codex alimentarius commission E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/FA 08/40/8**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

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PROPOSED DRAFT GUIDELINES FOR THE USE OF FLAVOURINGS (SECTION 4 AND ANNEXES A AND B)

(N03-2006)

(at Step 3)

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments at Step 3 of the proposed draft Guidelines for the Use of Flavourings (Section 4 and Annexes) are invited to do so **no later than 29 February 2008** 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***).

BACKGROUND

1. The development of a Guideline for the Use of Flavourings was endorsed as new work for the Codex Committee on Food Additives (CCFA) by the 29th Session of the Codex Alimentarius Commission (CAC).[1] This new work was undertaken with the understanding that the Codex General Requirements for Natural Flavourings (CAC/GL 29-1987) will be revoked upon its completion.

2. The 39th Session of the CCFA agreed on the sections describing: Scope; Definitions; General Principles for the Use of Flavourings; Hygiene; Labeling; JECFA Evaluations of Flavourings and their specifications; and Aromatic Raw Materials for the Preparation of Natural Flavourings. However, the Committee noted that many of the issues regarding Section 4 "Biologically Active Substances," and Annex A "Biologically Active Substances and Associated Methods of Analysis," remained unresolved, including whether Section 4 and Annex A should remain in the Guideline and, if so, the criteria for their inclusion.

[1] ALINORM 6/29/41 Appendix VIII.

3. The Committee agreed to forward the proposed draft Guideline to the 30th Session of the CAC for adoption at Step 5, with the exception of Section 4 and Annexes A and B, which were returned to Step 2 for redrafting.[2] The 30th CAC adopted the proposed draft Guideline at Step 5 and advanced it to Step 6, with the exception of Section 4 and Annexes A and B, with the understanding that several translation issues in Spanish would be addressed by the next session of the Committee.[3] The 39th CCFA also agreed to establish an electronic working group led by the United States of America,[4] working in English, to prepare a proposal for a revised Section 4, and Annexes A and B, for circulation and comment at Step 3.

4. It was further agreed that the electronic Working Group would consider the following issues in elaborating a revised, proposed draft Section 4, and Annex A:

- What criteria should govern inclusion in the list appearing in Annex A;
- What substances should be included in that list;
- What information should accompany requests for inclusion in the list;
- How should the evaluation of substances included in the list proceed;
- How should substances appearing in the list be prioritized for evaluation by JECFA; and,
- What is an appropriate title for Annex A (and Section 4.0)?[5]

5. Although Annex B was returned to Step 2 for redrafting, there is no discussion in either the report of the 39th Session of CCFA, or the report of the 30th Session of the CAC regarding the needed revisions.

6. The recommendations in this discussion paper are based on the deliberations of the working group on drafts of the paper that were twice circulated within the working group. Most suggestions offered were included in the discussion paper. There was, however, some discussion around a proposal to include a new subsection in the proposed draft Section 4 that would list components of natural flavouring complexes that are genotoxic, along with the natural flavouring complexes from which they originate. Because the assessment of genotoxic potential and the consequences in relation to safe human exposure levels is an integral part of the JECFA risk assessment, this proposal was not included in the discussion paper.

7. The working group also considered a proposal to broaden the scope of the revised proposed draft Section 4 to include both flavouring substances and substances that become components of food only as a result of their presence in natural flavouring complexes. While one member opposed this idea, this proposal was taken on in the working group's final report.

8. Finally, one member of the working group proposed that a new subsection of the revised proposed draft Section 4 be used to temporarily list components of natural flavouring complexes that have been identified by the Scientific Committee on Food (SCF) and the European Food Safety Authority (EFSA) to be of concern. It was suggested that the temporary listing be retained until such time as JECFA completed it review of those substances. This suggestion was not included in the proposal contained in this discussion paper because the Codex Procedural Manual provides that CCFA shall base its risk management recommendations to the CAC on JECFA's risk assessments, including safety assessments, of food additives.[6]

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[2] CX/FA 07/39/12
[3] ALINORM 07/30/REP, para. 82
[4] The following members and observers actively participated in the electronic working group: Australia, Canada, European Community, Indonesia, Norway, South Africa, United States, ICBA, IOFI, FAO and WHO.
[5] ALINORM 07/30/12, para 123
[6] ALINORM 07/30/REP, Appendix III, p. 116

INTRODUCTION

9. Section 4 of the proposed draft guideline (CX/FA 07/39/12) contains general recommendations for the use of natural flavourings that may contain "biologically active substances," and a reference to Annex A which contains a list of such substances and their associated maximum levels in food. The substances and maximum levels appearing in Annex A of the draft Guideline originated from the list of "Biologically Active Substances" currently found in the *General Requirements for Natural Flavourings* (CAC/GL 29-1987). The maximum levels in the table represent either limits of detection, or are based on toxicological or technological considerations. The 13th Session of the CCFA (1979) referred these substances to the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and requested advice on the appropriateness of the proposed maximum levels. JECFA reviewed ß-asarone, coumarin, estragole, methyl eugenol, safrole and isosafrole, thujones, and hydrocyanic acid in 1981. Acceptable daily intakes (ADIs) were not established for these substances at that time, as there were inadequate data to conclude the evaluation. Newer data relevant to an updated risk assessment have become available for many of these substances. JECFA evaluated quinine in 1993 and pulegone in 2000, and determined them to be safe under current conditions of use as flavouring substances. The remaining substances listed in Annex A of the draft Guideline have not been reviewed by JECFA for use as flavourings (i.e., agaric acid, aloin, berberine, cocaine, hypericine, quassine, santonin, caffein, spartein, and rue oil). The 69th JECFA (2008) is scheduled to review the safe use of estragole, methyl eugenol, and safrole among other flavours.

10. Annex A also contains a list of references to both general and specific methods of analysis for the determination of the listed biologically active substances in food. The list of references to analytical methods originated from CAC/GL 29-1987, but was revised and updated with the addition of new references for discussion at the 39th CCFA.

11. Annex B of the draft Guideline contains references to lists of aromatic raw materials that may be suitable for the preparation of natural flavourings. This list also originated from CAC/GL 29-1987, and was revised and updated with the addition of new references for discussion at the 39th CCFA. Although the report of the 39th Session of the CCFA recommends that Annex B be returned to Step 2 for redrafting, there is no discussion regarding the issues that need to be addressed.

12. Appendix I to this document contains the revised proposed draft Section 4 and Annex A.

PURPOSE

13. The purpose of this discussion paper is to provide a proposal for, and to request comments on, the issues relating to the proposed draft Section 4 and Annexes A and B of the draft Guideline. A revised Section 4 and Annex A are proposed and discussed in this paper. It is further proposed that Annex B be removed from the Guideline. These proposals are presented without prejudice of a decision that the Committee may make at its 40th session on whether to include a revised Section 4 and its related Annexes, or to simply delete those provisions of the guideline as discussed by the 39th session of the Committee.[7]

14. The revised Section 4 and Annex A (Appendix I), proposed here include both flavouring substances and substances that become components of food only as a result of their presence in natural flavouring complexes. This proposed change is intended to include in Annex A all flavouring substances and constituents of flavouring complexes for which specific recommendations would be appropriate for managing risk. Comments are requested on this proposed change in the scope of Annex A and Section 4.

15. The revised Annex A described here proposes to eliminate the references to analytical methods that were included in Annex A of CX/FA 07/39/12. Many of the methods previously listed are known to be obsolete, and the criteria proposed here for inclusion in the list of Annex A includes a request for a validated method of determination of each substance in food.

16. It is proposed that the references to lists of aromatic raw materials suitable for the preparation of flavourings (Annex B) be eliminated from the guideline. Because the purpose of the list in Annex B is unclear, and because the list needs to be maintained and regularly updated, therefore its value over time was questioned and it is recommended that the Committee discontinue work on this aspect of the draft guideline.

[7] ALINORM 07/30/12 Rev. para. 121

17. It was suggested in the discussions of the 39th Codex Committee on Food Additives that the term "Biologically Active Substances" used in the title for the proposed Section 4 of the Guideline was inappropriate.[8] New titles for the revised proposed draft Section 4 and Annex A are proposed that are descriptive of the purpose of both the section and the list in Annex A rather than the type of substances listed.

Revised, Proposed Section 4 and Criteria for Inclusion of Substances in Annex A

18. Whenever the use of a flavouring substance, or a substance that is a component of a natural flavouring complex, or of a food ingredient with flavouring properties raises safety concerns identified by JECFA, the risk may be managed through specific risk management measures (e.g., maximum levels in food, additional labeling requirements) to protect the health of consumers. Criteria for the inclusion of additional risk management recommendations including maximum levels in specific foods or food categories are described in the revised proposed draft Section 4 (Appendix I). In addition, it is proposed that the references to lists of aromatic raw materials suitable for the preparation of flavourings in Annex B be eliminated as its value and purpose are unclear.

19. It is further proposed that substances be listed in Annex A only after criteria for inclusion in the Annex are adopted and then only when proposed listings meet the adopted criteria.

Pros:

20. This proposal provides a mechanism for CCFA to make risk management recommendations regarding any substance for which JECFA has identified a potential health concern based upon their use as flavourings or as components of natural flavouring complexes, and has established a numeric ADI, or provided other specific safety recommendations.

21. Entry into the Annex is based upon objective criteria, and is intended to ensure that the use of flavouring substances or components of natural flavouring complexes are safe and protect consumer health.

Cons:

22. CCFA will periodically need to commit time and resources to updating the list. However, this effort is anticipated to be minimal and within the Committee's scope of work in establishing a priority list for JECFA review.

23. Annex A will not list any substances until criteria for inclusion of substances in the Annex are identified and adopted by CAC. The substances currently listed in the *General Requirements for Natural Flavourings* (CAC/GL 29-1987), if not already evaluated by JECFA must be prioritized for evaluation by JECFA using the current procedures for JECFA priority-setting by CCFA and are consistent with Codex's Risk Analysis Principles Applied by the Codex Committee on Food Additives[9] as adopted by the 30th Session of the Codex Alimentarius Commission.[10]

RECOMMENDATIONS

24. The Committee should discuss and agree on the approach presented above. In addition, it is recommended that:

- The substances listed as "Biologically Active Substances" in CAC/GL 29-1987 should be proposed for review by JECFA for use as flavouring substances or as components of natural flavouring complexes, or other food ingredients with flavouring properties;
- The redrafted text for Section 4 and Annex A provided in Appendix I should be considered by the Committee along with the other sections of the draft Guideline (adopted at Step 5), with a view toward consolidating them into a single document.

[8] ALINORM 07/30/12 Rev. para. 122.
[9] ALINORM 07/30/12, App. III
[10] ALINORM 07/30/REP, para. 35.

Appendix I

PROPOSED DRAFT GUIDELINES FOR THE USE OF FLAVOURINGS (SECTION 4 AND ANNEXES A AND B)

(N03-2006)

(at Step 3)

4.0 FLAVOURING SUBSTANCES AND COMPONENTS OF NATURAL FLAVOURING COMPLEXES WITH SPECIFIC RECOMMENDATIONS

4.1 Some flavouring substances, and substances that may be components of natural flavouring complexes, or of food ingredients with flavouring properties (e.g., herbs and spices) have been identified to be of potential health concern by JECFA. The levels of these substances in food should not pose a risk to health. Annex A contains a list of such substances with associated acceptable maximum levels or other risk management measures. The presence of these substances in food should comport with the conditions of use guidance provided in Annex A. Annex A also contains provisions for the analytical determination of the listed substances in food.

4.2 All of the following criteria must be met for inclusion into Annex A:

a) The substance has been evaluated by JECFA as a flavouring substance and/or as a component of a natural flavouring complex or other food ingredient with flavouring properties (e.g., herbs and spices;

b) JECFA's risk assessment output identifies a specific health risk associated with the presence of the substance in food as a result of its use as a flavouring substance or its presence in a component of a natural flavouring complex for which additional risk management measures are needed to protect the health of consumers;

c) Acceptable maximum levels in specific foods have been subjected to an assessment of dietary exposure using an appropriate method to ensure that the intake of the substance from all uses does not exceed JECFA's numeric ADI;[3] and,

d) A reference to a validated analytical method for the determination of the substance in food is available. Methods of analysis should comply with the Principles for the Establishment of Codex Methods of Analysis (CAC Procedural Manual, 15th Edition, p. 71) and should be endorsed by the Codex Committee on Methods of Analysis and Sampling.

[3] Annex A of the Codex General Standard for Food Additives may be used as a first step in this regard.

ANNEX A: FLAVOURING SUBSTANCES AND COMPONENTS OF NATURAL FLAVOURING COMPLEXES WITH SPECIFIC RECOMMENDATIONS

Substance	Risk Management Measure	Analytical Methods