

Flavouring Group Evaluation 87, Revision 3 (FGE.87Rev3): Consideration of bicyclic secondary alcohols, ketones and related esters evaluated by JECFA (63rd meeting) structurally related to bicyclic secondary alcohols, ketones and related esters evaluated in FGE.47Rev1

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The declarations of interest of all scientific experts active in EFSA's work are available at <https://open.efsa.europa.eu/experts>.

Abstract

The Panel on Food Additives and Flavourings (FAF) of the European Food Safety Authority was requested to consider evaluations of flavouring substances assessed since 2000 by the Joint FAO/WHO Expert Committee on Food Additives (the JECFA) and to decide whether further evaluation is necessary, as laid down in Commission Regulation (EC) No. 1565/2000. The present consideration concerns a group of 19 bicyclic secondary alcohols, ketones and related esters evaluated by JECFA at the 63rd meeting. This revision of FGE.87 is made due to new information on annual production volume, allowing the calculation of maximised survey-derived daily intake (MSDI) for 4,4a,5,6-tetrahydro-7-methylnaphthalen-2(3H)-one [FL-no: 07.136]. In addition, new data on uses and use levels for the substances [FL-no: 07.089, 07.0136, 07.153 and 07.159] have been provided and considered for the estimation of exposure (mTAMDI approach). For [FL-no: 07.136], the Panel agrees with the Procedure as applied by JECFA and with JECFA conclusion: 'No safety concern at estimated levels of intake as flavouring substance', when based on the MSDI approach. For the other 18 substances considered in FGE.87Rev3, the same conclusion was already drawn in FGE.87Rev2. For [FL-no: 07.136], the mTAMDI exposure estimate is below the TTC for structural class II substances. Accordingly, no further data are required in the context of the current evaluation programme. For [FL-no: 07.089, 07.153, 07.159], mTAMDI exposure estimates are above the TTC for structural class II substances; therefore, more reliable data on uses and use levels should be provided in order to refine the exposure assessment and to finalise their safety evaluation. For the remaining 15 substances, use levels are needed to calculate the mTAMDI in order to identify those flavouring substances that need more refined exposure assessments and to finalise the evaluation. Information on specifications for the materials of commerce is considered adequate for all 19 substances.

KEYWORDS

bicyclic, esters, FGE.47, FGE.87, flavouring, ketones, secondary alcohols

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1 | INTRODUCTION

The present revision of FGE.87 (FGE.87Rev3) is made due to new information on annual production volume for 4,4a,5,6-tetrahydro-7-methylnaphthalen-2(3H)-one [FL-no: 07.136] that allows the calculation of maximised survey-derived daily intake (MSDI) for this substance. In addition, new data on uses and use levels for the substances [FL-no: 07.089, 07.0136, 07.153 and 07.159] have been provided and considered for the estimation of exposure (modified theoretical added maximum daily intake (mTAMDI) approach).

1.1 | Background and terms of reference as provided by the requestor

1.1.1 | Background

The use of flavourings in food is regulated under Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008¹ on flavourings and certain food ingredients with flavouring properties for use in and on foods. On the basis of Article 9(a) of this Regulation, an evaluation and approval are required for flavouring substances.

The Union list of flavourings and source materials was established by Commission Implementing Regulation (EC) No. 872/2012.² The list includes flavouring substances for which the scientific evaluation should be completed in accordance with Commission Regulation (EC) No. 1565/2000.³

In the scientific opinion on Flavouring group evaluation 87 revision 2 (FGE.87Rev2) adopted on 25 September 2014, the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and processing Aids (CEF) concluded that the evaluation of 4,4a,5,6-tetrahydro-7-methylnaphthalen-2(3H)-one [FL-no: 07.136] cannot be finalised because the production volume of this substance for Europe is not available.

In March 2025, the European Flavour Association submitted to the Commission the missing data.

1.1.2 | Terms of Reference

The European Commission requests the European Food Safety Authority (EFSA) to evaluate the newly submitted information and to proceed to the full evaluation of the flavouring substance [FL No. 07.136], in accordance with Commission Regulation (EC) No. 1565/2000.³

1.2 | Interpretation of the Terms of Reference

In addition to assess the new data submitted for [FL-no: 07.136], new data on uses and use levels provided for [FL-no: 07.089, 07.153, 07.159] (Documentation provided to EFSA No. 2) are considered in the present revision to estimate the exposure based on the mTAMDI approach.

1.3 | History of the evaluation and presentation of the substances in the present FGE

FGE.87

At its 63rd meeting, the JECFA evaluated a group of 32 flavouring substances consisting of monocyclic and bicyclic secondary alcohols, ketones and related esters (JECFA, 2005, 2006) and established the corresponding specifications (JECFA, 2004). As concerns the EU, three of the JECFA-evaluated substances (alpha-isomethylionyl acetate (JECFA-no: 1410), d,l-menthol-(±)-propylene glycol carbonate (JECFA-no: 1413) and l-monomenthyl glutarate (JECFA-no: 1414)) were not in the Register.⁴

Six monocyclic secondary alcohols, ketones and related esters [FL-no: 02.224, 02.246, 02.254,⁵ 07.110, 07.111,⁶ 09.521] were considered in FGE.56 (EFSA, 2008a).

¹Regulation (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. OJ L 354, 31.12.2008, pp. 34–50.

²Commission 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, pp. 1–161.

³Commission 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. OJ L 180, 19.7.2000, pp. 8–16.

⁴Commission Decision of 23 February 1999 adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996. OJ L 84, 27.3.1999, pp. 1–215.

⁵The assessment of the substances [FL-no: 02.224, 02.246, 02.254] was finalised in FGE.96 (EFSA CEF Panel, 2011d).

⁶The substances [FL-no: 07.110 and 07.111] were not included in the Union List because toxicological data were not available (Documentation provided to EFSA No. 3).

In addition, (1R)-1,7,7-trimethylbicyclo[2.2.1]heptan-2-one (camphor [FL-no: 07.215]) was considered separately (EFSA, 2008b) by the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC Panel). Finally, one ether [FL-no: 16.088] was considered at a later stage in FGE.59 Rev1 (EFSA CEF Panel, 2011a).

The α,β -unsaturated carbonyl is a structural alert for genotoxicity. Six substances are α,β -unsaturated ketones [FL-no: 07.089, 07.136 and 07.140] or precursors of α,β -unsaturated ketones [FL-no: 02.100, 02.101, and 09.305]. For [FL-no: 02.100], [FL-no: 02.101], [FL-no: 07.140] and [FL-no: 07.089, 07.136, 09.305], it has been concluded, in FGE.211 (EFSA CEF Panel, 2011b), FGE.212Rev1 (EFSA CEF Panel, 2011c), FGE.212Rev3 (EFSA CEF Panel, 2015) and FGE.213Rev1 (EFSA CEF Panel, 2014b), that a concern for genotoxicity could be ruled out based on experimental data for structurally related substances (supporting substances). Thus, the CEF Panel concluded that these substances could be evaluated through the Procedure (see Appendix A for details on the Procedure). 3-Methyl-2-pentylcyclopent-2-en-1-one [FL-no: 07.140] and beta-ionyl acetate [FL-no: 09.305] were evaluated through the Procedure in FGE.51Rev2 (EFSA CEF Panel, 2016) and in FGE.73Rev3 (EFSA CEF Panel, 2014c), respectively. The substances pinocarveol [FL-no: 02.100] and pin-2-en-4-ol [FL-no: 02.101] were evaluated through the Procedure in FGE.87Rev1 (EFSA CEF Panel, 2012a). Nootkatone [FL-no: 07.089] and 4,4a,5,6-tetrahydro-7-methylnaphthalen-2(3H)-one [FL-no: 07.136] were evaluated through the Procedure in FGE.87Rev2 (EFSA CEF Panel, 2014a).

The remaining 15 flavouring substances [FL-no: 02.016, 02.038, 02.059, 07.153, 07.159, 09.017, 09.082, 09.131, 09.153, 09.176, 09.218, 09.269, 09.319, 09.456 and 09.457] were considered by the AFC Panel in FGE.87 (EFSA, 2008c).

Based on genotoxicity data reported by JECFA (2006), the AFC Panel considered that '*Genotoxicity data are available only for a limited number of structurally related substances, and the genotoxicity could not be assessed adequately. However, the data available do not preclude the evaluation of the candidate substances using the Procedure*' (EFSA, 2008c).

In FGE.87, the AFC Panel agreed with the application of the Procedure as performed by JECFA. However, for two substances, DL-bornyl valerate [FL-no: 09.153] and DL-bornyl butyrate [FL-no: 09.319], the JECFA evaluation was based only on MSDI values derived from production figures from the USA. The AFC Panel concluded that EU production figures were needed in order to finalise the evaluation of these substances (EFSA, 2008c). Information on stereoisomeric composition was lacking for eight substances [FL-no: 02.016, 02.038, 07.159, 09.017, 09.131, 09.153, 09.176 and 09.218] included in FGE.87.

For all 15 substances evaluated through the Procedure, use levels were needed to calculate the mTAMDI estimates in order to identify those flavouring substances for which more refined exposure assessments are needed to finalise their evaluation.

For six of the 15 substances [FL-no: 02.059, 07.153, 09.082, 09.269, 09.456 and 09.457], the AFC Panel agreed with the JECFA conclusion that there is 'no safety concern at estimated levels of intake as flavouring substances', when based on the MSDI approach (EFSA, 2008c).

The FAF Panel noted that all the substances in FGE.87 (and revisions thereof) are structurally related to the group of four bicyclic secondary alcohols, ketones and related esters evaluated by EFSA in the Flavouring Group Evaluation 47 (EFSA, 2008d; EFSA CEF Panel, 2012b), which had not been evaluated by JECFA⁷ and are not related to any other flavouring substances considered in FGEs 50–99. This is in line with the considerations of the AFC Panel (EFSA, 2008c) and the CEF Panel (EFSA CEF Panel, 2012a, 2014a).

FGE.87Rev1

In FGE.87Rev1 (EFSA CEF Panel, 2012a), two additional substances, pinocarveol [FL-no: 02.100] and pin-2-en-4-ol [FL-no: 02.101], were included. The potential genotoxicity of these precursors of α,β -unsaturated ketones had been evaluated in FGE.211 (EFSA CEF Panel, 2011b) and FGE.212Rev1 (EFSA CEF Panel, 2011c), respectively. Both substances [FL-no: 02.100 and 02.101] were considered as of no safety concern with respect to genotoxicity and therefore evaluated through the Procedure in FGE.87Rev1.

EU production volumes were provided for [FL-no: 09.153 and 09.319] and evaluated in FGE.96 (EFSA CEF Panel, 2011d), but for the sake of completion, the information was included also in FGE.87Rev1 (EFSA CEF Panel, 2012a).

New information on stereoisomerism was provided for 13 substances [FL-no: 02.016, 02.038, 02.059, 07.159, 09.017, 09.082, 09.131, 09.153, 09.176, 09.218, 09.319, 09.456 and 09.457] (EFSA CEF Panel, 2012a). For [FL-no: 02.100 and 02.101], information on the stereoisomeric composition was lacking.

For the remaining 15 substances [FL-no: 02.016, 02.038, 02.059, 07.153, 07.159, 09.017, 09.082, 09.131, 09.153, 09.176, 09.218, 09.269, 09.319, 09.456 and 09.457], the CEF Panel agreed with the JECFA conclusion: 'No safety concern at estimated levels of intake as flavouring substances', when based on the MSDI approach.

For all 17 substances evaluated through the Procedure, use levels were needed to calculate the mTAMDI estimates to identify those flavouring substances for which more refined exposure assessments are needed to finalise the evaluation.

FGE.87Rev2

In FGE.87Rev2 (EFSA CEF Panel, 2014a), two additional substances, nootkatone [FL-no: 07.089] and 4,4a,5,6-tetrahydro-7-methylnaphthalen-2(3H)-one [FL-no: 07.136], which are α,β -unsaturated alicyclic ketones, were included. The potential

⁷Flavouring Group Evaluation 1 to 49 (FGE.01 to FGE.49) include substances that have not been evaluated by JECFA after the year 2000. Flavouring Group Evaluation 50 to 99 (FGE.50 to FGE.99) include substances which were evaluated by JECFA after the year 2000. Flavouring substances that were evaluated by JECFA before the year 2000 do not need to be evaluated by EFSA (see Art.2 of Regulation (EC) 1565/2000).

genotoxicity of [FL-no: 07.089 and 07.136] had been evaluated in FGE.213Rev1 (EFSA CEF Panel, 2014b) in which they were considered not to be of concern with respect to genotoxicity.

For two substances [FL-no: 02.100 and 02.101], the information on stereoisomeric composition was provided and included in FGE.87Rev2.

The CEF Panel agreed with the application of the Procedure as performed by the JECFA for the 19 bicyclic secondary alcohols, ketones and related esters.

For 18 substances [FL-no: 02.016, 02.038, 02.059, 02.100, 02.101, 07.089, 07.153, 07.159, 09.017, 09.082, 09.131, 09.153, 09.176, 09.218, 09.269, 09.319, 09.456 and 09.457], the CEF Panel agreed with the JECFA conclusion: 'No safety concern at estimated levels of intake as flavouring substances', when based on the MSDI approach. For one substance [FL-no: 07.136], the evaluation through the Procedure could not be finalised because no EU production volume (synonym of poundage data) was available to estimate the exposure based on the MSDI approach.

For all 19 substances evaluated through the Procedure, use levels were needed to calculate the mTAMDI in order to identify those flavouring substances that need more refined exposure assessments and to finalise the evaluation.

Table 1 gives references to the revisions of FGE.87.

TABLE 1 References to the revisions of FGE.87.

FGE	Reference	Substances
FGE.87	EFSA (2008c)	15
FGE.87Rev1	EFSA CEF Panel (2012a)	17
FGE.87Rev2	EFSA CEF Panel (2014a)	19
FGE.87Rev3	Current opinion	19

A summary of the history of the evaluation of the substances in FGE.87 is presented in Figure 1.

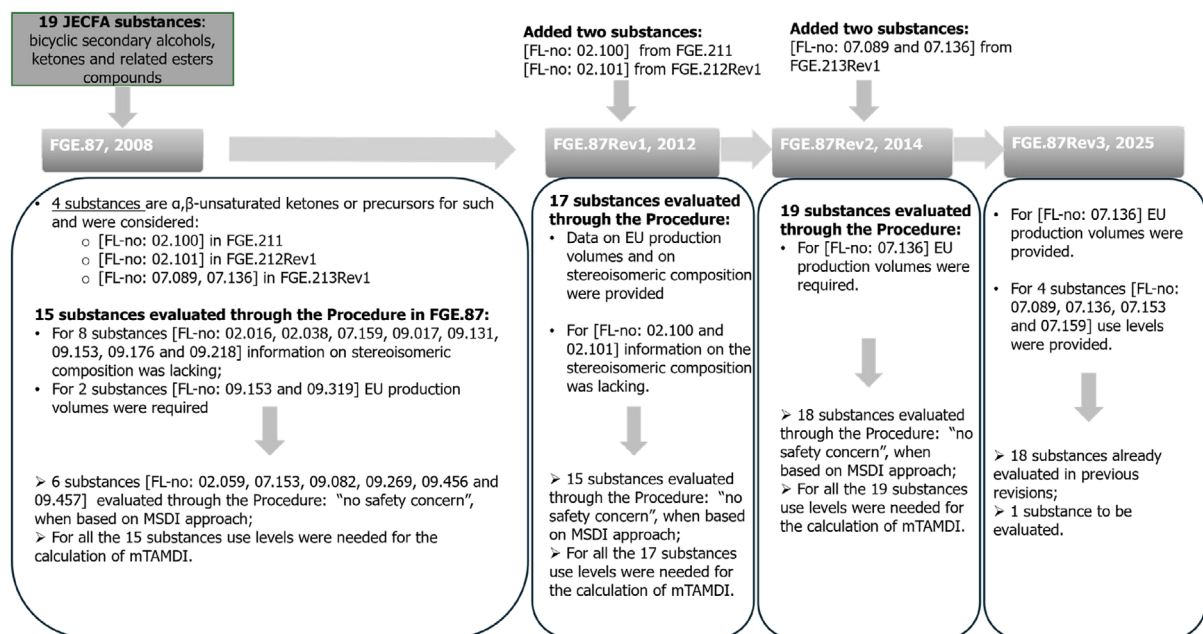


FIGURE 1 Summary of the history of evaluation of the substances in FGE.87.

2 | DATA AND METHODOLOGIES

2.1 | Data

In the present revision (FGE.87Rev3), the following data were considered:

- EU poundage data and uses and use levels for [FL-no: 07.136] (Documentation provided to EFSA No. 1);

- Uses and use levels for three substances [FL-no: 07.089, 07.153, 07.159] (Documentation provided to EFSA No. 2) that were submitted to EFSA in the context of the 'Request for scientific and technical assistance in the preparatory work for the implementation of the common methodology for the monitoring of food additives in accordance with Article 27 of Regulation (EC) No. 1333/2008⁸ and food flavourings in accordance with Article 20 of Regulation (EC) No. 1334/2008⁹'.

2.2 | Methodologies

This opinion was prepared following the principles described in the EFSA Guidance on transparency with regard to scientific aspects of risk assessment (EFSA Scientific Committee, 2009) and following the relevant existing Guidelines from the EFSA Scientific Committee. As requested in the European Commission mandate, the assessment strategy applied is in line with the evaluation programme of flavouring substances, as laid down in Commission Regulation (EC) No 1565/2000,³ which is based on the Opinion on a Programme for the Evaluation of Flavouring substances of the Scientific Committee on Food (SCF, 1999).

The approach for safety evaluation of chemically defined flavouring substances as referred to in Commission Regulation (EC) No. 1565/2000,³ named the 'Procedure', is described in [Appendix A](#).

The approach used for calculation of the intake of the flavouring substances is described in [Appendix A](#) (point a 'Intake') and in [Appendix C](#) (Appendix C.2 'mTAMDI calculation').

3 | ASSESSMENT

The present revision 3 of FGE.87 (FGE.87Rev3) deals with the evaluation of [FL-no: 07.136] for which poundage data and use level data were provided (Documentation provided to EFSA No. 1). Additionally, mTAMDI estimates for three substances [FL-no: 07.089, 07.153, 07.159] were included in this opinion, based on information on uses and use levels provided (Documentation provided to EFSA No. 2).

FGE.87Rev3 includes 19 substances, of which 18 were already considered in FGE.87Rev2 as of no safety concern when based on the MSDI approach. For the sake of completeness, information already available for all 19 substances in this FGE in previous assessments on specifications, intake and evaluation status is presented in the respective Appendices B–D.

3.1 | Specifications

JECFA status

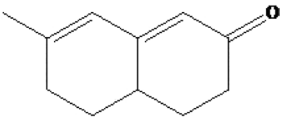
JECFA specifications are available for all substances (JECFA, 2004). All 19 substances have one or more chiral centres (see [Appendix B](#)).

EFSA considerations

The chemical name, structure and structural class of the flavouring substance [FL-no: 07.136] considered in FGE.87Rev3 are reported in [Table 2](#).

Specifications for all 19 substances in FGE.87Rev3 are summarised in [Appendix B, Table B1](#), according to information reported in FGE.87Rev2 and the latest information reported in Regulation (EC) No 1334/2008.¹ The available specifications are considered adequate for all 19 substances.

TABLE 2 Chemical name, structure and structural class of the flavouring substance under evaluation in FGE.87Rev3.

FL-no JECFA no	Structural formula	Chemical name	Structural class ^a
07.136 1405		4,4a,5,6-tetrahydro-7-methylnaphthalen-2(3H)-one	II

Abbreviations: FL-no, FLAVIS number; JECFA, The Joint FAO/WHO Expert Committee on Food Additives; JECFA no, JECFA number.

^aDetermined with OECD Toolbox (version 4.7.1 available at <https://qsartoolbox.org/>)

⁸Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16.

⁹<https://open.efsa.europa.eu/question/EFSA-Q-2023-00026>.

3.2 | Estimation of intake

JECFA status

For 21 of the 32 substances evaluated by JECFA, data on production volumes were available for the EU. For the remaining 11 substances evaluated by JECFA, including [FL-no: 07.136], production figures were only available for the USA (JECFA, 2005, 2006).

EFSA considerations

The EU production figure for the flavouring substance [FL-no: 07.136] was submitted by industry (Documentation provided to EFSA No. 1) and considered in the present revision (FGE.87Rev3). Based on this new information, the calculated MSDI value is 0.06 µg/capita per day (see Table C4, Appendix C).

Also, updated use levels were submitted for the flavouring substance [FL-no: 07.136] (Documentation provided to EFSA No. 1) as well as for three flavouring substances [FL-no: 07.089, 07.153, 07.159] previously evaluated (Documentation provided to EFSA No. 2). Therefore, in the current opinion, the mTAMDI estimates were calculated for these four substances (see Tables C1 and C2, Appendix C).

The MSDI and mTAMDI estimates of the current assessment and of the previous revisions for all the flavouring substances in FGE.87Rev3 are shown in Table C4 – Appendix C.

3.3 | Biological and toxicological data

3.3.1 | ADME data

JECFA status

Regarding the group of monocyclic and bicyclic secondary alcohols, ketones and related esters JECFA (2005, 2006) reported that 'Studies in humans, dogs, and rabbits, have shown that the mono- and bicyclic secondary alcohols and ketones in this group are rapidly absorbed, distributed, metabolized, and excreted mainly in the urine. Small amounts may be eliminated in exhaled air. In humans, the esters within this group are expected to be hydrolysed to their component secondary alcohol and carboxylic acid. The major metabolic pathway for the ketones involves reduction to the corresponding secondary alcohols, which are subsequently excreted, primarily as the glucuronic acid conjugates (Williams, 1959; Lington & Bevan, 1994; Topping et al., 1994). Metabolites containing a double bond that are excreted into the bile may be reduced to the corresponding dihydro derivatives by the gut microflora (Krasavage et al., 1982). In addition to reductive pathways, alicyclic ketones and, to a lesser extent, secondary alcohols containing an alkyl side-chain, undergo oxidation of the side-chain to form polar poly-oxygenated metabolites that are excreted mainly in the urine, either unchanged or as the glucuronide or sulfate conjugates. For more lipophilic ketones (e.g. nootkatone, No. 1398) or those with sterically hindered functional groups (e.g. d-camphor, No. 1395), oxidation of a ring position by cytochrome P450 (CYP) may compete with reduction of the ketone group or oxidation of the alcohol group (Asakawa et al., 1986; Nelson et al., 1992). For example, bicyclic ketones tend to show greater lipophilicity and steric hindrance of the carbonyl function than do short-chain aliphatic or monocyclic ketones. As such, bicyclic ketones are expected to be poor substrates for cytosolic reducing enzymes. Consequently, the predominant detoxication route is CYP-mediated ring hydroxylation to yield polar, excretable poly-oxygenated metabolites. The pathways by which fused ring and macrocyclic ketones are detoxified are similar to those for the bridged bicyclic substances. Activated ring positions (e.g. tertiary and allylic positions) and ring substituents are oxidized primarily by CYP, introducing additional polar groups into the molecule. The resulting metabolites are then excreted, mainly in the urine.'

For mono- and bicyclic secondary alcohols, ketones and related esters in this group of flavouring substances, JECFA (2005, 2006) concluded that 'All the flavouring agents in this group are expected to be metabolized to innocuous products.'

EFSA considerations

The Panel agrees with the considerations on ADME, including metabolic pathways outlined by JECFA and with JECFA conclusion (JECFA, 2005, 2006).

3.3.2 | Genotoxicity studies

JECFA status

JECFA (2006) reported genotoxicity data for seven substances, among which [FL-no: 02.016 and 09.131] are considered in FGE.87 and further revisions (EFSA, 2008c; EFSA CEF Panel, 2012a, 2014a).

JECFA reported that *'the testing of these representative bicyclic secondary alcohols, ketones and related esters in bacterial (Ames assay) and mammalian (micronucleus formation) in vivo systems showed no evidence of genotoxic potential, and these results are further supported by the lack of positive findings in the Drosophila Basc test'*. These data are supported by the lack of genotoxic potential of the related α,β -unsaturated monocyclic ketones, isophorone [FL-no: 07.126], d-carvone [FL-no: 07.146] and l-carvone [FL-no: 07.147]. These substances were evaluated by JECFA to be of no safety concern.

Based on the available data, JECFA concluded that there was no evidence of genotoxic potential for the group of mono- and bicyclic secondary alcohols, ketones and related esters, among which [FL-no: 07.136] is included.

EFSA considerations

The genotoxic potential of [FL-no: 07.136], an α,β -unsaturated ketone, was assessed in FGE.213Rev1 (EFSA CEF Panel, 2014b) where the concern was ruled out. Therefore, the safety evaluation through the Procedure can be performed for the flavouring substance [FL-no: 07.136].

4 | APPLICATION OF THE PROCEDURE

4.1 | Application of the Procedure by JECFA

According to JECFA (2005, 2006), 15 of the 19 substances that are relevant for FGE.87Rev3 (out of 32 substances considered by JECFA) belong to structural class I and four to structural class II (including [FL-no: 07.136]) using the decision tree approach presented by Cramer et al. (Cramer et al., 1978).

JECFA considered that 19 bicyclic secondary alcohols, ketones and related esters (considered in FGE.87Rev3) are expected to be metabolised to innocuous products (step 2 of the Procedure) and that the intakes of all 19 compounds are below the thresholds of toxicological concern (TTC) for their structural classes I and II (step A3 of the Procedure).

JECFA concluded that these substances were of no safety concern at the estimated levels of intakes based on the MSDI approach.

The summary evaluations of the 19 substances considered in FGE.87Rev3 are presented in [Appendix D, Table D1](#).

4.2 | EFSA considerations

Taking into account the ADME considerations (Section 3.3.1), genotoxicity (Section 3.3.2) and the structural class of the substances, the Panel agrees with the application of the Procedure as performed by JECFA for 4,4a,5,6-tetrahydro-7-methylnaphthalen-2(3H)-one [FL-no: 07.136], as well as for the other 18 flavouring substances considered in FGE.87Rev3 and described in FGE.87Rev2 (EFSA CEF Panel, 2014a).

For the flavouring substance [FL-no: 07.136], EU poundage data have been provided (0.5 kg/year) (Documentation provided to EFSA No. 1) resulting in an MSDI of 0.06 $\mu\text{g}/\text{capita}$ per day. Considering that MSDI for [FL-no: 07.136] is below the TTC of 540 $\mu\text{g}/\text{person}$ per day for structural class II substances, the Panel considered that [FL-no: 07.136] as well as the other 18 substances in FGE.87Rev3 do not pose a safety concern when used as flavouring substances at estimated levels of intake, when based on the MSDI approach.

Based on the use levels provided for [FL-no: 07.136] (Documentation provided to EFSA No. 1), the mTAMDI resulted in 489 $\mu\text{g}/\text{person}$ per day, which is below the TTC of 540 $\mu\text{g}/\text{person}$ per day for structural class II substances. Accordingly, no further data are required in the context of the current evaluation programme.

In addition, industry provided information on uses and use levels for three structural class II substances [FL-no: 07.089, 07.153, 07.159], allowing their mTAMDI estimation, which resulted in 2041, 2278 and 1836 $\mu\text{g}/\text{person}$ per day, respectively. Since these values are above the above-mentioned TTC for structural class II substances, the Panel concluded that more reliable data on uses and use levels are still required for [FL-no: 07.089, 07.153, 07.159] in order to finalise their evaluation.

For the remaining 15 substances [FL-no: 02.016, 02.038, 02.059, 02.100, 02.101, 09.017, 09.082, 09.131, 09.153, 09.176, 09.218, 09.269, 09.319, 09.456, 09.457] considered in FGE.87Rev3, which were already evaluated through the Procedure in FGE.87Rev2, the Panel reiterates that use levels are needed to calculate their mTAMDI values. This is necessary to identify those flavouring substances that need more refined exposure assessment and to finalise their evaluation.

5 | DISCUSSION

The present revision of FGE.87 (FGE.87Rev3) is based on new information on annual production volume for 4,4a,5,6-tetrahydro-7-methylnaphthalen-2(3H)-one [FL-no: 07.136] that allowed the calculation of MSDI for this substance. In addition, new data on uses and use levels for this substance [FL-no: 07.0136] and for three additional substances [FL-no: 07.089, 07.153 and 07.159] have been provided and considered for the estimation of their intake with the mTAMDI approach.

Taking into account the ADME considerations (Section 3.3.1), genotoxicity (Section 3.3.2) and the structural class, the Panel agrees with the application of the Procedure as used by JECFA for [FL-no: 07.136] as well as for the other 18 flavouring substances considered in FGE.87Rev3 and described in FGE.87Rev2 (EFSA CEF Panel, 2014a).

Since the calculated MSDI for [FL-no: 07.136], based on the newly submitted annual production volume for Europe, is below the TTC of 540 µg/person per day for structural class II substances, the Panel considered that [FL-no: 07.136] does not pose a safety concern when used as a flavouring substance at estimated levels of intake when based on the MSDI approach. This consideration for [FL-no: 07.136] is in line with the CEF Panel conclusions for the other 18 substances, already considered in FGE.87Rev2 (EFSA CEF Panel, 2014a).

Based on information on uses and use levels provided for [FL-no: 07.136], the mTAMDI estimate of 489 µg/person per day was below the TTC of 540 µg/person per day for structural class II substances. Accordingly, no further data are required in the context of the current evaluation programme.

For the other three substances [FL-no: 07.089, 07.153, 07.159] for which uses and use levels were provided, mTAMDI estimates exceeded the TTC of 540 µg/person per day for structural class II substances. For these substances, more reliable data on uses and use levels should be provided to refine the exposure assessment to finalise their safety evaluation.

For the remaining 15 substances [FL-no: 02.016, 02.038, 02.059, 02.100, 02.101, 09.017, 09.082, 09.131, 09.153, 09.176, 09.218, 09.269, 09.319, 09.456, 09.457] considered in FGE.87Rev3, which were already evaluated through the Procedure in FGE.87Rev2, the Panel reiterates that use levels are needed to calculate their mTAMDI estimates. This is necessary to identify those flavouring substances that need more refined exposure assessment to finalise their evaluation.

In order to determine whether the conclusion for the 19 JECFA-evaluated substances, in FGE.87Rev3, can be applied to the materials of commerce, the Panel considered the available specifications. Specifications are available for all 19 substances and are considered adequate by the Panel.

6 | CONCLUSIONS

The Panel agrees with the JECFA conclusion on the flavouring substance [FL-no: 07.136] that there is 'No safety concern at estimated levels of intake as flavouring substance', when based on the MSDI approach.

For the other 18 substances considered in FGE.87Rev3, [FL-no: 02.016, 02.038, 02.059, 02.100, 02.101, 07.089, 07.153, 07.159, 09.017, 09.082, 09.131, 09.153, 09.176, 09.218, 09.269, 09.319, 09.456 and 09.457], the same conclusion was already drawn in the previous revision (FGE.87Rev2).

For [FL-no: 07.136], the mTAMDI estimate (489 µg/person per day) was below the TTC of 540 µg/person per day for structural class II substances. Accordingly, no further data are required in the context of the current evaluation programme. For three substances [FL-no: 07.089, 07.153, 07.159], mTAMDI estimates were above this TTC. For these structural class II substances, more reliable data on uses and use levels should be provided in order to refine the exposure assessment to finalise their safety evaluation.

For 15 substances [FL-no: 02.016, 02.038, 02.059, 02.100, 02.101, 09.017, 09.082, 09.131, 09.153, 09.176, 09.218, 09.269, 09.319, 09.456, 09.457], data on uses and use levels are needed to calculate the mTAMDI estimates in order to identify those flavouring substances that require more refined exposure assessments to finalise their evaluation.

7 | RECOMMENDATION

The Panel recommends the European Commission that:

- the name of the flavouring substance 4,4a,5,6-tetrahydro-7-methylnaphthalen-2(3H)-one [FL-no: 07.136] in the Union List should be corrected to 4,4a,5,6-tetrahydro-7-methylnaphthalen-2(3H)-one [FL-no: 07.136].

8 | DOCUMENTATION AS PROVIDED TO EFSA

1. Information on poundage data, uses and use levels for 4,4a,5,6-tetrahydro-7-methylnaphthalen-2(3H)-one [FL-no: 07.136] submitted by EFFA on 4 June 2025.
2. EFFA (European Flavour Association), 2024 e-mail from EFFA to DG SANTE on Commission Request for Use Levels – submission of use level information & m-TAMDI calculations for 265 Class II substances.
3. DG SANCO (Directorate General for Health and Consumer Affairs), 2012. Information from DG SANCO 07/022012, concerning a list of 85 substances in the Register and 15 substances not in the Register which are non-supported substances and one list of 30 substances in the Register for which no data have been submitted or which are duplicates. FLAVIS.2.23rev1.
4. EFFA (European Flavour Association), 2002. Letter from EFFA to Danish Veterinary and Food Administration. Dated 31 October 2002. Re.: Second group of questions. FLAVIS/8.26.
5. EFFA (European Flavour Association), 2010. EFFA Letters to EFSA for clarification of specifications and isomerism for which data were requested in published FGEs.

6. EFFA (European Flavour Association), 2014. E-mail from EFFA to FLAVIS Secretariat, Danish Food Institute, Technical University of Denmark. Dated 1 July 2014. Information on substances [FL-no: 02.100, 02.101, 07.089, 07.136] in FGE.87Rev2. FLAVIS/8.250.

ABBREVIATIONS

AFC	Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food
BW	body weight
CAS	Chemical Abstracts Service
CEF	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
FAO	Food and Agriculture Organization of the United Nations
FEMA	Flavor and Extract Manufacturers Association
FGE	Flavouring Group Evaluation
FLAVIS (FL)	Flavour Information System (database)
GC-MS	gas chromatography-mass spectrometry
ID	identity
IR	infrared spectroscopy
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
MSDI	maximised survey-derived daily intake
mTAMDI	modified theoretical added maximum daily intake
No	number
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
WHO	World Health Organization

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European Commission

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APPENDIX A

Procedure for the safety evaluation

The approach for a safety evaluation of chemically defined flavouring substances as referred to in Commission Regulation (EC) No 1565/2000,³ named the 'Procedure', is shown in schematic form in [Figure A1](#). The Procedure is based on the Opinion of the Scientific Committee on Food expressed on 2 December 1999 (SCF, 1999), which is derived from the evaluation Procedure developed by the Joint FAO/WHO Expert Committee on Food Additives at its 44th, 46th and 49th meetings (JECFA, 1995, 1996, 1997, 1999), hereafter named the 'JECFA Procedure'.¹⁰

The Procedure is a stepwise approach that integrates information on intake from current uses, structure–activity relationships, metabolism and, when needed, toxicity. One of the key elements in the Procedure is the subdivision of flavourings into three structural classes (I, II and III) for which toxicological thresholds of concern (TTCs) (human exposure thresholds) have been specified. Exposures below these TTCs are not considered to present a safety concern.

Class I contains flavourings that have simple chemical structures and efficient modes of metabolism, which would suggest a low order of oral toxicity. Class II contains flavourings that have structural features that are less innocuous than Class I flavourings but are not suggestive of toxicity. Class III comprises flavourings that have structural features that permit no strong initial presumption of safety, or may even suggest significant toxicity (Cramer et al., 1978). The TTCs for these structural classes of 1800, 540 or 90 µg/person per day, respectively, are derived from a large database containing data on subchronic and chronic animal studies (JECFA, 1996).

In step 1 of the Procedure, the flavourings are assigned to one of the structural classes. The further steps address the following questions:

- Can the flavourings be predicted to be metabolised to innocuous¹¹ products (step 2)?
- Do their exposures exceed the TTC for the structural class (steps A3 and B3)?
- Are the flavourings or their metabolites endogenous (step A4)?
- Does a NOAEL exist on the flavourings or on structurally related substances (steps A5 and B4)?

In addition to the data provided for the flavouring substances to be evaluated (candidate substances), toxicological background information available for compounds structurally related to the candidate substances is considered (supporting substances) in order to assure that these data are consistent with the results obtained after application of the Procedure.

The Procedure is not to be applied to flavourings with existing unresolved problems of toxicity. Therefore, the right is reserved to use alternative approaches if data on specific flavourings warranted such actions ([Figure A1](#)).

¹⁰The FAF Panel is aware that a Revised Procedure for the Safety Evaluation of Flavouring agents has been agreed by JECFA (JECFA, 2016). Also, the EFSA Scientific Committee has developed a modified procedure for evaluation of substances based on the TTC approach (EFSA Scientific Committee, 2019). However, these developments have no impact on the present evaluation, which should follow the requirements as set out in Commission Regulation (EC) No 1565/2000.

¹¹*Innocuous products*: products that are known or readily predicted to be harmless to humans at the estimated intake of the flavouring agent (JECFA, 1997).

Endogenous substances: intermediary metabolites normally present in human tissues and fluids, whether free or conjugated; hormones and other substances with biochemical or physiological regulatory functions are not included (JECFA, 1997).

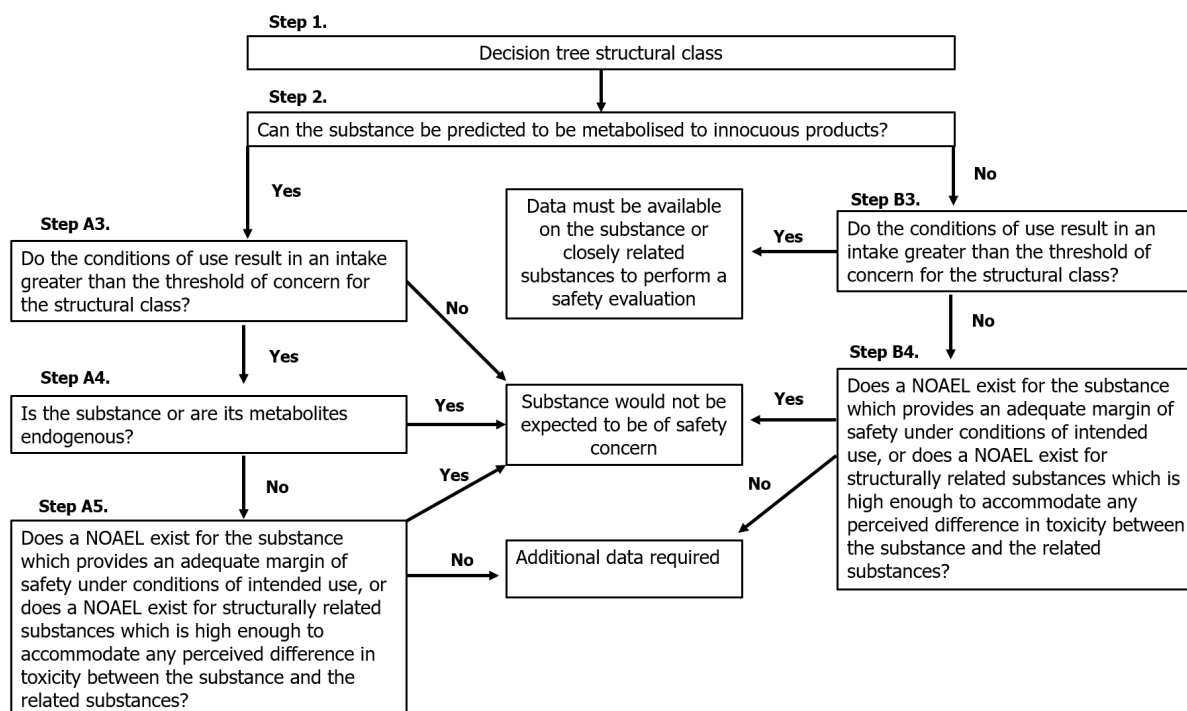


FIGURE A1 Procedure for the safety evaluation of chemically defined flavouring substances.

For the flavouring substances considered in this FGE, the FAF Panel compares the JECFA evaluation of structurally related substances with the result of a corresponding EFSA evaluation, focusing on specifications, intake estimations and toxicity data, especially genotoxicity data. The considerations by EFSA will conclude whether the flavouring substances are of no safety concern at their estimated levels of intake, whether additional data are required or whether certain substances should not be evaluated through the EFSA Procedure.

The following issues are of special importance:

a. Intake

In its evaluation, the Panel as a default uses the 'maximised survey-derived daily intake' (MSDI)¹² approach to estimate the per capita intakes of the flavouring substances in Europe.

In its evaluation, the JECFA includes intake estimates based on the MSDI approach derived from both European and USA production figures. The highest MSDI figure is used in the evaluation by the JECFA. It is noted that, in several cases, only the MSDI figures from the USA were available for the JECFA evaluation. For relevant substances in the Union List of flavouring substances,¹³ the Panel needs European Union (EU) production figures in order to finalise its evaluation.

When the Panel examined the information provided by the European Flavour Industry on the use levels in various foods, it appeared obvious that the MSDI approach in a number of cases would grossly underestimate the intake by regular consumers of products flavoured at the use levels reported by the industry, especially in those cases where the annual production values were reported to be small. In consequence, the Panel had reservations about the data on use and use levels provided and the intake estimates obtained by the MSDI approach. It is noted that the JECFA, at its 65th meeting, considered how to improve the identification and assessment of flavouring agents, for which the MSDI estimates may be substantially lower than the dietary exposures that would be estimated from the anticipated average use levels in foods (JECFA, 2006).

In the absence of more accurate information that would enable the Panel to make a more realistic estimate of the intakes of the flavouring substances, the Panel decided to perform an estimate of the daily intake per person using a modified theoretical added maximum daily intake (mTAMDI) approach based on the normal use levels reported by Industry (see Appendix B).

As information on use levels for the flavouring substances had not been requested by the JECFA or had not otherwise been provided to the Panel, it was not possible to estimate the daily intakes using the mTAMDI approach for many of the substances evaluated by JECFA. The Panel will need information on use levels in order to finalise the evaluation.

¹²EU MSDI: Amount added to food as flavour in (kg/year) × 10⁹ / (0.1 × population in Europe (= 375 × 10⁶) × 0.6 × 365) = µg/capita per day.

¹³Commission 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, pp. 1–161.

b. Threshold of 1.5 µg/person per day (step B5) used by the JECFA

JECFA uses the threshold of concern of 1.5 µg/person per day as part of the evaluation procedure:

'The Committee noted that this value was based on a risk analysis of known carcinogens which involved several conservative assumptions. The use of this value was supported by additional information on developmental toxicity, neurotoxicity and immunotoxicity. In the judgement of the Committee, flavouring substances for which insufficient data are available for them to be evaluated using earlier steps in the Procedure, but for which the intake would not exceed 1.5 µg/person per day would not be expected to present a safety concern. The Committee recommended that the Procedure for the Safety Evaluation of Flavouring Agents used at the forty-sixth meeting be amended to include the last step on the right-hand side of the original procedure ("Do the condition of use result in an intake greater than 1.5 µg per day?")' (JECFA, 1999).

In line with the opinion expressed by the Scientific Committee on Food (SCF, 1999), the Panel does not make use of this threshold of 1.5 µg/person per day.

c. Genotoxicity

As reflected in the opinion of SCF (SCF, 1999), the Panel has in its evaluation focussed on a possible genotoxic potential of the flavouring substances or of structurally related substances. Generally, substances for which the Panel has concluded that there is an indication of genotoxic potential in vitro will not be evaluated using the EFSA Procedure until further genotoxicity data are provided. Substances for which a genotoxic potential in vivo has been identified will not be evaluated through the Procedure.

d. Specifications

Regarding specifications, the evaluation by the Panel could lead to a different opinion than that of JECFA, since the Panel requests additional information, e.g. isomerism.

e. Structural relationship

In the consideration of the JECFA evaluated substances, the Panel will examine the structural relationship and metabolism features of the substances within the flavouring group and compare this with the corresponding Flavouring Group Evaluation (FGE).

APPENDIX B

Specifications

TABLE B1 Summary table on specifications data for flavouring substances in FGE.87Rev3 (for chemical structures, see [Appendix D](#)) that are included in the Union List.

Information included in the EU Union list Regulation (EC) No. 1334/2008 as amended			Most recent available specifications data ^a				
FL-no			Phys. form	Solubility ^c	Boiling point, °C ^e	Refrac. index ^f	
JECFA-no			Mol. formula		Melting point, °C		
CoE no		Purity of the named compound			ID test		
CAS no	Chemical name		Mol. weight	Solubility in ethanol ^d	Assay minimum	Spec. gravity ^g	EFSA comments
02.016 1385 64 507-70-0	DL-Borneol	^b	Solid C ₁₀ H ₁₈ O 154.25	Very slightly soluble Soluble	n.a. 202 IR 97%	n.a. n.a.	CAS no. refers to (1R,2S,4R)-rel. According to JECFA 'Minimum assay value may include isoborneol and other isomers of borneol as well as trace amounts of fenchyl alcohol and other C ₁₀ H ₁₈ O compounds'
02.038 1397 87 1632-73-1	Fenchyl alcohol	^b	Solid C ₁₀ H ₁₈ O 154.25	Very slightly soluble Soluble	n.a. 35–40 IR 97%	n.a. n.a.	Racemate (EFFA, 2010). According to JECFA 'Minimum assay value may include small amounts of borneol and isoborneol'
02.059 1386 2020 124-76-5	DL-Isoborneol	At least 92%; secondary component 3%–5% borneol	Solid C ₁₀ H ₁₈ O 154.25	Very slightly soluble Soluble	n.a. 212–214 IR 92%	n.a. n.a.	CAS no. refers to (1R,2R,4R)-rel.
02.100 1403 10303 5947-36-4	Pinocarveol	^b	Liquid C ₁₀ H ₁₆ O 152.24	Insoluble Soluble	210 n.a. NMR 95%	1.445–1.451 0.977–0.983	Racemate (EFFA, 2014)
02.101 1404 10304 473-67-6	Pin-2-en-4-ol	^b	Solid C ₁₀ H ₁₆ O 152.24	Very slightly soluble Soluble	n.a. 63–67 NMR 95%	n.a. n.a.	Racemate (EFFA, 2014)
07.089 1398 11164 4674-50-4	Nootkatone	At least 93%; secondary component 3%–4% dihydronootkatone	Liquid C ₁₅ H ₂₂ O 218.35	Slightly soluble Soluble	73–103 (1 hPa) n.a. NMR 93%	1.510–1.523 1.003–1.032	(+)-Nootkatone which refers to the (4R,4aS,6R)-isomer (EFFA, 2014)

TABLE B1 (Continued)

Information included in the EU Union list Regulation (EC) No. 1334/2008 as amended			Most recent available specifications data ^a				
FL-no			Phys. form	Solubility ^c	Boiling point, °C ^e	Refrac. index ^f	
JECFA-no			Mol. formula		Melting point, °C		
CoE no					ID test		
CAS no	Chemical name	Purity of the named compound	Mol. weight	Solubility in ethanol ^d	Assay minimum	Spec. gravity ^g	EFSA comments
07.136 1405 34545-88-5	4,4a,5,6-Tetrahydro-7-methylnaphthalen-2(3H)-one	^b	Solid C ₁₁ H ₁₄ O 162.23	Insoluble Soluble	n.a. 36–37 IR 99%	n.a. n.a.	Racemate (EFFA, 2014) The name should be corrected to 4,4a,5,6-tetrahydro-7-methylnaphthalen-2(3H)-one
07.153 1407 3776 20489-53-6	(4R,4aS,6R,8aS)-1,10-Dihydronootkatone	At least 90%; secondary component 5%–6% nootkatone	Liquid C ₁₅ H ₂₄ O 220.36	Very slightly soluble Soluble	100–104 (0.09 hPa) n.a. NMR 90%	1.502–1.508 0.975–0.988	
07.159 1396 551 4695-62-9	d-Fenchone	^b	Liquid C ₁₀ H ₁₆ O 152.24	Insoluble Soluble	192 n.a. IR 97%	1.460–1.467 0.940–0.948	CAS no. refers to (1S,4R)- isomer. According to JECFA 'Minimum assay value may include small amounts of d-camphor'
09.017 1387 207 76-49-3	DL-Bornyl acetate	^b	Liquid C ₁₂ H ₂₀ O ₂ 196.29	Slightly soluble Soluble	226 25 IR 98%	1.462–1.466 0.981–0.985	CAS no. refers to (1R,2S,4R)- rel.
09.082 1389 349 7492-41-3	DL-Bornyl formate	^b	Liquid C ₁₁ H ₁₈ O ₂ 182.26	Slightly soluble Soluble	106–108 (27 hPa) n.a. NMR 95%	1.466–1.472 1.007–1.013 (20°)	CAS no. refers to (1R,2S,4R)-rel.
09.131 1391 412 2756-56-1	DL-Isobornyl propionate	^b	Liquid C ₁₃ H ₂₂ O ₂ 210.32	Soluble Soluble	245 n.a. NMR 97%	1.462–1.466 0.981–0.985	CAS no. refers to (1R,2R,4R)-rel. According to JECFA 'Minimum assay value may include small amounts of bornyl propionate'
09.153 1392 471 7549-41-9	DL-Bornyl valerate	^b	Liquid C ₁₅ H ₂₆ O ₂ 238.37	Insoluble Soluble	136–137 (16hPa) n.a. NMR 96%	1.459–1.465 0.957–0.963	CAS no. refers to (1R,2S,4R)- rel.
09.176 1390 565 1200-67-5	DL-Isobornyl formate	^b	Liquid C ₁₁ H ₁₈ O ₂ 182.26	Slightly soluble Soluble	94–95 (20 hPa) n.a. NMR 96%	1.469–1.473 1.011–1.017	CAS no. refers to (1R,2R,4R)- rel. According to JECFA: 'Minimum Assay value may include small amounts of bornyl formate'

(Continues)

TABLE B1 (Continued)

Information included in the EU Union list Regulation (EC) No. 1334/2008 as amended			Most recent available specifications data ^a				
FL-no	Chemical name	Purity of the named compound	Phys. form	Solubility ^c	Boiling point, °C ^e	Refrac. index ^f	EFSA comments
JECFA-no			Mol. formula	Melting point, °C			
CoE no	Chemical name	Purity of the named compound	Mol. weight	Solubility in ethanol ^d	ID test	Spec. gravity ^g	EFSA comments
CAS no					Assay minimum		
09.218 1388 2066 125-12-2	DL-Isobornyl acetate	^b	Liquid C ₁₂ H ₂₀ O ₂ 196.29	Insoluble Soluble	227 n.a. IR 97%	1.462–1.465 0.979–0.984	CAS no. refers to (1R,2R,4R)-rel. According to JECFA 'Minimum assay value may include small amounts of bornyl acetate'
09.269 1399 11769 13851-11-1	Fenchyl acetate	^b	Liquid C ₁₂ H ₂₀ O ₂ 196.29	Slightly soluble Soluble	220 n.a. NMR 98%	1.456–1.462 0.973–0.979	Racemate
09.319 1412 13109-70-1	DL-Bornyl butyrate	^b	Liquid C ₁₄ H ₂₄ O ₂ 224.34	Slightly soluble Soluble	247 n.a. MS 97%	1.462–1.469 0.981–0.991	CAS no. refers to (1R,2S,4R)-rel.
09.456 1393 451 76-50-6	DL-Bornyl isovalerate	^b	Liquid C ₁₅ H ₂₆ O ₂ 238.37	Insoluble Soluble	260 n.a. NMR 97%	1.458–1.461 0.944–0.947	CAS no. refers to (1R,2S,4R)-rel.
09.457 1394 452 7779-73-9	DL-Isobornyl isovalerate	^b	Liquid C ₁₅ H ₂₆ O ₂ 238.37	Insoluble Soluble	266–269 n.a. NMR 96%	1.463–1.469 0.900–0.906	CAS no. refers to (1R,2R,4R)-rel.

Abbreviations: CAS, Chemical Abstract Service; CoE, Council of Europe; FL-no, FLAVIS number; ID, identity; IR, infrared spectroscopy; JECFA, The Joint FAO/WHO Expert Committee on Food Additives; MS, mass spectrometry; n.a., not applicable; NMR, nuclear magnetic resonance.

^aJECFA (2004) and EFSA CEF Panel (2014a).

^bAt least 95% unless otherwise specified.

^cSolubility in water, if not otherwise stated.

^dSolubility in 95% ethanol, if not otherwise stated.

^eAt 1013.25 hPa, if not otherwise stated.

^fAt 20°C, if not otherwise stated.

^gAt 25°C, if not otherwise stated.

APPENDIX C

Exposure estimates

C.1 | NORMAL AND MAXIMUM USE LEVELS

For the flavouring substance [FL-no: 07.136], use levels were provided by industry (Documentation provided to EFSA No. 1) for the different food categories reported in Annex III of Regulation (EC) 1565/2000.³ Data on uses and use levels for the substances [FL-no: 07.089, 07.153, 07.159] have also been provided (Documentation provided to EFSA No. 2) for the different food categories reported in Annex III of Regulation (EC) 1565/2000.³ These data were included in the present revision, FGE.87Rev3, and used for the calculation of modified theoretical added maximum daily intake (mTAMDI) estimates (Tables C1 and C4).

TABLE C1 Normal and maximum use levels (mg/kg) for 4 out of 19 flavouring substances evaluated in FGE.87Rev3 (Documentation provided to EFSA No. 1 and No. 2).

FL-no	Food categories																		
	Normal use ^a levels (mg/kg)																		
	01.0	02.0	03.0	04.1	04.2	05.0	05.3 ^b	06.0	07.0	08.0	09.0	10.0	11.0	12.0	13.0	14.1	14.2	15.0	16.0
07.089	4.68	–	–	–	–	6.23	–	3.98	6.96	–	–	–	–	–	–	2.72	3.17	–	–
	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
07.136	1.50	–	–	–	–	3.00	8.00	1.50	1.00	0.50	–	–	–	0.50	–	0.50	1.00	–	–
	9.81	–	–	–	–	8.30	12.18	8.68	9.98	1.00	–	–	–	1.00	–	2.03	1.55	–	–
07.153	9.81	–	–	–	–	8.30	12.18	8.68	9.98	1.00	–	–	–	0.63	–	2.03	1.55	–	–
	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
07.159	3.21	–	–	–	–	7.25	–	3.21	9.86	–	–	–	–	–	–	1.08	0.10	–	–
	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–

Note: '–' no value for normal or maximum use level was provided.

Abbreviation: FL-no, FLAVIS number.

^a'Normal use' is defined as the average of the reported use levels and 'maximum use' is defined as the 95th percentile of reported use levels (EFFA, 2002).

^bAdditional food category 05.3 (chewing gum as per Annex II part D of Regulation (EC) 1333/2008) for which industry submitted use levels (Documentation provided to EFSA No. 1 and No. 2). This food category is not present in the food categorisation system reported in Annex III of Regulation (EC) 1565/2000.³ However, these data were considered in the calculation of mTAMDI.

C.2 | mTAMDI CALCULATIONS

The method to calculate mTAMDI estimates is based on the approach used by the SCF up to 1995 (SCF, 1995). The assumption is that a person may consume the amounts of flavourable foods and beverages as listed in [Table C2](#). These consumption amounts are then multiplied by the reported use levels in the different food categories and summed up.

TABLE C2 Estimated consumption amounts per person per day of flavourable foods and beverages and five exceptions (SCF, 1995).

Class of product category	Intake estimate (g/day)
Beverages (non-alcoholic)	324.0
Foods	133.4
Exception a: Candy, confectionery	27.0
Exception b: Condiments, seasonings	20.0
Exception c: Alcoholic beverages	20.0
Exception d: Soups, savouries	20.0
Exception e: Others, e.g. chewing gum	e.g. 2.0 (chewing gum)

The mTAMDI calculations are based on the normal use levels reported by industry. The seven food categories used in the SCF TAMDI approach (SCF, 1995) correspond to the 18 food categories as outlined in Commission Regulation (EC) No 1565/2000 and reported by the Flavour Industry in the following way (see [Table C3](#)):

- Beverages (SCF, 1995) correspond to food category 14.1
- Foods (SCF, 1995) correspond to the food categories 1, 2, 3, 4.1, 4.2, 6, 7, 8, 9, 10, 13 and/or 16
- Exception a (SCF, 1995) corresponds to food category 5 and 11
- Exception b (SCF, 1995) corresponds to food category 15
- Exception c (SCF, 1995) corresponds to food category 14.2
- Exception d (SCF, 1995) corresponds to food category 12
- Exception e (SCF, 1995) corresponds to others, e.g. chewing gum.

The resulting mTAMDI estimates are listed in [Table C4](#) as well as the MSDI estimates.

TABLE C3 Distribution of the 18 food categories listed in Commission Regulation (EC) No 1565/2000 into the seven SCF food categories used for mTAMDI calculations (SCF, 1995).

Key	Food categories according to Commission Regulation 1565/2000 Food category	Distribution of the seven SCF food categories		
		Foods	Beverages	Exceptions
01.0	Dairy products, excluding products of category 02.0	Foods		
02.0	Fats and oils, and fat emulsions (type water-in-oil)	Foods		
03.0	Edible ices, including sherbet and sorbet	Foods		
04.1	Processed fruit	Foods		
04.2	Processed vegetables (incl. mushrooms & fungi, roots & tubers, pulses and legumes) and nuts & seeds	Foods		
05.0	Confectionery			Exception a
06.0	Cereals and cereal products, incl. flours & starches from roots & tubers, pulses & legumes, excluding bakery	Foods		
07.0	Bakery wares	Foods		
08.0	Meat and meat products, including poultry and game	Foods		
09.0	Fish and fish products, including molluscs, crustaceans and echinoderms	Foods		
10.0	Eggs and egg products	Foods		
11.0	Sweeteners, including honey			Exception a
12.0	Salts, spices, soups, sauces, salads, protein products, etc.			Exception d
13.0	Foodstuffs intended for particular nutritional uses	Foods		
14.1	Non-alcoholic ('soft') beverages, excl. dairy products		Beverages	
14.2	Alcoholic beverages, incl. alcohol-free and low-alcoholic counterparts			Exception c
15.0	Ready-to-eat savouries			Exception b
16.0	Composite foods (e.g. casseroles, meat pies, mincemeat) – foods that could not be placed in categories 01.0–15.0	Foods		

TABLE C4 Estimated intakes based on the MSDI approach and the mTAMDI approach (Documentation provided to EFSA No. 1 and 2).

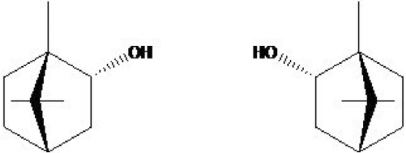
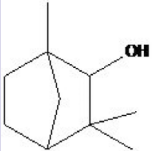
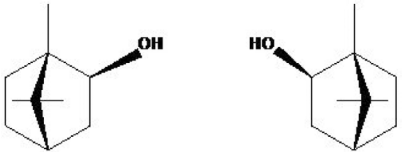
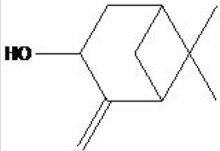
FL-no	EU Union list chemical name	MSDI – EU ($\mu\text{g}/\text{capita}/\text{day}$)	mTAMDI ($\mu\text{g}/\text{person}/\text{day}$)	Structural class	TTC ($\mu\text{g}/\text{person}/\text{day}$)
07.136	4,4a,5,6-Tetrahydro-7-methylnaphthalen-2(3H)-one	0.06	489	Class II	540
07.089	Nootkatone	130	2041	Class II	540
07.153	(4R,4aS,6R,8aS)-1,10-Dihydronootkatone	0.24	2278	Class II	540
07.159	<i>d</i> -Fenchone	6.3	1863	Class II	540
02.016	DL-Borneol	130	n.a.	Class I	1800
02.038	Fenchyl alcohol	55	n.a.	Class I	1800
02.059	DL-Isoborneol	21	n.a.	Class I	1800
02.100	Pinocarveol	0.012	n.a.	Class I	1800
02.101	Pin-2-en-4-ol	0.012	n.a.	Class I	1800
09.017	DL-Bornyl acetate	18	n.a.	Class I	1800
09.082	DL-Bornyl formate	1.2	n.a.	Class I	1800
09.131	DL-Isobornyl propionate	2.6	n.a.	Class I	1800
09.153	DL-Bornyl valerate	3.7	n.a.	Class I	1800
09.176	DL-Isobornyl formate	0.61	n.a.	Class I	1800
09.218	DL-Isobornyl acetate	890	n.a.	Class I	1800
09.269	Fenchyl acetate	2.9	n.a.	Class I	1800
09.319	Bornyl butyrate	6.1	n.a.	Class I	1800
09.456	DL-Bornyl isovalerate	0.12	n.a.	Class I	1800
09.457	DL-Isobornyl isovalerate	0.012	n.a.	Class I	1800

Abbreviations: FL-no, FLAVIS number; MSDI, Maximised Survey-derived Daily Intake; mTAMDI, modified Theoretical Added Maximum Daily Intake; n.a., not available.

APPENDIX D

Summary of safety evaluations

TABLE D1 Summary of Safety Evaluation performed by JECFA (2005, 2006) and EFSA conclusions on flavouring substances in FGE.87Rev3.

FL-no	JECFA-no	EU Union List chemical name	Structural formula	JECFA conclusions Class ^a Evaluation procedure path ^b Outcome on the named compound based on the MSDI approach	EFSA conclusion Procedural path if different from JECFA, Conclusion based on the MSDI ^c approach on the named compound and on the material of commerce
02.016 1385		DL-Borneol		Class I A3: Intake below threshold No safety concern	No safety concern at the estimated level of intake Concluded in FGE.87Rev1
02.038 1397		Fenchyl alcohol		Class I A3: Intake below threshold No safety concern	No safety concern at the estimated level of intake Concluded in FGE.87Rev1
02.059 1386		DL-Isoborneol		Class I A3: Intake below threshold No safety concern	No safety concern at the estimated level of intake Concluded in FGE.87
02.100 1403		Pinocarveol		Class I A3: Intake below threshold No safety concern	No safety concern at the estimated level of intake Concluded in FGE.87Rev2

(Continues)

TABLE D1 (Continued)


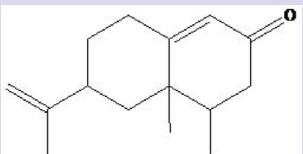
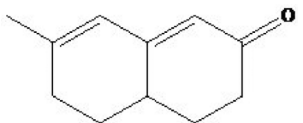
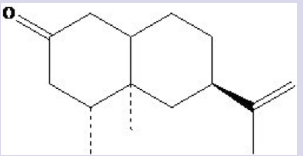
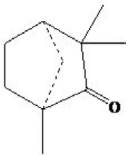
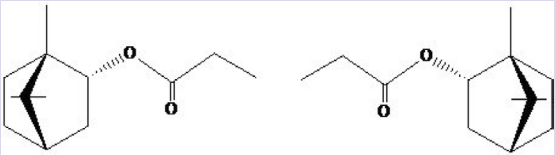
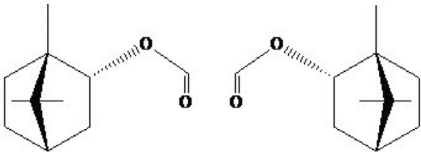
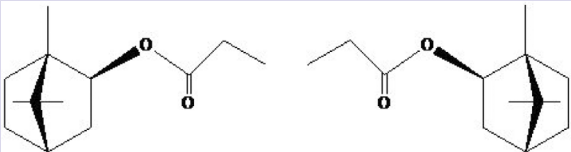
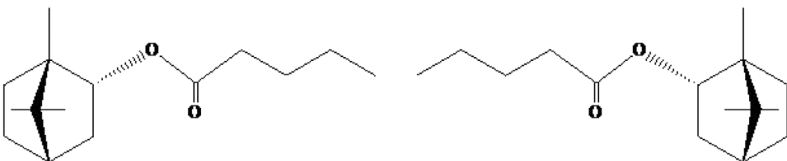
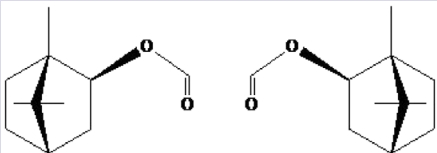
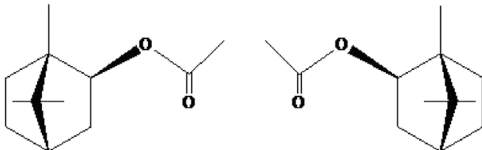
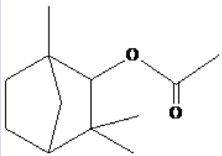
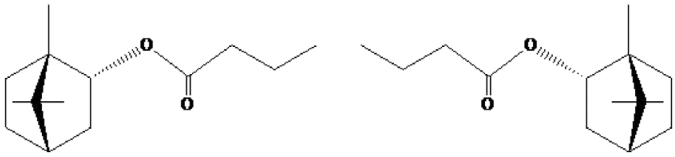
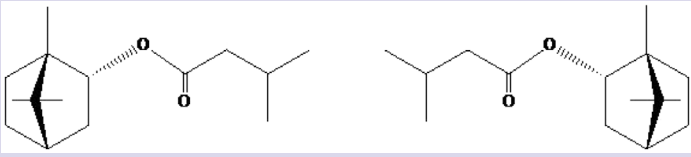
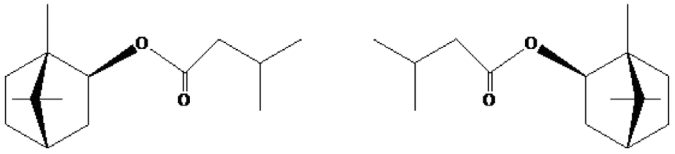
			JECFA conclusions	EFSA conclusion
FL-no			Class ^a	
			Evaluation procedure path ^b	
JECFA-no	EU Union List chemical name	Structural formula	Outcome on the named compound based on the MSDI approach	Procedural path if different from JECFA, Conclusion based on the MSDI ^c approach on the named compound and on the material of commerce
02.101 1404	Pin-2-en-4-ol		Class I A3: Intake below threshold No safety concern	No safety concern at the estimated level of intake Concluded in FGE.87Rev2
07.089 1398	Nootkatone		Class II A3: Intake below threshold No safety concern	No safety concern at the estimated level of intake Concluded in FGE.87Rev2
07.136 1405	4,4a,5,6-Tetrahydro-7-methylnaphthalen-2(3H)-one		Class II A3: Intake below threshold No safety concern	No safety concern at the estimated level of intake Concluded in FGE.87Rev3
07.153 1407	(4R,4aS,6R,8aS)-1,10-Dihydronootkatone		Class II A3: Intake below threshold No safety concern	No safety concern at the estimated level of intake Concluded in FGE.87
07.159 1396	d-Fenchone		Class II A3: Intake below threshold No safety concern	No safety concern at the estimated level of intake Concluded in FGE.87Rev1
09.017 1387	DL-Bornyl acetate		Class I A3: Intake below threshold No safety concern	No safety concern at the estimated level of intake Concluded in FGE.87Rev1

TABLE D1 (Continued)

			JECFA conclusions	EFSA conclusion
FL-no			Class ^a	
			Evaluation procedure path ^b	
JECFA-no	EU Union List chemical name	Structural formula	Outcome on the named compound based on the MSDI approach	Procedural path if different from JECFA, Conclusion based on the MSDI ^c approach on the named compound and on the material of commerce
09.082 1389	DL-Bornyl formate		Class I A3: Intake below threshold No safety concern	No safety concern at the estimated level of intake Concluded in FGE.87
09.131 1391	DL-Isobornyl propionate		Class I A3: Intake below threshold No safety concern	No safety concern at the estimated level of intake Concluded in FGE.87Rev1
09.153 1392	DL-Bornyl valerate		Class I A3: Intake below threshold No safety concern	No safety concern at the estimated level of intake Concluded in FGE.87Rev1
09.176 1390	DL-Isobornyl formate		Class I A3: Intake below threshold No safety concern	No safety concern at the estimated level of intake Concluded in FGE.87Rev1
09.218 1388	DL-Isobornyl acetate		Class I A3: Intake below threshold No safety concern	No safety concern at the estimated level of intake. Concluded in FGE.87Rev1

(Continues)

TABLE D1 (Continued)

FL-no			JECFA conclusions	EFSA conclusion
JECFA-no	EU Union List chemical name	Structural formula	Class ^a	Procedural path if different from JECFA, Conclusion based on the MSDI ^c approach on the named compound and on the material of commerce
			Evaluation procedure path ^b	Outcome on the named compound based on the MSDI approach
09.269 1399	Fenchyl acetate		Class I A3: Intake below threshold No safety concern	No safety concern at the estimated level of intake Concluded in FGE.87
09.319 1412	DL-Bornyl butyrate		Class I A3: Intake below threshold No safety concern	No safety concern at the estimated level of intake Concluded in FGE.87Rev1
09.456 1393	DL-Bornyl isovalerate		Class I A3: Intake below threshold No safety concern	No safety concern at the estimated level of intake Concluded in FGE.87
09.457 1394	DL-Isobornyl isovalerate		Class I A3: Intake below threshold No safety concern	No safety concern at the estimated level of intake Concluded in FGE.87

Abbreviations: bw, body weight; FGE, Flavouring Group Evaluation; FL-no, FLAVIS number; JECFA, The Joint FAO/WHO Expert Committee on Food Additives; NOAEL, No observed adverse effect level.

^aThresholds of concern: Class I = 1800 µg/person per day, Class II = 540 µg/person per day, Class III = 90 µg/person per day.

^bJECFA (2005, 2006).

^cEU MSDI: Amount added to food as flavouring in (kg/year) × 10⁹ / (0.1 × population in Europe (= 375 × 10⁶) × 0.6 × 365) = µg/capita per day.