

Union List of Flavouring Substances

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

Commission Regulation (EU) 2016/637, adopted on 22 April and published on 23 April 2016, amends the List of flavouring substances. It relates to the removal of the four substances from FGE.208rev1 for which EFSA concluded on a '*potential safety concern*' and which are no longer supported by the Industry.

Background

This Information Letter informs about the adoption and publication of **Commission Regulation (EU) 2016/637** amending the list of flavouring substances (Annex I Part A to Regulation (EC) No 1334/2008).

This Regulation removes the following four (4) flavouring substances from the Union List (UL):

FL-no	Chemical Name	CAS-no	JECFA-no	CoE-no	FEMA-no
05.121	2,6,6-Trimethyl-1-cyclohexen-1-carboxaldehyde	432-25-7	979	2133	3639
09.272	Myrtenyl formate	72928-52-0	983	10858	3405
09.899	Myrtenyl-2-methylbutyrate	138530-44-6			
09.900	Myrtenyl-3-methylbutyrate	33900-84-4			

These substances are part of FGE.208rev1 (i.e. FGE.19-subgroup 2.2). This group includes the representative substance, *p*-mentha-1,8-dien-7-al (= perilla aldehyde) [FL No 05.117], for which EFSA concluded in a safety concern (genotoxicity). Perilla aldehyde was removed from the UL by Commission Regulation (EU) 2015/1760. EFSA concluded that there is a '*potential safety concern*' for the other nine substances of the group.

Following the EFSA opinion, EFFA launched a survey in July/August 2015 regarding the use of the nine substances. Results showed that there was no use in the EU for the four substances mentioned in the above table. Therefore the Industry decided to no longer support anymore these substances for their safety assessment. Their removal from the UL was an expected Risk Management decision.

Regarding the other five supported flavouring substances of FGE.208, please refer to the recent EFFA updates on FGE.208 & FGE.203 sent to the membership.

Adoption, publication and application

This modification of the Union List of flavouring substances has been adopted on 22 April 2016 and published in the Official Journal on 23 April 2016 [L 108/24]:

- **Commission Regulation (EU) 2016/637** of 22 April 2016 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of certain flavouring substances.

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.108.01.0024.01.ENG

european flavour association

This Regulation shall enter into force the 20th day following its publication, i.e. on 13 May 2016. It shall be binding in its entirety and directly applicable in all Member States.

Transitional period

Foods containing one of the four flavouring substances mentioned in the Annex to this Regulation, which are lawfully placed on the market before the date of entry into force of this Regulation (i.e. 13 May 2016), may be marketed until their date of minimum durability or use by date.

Mixtures of flavourings are explicitly excluded and cannot benefit from the transitional measures.

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

EFFA Secretariat – 25 April 2016

Enclosures:

Commission Regulation (EU) 2016/637 of 22 April 2016 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of certain flavouring substances. (FL/16/15)

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 872/2012	Adoption of the list of flavouring substances (UL, Annex I Part A)	<i>EFFA IL 12/07</i>
15 June 2013	Commission Regulation (EU) No 545/2013	Removal of substance 3-acetyl-2,5-dimethylthiophene from the UL	<i>EFFA IL 13/10 & 13/11</i>
15 October 2013	Commission Regulation (EU) No 985/2013	23 fully evaluated substances (deletion of footnotes) and corrections	<i>EFFA IL 13/21</i>
14 March 2014	Commission Regulation (EU) No 246/2014	Removal of 19 flavouring substances (Non Supported substances) from the UL	<i>EFFA IL 14/03</i>
18 October 2014	Commission Regulation (EU) No 1098/2014	8 fully evaluated substances (deletion of footnotes) and corrections	<i>EFFA IL 14/13</i>
25 April 2015	Commission Regulation (EU) 2015/648	Removal of substance N-Ethyl (2E,6Z)-nonadienamide from the UL	<i>EFFA IL 15/04</i>
9 July 2015	Commission Regulation (EU) 2015/1102	Removal of 5 Footnote-10 substances from the UL	<i>EFFA IL 15/07</i>
2 October 2015	Commission Regulation (EU) 2015/1760	Removal of perilla aldehyde [FL-no: 05.117]	<i>EFFA IL 15/11</i>
20 January 2016	Commission Regulation (EU) 2016/54	New authorised flavouring substance: gamma-glutamyl-valyl-glycine [FL-no: 17.038]	<i>EFFA IL 16/01</i>
20 January 2016	Commission Regulation (EU) 2016/55	5 fully evaluated substances (deletions of footnotes), corrections of name and specifications, restrictions of use defined for one substance.	<i>EFFA IL 16/02</i>
11 February 2016	Commission Regulation (EU) 2016/178	Removal of 5 flavouring substances (Non Supported substances) from the UL	<i>EFFA IL 16/03</i>
23 April 2016	Commission Regulation (EU) 2016/637	Removal of 4 flavouring substances FGE.208rev1 from the UL	<i>EFFA IL 16/15</i>