

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 6

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

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GUIDELINES FOR THE USE OF FLAVOURINGS (N03-2006)

COMMENTS AT STEP 6 AND AT STEP 3

(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:

Norway and United States of America

Norway:

Norway would like to thank the Working Group and especially the US delegation for the extensive work on the proposed draft guidelines for the use of flavourings.

Section 4

Originally Norway supported that Section 4 should include substances that become components of food only as a result of their presence in natural flavouring complexes. This has now been broadened as also flavouring substances are included. Norway conditionally supports this approach, providing some amendments to the texts that clarify the difference in nature of these two components of food which require specific recommendations.

Flavouring substances are intentionally added to food. Substances that are naturally occurring toxicants in certain natural flavouring complexes are not intentionally added to food. The latter should in general not be added to food as such in order to minimize the potential hazard to health that these may constitute. The latter should also be distinguished from flavouring that have and ADI and are part of natural flavouring complexes.

JECFA evaluations may identify the need for risk management for both these types of substances. For governments and industry it might increase the user friendliness to have the specific recommendations in a single annex.

We propose the following addition to 4.1 to clarify the difference between these two substances, proposals are in bold or ~~strikethrough~~:

“4.1. Some flavouring substances, and **naturally occurring toxicants** ~~substances~~ that may be components of natural flavouring complexes 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 the health **of the consumer. Naturally occurring toxicants for which JECFA cannot establish an ADI should not be added directly to food.** Annex A contains a list of such substances with associated acceptable maximum limits or other risk management measures. The presence of these substances

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/**naturally occurring toxicant** has been evaluated by JECFA as a flavouring substance and/or as a component of natural flavouring complex of 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 substance/**naturally occurring toxicant** 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 the 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 sources does not exceed JECFA’s numerical ADI. **Whenever JECFA cannot establish a numerical ADI for a naturally occurring toxicant it should not be added to food as such. The use of the natural flavouring complex should be so that the intake of the naturally occurring toxicant is as low as reasonably achievable. The establishment of a maximum limit should take into account the need to protect human health and at the same time their unavoidable presence in traditional foods and source materials;**

d) A reference to a validated analytical method for the determination of the substance/**naturally occurring toxicant** in food is available. Methods of analysis should comply with the Principles for the Establishment of Codex Methods of Analysis (CAC Procedural manual, ~~15th~~ **17th** Edition, p. ~~71~~ **73**) and should be endorsed by the Codex committee on Methods of Analysis and Sampling (CCMAS). **In the absence of methods endorsed by the CCMAS methods for determination of the substance/naturally occurring toxicant in food should comply with internationally recognised rules or protocols or with other methods fit for the intended purpose or developed in accordance with scientific protocols.**

Annex A

Norway supports that the entry in annex A should be based on objective criteria and the results of JECFA evaluations.

Annex B

Norway supports a list of aromatic raw materials suitable for the preparation of flavourings. The purpose of this document is to provide manufacturers as well as National authorities with guidance to the safe use of flavourings. A list of raw materials will add useful guidance to manufacturers as well and will in our opinion contribute to a comprehensive Guideline. Such a list will have to be dynamic and must be maintained and regularly updated.

However, at current CCFA should focus on its main objective: to finish the General Standard for Food Additives. It might therefore be prudent for the time being to not include Annex B. Norway proposes that the 40th CCFA considers discontinuing work on Annex B for the time being, but includes an intention in the Alinorm to revise this subject as soon as the GSFA is finished.

United States of America:

This responds to CX/FA 08/40/8 (December 2007) which requests comments at Step 3 on Section 4 and Annexes A and B of the Codex Draft *Guidelines for the Use of Flavourings*. The United States of America appreciates the opportunity to provide the following comments for consideration at the forthcoming 40th Session of the Codex Committee on Food Additives (CCFA).

The current proposed draft Section 4 and Annex A is intended to revise and update the list of “Biologically Active Substances” found in CAC/GL 29-1987 *General Requirements for Natural Flavourings*. The proposed draft Annex A provides for a list of such substances, along with specific risk management recommendations and methods of determination, while the proposed draft Section 4 provides the criteria for inclusion in the list of Annex A. It is proposed that the list in Annex A remain empty until the criteria for inclusion are adopted and substances are identified that meet the criteria.

The United States offers the following general comment on Section 4 and Annex A of the Draft *Guidelines for the Use of Flavourings*, Section 4 and Annex A.

The list in CAC/GL 29-1987 contains substances that are used as flavourings and substances that are naturally-occurring toxicants that are constituents of natural flavouring complexes or other food ingredients with flavouring properties (e.g., herbs and spices). Some of the substances in the list have been evaluated by JECFA for use as flavouring substances, while others have not been evaluated by JECFA.

Although the United States does not see an immediate need to include the proposed draft Section 4 and Annex A in the Codex Draft *Guidelines for the Use of Flavourings* at this time, we recognize that other members of the electronic working group strongly supported the inclusion of these sections. The United States supports the Codex Alimentarius Commission establishing risk management measures based on JECFA's risk assessment. Consequently, the United States considers that the reference to JECFA's risk assessments in Section 7 of the Draft *Guidelines for the Use of Flavourings* is sufficient and Section 4 and Annexes A and B are unnecessary at this time.

In addition, we note that any Codex risk management measure established to manage risks due to substances that are flavors or naturally-occurring constituents in natural flavoring complexes or other food ingredients with flavoring properties may require consultation with the Codex Committee on Contaminants in Food (CCCF).

If the Committee supports the inclusion of the proposed draft Section 4 and Annex A in the draft guideline, the United States offers the following specific suggestions:

1. The first sentence in the proposed subsection 4.1, states that "*Some flavouring substances . . . have been identified to be of potential health concern by JECFA.*" Since the Table in Annex A is proposed to remain empty until the criteria for inclusion are adopted and substances that meet such criteria are identified, we suggest revising this sentence to read "*Some flavouring substances . . . **may be** identified to be of potential health concern by JECFA.*"
2. Item b) in the proposed subsection 4.2 states "*. . . or its presence in a component of a natural flavouring complex . . .*". We suggest revising to state "*. . . or its presence **as** a component of a natural flavouring complex . . .*"
3. Item d) in the proposed subsection 4.2 indicates the need for a validated analytical method for the determination of the substances listed in Annex A. However, depending on the nature of the risk management measure, such a method of analysis may not be necessary. For example, if the Committee agrees that a potential risk may be managed through labeling, or by restricting use in specific types of foods, there may be no need to quantify the substance in specific foods. The United States suggests that the first sentence in this item be revised to read "*A reference to a validated analytical method for the determination of the substance in food is available **to support proposed risk management measure (e.g., maximum use levels).***"

Finally, the United States notes that if the Committee agrees to eliminate Annex B *References to Lists of Aromatic Raw Materials Suitable for the Preparation of Flavourings*, as recommended in CX/FA 08/40/8, then Section 8 of the draft guideline, which references Annex B, would also need to be eliminated as a consequence.