

codex alimentarius commission



FOOD AND AGRICULTURE
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

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DISCUSSION PAPER ON FLAVOURING AGENTS

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments on the following subject matter are invited to do so **no later than 31 January 2005** as follows: Netherlands Codex Contact Point, Ministry of Agriculture, Nature and Food Quality, P.O. Box 20401, 2500 E.K., The Hague, The Netherlands (Telefax: +31.70.378.6141; E-mail: info@codexalimentarius.nl - *preferably*), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: Codex@fao.org - *preferably*).

INTRODUCTION

1. The 36th Session of the Codex Committee on Food Additives and Contaminants (CCFAC) agreed that the United States with assistance provided by the European Community, Finland, India, Italy, Japan, Norway, United Kingdom, and the International Organization of the Flavour Industry (IOFI) would prepare a discussion paper on possible options to integrate flavouring agents into the Codex system for circulation, comment and consideration at the 37th Session of the CCFAC, in view of the completion of several hundred safety evaluations of flavours by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

2. During the 36th CCFAC, the Delegation of France suggested that in view of the magnitude of this new task and the current workload of CCFAC “the drafting group address, in detail, the practical constraints that such a long-term project would face, particularly as to the updating of flavouring agents in a regular and timely manner.”

3. This paper discusses possible options for CCFAC to consider for integrating flavouring substances into the Codex Alimentarius system. Summaries of previous considerations of flavouring substances by the Codex Alimentarius Commission (CAC) and the safety assessments of flavouring substances by JECFA are also provided to add context.

BACKGROUND

Codex Definitions

4. At its 8th Session (1972), the Codex Committee on Food Additives (CCFA) endorsed the following three definitions for flavouring substances:

- a. Natural flavours and natural flavouring substances are preparations and single substances respectively, acceptable for human consumption, obtained exclusively by physical processes from vegetable, sometime animal, raw materials either in their natural state or processed, for human consumption.

- b. Nature-identical flavouring substances are substances chemically isolated from aromatic raw materials or obtained synthetically; they are chemically identical to substances present in natural products intended for human consumption, either processed or not.
- c. Artificial flavouring substances are those substances which have not yet been identified in natural products intended for human consumption, either processed or not.¹

5. The 9th Session of the CAC (1972) adopted these definitions as Codex text. The report of the 9th CAC states "...It was pointed out that the definition of "food additive," as drafted, would include certain flavouring substances which were considered by many as ingredients, and that this matter should be given special attention by the Codex Committee on Food Additives. Noting that the Codex Committee on Food Additives had considered these definitions in great detail, and also noting that they were working definitions intended for the purposes of the Codex Alimentarius, i.e., they were not intended for acceptance by governments, the Commission adopted the definitions without any amendment."²

6. In 1973 the three definitions for flavouring substances were published by the FAO and WHO Joint Secretariat in the "List of Food Additives Evaluated for Their Safety-in-Use in Food" (CAC/FAL 1-1973) and maintained in its update "Guide to the Safe Use of Food Additives (CAC/FAL 5-1979). These two Codex documents were often referenced in Codex commodity standards that contained provisions for flavourings.

7. The Codex General Standard for the Labelling of Prepackaged Foods provides for the qualification of the expression "flavours" by "natural", "nature identical" or "artificial" as appropriate.

8. The 16th CAC (1985) adopted the 'General Requirements for Natural Flavourings, which were published in 1987 as CAC/GL 29-1987. This document contains the following definitions of natural flavourings, natural flavours and natural flavouring substances, and adjuncts:

- a. Natural Flavourings are products used to impart flavour to a food or beverage – with the exceptions of only salty, sweet or acid tastes. Their aromatic part consists exclusively of "natural flavours" and/or "natural flavouring substances" and they may or may not contain adjuncts. They are not intended to be consumed as such.
- b. Natural flavours and natural flavouring substances are preparations and single substances respectively, acceptable for human consumption, obtained exclusively by physical, microbial or enzymatic processes from material of vegetable or animal origin either in the raw state or after processing for human consumption by traditional food preparation processes (including drying, roasting and fermentation).
- c. Adjuncts are foodstuffs and food additives which are essential in the manufacture and use of "natural flavourings".

CAC/GL 29-1987 also contains information on biologically active substances with recommendations on use. The CAC expressed the view that this advisory text might provide useful checklists of requirements for national food control or enforcement authorities.

9. Volume XIV ("Food Additives") of the first edition (1983) of the Codex Alimentarius (blue volume series) maintained the three definitions for flavouring substances adopted by the 9th CAC. However, when the Codex Alimentarius was updated (yellow volume series), the three definitions were inadvertently omitted from Section 2 of Volume 1A on definitions. As these definitions are important, they should be included in the definition section of the Codex Alimentarius.

Prior Endorsements of Flavouring Substances by the CCFAC

10. The CCFAC is charged with endorsing permitted maximum or guideline levels for individual food additives, including flavouring agents. At its 3rd Session the CCFA (1966) recognized the need for a Codex procedure for the elaboration of provisions for the use of flavouring agents.³

¹ ALINORM 71/12, para. 59

² ALINORM 72/35, para. 294

³ ALINORM CCFA/3/66

11. Flavourings, including natural flavours and their natural synthetic equivalents have been either endorsed or temporarily endorsed by referencing the definitions for these two classes adopted by the 9th CAC (See paragraph 4, above). There are a few exceptions whereby a single natural flavouring substance or an artificial flavouring substance has been endorsed. Examples of single artificial flavouring substances or named natural flavourings that have been endorsed are vanilla extract, ethyl vanillin, vanillin, mint oil, cherry laurel oil, bitter almond oil, natural cinnamon flavour and smoke flavourings.

12. A brief chronology of the consideration of flavouring substances by the CCFA/CCFAC is given in Annex 1.

Establishing Safe Conditions for use of Flavours

13. Flavourings or flavouring substances are added to food to impart aroma or taste. Like other food additives their use should not present an unacceptable risk to human health and should not mislead consumers. The quantity added to foods should be at the lowest level necessary to achieve the intended flavouring effect. Flavours and flavouring substances should also be of appropriate food grade quality; and be prepared and handled in the same way as a food ingredient.

JECFA's Safety Assessments

14. Between 1956 and 1991, JECFA evaluated the safety in use of less than one hundred flavouring substances- those that could be included in Codex commodity standards. In 1996 JECFA began the systematic evaluation of chemically-defined flavours and has now evaluated nearly 1500. In addition, JECFA's specifications of identity and purity for these substances have been systematically presented to CCFAC for review and recommendation for adoption by the CAC as Codex advisory specifications. It is anticipated that by 2005 over 1600 chemically defined flavours will have been evaluated by JECFA. The JECFA is currently developing a procedure to evaluate natural flavouring complexes. Intake assessment is an integral part of the JECFA safety evaluation of all flavouring substances. Because JECFA has established a "no safety concern" status at estimated levels of intake at a certain time, for nearly all of the 1500 chemically-defined flavouring substances and established JECFA numbers for easy reference and electronic sorting, the CCFAC has now agreed that the time is ripe to discuss options for integrating into the Codex system the flavouring substances reviewed by JECFA. The evolution of JECFA's systematic approach to the safety evaluation of chemically defined flavours is summarized in Annex 2.

Need for a Codex Standard for Flavouring Substances

15. Current conditions in the global marketplace are such that there is a lack of uniformity in the safety evaluation and regulation of flavourings among different countries and continents. This presents significant non-tariff barriers to the free movement of foods. Their large numbers and widespread use in foodstuffs along with the lack of harmonized lists of safe flavouring substances in most countries sets the stage for disruptions in international food trade. National authorities are hampered by the lack of readily available international standards for the use of flavouring substances. Many customs and other declarations of the use of flavouring substances are required due to the lack of an international standard. If Codex were to elaborate a standard establishing safe conditions of use for flavouring substances and flavourings, this impediment to international trade would be alleviated. In addition, since JECFA has completed its safety evaluation of a significant number of chemically defined flavouring substances it is appropriate for CCFAC to consider incorporating them into the Codex system.

Options

16. The following are proposed as alternative options for consideration by the 37th CCFAC. The option chosen by Codex should be one that allows for the timely integration of flavouring substances into the Codex Alimentarius. Consideration should also be given toward efficient updating of the positive list of safe flavouring substances.

Option 1: Postpone further discussions until JECFA has completed the evaluation of the majority of the chemically defined and the natural flavouring complexes and continue the current practice of endorsing flavouring substances in Codex commodity standards by referencing the definitions adopted by the Commission at its 9th and 16th Sessions.

Option 2: Begin new work on the elaboration of a Codex General Standard for the use of Flavouring Substances. This general standard would establish safe conditions of use for flavouring substances similar to the principles for the safe use of food additives contained in the Preamble of the Codex General Standard for Food Additives (GSFA). It would also contain a positive list of flavouring substances and natural complexes evaluated by JECFA. These lists would be updated by the CCFAC as appropriate in response to evaluations by JECFA.

Option 3: Begin new work on the incorporation of flavouring substances and natural flavouring complexes evaluated by JECFA into the GSFA. This could be accomplished by revising the Preamble of the GSFA as appropriate and adding a new table with a positive list of flavouring substances in a format similar to the current Table 3 of the GSFA.

Option 4: Begin new work on the elaboration of a Codex Guideline for the Use of Flavouring Substances and Natural Flavouring Complexes that establishes safe conditions of use for flavouring substances and natural flavouring complexes in foods similar to the principles for the safe use of food additives contained in the Preamble of the Codex General Standard for Food Additives (GSFA) and with a reference to the evaluations completed by JECFA.

Option 5: Begin new work on revising the Preamble to the GSFA to establish safe conditions of use for flavouring substances and natural flavouring complexes in foods with a reference to the evaluations completed by JECFA.

17. Option 1 would not require the CCFAC to expend any significant resources; however, this option disregards the urgency of providing recommendations to member countries that have no safety evaluation process in place or regulations for use of flavourings.

18. Options 2 and 3 would require the CCFAC to develop text establishing safe conditions of use for flavouring substances and the establishment and maintenance of a Codex positive list of flavouring substances. Considering the large number of agents evaluated at each JECFA meeting, this could create a significant time gap between decision and execution. Either of these options would require the CCFAC to commit significant resources over several years. Option 2 would likely be more burdensome in terms of resource expenditures.

19. Options 4 and 5 would require the CCFAC to develop text establishing safe conditions of use for flavouring substances. These options do not require that CCFAC establish and maintain a positive list of flavouring substances. These options would provide Codex with the greatest flexibility to maintain and regularly update an open positive list of flavouring substances. Additionally, since Codex has already established definitions for flavouring substances, option 5 may present the most efficient pathway to establish safe conditions for use of flavouring substances within the Codex system. Work on implementing either of these options should be completed by CCFAC in less than 5 years.

RECOMMENDATIONS

20. The CCFAC should request that the Codex Secretariat publish the definitions for natural flavours; natural flavours and natural flavouring substances; nature-identical flavouring substances; and artificial flavouring substances as adopted by the 9th CAC in the next revision of Section 2 of Volume 1A of the Codex Alimentarius.

21. The CCFAC should endorse one of the options described in paragraph 16 and identify a drafting group to prepare a project paper⁴ for new work as adopted by the 27th CAC.⁵

⁴ ALINORM 04/27/33, Appendix III

⁵ ALINORM 04/27/41

Definition of flavourings

22. The 36th session of the CCFAC has taken an initiative to look at different options to integrate flavouring agents into the Codex system. During the preparation of this discussion paper it became evident that Codex at present does not provide a definition of flavourings in general. At present several undefined terms, such as flavour, flavourings, flavouring agents and natural flavouring complexes, are used in the Codex system. In addition the definitions of flavouring substances endorsed by the Codex Commission from 1972 through 1985 are not identical. In order to facilitate current work on the integration of flavouring substances and possible future work on flavourings and other subcategories thereof, it might be useful for the CCFAC to consider establishing definitions.

RECOMMENDATION

23. The 37th CCFAC should consider establishing a working group with a mandate to develop proposals for definitions of flavourings in general and subcategories thereof.

Annex 1**Discussions of Flavouring Substances by the CCFA/CCFAC**

1. At the 10th session (1975) of the CCFA, an *ad hoc* Working Group on Flavours was established specifically to address the approach that should be taken in establishing the safety of and adopting standards for the use of flavouring substances. The CCFAC regularly re-established the Working Group at each meeting until 1988. The first report of the *ad hoc* Working Group on Flavours was presented to the 11th CCFA (1977).¹ The *ad hoc* Working Group adopted a pragmatic approach to resolve the question of grouping flavouring agents, as it would provisionally not be possible to test all flavouring agents. The Working Group recommended that priority be given to:

- a) The establishment of criteria to be used for the safety evaluation of flavouring substances irrespective of their nature;
- b) The preparation of specifications on chemical purity of artificial and nature-identical flavouring substances; and
- c) The toxicological evaluation of artificial flavouring substances, in order to establish a positive and open list of these additives.

2. Of particular interest at the 11th CCFA meeting (1977) was the JECFA Secretariat's report on the findings of the 20th meeting of JECFA, which had also discussed the question of priorities for the evaluation of flavouring substances. JECFA recommended that the best approach to the question would be to compile lists of the various flavouring substances and to estimate the likely degree of human exposure to each of them. The substances would then be classified in terms of possible health hazard and priorities for their evaluation would then be established; however, in the meantime CCFA could tentatively accept for use in food those substances deemed to be of a lower priority with regard to toxicological evaluation if they were listed as acceptable by bodies such as the Council of Europe (CoE) or on other acceptable advisory lists.²

3. At the 12th CCFA (1978), a priority list of flavouring substances pending JECFA evaluation was available. Significantly, List B consisted only of artificial flavouring substances listed both by CoE number and Flavor Extract Manufacture Association (FEMA) number. It was at this meeting that the concept of a priority ranking scheme for flavouring substances pending JECFA evaluation was introduced.³

4. The 13th CCFA (1979) considered a revised list of maximum limits for certain substances having biological activity present in food, as consumed, as a result of the use of natural flavouring materials and discussed a revised list of botanicals which should not be used as a source of natural flavours or flavouring substances.⁴

5. At the 14th CCFA (1980), JECFA announced its intention to set priorities for the evaluation of flavouring substances.

6. At its 15th Session, CCFA (1982) decided to withdraw the "List of plants unsuitable as a source of natural flavours" that had been published by Codex⁵ The committee also considered whether natural flavours could be fully endorsed by separating them from nature-identical flavouring substances in Codex standards. The 15th CCFA agreed to embark on the elaboration of general specifications for natural flavours. The Committee was also informed of the publication of a manuscript⁶ that examined the relative contribution of added flavours to the daily intake of flavour components already contained in traditional foods. The relative contribution was expressed as a "consumption ratio." The Committee recognized the value of viewing intake of flavouring substances in terms of this ratio to be a valuable tool in priority setting, along with the decision tree approach.⁷

¹ ALINORM 78/12

² WHO Tech. Rep. Ser. No. 599, Chapter 4

³ ALINORM 79/12

⁴ ALINORM 79/12A

⁵ CAC/FAL 5-1979

⁶ Stofberg, J. "Consumption of flavoring materials as food ingredients and food additives." *Perfumer and Flavorist* December/January 1981.

⁷ ALINORM 83/12

7. The 16th CCFA (1983) agreed to elaborate a document on “General Requirements for Natural Flavourings.” It also noted the publication of the first volume of a series which contained quantitative data on volatile substances in food and agreed that the consumption ratio was a valuable tool in setting priorities.⁸

8. At its 17th Session (1984), CCFA made note of a draft of the “General Requirements for Natural Flavourings” and a report on 350 nature-identical substances regarding their consumption as food additives when compared to amounts of the same substance naturally present in foods. The consumption ratio, along with the consideration of molecular structure and estimated levels of human exposure were endorsed as useful in setting priorities for and screening of synthetic artificial and nature-identical flavouring substances by a group of experts. Some revisions, deletions and editorial amendments were adopted on Codex List B, but the Committee decided to retain nature-identical as well as artificial flavouring substances on the list.⁹

9. The 18th CCFA (1985) agreed to circulate at Step 3 the general requirements for natural flavourings. The Committee also agreed that the question of priority setting and consideration of flavouring substances should be undertaken by an FAO/WHO Group of Experts especially convened for this purpose.¹⁰

10. At the 19th CCFA (1987), the committee recommended the final version of the “General Requirements for Natural Flavourings” to the CAC for endorsement and publication in the appropriate Codex document as an advisory text. Significant among the requirements was the definition for natural flavours and natural flavouring substances which was expanded from the definition adopted by CAC at its 9th Session (See paragraph, 4b, above). These general requirements for natural flavourings were adopted by the CAC at its 16th Session in 1985. The 19th CCFA also agreed that the priority ranking approach¹¹ along with use of the consumption ratio¹² should be referred to JECFA for its view.¹³

11. The 20th CCFAC (1988), agreed to submit the priority ranking system to JECFA for application to the established lists of flavouring substances on the Codex List B with a request that JECFA evaluate substances with the highest priority as soon as possible. The CCFAC Working Group on flavourings was not reinstated since the Committee felt that its work had been accomplished.¹⁴

⁸ ALINORM 83/12A, para. 168

⁹ ALINORM 85/12, para 134-139.

¹⁰ ALINORM 87/12, para 162-165

¹¹ Rulis, A.M., R.L. Hall, R.A. Ford, J. Stofberg, and O.D. Easterday (1987) “A Codex Flavour Priority Ranking System”

¹² Stofberg, J and F. Grundschober (1987) “Consumption Ratio and Food Predominance of Flavoring Materials. Third Cumulative Series”

¹³ ALINORM 87/12A

¹⁴ ALINORM 89/12

Annex 2**Evolution of JECFA's Approach to the Safety Evaluation of Flavours¹**

1. At its 20th Meeting, JECFA (1976) examined the question of priorities for the evaluation of flavouring substances. At that time it recommended that the best approach to the question would be to compile lists of the various flavouring substances and to estimate the likely degree of human exposure to each of them. These substances would then be classified in terms of possible health hazard and priorities for their evaluation would be established. JECFA would relate the flavouring substances to their origin and occurrence and divide the flavouring substances into four groups. It also stressed that all flavouring substances, whether natural or not, should be evaluated for their safety. JECFA also recommended that flavouring substances should be examined through a working group in order to establish priorities for the purpose of generating data for the evaluation of flavouring substances. In the meantime, JECFA recommended to CCFA that substances deemed to be of a low priority with regard to toxicological evaluation might be tentatively accepted for use in foods, if they were listed as acceptable by bodies such as the Council of Europe or by national regulatory authorities that have carried out detailed evaluations. Priority-setting, including the decision-tree approach, resulted in the establishment of three categories of flavouring substances, which, from the point of view of safety, could serve as a screening tool for deciding which substances should be tested toxicologically.

2. JECFA and WHO have recognized several characteristics of the use and nature of flavouring substances that would be useful for developing a logical and practical means of establishing their safety.² Among these characteristics are the low and self-limiting concentrations used in foods, human data that may have a bearing on the extent of toxicity testing required and the use of data from large numbers of structurally similar compounds.

3. In 1995, the 44th JECFA considered a new approach for the safety evaluation of chemically defined flavouring substances designed to provide a means of conducting evaluations in a consistent and timely manner. The Committee recommended that the procedure should be applied to the evaluation of a number of flavouring agents belonging to different chemical classes in order to assess its utility in practice. The procedure integrates information on dietary exposure, chemical structure classes, metabolism and toxicity to assess the safety of flavouring substances under conditions of use.

4. At its 46th meeting, JECFA (1996) used the procedure considered at its 44th meeting to evaluate three groups of flavouring substances. This procedure is described in detail in Annex 5 of the toxicological monographs resulting from the 44th meeting of JECFA (1995), the 46th meeting of JECFA (1996), and the 49th meeting of JECFA (1997). The Committee noted in particular that the safety evaluation procedure is intended for flavouring agents added to food and not to other uses of these substances. The procedure is also intended to identify those flavouring substances that may require additional data for further evaluation. The procedure is not intended to be applied to flavouring substances with unresolved safety issues. The procedure is effective in reaching conclusions on the safety of individual flavour substances when groups of structurally related substances (congeneric groups) are evaluated together because congeners share in common the same chemical class, similar metabolic fate and similar patterns of exposure from their use as flavours. Since 1996, JECFA has engaged in an annual review of 150-200 flavouring agents.

5. Through 2004, JECFA has concluded that about 99% of the nearly 1500 flavouring substances submitted for its review are safe for use as flavouring agents at current levels of intake and has assigned them a "no safety concern" status. In those cases where a flavouring substance already had an ADI, it has been retained.

¹ For a more complete description of JECFA's procedure for the safety evaluation of flavours, see Forty-ninth Report of the Joint FAO/WHO Expert Committee on Food Additives WHO Technical Series No. 884, 1999.

² International Programme on Chemical Safety in cooperation with the Joint FAO/WHO Expert Committee on Food Additives. 1987. Principles for the Safety Assessment of Food Additives and Contaminants in Food, Environmental Health Criteria 70, WHO, Geneva.

Natural Flavouring Complexes

6. At its 61st meeting (2003), JECFA noted that in addition to the chemically defined natural flavouring substances, there are natural flavouring complexes obtained by physical processes, such as distillation, and expression or extraction with water or organic solvents that need to be evaluated. The Committee considered a working paper outlining a revision of the its Procedure for the Safety Evaluation of Flavouring Agents applied to chemically defined flavours that could be applied to the evaluation of natural flavour complexes. These natural flavouring complexes are similar to compounded flavours in that they are complex mixtures of many individual flavouring substances. These complexes also include essential oils, extracts and oleoresins in which many of the individual constituents have been identified.

7. At the 63rd meeting of the JECFA (2004), the committee continued its discussion on a possible approach to the safety assessment of natural flavouring complexes and defined the information required for testing the proposed revised safety evaluation procedure at a future meeting³.

³ Summary and Conclusions of the 63rd JECFA (2003).