

# codex alimentarius commission



FOOD AND AGRICULTURE  
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**Agenda Item 8**

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## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX COMMITTEE ON FOOD ADDITIVES**

**Thirty-ninth Session**

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#### **COMMENTS ON THE PROPOSED DRAFT GUIDELINES FOR THE USE OF FLAVOURINGS**

**(Comments at Step 3)**

The following comments have been received from the following Codex Members and observers: European Community, Republic of Korea, Mexico, Norway, Switzerland and United States of America

This document contains late submissions of comments received after the deadline, but those were submitted before 12 April 2007.

#### **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 been done. The legislation on flavourings is currently under revision in the EC. However the ECMS wish to make the following preliminary comments:

##### **General Comments**

The ECMS agree that the list of biological active substances should be reviewed. The list of substances as well as the maximum levels in certain food categories should take into account the latest scientific evaluations. The Scientific Committee on Food (SCF) and the European Food Safety Authority (EFSA) have recently adopted opinions on most of those substances. These opinions can be used as guidance (see Annex).

The basic approach for the substances in the Annex A is that, because of their toxicological concern, they should not be added as such to food. Biological active substances can only be tolerated because they are present in "natural flavouring complexes" or in food ingredients with flavouring properties. It is therefore not acceptable that biological active substances would also consist of flavouring substances.

The ECMS do not agree that the list should contain substances because they are member of a class of related substances that could raise similar toxicological concern. This is unclear and may lead to a wide-ranging list which is not scientifically based.

The ECMS prefer a list which pays special attention to the substances of real, proven toxicological concern and to categories of food that contribute most to the intake.

Concerning the methods of analyses in Annex A the ECMS support the general principle that they should comply with internationally recognized rules or protocols or with other methods fit for the intended purpose or developed in accordance with scientific protocols. We furthermore consider the list with general methods of analysis as informative and not exclusive.

## Specific comments

### 1.0 SCOPE

The ECMS regret that the guidelines do not recognise the work done by other authorities using the same methodology and having the same expertise as JECFA. We suggest that the guidelines should also refer to substances that have been evaluated by others and that in the future may be endorsed by JECFA. A systematic re-evaluation of these substances would be a waste of resources.

The ECMS therefore suggest that JECFA should be requested to provide specific guidelines for the evaluation of flavourings. This would allow JECFA to endorse substances without need for a systematic re-evaluation.

The EC can not accept substances considered safe by JECFA on the sole basis that their estimated intake is lower than 1,5 µg per person per day (step B5 of the evaluation procedure).

JECFA has undertaken additional work in order to estimate dietary exposure to flavourings (using a method based on used levels in addition to the estimations based on named MSDI (see 67th session in Rome 20-29th June 2006). Conclusions of these additional works should be taken into account.

### 2.0 DEFINITIONS

#### 2.2 Flavourings

We suggest the following changes:

Flavourings are products that are added to food to impart or modify the flavour of food. ~~rather-They should not be used~~ to enhance nutritional quality or to fulfil 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, among others, consist of flavouring substances, natural flavouring complexes, smoke flavourings and may contain none flavouring food ingredients (see section 2.2.4) within the conditions as referred to in point 3.5. ~~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

We suggest the following change:

Flavouring substances are chemically-defined substances. They include substances either formed by chemical synthesis, or natural flavouring substances obtained from materials obtained from materials of plant or animal origin.

##### 2.2.2.1 Natural flavouring substances

We suggest adding at the end:

The flavouring substances must have been identified in these materials.

#### Natural flavouring complexes:

The last sentence should be deleted: "~~Natural flavouring complexes include the essential oil, essence, or extractive, protein hydrolysate, distillate, or any product of roasting, heating, or enzymolysis~~"

#### Smoke flavourings

We do not agree with the definition of smoke flavouring which is too descriptive and allows further processing of the condensed smoke. We therefore suggest:

Smoke flavourings are complex mixtures of components of smoke obtained by subjecting untreated ~~hard~~ woods 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 followed by condensation and purification by physical processes (such as decantation, filtration...) of the smoke obtained. The major flavouring principles of smoke flavourings are carboxylic acids, compounds with carbonyl groups and phenolic compounds.

**Non food flavouring ingredient:** We prefer to place this under heading 2.3 and not 2.2.4 since this does not concern a category of flavourings.

#### 4: BIOLOGICAL ACTIVE SUBSTANCES

We suggest to insert: "Biologically active substances are substances naturally occurring in materials of vegetable or animal origin and identified to be of toxicological concern. They thus can be present (...)."

The second part of the second sentence in Chapter 4.0 Biologically Active Substances should read "with the exception of quinine and ~~caffeine~~ ~~quassine~~." Caffeine like quinine is added directly to food as flavouring. Quassine on the contrary should not be added directly to food because of its antifertility activity<sup>1</sup>.

It could also be discussed if quinine and caffeine could be deleted from the list in Annex A and evaluated as flavouring substances (e.g. with certain restrictions). The ECMS also question the inclusion of cocaine in the list of Annex A as this substance is a drug and not a flavouring. Addition of cocaine to food is not allowed anyway.

The ECMS are also of the opinion that Capsaicin and Menthofuran should not be added as such to food.

##### Annex: Scientific opinions on Biological Active Substances

- **4-Allyl-1,2-dimethoxybenzene (methyleugenol)** (SCF, September 2001):  
[http://ec.europa.eu/food/fs/sc/scf/out102\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out102_en.pdf)
- **1-Allyl-3,4- methylene dioxy benzene (safrole)** (SCF, December 2001):  
[http://ec.europa.eu/food/fs/sc/scf/out116\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out116_en.pdf)
- **1-Allyl-4-methoxybenzene (estragole)** (SCF, September 2001):  
[http://ec.europa.eu/food/fs/sc/scf/out104\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out104_en.pdf)
- **Beta-Asarone** (SCF, December 2001): [http://ec.europa.eu/food/fs/sc/scf/out111\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out111_en.pdf)
- **Capsaicin** (SCF, February 2002):  
[http://ec.europa.eu/food/fs/sc/scf/out120\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out120_en.pdf)
- **Coumarin** (EFSA, October 2004): [http://www.efsa.europa.eu/en/science/afc/afc\\_opinions/726.html](http://www.efsa.europa.eu/en/science/afc/afc_opinions/726.html)
- **Hypericin and extracts of Hypericum sp.** (SCF, December 2001):  
[http://ec.europa.eu/food/fs/sc/scf/out113\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out113_en.pdf)
- **Hydrocyanic acid, minutes' statement** (EFSA, October 2004):  
[http://www.efsa.europa.eu/en/science/afc/afc\\_opinions/698.html](http://www.efsa.europa.eu/en/science/afc/afc_opinions/698.html)
- **Menthofuran** (SCF, July 2002): [http://ec.europa.eu/food/fs/sc/scf/out133\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out133_en.pdf)
- **Pulegone** (SCF, July 2002):  
[http://ec.europa.eu/food/fs/sc/scf/out133\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out133_en.pdf)
- **Quassin** (SCF, July 2002):  
[http://ec.europa.eu/food/fs/sc/scf/out134\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out134_en.pdf)
- **Teucrin A** (SCF, March 2003):  
[http://ec.europa.eu/food/fs/sc/scf/out173\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out173_en.pdf)
- **Thujone** (SCF, December 2002): [http://ec.europa.eu/food/fs/sc/scf/out162\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out162_en.pdf)
- **Isosafrole** (SCF, April 2004):  
[http://ec.europa.eu/food/fs/sc/scf/out188\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out188_en.pdf)

<sup>1</sup> Opinion of the Scientific Committee on food on Quassine (expressed on 2 July 2002):  
[http://ec.europa.eu/food/fs/sc/scf/out134\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out134_en.pdf)

## **Republic of Korea**

The Republic of Korea is pleased to provide the following comments on proposed draft guidelines for the use of flavourings.

Generally, the Republic of Korea is content with the proposed draft guidelines presented in CX/FA 07/39/12 and wishes to suggest following comments to clarify the definition of flavorings and biological active substance in the Session 2.0 and Session 4.0:

### **2.0 DEFINITIONS**

The scope of the flavourings in this guideline should be limited to flavourings for the appropriate use of flavourings. Therefore, we suggest that in Section 2.0, 2.2.4 Non-flavouring food ingredients, which is not related with flavourings, is should be deleted. Under regulations of Republic of Korea, non-flavouring food ingredients are not included in the scope of flavourings. In principle, we control non-flavouring food ingredients as the subgroup of food additives.

### **4.0 BIOLOGICALLY ACTIVE SUBSTANCES**

In section 4.0, we suggest that caffeine should be deleted in Annex A. In general, caffeine is used as flavourings that directly add to food.

## **Mexico**

México agradece la oportunidad de hacer comentarios a **CX/FA/07/39/12 ANTEPROYECTO DE DIRECTRIZ PARA EL USO DE AROMATIZANTES (N03-2006)** respecto a la petición de observaciones con relación a:

- 1. La estructura general y la exhaustividad de la directriz (Apéndice I);**
- 2. La exhaustividad y pertinencia de las definiciones (Apéndice I, sección 2.0); y**
- 3 Las referencias a listas de materias primas aromáticas aptas para la preparación de losaromatizantes (Apéndice I, Anexo B).**

### **2.0 DEFINICIONES**

**2.1 Aroma** es la suma de aquellas características de cualquier material que se toma en la boca, percibidas principalmente por los sentidos del gusto y el olfato, y también por los receptores generales del dolor y el tacto de la boca, según los recibe e interpreta el cerebro. La percepción del sabor es una propiedad de los aromas.

**2.2 Aromatizantes**, son los productos que se añaden a los alimentos para impartirles o modificar su sabor, en vez de para incrementar su calidad nutricional o producir otros efectos tecnológicos. Los aromatizantes no incluyen las sustancias que tienen un sabor exclusivamente dulce, amargo o salado (**por ejemplo, el azúcar, el vinagre y la sal de mesa**). Los aromatizantes pueden ser sustancias aromatizantes, compuestos aromatizantes naturales o aromatizantes para dar sabor ahumado, y pueden contener ingredientes de alimentos no aromatizantes (sección 2.2.4) que hacen compatibles los aromatizantes con los alimentos y las bebidas en los que se utilizan. Su objetivo no es su consumo como tales.

### **Comentarios a la sección 2.0 Definiciones.**

En México y algunos otros países de América Latina, los términos “sabor” (flavour), “saborizante/aromatizante” (flavouring) y “olor, aroma” (odour, aroma) se utilizan en situaciones y aplicaciones que no necesariamente estar relacionadas con sabor/aroma en el contexto de alimentos, y la traducción de “flavouring” como “aromatizante” puede desorientar en el sentido de que se puede interpretar como la percepción de olor o aroma, en cualquier contexto (incluso pero no limitándose a los alimentos), por lo que recomendamos que en la traducción del término al español, se considere traducir “flavouring” como saborizante/aromatizante y “flavour” como sabor/aroma, dado que el término “sabor” incluye ambos y aroma, por si solo, no. En atención a lo anterior, es importante señalar que tan sólo en Normas Oficiales Codex, se han encontrado cerca de 170 referencias en español al uso del término “sabor” mismo que coincide con la mayoría de los correspondientes documentos en inglés y que emplean el término “flavour”, por lo que se considera justificación suficiente para que en lo sucesivo, se contemple incluir éste término

(sabor) en los trabajos relacionados; consecuentemente y para tener consistencia con la terminología, debería reconocerse el término “saborizante” en el mismo sentido que actualmente se reconoce “aromatizante”.

### **Comentarios a la sección 2.2.1 Sustancias aromatizantes**

consideramos importante señalar que de acuerdo con varias Normas Oficiales de Productos de Codex, se reconoce el uso de “**Aromas naturales y sus equivalentes sintéticos idénticos**” (o, la denominación en inglés “Natural flavours and their **identical synthetic equivalents**”) e incluso en la [Norma General para el Etiquetado de los Alimentos Preenvasados, CODEX STAN 1, se establece bajo la sección 4.2.3.4](#) “La expresión "aroma" podrá estar calificada con los términos "naturales", "**idénticos a los naturales**", "artificiales" o con una combinación de los mismos, según corresponda.”. Con el objeto de armonizar terminología, ser exhaustivos en cuanto a definiciones se refiere y dado que una de las enmiendas propuestas a esta Directriz es la de abarcar todos los tipos de aromatizantes, México propone la inclusión del término “idéntico al natural” como una sub-clase de los saborizantes artificiales, como se detalla a continuación:

2.2.1.2.1 Sustancias saborizantes/aromatizantes sintéticas idénticas al natural: son las sustancias saborizantes/aromatizantes obtenidas por síntesis química, destinadas para consumo humano y que son equivalentes a las que ocurren de manera natural en material de origen vegetal o animal.

### **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.

Norway has some comments, and they are divided into general comments, and specific comments on each part of the document.

#### **The list of biologically active substances in Annex A**

- Norway supports a list of biologically active substances as an annex to the Codex Guideline for the Use of Flavourings.
- Norway also supports the proposal of the recommendation that the CCFA should consider to review the list 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.

In our opinion this guideline is to provide advice for safe use of flavourings and flavouring substances. Some flavouring substances are biologically active substances that may be undesirable in food from a toxicological point of view. They should, with a few exceptions, not be added to food as such.

At the same time these biologically active substances are often essential parts of a natural flavouring complex or a food, and it may not be possible to prohibit the presence of these substances in food, as this would prohibit common food ingredients such as cinnamon (coumarin) and almonds (hydrocyanic acid). Nor can they be removed from the food ingredients as they often provide a flavouring that is distinctive for that food. We find it positive that a guideline for the safe use of flavourings addresses ingredients that contain such flavouring substances, in order to provide guidance on maximum levels in food and also on which ones that may or may not be added to food as such.

#### **Overall structure and completeness of the guideline**

- Norway supports the proposed structure of the guideline.

With regard to the scope as described in section 1.0 we are not certain what is meant by the wording “...components of flavourings evaluated by ...”. However we support that these guidelines provides principles for the safe use of flavourings and flavourings containing biologically active substances that have been evaluated by JECFA.

#### **Definitions**

- Norway supports all the definitions of flavour, flavourings, flavouring substances, smoke flavouring and non-flavouring food ingredients. Norway supports that the category “nature identical flavouring substances” is left out.

- Norway also supports the definition of natural flavouring complexes and it is our understanding that this definition covers what is defined as flavouring preparations and thermal process flavourings in the European legislation.

### **General principles for the use of flavourings**

Norway would like to make a comment regarding general principles for the use of flavourings and the assessments that have been performed by JECFA. These say that the flavouring substance presents no safety concern at the current estimated levels of intake. They do not address the use levels in food. It is therefore difficult to address the safe use in food as we have no knowledge of the use, only that the current intake is not of a safety concern. The guidelines must be very general and cannot say anything about use levels except for the natural toxicants. We would like to be able to provide the governments and industry with more accurate advice, for instance what are the typical use levels of the flavouring in food that has been found to present no safety concern at the current estimated level of intake. This is not possible for the moment, but for the future it might be possible to ask JECFA to have a look at the method for evaluation of flavouring substances in order for governments to provide more accurate advice to the industry.

#### 3.5

- Norway would like to propose the following wording of 3.5.c) used in accordance with the provisions of the Codex Standard for Food Additives (GSFA; CODEX STAN 192) whenever they **provide** a technological function in the finished food.

If a substance has a technological effect in the finished food the use should be in accordance with the GSFA whether this effect is intended or not.

#### 6.0

- The reference to the Codex' standards for labelling might also include the year for clarity reading CODEX STAN 107-1981 and CODEX STAN 1- 1985 (Rev. 1991)

### **Aromatic raw materials suitable for the preparation of flavourings**

- Norway supports the proposal for a list of aromatic raw materials suitable for the preparation of flavourings.

## **Switzerland**

### **1. Proposed Draft Guidelines for the Use of Flavourings**

In the Proposed Draft Guidelines for the Use of Flavourings, reference is made to two Council of Europe publications which have so far had a high impact on the regulation of flavourings in Europe. However, the latest publication in which new limits for most of the listed active principles have been proposed has not been mentioned. The document (150 p) is available online at [http://www.coe.int/t/e/social\\_cohesion/soc-sp/public\\_health/flavouring\\_substances/Active%20principles.pdf](http://www.coe.int/t/e/social_cohesion/soc-sp/public_health/flavouring_substances/Active%20principles.pdf).

In our view, these recent flavouring evaluations should be given due consideration during the revision of the Proposed Draft Guidelines.

### **2. Annex A of the Proposed Draft Guidelines for the Use of Flavourings**

Switzerland welcomes the proposal made to maintain the concept of limiting levels of biologically active compounds (or active principles) in food and beverages in general and additionally setting limits for exceptions.

## **United States of America**

This responds to CX/FA 07/39/12 (December 2006) which requests comments for additional revisions to the Proposed 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 39<sup>th</sup> Session of the Codex Committee on Food Additives (CCFA).

Paragraph 7 of CX/FA 07/39/12 recommends that the CCFA review the list of biologically active substances in Annex A of the Guideline (Appendix I) with the view to developing specific questions for the Joint

FAO/WHO Expert Committee on Food Additives (JECFA) regarding those substances. The United States offers the following specific comments on the table of biologically active substances in Annex A of the Guideline.

The maximum limits in the table originated from the deliberations of the 10<sup>th</sup> Session of the CCFAC, and represent either limits of detection, or are based on toxicological or technological considerations. The substances in the list were not intended to be used as flavourings, but were expected to become components of food as a result of the use of natural flavouring substances. The 13<sup>th</sup> Session of the CCFAC decided to refer these substances to JECFA, and requested advice on the appropriateness of the proposed maximum limits. JECFA reviewed  $\beta$ -asarone, coumarin, estragole, methyl eugenol, safrole and isosafrole, thujones, and hydrocyanic acid in 1981. JECFA reviewed quinine in 1993 and pulegone in 2000. The conclusions of these reviews are summarized in the Annex to this comment. The other substances listed in Annex A of the proposed draft guideline (i.e., agaric acid, aloin, berberine, cocaine, hypericine, quassine, santonin, caffeine, spartein, and rue oil) have to our knowledge not been reviewed by JECFA.

The United States agrees with the recommendation (para. 7) that the substances in the table in Annex A should be referred to JECFA for review. Although JECFA has reviewed some of the substances in the table in the past, it is likely that newer data have become available in the past 25 years that would be relevant for an updated risk assessment. To that end, the United States suggests dividing the substances in the table into two groups:

- 1) Substances that may be used directly as flavouring substances; and
- 2) Substances that become components of food only because they are unavoidable constituents of natural flavouring substances.

For those substances in the first group, the United States suggests that JECFA evaluate the use of the substances using the same paradigm as the other chemically-defined flavouring substances that have already been evaluated. The substances in the second group should be referred to JECFA with a view towards obtaining advice on the appropriateness of the maximum limits in food and drink expressed in the table, and on the exceptions listed therein. Finally, the United States suggests that the safety of the substances listed in Annex A that are known to be used consistent with that described in both groups 1 and 2, above, be assessed for both types of use.

The United States agrees with the recommendation (para. 8) that the list of validated methods of analysis in Annex A should be updated. The Committee may also wish to consider an approach for regular review and updating of both the table and list of analytical methods in Annex A of the Guideline.

Paragraph 9 of CX/FA 07/39/12 requests specific comments on the Guideline (Appendix I). The United States has:

- no comment at this time on the overall structure and completeness of the Guideline (Appendix I), with the exception of the information in the table of biologically active substances (Appendix I, Annex A), which was discussed above;
- no comment at this time on the completeness and relevance of the definitions (Appendix I, Section 2.0); and
- no comment at this time on the inclusion of references to the lists of aromatic raw materials suitable for the preparation of flavourings (Appendix I, Annex B), but is of the opinion that the list of references should be updated as needed. The Committee may wish to consider an approach for regular review and updating of the information in Annex B.

Finally, the United States notes a typographical error in the title to the table in Annex A of the Guideline (Appendix I). We believe the title should read “Biologically Active Substances and Associated Methods of Analysis **for** Biologically Active Substances.”