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JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 6

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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GUIDELINES FOR THE USE OF FLAVOURINGS (N03-2006)

COMMENTS AT STEP 6 AND AT STEP 3

PART 1 (COMMENTS AT STEP 6 TO THE DRAFT GUIDELINES FOR THE USE OF FLAVOURINGS, WITH THE EXCEPTION OF SECTION 4 AND ANNEXES A AND B

(in response to CL 2007/24-FA)

The following comments have been received from the following Codex members and observers:

Australia, Dominican Republic, European Community, ICBA and IOFI

Australia:

Australia supports the Draft Guidelines for the Use of Flavourings with the exemption of Section 4 and Annexes A and B and proposed no specific amendments to the text.

Dominican Republic:

A) In paragraph 2.2 «**Flavourings** are products that are added to foodstuffs to impart, modify or enhance the flavour of these foodstuffs (with the exception of »

The Dominican Republic suggest deleting «of these **foodstuffs**» and changing «**modify or enhance**» to the **plural** so that the paragraph reads as follows:

«**Flavourings** are products that are added to foodstuffs to impart, modify or enhance their flavour (with the exception of »

B) In paragraph 2.2.2, we suggest changing the Spanish article «**el**» to «**los**» in the sentence that reads «**el aceites esenciales**»..... so that it reads «**los aceites esenciales**» (**the essential oils**).....

C) In paragraph 3.5, we suggest placing a **comma (,)** after «**almacenarlos**» (storage) in the Spanish sentence: «.....**necesarios para producirlos, almacenarlos manipularlos y utilizarlos.**» (necessary for their production, storage, handling, and use)

So that it reads: “.....**necesarios para producirlos, almacenarlos, manipularlos y utilizarlos.**”

D)In paragraph 5.1 the revision made in (CAC/RCP 1-1969) must be inserted.

So that it reads: (CAC/RCP 1-1969, Rev.4-2003).

E) In paragraph 6.0 the revision made in (CODEX STAN 1-1985, Rev. 1-1991.) must be inserted.

So that it reads: (CODEX STAN 1-1985, Rev. 1-1991.)

European Community:**1.0 Scope**

JECFA has started additional work to evaluate the exposure to flavouring substances based on use levels (cf. Conclusions of the 67th and 68th Sessions in Rome, June 2006 and June 2007). The EC proposes that the conclusions of this additional work should be taken into account.

2.0 Definitions**EC proposal for further clarification of the definition of flavourings:**

2.2. Flavourings are products that are added to food to impart, modify, or enhance the flavour of food (with the exception of flavour enhancers considered as food additives under the Codex Class Names and the International Numbering System for Food Additives - CAC/GL 36-1989). 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, **thermal process flavourings** or smoke flavourings **and mixtures of them** and may contain non-flavouring food ingredients (Section 2.3) ~~that make flavourings compatible with the foods and beverages in which they are used~~ **within the conditions as referred to in point 3.5.** They are not intended to be consumed as such.

EC proposal to insert the following sentence at the end of "2.2.1.1. Natural flavouring substances":

...**"This means substances that have been identified / detected in a natural material of animal or vegetable origin."**

ICBA:

ICBA supports adopting the Draft Guidelines for the Use of Flavorings (with the exception of Section 4 and Annexes A and B) at Step 6 as written based on an agreement reached at the 39th CCFA.

IOFI:

IOFI is pleased with the decision to advance the Draft Guidelines for the Use of Flavorings (N03-2006) (with the exception of Section 4 and Annexes A and B) to Step 6 of the Procedure by the 30th Session of the Codex Alimentarius Commission. IOFI supports the text as developed upon the agreements reached at the 39th Session of the Codex Committee on Food Additives.

PART 2 (COMMENTS AT STEP 3 TO THE PROPOSED DRAFT SECTION 4 AND ANNEXES A AND B OF THE GUIDELINES FOR THE USE OF FLAVOURINGS

The following comments have been received from the following Codex members and observers:

Australia, the European Community and ICBA

Australia:

Australia has participated on the electronic working group established at the 39th session of CCFA to review section 4 and the annexes of the Proposed Draft Guidelines for the Use of Flavourings. Australia supports the draft document for the 40th session of the CCFA and the proposed recommendations contained within. Australia also support the removal of Annex B from the guideline.

One suggested amendment to the proposed text in Appendix 1 (section 4, 4.2 c)) is provided for consideration. Australia suggested amendments are indicated by ~~striketrough~~ for current text proposed for deletion and **bold** for proposed alternative text:

Appendix 1, Section 4, 4.2, c) Acceptable maximum levels in specific foods have been ~~subjected to~~ **established based on** 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

European Community

The European Community and its Member States (ECMS) thank the members of the working group and in particular the United States for the work that has been done.

The ECMS wish to make the following preliminary comments.

ECMS support the need to establish maximum limits in food for substances that are unavoidably present in natural flavouring complexes and in food ingredients with flavouring properties and for which the intake resulting from their use in food is of safety concern.

The ECMS is however of the opinion that section 4 should not cover flavouring substances as defined in 2.2.1 of the guidelines. The status of flavouring substances is totally different from that of naturally occurring toxicants in certain natural source materials. As the latter are naturally occurring, they are unavoidable in natural flavouring complexes derived from these materials and in food ingredients with flavouring properties. Flavouring substances in contrast are voluntary added to food. The responsibility is totally different for a food producer (and for control services).

In addition, the ECMS is of the opinion that additional assessments may be required to decide whether specific risk management measures are needed for certain flavouring substances. JECFA concludes that the substances are of no safety concern at estimated current intakes. For this estimation, the so called Maximised Survey-Derived Daily Intake (MSDI) approach is applied. This approach is based on production figures. Use levels have not been considered to estimate intake. In our opinion such estimations based on use levels also are required to evaluate the need for additional risk management decisions on flavouring substances.

E.g. we have calculated based on use levels provided by the industry that for more than half of 133 class III substances evaluated by JECFA, the possible intake may be above the threshold of concern.

Therefore, at the current stage, the European Community and its Member States can not support that section 4 would also cover flavouring substances. In the current situation, the ECMS is of the opinion that it is sufficient to refer to the general principle as mentioned under 3.1 of the draft guidelines: "The use of flavourings in food should not lead to unsafe levels of their intake."

The ECMS would have appreciated that this would have been presented as an option to the members of the electronic working group so that this could have been further discussed and considered.

The ECMS supports that the entry in the annex should be based upon objective criteria and that in principle they should be evaluated by JECFA. The ECMS wants however to avoid that a gap would be created between the provisions in "General Requirements for Natural Flavourings," CAC/GL 29-1987 and new provisions in the Guidelines, as most of the substances have however not been evaluated by JECFA or the evaluation were not conclusive.

E.g. Pulegone was evaluated since in 2000, but was only assessed as a flavouring substance and not for its presence, as naturally occurring toxicant, in peppermint oil and other natural flavouring complexes. The estimation of intake for its use as flavouring substance was estimated at 2 µg/person/day. The European Food Safety Authority calculated that the intake via confectionary or via non-alcoholic beverages to which peppermint oil has been added may be more than 1000 µg/person/day.

The ECMS therefore requests that until the substances have been evaluated by JECFA for their presence in natural flavouring complexes and other food ingredients with flavouring properties, the limits in the General Requirements for Natural Flavourings can be maintained. This is in line with the project document proposing the new work on the elaboration of the guidelines for the use of flavourings (ALINORM 06/29/12, appendix XIV, para 6), which proposed that the new work would incorporate the General Requirements for Natural Flavourings.

The ECMS would have appreciated that this would have been presented as an option to the members of the electronic working group for discussion and consideration.

Taking into account the list of the General Requirements for Natural Flavouring, the ECMS consider it necessary to maintain measures on the following substances: agaric acid, aloin, beta-azarone, capsaicin, coumarin, hypericine, hydrocyanic acid, pulegone, quassin, safrole, thujone (alpha and beta).

In relation to the method of analyses, the ECMS would like to add that in absence of methods endorsed by the codex Committee on Methods of Analysis and Sampling, it should be specified that methods for determination of the substance in food should comply with internationally recognized rules or protocols or with other methods fit for the intended purpose or developed in accordance with scientific protocols.

ANNEX

4.0 ~~FLAVOURING SUBSTANCES AND~~ COMPONENTS OF NATURAL FLAVOURING COMPLEXES OR OF FOOD INGREDIENTS WITH FLAVORUING PROPERTIES, WITH SPECIFIC RECOMMENDATIONS

4.1 ~~Flavouring substances and~~ Certain 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. Their presence in foods as ready for consumption can occur from the use of certain natural flavouring complexes or food ingredients with flavouring properties. The levels of these substances in food should not pose a risk to health.

The substances should not be added as such to food.

Annex A contains a list of such substances with associated acceptable maximum levels, or other risk management measures. The presence use of these substances in food should ~~comport~~ 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 ~~a flavouring substance and/or~~ as a component of natural flavouring complexes or ~~of a food ingredients~~ with flavouring properties;
- b) JECFA's risk assessment output identifies a specific health risk associated with the use of the ~~flavouring substance or a component of a natural flavouring complex~~ or of food ingredients with flavouring properties for which additional risk management measures are needed to protect the health of consumers;³
- c) To establish acceptable maximum levels, specific foods and the acceptable maximum level for the substances in those foods must be identified. These acceptable maximum levels have been subjected to an assessment of dietary exposure using an appropriate method. The establishment of the maximum limits should take into account the need to protect human health and at the same time their unavoidable presence in traditional foods and source materials ~~to ensure that the intake of the substance from all uses does not exceed JECFA's numeric ADI; 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. In absence of methods endorsed by the CCMAS, methods for determination of the substance in food should comply with internationally recognized rules or protocols or with other methods fit for the intended purpose or developed in accordance with scientific protocols.

4.3 Members can maintain restrictions for the substances listed in the General Requirements for Natural Flavourings (CAC/GL 291987), in annex B, until they have been evaluated by JECFA and the CAC has adopted specific risk management measures.

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

Substance	Risk Management Measure	Analytical Methods

ICBA

The International Council of Beverages Associations (ICBA) was a member of the electronic working group and supports the approach presented in the document concerning the revised, proposed Section 4 and criteria for inclusion of substances in Annex A (paragraphs 18 and 19). We urge the Committee to endorse the recommendations in paragraph 24 and the revised proposed Section 4 and Annex A that are presented as Appendix 1 of the document. Further, ICBA would support forwarding the consolidated single document for adoption by the Commission.