

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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HEALTH
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JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 7

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

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DISCUSSION PAPER ON THE DEVELOPMENT OF GUIDELINES FOR FLAVOURING AGENTS

Prepared by the United States with the assistance of Australia, European Commission, France, Norway, the International Council of Beverages Associations (ICBA), and the International Organization of the Flavor Industry (IOFI)

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments on the following subject matter are invited to do so **no later than 28 February 2006** as follows: Netherlands Codex Contact Point, Ministry of Agriculture, Nature and Food Quality, P.O. Box 20401, 2500 E.K., The Hague, The Netherlands (Telefax: +31.70.378.6141; E-mail: info@codexalimentarius.nl - *preferably*), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00100 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: Codex@fao.org - *preferably*).

INTRODUCTION

1. The 37th Session of the Codex Committee on Food Additives and Contaminants (CCFAC), after a discussion of options for integrating flavouring agents into the Codex system, agreed to propose new work on the elaboration of a Codex Guideline for the Use of Flavourings that establishes safe conditions of use for such substances in foods. It was agreed that the principles for the safe use of flavouring substances should be similar to the principles for the safe use of food additives contained in the Preamble of the Codex General Standard for Food Additives (GSFA), with a reference to the evaluation of flavouring substances completed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

2. The Committee established an electronic Working Group, led by the United States, with the assistance of Australia, Austria, Denmark, European Commission, France, India, Italy, Japan, Norway, Switzerland, United Kingdom, ICBA, ICDI, and IOFI, to prepare a discussion paper on the development of this Guideline, taking into account the various terms and definitions used in Codex related to 'flavourings.' The Committee also agreed to include a project document for starting new work for possible submission to the Codex Alimentarius Commission.¹

PURPOSE

3. This discussion paper contains, as Appendix I, a proposed project document that addresses the nine elements listed in the Codex Alimentarius Commission Procedural Manual, 14th Ed., pp. 20-21, that must accompany any proposals to the Commission to undertake new work.

¹ ALINORM 05/28/12, paras. 100-102.

4. This discussion paper also contains a draft of the proposed Codex Guideline for the Use of Flavourings (Appendix II). The attached proposed Guideline closely follows the format and content of the “General Requirements for Natural Flavourings” which was adopted by the Commission in 1985 and published in 1987 as CAC/GL 29-1987, but expands upon that document by including additional recommendations regarding Definitions, General Principles for the Safe Use of Flavourings, Labeling, and Specifications. In addition it provides a reference to the safety evaluations of flavouring substances completed by JECFA. Appendix A of CAC/GL 29-1987 (References to Lists of Raw Materials Suitable for the Preparation of Natural Flavors) remains as Annex A in the proposed draft guideline. It is proposed that CAC/GL 29-1987 be revoked upon completion of this new work.

5. Specifically, Appendix II contains a description of the changes to the “General Requirements for Natural Flavourings” Guideline (CAC/GL 29-1987) and the new proposed draft Codex Guideline for the Use of Flavourings with the following main elements:

- i. Scope
- ii. Definitions
- iii. General Principles for the Use of Flavoring Substances
- iv. Flavour Adjuvants
- v. Substances of Toxicological Concern
- vi. Methods of Analysis
- vii. Hygiene
- viii. Labeling
- ix. Specifications of Identity and Purity
- x. References to the Evaluations of Flavouring Substances Completed by JECFA

REQUEST FOR COMMENT AND INFORMATION

6. Codex Members are encouraged to provide comments and additional information on the attached draft Project Document (Appendix I), and the proposed Guideline for the Use of Flavourings (Appendix II). In particular, comments and specific information are requested relating to:

- i) the overall structure and completeness of the guideline (Appendix II);
- ii) the completeness and relevance of the definitions (Appendix II, Section 2.0);
- iii) the section relating to General Principles for the Safe Use of Flavourings (Appendix II, Section 3.0);
- iv) whether maximum levels should be explicitly cited in the Table of Biologically Active Substances (Appendix II, Section 5.0), or whether a general statement that the levels should not exceed thresholds of toxicological concern is appropriate;
- v) the section relating to Methods of Analysis (Appendix II, Section 6.0); and,
- vi) the references to lists of aromatic raw materials suitable for the preparation of flavourings (Appendix II, Annex A).

Appendix I

Project Document - Proposal for New Work

Codex Guideline for the Use of Flavourings

Codex Committee on Food Additives and Contaminants (CCFAC)

1. The purpose and scope of the guideline;

To integrate flavourings into the Codex system by elaborating a Codex Guideline for flavourings that establishes safe conditions of use, and practices that do not mislead consumers, similar to the Codex principles for the safe use of food additives described in the Preamble of the General Standard for Food Additives (GSFA; CODEX STAN 192-1995 Rev. 6-2005). The Guideline will reference the safety assessments completed by JECFA.

2. Its Relevance and timeliness;

Flavourings are a major category of ingredients intentionally added to food. Development of a guideline will provide a means for Codex to offer advice and information on the safe conditions of use for flavouring substances, and to facilitate fair trade of foods in international commerce.

JECFA has evaluated over 1600 flavouring substances and assigned them a status of "no safety concern at estimated levels of intake." It is appropriate to elaborate a guideline for the safe use of flavouring substances with reference to the evaluations completed by JECFA.

JECFA has also embarked on work to establish a method for evaluation of natural flavouring complexes. So far only a few natural flavouring complexes have been evaluated. Nevertheless, it would be prudent to include these in the guidelines for future reference.

3. The main aspects to be covered;

This Guideline would provide definitions, and principles for the safe use of flavorings similar to the Codex principles for the safe use of other food additives described in the Preamble of the GSFA. Appendix II contains a description of the changes to the "General Requirements for Natural Flavourings" Guideline (CAC/GL 29-1987) and the new proposed draft Codex Guideline for the Use of Flavourings. The main aspects to be covered by the proposed draft guideline are:

- i. Scope;
- ii. Definitions;
- iii. General Principles for the Use of Flavourings;
- iv. Flavouring Adjuvants;
- v. Substances of Toxicological Concern;
- vi. Methods of Analysis;
- vii. Hygiene;
- viii. Labeling;
- ix. Specifications of Identity and Purity; and,
- x. References to the Evaluations of Flavourings Completed by JECFA.

4. An assessment against the *Criteria for the establishment of work priorities*;

This proposal is consistent with the Criteria applicable to general subjects:

a. Consumer protection from the point of view of health and fraudulent practice.

By acknowledging the safety evaluations performed by JECFA, a Codex guideline will lead to more consistent protection of consumer health by ensuring the safe use of flavourings internationally.

b. Diversification of national legislations and apparent resultant or potential impediments to international trade.

The absence of a Codex guideline for flavourings contributes to inconsistencies in the regulation of flavouring substances among different countries. This may present non-tariff barriers to the free movement of foods and disruptions in international food trade.

c. Scope of work and establishment of priorities between the various sections of work.

The scope of work is provided in Item 1, above.

d. Work already undertaken by other international organizations in this field.

Other than the safety assessments performed by JECFA, other Codex Members including the European Community's European Food Safety Authority (EFSA), the Council of Europe and Korea's Food and Drug Administration have initiated their own evaluation of flavoring substances.

5. Relevance to the Codex Strategic objectives;

The new work contributes to the safety of human health and fair trade practices by satisfying the need for advice to governments on the safe use of flavouring substances in food.

6. Information on the relation between the proposal and other existing Codex documents;

In 1972, Codex published three definitions for flavouring substances in their "List of Food Additives Evaluated for Their Safety-in-Use in Food" (CAC/FAL 1-1973). In 1985, the Commission adopted the "General Requirements for Natural Flavourings," which was published as CAC/GL 29-1987, and contained revised definitions for natural flavourings. The proposed new work would incorporate CAC/GL 29-1987, and augment it with additional guidance on definitions, General Principles for the Safe Use of Flavourings, labeling, and specifications. In addition, it would provide a reference to the safety evaluations of flavouring substances completed by JECFA to augment Appendix A of CAC/GL 29-1987 (References to Lists of Raw Materials Suitable for the Preparation of Natural Flavors) which is retained as Appendix A in the proposed new guideline. It is proposed that CAC/GL 29-1987 be revoked upon completion of this new work.

7. Identification of any requirement for and availability of expert scientific advice;

JECFA has already conducted evaluations of the majority of the chemically-defined flavouring substances, and has embarked on work to establish a method to evaluate natural flavouring complexes. The conclusions are available on the JECFA website. No other expert scientific advice is needed.

8. Identification of any need for technical input to the guideline from external bodies So that plans may be made.

See Item 7.

9. The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.

The time-line for completing work on the proposed guideline is four years. Therefore, if the new work is approved by the Commission in 2006, a proposed draft guideline could be considered at Step 3 by CCFAC at its 39th session in 2007, and adopted by the Commission at Step 5 and at Step 8 in 2008, and in 2009, respectively.

Appendix II**Changes to the Codex Guideline CAC/GL 29-1987**

This Guideline replaces Codex Guideline CAC/GL 29-1987 “*General Requirements for Natural Flavourings*,” and expands its scope by including guidance on the use of all types of flavourings in food. This guideline incorporates the following changes to CAC/GL 29-1987:

- a) A revised and hierarchical set of definitions that encompass all types of flavourings;
- b) General principles for the use of flavourings;
- c) A definition and principles for the use of flavouring adjuncts; and,
- d) A revised section on hygiene.

Appendix A of CAC/GL 29-1987 has been updated and incorporated into this guideline as Annex A..

CODEX GUIDELINE FOR THE USE OF FLAVOURINGS**1.0 SCOPE**

This guideline provides principles for the safe use of flavorings evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and determined to present no safety concern at current estimated levels of intake, or that have established JECFA acceptable daily intakes (ADIs), and for which corresponding specifications of identity and purity have been established. In addition, the guideline provides principles for the establishment of practices that do not mislead the consumer.

2.0 DEFINITIONS

- 1) **Flavour** is the sum of those characteristics of any material taken in the mouth, perceived principally by the senses of taste and smell, and also the general pain and tactile receptors in the mouth, as received and interpreted by the brain. The perception of flavour is a property of **flavourings**.
 - a) **Flavourings** are products intended to be added in small amounts to foods, the primary purpose of which is to impart, modify, or fortify the flavour of food rather than to enhance nutritional quality. Flavourings are not intended to be consumed alone. Not included are substances that have an exclusively sweet, sour, or salty taste.
 - i) **Flavouring substances** are chemically-defined substances either formed by chemical synthesis, or obtained from materials of vegetable or animal origin. Classes of chemically-defined flavouring substances include *natural*, and *artificial flavouring substances*.
 - (1) **Natural flavouring substances** are chemically-defined substances obtained by physical processes (including distillation and solvent extraction), or by enzymatic or microbiological processes, from material of vegetable or animal origin either in the raw state, or after processing for human consumption by traditional food-preparation processes (including drying, torrefaction and fermentation).
 - (2) **Artificial flavouring substances** are chemically-defined substances formed by chemical synthesis that have not been identified in natural products intended for human consumption.
 - ii) **Natural flavouring complexes** are preparations that contain flavouring constituents obtained exclusively by physical, microbiological, or enzymatic processes from material of plant or animal origin, either in the raw state, or after processing for human consumption by traditional food preparation processes (including drying, roasting, and fermentation). Natural flavouring complexes include the essential oil, essence, or extractive, protein hydrosylate, distillate, or any product of roasting, heating, or enzymolysis.
 - b) **Flavouring adjuvants** are foodstuffs or food additives that are essential to the manufacture, storage and use of flavourings. Flavour **adjuvants** may or may not have an intended technical effect in the finished food.

3.0 GENERAL PRINCIPLES FOR THE USE OF FLAVOURINGS

3.1 All flavourings should have been evaluated, by experts qualified in scientific training and experience to evaluate the safety of flavourings, and shown to be safe at the proposed level of use in food. Flavourings that have been evaluated by JECFA to present no safety concern at current estimated levels of intake, or that have established JECFA ADIs, are acceptable for use in food.

3.2 All flavourings should be of a purity suitable for use in food. Those flavourings that have been evaluated by JECFA should conform to Codex specifications of identity and purity.

3.3 The use of flavourings is justified only where they impart organoleptic properties to food, provided that such use does not deceive the consumer about the nature or quality of food.

3.4 All flavourings should be used under conditions of good manufacturing practice, which includes the following:

- a) the quantity of the flavourings used in food should be limited to the lowest possible level necessary to accomplish the desired organoleptic effect;
- b) the quantity of any carrier, or flavour adjuvant used in the manufacturing, processing, or delivery of flavourings to food that is not intended to accomplish any physical or technical effect in the food itself, should be reduced to the extent reasonably possible; and,
- c) flavourings should be prepared and handled using the same hygienic principles as those used when handling a food ingredient.

4.0 FLAVOURING ADJUVANTS

All flavourings may contain flavouring adjuvants (foodstuffs or food additives) that are essential to the manufacture and use of the flavourings. Flavouring adjuvants may, or may not, have an intended technical effect in the finished food.

Flavouring adjuvants that are used at levels that provide a functional effect in the finished food are food additives and may only be used in accordance with the provisions of the General Standard for Food Additives (GSFA; CODEX STAN 192-1995 Rev. 6-2005). Flavouring adjuvants used at levels that do not provide a functional effect in the finished food may be used in any food.

5.0 SUBSTANCES OF TOXICOLOGICAL CONCERN

Substances of toxicological concern should not be added to food. The intake resulting from their presence in flavourings should not exceed thresholds of toxicological concern. With the exception of quinine and quassine, the following biologically active substances should not be added directly to food. Their presence in foods that are ready for consumption should be as low as possible, but not exceed the maximum levels specified in the Table below. The maximum levels for quinine and quassine should not be exceeded whether they are added directly to food, or are present only through the use of flavourings in foods.

Biologically Active Substance	Maximum Levels (mg/kg)		
	In Food as Consumed	In Beverages as Consumed	Exceptions
Agaric acid	20	20	100 mg/kg in alcoholic beverages and in food containing mushrooms
Aloin	0.1	0.1	50 mg/kg in alcoholic beverages
beta-Azarone	0.1	0.1	1 mg/kg in alcoholic beverages
Berberine	0.1	0.1	10 mg/kg in alcoholic beverages
Cocaine	cocaine-free by agreed test		
Coumarin	2	2	10 mg/kg in special caramels and in alcoholic beverages

Biologically Active Substance	Maximum Levels (mg/kg)		
	In Food as Consumed	In Beverages as Consumed	Exceptions
Total hydro-Cyanic acid (free and combined)	1	1	25 mg/kg in confectionery 50 mg/kg in marzipan 5 mg/kg in stone fruit juices 1 mg/kg per % volume in alcoholic beverages
Hypericine	0.1	0.1	1 mg/kg in pastilles (lozenges) 2 mg/kg in alcoholic beverages
Pulegone	25	100	250 mg/kg in pepper-mint or mint flavored beverages 350 mg/kg in mint confectionery (higher levels are to be found in strong mint)
Quassine	5	5	20 mg/kg in pastilles (lozenges) 50 mg/kg in alcoholic beverages
Quinine	0.1	85	300 mg/kg in alcoholic beverages 40 mg/kg in fruit curds
Safrole	1	1	2 mg/kg in alcoholic beverages containing less than 25% alcohol by volume 5 mg/kg in alcoholic beverages containing greater than 25% alcohol by volume 15 mg/kg in food containing mace and nutmeg
Santonin	0.1	0.1	1 mg/kg in alcoholic beverages containing greater than 25% alcohol by volume
Thujones (α and β)	0.5	0.5	10 mg/kg in alcoholic beverages containing greater than 25% alcohol by volume 5 mg/kg in alcoholic beverages containing less than 25% alcohol by volume 35 mg/kg in bitters 25 mg/kg in food containing sage 250 mg/kg in sage stuffing

6.0 METHODS OF ANALYSIS

6.1 General Methods:

Analytical Procedure for a General Headspace Method. Recommended Method 1 (1973). *Int. Flav. Food Add.*, **6**(2), 128 (1975).

Analytical Procedure for a General Method for Gas Chromatography. Recommended Method 4 (1974). *Int. Flav. Food Add.*, **7**(2), 55-56 (1976).

Analytical Procedure for a General Method for High Pressure - (high performance) Liquid Chromatography. *ISO 7609 (1985) Huile essentielle Analyse par CPG sur colonne capillaire - Méthode Générale.*

ISO 22972-2004 - *Huiles essentielles - Analyse par CPG sur colonne capillaire chirale - Méthode générale.*

Recommended Method 17 (1980). *Z. Lebensm.-Unters. Forsch.* **174**, 396-398 (1982).

Analytical Procedure for a General Method for Gas Chromatography on Capillary Columns.

Recommended Method 18 (1980). *Z. Lebensm.-Unters. Forsch.* **174**, 399-400 (1982).

6.2 Specific methods:

Agaric Acid - Gas chromatographic Determination. Recommended Method 14 (1979). *FFIP*, **1**(4), 193 (1979).

Dosage de l'acide agarique dans les boissons alcooliques. P.A.P. Liddle c.s. *Ann. Fals. Exp. Chim.* **72**, 125-132 (1979).

Beta-Azarone - Gas chromatographic Determination. Recommended Method 10 (1978). *Int. flav. Food Add.*, **9**(5), 228 (1978).

Dosage de la β -azarone par HPLC. G. Mazza, *Sciences des aliments* **4**, 233-245 (1984).

ISO 7357-1985 Determination of *cis*- β -azarone in oil of calamus by GLC.

Coumarin in Certain Foods - Isolation by Extraction. Recommended Method 8 (1978). *Int. Flav. Food Add.*, **9**(5), 223(1978).

Coumarin - Gas chromatographic Determination. Recommended Method 9 (1978). *Int. Flav. Food Add.*, **9**(5), 223, 228 (1978).

Coumarin in Certain Foods - Isolation by Steam Distillation. Recommended Method 12 (1979) Revised version. *FFIP*, **1**(2) 93 (1979).

La determinazione della cumarine nelle bevande alcoliche aromatizzate. *ibid.* **33**, 247-256 (1980).

La determinazione della cumarine mediante HPLC. G. Mazza. *ibid.* **37**, 316-323 (1984).

Hydrocyanic Acid - Photometric Determination. Recommended Method 13 (1979). *FFIP*, **1**(3), 140 (1979).

Pulegone - Gas chromatographic Determination. Recommended Method 7 (1976). *Int. Flav. Food Add.*, **8**(4), 161 (1977).

Quassine - Gas Chromatographic Determination. Recommended Method 11 (1978). *FFIP*, **1**(1), 24 (1979).

Quinine-Spectrophotometric Determination. Recommended Method 2 (1973). *Int. Flav. Food Add.*, **6**(3), 184 (1975).

Safrole and Isosafrole - Gas Chromatographic Determination. Recommended method 5 (1976). *Int. Flav. Food Add.*, **8**(1), 27 (1977).

La determinazione del safrolo nelle bevande alcoliche aromatizzate, L. Ussegli-Tommaset & G. Mazza, *Riv. Viticolt. e Enol. Conegl.* **33**, 435-452 (1980).

La determinazione del safrolo mediante HPLC. G. Mazza, *Riv. Soc. Ital. Sc. aliment.* **12**, 159-166 (1983).

ISO 7355-1985 Determination of safrole and *cis*- and *trans*-isosafrole in oils of sassafras and nutmeg by GLC.

Thujone - Gas Chromatographic Determination. Recommended Method 6 (1976). *Int. Flav. Food Add.*, **8**(1), 28(1977).

Détection et dosage de quatre composés (thujone, safrole, β -azarone et coumarine) dans les boissons alcooliques. P.A.P. Liddle c.s. *Ann. Fals. Exp. Chim.* **69**, 857-864 (1976).

ISO 7356-1986 Determination of α - and β -thujone in oils of artemisia and sage by GLC.

7.0 HYGIENE

7.1 Flavourings should be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 2 (1985)), and other Codes of Practice recommended by the Codex Alimentarius Commission relevant to these products.

7.2 To the extent possible under Good Manufacturing Practice, the flavourings covered by this guideline should be free from objectionable matter.

7.3 When tested by appropriate methods of sampling and examination, all flavourings:

- a) should be free from micro-organisms and parasites in amounts which might represent a hazard to health when used at appropriate levels in food; and
- b) should not contain any substance originating from micro-organisms in amounts which might represent a hazard to health when used at appropriate levels in food.

8.0 LABELING

Labeling of flavourings should be in accordance with the requirements of the Codex General Standard for the Labeling of Food Additives (CODEX STAN 107-1981). Labeling of foods containing flavourings should be in accordance with the requirements of the General Standard for the Labeling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991)).

9.0 SPECIFICATIONS OF IDENTITY AND PURITY

Specifications of identity and purity for flavourings should be those recognized by the Codex Alimentarius Commission.

10.0 REFERENCE TO THE EVALUATIONS OF FLAVORING SUBSTANCES COMPLETED BY JECFA.

A list of the flavourings for which JECFA has completed its safety evaluation is available from the JECFA website or by contacting the WHO JECFA Secretariat. References to lists of aromatic raw materials suitable for the preparation of natural flavourings may be found in Appendix A of this guideline.

ANNEX A**REFERENCES TO LISTS OF AROMATIC RAW MATERIALS SUITABLE FOR THE PREPARATION OF FLAVOURINGS^{2,3}**

The following list provides references to lists of aromatic raw materials that are suitable for the preparation of flavourings only, and does not necessarily reference sources and/or substances which have been evaluated by JECFA.

1. Flavouring Substances and Natural Sources of Flavourings, Council of Europe, 3rd ed. 1981.
2. International Standard ISO 676 Spices and condiments. 1st List.
3. United States of America Code of Federal Regulations (Revised as of April 1, 2005), Title 21, Parts 172.510, 182 and 184.
4. Canada, Food and Drugs Regulations Part B, Division 10.
5. AFNOR Norme Française NF V00-001.
6. Payom Tuntiwat, 1984, Creungthate, Mahidol University, Bangkok, Thailand.
7. Fenaroli's Handbook of Flavour Ingredients (3rd ed., Volume I) by CRC Press Inc., Boca Raton, FL 1995.
8. Tanaka's Cyclopedia of Edible Plants of the World by Tyôzaburô, Tanaka Keigaku Publishing co., Tokyo, 1976.
9. Reports of the Flavor and Extract Manufacturers' Association of the United States (FEMA) Expert Panel's publications on generally recognized as safe (GRAS) status:

Food Technology	19(2): 151-197, 1965;
“	“ 24(5): 25-28, 30-32 & 34, 1970;
“	“ 26(5): 35-42, 1972;
“	“ 27(1): 64-67, 1973;
“	“ 27(11): 56-57, 1973;
“	“ 28(9): 76-80, 1974;
“	“ 29(1): 70-72, 1975;
“	“ 31(1): 65-67, 70, 72 & 74, 1977;
“	“ 32(2): 60-62, 64-66, 68-70, 1978;
“	“ 33(7): 65-73, 1979;
“	“ 38(10): 70-72, 74, 76-78, 80-85 & 88-89, 1984;
“	“ 39(11): 108, 110, 112, 114 & 116-117, 1985;
“	“ 44 (8), 78-86, 1990
“	“ 47(6), 104-117, 1993;
“	“ 50 (10), 72-78, 80-81, 1996;
“	“ 52(9), 65-76, 79-92, 1998;
“	“ 54 (6) 66-68, 70, 72-74, 76-84, 2000;
“	“ 55(12) 1-17, 2001;
“	“ 57 (5) 46-48, 50, 52-55, 56-59, 2003; and
“	“ 58 (8) 24-28, 31-32, 34, 36, 37, 38-62, 2004.

² It should be understood that the references contain potential sources for natural flavours without reference to the safety or acceptability for human consumption of any specific source.

³ This list is not exhaustive and will be up-dated from time to time.