codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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PROPOSED DRAFT GUIDELINES FOR THE USE OF FLAVOURINGS (N03-2006)

At Step 3

(prepared by United States of America with the assistance of Australia, Canada, European Community, France, Indonesia, Japan, Mexico, Norway, Switzerland, FAO, WHO, CIAA, ICBA, ICGA, IFT, IOFI and ISDI)

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments at Step 3 on the proposed draft Guidelines for the Use of Flavourings are invited to do so **no later than 28 February 2007** as follows: Secretariat, Codex Committee on Food Additives, National Institute of Nutrition and Food Safety, China CDC, 7 Panjiayuan Nanli, Chaoyang District, Beijing 100021, China (Telefax: + 86 10 67711813, E-mail: secretariat@ccfa.cc ***preferably***), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 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) proposed new work on the elaboration of a Codex Guideline for the Use of Flavourings that establishes conditions of safe use for flavourings in food. 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) (CODEX STAN 192), with a reference to the evaluation of flavouring substances completed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

2. An electronic Working Group was established to draft a discussion paper on the development of this Guideline, and a project document for starting new work for submission to the Codex Alimentarius Commission.[1]

[1] ALINORM 05/28/12, paras. 100-102.

3. The discussion document and the project document were discussed at the 38th CCFAC.[2] The Committee agreed that, subject to the approval of the proposed new work by the Commission, an electronic Working Group led by the United States[3] would prepare a proposed draft Guideline for circulation, comments at Step 3, and further consideration at its next session. The Committee also agreed to establish a physical Working Group prior to its next Session, under the Chairmanship of the European Community, to consider the proposed draft Guideline along with comments submitted at Step 3.

4. The project document was revised by identifying a need for industries to provide JECFA with updated poundage and use level data, and then submitted to the 29th Session of the Codex Alimentarius Commission for approval as new work with the understanding that once work on this project was completed the Codex General Requirements for Natural Flavourings (CAC/GL 29) would be revoked. The CCFA Guidelines for the Use of Flavourings was approved as new work by the 29th Session of the Codex Alimentarius Commission.[4]

PURPOSE

5. This paper contains, as Appendix I, a proposed draft Codex Guideline for the Use of Flavourings. The attached proposed draft 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, Labelling, 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 Flavours) remains as Annex B in the proposed draft guideline.

6. Specifically, Appendix I 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:

1. Scope
2. Definitions
3. General Principles for the Use of Flavourings
4. Biologically Active Substances
5. Hygiene
6. Labelling
7. JECFA Evaluations of Flavourings and their Specifications
8. Aromatic Raw Materials Suitable for the Preparation of Natural Flavourings

RECCOMMENDATIONS AND REQUEST FOR COMMENT

7. The substances identified in Annex A of the proposed draft guideline as biologically active substances consist of flavouring substances, and substances that are unavoidable constituents of natural flavouring substances, as well as some that are both. The list also contains individual, chemically-defined substances that may be of toxicological concern or substances that are members of a class of related substances that could raise similar toxicological concerns. Some of the substances in the annex have been reviewed by JECFA, including some recent reviews, while others have never been the subject of a JECFA review. The Working group recommends that the CCFA review the list of biologically active substances in Annex A and develop specific questions for each of the substances in the list that are not currently the subject of a JECFA review, with a view toward obtaining JECFA's science-based guidance.

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2 ALINORM 06/29/12 paras. 85-88, Appendix XIV.

3 With assistance of Australia, Canada, European Community, France, Indonesia, Japan, Mexico, Norway, Switzerland, FAO, WHO, CIAA, ICBA, ICGA, IFT, IOFI and ISDI.

4 ALINORM 6/29/41 Appendix VIII.

8. The guideline, as presently drafted, recommends maximum levels for certain biologically active substances in food. For these recommendations to be meaningful, modern, validated analytical methods for the determination of such substances should be available. Therefore, information is requested on validated methods of analysis for the purpose of updating the list of methods in Annex A, and comment on whether the methods listed in the guideline should be specific with respect to the analyte, general methods of analysis, or both.

9. In addition, Codex members are encouraged to provide comments and additional information on the attached proposed draft Codex Guideline for the Use of Flavourings (Appendix I) for consideration by the Committee during its next session. In particular, comments and specific information are requested relating to:

1. the overall structure and completeness of the guideline (Appendix I);
2. the completeness and relevance of the definitions (Appendix I, Section 2.0); and,
3. the references to lists of aromatic raw materials suitable for the preparation of flavourings (Appendix I, Annex B).

Appendix I

Changes to the Codex Guideline CAC/GL 29

This Guideline replaces Codex Guideline CAC/GL 29 "*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:

1) A revised and hierarchical set of definitions that are intended to encompass all types of flavourings;

2) General principles for the use of flavourings; and,

3) A revised section on hygiene.

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

PROPOSED DRAFT CODEX GUIDELINE FOR THE USE OF FLAVOURINGS

(N03-2006)

AT STEP 3

1.0 SCOPE

This guideline provides principles for the safe use of the components of flavourings evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and determined to present no safety concern at 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 and adopted by Codex.[5] In addition, the guideline provides principles for the establishment of practices that do not mislead the consumer.

2.0 DEFINITIONS

2.1 **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.

2.2 **Flavourings** are products that are added to food to impart or modify the flavour of food, rather than to enhance nutritional quality or to fulfill other technological effects. Flavourings do not include substances that have an exclusively sweet, sour, or salty taste (e.g. sugar, vinegar, and table salt). Flavourings may consist of flavouring substances, natural flavouring complexes, or smoke flavourings and may contain non-flavouring food ingredients (Section 2.2.4) that make flavourings compatible with the foods and beverages in which they are used. They are not intended to be consumed as such.

2.2.1 **Flavouring substances** are chemically-defined substances either formed by chemical synthesis, or obtained from materials of plant or animal origin.

2.2.1.1 **Natural flavouring substances** are flavouring substances obtained by physical processes that do not intentionally modify the chemical identity of the components of the flavouring (e.g. distillation and solvent extraction), or by enzymatic or microbiological processes, from material of plant or animal origin. Such material may be unprocessed, or processed for human consumption by traditional food-preparation processes (e.g. drying, torrefaction (roasting) and fermentation).

2.2.1.2 **Synthetic flavouring substances** are flavouring substances formed by chemical synthesis.

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[5] This guideline does not imply that the uses of flavouring components that have not yet been evaluated by JECFA are unsafe or otherwise unacceptable for use in food.

2.2.2 Natural flavouring complexes are preparations that contain flavouring substances obtained by physical processes that do not intentionally modify the chemical identity of the components of the flavouring (e.g. distillation and solvent extraction), or by enzymatic or microbiological **processes**, from material of plant or animal origin. Such material may be unprocessed, or processed for human consumption by traditional food-preparation processes (e.g. drying, torrefaction (roasting) and fermentation). Natural flavouring complexes include the essential oil, essence, or extractive, protein hydrolysate, distillate, or any product of roasting, heating, or enzymolysis.

2.2.3 Smoke flavourings are complex mixtures of components of smoke obtained by subjecting untreated hardwoods to pyrolysis in a limited and controlled amount of air, dry distillation, or superheated steam, then subjecting the wood smoke to an aqueous extraction system or to distillation, condensation, and separation for collection of the aqueous phase. The major flavouring principles of smoke flavourings are carboxylic acids, compounds with carbonyl groups and phenolic compounds.[6]

2.2.4 Non-flavouring food ingredients are food ingredients, such as food additives and foodstuffs that can be added to flavourings and are necessary for dissolving, dispersing, or diluting flavourings, or are necessary for the production, storage, handling and use of flavourings.

3.0 GENERAL PRINCIPLES FOR THE USE OF FLAVOURINGS

3.1 The use of flavourings in food should not lead to unsafe levels of their intake.

3.2 Flavourings should be of a purity suitable for use in food. Unavoidable impurities, including biologically active substances (see section 4.0), should not be present in the final food at levels that would pose an unacceptable risk to health.

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

3.4 Flavourings should be used under conditions of good manufacturing practice, which includes limiting the quantity used in food to the lowest level necessary to accomplish the desired flavouring effect.

3.5 Flavourings may contain non-flavouring food ingredients, including food additives and foodstuffs, necessary for their production, storage, handling, and use. Such ingredients may also be used to facilitate the dilution, dissolution, or dispersion of flavourings in food. Non-flavouring food ingredients should be:

a) Limited to the lowest level required to ensure the safety and quality of the flavourings, and to facilitate their storage and ease of use;

b) Reduced to the lowest level reasonably possible when not intended to accomplish a technological function in the food itself; and,

c) used in accordance with the provisions of the Codex General Standard for Food Additives (GSFA; CODEX STAN 192) whenever they are intended to provide a technological function in the finished food.

4.0 BIOLOGICALLY ACTIVE SUBSTANCES

Biologically active substances identified to be of potential toxicological concern can be present in flavourings or in food ingredients with flavouring properties (e.g. herbs and spices). Annex A contains a list of biologically active substances that should not be added directly to food, with the exception of quinine and quassine. The presence of these biologically active substances in foods that are ready for consumption can occur from the use of certain natural flavourings or food ingredients with flavouring properties (herbs and spices). Their presence in food should not pose a risk to health and therefore, should not exceed the maximum levels indicated in the Annex. Annex A also contains references to analytical methods for the determination of such biologically active substances.

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[6] FAO JECFA Monographs 1 (Volume 3) 2005 FAO Rome.

5.0 HYGIENE

5.1 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).

5.2 Flavourings should be free from contamination by soil, food residue, dirt, grease, contamination by pests, or by chemical, physical or microbiological contaminants, or other objectionable matter to the extent possible under Good Manufacturing Practice.

5.3 When used at appropriate levels in food, and tested by appropriate methods of sampling and examination, flavourings should not contain micro-organisms, parasites, or substances originating from micro-organisms in amounts that pose an unacceptable risk to health.

6.0 LABELLING

Labelling of flavourings should be in accordance with the requirements of the Codex General Standard for the Labelling of Food Additives (CODEX STAN 107). Labelling of foods containing added flavourings should be in accordance with the requirements of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1).

7.0 JECFA EVALUATIONS OF FLAVOURINGS AND THEIR SPECIFICATIONS

The flavourings for which JECFA has completed its safety evaluation are available from the WHO JECFA website (http://www.who.int/ipcs/publications/jecfa/en/index.html), through the link *Database of evaluation summaries,* or by contacting the WHO JECFA Secretariat. Specifications for flavouring substances evaluated by JECFA are available, in an on-line searchable database at the FAO JECFA website (http://apps3.fao.org/jecfa/flav_agents/flavag-q.jsp), or by contacting the FAO JECFA Secretariat.

8.0 AROMATIC RAW MATERIALS SUITABLE FOR THE PREPARATION OF NATURAL FLAVOURINGS.

References to lists of aromatic raw materials suitable for the preparation of natural flavouring substances and natural flavouring complexes may be found in Annex B of this guideline.

ANNEX A

BIOLOGICALLY ACTIVE SUBSTANCES AND ASSOCIATED METHODS OF ANALYSIS

BIOLOGICALLY ACTIVE SUBSTANCES

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
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 flavoured 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
Estragole			
Methyl eugenol			
Caffeine			
Spartein	0.1	0.1	5 mg/kg in alcoholic beverages
Rue Oil	4		10 mg/kg in bakery products 10 mg/kg in milk based dessert 10 mg/kg in soft candy

Substance	Maximum Levels (mg/kg)		
	In Food as Consumed	**In Beverages as Consumed**	**Exceptions**
Iso safrol	1	1	2 mg/kg in alcoholic beverages containing less than 20% alcohol by volume 5 mg/kg in alcoholic beverages containing greater than 20% alcohol by volume

METHODS OF ANALYSIS

Methods of analysis should comply with internationally recognized rules or protocols or with other methods fit for the intended purpose or developed in accordance with scientific protocols.

General Methods of Analysis:

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).

Specific Methods of Analysis

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).

Coumarin, HPLC Determination Journal of Chromatography **246** 313-316 (1982).

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.

ANNEX B

REFERENCES TO LISTS OF AROMATIC RAW MATERIALS SUITABLE FOR THE PREPARATION OF FLAVOURINGS [7,8]

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 (5rd ed., Volume I) by CRC Press Inc., Boca Raton, FL 2005.
8. Tanaka's Cyclopedia of Edible Plants of the World by Tyôzaburô, Tanaka Keigaku Publishing co., Tokyo, 1976.
9. Natural Sources of Flavourings, Council of Europe, July 2000.
10. 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;

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7 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.

8 This list is not exhaustive and will be updated from time to time.

" " 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.

11. List of Origin of Natural Flavouring Agents Ministry of Health, Labor, and Welfare, Japan, Last Amendment November 17, 1997.