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Scientific Opinion on Flavouring Group Evaluation 7, Revision 6 (FGE.07Rev6): saturated and unsaturated aliphatic secondary alcohols, ketones and esters of secondary alcohols and saturated linear or branched-chain carboxylic acids from chemical group 5

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Abstract

The EFSA Panel on Food Additives and Flavourings was requested to evaluate 55 flavouring substances assigned to the Flavouring Group Evaluation 07 (FGE.07), using the Procedure as outlined in the Commission Regulation (EC) No 1565/2000. Fifty-three substances have already been considered in FGE.07 and its revisions. This revision 6 includes two additional substances which have been cleared with respect to genotoxicity in FGE.201Rev2 (4-methyl-3-hepten-5-one [FL-no: 07.261]) and FGE.204Rev1 (non-2-en-4-one, [FL-no: 07.187]). The substances were evaluated through a stepwise approach that integrates information on the structure–activity relationships, intake from current uses, toxicological threshold of concern (TTC) and available data on metabolism and toxicity. The Panel concluded that none of the 55 substances gives rise to safety concerns at their levels of dietary intake, when estimated on the basis of the 'Maximised Survey-derived Daily Intake' (MSDI) approach. Besides the safety assessment of the flavouring substances, the specifications for the materials of commerce have also been considered and found adequate. Normal and maximum use levels were available for all flavouring substances. For 52 substances, including the newly included substances [FL-no: 07.187 and 07.261], their 'modified Theoretical Added Maximum Daily Intakes' (mTAMDIs) estimates were above the TTC for their structural classes (I and II). Therefore, for these 52 flavouring substances, more detailed data on uses and use levels should be provided to finalise their safety evaluations.

Keywords: Flavourings, α,β-unsaturated carbonyls and precursors, FGE.63, JECFA

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1. Introduction

The present revision of this Flavouring Group Evaluation (FGE) concerns the inclusion of two α,β-unsaturated aliphatic ketones which have been evaluated with respect to genotoxicity in FGE.201Rev2 ([FL-no: 07.261]) and FGE.204Rev1 ([FL-no: 07.187]). According to the mandates and terms of reference of these FGEs, when for a flavouring substance, the concern for genotoxicity is ruled out, the European Food Safety Authority (EFSA) proceeds to the full evaluation of these flavouring substances, taking into account the requirements of the Commission Regulation (EC) No 1565/2000 and of Regulation (EU) No 1334/2008.

1.1. Background and Terms of Reference as provided by the requestor

1.1.1. Background to Mandate from FGE.201Rev2 (M-2017-0048)

The use of flavouring is regulated under Regulation (EC) No 1334/2008[1] of the European Parliament and Council of 16 December 2008 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 a number of flavouring substances for which the safety evaluation should be completed in accordance with Commission Regulation (EC) No 1565/2000[3].

The substances in this group were included in the Union list with a footnote 1 (under evaluation by EFSA).

In its opinion about this subgroup of 2012, the EFSA Panel considered that the mutagenicity hazard could not be cleared by the endpoints evaluated in the *in vivo* micronucleus assay submitted. The Panel therefore conclude that further data were required in order to clarify the genotoxic potential of this subgroup. The Panel considered the Comet assay with [FL-no: 05.095] as test material and performed on liver, blood and first site of contact, as a preferred option to further investigate the genotoxicity *in vivo*. The additional data submitted by the applicant consist essentially of:

- a transgenic mutation assay in combination with an *in vivo* micronucleus assay for the substance 2-methylcrotonaldehyde [FL-no: 05.095];
- a combination of a Comet/micronucleus assay for the substance 2-methylpent-2-enal [FL-no: 05.090].

The Panel also considered in this opinion on FGE.201 rev.1 that the additional data on 2-methylcrotonaldehyde [FL-no: 05.095] could also be considered representative for the following substances: 2,8-dithianon-4-en-4-carboxaldehyde [FL-no: 12.065] and 2-(methylthiomethyl)but-2-enal [FL-no: 12.079].

1.1.2. Terms of Reference of Mandate from FGE.201Rev2 (M-2017-0048)

The European Commission requests the European Food Safety Authority (EFSA) to evaluate the new information submitted on 2-methylpent-2-enal [FL-no: 05.090] and 2-methylcrotonaldehyde [FL-no: 05.095] including also 2,8-dithianon-4-en-4-carboxaldehyde [FL-no: 12.065] and 2-(methylthiomethyl) but-2-enal [FL-no: 12.079] and, depending on the outcome, proceed to the full evaluation of the substances of this group listed in the table below, in accordance with Commission Regulation (EC) No 1565/2000, within 9 months.

In case the genotoxic potential cannot be ruled out or the procedure cannot be applied, EFSA is asked to characterise the hazards and also quantify the exposure.

[1] 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. OJ L 354, 31.12.2008, p. 34–50.

[2] 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. 1–161.

[3] 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. OJ L 180, 19.7.2000, p. 8–16.

As regards the substance 2,6-Dimethyl-2,5,7-octatriene-1-ol acetate ([FL-no: 09.931] CAS no 999999-91-4) the applicant indicate that it is included in this subgroup 1.1.2 of FGE19 (FGE.201). However, this substance has been already evaluated by EFSA in FGE 207 and FGE 72 Rev.1 of 2013.

As regards substance 4-methyl-3-hepten-5-one ([FL-no: 07.261] CAS no 22319-31-9) EFSA indicated in its opinion FGE.204 that 'the 2-methyl substituted alpha, beta-unsaturated aldehydes in FGE.201Rev1 can be considered as structurally related to it [FL-no: 07.261]. Thus the final conclusion on [FL-no: 07.261] will be drawn based on the outcome of the evaluation of FGE.201Rev1'.

1.1.3. Background to Mandate from FGE.204Rev1 (M-2015-0114)

The use of flavourings is regulated under Regulation (EC) No 1334/2008[1] of the European Parliament and Council of 16 December 2008 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 contains flavouring substances for which the scientific evaluation should be completed in accordance with Commission Regulation (EC) No 1565/2000[3].

On 21 November 2012, the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids adopted an opinion on Flavouring Group Evaluation 204 (FGE.204): Consideration of genotoxicity data on 18 monounsaturated, aliphatic, α,β-unsaturated ketones and precursors from chemical subgroup FGE.204 (FGE.19 s.g. 1.2.1).

The Panel concluded that for the representative substance 7-Methyl-3-octen-2-one [FL-no: 07.177] of subgroup 1.2.1 of FGE.19, the Panel's concern with respect to genotoxicity could not be ruled out and consequently additional data are requested.

On 31 September 2014 (Ares (2014) 207551) the applicant submitted to the Commission and to EFSA data on the potential presence of the substance FL-no 07.177 in plasma (analytical data).

On 9 January 2015 (Ares (2015) 202297) the applicant submitted additional studies on the representative substance [FL-no: 07.177] in relation to this EFSA evaluation. This additional data examines the systemic exposure of rats following oral administration of this substance, using the same dosing regimen employed in the combined micronucleus and comet test previously submitted. The data on this representative substance is intended to cover the following 16 substances in this group, namely [FL-no: 02.102, 02.193, 07.044, 07.048, 07.082, 07.104, 07.105, 07.106, 07.107, 07.121,07.139, 07.187, 07.188, 07.244 and 07.258].

1.1.4. Terms of Reference of Mandate from FGE.204Rev1 (M-2015-0114)

The European Commission requests the European Food Safety Authority (EFSA) to evaluate this new information and, depending on the outcome, proceed to the full evaluation of the flavouring substances mentioned above in accordance with Commission Regulation (EC) No 1565/2000[3].

1.2. Interpretation of the Terms of Reference

The two candidate flavouring substances were first allocated to FGE.201Rev2 ([FL-no: 07.261] and FGE.204Rev1 ([FL-no: 07.187]) for evaluation with respect to genotoxicity. Based on new genotoxicity data submitted, the Panel concluded that these two flavouring substances do not give rise to concern with respect to genotoxicity and can accordingly be evaluated through the Procedure in the present revision 6 of FGE.07 (FGE.07Rev6), in accordance with Commission Regulation (EC) No 1565/2000[3].

The flavouring substance 6-methyl-3-hepten-2-one [FL-no: 07.258] was evaluated with respect to genotoxicity in FGE.204Rev1 and allocated to the present revision of this FGE. However, the industry informed that the evaluation of this substance is no longer supported (Documentation provided to EFSA nr: 1). On the basis that this flavouring substance is no longer supported by any interested party, the European Commission on 18/5/2020 (Ares(2020)2601393 – 18/5/2020) informed that it is going to proceed with the withdrawal of [FL-no: 07.258] from the Union List of flavourings. Accordingly, the EFSA evaluation of this flavouring substance is closed and [FL-no: 07.258] is no longer included in FGE.07 Revision 6.

The methodology for the evaluation of these substances is clarified in Appendix A.

2. Data and methodologies

2.1. Data

The present opinion is based on the data presented in Table 1.

Table 1: Data considered in the current revision 6 of FGE.07 (FGE.07Rev6)

FL-no	Chemical name	Data provided for the current revision 6 of FGE.07	Appendix (Table nr) and relevant section of the opinion	Documentation provided to EFSA nr:
07.187	Non-2-en-4-one	Specifications, EU poundage data (MSDI), use levels (mTAMDI)	Appendix B (Table B.1) Appendix C (Tables C.1 and C.4)	Documentation provided to EFSA nr: 1 and 2
07.261	4-Methyl-3-hepten-5-one			

In addition, the following documentation has been consulted for the safety evaluation of FGE.07Rev6:

- Genotoxicity data evaluated in FGE.201Rev2 (EFSA FAF Panel, 2018a) and FGE.204Rev1 (EFSA FAF Panel, 2019);
- EFSA Scientific Opinion on FGE.07Rev5 (EFSA CEF Panel, 2017a) and its revisions (EFSA AFC Panel, 2004, 2008; EFSA CEF Panel, 2009, 2010, 2012);
- EFSA Scientific Opinion on FGE.63Rev3 (EFSA CEF Panel, 2017b);
- EFSA Scientific Opinion on FGE.63Rev4 (EFSA FAF Panel, 2022).

2.1.1. History of the evaluation of the substances in FGE.07

In the first version of Flavouring Group Evaluation 07 (FGE.07), EFSA considered a group of 35 saturated and unsaturated aliphatic secondary alcohols, ketones and esters with secondary alcohol moiety ([FL-no: 02.077, 02.142, 02.148, 02.177, 02.182, 02.183, 02.124, 07.072, 07.084, 07.150, 07.157, 07.158, 07.160, 07.178, 07.181, 07.182, 07.185, 07.189, 07.199, and 07.205, 07.156, 09.304, 09.323, 09.325, 09.328, 09.332, 09.386, 09.388, 09.391, 09.604, 09.605, 09.606, 09.608, 09.609 and 09.880]).

The revision 1 of FGE.07, FGE.07Rev1 (EFSA AFC Panel, 2008) was prepared due to the inclusion of six additional substances [FL-no: 02.190, 07.162, 07.201, 07.236, 07.676 and 09.926]. For two of the newly allocated substances [FL-no: 07.162 and 07.201], data on metabolism were provided. Furthermore, additional information on 20 flavouring substances [FL-no: 02.124, 02.142, 02.148, 02.177, 02.182, 02.183, 07.156, 07.157, 07.182, 07.185, 07.205, 09.304, 09.323, 09.325, 09.328, 09.332, 09.386, 09.388, 09.391 and 09.880] was made available since the first publication of FGE.07 (EFSA AFC Panel, 2004).

The second revision of FGE.07, FGE.07Rev2 (EFSA CEF Panel, 2009) included the assessment of two additional substances [FL-no: 02.255 and 07.239]. No new data on toxicity and metabolism were provided.

The third revision of FGE.07, FGE.07Rev3 (EFSA CEF Panel, 2010) dealt with the assessment of one additional flavouring substance [FL-no: 07.262]. Genotoxicity data (Ames test) and toxicological data (acute toxicity and 28-day study) were submitted. No metabolism data were provided for this substance. A search in open literature did not provide any further data on toxicity or metabolism for this substance. Furthermore, additional information on the specifications for eight candidate substances requested in FGE.07Rev2 had been submitted by industry and included in this FGE.

The fourth revision of FGE.07, FGE.07Rev4 (EFSA CEF Panel, 2012), included the assessment of five additional candidate flavouring substances [FL-no: 02.145, 02.194, 02.211, 07.198 and 07.204]. These substances had been considered with respect to genotoxicity in FGE.206 (EFSA CEF Panel, 2011) and the Panel concluded that the data available ruled out the concern for genotoxicity, and accordingly, the substances could be evaluated through the Procedure.

The fifth revision of FGE.07, FGE.07Rev5 (EFSA CEF Panel, 2017a), dealt with the assessment of four additional candidate flavouring substances [FL-no: 02.131, 02.187, 07.161 and 07.210]. These substances were initially allocated in FGE.205Rev1 (EFSA CEF Panel, 2016) where their genotoxicity potential was considered and ruled out. Therefore, these four substances could be evaluated through

the Procedure in FGE.07Rev5. A search in open literature for these four new substances, conducted for metabolism and toxicity data, did not reveal any pertinent new information.

Adequate specifications including purity and identity for the materials of commerce have been provided for all 53 candidate substances.

Overall, for all 53 candidate flavouring substances in FGE.07Rev5 ([FL-no: 02.077, 02.124, 02.131, 02.142, 02.145, 02.148, 02.177, 02.182, 02.183, 02.187, 02.190, 02.194, 02.211, 02.255, 07.072, 07.084, 07.150, 07.156, 07.157, 07.158, 07.160, 07.161, 07.162, 07.178, 07.181, 07.182, 07.185, 07.189, 07.198, 07.199, 07.201, 07.204, 07.205, 07.210, 07.236, 07.239, 07.262, 09.304, 09.323, 09.325, 09.328, 09.332, 09.386, 09.388, 09.391, 09.604, 09.605, 09.606, 09.608, 09.609, 09.676, 09.880 and 09.926]), evaluated through the EFSA Procedure, the Panel concluded that none of these substances would be expected to present a safety concern at their estimated levels of intake when based on the 'Maximised Survey-derived Daily Intake' (MSDI).

For all 53 candidate substances, normal and maximum use levels have been provided. For all candidate substances, except substances [FL-no: 07.084, 07.178 and 07.239], the mTAMDI intake estimates are above the toxicological threshold of concern (TTC) for their structural classes (I and II). Therefore, except for [FL-no: 07.084, 07.178 and 07.239], more detailed data on uses and use levels should be provided in order to refine the exposure assessment and to finalise their safety evaluation.

The present revision 6 of FGE.07 (FGE.07Rev6) deals with the assessment of two additional candidate flavouring substances [FL-no: 07.187 and 07.261]. These substances were first evaluated by EFSA in FGE.201Rev2 ([FL-no: 07.261]) and FGE.204Rev1 ([FL-no: 07.187]), where it was concluded that the concern for genotoxicity for these substances could be ruled out. Therefore, the two flavouring substances can be now evaluated through the Procedure in this FGE.

Together with the 53 substances that were already considered in FGE.07Rev5, the current revision comprises 55 substances. The 53 flavouring substances, for which the evaluation was finalised in FGE.07Rev5, will not be further discussed. Nevertheless, for the sake of completeness, the information for all the 55 substances is maintained in the various tables in this FGE.

The Panel considered that the 55 flavouring substances in FGE.07Rev6 are closely related to 67 flavouring substances (supporting substances) evaluated at the 51st, 59th and 69th meetings of the Joint FAO/WHO Expert Committee on Food Additives (JEFCA) in the group 'Saturated Aliphatic Acyclic Secondary Alcohols, Ketones, and Related Saturated and Unsaturated Esters' (JECFA, 2000, 2002a, 2003, 2009).

FGE	Adopted by EFSA	Link	No of substances
FGE.07	9 December 2004	https://www.efsa.europa.eu/en/scdocs/scdoc/164.htm	35
FGE.07Rev1	26 September 2007	https://www.efsa.europa.eu/en/scdocs/scdoc/722.htm	41
FGE.07Rev2	26 March 2009	https://www.efsa.europa.eu/en/scdocs/scdoc/1020.htm	43
FGE.07Rev3	30 September 2010	https://www.efsa.europa.eu/en/efsajournal/pub/1845.htm	44
FGE.07Rev4	27 September 2012	https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2012.2899/full	49
FGE.07Rev5	1 February 2017	https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4725/full	53
FGE.07Rev6	15 December 2021	https://doi.org/10.2903/j.efsa.2022.7090	55

2.2. Methodologies

This opinion was elaborated 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 guidance documents from the EFSA Scientific Committee. The assessment strategy applied for the evaluation programme of flavouring substances, as laid down in Commission Regulation (EC) No 1565/2000, is based on the Opinion on a Programme for the Evaluation of Flavouring substances of the Scientific Committee on Food (SCF, 1999).

2.2.1. Procedure for the safety evaluation of flavouring substances

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

2.2.2. Approach used for the calculation of exposure

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

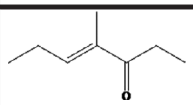
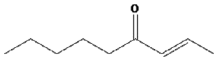
3. Assessment

3.1. Presentation of the substances in Flavouring Group Evaluation 07, Revision 6

The present Flavouring Group Evaluation 07 Revision 6 (FGE.07Rev6) deals with the inclusion of two additional candidate substances [FL-no: 07.187 and 07.261].

These flavouring substances are two α,β unsaturated aliphatic ketones. Table 2 shows their chemical structures.

Table 2: Flavouring substances under evaluation in FGE.07Rev6

FL-no	Chemical name	Structural formula	Structural class*
07.261	4-Methyl-3-hepten-5-one		Class I
07.187	Non-2-en-4-one		Class II

*: Determined with OECD Toolbox (version 4.4 available at https://www.oecd.org/chemicalsafety/risk-assessment/oecd-qsar-toolbox.htm).

The two candidate substances under assessment, with their EU Union List chemical names, FLAVIS-(FL), Chemical Abstract Service (CAS), Council of Europe (CoE) and Flavor and Extract Manufacturers Association (FEMA) numbers, structures and specifications, are also listed in Appendix B – Table B.1. In this Appendix also the previously evaluated substances are presented.

3.1.1. Supporting substances

The two candidate flavouring substances are structurally related to 81 flavouring substances (supporting substances) which were evaluated by JECFA at its 51st, 55th, 59th and 69th meetings in the flavourings group *'Saturated Aliphatic Acyclic Secondary Alcohols, Ketones, and Related Saturated and Unsaturated Esters'* (JECFA, 2000, 2002a, 2003, 2009). The supporting substances for FGE.07 are listed in Appendix B – Table B.2.

3.2. Specifications

Specifications including complete purity criteria and information on chemical identity for the materials of commerce have been provided for the two candidate flavouring substances [FL-no: 07.187 and 07.261], assessed in the present revision FGE.07Rev6 (Table B.1 – Appendix B).

The Panel judged the specifications provided for the two candidate substances against the requirements in Annex II of Commission Regulation (EC) No 1565/2000 and found them adequate.

3.2.1. Stereoisomers

It is recognised that geometrical and optical isomers of substances may have different properties. Their flavour may be different, and they may have different chemical properties resulting in possible variability in their absorption, distribution, metabolism, elimination and toxicity. Thus, information must be provided on the configuration of the flavouring substance, i.e. whether it is one of the geometrical/optical isomers, or a defined mixture of stereoisomers. The available specifications of purity will be considered in order to determine whether the safety evaluation carried out for candidate substances, for which stereoisomers may exist, can be applied to the materials of commerce. Flavouring substances with different configurations should have individual chemical names and codes (CAS number, FLAVIS number, etc.).

The two newly included flavouring substances ([FL-no: 07.187 and 07.261]) in FGE.07Rev6 can exist as geometrical stereoisomers.

Adequate information on the stereoisomeric composition for flavouring substances [FL-no: 07.187 and 07.261] has been submitted by industry (Documentation provided to EFSA nr: 1). Based on this information, the chemical names and the CAS numbers for these two flavouring substances should be changed in the Union List (UL) to reflect their stereochemical configuration (see 'EFSA comments' column in Table B.1 – Appendix B).

In addition, the Panel noted that the CAS number for flavouring substance [FL-no: 02.211], previously considered in FGE.07Rev5, should still be changed to 319497-21-7.

For flavouring substance [FL-no: 02.255], previously considered in FGE.07Rev5, the CAS number should be changed to 34146-55-9 to reflect the stereochemical configuration of the substance.

The most recent specifications data for all 55 substances in FGE.07Rev5 are summarised in Table B.1 – Appendix B.

3.3. Estimation of intake

3.3.1. Natural occurrence in food

The two candidate flavouring substances [FL-no: 07.187 and 07.261] have been reported to occur in capsicum species, muruci *(Byrsonima crassifolia*), wheaten bread and wine ([FL-no: 07.187]) and in beef ([FL-no: 07.261]) (VCF Volatile Compounds in Food database, 2020, 16.8 version).

Quantitative data for their natural occurrences are only reported for [FL-no: 07.187] in capsicum species: 0.3 mg/kg food (VCF Volatile Compounds in Food database, 16.8 version).

The complete data set retrieved on the natural occurrence for flavouring substances in FGE.07Rev6 is presented in Appendix E.

3.3.2. Estimated daily per capita intake (MSDI approach)

The intake estimation is based on the MSDI approach, which involves the acquisition of data on the amounts used in food as flavourings (SCF, 1999). These data are derived from surveys on annual production volumes in Europe. The intake approach does not consider the possible natural occurrence in food. Average per capita intake (MSDI) is estimated on the assumption that the amount added to food is consumed by 10% of the population[4] (Eurostat, 1998). This is derived for candidate substances from estimates of annual volume of production provided by industry and incorporates a correction factor of 0.6 to allow for incomplete reporting (60%) in the industry surveys (SCF, 1999 and see also Appendix A, section Intake).

The MSDI values for the two newly included flavouring substances in FGE.07Rev6 ([FL-no: 07.187 and 07.261]) are derived from surveys on annual production volumes (poundage data) conducted in Europe by European Flavours Association (EFFA) for the calendar years 2010 and 2015 (Documentation provided to EFSA nr: 1 and 2). The most recent poundage data, i.e. from survey on year 2015, have been considered in the MSDI calculations for the two candidate substances.

The MSDI value for [FL-no: 07.187] is 0.01 μg/*capita* per day, and for [FL-no: 07.261], it is 0.12 μg/*capita* per day (see Appendix C – Table C.4).

3.3.3. Intake estimated on the basis of the modified TAMDI (mTAMDI)

The method for calculation of modified Theoretical Added Maximum Daily Intake (mTAMDI) values is based on the approach used by SCF up to 1995 (SCF, 1995). The assumption is that a person may consume a certain amount of flavourable foods and beverages per day.

For all 55 flavouring substances contained in FGE.07Rev6, including also the two newly added candidate substances [FL-no: 07.187 and 07.261], information on food categories and normal and maximum use levels have been submitted by industry (EFSA CEF Panel, 2017a and Documentation provided to EFSA nr: 1).

The two candidate substances are used in flavoured food products divided into the food categories, outlined in Annex III of the Commission Regulation (EC) No 1565/2000, as shown in Appendix C – Table C.3. The mTAMDI intake estimates for the two candidate substances are above the TTC for their

[4] EU figure: 375 million. This figure relates to EU population at the time for which production data are available and is consistent (comparable) with evaluations conducted prior to the enlargement of the EU. No production data are available for the enlarged EU (Eurostat, 1998).

structural class (I and II). Therefore, for these flavouring substances, more detailed data on normal and maximum use levels should be provided in order to refine the exposure assessment and to finalise their safety evaluation. This also applies to 50 flavouring substances previously evaluated in FGE.07Rev5 and former revisions.

The detailed information on the uses and use levels and the comparison of the MSDI and mTAMDI intake estimations are reported in Appendix C – Tables C.1 and C.4, respectively, for all 55 candidate substances in FGE.07.

3.3.4. Considerations of combined intakes from use as flavouring substances

Because of structural similarities of candidate and supporting substances, it can be anticipated that many of the flavourings are metabolised through the same metabolic pathways and that the metabolites may affect the same target organs. Furthermore, in case of combined exposure to structurally related flavourings, the pathways could be overloaded. Therefore, combined intake should be considered. As flavouring substances not included in this FGE may also be metabolised through the same pathways, the combined intake estimates presented here are only preliminary. Currently, the combined intake estimates are only based on MSDI exposure estimates, although it is recognised that this may lead to underestimation of exposure. After completion of all FGEs, this issue should be readdressed. The combined exposure will take into account exposures to the flavouring substances evaluated in the previous revisions, the two candidate substances [FL-no: 07.187 and 07.261] and the 81 supporting substances (see Section 3.1.1). The total estimated daily per capita intake of FGE.07 is estimated by summing up the MSDI of the individual substances within the FGE. On the basis of the reported annual production volumes in Europe (EFSA CEF Panel, 2017a), the total estimated daily per capita intake as flavourings of the 29 candidate flavouring substances assigned to structural class I is 6 μg, which does not exceed the threshold of concern for a substance belonging to structural class I of 1,800 μg/person per day. The combined intake of the 26 candidate flavouring substances assigned to structural class II is 78 μg, which does not exceed the threshold of concern for a substance belonging to structural class II of 540 μg/person per day. The 55 candidate substances are structurally related to 81 supporting substances evaluated by JEFCA at its 51st, 55th, 59th and 69th meetings in the groups 'Saturated aliphatic acyclic secondary alcohols, ketones, and related saturated and unsaturated esters' (JECFA, 2000, 2002a, 2003, 2009). The total combined intake of candidate and supporting substances of structural class I and II would be 90,470 μg/capita per day and 1,600 μg/capita per day, respectively. Both intakes exceed the respective threshold of their structural class of 1,800 and 540 μg/person per day. For the substances belonging to structural class I, the major contribution (> 99%) was provided by two supporting substances, namely acetone [FL-no: 07.050] (6,100 μg/capita per day) and isopropanol [FL-no: 02.079] (84,000 μg/capita per day). These are present in the body as endogenous compounds, which are easily eliminated, either by excretion into the urine and exhaled air or after enzymatic metabolism (Morgott, 1993). Therefore, they would not be expected to give rise to perturbations outside the physiological range (JECFA, 1999). Excluding the two major contributors, the estimated total combined intake (in Europe) for the candidate (Table C.4) and supporting substances (Table B.2) belonging to structural class I would be 370 μg/capita per day, which does not exceed the threshold of concern for the corresponding structural class (1,800 μg person per day).

The estimated total combined intake (in Europe) for the candidate (Table C.4) and supporting substances (Table B.2) belonging to structural class II would be 1,600 μg/capita per day, which is nearly threefold higher than the threshold of concern for the corresponding structural class (540 μg/person per day). Five of the supporting substances from structural class II, oct-1-en-3-ol, heptan-2-one, undecan-2-one, nonan-2-one and tridecan-2-one [FL-no: 02.023, 07.002, 07.016, 07.020 and 07.103], contribute with 1200 μg/capita per day to the combined MSDI of 1600 μg/capita per day (Table B.2). A 90-day study for nonan-2-one [FL-no: 07.020] (Krasavage and O'Donoghue, 1979) provides a no observed adverse effect level (NOAEL) of 2,000 mg/kg body weight (bw) per day. Based on this NOAEL, a margin of safety of more than 100,000 can be derived for the combined intake of [FL-no: 02.023, 07.002, 07.016, 07.020 and 07.103]. For the remaining substances from structural class II, the estimated combined intake of 400 μg/capita per day is below the threshold of structural class II of 540 μg/capita per day.

If the candidate substance 5-methylheptan-3-one [FL-no: 07.182] and the supporting substance 3-heptanone [FL-no: 07.003], which can all be metabolised to neurotoxic γ-diketones, were consumed concomitantly on a daily basis, the estimated combined intake (in Europe) would be 3.4 μg/capita per day, corresponding to 0.06 μg/kg bw per day. This value does not exceed the threshold of concern for

the corresponding structural class II (540 μg/person per day) and is also much lower than the NOAEL for 5-methylheptan-3-one [FL-no: 07.182] of 82 mg/kg bw per day for neurotoxicity in the rat. Therefore, it can be concluded that there is no safety concern for neurotoxicity in humans that might result from the combined exposure to these two substances at the estimated level of intake as flavourings. In principle, the supporting substance heptan-3-ol [FL-no: 02.044] could also be metabolised into a neurotoxic γ-diketone, but for reasons explained in FGE.63Rev4 (Section 3.3.1) (EFSA FAF Panel, 2022), the formation of the γ-diketone from this secondary alcohol is anticipated to be so limited that it would not result in neurotoxicity. For that reason, this flavouring substance is no longer included in the calculation of the combined exposure for this effect.

The Panel concluded that the total combined exposure does not raise a safety concern. Moreover, the Panel observed that simultaneous exposure to all 136, candidate plus supporting substances (see Table 3 below), on a single day is unlikely and it is even more unlikely that this could occur repeatedly over a lifetime.

Table 3: Overview of number of candidate and supporting flavouring substances in FGE.07Rev6 and their combined intake based on structural class

Class I		**Class II**		**Total substances**
No. of substances		**No. of substances**		
Candidate	29	Candidate	26	55
Supporting	40	Supporting	41	81
Combined	69	Combined	67	136
	MSDI μg/cap per day		**MSDI μg/cap per day**	
Candidate	6	Candidate	78	
Supporting	364	Supporting	322	
Combined	**370**	Combined	**400**	
FL-no: 07.050	6,100	FL-no: 02.023	390	
FL-no: 02.079	84,000	FL-no: 07.002	96	
Total for class I	**90,470**	FL-no: 07.016	330	
		FL-no: 07.020	320	
		FL-no: 07.103	62	
		Total for class II	**1,600**	

3.4. Biological and toxicological data

3.4.1. ADME data

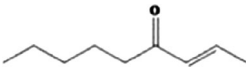
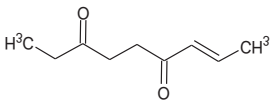
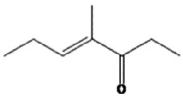
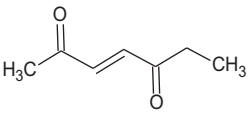
The candidate substances evaluated in the present revision 6 of FGE.07 are two aliphatic α,β-unsaturated ketones: non-2-en-4-one [FL-no: 07.187] and 4-methyl-3-hepten-5-one [FL-no: 07.261]. Generally, aliphatic secondary alcohols and ketones are expected to be rapidly absorbed in the gastrointestinal tract. Particularly, for aliphatic ketones, the main detoxification pathway expected would be the (enzymatic) reduction of the carbonyl function to the corresponding secondary alcohol followed by subsequent conjugation to glucuronic acid and excretion (Felsted and Bachur, 1980; JECFA, 1999). If the substance is α,β unsaturated, such as the two candidate substances in the present FGE, conjugation with glutathione can also occur. The glutathione conjugates are transformed to the corresponding mercapturic acid derivatives and excreted (JECFA, 2003. The Panel considered these candidate substances structurally and metabolically related to the JECFA flavourings group '*Saturated Aliphatic Acyclic Secondary Alcohols, Ketones, and Related Saturated and Unsaturated Esters*', evaluated at the 59th and 68th JECFA meeting (JECFA, 2003,2007). Therefore, further relevant information on the expected metabolic pathways for the candidate substances in FGE.07 can be found in the corresponding JECFA reports (JECFA, 2003, 2009).

Notwithstanding, the Panel also noted that ω and ω-1 oxidation can be competing pathways at high tissue concentrations (Topping et al., 1994). ω-1 oxidation of a ketone results in a hydroxy-ketone which subsequently can be oxidised to a diketone. If the two ketone functions are in γ position relative to each other, such diketones are known to be neurotoxic (e.g. axonal swelling, axonal atrophy)

(Topping et al., 1994). In this respect, the Panel observed that the two candidate substances, non-2-en-4-one [FL-no: 07.187] and 4-methyl-3-hepten-5-one [FL-no: 07.261], might be oxidised in γ position leading to the formation of a γ-diketone (see Table 4 below). With regard to [FL-no: 07.261], the Panel observed that the respective γ-diketone would be formed along the unsaturated part of the carbon chain, and therefore, the unsaturation would prevent the formation of the neurotoxic protein-pyrrole adduct from the γ-diketone, as thoroughly described in FGE.63Rev4 (EFSA FAF Panel, 2022). Therefore, the Panel concluded that this flavouring substance [FL-no: 07.261] can be evaluated along the A-side of the Procedure.

Regarding the other candidate substance [FL-no: 07.187], the Panel noted that if ω-2 oxidation occurs, a γ-diketone (non-2-en-4,7-dione) might be generated along the saturated part of the aliphatic chain (see Table 4). Therefore, the double bond in [FL-no: 07.187] cannot prevent the formation of the neurotoxic protein-pyrrole adduct for this flavouring substance (EFSA FAF Panel, 2022). Upon request to industry to investigate the possible generation of the γ-diketone non-2-en-4,7-dione from [FL-no: 07.187] and its neurotoxic potency, the industry informed that the *in vitro* biotransformation study using cryopreserved rat and human hepatocytes performed with oct-2-en-4-one [FL-no: 07.082], a flavouring substance evaluated in the FGE.63Rev4, would serve to cover also the candidate substance [FL-no: 07.187]. The Panel considered the proposal from industry to read-across between the candidate substances non-2-en-4-one [FL-no: 07.187] and oct-2-en-4-one [FL-no: 07.082] acceptable considering the structural similarities amongst the two compounds (unsaturation and carbonyl function in the same position, differing only in the presence of one carbon atom). Nevertheless, as described in FGE.63Rev4 (EFSA FAF Panel, 2022), the experimental design in the *in vitro* biotransformation study provided for of oct-2-en-4-one [FL-no: 07.082] was not adequate to judge the possible γ-diketone formation (the positive control (2-hexanone) was not metabolised into detectable amounts of 2,5-hexandione). Therefore, the Panel agreed that the information provided for oct-2-en-4-one [FL-no: 07.082], supposed to assist also the assessment of the candidate substance [FL-no: 07.187], is not sufficient to draw any conclusions about the potential formation of neurotoxic metabolites. Accordingly, the Panel concluded that the candidate substance non-2-en-4-one [FL-no: 07.187] should be evaluated along the B-side of the Procedure.

Table 4: Candidate flavouring substances in FGE.07Rev6 and the potentially resulting γ-diketones

FL-no	Chemical name	Chemical structure	γ-diketone	Comments
07.187	non-2-en-4-one			Via ω-2 oxidation: neurotoxicity may be expected because of probable formation of stable pyrrole-protein adduct and no prevention by the unsaturation
07.261	4-methyl-3-hepten-5-one			Via ω-1 oxidation: No neurotoxicity is expected because of prevention of formation of the stable pyrrole-protein adduct by the unsaturation

3.4.2. Genotoxicity data

This revision involves the inclusion of two flavouring substances ([FL-no: 07.187 and 07.261]), which have a structural alert for genotoxicity (i.e. α,β-unsaturated carbonyl substance or precursor for that), preventing their evaluation through the Procedure (see also Appendix A). Therefore, these flavouring substances were evaluated in FGE.201Rev2 ([FL-no: 07.261]) and FGE.204Rev1 ([FL-no: 07.187]) where their genotoxic potential has been assessed and ruled out (EFSA FAF Panel, 2018a, 2019). Therefore, the safety evaluation through the Procedure can be performed for these two flavouring substances.

3.4.3. Toxicological data

No subacute, subchronic/chronic toxicity and carcinogenicity studies are available on either of the two newly included candidate substances [FL-no. 07.187 and 07.261].

For structurally related substances, coming from the previous revision of this FGE (FGE.07Rev5), there are available acute/subacute, subchronic, developmental and reproductive toxicity studies. These studies are listed in FGE.07Rev5, (EFSA CEF Panel, 2017a). Particularly, for flavouring substance 5-methylheptan-3-one [FL-no: 07.182], evaluated in FGE.07Rev5, a subchronic 13-week study is available in which an NOAEL of 82 mg/kg bw per day was identified based on neurotoxicity endpoints (behavioural effects) and microscopic changes. The details of the study are available in FGE.07Rev5.

The Panel noted that flavouring substance 5-methylheptan-3-one [FL-no: 07.182], according to its chemical structure, can be considered structurally related to the candidate substance non-2-en-4-one [FL-no: 07.187]. Based on the available information on absorption, distribution, metabolism and excretion (ADME) reported in the former revision of this FGE (FGE.07Rev5) (EFSA CEF Panel, 2017a; see Appendix D), 5 methylheptan-3-one [FL-no: 07.182], similarly to the candidate substance [FL-no: 07.187], may potentially undergo ω-1 oxidation leading first to a hydroxy-ketone and then to a γ-diketone (3-methyl-2,5-heptanedione). The Panel also noted that in the γ-diketone potentially generated by 5 methylheptan-3-one [FL-no: 07.182], there is a single methyl group on the carbon located between the two carbonyl groups of the γ-diketone (EFSA FAF Panel, 2022; see figure 1); this would increase the potential neurotoxicity of the compound (Topping et al.; 1994). Thus, the use of 5-methylheptan-3-one [FL-no: 07.182] as reference substance represents a conservative scenario with regard to the formation of neurotoxic metabolites. Therefore, the Panel used the NOAEL of 82 mg/kg bw per day for 5-methylheptan-3-one [FL-no: 07.182] from a 13-week study to derive a margin of safety for the candidate substance non-2-en-4-one [FL-no: 07.187].

3.5. Application of the Procedure for the safety evaluation of flavouring substances

The application of the Procedure is based on intakes estimated on the basis of the MSDI approach. Where the mTAMDI approach indicates that the intake of a flavouring substance might exceed its corresponding TTC, a formal safety assessment is not carried out using the Procedure. In these cases, the Panel requires more detailed data on use and use levels. For comparison of the intake estimations based on the MSDI approach and the mTAMDI approach, see Appendix C – Table C.4.

Based on the conclusions reached in FGE.201Rev2 for [FL-no: 07.261] and FGE.204Rev1 for [FL-no: 07.187], i.e. the substances can be considered as non-genotoxic, they can be evaluated through the Procedure accordingly (see for further details Appendix A – Figure A.1).

The safety evaluation sequence applied to the two candidate substances is here below explained.

The safety evaluations of the flavouring substances in FGE.07 are summarised in Appendix D – Table D.1.

Step 1: Assignment to structural class

Of the two candidate flavouring substances, one ([FL-no: 07.261]) is assigned to structural class I and one ([FL-no: 07.187]) to structural class II according to the OECD Toolbox predictions (version 4.3.1 available at https://www.oecd.org/chemicalsafety/risk-assessment/oecd-qsar-toolbox.htm).

Step 2: Expected metabolites

One candidate substance, 4-methyl-3-hepten-5-one [FL-no: 07.261], was considered being metabolised to innocuous products, as outlined in Section 3.4.1. It would not be expected to saturate available detoxification metabolic pathways at the estimated levels of the intake, based on the MSDI approach, from use as flavouring substance. Therefore, the evaluation of this candidate substance proceeds along the A-side of the Procedure scheme.

For the other candidate substance, non-2-en-4-one [FL-no: 07.187], the potential formation of noxious metabolites could not be excluded, as outlined in Section 3.4.1, and accordingly, its safety evaluation proceeds along the B-side of the Procedure scheme.

Step A3/B3: Comparison of the estimated exposure to the TTC

The candidate flavouring substance [FL-no: 07.261], assigned to structural class I, has an MSDI of 0.12 μg/*capita* per day (Appendix C – Table C.4). This intake is below the TTC for structural class I (1,800 μg/*capita* per day). Therefore, the candidate substance [FL-no: 07.261] can be concluded at step A-3 of the Procedure scheme as of no safety concern when used as flavouring substance at the estimated levels of intake based on the MSDI approach.

According to the Procedure scheme (see Appendix A), no toxicological data are required. The toxicological information available for the supporting substances does not conflict with the application of the Procedure or with the outcome of the evaluation.

The other candidate flavouring substance [FL-no: 07.187], which have been assigned to structural class II, has MSDI accounting 0.012 μg/*capita* per day which is below the TTC for structural class II (540 μg/person per day) and the assessment proceeds to step B4 of the Procedure.

For flavouring substance non-2-en-4-one [FL-no: 07.187], the Panel considered that the available NOAEL on the structurally related substance 5 methylheptan-3-one [FL-no: 07.182] is suitable for a further evaluation of this substance (see EFSA considerations in Section 3.4.3). Comparison of the MSDI of [FL-no: 07.187] (0.01 μg/*capita* per day) with the NOAEL of the 90-day study with 5 methylheptan-3-one [FL-no: 07.182] (82 mg/kg bw per day) provides an adequate margin of safety of 4.9×10^7 for the candidate substance [FL-no: 07.187].

Therefore, the Panel concluded, at step B4 of the Procedure scheme, that the flavouring substance non-2-en-4-one [FL-no: 07.187] does not pose a safety concern when used as flavouring substance at the estimated levels of intake, when based on the MSDI approach.

4. Discussion

Following a request from the European Commission, the EFSA Panel on Food Additives and Flavourings (FAF) was asked to deliver a scientific opinion on the implications for human health of chemically defined flavouring substances used in or on foodstuffs in the Member States. In particular, the Panel was requested to evaluate a group of two flavouring substances (4-methyl-3-hepten-5-one [FL-no: 07.261] and non-2-en-4-one [FL-no: 07.187]), allocated to FGE.07Rev6 using the Procedure as referred to in the Commission Regulation (EC) No 1565/2000. These flavouring substances are listed in the Union List, which was adopted by Commission Regulation (EU) No 872/2012 and its consecutive amendments. In total, FGE.07 consists of 55 substances, 53 of which have already been evaluated in the previous five revisions of this FGE. The present revision of FGE.07, FGE.07Rev6, therefore, deals with the assessment of two additional candidate substances [FL-no: 07.187 and 07.261].

These substances possess an α,β-unsaturated carbonyl structure which is considered a structural alert for genotoxicity. They have been evaluated by EFSA in FGE.201Rev2 ([FL-no: 07.261]) and in FGE.204Rev1 ([FL-no: 07.187]) in which FGEs the concern for genotoxicity concern could be ruled out. Accordingly, the Panel concluded that these flavouring substances can be evaluated through the Procedure.

One candidate flavouring substance, 4-methyl-3-hepten-5-one [FL-no: 07.261], was assigned to structural class I; the other candidate substance non-2-en-4-one [FL-no: 07.187] to structural class II.

Two candidate flavouring substances [FL-no: 07.187 and 07.261] have been reported to occur naturally. Quantitative data are available only for [FL-no: 07.187] (see Appendix E). Based on the assessment of the available *in vitro* and *in vivo* genotoxicity tests issued in FGE.201Rev2 and FGE.204Rev1, no concern is raised with respect to genotoxicity for the two candidate substances under evaluation in the present revision of FGE.07. One candidate substance, methyl-3-hepten-5-one [FL-no: 07.261], would be expected to be metabolised to innocuous substances at the estimated levels of intake as flavouring substance and therefore its safety evaluation can proceed along the A-side of the Procedure. Conversely, the other candidate substance non-2-en-4-one [FL-no: 07.187] cannot be predicted to be metabolised into innocuous metabolites and accordingly the Panel concluded that [FL-no: 07.187] should be evaluated along the B-side of the Procedure.

According to the default MSDI approach, the two flavouring substances have European daily per capita intakes (MSDI) ranging from 0.01 to 0.12 μg/*capita* per day, which are below the TTC for structural class I and class II substances (i.e. 1,800 μg/person per day and 540 μg/person per day, respectively). At step B4 of the Procedure, an adequate margin of safety could be calculated for [FL-no: 07.187]. Therefore, based on results of the safety evaluation sequence (as outlined in Section 3.5), none of these two additional candidate substances in FGE.07Rev6 would give rise to safety concerns at the estimated levels of intake arising from their use as flavouring substances, when based on the MSDI approach.

The MSDI contribution of the two candidate flavouring substances [FL-no: 07.187 and 07.261] (0.13 μg/*capita* per day) is negligible in relation to the total estimated combined exposure of the candidate and supporting substances in FGE.07 (as outlined in Section 3.3.4).

The estimated intakes based on modified theoretical added maximum daily intake (mTAMDI) for the two newly included candidate substances, for which normal and maximum use levels were

submitted, are above the TTC for structural class I and II substances. Therefore, for these two flavouring substances, more detailed data on normal and maximum use levels should be provided in order to refine the exposure assessment and to finalise their safety evaluation. This also applies to 50 flavouring substances previously evaluated in FGE.07Rev5. For three previously evaluated flavouring substances ([FL-no: 07.084, 07.178 and 07.239]), the mTAMDIs are below the respective TTCs.

In order to determine whether the conclusion for the two additional candidate substances evaluated through the Procedure can be applied to the materials of commerce, the Panel considered the available specifications. Adequate specifications, including purity and chemical identity for the materials of commerce, have been provided for the two additional candidate substances.

5. Conclusions

Overall, the Panel concluded that the two candidate flavouring substances, cleared with respect to genotoxicity in FGE.201Rev2 [FL-no: 07.261] and FGE.204Rev1 [FL-no: 07.187] and evaluated through the Procedure in this revision of FGE.07 would not be expected to present a safety concern at their estimated levels of intake when based on the MSDI approach. For the two candidate substances and 50 flavouring substances, previously considered in FGE.07Rev5 and the former revisions, their mTAMDI estimates are above the TTC for their structural classes (I and II). Therefore, for these 52 flavouring substances, more detailed data on uses and use levels should be provided in order to finalise their safety evaluations.

6. Recommendations

The Panel recommends the European Commission to consider:

- requesting more detailed data on uses and use levels for substances ([FL-no: 07.187, 07.261, 02.077, 02.124, 02.131, 02.142, 02.145, 02.148, 02.177, 02.182, 02.183, 02.187, 02.190, 02.194, 02.211, 02.255, 07.072, 07.150, 07.156, 07.157, 07.158, 07.160, 07.161, 07.162, 07.181, 07.182, 07.185, 07.189, 07.198, 07.199, 07.201, 07.204, 07.205, 07.210, 07.236, 07.262, 09.304, 09.323, 09.325, 09.328, 09.332, 09.386, 09.388, 09.391, 09.604, 09.605, 09.606, 09.608, 09.609, 09.676, 09.880 and 09.926]). When these data are received, the assessment for these flavouring substances should be updated accordingly and expanded if necessary (i.e. request of additional toxicology data);
- in accordance with the latest specifications for the materials of commerce provided by industry, changing the chemical names and the CAS numbers in the Union List for flavouring substances [FL-no: 07.187 and 07.261] to reflect their stereochemical configuration (see Table B.1 of Appendix B);
- changing the CAS numbers in the Union List for flavouring substances [FL-no: 02.211 and 02.255], previously considered in FGE.07Rev5, as indicated in Table B.1 of Appendix B.

7. Documentation provided to EFSA

1) EFFA (European Flavour Association), 2019. Submission of additional information on isomeric composition, poundage and refined use levels data of substances of FGE.204 Rev1 (FGE.19 Subgroup 1.2.1).
2) EFFA (European Flavour Association), 2020. Submission of additional information on EU poundage data, info on use and potential oxidation of substances of FGE.204 Rev1 (FGE.19 Subgroup 1.2.1) for evaluation in FGE.07 Rev6.

References

Cramer GM, Ford RA and Hall RL, 1978. Estimation of toxic hazard - a decision tree approach. Food and Cosmetics Toxicology, 16, 255–276.

EFSA AFC Panel (EFSA panel on Food Additives, Flavourings, Processing Aids and Materials in Contacts with Food), 2004. Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) related to Flavouring Group Evaluation 7 (FGE.07): Saturated and unsaturated aliphatic secondary alcohols, ketones and esters of secondary alcohols and saturated linear or branched-chain carboxylic acids from chemical group 5. EFSA Journal 2004;3(2):164, 63 pp. https://doi.org/10.2903/j.efsa.2005.164

EFSA AFC Panel (EFSA panel on Food Additives, Flavourings, Processing Aids and Materials in Contacts with Food), 2008. Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission. EFSA Journal 2008;6(6):722, 64 pp. https://doi.org/10.2903/j.efsa.2008.722

EFSA CEF Panel (EFSA panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2009. Flavouring Group Evaluation 7, Revision 2 (FGE.07Rev2) 1: Saturated and unsaturated aliphatic secondary alcohols, ketones and esters of secondary alcohols and saturated linear or branched-chain carboxylic acids from chemical group 5. EFSA Journal 2009;7(7):1020, 70 pp. https://doi.org/10.2903/j.efsa.2009.1020

EFSA CEF Panel (EFSA panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2010. Flavouring Group Evaluation 7, Revision 3 (FGE.07Rev3): Saturated and unsaturated aliphatic secondary alcohols, ketones and esters of secondary alcohols and saturated linear or branched-chain carboxylic acids from chemical group 5. EFSA Journal 2010;8(12):1845, 45 pp. https://doi.org/10.2903/j.efsa.2010.1845

EFSA CEF Panel (EFSA panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2011. Scientific Opinion on Flavouring Group Evaluation 206 (FGE.206): Consideration of genotoxicity data on representatives for 12 alpha,beta-unsaturated ketones and precursors from chemical subgroup 1.2.3 of FGE.19 by EFSA. EFSA Journal 2011;9(3):1922, 45 pp. https://doi.org/10.2903/j.efsa.2011.1922

EFSA CEF Panel (EFSA panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2012. Scientific Opinion on Flavouring Group Evaluation 7, Revision 4 (FGE.07Rev4): Saturated and unsaturated aliphatic secondary alcohols, ketones and esters of secondary alcohols and saturated linear or branched-chain carboxylic acids from chemical group 5. EFSA Journal 2012;10(10):2899, 78 pp. https://doi.org/10.2903/j.efsa.2012.2899

EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2016. Scientific opinion of Flavouring Group Evaluation 205 Revision 1 (FGE.205Rev1): consideration of genotoxicity data on representatives for 13 α,β-unsaturated aliphatic ketones with terminal double bonds and precursors from chemical subgroup 1.2.2 of FGE.19. EFSA Journal 2016;14(7):4535, 69 pp. https://doi.org/10.2903/j.efsa.2016.4535

EFSA CEF Panel (EFSA panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2017a. Scientific Opinion on Flavouring Group Evaluation 7, Revision 5 (FGE.07Rev5): saturated and unsaturated aliphatic secondary alcohols, ketones and esters of secondary alcohols and saturated linear or branched-chain carboxylic acids from chemical group 5. EFSA Journal 2017;15(3):4725, 89 pp. https://doi.org/10.2903/j.efsa.2017.4725

EFSA CEF Panel (EFSA panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2017b. Scientific Opinion on Flavouring Group Evaluation 63, Revision 3 (FGE.63Rev3): aliphatic secondary alcohols, ketones and related esters evaluated by JECFA (59th and 69th meetings) structurally related to saturated and unsaturated aliphatic secondary alcohols, ketones and esters of secondary alcohols and saturated linear or branched-chain carboxylic acids evaluated by EFSA in FGE.07Rev4. EFSA Journal 2017;15(1):4662, 78 pp. https://doi.org/10.2903/j.efsa.2017.4662

EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), 2018a. Scientific Opinion on Flavouring Group Evaluation 201 Revision 2 (FGE.201Rev2): 2-alkylated, aliphatic, acyclic alpha,beta-unsaturated aldehydes and precursors, with or without additional double-bonds, from chemical subgroup 1.1.2 of FGE.19. EFSA Journal 2018;16(10):5423, 45 pp. https://doi.org/10.2903/j.efsa.2018.5423

EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), 2018b. Scientific Opinion on Flavouring Group Evaluation 200. Revision 1 (FGE.200 Rev.1): 74 α,β-unsaturated aliphatic aldehydes and precursors from chemical subgroup 1.1.1 of FGE.19. EFSA Journal 2018;16(10):5422, 60 pp. https://doi.org/10.2903/j.efsa.2018.5422

EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), 2019. Scientific Opinion on Flavouring Group Evaluation 204 Revision 1 (FGE.204Rev1): consideration of genotoxicity data on representatives for 17 monounsaturated, aliphatic, α,β-unsaturated ketones and precursors from chemical subgroup 1.2.1 of FGE.19. EFSA Journal 2019;17(7):5750, 45 pp. https://doi.org/10.2903/j.efsa.2019.5750

EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), 2022. Scientific Opinion on Flavouring Group Evaluation 63, revision 4 (FGE.63Rev4): consideration of aliphatic secondary alcohols, ketones and related esters evaluated by JECFA (59th and 69th meetings) structurally related to flavourings substances evaluated by EFSA in FGE.07Rev6. EFSA Journal 2022;20(2):7102, 46 pp. https://doi.org/10.2903/j.efsa.2022.7102

EFSA Scientific Committee, 2009. Guidance of the Scientific Committee on Transparency in the Scientific Aspects of Risk Assessments carried out by EFSA. Part 2: general Principles. EFSA Journal 2009;7(7):1051, 22 pp. https://doi.org/10.2903/j.efsa.2009.1051

Eurostat, 1998. Total population. Cited in Eurostat, 2004. The EU population, Total population. Available online: https://epp.eurostat.ec.europa.eu/portal/page?_pageid=1090,30070682,1090_33076576&_dad=portal&_schema=PORTAL, Population and social conditions, Population, Demography, Main demographic indicators, Total population. December 2008.

Felsted RL and Bachur NR, 1980. Mammalian carbonyl reductases. Drug Metabolism Reviews, 11, 1–60. https://doi.org/10.3109/03602538008994021. PMID: 7000481.

JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1995. Evaluation of certain food additives and contaminants. Forty-fourth Meeting of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series, no. 859. Geneva.

JECFA (Joint FAO, WHO Expert Committee on Food Additives), 1996. Toxicological evaluation of certain food additives. The forty-fourth meeting of the Joint FAO/WHO Expert Committee on Food Additives and contaminants.
JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1997. Evaluation of certain food additives and contaminants. Forty-sixth report of the Joint FAO/WHO Expert Committee on Food Additives. Geneva, 6–15 February 1996. WHO Technical Report Series, no. 868. Geneva.
JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1998. Compendium of food additive specifications. Addendum 6. Joint FAO/WHO Expert Committee of Food Additives 51st session. Geneva, 9-18 June 1998. FAO Food and Nutrition paper 52 Add. 6.*
JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1999. Evaluation of certain food additives and contaminants. Forty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives. Rome, 17–26 June 1997. WHO Technical Report Series, no. 884. Geneva.
JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2000. Evaluation of certain food additives. Fifty first Meeting of the Joint FAO/WHO Expert Committee on Food Additives. Geneva, 9–18 June 1998. WHO Technical Report Series, no. 891. Geneva.
JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2002a. Evaluation of certain food additives. Fifty ninth report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series, no. 913. Geneva, 4–13 June 2002.
JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2002b. Evaluation of certain food additives and contaminants. Fifty-seventh report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series, no. 909. Geneva, 5–14 June 2001.
JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2003. Safety evaluation of certain food additives. Fifty-ninth Meeting of the Joint FAO/WHO Expert Committee on Food Additives, WHO Food Additives Series: 50. IPCS, WHO, Geneva.
JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2006. Evaluation of certain food additives. Sixty-fifth report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series, no. 934. Geneva, 7-16 June 2005.
JECFA (Joint FAO, WHO Expert Committee on Food Additives), 2007. Evaluation of certain food additives and contaminants. Sixty-eighth report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series, 947.
JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2009. Evaluation of certain food additives. Sixty ninth report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series, no. 952. Rome, 17-26 June 2008. Available online: https://whqlibdoc.who.int/trs/WHO_TRS_952_eng.pdf [Accessed: May 2009].
Krasavage WJ and O'Donoghue JL, 1979. Repeated oral administration of five ketones and n-heptane to rats. March 1, 1979. Unpublished report submitted by EFFA to SCF.
Morgott DA, 1993. Acetone. In: Clayton GD and Clayton FE (eds.). Patty's Industrial Hygiene and Toxicology, 4th Edition. Vol. II, Part A, John Wiley & Sons, New York, pp. 149–281.
SCF (Scientific Committee on Food), 1995. First annual report on chemically defined flavouring substances. May 1995, 2nd draft prepared by the SCF Working Group on Flavouring Substances (Submitted by the SCF Secretariat, 17 May 1995). CS/FLAV/FL/140-Rev2. Annex 6 to Document III/5611/95, European Commission, Directorate-General III, Industry.
SCF (Scientific Committee on Food), 1999. Opinion on a programme for the evaluation of flavouring substances (expressed on 2 December 1999). SCF/CS/FLAV/TASK/11 Final 6/12/1999. Annex I the minutes of the 119th Plenary meeting. European Commission, Health & Consumer Protection Directorate-General.
Topping DC, Morgott DA, David RM and O'Donoghue JL, 1994. Ketones. In: Clayton GD and Clayton FE (eds.), Patty's Industrial Hygiene and Toxicology, 4th Edition. vol. 2C. John Wiley & Sons Inc, New York. pp. 1739–1878.
VCF (Volatile Compounds in Food) online database, 2021. Version 16.8, BeWiDo BV 1992–2021. Available online: https://www.vcf-online.nl/VcfHome.cfm

Abbreviations

ADME	absorption, distribution, metabolism and excretion
bw	body weight
EFFA	European Flavours Association
FGE	Flavouring Group Evaluation
JEFCA	Joint FAO/WHO Expert Committee on Food Additives
MSDI	Maximised Survey-derived Daily Intake
mTAMDI	modified Theoretical Added Maximum Daily Intakes
NOAEL	Mo observed adverse effect level
SCF	Scientific Committee on Food
TTC	toxicological threshold of concern

Appendix A – Procedure of the safety evaluation

The approach for a safety evaluation of chemically defined flavouring substances as referred to in Commission Regulation (EC) No 1565/2000, named the 'Procedure', is shown in schematic form in Figure A.1. 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'.[5]

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 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 1,800, 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 innocuous products[6] (step 2)?
- Do their exposures exceed the TTC for the structural class (steps A3 and B3)?
- Are the flavourings or their metabolites endogenous[7] (step A4)?
- Does an 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.

[5] The FAF Panel is aware that a revised Procedure for the Safety Evaluation of Flavouring agents has been agreed by JECFA (2016). 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.

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

[7] 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).

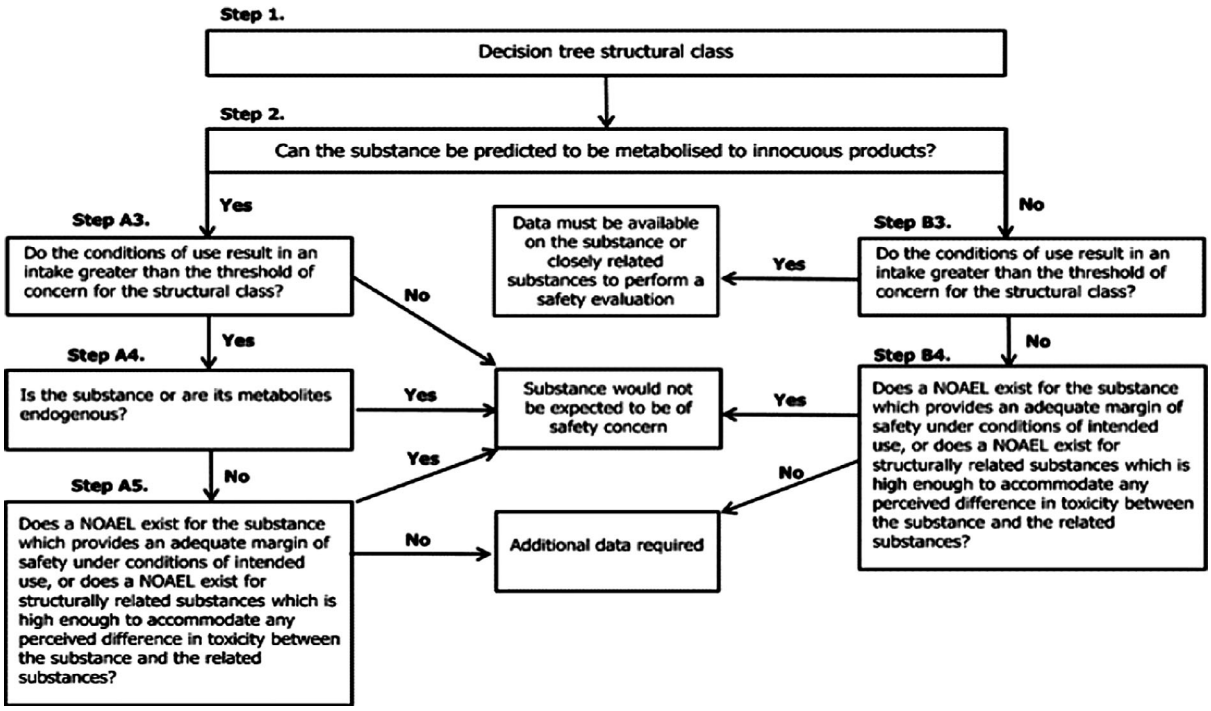


Figure A.1: Procedure for the safety evaluation of chemically defined flavouring substances

For the flavouring substances considered in this Flavouring Group Evaluation (FGE), the EFSA Panel on Food Additives and Flavourings (FAF) compares the JECFA evaluation of structurally related substances with the result of a corresponding EFSA evaluation, focussing 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)[8] approach to estimate the per capita intakes of the flavouring substances in Europe.

In its evaluation, JECFA includes intake estimates based on the MSDI approach derived from both European and USA production figures. The highest of the two MSDI figures is used in the evaluation by JECFA. It is noted that in several cases, only the MSDI figures from the USA were available, meaning that certain flavouring substances have been evaluated by JECFA only on the basis of these figures. For substances in the Union List[9] of flavouring substances for which this is the case, the Panel will need European Union (EU) production figures in order to finalise the 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 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).

[8] EU MSDI: Amount added to food as flavour in (kg/year) 9 109/(0.1 9 population in Europe (= 375 9 106) 9 0.6 9 365) = μg/capita per day.

[9] 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. 1–161.

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 has decided also to perform an estimate of the daily intakes per person using a modified Theoretical Added Maximum Daily Intake (mTAMDI) approach based on the normal use levels reported by Industry (see Appendix C.2).

As information on use levels for the flavouring substances has not been requested by JECFA or has not otherwise been provided to the Panel, it is 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.

b) Threshold of 1.5 microgram/person per day (step B5) used by JECFA

JECFA uses the threshold of concern of 1.5 j.tg/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 j.tg/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, should be amended to include the last step on the right-hand side of the original procedure ('Do the conditions of use result in an intake greater than 1.5 j.tg 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 j.tg per person per day.

c) Genotoxicity

As reflected in the opinion of 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 concluded 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 information on 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 FGE.

Appendix B – Specifications

Table B.1: Summary table on specifications data for flavouring substances in FGE.07Rev6, for chemical structures, see Appendix D

Information included in the EU Union list Regulation No (EU) 1334/2008 as amended			Most recent available specifications data[a]				
FL-no FEMA no CoE no CAS no	**Chemical name**	**Purity of the named compound**	**Phys. form Mol. formula Mol. weight**	**Solubility[c] Solubility in ethanol[d]**	**Boiling point, °C[e] Melting point, °C ID test Assay minimum (isomers distribution/SC[h])**	**Refrac. Index[f] Spec. gravity[g]**	**EFSA Comments**
02.077 2349 584-02-1	Pentan-3-ol	[b]	Liquid $C_5H_{12}O$ 88.15	Slightly soluble Freely soluble	115 MS 98%	1.407–1.413 0.815–0.822	
02.124 10264 1569-60-4	6-Methylhept-5-en-2-ol	[b]	Liquid $C_8H_{16}O$ 128.21	Slightly soluble Freely soluble	77 (20 hPa) MS 95% (racemate)	1.447–1.453 0.848–0.854	
02.131 598-32-3	But-3-en-2-ol	[b]	Liquid C_4H_8O 72.11	Slightly soluble Freely soluble	90 MS 95% (racemate)	1.409–1.415 0.831–0.837	
02.142 464-07-3	3,3-Dimethylbutan-2-ol	[b]	Liquid $C_6H_{14}O$ 102.18	Slightly soluble Freely soluble	120 MS 95% (racemate)	1.410–1.416 0.814–0.820	
02.145 29414-56-0	2,6-Dimethylocta-1,5,7-trien-3-ol	[b]	Liquid $C_{10}H_{16}O$ 152.24	Slightly soluble Freely soluble	240 MS 95% (racemate) Mixture of *E/Z* stereoisomers: 50–80% (*E*)	1.484–1.490 0.895–0.901	
02.148 11760 10203-28-8	Dodecan-2-ol	[b]	Liquid $C_{12}H_{26}O$ 186.34	Insoluble Freely soluble	129 (15 hPa) 19 MS 95% (racemate)	1.438–1.444 0.829–0.835	

Information included in the EU Union list Regulation No (EU) 1334/2008 as amended			Most recent available specifications data[a]				EFSA Comments
FL-no FEMA no CoE no CAS no	**Chemical name**	**Purity of the named compound**	**Phys. form Mol. formula Mol. weight**	**Solubility[c] Solubility in ethanol[d]**	**Boiling point, °C[e] Melting point, °C ID test Assay minimum (isomers distribution/SC[h])**	**Refrac. Index[f] Spec. gravity[g]**	
02.177 10266 617-29-8	2-Methylhexan-3-ol	(b)	Liquid $C_7H_{16}O$ 116.20	Slightly soluble Freely soluble	144 MS 95% (racemate)	1.418–1.424 0.820–0.826	
02.182 10276 565-60-6	3-Methylpentan-2-ol	(b)	Liquid $C_6H_{14}O$ 102.18	Insoluble Freely soluble	134 MS 95% (racemate)	1.415–1.421 0.827–0.833	
02.183 10279 108-11-2	4-Methylpentan-2-ol	(b)	Liquid $C_6H_{14}O$ 102.18	Slightly soluble Freely soluble	132 MS 99% (racemate)	1.407–1.414 0.802–0.808	
02.187 10291 21964-44-3	Non-1-en-3-ol	b)	Liquid $C_9H_{18}O$ 142.24	Practically insoluble or insoluble Freely soluble	195 MS 98%(racemate)	1.438–1.444 0.835–0.845	
02.190 10290 624-51-1	Nonan-3-ol	(b)	Liquid $C_9H_{20}O$ 144.26	Practically insoluble or insoluble Freely soluble	195 MS 95% (racemate)	1.425–1.431 0.818–0.824	
02.194 83861-74-9	Octa-1,5-dien-3-ol	(b)	Liquid $C_8H_{14}O$ 126.20	Practically insoluble or insoluble Freely soluble	187 MS 95% (racemate) Mixture of *E/Z* stereoisomers: 60–90%(*E*)	1.441–1.447 0.832–0.838	

Information included in the EU Union list Regulation No (EU) 1334/2008 as amended			Most recent available specifications data[a]				
FL-no FEMA no CoE no CAS no	**Chemical name**	**Purity of the named compound**	**Phys. form Mol. formula Mol. weight**	**Solubility[c] Solubility in ethanol[d]**	**Boiling point, °C[e] Melting point, °C ID test Assay minimum (isomers distribution/SC[h])**	**Refrac. Index[f] Spec. gravity[g]**	**EFSA Comments**
02.211 56722-23-7	Undeca-1,5-dien-3-ol	[b]	Liquid $C_{11}H_{20}O$ 168.28	Practically insoluble or insoluble Freely soluble	244 NMR 95% (racemate) Mixture of *E/Z* stereoisomers: 60–90% (*E*)	1.456–1.462 0.872–0.878	The CAS number should be changed to 319497-21-7 to reflect the stereochemical configuration of the substance
02.255 66642-85-1	(*Z*)-4-Hepten-2-ol	[b]	Liquid $C_7H_{14}O$ 114.19	Insoluble Freely soluble	154 MS 92% (racemate) Mixture of *E/Z* stereoisomers: (*Z*)-isomer (approx. 92%), (*E*)-isomer (approx. 4%). SC: 2-heptanol (< 1), trans-3-hepten-2-ol (< 1%), cis-3-hepten-2-ol (< 1%)	1.433–1.453 0.832–0.852	The CAS number should be changed to 34146-55-9 which is referring to the *Z* stereoisomer.
07.072 2143 624-42-0	6-Methylheptan-3-one	[b]	Liquid $C_8H_{16}O$ 128.21	Insoluble Freely soluble	162 MS 95%	1.412–1.418 0.813–0.819	
07.084 2350 96-22-0	Pentan-3-one	[b]	Liquid $C_5H_{10}O$ 86.13	Partly soluble Freely soluble	102 MS 99%	1.389–1.395 0.812–0.818	
07.150 4271 11055 693-54-9	Decan-2-one	[b]	Liquid $C_{10}H_{20}O$ 156.27	Insoluble Freely soluble	210 MS 98%	1.423–1.429 0.821–0.827	

Information included in the EU Union list Regulation No (EU) 1334/2008 as amended			Most recent available specifications data[a]				EFSA Comments
FL-no FEMA no CoE no CAS no	**Chemical name**	**Purity of the named compound**	**Phys. form Mol. formula Mol. weight**	**Solubility[c] Solubility in ethanol[d]**	**Boiling point, °C[e] Melting point, °C ID test Assay minimum (isomers distribution/SC[h])**	**Refrac. Index[f] Spec. gravity[g]**	
07.156 90975-15-8	2,6-Dimethyloct-6-en-3-one (mixture of *E* and *Z*)	[b]	Liquid $C_{10}H_{18}O$ 154.25	Insoluble Freely soluble	80 (13 hPa) NMR 95% Mixture of (*Z*)- and (*E*)-isomers	1.442–1.448 0.823–0.829	
07.157 11068 1604-34-8	6,10-Dimethylundecan-2-one	[b]	Liquid $C_{13}H_{26}O$ 198.35	Insoluble Freely soluble	121 (16 hPa) MS 95% (racemate)	1.433–1.439 0.828–0.834	
07.158 11069 6175-49-1	Dodecan-2-one	[b]	Liquid $C_{12}H_{24}O$ 184.32	Insoluble Freely soluble	119 (13 hPa) 20 MS 99%	1.431–1.437 0.825–0.835	
07.160 11089 2922-51-2	Heptadecan-2-one	[b]	Solid $C_{17}H_{34}O$ 254.46	Insoluble Freely soluble	144 (1 hPa) 48 MS 95%	n.a. n.a.	
07.161 1629-60-3	Hex-1-en-3-one	[b]	Liquid $C_6H_{10}O$ 98.14	Practically insoluble or insoluble Freely soluble	128 MS 95%	1.420–1.426 0.849–0.855	
07.162 109-49-9	Hex-5-en-2-one	[b]	Liquid $C_6H_{10}O$ 98.14	Slightly soluble Freely soluble	128 MS 95%	1.418–1.424 0.839–0.845	

Information included in the EU Union list Regulation No (EU) 1334/2008 as amended			Most recent available specifications data[a]				
FL-no FEMA no CoE no CAS no	**Chemical name**	**Purity of the named compound**	**Phys. form Mol. formula Mol. weight**	**Solubility[c] Solubility in ethanol[d]**	**Boiling point, °C[e] Melting point, °C ID test Assay minimum (isomers distribution/SC[h])**	**Refrac. Index[f] Spec. gravity[g]**	**EFSA Comments**
07.178 11131 563-80-4	3-Methylbutan-2-one	[b]	Liquid $C_5H_{10}O$ 86.13	Slightly soluble Freely soluble	94 MS 95%	1.387–1.393 0.801–0.807	
07.181 11146 928-68-7	6-Methylheptan-2-one	[b]	Liquid $C_8H_{16}O$ 128.21	Insoluble Freely soluble	167 MS 95%	1.412–1.418 0.813–0.819	
07.182 541-85-5	5-Methylheptan-3-one	[b]	Liquid $C_8H_{16}O$ 128.21	Insoluble Freely soluble	158 MS 95% (racemate)	1.418–1.424 0.816–0.824	
07.185 11157 565-61-7	3-Methylpentan-2-one	[b]	Liquid $C_6H_{12}O$ 100.16	Insoluble Freely soluble	117 MS 95% (racemate)	1.398–1.404 0.810–0.816	
07.187 11162 32064-72-5	Non-2-en-4-one	[b]	Liquid $C_9H_{16}O$ 140.22	Insoluble Freely soluble	82 (27 hPa) MS 95% (90% *E*-isomer and 5–6% *Z*-isomer)	1.422–1.428 0.823–0.829	The chemical name should be changed to Non-(2*E*)-en-4-one and the CAS number to 27743-70-0 to reflect its stereochemical configuration. (Documentation provided to EFSA nr: 1)
07.189 11161 4485-09-0	Nonan-4-one	[b]	Liquid $C_9H_{18}O$ 142.24	Insoluble Freely soluble	188 MS 95%	1.416–1.422 0.821–0.827	
07.198 4299 11191 141-10-6	Pseudo-ionone	[b]	Liquid $C_{13}H_{20}O$ 192.30	Insoluble Freely soluble	144 (16 hPa) MS 95% Mixture of *E/Z* stereoisomers: > 50% (*E,E*)	1.529–1.535 0.894–0.903	

Information included in the EU Union list Regulation No (EU) 1334/2008 as amended			Most recent available specifications data[a]				
FL-no FEMA no CoE no CAS no	**Chemical name**	**Purity of the named compound**	**Phys. form Mol. formula Mol. weight**	**Solubility[c] Solubility in ethanol[d]**	**Boiling point, °C[e] Melting point, °C ID test Assay minimum (isomers distribution/SC[h])**	**Refrac. Index[f] Spec. gravity[g]**	**EFSA Comments**
07.199 11192 2345-27-9	Tetradecan-2-one	[b]	Solid $C_{14}H_{28}O$ 212.37	Insoluble Freely soluble	146 (16 hPa) 33 MS 95%	n.a. n.a.	
07.201	Tridec-12-en-2-one	[b]	Liquid $C_{13}H_{24}O$ 196.33	Insoluble Freely soluble	129 (13 hPa) NMR 95%	1.441–1.447 0.815–0.821	
07.204 546-49-6	3,3,6-Trimethylhepta-1,5-dien-4-one	[b]	Liquid $C_{10}H_{16}O$ 152.24	Practically insoluble or insoluble Freely soluble	181 MS 95%	1.462–1.468 0.867–0.873	
07.205 11205 502-69-2	6,10,14-Trimethylpentadecan-2-one	[b]	Liquid $C_{18}H_{36}O$ 268.48	Insoluble Freely soluble	174 (13 hPa) MS 95% (racemate)	1.445–1.451 0.834–0.840	
07.210 24415-26-7	1-Nonene-3-one	[b]	Liquid $C_9H_{16}O$ 140.22	Insoluble Freely soluble	80 (16 hPa) MS 95%	1.436–1.442 0.826–0.830	
07.236 11171 22610-86-2	(*Z*)-5-Octen-2-one	[b]	Liquid $C_8H_{14}O$ 126.20	Practically insoluble or insoluble Freely soluble	115 NMR 95%	1.431–1.437 0.842–0.848	
07.239 4331 2278-53-7	[*R*-(*E*)]-5-Isopropyl-8-methylnona-6,8-dien-2-one	[b]	Liquid $C_{13}H_{22}O$ 194.31	Practically insoluble or insoluble Freely soluble	238 MS 95%	1.471–1.477 0.846–0.852	JECFA: 1840

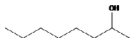
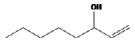
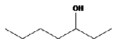
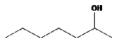
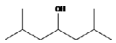
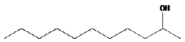
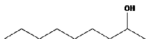
Information included in the EU Union list Regulation No (EU) 1334/2008 as amended			Most recent available specifications data[a]				
FL-no FEMA no CoE no CAS no	**Chemical name**	**Purity of the named compound**	**Phys. form Mol. formula Mol. weight**	**Solubility[c] Solubility in ethanol[d]**	**Boiling point, °C[e] Melting point, °C ID test Assay minimum (isomers distribution/SC[h])**	**Refrac. Index[f] Spec. gravity[g]**	**EFSA Comments**
07.258 2009-74-7	6-Methyl-3-hepten-2-one	(b)	Liquid $C_8H_{14}O$ 126.20	Practically insoluble or insoluble Freely soluble	179 96%	1.436–1.442 0.842–0.848	No longer supported by industry (Documentation provided to EFSA nr: 2)
07.261 22319-31-9	4-Methyl-3-hepten-5-one	(b)	Liquid $C_8H_{14}O$ 126.20	Insoluble Freely soluble	273 MS 95% (*E* isomer)	1.442–1.462 0.851–0.871	The chemical name should be changed to 4-methyl-(3*E*)-hepten-5-one and the CAS number to 27771-19-3 to reflect its stereochemical configuration. (Documentation provided to EFSA nr:1)
07.262 4706 35194-30-0	9-Decen-2-one	(b)	Liquid $C_{10}H_{18}O$ 154	Slightly soluble Soluble	206.3 IR NMR MS 99%	1.426–1.446 0.834–0.854	
09.304 10806 238757-71-6	*sec*-Heptyl isovalerate	(b)	Liquid $C_{12}H_{24}O_2$ 200.32	Insoluble Freely soluble	235 NMR 95% (racemate)	1.423–1.429 0.867–0.873	
09.323 10527 105-46-4	*sec*-Butyl acetate	(b)	Liquid $C_6H_{12}O_2$ 116.16	Slightly soluble Freely soluble	111 MS 95% (racemate)	1.385–1.391 0.867–0.873	
09.325 10528 819-97-6	*sec*-Butyl butyrate	(b)	Liquid $C_8H_{16}O_2$ 144.21	Slightly soluble Freely soluble	152 MS 95% (racemate)	1.399–1.405 0.858–0.864	
09.328 10532 589-40-2	*sec*-Butyl formate	(b)	Liquid $C_5H_{10}O_2$ 102.13	Slightly soluble Freely soluble	94 MS 95% (racemate)	1.386–1.392 0.877–0.883	

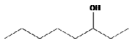
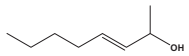
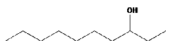
Information included in the EU Union list Regulation No (EU) 1334/2008 as amended			Most recent available specifications data[a]				EFSA Comments
FL-no FEMA no CoE no CAS no	**Chemical name**	**Purity of the named compound**	**Phys. form Mol. formula Mol. weight**	**Solubility[c] Solubility in ethanol[d]**	**Boiling point, °C[e] Melting point, °C ID test Assay minimum (isomers distribution/SC[h])**	**Refrac. Index[f] Spec. gravity[g]**	
09.332 10533 820-00-8	*sec*-Butyl hexanoate	[b]	Liquid $C_{10}H_{20}O_2$ 172.27	Insoluble Freely soluble	82 (21 hPa) NMR 95% (racemate)	1.408–1.414 0.861–0.867	
09.386 94088-33-2	*sec*-Hept-4(cis)-enyl acetate	[b]	Liquid $C_9H_{16}O_2$ 156.22	Insoluble Freely soluble	185 MS 95% (racemate)	1.412–1.418 0.854–0.860	
09.388 10802 5921-82-4	*sec*-Heptyl acetate	[b]	Liquid $C_9H_{18}O_2$ 158.24	Insoluble Freely soluble	172 MS 95% (racemate)	1.406–1.412 0.862–0.868	
09.391 10805 6624-58-4	*sec*-Heptyl hexanoate	[b]	Liquid $C_{13}H_{26}O_2$ 214.35	Insoluble Freely soluble	126 (20 hPa) MS 95% (racemate)	1.421–1.427 0.851–0.857	
09.604 10730 2311-59-3	Isopropyl decanoate	[b]	Liquid $C_{13}H_{26}O_2$ 214.35	Insoluble Freely soluble	88 (3 hPa) MS 95%	1.421–1.427 0.851–0.857	
09.605 10233-13-3	Isopropyl dodecanoate	[b]	Liquid $C_{15}H_{30}O_2$ 242.40	Insoluble Freely soluble	105 (1 hPa) MS 95%	1.427–1.433 0.851–0.857	
09.606 10732 142-91-6	Isopropyl hexadecanoate	[b]	Liquid $C_{19}H_{38}O_2$ 298.51	Insoluble Freely soluble	342 13 MS 95%	1.433–1.439 0.852–0.858	

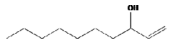
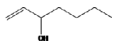
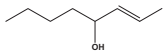
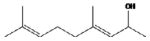
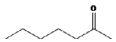
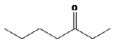
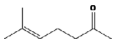
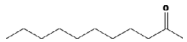
Information included in the EU Union list Regulation No (EU) 1334/2008 as amended			Most recent available specifications data[a]				EFSA Comments
FL-no FEMA no CoE no CAS no	**Chemical name**	**Purity of the named compound**	**Phys. form Mol. formula Mol. weight**	**Solubility[c] Solubility in ethanol[d]**	**Boiling point, °C[e] Melting point, °C ID test Assay minimum (isomers distribution/SC[h])**	**Refrac. Index[f] Spec. gravity[g]**	
09.608 10731 5458-59-3	Isopropyl octanoate	[b]	Liquid $C_{11}H_{22}O_2$ 186.29	Insoluble Freely soluble	124 (53 hPa) MS 95%	1.414–1.420 0.853–0.859	
09.609 18362-97-5	Isopropyl valerate	[b]	Liquid $C_8H_{16}O_2$ 144.21	Insoluble Freely soluble	165 MS 95%	1.398–1.404 0.855–0.861	
09.676 10799 2051-50-5	sec-Octyl acetate	[b]	Liquid $C_{10}H_{20}O_2$ 172.27	Practically insoluble or insoluble Freely soluble	193 MS 95% (racemate)	1.409–1.415 0.857–0.863	
09.880 94088-12-7	(*Z*)-Hept-4-enyl-2 butyrate	[b]	Liquid $C_{11}H_{20}O_2$ 184.28	Practically insoluble or insoluble Freely soluble	224 MS 95% (racemate)	1.414–1.420 0.852–0.858	
09.926 4009 84434-65-1	Octan-3-yl formate	[b]	Liquid $C_9H_{18}O_2$ 158.24	Practically insoluble or insoluble Freely soluble	71 (9 hPa) IR NMR MS 98% (racemate)	1.413–1.417 0.865–0.875	

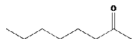
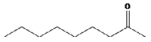
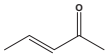
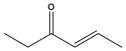
UL: Union List.
(a): JECFA 2002a; EFSA CEF Opinion, 2017a; Documentation provided to EFSA nr: 1 and 2.
(b): At least 95% unless otherwise specified.
(c): Solubility in water, if not otherwise stated.
(d): Solubility in 95% ethanol, if not otherwise stated.
(e): At 1,013.25 hPa, if not otherwise stated.
(f): At 20°C, if not otherwise stated.
(g): At 25°C, if not otherwise stated.
(h): Secondary components.

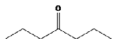
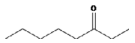
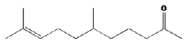
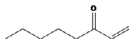
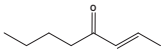
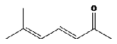
Table B.2: Summary of supporting substances for FGE.07Rev6

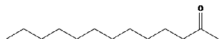
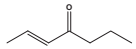
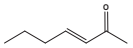
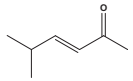
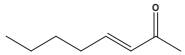
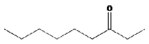
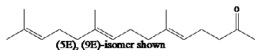
FL-no FEMA no CoE no CAS no	EU Union list name	Structural formula	JECFA no Specification available	MSDI (EU)[a] (μg/*capita* per day)	SCF status[b] JECFA status[c] CoE status[d]	EFSA status
02.022 2801 71 123-96-6	Octan-2-ol		289 JECFA specification (JECFA, 1998)	11	Category 1 (SCF, 1995) No safety concern (JECFA, 2000) Category B (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required
02.023 2805 72 3391-86-4	Oct-1-en-3-ol		1152 JECFA specification, 1-Octen-3-ol (JECFA, 2002b)	390	– No safety concern (JECFA, 2002a) Category A (CoE, 1992)	Concluded in FGE.63Rev3
02.044 3547 544 589-82-2	Heptan-3-ol		286 JECFA specification (JECFA, 1998)	0.12	Category 2 (SCF, 1995) No safety concern (JECFA, 2000) Category B (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required
02.045 3288 554 543-49-7	Heptan-2-ol		284 JECFA specification (JECFA, 1998)	6.8	Category 1 (SCF, 1995) No safety concern (JECFA, 2000) Category B (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required
02.079 2929 - 67-63-0	Isopropanol		277 JECFA specification (JECFA, 1998)	84000	Category 1 (SCF, 1995) No safety concern (JECFA, 2000) –	Evaluated by JECFA before 2000 – No EFSA consideration required
02.081 3140 11719 108-82-7	2,6-Dimethylheptan-4-ol		303 JECFA specification (JECFA, 2003a)	ND	Category 2 (SCF, 1995) No safety concern (JECFA, 2000) –	Evaluated by JECFA before 2000 – No EFSA consideration required
02.086 3246 11826 1653-30-1	Undecan-2-ol		297 JECFA specification (JECFA, 1998)	0.24	Category 1 (SCF, 1995) No safety concern (JECFA, 2000) –	Evaluated by JECFA before 2000 – No EFSA consideration required
02.087 3315 11803 628-99-9	Nonan-2-ol		293 JECFA specification (JECFA, 1998)	0.61	Category 1 (SCF, 1995) No safety concern (JECFA, 2000) –	Evaluated by JECFA before 2000 – No EFSA consideration required

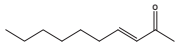
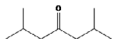
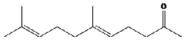
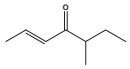
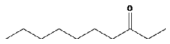
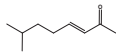
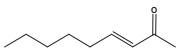
FL-no FEMA no CoE no CAS no	EU Union list name	Structural formula	JECFA no Specification available	MSDI (EU)[a] (μg/*capita* per day)	SCF status[b] JECFA status[c] CoE status[d]	EFSA status
02.088 3316 11696 6032-29-7	Pentan-2-ol		280 JECFA specification (JECFA, 1998)	5.4	Category 1 (SCF, 1995) No safety concern (JECFA, 2000) –	Evaluated by JECFA before 2000 – No EFSA consideration required
02.089 3351 11775 623-37-0	Hexan-3-ol		282 JECFA specification (JECFA, 1998)	11	Category 2 (SCF, 1995) No safety concern (JECFA, 2000) –	Evaluated by JECFA before 2000 – No EFSA consideration required
02.098 3581 11715 589-98-0	Octan-3-ol		291 JECFA specification (JECFA, 1998)	4.7	Category 2 (SCF, 1995) No safety concern (JECFA, 2000) –	Evaluated by JECFA before 2000 – No EFSA consideration required
02.099 3584 11717 616-25-1	Pent-1-en-3-ol		1150 JECFA specification (JECFA, 2002b)	4.3	– No safety concern (JECFA, 2002a) –	Concluded in FGE.63Rev3
02.102 3602 - 76649-14-4	Oct-3-en-2-ol		1140 JECFA specification (JECFA, 2002b)	1.2	– No safety concern (JECFA, 2002a) –	Concluded as of no safety concern in FGE.63Rev4
02.103 3605 10194 1565-81-7	Decan-3-ol		295 JECFA specification (JECFA, 1998)	ND	Category 2 (SCF, 1995) No safety concern (JECFA, 2000) –	Evaluated by JECFA before 2000 – No EFSA consideration required
02.104 3608 10220 4798-44-1	Hex-1-en-3-ol		1151 JECFA specification (JECFA, 2002b)	0.012	– No safety concern (JECFA, 2002a) –	Concluded in FGE.63Rev3
02.111 3703 - 598-75-4	3-Methylbutan-2-ol		300 JECFA specification (JECFA, 2000)	0.49	Category 2 (SCF, 1995) No safety concern (JECFA, 2000) –	Concluded in FGE.63Rev3

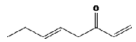
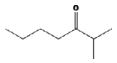
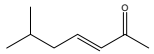
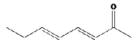
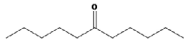
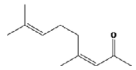
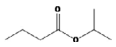
FL-no FEMA no CoE no CAS no	EU Union list name	Structural formula	JECFA no Specification available	MSDI (EU)[a] (μg/*capita* per day)	SCF status[b] JECFA status[c] CoE status[d]	EFSA status
02.136 3824 - 51100-54-0	Dec-1-en-3-ol		1153 JECFA specification (JECFA, 2002b)	0.012	– No safety concern (JECFA, 2002a)	Concluded in FGE.63Rev3
02.155 4129 10218 4938-52-7	1-Hepten-3-ol		1842	0.13	– No safety concern (JECFA, 2009b) –	Concluded in FGE.63Rev3
02.193 3888 - 4798-61-2	Oct-2-en-4-ol		1141 JECFA specification (JECFA, 2002b)	1.8	– No safety concern (JECFA, 2002a) –	Concluded as of no safety concern in FGE.63Rev4
02.252 4102 - 67845-50-5	4,8-Dimethyl-3,7-nonadien-2-ol		1841 JECFA specification (JECFA, 2009a).	3	– No safety concern (JECFA, 2009b) –	Concluded in FGE.63Rev1
07.002 2544 136 110-43-0	Heptan-2-one		283 JECFA specification (JECFA, 1998)	96	Category 1 (SCF, 1995) No safety concern (JECFA, 2000) Category A (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required
07.003 2545 137 106-35-4	Heptan-3-one		285 JECFA specification (JECFA, 1998)	3.3	Category 2 (SCF, 1995) No safety concern (JECFA, 2000) Category B (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required
07.015 2707 149 110-93-0	6-Methylhept-5-en-2-one		1120 JECFA specification (JECFA, 2002b).	100	– No safety concern (JECFA, 2002a) Category B (CoE, 1992)	Concluded in FGE.63
07.016 3093 150 112-12-9	Undecan-2-one		296 JECFA specification (JECFA, 1998)	330	Category 1 (SCF, 1995) No safety concern (JECFA, 2000) Category A (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required

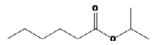
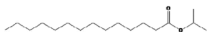
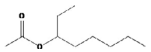
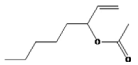
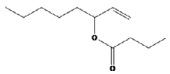
FL-no FEMA no CoE no CAS no	EU Union list name	Structural formula	JECFA no Specification available	MSDI (EU)[a] (μg/*capita* per day)	SCF status[b] JECFA status[c] CoE status[d]	EFSA status
07.017 2731 151 108-10-1	4-Methylpentan-2-one		301 JECFA specification (JECFA, 1998)	6.1	– No safety concern (JECFA, 2000) Category B (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required
07.019 2802 153 111-13-7	Octan-2-one		288 JECFA specification (JECFA, 1998)	93	Category 1 (SCF, 1995) No safety concern (JECFA, 2000) Category A (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required
07.020 2785 154 821-55-6	Nonan-2-one		292 JECFA specification (JECFA, 1998)	320	Category 1 (SCF, 1995) No safety concern (JECFA, 2000) Category A (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required
07.044 3417 666 625-33-2	Pent-3-en-2-one		1124 JECFA specification (JECFA, 2002b)	0.26	– No safety concern (JECFA, 2002a)	Concluded as of no safety concern in FGE.63Rev4
07.048 3352 718 2497-21-4	4-Hexen-3-one		1125 JECFA specification (JECFA 2020, Session 89)	13	– No safety concern (JECFA 2020, Session 89)	Concluded as of no safety concern in FGE.63Rev4
07.050 3326 737 67-64-1	Acetone		139 JECFA specification (JECFA, 1998)	6100	Category 1 (SCF, 1995) No safety concern (JECFA, 2000) Category A (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required
07.053 2170 753 78-93-3	Butan-2-one		278 JECFA specification (JECFA, 1998)	96	Category 1 (SCF, 1995) No safety concern (JECFA, 2000) Category A (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required
07.054 2842 754 107-87-9	Pentan-2-one		279 JECFA specification (JECFA, 1998)	120	Category 1 (SCF, 1995) No safety concern (JECFA, 2000) Category A (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required

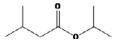
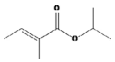
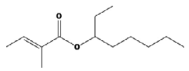
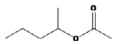
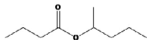
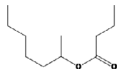
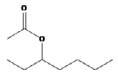
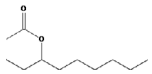
FL-no FEMA no CoE no CAS no	EU Union list name	Structural formula	JECFA no Specification available	MSDI (EU)[a] (μg/*capita* per day)	SCF status[b] JECFA status[c] CoE status[d]	EFSA status
07.058 2546 2034 123-19-3	Heptan-4-one		287 JECFA specification (JECFA, 1998)	1.9	Category 2 (SCF, 1995) No safety concern (JECFA, 2000) Category B (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required
07.062 2803 2042 106-68-3	Octan-3-one		290 JECFA specification (JECFA, 1998)	2.8	Category 2 (SCF, 1995) No safety concern (JECFA, 2000) Category B (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required
07.069 3059 2053 4433-36-7	Tetrahydro-pseudo-ionone		1121 JECFA specification (JECFA, 2002b).	0.012	– No safety concern (JECFA, 2002a) Category B (CoE, 1992)	Concluded in FGE.63
07.081 3515 2312 4312-99-	Oct-1-en-3-one		1148 JECFA specification (JECFA, 2002b)	1.5	– No safety concern (JECFA, 2002a) Category B (CoE, 1992)	Concluded in FGE.63Rev3
07.082 3606 2313 4643-27-0	Oct-2-en-4-one		1129 JECFA specification (JECFA, 2002b)	0.85	– No safety concern (JECFA, 2002a)	Concluded as of no safety concern in FGE.63Rev4
07.096 3290 11097 589-38-8	Hexan-3-one		281 JECFA specification (JECFA, 1998)	0.37	Category 2 (SCF, 1995) No safety concern (JECFA, 2000)	Concluded in FGE.63Rev3
07.099 3363 11143 1604-28-0	6-Methylhepta-3,5-dien-2-one		1134 JECFA specification (JECFA, 2002b).	13	– No safety concern (JECFA, 2002a)	Concluded in FGE.63Rev1
07.100 3365 11150 3240-09-3	5-Methylhex-5-en-2-one		1119 JECFA specification (JECFA, 2002b).	0.24	– No safety concern (JECFA, 2002a)	Concluded in FGE.63

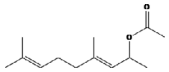
FL-no FEMA no CoE no CAS no	EU Union list name	Structural formula	JECFA no Specification available	MSDI (EU)[a] (μg/*capita* per day)	SCF status[b] JECFA status[c] CoE status[d]	EFSA status
07.102 3382 11179 1629-58-9	Pent-1-en-3-one		1147 JECFA specification (JECFA, 2002b)	1.6	– No safety concern (JECFA, 2002a)	Concluded in FGE.63Rev3
07.103 3388 11194 593-08-8	Tridecan-2-one		298 JECFA specification (JECFA, 2000)	62	Category 1 (SCF, 1995) No safety concern (JECFA, 2000)	Evaluated by JECFA before 2000 – No EFSA consideration required
07.104 3399 11093 4643-25-8	Hept-2-en-4-one		1126 JECFA specification (JECFA, 2002b)	0.012	– No safety concern (JECFA, 2002a) –	Concluded as of no safety concern in FGE.63Rev4
07.105 3400 11094 1119-44-4	Hept-3-en-2-one		1127 JECFA specification (JECFA, 2002b)	0.16	– No safety concern (JECFA, 2002a) –	Concluded as of no safety concern in FGE.63Rev4
07.106 3409 11149 5166-53-0	5-Methylhex-3-en-2-one		1132 JECFA specification (JECFA, 2002b)	0	– No safety concern (JECFA, 2002a) –	Concluded as of no safety concern in FGE.63Rev4
07.107 3416 11170 1669-44-9	Oct-3-en-2-one		1128 JECFA specification (JECFA, 2002b)	0.63	– No safety concern (JECFA, 2002a) –	Concluded as of no safety concern in FGE.63Rev4
07.113 3440 11160 925-78-0	Nonan-3-one		294 JECFA specification (JECFA, 1998)	0.12	Category 2 (SCF, 1995) No safety concern (JECFA, 2000)	Evaluated by JECFA before 2000 – No EFSA consideration required
07.114 3442 11206 762-29-8	6,10,14-Trimethylpentadeca-5,9,13-trien-2-one		1123 JECFA specification (JECFA, 2002b).	0.085	– No safety concern (JECFA, 2002a)	Concluded in FGE.63

FL-no FEMA no CoE no CAS no	EU Union list name	Structural formula	JECFA no Specification available	MSDI (EU)[a] (μg/*capita* per day)	SCF status[b] JECFA status[c] CoE status[d]	EFSA status
07.121 3532 11751 10519-33-2	Dec-3-en-2-one		1130 JECFA specification (JECFA, 2002b)	0.012	– No safety concern (JECFA, 2002a) –	Concluded as of no safety concern in FGE.63Rev4
07.122 3537 11914 108-83-8	2,6-Dimethylheptan-4-one		302 JECFA specification (JECFA, 1998)	0.18	– No safety concern (JECFA, 2000)	Evaluated by JECFA before 2000 – No EFSA consideration required
07.123 3542 11088 3796-70-1	Geranylacetone		1122 JECFA specification (JECFA, 2002b).	41	– No safety concern (JECFA, 2002a)	Concluded in FGE.63
07.137 3724 11808 2345-28-0	Pentadecan-2-one		299 JECFA specification (JECFA, 2000)	18	Category 1 (SCF, 1995) No safety concern (JECFA, 2000)	Evaluated by JECFA before 2000 – No EFSA consideration required
07.139 3761 - 81925-81-7	5-Methylhept-2-en-4-one		1133 JECFA specification (JECFA, 2002d)	5.8	– No safety concern (JECFA, 2002c) –	Concluded as of no safety concern in FGE.63Rev4
07.151 3966 11056 928-80-3	Decan-3-one		1118 JECFA specification (JECFA, 2002b)	3	– No safety concern (JECFA, 2002a)	Evaluated by JECFA before 2000 – No EFSA consideration required
07.177 3868 - 33046-81-0	7- Methyl-3-octenone-2		1135 JECFA specification (JECFA, 2002b)	0.037	– No safety concern (JECFA, 2002a) –	Concluded as of no safety concern in FGE.63Rev4
07.188 3955 11163 14309-57-0	Non-3-en-2-one		1136 JECFA specification (JECFA, 2002b)	0.024	– No safety concern (JECFA, 2002a) –	Concluded as of no safety concern in FGE.63Rev4

FL-no FEMA no CoE no CAS no	EU Union list name	Structural formula	JECFA no Specification available	MSDI (EU)[a] (μg/*capita* per day)	SCF status[b] JECFA status[c] CoE status[d]	EFSA status
07.190 4405 65213-86-7	Octa-1,5-dien-3-one		1848 JECFA specification (JECFA, 2009a)	0.061	– No safety concern (JECFA, 2009b)	Concluded in FGE.63Rev1
07.240 4000 13019-20-0	2-Methylheptan-3-one		1156 JECFA specification (JECFA, 2002b)	3	– No safety concern (JECFA, 2002a)	Concluded in FGE.63Rev1
07.244 4001 - 20859-10-3	(6*E*)- Methyl-3-hepten-2-one		1138 JECFA specification (JECFA, 2002b)	0.012	– No safety concern (JECFA, 2002a) –	Concluded as of no safety concern in FGE.63Rev4
07.247 4008 - 30086-02-3	(*E,E*)-3,5-Octadien-2-one		1139 JECFA specification (JECFA, 2002b)	3	– No safety concern (JECFA, 2002a)	Concluded in FGE.63Rev1
07.249 4022 927-49-1	Undecan-6-one		1155 JECFA specification (JECFA, 2002b)	3	– No safety concern (JECFA, 2002a)	Concluded in FGE.63
07.256 3969 817-88-9	(*E*) & (*Z*)-4,8-Dimethyl-3,7-nonadiene-2- one		1137 JECFA specification (JECFA, 2002b)	6.1	– No safety concern (JECFA, 2002a)	Concluded in FGE.63Rev1
09.003 2926 193 108-21-4	Isopropyl acetate		305 JECFA specification (JECFA, 1998)	35	– No safety concern (JECFA, 2000) Category A (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required
09.041 2935 267 638-11-9	Isopropyl butyrate		307 JECFA specification (JECFA, 1998)	6	– No safety concern (JECFA, 2000) Category A (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required

FL-no FEMA no CoE no CAS no	EU Union list name	Structural formula	JECFA no Specification available	MSDI (EU)[a] (μg/*capita* per day)	SCF status[b] JECFA status[c] CoE status[d]	EFSA status
09.062 2950 312 2311-46-8	Isopropyl hexanoate		308 JECFA specification (JECFA, 2001b)	3.2	– No safety concern (JECFA, 2000) Category A (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required
09.105 3556 386 110-27-0	Isopropyl tetradecanoate		311 JECFA specification (JECFA, 2000b)	19	– No safety concern (JECFA, 2000) Category B (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required
09.123 2959 404 637-78-5	Isopropyl propionate		306 JECFA specification (JECFA, 2001b)	0.012	– No safety concern (JECFA, 2001a) Category A (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required
09.165 2944 503 625-55-8	Isopropyl formate		304 JECFA specification (JECFA, 2001b)	0.45	– No safety concern (JECFA, 2001a) Category A (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required
09.254 3583 2347 4864-61-3	3-Octyl acetate		313 JECFA specification (JECFA, 1998)	0.61	– No safety concern (JECFA, 2001a) Category B (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required
09.281 3582 11716 2442-10-6	Oct-1-en-3-yl acetate		1836 JECFA specification (JECFA, 2009b)	2.1	– No safety concern (JECFA, 2009a)	Concluded in FGE.63Rev3
09.282 3612 16491-54-6	Oct-1-en-3-yl butyrate		1837 JECFA specification (JECFA, 2009b)	0.0012	– No safety concern (JECFA, 2009a)	Concluded in FGE.63Rev3
09.415 2937 290 617-50-5	Isopropyl isobutyrate		309 JECFA specification (JECFA, 1998)	0.49	– No safety concern (JECFA, 2001a) Category A (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required

FL-no FEMA no CoE no CAS no	EU Union list name	Structural formula	JECFA no Specification available	MSDI (EU)[a] (μg/*capita* per day)	SCF status[b] JECFA status[c] CoE status[d]	EFSA status
09.450 2961 445 32665-23-9	Isopropyl isovalerate		310 JECFA specification (JECFA, 2002b)	0.24	– No safety concern (JECFA, 2001a) Category B (CoE, 1992)	Evaluated by JECFA before 2000 – No EFSA consideration required
09.513 3229 10733 1733-25-1	Isopropyl 2-methylcrotonate		312 JECFA specification (JECFA, 1998)	0.012	– No safety concern (JECFA, 2000)	Evaluated by JECFA before 2000 – No EFSA consideration required
09.539 3676 - 94133-92-3	Oct-3-yl 2-methylcrotonate		448 JECFA specification (JECFA, 2001b)	0.012	– No safety concern (JECFA, 2000)	Evaluated by JECFA before 2000 – No EFSA consideration required
09.657 4012 10761 626-38-0	1-Methylbutyl acetate		1146 JECFA specification (JECFA, 2002b)	2.9	– No safety concern (JECFA, 2002a)	Concluded in FGE.63
09.658 3893 10763 60415-61-4	1-Methylbutyl butyrate		1142 JECFA specification (JECFA, 2002b)	0.47	– No safety concern (JECFA, 2002a)	Concluded in FGE.63
09.923 3981 39026-94-3	Hept-2-yl butyrate		1144 JECFA specification (JECFA, 2002b)	3	– No safety concern (JECFA, 2002a)	Concluded in FGE.63
09.924 3980 5921-83-5	3-Heptyl acetate (mixture of R and S)		1143 JECFA specification (JECFA, 2002b)	3	– No safety concern (JECFA, 2002a)	Concluded in FGE.63
09.925 4007 60826-15-5	Nonan-3-yl acetate		1145 JECFA specification (JECFA, 2002b)	3	– No safety concern (JECFA, 2002a)	Concluded in FGE.63

FL-no FEMA no CoE no CAS no	EU Union list name	Structural formula	JECFA no Specification available	MSDI (EU)[a] (μg/*capita* per day)	SCF status[b] JECFA status[c] CoE status[d]	EFSA status
09.936 4103 91418-25-6	4,8-Dimethyl-3,7-nonadien-2-yl acetate		1847 JECFA specification (JECFA, 2009b)	3	– No safety concern (JECFA, 2009a)	Concluded in FGE.63Rev1

(a): EU MSDI: Amount added to food as flavouring substance in (kg/year) × 10E9/(0.1 × population in Europe (= 375 × 10E6) × 0.6 × 365) = μg/capita per day.
(b): Category 1: Considered safe in use, Category 2: Temporarily considered safe in use, Category 3: Insufficient data to provide assurance of safety in use, Category 4: Not acceptable due to evidence of toxicity.
(c): No safety concern at estimated levels of intake.
(d): Category A: Flavouring substance, which may be used in foodstuffs, Category B: Flavouring substance which can be used provisionally in foodstuffs.
(e): ND: No intake data reported.

Appendix C – Exposure estimates

C.1. Normal and Maximum Use Levels

Table C.1: Normal and maximum use levels (mg/kg) of flavouring substances in FGE.07Rev6 in food categories listed in Annex III of Reg. (EC) 1565/2000 (Documentation provided to EFSA n. 1)

FL-no	Food Categories Normal use levels (mg/kg)[a] Maximum use 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
02.077	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
02.124	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
02.131	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
02.142	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
02.145	7 35	8 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
02.148	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
02.177	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
02.182	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
02.183	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
02.187	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
02.190	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
02.194	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25

FL-no	Food Categories Normal use levels (mg/kg)[a] Maximum use 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
02.211	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
02.255	5 20	– –	10 50	– –	– –	10 60	– –	– –	10 60	– –	– –	– –	– –	– –	5 20	2 10	10 40	– –	– –
07.072	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	4 20	5 25	2 10
07.084	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	4 20	5 25	2 10
07.150	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	4 20	5 25	2 10
07.156	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	– –	3 15	2 10	4 20	5 25	2 10
07.157	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	5 25	2 10	4 20	– –	2 10
07.158	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	4 20	5 25	2 10
07.160	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	4 20	5 25	2 10
07.161	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	4 20	5 25	2 10
07.162	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	4 20	5 25	2 10
07.178	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	4 20	5 25	2 10
07.181	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	4 20	5 25	2 10
07.182	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	4 20	5 25	2 10
07.185	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	4 20	5 25	2 10

FL-no	Food Categories Normal use levels (mg/kg)[a] Maximum use 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
07.187	5 11.5	0.5 1.25	1.55 2.28	– –	4.6 8.36	6.92 11.63	2.00 6.63	5.71 10.4	8.75 15	2.13 2.60	1 1	– –	– –	2 5.6	– –	3 4.63	0.67 10	1 2	– –
07.189	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	4 20	5 25	2 10
07.198	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	4 20	5 25	2 10
07.199	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	4 20	5 25	2 10
07.201	3 15	2 10	3 10	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	4 20	5 25	2 10
07.204	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	4 20	5 25	2 10
07.205	3 15	2 10	3 15	2 10	– –	– –	– –	4 20	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	– –	5 25	2 10
07.210	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	4 20	5 25	2 10
07.236	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	4 20	5 25	2 10
07.239	3 15	2 10	3 15	2 10	– –	4 20	– –	2 10	5 25	1 5	1 5	– –	– –	2 10	3 15	2 10	4 20	5 25	2 10
07.261	5 11.5	0.5 1.25	– –	– –	4.6 8.36	6.92 11.63	2.00 6.63	5.71 10.4	8.75 15	2.13 2.6	– –	– –	– –	2 5.6	– –	3 4.63	0.67 10	1 2	– –
07.262	10 30	– –	5 15	10 30	10 30	30 150	– –	– –	– –	– –	– –	– –	– –	– –	10 50	5 25	10 50	– –	30 150
09.304	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
09.323	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
09.325	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25

FL-no	Food Categories Normal use levels (mg/kg)[a] Maximum use 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
09.328	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	2 25
09.332	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
09.386	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
09.388	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
09.391	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
09.604	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
09.605	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
09.606	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
09.608	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	– –	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
09.609	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	– –	5 25
09.676	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
09.880	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25
09.926	7 35	5 25	10 50	7 35	– –	10 50	– –	5 25	10 50	2 10	2 10	– –	– –	5 25	10 50	5 25	10 50	20 100	5 25

(a): 'Normal use' is defined as the average of reported usages and 'maximum use' is defined as the 95th percentile of reported usages.
(b): Additional food category 05.3 (chewing gum as per Annex II part D of Reg. (EC) 1333/2008) for which EFFA submitted use levels (Documentation provided to EFSA n. 1). These data have been considered in the calculation of mTAMDI.

C.2. mTAMDI calculations

The method for calculation of modified Theoretical Added Maximum Daily Intake (mTAMDI) values is based on the approach used by the SCF up to 1995 (SCF, 1995). The assumption is that a person may consume the amount of flavourable foods and beverages listed in Table C.2. These consumption estimates are then multiplied by the reported use levels in the different food categories and summed up.

Table C.2: Estimated amount of flavourable foods, beverages and exceptions assumed to be consumed per person per day (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 C.3)

- Beverages (SCF, 1995) correspond to food Table C.3): 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 categories 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.

Table C.3: 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)

	Food categories according to Commission Regulation 1565/2000	Distribution of the seven SCF food categories		
Key	**Food category**	**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		

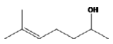
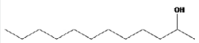
Table C.4: Estimated intakes based on the MSDI approach and the mTAMDI approach for substances in FGE.07Rev6

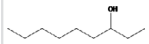
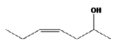
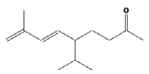
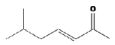
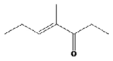
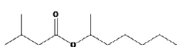
FL-no	EU Union List chemical name	MSDI (μg/*capita* per day)	mTAMDI (μg/person per day)	Structural class	TTC (μg/person per day)
02.077	Pentan-3-ol	0.19	3,900	Class I	1,800
02.124	6-Methylhept-5-en-2-ol	0.0061	3,900	Class I	1,800
02.142	3,3-Dimethylbutan-2-ol	0.24	3,900	Class I	1,800
02.148	Dodecan-2-ol	0.35	3,900	Class I	1,800
02.177	2-Methylhexan-3-ol	0.12	3,900	Class I	1,800
02.182	3-Methylpentan-2-ol	0.12	3,900	Class I	1,800
02.183	4-Methylpentan-2-ol	0.0012	3,900	Class I	1,800
02.190	Nonan-3-ol	0.011	3,900	Class I	1,800
02.255	(*Z*)-4-Hepten-2-ol	0.03	2,500	Class I	1,800
07.084	Pentan-3-one	0.24	1,600	Class I	1,800
07.178	3-Methylbutan-2-one	0.073	1,600	Class I	1,800
07.239	[R-(*E*)]-5-Isopropyl-8-methylnona-6,8-dien-2-one	0.24	1,600	Class I	1,800
07.261	4-Methyl-3-hepten-5-one	0.12	2,400	Class I	1,800
09.304	*sec*-Heptyl isovalerate	0.0012	3,900	Class I	1,800
09.323	*sec*-Butyl acetate	0.0012	3,900	Class I	1,800
09.325	*sec*-Butyl butyrate	1.3	3,900	Class I	1,800
09.328	*sec*-Butyl formate	0.12	3,900	Class I	1,800
09.332	*sec*-Butyl hexanoate	0.024	3,900	Class I	1,800
09.386	*sec*-Hept-4(cis)-enyl acetate	0.024	3,900	Class I	1,800
09.388	*sec*-Heptyl acetate	0.12	3,900	Class I	1,800
09.391	*sec*-Heptyl hexanoate	0.12	3,900	Class I	1,800
09.604	Isopropyl decanoate	0.12	3,900	Class I	1,800
09.605	Isopropyl dodecanoate	0.12	3,900	Class I	1,800
09.606	Isopropyl hexadecanoate	0.012	3,900	Class I	1,800
09.608	Isopropyl octanoate	1.3	3,900	Class I	1,800
09.609	Isopropyl valerate	0.012	3,500	Class I	1,800
09.676	*sec*-Octyl acetate	0.011	3,900	Class I	1,800
09.880	(*Z*)-Hept-4-enyl-2 butyrate	0.79	3,900	Class I	1,800
09.926	Octan-3-yl formate	0.24	3,900	Class I	1,800
02.145	2,6-Dimethylocta-1,5,7-trien-3-ol	0.0085	3,900	Class II	540

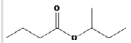
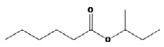
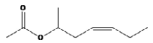
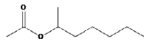
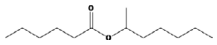
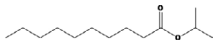
FL-no	EU Union List chemical name	MSDI (μg/*capita* per day)	mTAMDI (μg/person per day)	Structural class	TTC (μg/person per day)
02.194	Octa-1,5-dien-3-ol	0.061	3,900	Class II	540
02.211	Undeca-1,5-dien-3-ol	0.061	3,900	Class II	540
07.072	6-Methylheptan-3-one	0.19	1,600	Class II	540
07.150	Decan-2-one	0.52	1,600	Class II	540
07.156	2,6-Dimethyloct-6-en-3-one (mixture of *E* and *Z*)	0.0012	1,600	Class II	540
07.157	6,10-Dimethylundecan-2-one	0.085	1,500	Class II	540
07.158	Dodecan-2-one	0.73	1,600	Class II	540
07.160	Heptadecan-2-one	0.12	1,600	Class II	540
07.162	Hex-5-en-2-one	0.049	1,600	Class II	540
07.181	6-Methylheptan-2-one	0.0012	1,600	Class II	540
07.185	3-Methylpentan-2-one	1.2	1,600	Class II	540
07.189	Nonan-4-one	0.52	1,600	Class II	540
07.198	Pseudo-ionone	0.12	1,600	Class II	540
07.199	Tetradecan-2-one	0.073	1,600	Class II	540
07.201	Tridec-12-en-2-one	0.024	1,600	Class II	540
07.204	3,3,6-Trimethylhepta-1,5-dien-4-one	0.012	1,600	Class II	540
07.205	6,10,14-Trimethylpentadecan-2-one	0.0073	1,500	Class II	540
07.236	(*Z*)-5-Octen-2-one	0.0097	1,600	Class II	540
07.262	9-Decen-2-one	73	6,600	Class II	540
07.182	5-Methylheptan-3-one	0.32	1,600	Class II	540
02.131	But-3-en-2-ol	0.0012	3,900	Class II	540
02.187	Non-1-en-3-ol	0.58	3,900	Class II	540
07.161	Hex-1-en-3-one	0.012	1,600	Class II	540
07.187	Non-2-en-4-one	0.01	2,400	Class II	540
07.210	1-Nonene-3-one	0.0012	1,600	Class II	540

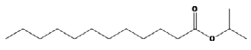
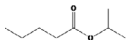
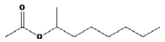
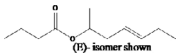
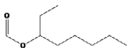
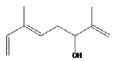
Appendix D – Summary of safety evaluations

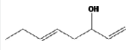
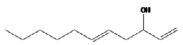
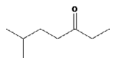
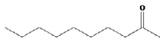
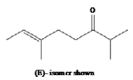
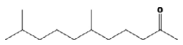
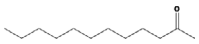
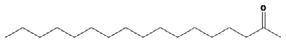
Table D.1: Summary of safety evaluations applying the Procedure for substances in FGE.07 and its revisions

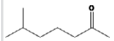
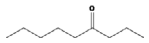
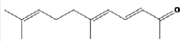
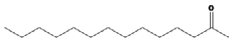
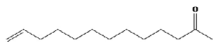
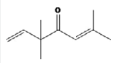
FL-no	EU Union List chemical name	Structural formula	MSDI[a] (μg/*capita* per day)	Class[b] Evaluation procedure path[c] Outcome on the named compound and on the material of commerce	EFSA comments
02.077	Pentan-3-ol		0.19	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
02.124	6-Methylhept-5-en-2-ol		0.0061	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
02.142	3,3-Dimethylbutan-2-ol		0.24	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
02.148	Dodecan-2-ol		0.35	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
02.177	2-Methylhexan-3-ol		0.12	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
02.182	3-Methylpentan-2-ol		0.12	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
02.183	4-Methylpentan-2-ol		0.0012	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07

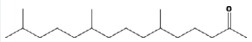
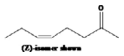
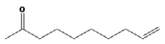
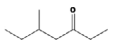
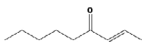
FL-no	EU Union List chemical name	Structural formula	MSDI[a] (μg/*capita* per day)	Class[b] Evaluation procedure path[c] Outcome on the named compound and on the material of commerce	EFSA comments
02.190	Nonan-3-ol		0.011	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07Rev1
02.255	(*Z*)-4-Hepten-2-ol		0.03	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07Rev2 The CAS number should be changed to 34146-55-9
07.084	Pentan-3-one		0.24	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
07.178	3-Methylbutan-2-one		0.073	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
07.239 1840	[R-(*E*)]-5-Isopropyl-8-methylnona-6,8-dien-2-one		0.24	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07Rev2
07.258	6-Methyl-3-hepten-2-one				No longer supported by industry (Documentation provided to EFSA nr: 2)
07.261	4-Methyl-3-hepten-5-one		0.12	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07Rev6 The chemical name should be changed to 4-Methyl-(3*E*)-hepten-5-one and the CAS number to 27771-19-3
09.304	*sec*-Heptyl isovalerate		0.0012	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07

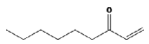
FL-no	EU Union List chemical name	Structural formula	MSDI[a] (μg/*capita* per day)	Class[b] Evaluation procedure path[c] Outcome on the named compound and on the material of commerce	EFSA comments
09.323	*sec*-Butyl acetate		0.0012	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
09.325	*sec*-Butyl butyrate		1.3	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
09.328	*sec*-Butyl formate		0.12	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
09.332	*sec*-Butyl hexanoate		0.024	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
09.386	*sec*-Hept-4(cis)-enyl acetate		0.024	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
09.388	*sec*-Heptyl acetate		0.12	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
09.391	*sec*-Heptyl hexanoate		0.12	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach	Concluded in FGE.07
09.604	Isopropyl decanoate		0.12	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07

FL-no	EU Union List chemical name	Structural formula	MSDI[a] (μg/*capita* per day)	Class[b] Evaluation procedure path[c] Outcome on the named compound and on the material of commerce	EFSA comments
09.605	Isopropyl dodecanoate		0.12	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
09.606	Isopropyl hexadecanoate		0.012	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
09.608	Isopropyl octanoate		1.3	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
09.609	Isopropyl valerate		0.012	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
09.676	*sec*-Octyl acetate		0.011	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
09.880	(*Z*)-Hept-4-enyl-2 butyrate		0.79	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
09.926 2070	Octan-3-yl formate		0.24	Class I A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07Rev1
02.145	2,6-Dimethylocta-1,5,7-trien-3-ol		0.0085	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07Rev4

FL-no	EU Union List chemical name	Structural formula	MSDI[a] (μg/*capita* per day)	Class[b] Evaluation procedure path[c] Outcome on the named compound and on the material of commerce	EFSA comments
02.194	Octa-1,5-dien-3-ol		0.061	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07Rev4
02.211	Undeca-1,5-dien-3-ol		0.061	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07Rev4
07.072	6-Methylheptan-3-one		0.19	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
07.150 2074	Decan-2-one		0.52	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
07.156	2,6-Dimethyloct-6-en-3-one (mixture of *E* and *Z*)		0.0012	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
07.157	6,10-Dimethylundecan-2-one		0.085	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
07.158	Dodecan-2-one		0.73	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
07.160	Heptadecan-2-one		0.12	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07

FL-no	EU Union List chemical name	Structural formula	MSDI[a] (μg/*capita* per day)	Class[b] Evaluation procedure path[c] Outcome on the named compound and on the material of commerce	EFSA comments
07.162	Hex-5-en-2-one		0.049	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07Rev1
07.181	6-Methylheptan-2-one		0.0012	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
07.185	3-Methylpentan-2-one		1.2	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
07.189	Nonan-4-one		0.52	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
07.198	Pseudo-ionone		0.12	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07Rev4
07.199	Tetradecan-2-one		0.073	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
07.201	Tridec-12-en-2-one		0.024	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07Rev1
07.204	3,3,6-Trimethylhepta-1,5-dien-4-one		0.012	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07Rev4

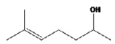
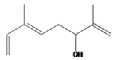
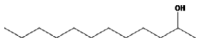
FL-no	EU Union List chemical name	Structural formula	MSDI[a] (μg/*capita* per day)	Class[b] Evaluation procedure path[c] Outcome on the named compound and on the material of commerce	EFSA comments
07.205	6,10,14-Trimethylpentadecan-2-one		0.0073	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07
07.236	(*Z*)-5-Octen-2-one		0.0097	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07Rev1
07.262	9-Decen-2-one		73	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07Rev3
07.182	5-Methylheptan-3-one		0.32	Class II B3: Intake below threshold, B4: Adequate NOAEL exists No safety concern based on intake calculated by the MSDI approach	Concluded in FGE.07
02.131	But-3-en-2-ol		0.0012	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07Rev5
02.187	Non-1-en-3-ol		0.58	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07Rev5
07.161	Hex-1-en-3-one		0.012	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07Rev5
07.187	Non-2-en-4-one		0.012	Class II B3: Intake below threshold B4: An adequate NOAEL exists No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07Rev6. The chemical name should be changed to Non-(2*E*)-en-4-one and the CAS number to 27743-70-0

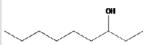
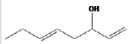
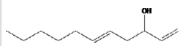
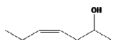
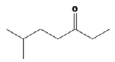
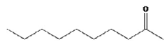
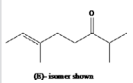
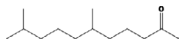
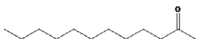
FL-no	EU Union List chemical name	Structural formula	MSDI[(a)] (μg/*capita* per day)	Class[(b)] Evaluation procedure path[(c)] Outcome on the named compound and on the material of commerce	EFSA comments
07.210	1-Nonene-3-one		0.0012	Class II A3: Intake below threshold No safety concern based on intake calculated by the MSDI approach.	Concluded in FGE.07Rev5

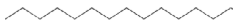
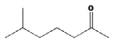
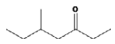
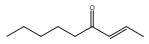
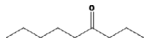
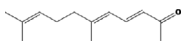
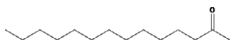
(a): Thresholds of concern: Class I = 1800 μg/person per day, Class II = 540 μg/person per day, Class III = 90 μg/person per day.
(b): Procedure path A substances can be predicted to be metabolised to innocuous products. Procedure path B substances cannot.
(c): EU MSDI: Amount added to food as flavour in (kg/year) × 10^9/(0.1 × population in Europe (= 375 × 10^6) × 0.6 × 365) = μg/capita per day.
(d): Refer to Appendix C for MSDI values considered by EFSA based on EU production figures submitted by industry (Documentation provided to EFSA n.: 1 and 2).

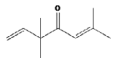
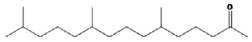
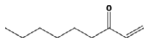
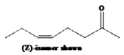
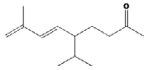
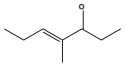
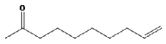
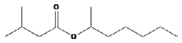
Appendix E – Natural food occurrence

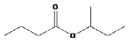
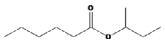
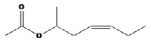
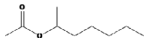
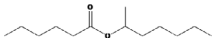
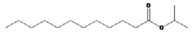
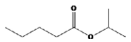
Table E.1: Natural food occurrence of flavouring substance in FGE.07

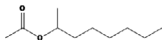
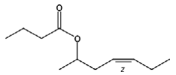
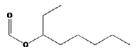
FL-no	EU Register name	Structural formula	CAS no	VCF online search 15-11-2016* and 06-12-2021**
02.077	Pentan-3-ol		584-02-1	Quantified in: apricot, grape, grape brandy, guinea hen, loquat, milk and milk products, mushroom, olive, papaya, red currants, rum, shrimps from trace amount up to 1.3 mg/kg and up to 34 mg/kg in tea. Has been identified in a further 36 food items
02.124	6-Methylhept-5-en-2-ol		1569-60-4	Quantified in: annatto, litchi, macadamia nut, tomato from 0.0125 mg/kg and up to 50 mg/kg in citrus fruits. Has been identified in a further 18 food items
02.131	But-3-en-2-ol		598-32-3	Identified in citrus fruits
02.142	3,3-Dimethylbutan-2-ol		464-07-3	Identified in melon
02.145	2,6-Dimethylocta-1,5,7-trien-3-ol		29414-56-0	Quantified in salvia species up to 100 mg/kg
02.148	Dodecan-2-ol		10203-28-8	Quantified in mastic up to 1,300 mg/kg. Identified apple, banana, beer and cheddar cheese
02.177	2-Methylhexan-3-ol		617-29-8	Quantified in tomato up to 2.5 mg/kg
02.182	3-Methylpentan-2-ol		565-60-6	Quantified in pineapple up to 0.009 mg/kg. Identified in capsicum species, date, shrimps and tea
02.183	4-Methylpentan-2-ol		108-11-2	Quantified in annatto and citrus fruits from 0.027 up to 0.111 mg/kg. Identified in apple brandy, bantu beer, cocoa, peanut and peas

FL-no	EU Register name	Structural formula	CAS no	VCF online search 15-11-2016* and 06-12-2021**
02.187	Non-1-en-3-ol		21964-44-3	Identified in banana, beef, chervil, date and rambutan
02.190	Nonan-3-ol		624-51-1	Identified in: banana, beef, cherimoya, chervil, date, guava and feyoa, mentha oils and passion fruit
02.194	Octa-1,5-dien-3-ol		83861-74-9	Quantified in: cheese (various types), fish and oysters from 0.025 up to 0.26 mg/kg. Identified in chicken, scallop and tea
02.211	Undeca-1,5-dien-3-ol		56722-23-7	Identified in fish and katsuobushi
02.255	(*Z*)-4-Hepten-2-ol		66642-85-1	Identified in maize
07.072	6-Methylheptan-3-one		624-42-0	Identified in melon and potato
07.084	Pentan-3-one		96-22-0	Quantified in: guava and feyoa, mangifera species, milk and milk products, mushroom, olive, passion fruit and shrimps from 0.0007 up to 14 mg/kg. Identified in a further 41 food items
07.150	Decan-2-one		693-54-9	Quantified in: blue cheeses, cheese various types, chicken, milk and milk products, mountain papaya and shrimps from trace amounts up to 2.5 mg/kg and up to 2,600 mg/kg hop oil. Identified in a further 42 food items
07.156	2,6-Dimethyloct-6-en-3-one (mixture of *E* and *Z*)		90975-15-8 Search on substance name	Quantified up to 0.05 mg/kg in citrus fruits
07.157	6,10-Dimethylundecan-2-one		1604-34-8 Search on substance name	Quantified in up to 0.002 mg/kg in vaccinium species. Identified in buckwheat, coffee, mate, rooibos tea and tea
07.158	Dodecan-2-one		6175-49-1	Quantified in blue cheeses, chicken, cocoa category and milk and milk products from 0.0014 up to 1.8 mg/kg and up to 2,700 mg/kg in hop oil

FL-no	EU Register name	Structural formula	CAS no	VCF online search 15-11-2016* and 06-12-2021**
07.160	Heptadecan-2-one		2922-51-2	Quantified in blue cheeses, cocoa category, mangifera species and milk and milk products from trace amount up to 8.7 mg/kg and up to 100 mg/kg in hop oil
07.161	Hex-1-en-3-one		1629-60-3	Quantified in artichoke up to 0.00014 mg/kg. Identified in cocoa category, dill, honey, milk and milk products and passion fruit
07.162	Hex-5-en-2-one		109-49-9	No occurrence in food reported
07.178	3-Methylbutan-2-one		563-80-4	Quantified in: cheese various types, guava and feyoa, guinea hen, honey, milk and milk products, passion fruit, peanut and strawberry from trace amount up to 1.56 mg/kg and up to 14 mg/kg in hog plum. Identified in a further 23 food items
07.181	6-Methylheptan-2-one		928-68-7	Quantified in chicken, guinea hen and wine from 0.001 up to 0.1 mg/kg. Identified in beef, buckwheat, mate, peas and tea
07.182	5-Methylheptan-3-one		541-85-5	Quantified in lemon grass oil (14,300 mg/kg), mentha oils (1 mg/kg) and papaya (0.02 mg/kg). Identified in tomato
07.185	3-Methylpentan-2-one		565-61-7	Quantified in beer, dill, Filbert hazelnut, plum and tea from trace amount up to 1.7 mg/kg and up to 100 mg/kg in hop oil. Identified in apple brandy, beef, blue cheeses, cheese various types, egg, grape and peanut
07.187	Non-2-en-4-one		32064-72-5	Identified in capsicum species, muruci (Byrsonima crassifolia), wheaten bread and wine 0.3 mg/kg in capsicum**
07.189	Nonan-4-one		4485-09-0	Quantified in passion fruit up to 0.01 mg/kg and identified in beef
07.198	Pseudo-ionone		141-10-6	Quantified in licorice, tea and tomato from trace amount up to 5 mg/kg. Identified in mate, passion fruit and tamarind
07.199	Tetradecan-2-one		2345-27-9	Quantified in milk and milk products, mountain papaya and passion fruit from 0.01 up to 2.5 mg/kg and up to 1,600 mg/kg in hop. Identified in beef, cherimoya, ginger, lamb and mutton and mate

FL-no	EU Register name	Structural formula	CAS no	VCF online search 15-11-2016* and 06-12-2021**
07.201	Tridec-12-en-2-one		60437-21-0	No occurrence in food reported
07.204	3,3,6-Trimethylhepta-1,5-dien-4-one		546-49-6	Quantified in camomile from 500 up to 5,100 mg/kg and identified in tarragon
07.205	6,10,14-Trimethylpentadecan-2-one		502-69-2	Quantified in camomile, grape, lemon balm, mastic, tea and vaccinium species from 0.007 up to 2000 mg/kg and up to 50,000 mg/kg in maize. Identified in a further 12 food items
07.210	1-Nonene-3-one		24415-26-7	No occurrence in food reported
07.236	(*Z*)-5-Octen-2-one		22610-86-2	Identified in beans
07.239	[R-(*E*)]-5-Isopropyl-8-methylnona-6,8-dien-2-one		2278-53-7	No occurrence in food reported
07.261	4-Methyl-3-hepten-5-one		22319-31-9	Identified in beef**
07.262	9-Decen-2-one		35194-30-0	No occurrence in food reported
09.304	*sec*-Heptyl isovalerate		238757-71-6	Identified in banana
09.323	*sec*-Butyl acetate		105-46-4	Quantified in vinegar from 43 up to 67 mg/kg. Identified in banana, beans, beer, cheddar cheese, cheese various types, cocoa category, coffee, potato and walnut

FL-no	EU Register name	Structural formula	CAS no	VCF online search 15-11-2016* and 06-12-2021**
09.325	*sec*-Butyl butyrate		819-97-6	Quantified in strawberry from 0.0054 up to 0.0086 mg/kg and identified in cheddar cheese, cheese various types, custard apple, atemoya, plum and tomato
09.328	*sec*-Butyl formate		589-40-2	Identified in apple fresh and cheese various types
09.332	*sec*-Butyl hexanoate		820-00-8	No occurrence in food reported
09.386	*sec*-Hept-4(cis)-enyl acetate		94088-33-2	Quantified in banana up to 0.18 mg/kg
09.388	*sec*-Heptyl acetate		5921-82-4	Quantified in guava, feyoa and passion fruit from 0.01 up to 0.563 mg/kg and up to 400 mg/kg in cloves. Identified in banana, beans, soybean and strawberry
09.391	*sec*-Heptyl hexanoate		6624-58-4	Quantified in passion fruit from 0.036 up to 6634 mg/kg and identified in banana and strawberry
09.604	Isopropyl decanoate		2311-59-3	Identified in blue cheeses, citrus fruits and strawberry
09.605	Isopropyl dodecanoate		10233-13-3	Identified in blue cheeses and melon
09.606	Isopropyl hexadecanoate		142-91-6	Quantified in macadamia nut up to 0.04 mg/kg and identified in buckwheat and citrus fruits
09.608	Isopropyl octanoate		5458-59-3	Identified in blue cheeses, nectarine and strawberry
09.609	Isopropyl valerate		18362-97-5	Identified in cashew apple, cheddar cheese and vanilla

FL-no	EU Register name	Structural formula	CAS no	VCF online search 15-11-2016* and 06-12-2021**
09.676	*sec*-Octyl acetate		2051-50-5	Identified in chicken
09.880	(*Z*)-Hept-4-enyl-2 butyrate		233666-01-8	No occurrence in food reported
09.926	Octan-3-yl formate		84434-65-1	No occurrence in food reported

*: Triskelion, VCF online, Volatile Compounds in Food. Version 16.2, 2016.
**: VCF Volatile Compounds in Food database. Version 16.8, 2020.