codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 7 **CX/FAC 06/38/12, Add.1**
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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

Comments by Canada, European Community, New Zealand, United States, ICBA, ICGA and IOFI

CANADA

Appendix II, Section 2.0, Definitions

2.1. a) Flavourings

The first sentence of the definition for a flavouring should have added to it (i.e. after the word "quality") "… or to otherwise fulfill a technological effect".

2.1. a) i) (2) Artificial flavouring substances

The definition of artificial flavouring substances refers to substances formed by chemical synthesis that have not been identified in natural products intended for human consumption. However, there is a group of flavouring substances obtained through chemical synthesis which are identical to those substances encountered in natural products (so-called "nature-identical" substances). Therefore, either the definition of artificial flavouring substances should cover these types of substances or a separate "nature-identical" sub-class should be created.

2.1. b) Flavouring adjuvants

With regard to flavouring adjuvants, these substances should not have a technical effect upon the finished food. Flavouring adjuvants that have a technical effect upon the finished food should be viewed as food additives insofar as, essentially, they are being added to the finished food with a view to having a technological effect, even if the effect is related to the flavouring (e.g. carrying or solubilization of the flavour into the food). In short, flavourings should not be used as vehicles for deliberate misuse of carry-over, i.e. substances, added as food additives to the flavouring preparation, which could subsequently exhibit their technological effect in a finished food product.[1]

The presence in a flavouring of an adjuvant that is functional in the finished food would render the flavouring a food additive/flavouring mixture.

Canada suggests that the present text be deleted and that the definition for "Flavouring adjuvants" be rewritten to essentially convey the following:

"Flavouring adjuncts are substances (food ingredients or food additives, excluding flavour enhancer), without flavour in themselves, that are only functional within a flavour preparation."

4.0 Flavouring Adjuvants

The last sentence of the first paragraph to Section 4 is confusing. As previously indicated in our comments under 2.1(b), the presence in a flavouring of an adjuvant that is functional in the finished food would render the flavouring a food additive/flavouring mixture, suggesting that such an adjuvant be listed in the GSFA as an additive. Canada suggests deletion of this sentence. Canada also suggests deletion of the last sentence of the second paragraph of this Section.

Annex A

Canada suggests a minor correction to the list of references cited in Annex A, i.e. the reference No 7 should be up-dated. The fifth edition of Fenaroli's Handbook of Flavour Ingredients is now available (2005).

EUROPEAN COMMUNITY

The European Community and its Member States thank the members of the working group and in particular the United States for the intensive work that has already been done and wishes to make the following comment:

The European and its Member States are in favour of the elaboration of a project document for new work to prepare Codex guidelines for the use of flavourings and propose to focus discussion on the draft in Appendix 1 and specifically the sections on scope and objectives.

The European Community and its Member States support in principle JECFA's evaluations of flavouring substances to which will be referred in the guidelines. The evaluations are based on a pragmatic approach that allows for an efficient method to evaluate the huge amount of different flavouring substances that are currently being used.

A solution should however be found for substances that are classified by JECFA as of "No safety concern at the estimated levels of intake" on the sole bases that their estimated intake is lower that 1,5 µg per day.

During the 65th JECFA meeting of 7 – 16 June 2005, there have been discussions identifying limitations in the use of the Maximized Survey-derived Daily Intake (MSDI) for estimation of dietary exposure. The MSDI might in some cases result in an underestimate of dietary exposure of those persons with high levels of consumption of specific foods. The estimates of current dietary exposure are difficult to reconcile with reported maximum use levels of some flavouring agents in foods. It was therefore recommended to the JECFA secretariat to form a working group to deal with these issues. The issue of correct estimation of exposure is also demonstrated in the Flavouring Group Evaluations adopted by the European Food Safety Authority.

As exposure assessment is one of the four steps in the scientifically based Risk Assessment, the European Community and its Member States prefer that a first draft of the guidelines would be considered at Step 3 by CCFAC after the concern about the estimation of dietary exposure has been sorted out by JECFA. The European Community and its Member States will therefore propose to the CCFAC to request JECFA to deal with this issue with first priority.

Pending conclusions and recommendations of JECFA, the European Community and its Member States may then suggest that the guidelines should allow for extra measures or considerations if the estimation of intake based on alternative methods would give raise to concern.

SPECIFIC COMMENTS:

Appendix I: Project Document – Proposal for New Work

Point 1

The phrase "safety assessment" is not defined in the Procedural Manual. The wording of the last sentence should be brought into line with the terms already adopted by the Codex Alimentarius Commission. We suggest using "risk assessment" which is defined by the Codex Alimentarius Commission as the scientifically based process consisting of the following (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment and (iv) risk characterisation.

Point 2

The definition of “Natural Flavouring complexes” should be clarified. E.g. the European Community and its Member States are of the opinion that “smoke flavourings” and “thermal process flavourings” are not covered by the definition “natural flavouring complexes”. The European Community and its Member States agree with the exclusion of “smoke flavourings” and “thermal process flavourings”.

Point 3

A chapter on specific conditions of use necessary to protect the health of the consumer, may be needed following additional scientific advice on exposure assessment.

Point 7

During the 65th JECFA meeting on June 2005, it was already recommended to form a working group to consider some difficulties encountered by JECFA for the estimation of intake. The European Community and its Member States are of the opinion that this additional expert scientific advice is needed and propose that this should be placed on the priority list for JECFA evaluations.

The European Community and its Member States propose to delete the last sentence.

Point 8

Technical input is still needed to obtain more reliable estimations of intake.

Point 9

Considering the additional work that needs to be carried out by JECFA, the European Community and its Member States have serious doubts that a draft guideline can be proposed for consideration by CCFAC at Step 3 in 2007. They suggest fixing a timeline when this issue is solved.

Appendix II

The European Community and its Member States welcome this first draft of the proposed guidelines.

They have however several reservations on its content.

All chapters need careful revision, taking into account the result of the discussion on Appendix 1. In addition, depending on conclusions and recommendations of the JECFA concerning the exposure an additional chapter on the intake may have to be added.

At this stage, as examples, the European Community and its Member States wish to give some first comments:

2.0 DEFINITIONS

If the definition of “artificial flavouring substances” is to be maintained, the definition of “natural identical flavouring substances” should be introduced.

In that case, the European Community and its Member States propose to introduce the definition of “natural identical flavouring substances”.

If only the two definitions of “natural flavouring substances” and “artificial flavouring substances” were to be maintained, the definition of “nature identicals” would be covered under “artificials”. This would not be justified.

We suggest the following definition for flavouring:

'flavourings' means products, not intended to be consumed as such, which are added or intended to be added to food in order to impart odour and/or taste, with exception of substances which have exclusively a sweet, a sour or a salty taste.

The definition ‘Natural flavouring complexes’ should be revised. The physical processes used should not intentionally modify the chemical nature of the components of the flavouring. It should be further clarified what traditional food preparation processes mean. The last sentence of the definition should be deleted because it appears not necessary, is not very distinct and includes smoke flavourings and thermal process flavourings.

We can not agree with the definition of 'flavouring adjuvants'. We suggest deleting this definition. It seems not necessary to cover foodstuffs (as e. g. starch used as a carrier).

3.0 GENERAL PRINCIPLES FOR THE USE OF FLAVOURINGS

3.1:

It should be declared that the use of flavourings shall not lead to intakes that are above thresholds of toxicological concern.

3.3: Should be brought in line with the definition of flavourings:

The use of flavourings is justified only where they *impart flavour and/or taste to food*, provided that such use does not deceive the consumer about the nature or quality of food.

3.4 b: should be replaced with the following:

- additives should be used in accordance with the provision under 4.0.

3.4.c: can be deleted since it is covered by 7.0.

4.0 FLAVOURING ADJUVANTS ; replace adjuvants by **ADDITIVES**

The European community and its Member States suggest replacing the whole text by the following:

"Flavourings may contain foodstuff necessary as a matrix for dissolving or diluting flavourings in food and food additives necessary for production, storage, handling and use of flavouring.

The use of additives in flavourings shall be limited to the lowest level required to guarantee the safety and quality of flavourings and to facilitate their storage.

Food additives that are used together with flavourings at levels that provide a functional effect in the finished food are additives of the food and may only be used in accordance with the provisions of the GSFA (GSFA; CODEX STAN 192-1995 Rev. 6-2005)."

5.0 SUBSTANCES OF TOXICOLOGICAL CONCERN

The European Community and its Member States are of the opinion that the elaboration of the maximum levels at codex will be very difficult, especially since in a lot of cases they concern traditional foodstuffs. The guidance should be limited to general principles about their presence in foodstuffs due to the use of flavourings or food ingredients with flavouring properties.

We suggest:

"The substances of particular toxicological concern listed in annex should not be added as such to food. Their presence in foodstuffs through the use of flavourings or food ingredients with flavouring properties should be as low as possible. The intake resulting from their presence in flavourings and food ingredients with flavouring properties should not exceed thresholds of toxicological concern."

In addition, the list should be updated to take into new scientific information on such substances: e.g. *methyleugenol, estragole, coumarin …*

The provisions of other substances in the list such as *quassine, HCN, pulegone, quinine, thujone* need careful revision.

Cocaine should be deleted from the list at all because it is a drug and not a flavouring substance and should only be consumed under medical supervision.

6.0 METHODS OF ANALYSIS

The European Community and its Member States suggest referring to methods recommended by IOFI, FIVS, ISO etc. without enumerating them.

Performance criteria for the methods of analyses could be proposed if needed.

7.0 HYGIENE

The European Community and its Member States propose to replace 7.3 as below:

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

- *should not contain micro-organisms in amounts which might represent an unacceptable risk to health when used at appropriate levels in food*
- should not contain any substance originating from micro-organisms in amounts which might represent a risk to health when used at appropriate levels in food"

8.0 LABELLING

In order to avoid misleading and confusion of the consumer, specific provisions should be introduced to inform the consumer about the source of the natural flavouring.

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

The European Community and its Member States are of the opinion that the lists of aromatic raw materials suitable for the preparation of natural flavourings should be added as an appendix to the guideline.

ANNEX A

We suggest adding the following reference to the list:

Natural sources of flavourings, Council of Europe, July 2000.

NEW ZEALAND

The New Zealand Government would like to make the following comments:

We propose that the use of the word 'fortify'in the **Section 2.0 Definitions 1a Flavourings** is changed to 'strengthen'. The rationale for this is that nutritionally, 'fortify' means to add vitamins and minerals to a food product, and where this use has no nutritional benefit.

We suggest that the word 'torrefaction'in **section 2.0 Definitions 1ai1 Natural flavouring substances** is changed to 'roasting' or a more commonly understood term.

We propose that alternative wording is found for 'biologically active substance' in **Section 5.0 substances of toxicological concern** and suggest the term 'natural toxicant' be used. Whilst this term was used in the Codex Guidelines CAC/GL 29-1987 "General Requirements for Natural Flavourings" other associations are now in use for biologically active substances. In New Zealand biologically active substance is seen as a positive term. A draft variation to the Australia New Zealand Food Standards Code defines a biologically active substance as 'a substance, other than a nutrient, with which health effects are associated.'

The table in **Section 5.0 substances of toxicological concern** has been taken from CAC/GL 29-1987 General Requirements for Natural Flavourings and we suggest it is timely to review the contents of the table. For example, we would suggest the following change - in the 'Exceptions' column for Quinine add '100 mg/kg in non alcoholic tonic drinks, bitter drinks and quinine drinks'. Quinine is used in carbonated tonic water in New Zealand and Australia. The table would read better with a few minor formatting changes In the 'Exceptions' column the level for each product should be on a new line. A carriage return after the word 'beverages' in the lines for Pulegone and Quinine would achieve this.

UNITED STATES

This responds to CX/FAC 06/38/12 (December 2005) requesting comments on the "Discussion Paper on the Development of Guidelines for Flavouring Agents." The United States of America appreciates the opportunity to provide the following comments for consideration at the 38th Session of the Codex Committee on Food Additives and Contaminants (CCFAC).

The United States is in full agreement with the decision at the 37th CCFAC to move forward and propose new work on the elaboration of a Codex Guideline for the Use of Flavourings. We agree that the principles for the safe use of flavourings should be similar to those elaborated for food additives in the Preamble of the Codex General Standard for Food additives, with a reference to the evaluation of flavouring substances completed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The new work is consistent with Codex objectives by providing advice to governments on the safe use of flavourings in food and thereby contributing to human health and fair trade practices for foodstuffs.

Comments on Appendix I –Proposal for New Work

The United States is satisfied that the proposed project document adequately addresses the elements listed in the Procedural Manual of the Codex Alimentarius Commission (14th ed, pp. 20-21).

We have one comment, however, with respect to item 4d (Work already undertaken by other international organizations in this field). We believe it is preferable to reference JECFA as the sole international body to have performed work in the field. By referencing the Korean Food and Drug Administration and the European Food Safety Authority, the document does a disservice to other Codex members that have also been engaged in performing safety assessments for flavouring substances. We wish to propose alternative wording for item 4d for consideration by the CCFAC: "Safety assessments for over 1600 chemically defined flavouring substances have been completed by JECFA."

Comments on Appendix II – Codex Guideline for the Use of Flavourings

1.0 SCOPE and TITLE

The term "flavourings," as defined in Section 2.0 (a), excludes substances that are "flavouring adjuvants," which is defined in Section 2 (b). We recommend that CCFAC consider amending the title and scope to refer to both flavourings and flavouring adjuvants. The guideline will then limit flavouring adjuvants to those that have been evaluated by JECFA.

2.0 DEFINITIONS

In general, the United States is satisfied with the proposed definitions. However, we would like to propose the following:

- CCFAC may wish to consider replacing the terms "natural flavouring substance(s)" and "artificial flavourings substance(s)" by "natural flavour(s)" and "artificial flavour(s)," respectively, or at least agree to the latter terms as alternatives. We believe that the former terms are awkward and longer than necessary. Although we recognize that the term "flavour" has been defined from a phenomenological point of view, we believe that no confusion would arise as long as the word "flavour" is used with a modifying adjective.
- The definition for "natural flavouring substances" contains two parenthetical phrases with the word "including" starting a list of examples. We recommend changing "including" to either "for example" or "e.g.," because "including" suggests that the named processes might be overlooked if not explicitly mentioned, whereas the intention is to provide examples for the reader.
- In the first sentence of the definition for **"**natural flavouring complexes," we recommend that "flavouring constituents" should be changed to "flavouring substances" for consistency with the rest of the document.

3.0 GENERAL PRINCIPLES FOR THE USE OF FLAVOURINGS

In Section 3.4(c), we recommend that the phrase "when handling a food ingredient" be changed to "when handling any food ingredient." The difference is that the latter text recognizes flavourings as food ingredients, whereas the former does not.

5.0 SUBSTANCES OF TOXICOLOGICAL CONCERN

First, the United States observes that the scope of the guideline is clear in stating that it applies to the safe use of flavourings (and flavouring adjuvants) evaluated by JECFA. Thus, we do not see the need for Section 5 and would like the CCFAC to consider deleting this section. Moreover, we are unclear as to the basis for the maximum levels listed in the tables. Most of the listed substances appear in foods as the result of use of natural flavouring complexes. Several of the listed substances have not been considered by JECFA and others have not been allocated an ADI, following consideration by JECFA. If CCFAC determines that certain of these substances need evaluation for safety, CCFAC should place these substances, with their parent natural flavouring complexes, on its priority list for evaluation by JECFA.

Second, the United States wishes to take this opportunity to comment on the reference to the concept of "thresholds of toxicological concern" (TTC) in this guideline. The second sentence in this section refers to TTC that are to be compared to estimated intakes of suspect substances that could be present in flavourings (i.e., flavouring substances and natural flavouring complexes). We infer the second sentence to mean that the establishment of thresholds, i.e., levels of intakes below which no significant risks to health can be anticipated, even in the absence of toxicological data for the substance of concern, would fall to CCFAC. The United States believes that the establishment of such TTC is better left to JECFA, as part of its safety and risk assessments. Further, given that flavourings are evaluated for safety by JECFA and the presence of toxicants in flavourings is expected to be addressed in the JECFA evaluations, we believe that the first two sentences of this Section are inappropriate for this guideline.

6.0 METHODS OF ANALYSIS

Should the CCFAC agree to remove Section 5 from this guideline, it would follow that this Section 6 should also be removed.

7.0 HYGIENE

The first sentence of Sections 7.1, 7.2, and 7.3 should refer to flavourings and flavouring adjuvants.

8.0 LABELING

The first and second sentences should refer to flavourings and flavouring adjuvants.

9.0 SPECIFICATIONS FOR IDENTITY AND PURITY

Reference should be to flavourings and flavouring adjuvants.

10.0 REFERENCE TO THE EVALUATIONS OF FLAVOURING SUBSTANCES COMPLETED BY JECFA

The title and first sentence should refer to flavourings and flavouring adjuvants. The last sentence should refer to natural flavouring substances, rather than natural flavourings.

ICBA

The International Council of Beverages Associations (ICBA) is a nongovernmental organization that represents the interests of the worldwide non-alcoholic beverage industry. The members of ICBA operate in more than 200 countries and produce, distribute, and sell a variety of non-alcoholic beverages, including carbonated soft drinks and non-carbonated beverages such as juice-based drinks, bottled waters, and ready-to-drink coffees and teas. ICBA members also manufacture and package fruit juices and nectars. ICBA is pleased to provide comments on the *Discussion Paper on the Development of Guidelines for Flavouring Agents* (CX/FAC 06/38/12).

ICBA participated in the electronic working group and supports forwarding the project document for starting new work (Appendix I) to the Codex Alimentarius Commission. We offer the following comments on the specific questions raised in the discussion paper:

i) the overall structure and completeness of the guideline (Appendix II)

We agree with the proposed structure.

ii) the completeness and relevance of the definitions (Appendix II, Section 2.0)

We believe that the current definitions may require some further modification. For example, chemically defined substances that are identified naturally but not obtained from natural products fit neither "natural" nor "artificial" categories as defined in the document.

iii) the section relating to General Principles for the Safe Use of Flavourings (Appendix II, Section 3.0)

In general, we agree with the section as written. However, we have a concern that the sentence in 3.1 "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" could potentially be misinterpreted to mean that only those agents evaluated by JECFA are acceptable. While JECFA has evaluated a large number of flavouring substances, it only recently began to address natural flavour complexes. It should be made clear that all flavours evaluated by experts should be allowed in foods. This would avoid any potential misinterpretation.

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

We would prefer maintaining maximum levels since they are helpful for the manufacturers and provide regulatory harmonization.

v) The section relating to Methods of Analysis (Appendix II, Section 6.0)

The methods section requires a thorough review and update by experts in flavour analysis.

vi) The references to lists of aromatic raw materials suitable for the preparation of flavourings (Appendix II, Annex A)

We have no comments on the references except that Appendix A may require updating.

ICBA suggests that the guidelines (Appendix II) document, based on comments received, be further worked by the electronic working group and then circulated for comments at Step 3 after the Commission has agreed on the proposed new work.

ICBA expresses its wish to continue to serve as a member of the electronic working group.

ICGA

The International Chewing Gum Association (ICGA) represents the interests of the international chewing gum industry (chewing gum and gum base manufacturers and marketing organisations) and ensures that chewing gum and gum base products produced by its members are safe, wholesome and fulfil the highest quality standards wherever in the world they are manufactured and sold. It welcomes the opportunity to express its general support to the proposed 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, as outlined in Appendix 1 to Discussion Paper CX/FAC 06/38/12.

The ICGA will fully contribute to the work of the Committee in the elaboration of those Guidelines, once this new work has eventually been approved by the Codex Alimentarius Commission.

IOFI

The International Organization of the Flavor Industry (IOFI) is a nongovernmental organization representing the interests of the global flavor industry.

IOFI is an association of national/regional associations with membership in virtually any country in the world that produces, distributes and sells flavourings to the food industry.

On behalf of the International Organization of the Flavor Industry, I am pleased to provide comments on the Discussion Paper on the Development of Guidelines for Flavouring Agents (CX/FAC 06/38/12).

IOFI participated in the electronic working group assigned to the development of the discussion paper. IOFI strongly supports forwarding the project document for starting new work (Appendix I) to the Codex Alimentarius Commission.

In response to the set of specific questions provided in point 6 of CX/FAC 06/38/12, we would like to offer the following comments:

1) The overall structure and completeness of the guideline (Appendix II);

IOFI agrees with the proposed structure.

2) The completeness and relevance of the definitions (Appendix II, Section 2.0);

As presented, we recommend that the definitions be reviewed. Feedback from the membership indicates that, e.g., the current description of flavouring substances, including natural and artificial flavouring substances, is potentially leading to confusion regarding the status of flavouring substances that are still widely recognized as “nature-identical” in various regions.

3) The section relating to General Principles for the Safe Use of Flavourings (Appendix II, Section 3.0);

   Overall we agree with the section as presented. However, members have raised the concern that 3.1, "Flavourings that have been evaluated by JECFA to present no safety concern at current estimated levels of intake, or that have JECFA ADIs, are acceptable for use in food", could be potentially misread to indicate that ONLY those agents evaluated by JECFA are acceptable. In the view that many more materials need to be evaluated by JECFA and that JECFA only began to address the evaluation of natural flavour complexes recently, it should be made clear that flavourings that were not yet reviewed by JECFA should be allowed in foods, provided these were evaluated by experts.

4) 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;

   A general statement that levels should not exceed thresholds of toxicological concern is appropriate. However, this statement may not be easily understood. Therefore at this stage it may be simpler for industry and enforcement agencies to maintain maximum levels as currently presented in CAC/GL 29-1987. The maximum levels should be reviewed in the light of scientific progress.

5) The section relating to Methods of Analysis (Appendix II, Section 6.0);

   There is general agreement within IOFI that the methods need updating. IOFI would recommend that these methods also be replaced by general methods for the analysis of flavourings such as already available from IOFI or that are under development within IOFI for this purpose.

6) The references to lists of aromatic raw materials suitable for the preparation of flavourings (appendix II, Annex A)

   IOFI is in agreement to have such a list. However, the list as presented may require updating.

IOFI suggests that the guidelines (Appendix II) document be further worked by the electronic working group, based on comments received and then circulated for comments at the Step 3 after the Codex Alimentarius Commission has agreed on the proposed new work.

IOFI expresses the wish to continue to serve as a member of the electronic working group.