no 16.126 is authorised	Maximum level in the food category
1 - Dairy products and analogues	3 mg/kg
3 - Edible ices	5 mg/kg
5 - Confectionery	15 mg/kg
5.3 - Chewing gum	30 mg/kg
5.4 - Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4	10 mg/kg
6.3 - Breakfast cereals	15 mg/kg
7 - Bakery wares	10 mg/kg
12 - Salts, spices, soups, sauces, salads and protein products	10 mg/kg
14.1 - Non-alcoholic beverages	5 mg/kg
16 - Desserts excluding products covered in categories 1, 3 and 4	5 mg/kg

**Remark:** Categories 5.4. and 6.3. are not mentioned in Section 1 of Annex I Part A which describes the content of the list. However, the description of Column 7 (Restrictions of Use) mentioned that the food categories are those laid down in Annex II of Regulation (EC) No 1333/2008 on food additives.

Thirteen flavouring substances in the UL are now subject to restrictions of use in food categories.

## Adoption, publication and application

The current amendment of the Union List of flavouring substances has been adopted on 19 January 2016 and published in the Official Journal on 20 January 2016 [L 13/43]:

- **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.  
[http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2016.013.01.0043.01.ENG&toc=OJ:L:2016:013:TOC](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.013.01.0043.01.ENG&toc=OJ:L:2016:013:TOC)

This Regulation shall enter into force the 20<sup>th</sup> day following its publication, i.e. on 9 February 2016.

It shall be binding in its entirety and directly applicable in all Member States.

If you have further questions, please do not hesitate to contact EFFA at [info@effa.eu](mailto:info@effa.eu) or your respective national association.

### EFFA Secretariat – 20 January 2016

**Enclosures:**

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. (FL/16/05)

For information – UL part A, History of changes:

Date of publication	Reference	Subject matter	EFFA Info. Letter
2 October 2012	Commission Implementing Regulation (EU) No <b>872/2012</b>	Adoption of the list of flavouring substances (UL, Annex I Part A)	EFFA IL 12/07
15 June 2013	Commission Regulation (EU) No <b>545/2013</b>	Removal of substance 3-acetyl-2,5-dimethylthiophene from the UL	EFFA IL 13/10 & 13/11
15 October 2013	Commission Regulation (EU) No <b>985/2013</b>	23 fully evaluated substances (deletion of footnotes) and corrections	EFFA IL 13/21
14 March 2014	Commission Regulation (EU) No <b>246/2014</b>	Removal of 19 flavouring substances (Non Supported substances) from the UL	EFFA IL 14/03
18 October 2014	Commission Regulation (EU) No <b>1098/2014</b>	8 fully evaluated substances (deletion of footnotes) and corrections	EFFA IL 14/13
25 April 2015	Commission Regulation (EU) <b>2015/648</b>	Removal of substance N-Ethyl (2E,6Z)-nonadienamide from the UL	EFFA IL 15/04
9 July 2015	Commission Regulation (EU) <b>2015/1102</b>	Removal of 5 Footnote-10 substances from the UL	EFFA IL 15/07
2 October 2015	Commission Regulation (EU) <b>2015/1760</b>	Removal of perilla aldehyde [FL-no : 05.117]	EFFA IL 15/11
20 January 2016	Commission Regulation (EU) <b>2016/54</b>	New authorised flavouring substance: gamma-glutamyl-valyl-glycine [FL-no:17.038]	EFFA IL 16/01
20 January 2016	Commission Regulation (EU) <b>2016/55</b>	5 fully evaluated substances (deletions of footnotes), corrections of name and specifications, restrictions of use defined for one substance.	EFFA IL 16/02