

Union List of Flavouring Substances

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

Commission Regulation (EU) 2016/1244, adopted on 28 July and published on 29 July 2016, amends the List of flavouring substances. Conditions of use are set for the 5 supported substances of FGE.208rev1.

Background

This Information Letter informs about the adoption and publication of **Commission Regulation (EU) 2016/1244** amending the list of flavouring substances (Annex I Part A to Regulation (EC) No 1334/2008).

This Regulation sets conditions of use for five (5) flavouring substances.

FL-no	Chemical Name	CAS-no	JECFA-no	CoE-no
02.060	p-Mentha-1,8-dien-7-ol	536-59-4	974	2024
02.091	Myrtenol	515-00-4	981	10285
05.106	Myrtenal	564-94-3	980	10379
09.278	p-Mentha-1,8-dien-7-yl acetate	15111-96-3	975	10742
09.302	Myrtenyl acetate	1079-01-2	982	10887

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 a safety concern. 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, EFA launched a survey in July/August 2015 regarding the use of the nine substances. Results showed that there was use in the EU for only five substances. Therefore the Industry decided to support these five substances. The other four non-supported substances were removed from the UL by Commission Regulation (EU) 2016/637 published on 23 April 2016.

The Flavour Industry provided additional data to EFSA for the supported five substances. According to EFA/IOFI experts, **all new data support a conclusion for a lack of genotoxic potential for these substances.**

Despite these results and the important communication actions of the Flavour Industry towards Members States representatives, the PAFF Committee¹ decided to vote for restrictions of use. These restrictions, finally published in Regulation 2016/1244, consist only in authorizing the use of the substances for those food categories for which

¹ Standing Committee on Plants, Animals, Food and Feed

industry had reported use (=results of recent EFFA surveys). No maximum levels of use in the food categories are defined.

Consequence for the flavouring manufacturers:

Pursuant to Article 15.1.g of Regulation (EC) No 1334/2008, the presence of any of the five substances listed in Regulation 2016/1244 in flavourings and/or appropriate information in clear and easily understandable terms enabling the purchaser to comply with this regulation or other relevant Community law has to be provided. Quantitative disclosure is not required.

Adoption, publication and application

This modification of the List of flavouring substances has been adopted on 28 July 2016 and published in the Official Journal on 29 July 2016 [L 204/7]:

- **Commission Regulation (EU) 2016/1244** of 28 July 2016 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances from a group related with an alpha beta unsaturation structure
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.204.01.0007.01.ENG

This Regulation will enter into force the 20th day following its publication, i.e. on 18 August 2016. It shall be binding in its entirety and directly applicable in all Member States.

Transitional period

Foods containing one of the five flavouring substances mentioned in the Annex to this Regulation, which do not comply with the conditions of use and were lawfully placed on the market before the date of entry into force of this Regulation (i.e. 18 August 2016), may be marketed until their date of minimum durability or use by date.

Foods imported into the Union to which any of the five flavouring substances have been added and which do not comply with the conditions of use may be marketed until their date of minimum durability or use by date where the importer of such foods can demonstrate that they were dispatched from the third country concerned and were en route to the Union before the entry into force of this Regulation (i.e. 18 August 2016).

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 – 03 August 2016

Enclosures:

Commission Regulation (EU) 2016/692 of 4 May 2016 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances. (FL/16/25)

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) from the UL	<i>EFFA IL 16/03</i>
23 April 2016	Commission Regulation (EU) 2016/637	Removal of 4 flavouring substances FGE.208rev1 (Non supported) from the UL	<i>EFFA IL 16/05</i>
5 May 2016	Commission Regulation (EU) 2016/692	7 fully evaluated substances (deletion of footnotes)	<i>EFFA IL 16/06</i>
29 July 2016	Commission Regulation (EU) 2016/1244	Conditions of use defined for 5 flavourings substances FGE.208rev1 (supported substances).	<i>EFFA IL 16/12</i>