

Guidelines for the preparation of working papers (monographs) on flavouring agents

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These guidelines describe the format of working papers that are prepared on flavouring agents for the Joint FAO/WHO Expert Committee on Food Additives (JECFA) using the Procedure for the Safety Evaluation of Flavouring Agents (Appendix 1). These guidelines are intended to ensure consistency in reporting safety decisions and documenting the basis for them. Authors, however, should use judgement in applying these guidelines to the evaluation of different groups of flavouring agents.

Major revisions to the previous edition of the guidelines are the following:

1. The web site at which links to previous reports and monographs, most of which are available electronically, is provided (see section 1).
2. The significance of secondary components when the minimum assay value of the primary flavouring agent is less than 95% should be considered (see section 1.4).
3. The procedure to be followed when evaluating flavouring agents that are members of groups that have been evaluated previously by JECFA has been added (see Appendix 4).
4. Combined per capita intakes of the flavouring agents in the relevant structural classes should be included as a footnote to Table 1 (see 'formatting Table 1').
5. When an acceptable daily intake (ADI) that had been established previously by the Committee is maintained, the ADI should be referenced and the conclusion in the last column of Table 1 should no longer be "no safety concern" (see 'formatting Table 1'). The reason for this change is that having two endpoints for the same chemical leads to confusion.

General Information

A working paper for a group of flavouring agents consists of four sections, the report item (section 1), the relevant background information (section 2), the list of references (section 3), and a list of figures and tables (section 4). Section 1 is prepared with the expectation that it will be used as the first draft of the report item at the meeting. The monograph, which will be published after the meeting, will include the agreed report item (section 1) referenced appropriately, and revised sections 2 and 3 based on recommendations made at the meeting. Section 4 lists figures and tables to assist the Secretariat and editor in keeping track of the working papers, which may be electronically transmitted in a number of files.

The structure of a working paper for flavouring agents is outlined below. After the outline, the structure is repeated with specific information relevant to preparing each section. If there is no information to include under a particular heading, retain the heading with a notation that there is no information.

Table 1 is a key part of the working paper because it summarizes the application of the Procedure and the Committee's safety decisions for each member of the group of flavouring agents. Appendices with examples of flavouring agents that have been evaluated using the "A" side (Appendix 2) and the "B" side (Appendix 3) of the evaluation procedure are attached. Instructions for preparing the table, which accompanies the report item, are included in these guidelines. The author is encouraged to use as a model a recent report and monograph on a group of flavouring agents. If these documents are not readily available, please request them from the WHO Secretariat.

In preparing a working paper, it is conventional to list countries alphabetically. In describing intake estimates or margins of safety, Europe should be listed before the USA. JECFA describes flavours as "flavouring agents", not flavouring substances.

Separate instructions for preparing working papers on flavouring agents that are members of groups that have been evaluated previously by JECFA are included as Appendix 4.

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Specific Instructions for Each Section

- 1 Evaluation of the group of flavouring agents by the Committee (report item)
 - This section is intended as a report item. However, the author should include references in this section. The Secretariat will delete them from the report, but they will be retained in the monograph.
 - Specific meetings at which the flavouring agents were evaluated should be referenced. Publications produced at JECFA meetings are listed in Annex 1 of the WHO Technical Report Series (the blue book) and in their corresponding monographs (the yellow book). References to past JECFA evaluations should be thoroughly checked for accuracy (links to electronic versions are available at http://www.who.int/pcs/jecfa/JECFA_publications.htm).
 - The primary reference for the Procedure is the report of the forty-ninth meeting of JECFA (Annex 1, reference 131), since the figure that is included in subsequent reports was first used at that meeting.
 - Table 1 must accompany the report item.
- 1.1 Introduction
 - Identify the flavouring agents based on the characteristics of the group. Do not list each agent; instead, cite Table 1 (see details regarding Table 1 below).

- Cite the Procedure, relevant evaluations conducted using the Procedure, and other relevant Committee evaluations that resulted in an ADI, or not.
For example:
“The evaluations were conducted according to the Procedure for the Safety Evaluation of Flavouring Agents (Annex 1, reference 131).”
“One member of the group (name it) was evaluated by the Committee at the twenty-third meeting (Annex 1, reference 50), when an ADI of was established.”
“None of these agents has previously been evaluated by the Committee.”
- Note special considerations, if any (e.g., stereospecificity relevant to toxicity, exclusions from the group, etc.).
- Mention the natural occurrence; however, details including quantitative estimates and consumption ratios should be given only in section 2.
For example:
“Thirty-two of the x (state the number) flavouring agents in this group are natural components of foods. They have been detected in berries, coffee, and meats (CIVO-TNO, 1996).”

1.2 Estimated daily *per capita* intake

- Key information on individual flavouring agents from Table 1 and Table 2 is high-lighted in text in this section. Note that Table 2 (see part 2.2, Intake data) does not accompany the report item.
- Report the annual volume of production (i.e., poundage) for lead substances in the group (i.e., individual members of the group of flavouring agents with the highest annual volumes of production).
- Report intake for lead flavouring agents in terms of µg/person per day so that intake can be compared with the thresholds for human intake. In this section, do not express intake on a µg/kg bw per day basis.
- The appropriate citations include IOFI, 1995; Lucas et al., 1999; and, NAS, 1987.
- At the end of this section, refer to Table 1 for the intake of other members of the group.
For example:
“The per capita intake of each agent is reported in Table 1.”

1.3 Absorption, distribution, metabolism, and elimination

- Provide an overall summary of the most pertinent information and data.
- When considering flavouring agents with complicated structures, figures providing metabolic schemes may be provided. However, such figures are ordinarily included in section 2.3 rather than in the report.
- In Table 1, include a column with “Comments” on metabolism if such information is necessary for the evaluations. This may be especially relevant for Side A of the scheme.
- In some cases all of the available information on absorption and metabolism may be included in this section, in which case there will be no need to include section 2.3.1.

1.4 Application of the Procedure for the Safety Evaluation of Flavouring Agents

- The Procedure must be applied to each individual flavouring agent in the group.
- Pivotal toxicity data, as required, should be presented. However, study details should be provided in section 2.3.2 of the monograph for all available studies whether they are pivotal to the evaluation or not.
- Provide a step-by-step evaluation for members of the group. Use wording that is the same as the wording of the questions that are asked in applying the Procedure.
- If the minimum assay value of the flavouring agent is less than 95%, the specifications should be attached to the working paper so that the Committee is able to consider the significance of secondary components. The significance of such secondary components when applying the Procedure should be included in Table 1.

- In Steps A3 and B3, express intake as μg per day in order to compare intake to the human intake threshold for each structural class.
- In Steps A5 and B4, express intake as $\mu\text{g}/\text{kg}$ bw per day in order to compare intake to the NOEL. The approximate margin of safety should be provided (e.g. > 10 000 times). Do not provide study details here. In Step B5, express intake as μg per day to compare intake with the value of 1.5 μg per day.
- End the section with a reference to Table 1 (see 'Formatting Table 1' below).
For example:
"The intake considerations and other information used to evaluate xxx according to the Procedure are summarized in Table 1."

1.5 Consideration of combined intakes from use as flavouring agents

- Comment on combined intake for the whole group or a subgroup, where appropriate, in relation to the relevant human threshold or a relevant ADI.
For example:
"In the unlikely event that all xx substances were to be consumed concurrently on a daily basis, the estimated combined intake would/would not exceed the human intake threshold for class x."
"The estimated current intakes of xxx and xxx are below the individual ADIs previously allocated by the Committee."

1.6 Conclusions

- A statement should be included to address a new or previously established ADI, as appropriate.
For example:
"The Committee retained the previously established ADI of xxx for xxx."
- The conclusion should be general and not reiterate information in the steps.
For example:
"The Committee concluded that (some or all) the flavouring agents in this group (name the group) would not (or would) present safety concerns at the current levels of estimated intake.
"Other data on the toxicity of xxxxx were (or were not) consistent with the results of the safety evaluation."
- A monograph summarizing the safety data on this group of flavouring agents was (or was not) prepared."

2 Relevant background information

2.1 Explanation

- Section 2.1 should be included only if further introductory information not included in section 1.1 is necessary.

2.2 Additional considerations on intake

- Table 2 is the focus of this section.
- The annual volume of production in kilograms should be provided in Table 2.
- Intake values given in Table 2 should be expressed in terms of $\mu\text{g}/\text{person}$ per day and $\mu\text{g}/\text{kg}$ bw per day. Both expressions are needed to conduct the evaluations.
- Table 2 should also include information on natural occurrence and consumption ratios, if quantitative data are available.
- Regarding intake estimates:
 - (a) Intake estimates generally are derived from surveys in Europe and the USA. In using the survey data, it is assumed that only 60% in Europe and 80% in the USA of the total amount of each flavouring agent actually used is reported.
 - (b) In estimating intake, it is assumed that the total amount used in food is consumed by only 10% of the population. The population of consumers is assumed to be 32×10^6 in Europe and 26×10^6 in the USA.

(c) The intake calculation is as follows:

$$\text{Intake (}\mu\text{g/person per day)} = \frac{\text{annual volume of production (kg)} \times 10^9 (\mu\text{g/kg)}}{\text{population of consumers} \times \text{fraction reported} \times 365 \text{ days}}$$

2.3 Biological data

- Tables are appropriate to summarize biochemical data and toxicological studies (typically studies of 90 days in duration or longer and genotoxicity studies). Recent monographs should be consulted for examples of such tables.
- If data are available on only a few substances in a large group, it is appropriate to list in tabular form only those substances on which data exist.

2.3.1 Biochemical data

- In some cases, all the information on absorption, distribution, excretion, and metabolism will be included in section 1.3, in which case the information should not be repeated in this section.

2.3.1.1 Absorption, distribution, and excretion

2.3.1.2 Metabolism

- When considering agents with complicated structures, figures providing metabolic schemes may be provided in this section.
- Information on the hydrolysis of esters, acetals, ketals, etc., should be included in this section.

2.3.2 Toxicological studies

- Within each subsection listed below, discuss each flavouring agent for which there are data separately using the name of the flavouring agent and its 'JECFA' number as a heading.
- Study details should be provided in this section for all available animal studies whether they are pivotal to the evaluation or not.
- When animal studies are described, the descriptions should follow the same format as used for toxicological monographs for other food additives. It may be necessary in some cases to indicate the adequacy of the studies described.
- The data described in the text should also be presented in tabular form. The 'JECFA' number, name of the flavouring agent, test species, sex, number of animals used in the studies, route of administration, duration of the study, NOEL, and reference should be included when the data are tabulated. Tables should be numbered consecutively and the numbering will vary from one monograph to another, depending upon the number of tables that are included.

2.3.2.1 Acute toxicity

- In most cases, a brief paragraph describing the range of LD₅₀ values in various species will be adequate.
- At the author's discretion, either study details may be included or the data from acute studies may be presented in tabular form.

2.3.2.2 Short-term studies of toxicity

- Include all repeat-dose studies less than one year in duration in this section.

2.3.2.3 Long-term studies of toxicity and carcinogenicity

2.3.2.4 Genotoxicity studies

- In general, the usual tabular format described in the guidelines for the preparation of toxicological working papers on food additives is appropriate.

- If the author believes that the information given in the table is too cryptic, more information should be provided in footnotes or in a discussion in the text.
- Provide an interpretive discussion of the data from genotoxicity studies in the text.

2.3.2.5 Other relevant studies

- Examples of such studies include reproductive toxicity, teratogenicity, allergenicity, in vitro, and human studies.

3. References

4. List of tables and figures

- This listing will be deleted from the finished monograph. It is included for the convenience of the Secretariat to help assure that all parts of the working paper are received, photocopied, and transmitted.

Formatting Table 1

Examples of how to prepare Table 1 are provided in the appendices. In each case, however, Table 1 should be tailored to the relevant steps in the Procedure. The use of headings or footnotes, as appropriate, is encouraged to reduce the number of columns or amount of repetitive information in each column of Table 1.

If all of the members of the group of flavouring agents are not in the same structural class, then they should be grouped by structural class in Table 1.

Table title-column headings:

- The title of the table is typically presented as follows:
Table 1. Summary of results of safety evaluations of xxxxx^a.
- The footnote in the title should indicate step 2, if necessary:
Step 2: All of the agents in this group are expected to be metabolized to innocuous products. (If a simple statement cannot be made, see column 4 below.)
- Column 1 - Title "Flavouring agent"
The name used in the specifications should be used.
- Column 2 – Title "No."
This refers to the "JECFA number" that is assigned to each flavouring agent.
- Column 3 – Title "CAS Number and Structure"
CAS numbers and chemical structures should be included in the table, either in the same column or in separate columns. If the author has difficulty incorporating structures into the table, a separate figure containing the structures should be included, and they will be incorporated into the table by the Secretariat after the meeting.
- Column 4 – Step 2 - Title "Predicted to be metabolized to innocuous products?" - Yes/No, if this column is needed.
- Column 5 – Step A3/B3– Title "Does intake exceed the threshold for human intake?" – Yes/No; include under this daily per capita intake in Europe and the USA – use ND for *no intake data reported*. A footnote to the column should be included that provides the human intake threshold(s) for the structural class(es) relevant to the table and the combined per capita intakes of the flavouring agents in the relevant structural class(es) in Europe and the USA.

- Column 6 – Step A4 – Title “Is the flavouring agent or are its metabolites endogenous?” - Yes/No, or NR for *not required for the evaluation*.
- Column 7 – Step A5/B4 - Title “Adequate margin of safety for the flavouring agent or related substance?” - Yes/No, and give the NOEL and safety margin.
- Column 8 – Title “Comments”- include pertinent comments, if this column is needed – If appropriate, use Note 1, 2, 3, etc., defined in the footnotes to the table, in each column to avoid lengthy tables with repetitive comments.

Column 9 – Title “Conclusion based on current intake” – No safety concern/other conclusion. When a previous ADI for a member of the group is maintained, do not include the words *no safety concern*. Instead, include an asterisk, which is footnoted at the bottom with the following: ‘An ADI of 0-XX mg/kg bw was established for XXXX by the Committee at its XXth meeting (Annex 1, reference XX), which was maintained at the present meeting. Use of the chemical as a flavouring agent is subsumed in the ADI.’

Notes at the bottom of the table (examples are given here)

Provide an explanation of abbreviations.

Footnote to the title of the table:

Step 2: ‘All of the flavouring agents in this group were predicted to be metabolized to innocuous products’ *or* ‘none of the flavouring agents in this group were predicted to be metabolized to innocuous products’ *or* ‘except for No. XXX, all of the flavouring agents in this group were predicted to be metabolized to innocuous products’. If they are not all the same, Column 4 may be used.

Footnote to column 5:

The threshold(s) for human intake for class(es) I, II, and/or III are xx and yy µg per day. All intake values are expressed in µg per day. The combined per capita intakes of flavouring agents in structural class I are xxx µg per day in Europe and yyy µg per day in the USA. The combined per capita intakes of flavouring agents in structural class III are xxx µg per day in Europe and yyy µg per day in the USA.

Procedure for the safety evaluation of flavouring agents

Appendix 1

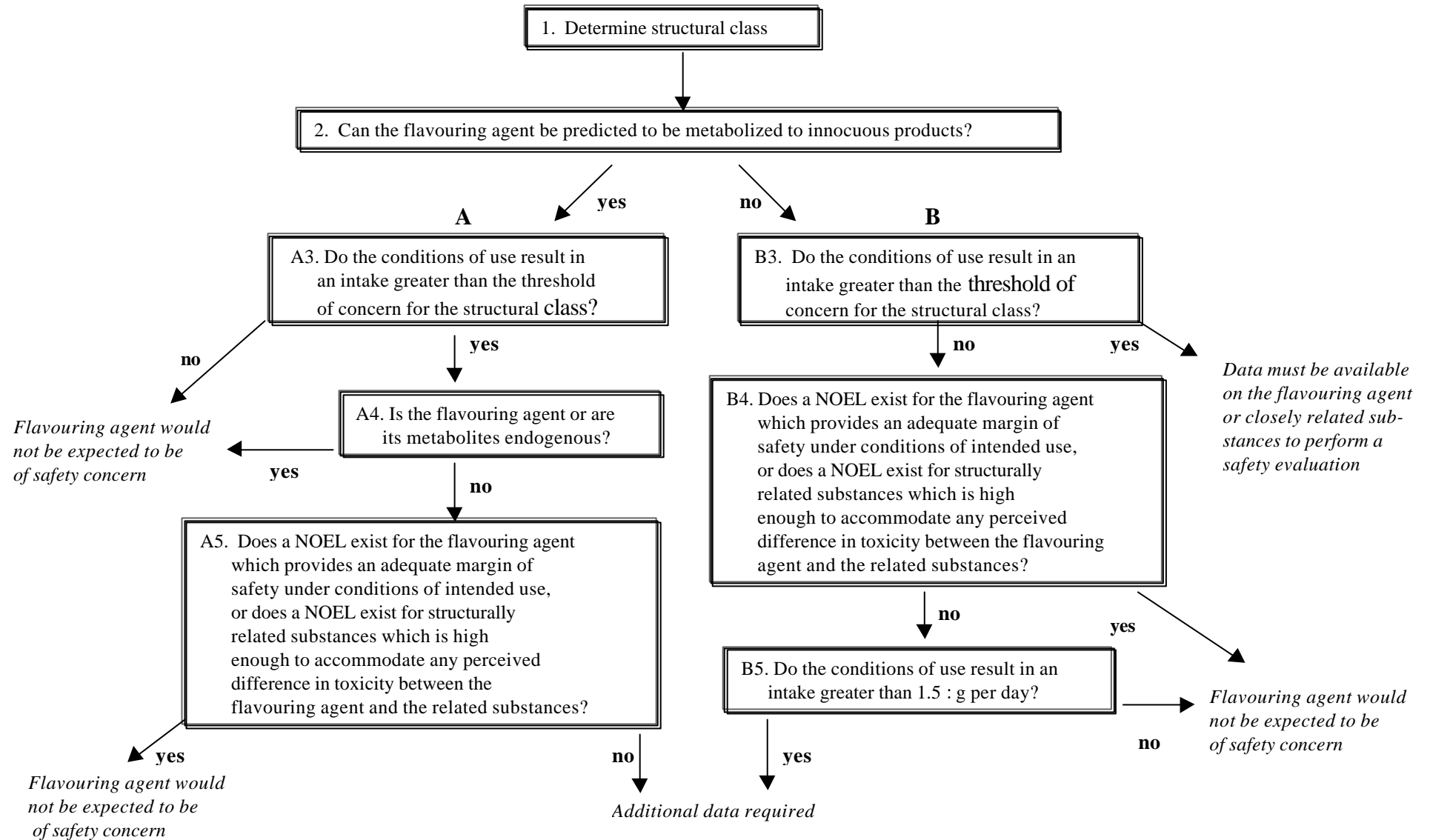
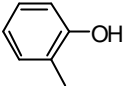
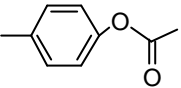
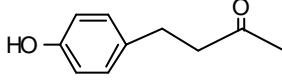
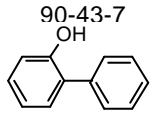


Table 1. Summary of results of safety evaluations of phenol derivatives^a

Appendix 2

Flavouring agent	No.	CAS Number and structure	Step A3 ^b Does intake exceed the threshold for human intake?	Step A4 Is the flavouring agent or are its metabolites endogenous?	Step A5 Adequate margin of safety for the flavouring agent or related substance?	Comments	Conclusion based on current intake
Structural class I							
o-Cresol	691	95-48-7 	No Europe: 290 USA: 0.1	NR	NR	See note 1.	No safety concern
p-Tolyl acetate	699	140-39-6 	No Europe: ND USA: 40	NR	NR	See note 2.	No safety concern
4-(p-Hydroxyphenyl)-2-butanone	728	5471-51-2 	Yes Europe: 2800 USA: 3800	No	Yes; the NOEL of 280 mg/kg bw per day in a 13-week study in rats given multiple doses is >1000 times the daily intake of 4-(p-hydroxyphenyl)-2-butanone when used as a flouring agent.	See note 1.	No safety concern
Structural class III							
2-Phenylphenol	735	90-43-7 	No Europe: 0.01 USA: 0.01	NR	NR	See note 1.	*

CAS: Chemical Abstracts Service; ND: No intake data reported; NR: Not required for evaluation.

^aStep 2: All of the flavouring agents in this group were predicted to be metabolised to innocuous products.

^bThe thresholds for human intake for structural classes I and III are 1800 µg per day and 90 µg per day, respectively. All intake values are expressed in µg per day. The combined per capita intakes of flavouring agents in structural class I are 3100 µg per day in Europe and 3800 µg per day in the USA. The combined per capita intake of flavouring agents in structural class III are 0.01 µg per day in both Europe and the USA.

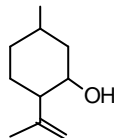
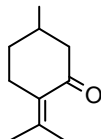
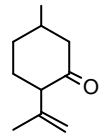
Notes to Table 1:

1. Detoxication of phenol primarily involves conjugation of the hydroxyl group with sulfate and glucuronic acid.
2. Phenyl acetate undergoes rapid hydrolysis followed by conjugation with sulfate and glucuronic acid.

* An ADI of 0-0.4 mg/kg bw was established for 2-phenylphenol and its sodium salt by the 1999 Joint FAO/WHO Meeting on Pesticide Residues (JMPR). Use of the chemical as a flavouring agent is subsumed in the ADI.

Table 2. Summary of the results of safety evaluations of pulegone and related flavouring agents^a

Appendix 3

Flavouring agent	No.	CAS No. and structure	Step B3 ^b Does intake exceed the threshold for human intake?	Step B4 Adequate NOEL for flavouring agent or related substance?	Conclusion based on current intake
Structural class I					
Isopulegol	755	89-79-2 	No Europe: 6 USA: 7	Yes The NOEL of 0.44 mg/kg bw per day for pulegone in a 90-day study is >1000 times the estimated daily intake of isopulegol when used as a flavouring agent.	No safety concern
Structural class II					
Pulegone	753	89-82-7 	No Europe: 2 USA: 2	Yes The NOEL of 0.44 mg/kg bw per day in a 90-day study is >10 000 times the estimated daily intake of pulegone when used as a flavouring agent.	No safety concern
Isopulegone	754	29606-79-9 	No Europe: 1 USA: 0.01	Yes The NOEL of 0.44 mg/kg bw per day for pulegone in a 90-day study is >10 000 times the estimated daily intake of isopulegone when used as a flavouring agent.	No safety concern

CAS: Chemical Abstracts Service

^aStep 2: None of the flavouring agents in this group were predicted to be metabolized to innocuous products.

^bThe thresholds for human intake for structural classes I and II are 1800 µg per day and 540 µg per day, respectively. All intake values are expressed in µg per day. The combined per capita intakes of flavouring agents in structural class I are 3100 µg per day in Europe and 3800 µg per day in the USA. The combined per capita intake of flavouring agents in structural class III are 0.01 µg per day in both Europe and the USA.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has evaluated a large number of flavouring agents grouped according to their chemical structure. On some occasions, flavouring agents in development and additional flavouring agents in commerce that require evaluation fit into groups that have been evaluated previously. This appendix provides guidelines for preparing report items and monographs for these additional flavouring agents.

Evaluations of these additional flavouring agents need to be conducted and documented in a manner consistent with existing practice and need to take into consideration information pertaining to the chemical groups into which they fit. Flavouring agents that fit into groups evaluated previously are evaluated in the same manner as other members of the group by using the Procedure for the Safety Evaluation of Flavouring Agents. However, there are overall group considerations that need to be addressed in the case of these additional substances, which are not specifically addressed in the Procedure. When preparing report items and monographs for these flavouring agents, authors should note that:

- past evaluations will form the basis for evaluating these additional flavouring agents;
- the cumulative intake for the 'amended group', which includes members of the original group plus the additional substances, must be considered; and
- when substantial new data are available, previous evaluations may need to be reconsidered.

As with any safety evaluation, scientific judgement is necessary and should be used in applying the Procedure. Generally, however, the approach to these evaluations will include the following steps:

1. group the additional flavouring agents according to their chemical structures;
2. identify and review relevant previous group evaluation(s);
3. make structural class assignments for each of the additional flavouring agents;
4. determine the current level of intake for each additional flavouring agent and combined intake for the amended group;
5. review new or additional information on metabolism, toxicity, and special studies;
6. reconsider the original safety evaluation for the group and determine whether significant changes are indicated;
7. prepare specifications for each of the additional flavouring agents;
8. prepare tables for the additional flavouring agents, including Table 1 (summary of the results of safety evaluations), Table 2 (annual volumes of use), and other tables as needed; and
9. draft the appropriate documentation.

Of the steps outlined above, only steps 2, 4 and 6 are unique to the evaluation of additional flavouring agents belonging to groups that have been evaluated previously. The remaining steps are conducted in the same manner as they were in applying the Procedure to the original evaluation of the group. The outline presented above is repeated below with specific information relevant to each step:

1. Group the additional flavouring agents according to their chemical structures
 - Structurally related flavouring agents should be grouped into broad chemical classes; it may be appropriate to include some flavouring agents in more than one group.
 - Define the chemical characteristics of the additional flavouring agents that qualify them for membership in the group.
 - Specific information relevant to this item should be included in the **Introduction** of the report item.
2. Identify and review relevant previous group evaluation(s)
 - Authors should adequately cross-reference previous reports and/or monographs; a concise summary of previous evaluations should be included in the **Introduction** of the report item.

- Authors should search the literature for new safety information relevant to the group that has been published since the original evaluation(s) was conducted.
3. Make structural class assignments for each of the additional flavouring agents
 - Structural class assignments should be made according to Cramer et al., 1978 (Step 1 of the Procedure for the Safety Evaluation of Flavouring Agents) for each additional flavouring agent.
 4. Determine the current level of intake for each additional flavouring agent and combined intake for the amended group
 - Include combined per capita intakes of the flavouring agents in the relevant structural classes as a footnote to **Table 1** (see 'formatting Table 1') for the additional flavouring agents and for the 'amended' group.
 5. Review new or additional information on metabolism, toxicity, and special studies
 - Follow the guidance in these guidelines for documenting and formatting the evaluation of such data.
 - Do not prepare a monograph addendum if acute studies are the only new data available.
 6. Reconsider the original safety evaluation for the group and determine whether significant changes are indicated.
 7. Prepare specifications for each of the additional flavouring agents
 - Consider the significance of secondary components when the minimum assay value of the primary flavouring agent is less than 95% (see section 1.4 of the guidelines).
 8. Prepare tables for the additional flavouring agents, including Table 1 (Summary of the results of safety evaluations), Table 2 (annual volumes of use), and other tables as needed
 - Table 1 is a key part of the working paper, as it is with all flavouring agents. Table 1 should be formatted as described in these guidelines and it should include only the additional flavouring agents.
 - The title should be the group previously evaluated and currently being amended to include the additional flavouring agents.
 - Per capita intake should be provided for each additional flavouring agent in Table 2.
 - Combined intake of the 'amended' group should be included in a footnote to Table 1 (see item 4 above).
 9. Draft the appropriate documentation
 - The report item alone, an addendum to the original monograph, or a new monograph for the 'amended' group are examples of appropriate documentation, depending on the additional data and information that is available.
 - When new data are not available, it should be possible to document the evaluation in the report of the Committee. Authors should use their discretion in deciding if it is appropriate to include a brief description of data available from acute studies in the report item.
 - When some new data are available, authors may need to prepare an addendum to the existing monograph. In this case, only relevant sections of the working paper should be included. The relevant sections should be formatted in the usual way using the same conventions and style as described in these guidelines.
 - If new data, intake considerations, or other information indicate that the original evaluation should be reconsidered, then the entire group (original members of the group and the additional flavouring agents) may need to be re-evaluated. (Typically, this will not be the case.) In such a situation, authors will follow the general guidelines for the preparation of working papers on flavouring agents.

Authors are advised to consult published evaluations for examples of appropriately formatted working papers.