

**COMMISSION REGULATION (EU) 2022/1465****of 5 September 2022****amending 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 <sup>(1)</sup>, 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 <sup>(2)</sup>, 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 approved for use in and on foods and their conditions of use.
- (2) Commission Implementing Regulation (EU) No 872/2012 <sup>(3)</sup> adopted a list of flavouring substances and inserted that list in Annex I, Part A, to Regulation (EC) No 1334/2008.
- (3) That list may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application submitted by a Member State or by an interested party.
- (4) The Union list of flavourings and source materials laid down in Annex I to Regulation (EC) No 1334/2008 contains, among others, a number of flavouring substances for which, at the time of adoption of the list by Implementing Regulation (EU) No 872/2012, the European Food Safety Authority ('the Authority') had not been able to rule out a safety risk to the health of the consumer on the basis of the data available and had, therefore, considered that additional data was necessary to complete their evaluation. Those substances were included in the Union list of flavouring substances but on the condition that safety data addressing the concerns expressed by the Authority was submitted before the expiry of specific deadlines established in Part A of Annex I to Regulation (EC) No 1334/2008. Among the substances included in the Union list of flavourings and source materials but identified by way of a footnote reference requiring the Authority to complete the evaluation, there were the following five substances of the Flavouring Group Evaluation 208 (FGE.208), namely p-mentha-1,8-dien-7-ol (FL No 02.060), myrtenol (FL No 02.091), myrtenal (FL No 05.106), p-Mentha-1,8-dien-7-yl acetate (FL No 09.278) and myrtenyl acetate (FL No 09.302). The Authority requested additional scientific data that were subsequently submitted by the applicants.
- (5) In its scientific opinion of 24 June 2015 <sup>(4)</sup>, the Authority evaluated the submitted data and concluded that the representative substance of the group, p-mentha-1,8-dien-7-al (FL no 05.117), was genotoxic *in vivo* and that, therefore, its use as a flavouring substance raised a safety concern.

<sup>(1)</sup> OJ L 354, 31.12.2008, p. 34.

<sup>(2)</sup> OJ L 354, 31.12.2008, p. 1.

<sup>(3)</sup> 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 (OJ L 267, 2.10.2012, p. 1).

<sup>(4)</sup> Scientific Opinion on Flavouring Group Evaluation 208 Revision 1 (FGE.208Rev1): Consideration of genotoxicity data on representatives for 10 alicyclic aldehydes with the  $\alpha,\beta$ -unsaturation in ring/side-chain and precursors from chemical subgroup 2.2 of FGE.19. EFSA Journal 2015;13(7):4173, 28 pp. doi:10.2903/j.efsa.2015.4173. Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

- (6) Following this opinion, the Commission withdrew this substance from the Union list of flavourings by means of Regulation (EU) 2015/1760 <sup>(5)</sup>.
- (7) As *p*-mentha-1,8-dien-7-al (FL no 05.117) is representative for four other substances belonging to Flavouring Group Evaluation 208 (FGE.208), the Commission further withdrew those four substances from the Union list by means of Commission Regulation (EU) 2016/637 <sup>(6)</sup>.
- (8) As regards *p*-mentha-1,8-dien-7-ol (FL No 02.060), myrtenol (FL No 02.091), myrtenal (FL No 05.106), *p*-mentha-1,8-dien-7-yl acetate (FL No 09.278) and myrtenyl acetate (FL No 09.302), the applicants for these substances indicated that they had launched specific individual sets of toxicity studies on them, addressing the concerns expressed by the Authority in its 24 June 2015 opinion. The applicants undertook to submit the requested new data before 30 April 2016.
- (9) Pending the evaluation, by the Authority, of those substances, their eventual full evaluation under the Authority's panel procedure and the completion of the subsequent regulatory process, the Commission adopted Regulation (EU) 2016/1244 <sup>(7)</sup> limiting the uses of these flavouring substances, whilst maintaining their status of substances under evaluation.
- (10) The applicants submitted scientific studies and other data relevant for the evaluation by 30 April 2016.
- (11) In its opinions of 22 March 2017 <sup>(8)</sup> and 11 December 2018 <sup>(9)</sup>, the Authority evaluated the submitted data and additional further data, ruled out the concern on genotoxicity for those five substances and decided that they could be evaluated under the procedure of evaluation of existing flavouring substances referred to in Commission Regulation (EC) No 1565/2000 <sup>(10)</sup>. For this purpose, the Authority allocated those five substances to the Flavouring Group Evaluation 73 (FGE.73). In its opinions of 19 September 2017 <sup>(11)</sup> and 10 December 2020 <sup>(12)</sup>, it updated the evaluations of this group of substances and concluded that those substances do not raise a safety concern. It also provided recommendations to change the name and the specifications of some of those substances.
- (12) Under Regulation (EC) No 1334/2008, the Authority had to complete the evaluation for the following 20 substances of the Flavouring Group Evaluation 203 (FGE.203 rev.1): deca-2,4-dien-1-ol (FL No 02.139); hepta-2,4-dien-1-ol (FL No 02.153); hexa-2,4-dien-1-ol (FL No 02.162); nona-2,4-dien-1-ol (FL No 02.188); hexa-2(trans),4(trans)-dienal (FL No 05.057); trideca-2(trans),4(cis),7(cis)-trienal (FL No 05.064); nona-2,4-dienal (FL No 05.071); 2,4-decadienal (FL No 05.081); hepta-2,4-dienal (FL No 05.084); penta-2,4-dienal (FL No 05.101); undeca-2,4-dienal (FL

<sup>(5)</sup> Commission Regulation (EU) 2015/1760 of 1 October 2015 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 the flavouring substance *p*-mentha-1,8-dien-7-al (OJ L 257, 2.10.2015, p. 27).

<sup>(6)</sup> 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 (OJ L 108, 23.4.2016, p. 24).

<sup>(7)</sup> 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 (OJ L 204, 29.7.2016, p. 7).

<sup>(8)</sup> Scientific Opinion on Flavouring Group Evaluation 208 Revision 2 (FGE.208Rev2): Consideration of genotoxicity data on alicyclic aldehydes with  $\alpha,\beta$ -unsaturation in ring/side-chain and precursors from chemical subgroup 2.2 of FGE.19. EFSA Journal 2017;15(5):4766. <https://doi.org/10.2903/j.efsa.2017.4766>

<sup>(9)</sup> Scientific Opinion on Flavouring Group Evaluation 208 Revision 3 (FGE.208Rev3): consideration of genotoxicity data on alicyclic aldehydes with  $\alpha,\beta$ -unsaturation in ring/side-chain and precursors from chemical subgroup 2.2 of FGE.19. EFSA Journal 2019;17(1):5569. <https://doi.org/10.2903/j.efsa.2019.5569>

<sup>(10)</sup> Commission Regulation (EC) No 1565/2000 of 18 July 2000 laying down the measures necessary for the adoption of an evaluation programme in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council (OJ L 180, 19.7.2000, p. 8).

<sup>(11)</sup> Scientific Opinion on Flavouring Group Evaluation 73, Revision 4 (FGE.73Rev4): consideration of alicyclic alcohols, aldehydes, acids and related esters evaluated by JECFA (59th and 63rd meeting) structurally related to primary saturated or unsaturated alicyclic alcohols, aldehydes, acids and esters evaluated by EFSA in FGE.12Rev5. EFSA Journal 2017;15(11):5010. doi: 10.2903/j.efsa.2017.5010. Available at [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

<sup>(12)</sup> Scientific Opinion on Flavouring Group Evaluation 73, Revision 5 (FGE.73Rev5): consideration of alicyclic alcohols, aldehydes, acids and related esters evaluated by JECFA (59th, 63rd and 86th meeting) and structurally related to substances evaluated in FGE.12Rev5. EFSA Journal 2020;18(1):5970. doi: 10.2903/j.efsa.2020.5970. Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

No 05.108); dodeca-2,4-dienal (FL No 05.125); octa-2(trans),4(trans)-dienal (FL No 05.127); deca-2(trans),4(trans)-dienal (FL No 05.140); deca-2,4,7-trienal (FL No 05.141); nona-2,4,6-trienal (FL No 05.173); 2,4-octadienal (FL No 05.186); tr-2,tr-4-nonadienal (FL No 05.194); tr-2,tr-4-undecadienal (FL No 05.196), and hexa-2,4-dienyl acetate (FL No 09.573). The Authority has requested additional scientific data that were subsequently submitted by the applicants.

- (13) The substances hexa-2(trans),4(trans)-dienal (FL No 05.057) and deca-2(trans),4(trans)-dienal (FL No 05.140) were used as representative substances for this group of substances, and toxicity data were submitted for them.
- (14) In its scientific opinion of 26 March 2014 <sup>(13)</sup>, the Authority evaluated the submitted data and concluded that it could not rule out safety concerns for both representative substances of the group. Therefore, the Authority could not complete the assessment of the substances belonging to FGE group 203.
- (15) The applicants for these substances indicated that they had launched a variety of specific toxicity studies on the substances of this group, addressing the concerns the Authority expressed in its 26 March 2014 opinion.
- (16) The Authority requested further data on identity and characterization, and also poundage and intake data, to allow a proper exposure assessment, in order to fully assess the safety of these substances.
- (17) The applicants undertook to submit the requested new data by 30 September 2016. Pending the submission of the additional data, the evaluation, by the Authority, of the genotoxicity of those substances, their eventual full evaluation under the Authority's panel procedure and the completion of the subsequent regulatory process, the Commission adopted Regulation (EU) 2017/378 <sup>(14)</sup> limiting the uses of these flavouring substances, whilst maintaining their status of substances under evaluation.
- (18) The applicants submitted scientific studies and data relevant for this evaluation by 30 September 2016.
- (19) In its opinion of 5 June 2018 <sup>(15)</sup>, the Authority evaluated the submitted data, ruled out the concern on genotoxicity for those substances and decided that they could be evaluated under the procedure for the evaluation of existing flavouring substances referred to in Regulation (EC) No 1565/2000. For this purpose, the Authority allocated 16 of those substances to Flavouring Group Evaluation 70 (FGE.70) and four of them to Flavouring Group Evaluation 05 (FGE.05). In its opinions adopted on 5 June 2019 <sup>(16)</sup> and 26 June 2019 <sup>(17)</sup>, it updated the evaluations of the substances in Flavouring Group Evaluation 70, Revision 1 (FGE.70 Rev1) and Flavouring Group Evaluation 05, Revision 3 (FGE.05 Rev3), respectively. As regards the 16 substances in FGE 70 Rev.1, the Authority concluded that they do not raise a safety concern and provided recommendations to change the name and the specifications of some of those substances. As regards the four substances in FGE.05 Rev.3, the Authority also concluded that they do not raise a safety concern and provided recommendations to change the name and the specifications of some of those four substances.

<sup>(13)</sup> Scientific Opinion on Flavouring Group Evaluation 203 Rev 1 (FGE.203 Rev1): EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2014. Scientific Opinion on Flavouring Group Evaluation 203 Revision 1 (FGE.203Rev1):  $\alpha,\beta$ -unsaturated aliphatic aldehydes and precursors from chemical subgroup 1.1.4 of FGE.19 with two or more conjugated double-bonds and with or without additional non-conjugated double-bonds. EFSA Journal 2014;12(4):3626, 31 pp. doi:10.2903/j.efsa.2014.3626. Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

<sup>(14)</sup> Commission Regulation (EU) 2017/378 of 3 March 2017 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances (OJ L 58, 4.3.2017, p. 14).

<sup>(15)</sup> Scientific Opinion on Flavouring Group Evaluation 203, Revision 2 (FGE.203Rev2):  $\alpha,\beta$ -unsaturated aliphatic aldehydes and precursors from chemical subgroup 1.1.4 of FGE.19 with two or more conjugated double-bonds and with or without additional non-conjugated double-bonds. EFSA Journal 2018;16(7):5322.

<sup>(16)</sup> Scientific Opinion on Flavouring Group Evaluation 70, Revision 1 (FGE.70Rev1): consideration of aliphatic, linear,  $\alpha,\beta$ -unsaturated, di- and trienals and related alcohols, acids and esters evaluated by JECFA (61st-68th-69th meeting). EFSA Journal 2019;17(7):5749.

<sup>(17)</sup> Scientific Opinion on Flavouring Group Evaluation 5, Revision 3 (FGE.05Rev3): Branched- and straight-chain unsaturated aldehydes, dienals, unsaturated and saturated carboxylic acids and related esters with saturated and unsaturated aliphatic alcohols and a phenylacetic acid related ester from chemical groups 1, 2, 3, 5 and 15. EFSA Journal 2019;17(8):5761

- (20) Annex I, part A, to Regulation (EC) No 1334/2008 should therefore be amended accordingly.
- (21) 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*

Annex I, Part A, to Regulation (EC) No 1334/2008 is amended in accordance with the Annex to this Regulation.

*Article 2*

This Regulation shall enter into force 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, 5 September 2022.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

Part A, Section 2, Table 1, of Annex I to Regulation (EC) No 1334/2008 is amended as follows:

(a) the entry concerning FL No 02.060 is replaced by the following:

'02.060	p-Mentha-1,8-dien-7-ol	536-59-4	974	2024				EFSA'
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(b) the entry concerning FL No 02.091 is replaced by the following:

'02.091	Myrtenol	515-00-4	981	10285				EFSA'
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(c) the entry concerning FL No 02.139 is replaced by the following:

'02.139	Deca-(2E,4E)-dien-1-ol	18409-21-7	1189	11748				EFSA'
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(d) the entry concerning FL No 02.153 is replaced by the following:

'02.153	Hepta-2,4-dien-1-ol	33467-79-7	1784					EFSA'
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(e) the entry concerning FL No 02.162 is replaced by the following:

'02.162	Hexa-2,4-dien-1-ol	111-28-4	1174					EFSA'
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(f) the entry concerning FL No 02.188 is replaced by the following:

'02.188	Nona-2,4-dien-1-ol	62488-56-6	1183	11802	At least 92 %; secondary component 3-4 % 2-nonen-1-ol			EFSA'
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(g) the entry concerning FL No 05.057 is replaced by the following:

'05.057	Hexa-2(trans),4(trans)-dienal	142-83-6	1175	640				EFSA'
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(h) the entry concerning FL No 05.064 is replaced by the following:

'05.064	Trideca-2(trans),4(cis),7(cis)-trienal	13552-96-0	1198	685	At least 71 %; secondary components 14 % 4-cis-7-cis-tridecadienol; 6 % 3-cis-7-cis- tridecadienol; 5 % 2-trans-7-cis-tridecadienal; 3 % 2-trans-4-trans-7-cis-tridecatrienal			EFSA'
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(i) the entry concerning FL No 05.071 is replaced by the following:

'05.071	Nona-2,4-dienal	6750-03-4	1185	732	At least 89 %; secondary components 5-6 % 2,4-nonadien-1-ol and 1-2 % 2-nonen-1-ol			EFSA'
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(j) the entry concerning FL No 05.081 is replaced by the following:

'05.081	2,4-Decadienal	2363-88-4	3135	2120	At least 89 %; secondary components: mixture of the (cis, cis)-; (cis, trans)- and (trans, cis)-2,4-decadienals (sum of all isomers 95 %); acetone and isopropanol			EFSA'
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(k) the entry concerning FL No 05.084 is replaced by the following:

'05.084	Hepta-(2E,4E)-dienal	4313-03-5	1179	729	At least 92 %; secondary components 2-4 % (E,Z)-2,4-heptadienal and 2-4 % 2,4-heptadienoic acid			EFSA'
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(l) the entry concerning FL No 05.101 is replaced by the following:

'05.101	Penta-2,4-dienal	764-40-9	1173	11695				EFSA'
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(m) the entry concerning FL No 05.106 is replaced by the following:

'05.106	Myrtenal	564-94-3	980	10379				EFSA'
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(n) the entry concerning FL No 05.108 is replaced by the following:

'05.108	Undeca-2,4-dienal	13162-46-4	1195	10385				EFSA'
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(o) the entry concerning FL No 05.125 is replaced by the following:

'05.125	Dodeca-(2E,4E)-dienal	21662-16-8	1196	11758	At least 85 %; secondary component 11-12 % 2-trans-4-cis isomer			EFSA'
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(p) the entry concerning FL No 05.127 is replaced by the following:

'05.127	Octa-2(trans),4(trans)-dienal	30361-28-5	1181	11805				EFSA'
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(q) the entry concerning FL No 05.140 is replaced by the following:

'05.140	Deca-2(trans),4(trans)-dienal	25152-84-5	1190	2120	At least 90 % minimum of the (E, E)-isomer; 95 % (sum of isomers)			EFSA'
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(r) the entry concerning FL No 05.141 is replaced by the following:

'05.141	Deca-2,4,7-trienal	51325-37-2	1786					EFSA'
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(s) the entry concerning FL No 05.173 is replaced by the following:

'05.173	Nona-(2E,4E,6E)-trienal	57018-53-8	1785					EFSA'
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(t) the entry concerning FL No 05.186 is replaced by the following:

'05.186	2,4-Octadienal	5577-44-6		11805	At least 85 % E,E with 10 % E, Z			EFSA'
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(u) the entry concerning FL No 05.194 is replaced by the following:

'05.194	(2E, 4E)-nona-2,4-dienal	5910-87-2		732	At least 89 %; secondary components at least 5 % 2,4-nonadien-1-ol and 2-nonen-1-ol and other isomers of 2,4-nonadienal			EFSA'
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(v) the entry concerning FL No 05.196 is replaced by the following:

'05.196	(2E, 4E)-undeca-2,4-dienal							EFSA'
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(w) the entry concerning FL No 09.278 is replaced by the following:

'09.278	p-Mentha-1,8-dien-7-yl acetate	15111-96-3	975	10742				EFSA'
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(x) the entry concerning FL No 09.302 is replaced by the following:

'09.302	Myrtenyl acetate	35670-93-0	982	10887				EFSA'
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(y) the entry concerning FL No 09.573 is replaced by the following:

'09.573	Hexa-2,4-dienyl acetate	1516-17-2	1780	10675				EFSA'
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