codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS **WORLD HEALTH ORGANIZATION**

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ALINORM 95/12

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-first Session
Rome. 3-12 July 1995

REPORT OF THE 26TH SESSION OF THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

The Hague. 7-11 March 1994

(Does not include Appendix I -List of Participants)

Note: *This report incorporates Codex Circular Letter CL 1994/9-FAC.*

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CX 4/30.2 **CL 1994/9-FAC**
April 1994

TO: - Codex Contact Points
- Interested International Organizations
- Participants at the 26th Session of the Codex Committee on Food Additives and Contaminants

FROM: Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: Distribution of the Report of the Twenty-sixth Session of the Codex Committee on Food Additives and Contaminants (ALINORM 95/12)

The report of the Twenty-sixth Session of the Codex Committee on Food Additives and Contaminants is attached. It will be considered by the Twenty-first Session of the Codex Alimentarius Commission to be held in Rome from 3-12 July 1995.

PART A: MATTERS FOR ADOPTION BT THE EXECUTIVE COMMITTEE OR THE COMMISSION ARISING FROM THE TWENTY-SIXTH SESSION OF THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

The following matters will be brought to the attention of the Forty-first Session of the Executive Committee or the Twenty-first Session of the Codex Alimentarius Commission for adoption:

1. Revised Draft Preamble to the Codex General Standard for Food Additives at Step 8; paras. 31-37 and Appendix II, ALINORM 95/12.

2. Specifications for the Identity and Purity of Food Additives arising from the 41st Session of JECFA Recommended for Adoption as Codex Advisory Specifications, paras. 56-64 and Appendix IV (Categories I and II), ALINORM 95/12.

3. Amendments to the International Numbering System, paras. 65-72 and Appendix V, ALINORM 95/12.

4. Proposed Draft Preamble to the Codex General Standard for Contaminants and Toxins in Foods, paras. 95-109 and Appendix III, ALINORM 95/12.

Governments wishing to propose amendments or to comment on the above matters or any provisions there of should do so in writing in conformity with the Procedures for the Elaboration of Codex Standards and Related Texts (at Steps 5 and/or 8) (see Codex Alimentarius Procedural Manual, Eighth Edition) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, not later than 1 June 1994 (Item 4) or 1 June 1995 (Items 1-3).

PART A: REQUEST FOR COMMENTS AND INFORMATION

1. Proposed Amendments to the International Numbering System
- para. 72, ALINORM 95/12

The Committee reconfirmed that proposed amendments to the INS would be a standing agenda item for the CCFAC.

2. Proposed Amendments to the Inventory of Processing Aids
-para 75, ALINORM 95/12

The Committee agreed to continue the revision of the inventory on the basis of government comments.

3. Information on Aflatoxin Levels and Sampling Plans in all Foodstuffs - para. 126, ALINORM 95/12

   The Committee agreed to solicit government comments and information on aflatoxin levels and sampling plans in all foodstuffs.

4. Information on Ochratoxin A and Trichothecenes - para. 133, ALINORM 95/12

   The Committee agreed to collect additional information concerning ochratoxin A and Trichothecenes.

5. Information on Lead. Cadmium. PCBs. PBBs. Tetrachlorobenzyltoluene. Dioxins. Polycyclic Aromatic Hydrocarbons. Hydrogen Cyanide. Phthalates and Ethyl Carbamate in Foods - paras. 150, 154 and 156, ALINORM 95/12

   The Committee agreed to collect additional information on the above contaminants.

6. Proposals for the Priority Evaluation of Food Additives and Contaminants by JECFA - para. 168 and Appendix VI, ALINORM 95/12

   The Committee agreed to continue the solicitation of proposals for the evaluation of food additives and contaminants by JECFA.

Governments and international organizations wishing to submit comments and information on the above matters are invited to do so no later than 1 October 1994 as follows: Mrs. A. Mortensen-Van der Veen, Executive Officer for Codex Alimentarius, Ministry of Agriculture, Nature Management and Fisheries, P.O. Box 20401, 2500 E.K. The Hague, The Netherlands (Telex No. 32040 LAVI NL, Telefax No. 70.347.7552), with a copy to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy.

SUMMARY AND CONCLUSIONS

The Twenty-sixth Session of the Codex Committee on Food Additives and Contaminants reached the following conclusions during its deliberations:

MATTERS FOR CONSIDERATION BY THE COMMISSION:

- Suggested that the Commission may wish to consider the elaboration of a Code of Practice for all foodstuffs transported in bulk (para. 17);
- Agreed that a document on Procedures for the Evaluation of Food Intake Data Used in Risk Analysis be prepared (para. 30);
- Decided to forward the revised draft Preamble to the Codex General Standard for Food Additives to the Commission for adoption at Step 8 (para. 37);
- Agreed to advance certain food additive specifications to the Commission for adoption as Codex Advisory Specifications (para. 58);
- Agreed to advance amendments to the International Numbering System to the Commission for adoption (para. 72);
- Agreed to forward the proposed draft Preamble to the Codex General Standard for Contaminants and Toxins in Foods to the Executive Committee for adoption at Step 5 (para. 109); and
- Agreed to forward a report on the CCFAC Current Status of Work, including revisions to their Medium-Term Objectives, to the Executive Committee as requested (paras. 169-170).

OTHER MATTERS OF INTEREST TO THE COMMISSION:

- Agreed to admit a representative of the Press to the meeting (paras. 9-10);
- Decided that the establishment of guideline levels for total mercury in fish was not necessary (para. 15);
- Agreed to several conclusions concerning risk assessment (para. 29);
- Agreed that a paper on the consideration of technological justification and need for the use of food additives be prepared (para. 43);
- Agreed that Schedules. 1, 2 and Annex A of the General Standard for Food Additives would be revised based on Committee discussions and responses to a questionnaire for circulation and additional comments Step 3 (para. 47);
- Agreed to endorse provisions for food additives and contaminants in Codex standards as presented, with the understanding that they would be subject to future review when incorporated into the general standards (paras. 50 and 91);
- Agreed that the Inventory of Processing Aids would be revised (para. 75);
- Agreed that a registry/inventory of food additives produced through biotechnology not be established (para. 78);
- Agreed on a specific procedure concerning the consideration of methods of analysis for food additives (para. 83);
- Agreed that several sections of the proposed draft General Standard for Food Contaminants and Toxins in Foods would be revised and circulated for government comments (para. 110);
- Agreed to maintain the draft maximum level for aflatoxin M_1 in milk at Step 7 (para. 119);

- Decided to discontinue the establishment of guideline levels for aflatoxin B_1 in supplementary feedingstuffs for milk producing animals (para. 123);
- Decided to seek additional comments and information on aflatoxin levels and sampling plans in all foodstuffs (para. 126);
- Decided to revise the proposed draft Code of Practice for the Reduction of Aflatoxins in Raw Materials and Supplementary Feedingstuffs for Milk Producing Animals for circulation and government comments (para. 130);
- Agreed to collect additional information on ochratoxin A and trichothecenes (para. 133);
- Agreed to revise the proposed draft Code of Practice on Source Directed Measures to Reduce Contamination of Foodstuffs for circulation and government comment (para.. 140);
- Agreed that discussion papers on lead, cadmium, PCBs and dioxins would be prepared for circulation and government comment (paras. 144-145, 150-151);
- Agreed to collect additional information on lead, cadmium, PCBs, PBBs, tetrachlorobenzyltoluene, dioxins, polycyclic aromatic hydrocarbons, hydrogen cyanide, phthalates and ethyl carbamate in foods (paras. 150, 154 and 156); and,
- Proposed a list of food additives and contaminants for priority evaluation by JECFA (para. 168).

OPENING OF THE SESSION (Agenda Item 1)

1. The Codex Committee on Food Additives and Contaminants held its 26th Session in The Hague, The Netherlands, from 7-11 March 1994, through the courtesy of the Government of the Netherlands. Mrs. C.G.M. Klitsie of The Netherlands acted as Chairman. The Session was attended by 210 participants, representing 36 member countries, two observer countries and 34 international organizations (see Appendix I for the list of participants).

2. On the invitation of the Chairman, the State Secretary for Agriculture, Nature Management and Fisheries, Mr. J.D. Gabor, welcomed everyone to the 26th Session of the Codex Committee on Food Additives and Contaminants and recalled the advances made in several important areas during last year's session.

3. The State Secretary invited the participants to take a look at the future. The completion of the Uruguay Round of the GATT talks in December 1993 emphasized the need for scientifically underpinned rules for trade. The development of such rules and their translation into feasible requirements was going to demand many hours and much effort. The State Secretary expected Codex Alimentarius to make a major contribution to this process.

4. Recent developments as regards bovine somatotropins, natural hormones and food irradiation once more underlined the pressing need for an adequate response to questions on how to cope in trade with consumer concerns. The State Secretary expected the formulation of this response to be a challenge to the Codex Alimentarius, in particular the Codex Committee on General Principles. The State Secretary called to the attention of the participants the fact that in line with the Dutch policy document on agricultural quality, which had passed Parliament late in 1993, consumer organizations were actively involved in the policy's implementations.

5. The State Secretary trusted that during this year's session important steps forward would be made and concluded his remarks by wishing the participants a satisfactory and productive session.

6. The Chairman stressed the fact that in view of recent international developments, the elaboration by Codex Alimentarius of clear horizontal procedures becoming increasingly important. The Chairman therefore concluded by urging that during this session as much progress as possible should be made on the elaboration of the general standards for food additives and for contaminants in foods.

ADOPTION OF THE AGENDA (Agenda Item 2)

7. The Committee adopted the Provisional Agenda (CX/FAC 94/1) and revisions to the Agenda (CX/FAC 94/1-Add. 1) as proposed.

8. In order to facilitate discussions concerning amendments to the INS system and the priority evaluation of compounds by JECFA, the Committee appointed informal working groups to discuss these subjects under the Chairmanship of Mr. L. Erwin (Australia) and Mr. R. Top (The Netherlands), respectively.

9. Pending discussions by the Codex Committee on General Principles concerning the participation of the Press at Codex meetings, the Committee agreed to the attendance of a representative of Food Chemical News, with the understanding that their participation would be limited to taking written notes of the proceedings.

10. The Committee, while noting that press participation could facilitate the dissemination of information concerning Codex, also cautioned that in view of the sensitivity of discussions under consideration, the implications of press participation should be carefully considered.

APPOINTMENT OF RAPPORTEUR (Agenda Item 3)

11. The Committee agreed with the suggestion of the Chairman to appoint Dr. Simon Brooke-Taylor of Australia as Rapporteur. The Committee gratefully acknowledged the contribution of Mr. R. Ronk (USA) for his assistance as rapporteur during previous years.

MATTERS OF INTEREST ARISING FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 4)

12. The Committee had for its consideration document CX/FAC 94/2 when discussing this agenda item, which summarized matters of interest arising from the Codex Alimentarius Commission and other Codex Committees. As it was noted that most of the items in the working paper were for information only or were scheduled for discussion elsewhere, the Committee focussed its discussions on the following matters.

Guideline Levels for Methylmercury in Fish

13. The Committee was informed that the 20th Session of the Codex Alimentarius Commission had decided (paras. 221-222, ALINORM 93/40) to maintain the guideline levels for methylmercury in fish as previously adopted, while recommending that the establishment of corresponding guideline levels for total mercury in fish be considered by the CCFAC at its 26th session.

14. The Committee also noted that the 21st Session of the Codex Committee on Fish and Fishery Products would be considering the identification of predatory species of fish to which the higher level of methylmercury applied, as requested by the CCFAC at its last session (para. 136, ALINORM 93/12A).

15. The Committee noted that an analysis for total mercury would generally be adequate to ensure that the levels for methylmercury were not exceeded (i.e., total mercury is approximately 90% methyl mercury). An analysis of methylmercury would only be required in those cases where a measurement of total mercury exceeded the guideline level of 1 mg/kg (predatory) and 0.5 mg/kg (others). Therefore, it was decided that the establishment of guideline levels for total mercury in fish was not necessary.-

Code of Practice for the Storage and Transport of Edible Fats and Oils in Bulk

16. The Committee was informed that the 14th Session of the Codex Committee on Fats and Oils (CCFO) had agreed (paras. 33-36, ALINORM 95/15) to forward a general text of the above Code concerning Contamination (Section 2.1.3) to the CCFAC for information and comment, with the understanding that details concerning the Lists of Acceptable and Banned Previous Cargoes would also be provided if requested.

17. The Committee also noted that the proposed draft Revised General Principles of Food Hygiene, which were currently being circulated for comment at Step 3 (CL 1994/4-FH) , also included a text concerning the hygienic transportation of foods in general. However, the Committee suggested that the Commission may wish to consider the elaboration of a code of practice for all foodstuffs transported in bulk, so that requirements could be elaborated for foods other than fats and oils.

18. The Committee noted the importance of avoiding cross-contamination of fats and oils through transport. Moreover, the Committee decided that the actual lists of

acceptable and banned previous cargoes should not be subject to endorsement by the CCFAC, as the elaboration of such lists was the responsibility of other international bodies. The Delegation of Malaysia did not support the text nor the inclusion of the actual cargo lists therein as it was felt that such provisions could create barriers to trade.

19. The Committee also agreed that the contamination of foodstuffs through transport should be considered as part of its proposed draft Code of Practice on Source Directed Measures to Reduce Contamination of Foodstuffs (see para. 139).

RISK ASSESSMENT PROCEDURES USED BY CODEX ALIMENTARIUS COMMISSION AND ITS SUBSIDIARY AND ADVISORY BODIES (Agenda Item 5)

20. The Committee had before it ALINORM 93/37 concerning the above subject, which was prepared by Dr. S.C. Hathaway as Consultant to the Secretariat for presentation at the 20th Session of the Codex Alimentarius Commission in July 1993.

21. The Secretariat referred to the deliberations which took place concerning this issue at the Commission (paras. 57-71, ALINORM 93/40), at which it was recommended that the paper should be brought to the attention of all relevant Codex Committees for review and discussion.

22. The Secretariat informed the Committee that the paper described how the work of JECFA, JMPR, and the relevant Codex Committees fitted into a risk analysis framework. It was noted that Dr. Hathaway had described the three main components of risk analysis, namely, risk assessment, risk management and risk communication. The author also identified the different procedures employed by JECFA and the JMPR, and described how these expert bodies formed a bridge between those carrying out scientific research and the risk management functions inherent of Codex Committees.

23. Dr. Hathaway advocated that Codex Committees would need to adopt common risk analysis principles and that there was a strong need to promote the availability of formal quantitative exposure assessments as a part of risk assessment. The Consultant also stressed that improved hazard identification procedures and consistent decision making criteria for risk management were required.

24. The Secretariat informed the Committee that the paper had already been presented and discussed by the most recent JECFA (for veterinary drug residues) and by the JMPR,. and it was anticipated that it would also be discussed at the upcoming JECFA session devoted to the evaluation of food additives in 1995.

25. It was also noted that the Codex Committee on General Principles would be discussing risk analysis and risk assessment in a general sense when considering the role of science in the Codex decision making process, especially as related to implications on procedure in the post GATT Uruguay Round environment.

26. In discussing those sections and recommendations of the document related to the CCFAC, the Committee welcomed the general direction of the paper which gave a broad overview of risk assessment within the Codex system. The Committee reaffirmed the importance of risk analysis and noted that the paper provided an initial basis for Codex to elaborate principles of risk analysis, risk assessment, risk management and risk communication. It was felt that risk assessment principles as included in the paper were critical in the development of the General Standards for Food Additives and for Contaminants.

27. Several delegations acknowledged the importance of risk analysis procedures and suggested that a further clarification of respective responsibilities between JECFA

and JMPR and Codex was required. Delegations felt that this should distinguish between risk assessment and risk management based on transparent principles. The clarification and standardization of terms and definitions such as risk analysis, risk assessment and risk management was also stressed. A number of delegations also noted that other international and national bodies undertook risk assessments and that a comparison of the procedures employed by these bodies with those of JECFA and JMPR may be of value.

28. Several delegations emphasized that, in addition to science based procedures, risk assessment included consensus building considerations. The importance of procedures for the evaluation of intake data to estimate risk, including the consideration of highly exposed consumers, was also highlighted. The possibility of creating a permanent secretariat to handle future initiatives in this area was suggested. The continuing importance of animal toxicological studies in risk assessment was also stressed.

29. The Committee, while reemphasizing the importance of risk assessment in its deliberations, reached the following conclusions:

- A clarification and standardization of various terms may be required;
- the role of JECFA, Codex and other international organizations should be clearly defined;
- risk assessment procedures should be as harmonized, open and transparent as possible;
- the creation of a special secretariat should be considered to develop and maintain data bases in this regard; and,
- the importance of consensus building within risk analysis should not be underestimated.

30. The Committee also gratefully accepted the offer of the United Kingdom to prepare a document on Procedures for the Evaluation of Food Intake Data Used in Risk Analysis for circulation and government comment well before the Committee's next session.

CONSIDERATION OF THE DRAFT PREAMBLE TO THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES (Agenda Item 6 (a))

31. The Committee had before it ALINORM 93/12A - Appendix II, containing the draft Preamble, CX/FAC 94/3 and Conference Room Document 3 containing comments from Canada, Spain, Thailand, United Kingdom and NACGM, and Conference Room Document 1, report of the Working Group on the General Standard on Food Additives held on March 4, 1994. Comments from Brazil (unnumbered) were also considered.

32. The Working Group meeting was chaired by R. Ronk and D. Dodgen acted as vice-chairman (USA); B. Fabech (DK) acted as rapporteur. Participants were: Australia, Belgium, Canada, Denmark, Egypt, Finland, Germany, Iceland, Italy, Japan, Malaysia, Mexico, the Netherlands, New Zealand, Norway, Switzerland, Sweden, Thailand, UK, USA, Confédération des Industries Agro-Alimentaires de la CEE (CIAA), Confederation of Danish Industries, European Association of Chewing Gum Industry, European Council of Chemical Manufacturers' Federation (CEFIC), European Economic Community (EEC), International Assembly of Grocery Manufacturers Association, International Dairy Federation (IDF) , International Food Additives Council (IFAC) , International Life

Sciences Institute (ILSI), the National Association of Chewing Gum Manufacturers, WHO and FAO.

33. The Chairman informed the Committee that the Commission had adopted the proposed draft Preamble (Appendix II, ALINORM 93/12A) at Step 5 at its 20th meeting in July 1993 (paras. 212-215, ALINORM 93/40). The Committee considered each section of the Preamble and decided on the following changes.

34. The Committee agreed to change the last sentence of Section 1.1 (Permitted Food Additives) of the Preamble to read as: "Only food additives which have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and found acceptable for use in foods are included in this standard" in order to further emphasize the restricted scope of the Standard.

35. The Committee also agreed to change the last sentence of Section 1.2 to the following: "The general basis for the provisions of this standard are set forth in Annex A. These provisions should also comply with the other requirements of the preamble.", in order to clarify that both Annex A and the Preamble were integral parts of the Standard.

36. The Committee agreed to delete para 4.1(d) (Compliance with the Carry-Over Principle) and 4.2 (Non-Compliance with the Carry-Over Principle), in order to clarify principles concerning the carry over of food additives into food. The Delegations of France, Spain and Germany expressed their reservations about the Section concerning the Carry Over Principle in general. These delegations noted that the definition of carry-over was not clear, reverse carry-over should be defined and that additives used in ingredients that had a function in a final composite product should be indicated on the label. The Committee was reminded by the Chairman of the Working Group, however, that the principles of carry-over in the context of the General Standard related to the permitted uses of food additives and not to labelling.

Status of the Revised Draft Preamble to the Codex General Standard for Food Additives

37. The Committee decided to forward the revised draft Preamble to the Codex General Standard for Food Additives to the 21st Session of the Commission for adoption at Step 8. The Preamble is attached to this report as Appendix II.

CONSIDERATION OF REVISED SCHEDULES 1.2 AND ANNEX A OF THE PROPOSED DRAFT CODEX GENERAL STANDARD FOR FOOD ADDITIVES (Agenda Item 6 (b))

38. The Committee had before it the above sections of the General Standard as contained in CX/FAC 94/4, and documents CX/FAC 94/4-Add. 1, Conference Room Documents 3 and 7, containing comments from CESDA, ILSI, New Zealand, UK, Canada, Finland, Norway, Spain, Sweden, EEC, CIAA, IFMA, CIMSCE and NACGM as well as comments from Denmark, Thailand, the United States and the International Pectin Producers Association (unnumbered). The report of the Working Group on the General Standard for Food Additives was contained in Conference Room Document 1.

Schedules 1 and 2

39. The Chairman of the Working Group referred to the proposal of the United Kingdom, as supported by some delegations and the EEC, to present the Standard in the form of three schedules as follows: 1) Foods Which May Not Contain Additives of One or More Classes Except Where Specifically Provided For in Schedule 3; 2) Food Additives Generally Permitted for Food Use in Accordance with GMP; and, 3) Food Additives Permitted for Certain Uses Only.

40. The Working Group appreciated the principles underlying this proposal which would enable the Committee to start to focus its attention on those additives with numerical ADIs. However, the Working Group did not support the proposal because it was felt that these principles could easily be implemented using the existing schedules. The WG concluded that the two existing schedules would be more effective for data collection and should therefore be retained. However, the presentation of the Standard in different formats in the future might also be considered.

41. The Committee noted that the current presentation, which was previously agreed to by the Committee and the Commission, followed a horizontal approach based on food additives and that nonetheless, specific listings, such as those proposed by the UK, could be easily extracted after the Standard was published in electronic form. However, it was agreed that the list of individual foods within food categories would need to be condensed further in this respect and that additives with acceptable daily intakes of "not specified" should be allowed for use under principles of GMP and based on technological justification and need.

42. In regard to the interpretation of ADI "not specified", the Committee was informed that such an ADI was normally assigned to additives with low toxicity, and that it was based on current or intended uses when evaluated by JECFA. The Committee noted that an ADI of "not specified" should not automatically translate to GMP use levels in all foods. The Committee agreed that technological justification and need always had to be taken into consideration irrespective of the ADI.

43. The Committee agreed to the offer of the Delegation of Iceland to prepare a document in cooperation with New Zealand on the consideration of technological justification and need for the use of food additives for discussion by the Committee at its next session.

44. The Committee reaffirmed its previous agreement on the horizontal approach based on the use of food additives in all foods, with the understanding that the two schedule format would be maintained. It was also agreed that the Standard would be revised based on current and additional information on use levels for antioxidants and preservatives used in various foods.

45. In order to facilitate the collection of such information, the Committee agreed that the following data would be requested:

1. Are there categories, sub-categories or specific foods in which you do not allow preservatives and antioxidants?

2. Which preservatives and antioxidants and uses do you propose for addition to the General Standard, based on the following:

    - Name of the additive
    - Additive class
    - INS number
    - Level of additive use and residual amount
    - Food category (including identification number) in which the additive is used
    - Technological justification for use

It was agreed that a list of all antioxidants and preservatives evaluated by JECFA would also be included in the questionnaire. The Chairman of the WG also invited those

countries with additive uses that did not fit into the existing food classification system to report such information.

Annex A

46. The Committee agreed to delete Guideline 14 in order to make the Annex consistent with the principle that the Standard only applied to additives which have been evaluated by JECFA and found acceptable for use in foods. The Committee also agreed to include the text of Footnote 1 at the beginning of Annex A to clarify that the Codex General Principles for the Use of Food Additives applied to the Standard in its entirety. The Committee also noted that other additive classes would be incorporated into the Standard in the future.

Status of Schedules 1. 2 and Annex A of the Codex General Standard for Food Additives

47. The Committee agreed that Schedules 1, 2 and Annex A of the proposed draft Codex General Standard for Food Additives would be revised based on the above discussions and circulated for comment at Step 3 prior to the next session of the Committee. The Committee reinstated the Working Group under the Chairmanship of the United States and expressed its appreciation to this Delegation for the progress achieved since the Committee's last session.

ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR FOOD ADDITIVES IN CODEX STANDARDS (Agenda Item 7)

48. The Committee had for its consideration document CX/FAC 94/5 presenting the food additive provisions in a number of Proposed Draft Standards forwarded by the Codex Committee on Fats and Oils and the Committee on Fish and Fishery Products.

49. Some delegations pointed out that specific food additives should be considered only in the framework of the General Standard for Food Additives, and that it might not be appropriate to endorse food additives proposed by commodity committees in this context. In reply to a question on the endorsement of such provisions at this stage, the Secretariat indicated that the current Codex procedure had been followed in this respect, and that commodity committees had proposed food additives provisions on the basis of technological justification. It was understood that they may be reassessed for inclusion in the General Standard at a later date. The Committee also noted that most provisions had been previously endorsed-, and agreed that the elaboration of standards which may be needed to facilitate trade should not be delayed pending finalization of the General Standard for Food Additives.

50. The Committee agreed to endorse the provisions for food additives as presented in the document, with the understanding that they would be subject to future review according to the procedure adopted for the elaboration of the General Standard for Food Additives.

51. The Committee agreed to amend the statement concerning flavours in the Proposed Draft Standards for Fats and Oils as follows:

> Natural flavours and their identical synthetic equivalents and other synthetic flavours, except those which are known to represent a toxic hazard.

52. In reply to a question concerning tartaric acid, the WHO Secretary to JECFA indicated that an ADI had been allocated for L tartaric acid and its salts, but not for DL tartaric acid; the Committee therefore agreed that this information should be forwarded

to the Committee on Fats and Oils and that clarification should be sought as to the actual substance included in the Proposed Draft Standard for Mayonnaise.

53. The Committee noted that for a number of additives, reference was made to GMP although a numerical ADI had been allocated by JECFA, and expressed the view that such provisions should be corrected according to the principles adopted under the Codex General Standard for Food Additives (see Agenda Item 6) .

54. The Committee took note of the following reservations on the use and levels of specific additives:

Proposed Draft Standards for Palm Olein, Palm Stearin, Fats and Oils not Covered by Individual Standards, Products Sold as an Alternative to Ghee, and Named Vegetable Oils

- Tertiary butyl hydroquinone (TBHQ) (319): Finland, Germany, Greece, Japan, the Netherlands, Norway, Poland, Sweden and the EEC.
- Dilauryl thiodipropionate (389): Germany, Norway, Poland, Sweden, EEC
- Propyl gallate (310): Greece, Poland
- Beta-apo-8'-carotenal (160e): Japan
- Beta-Apo-8'-carotenic acid, methyl or ethylester (160 f) : Japan
- BHA and BHT (320/321): Germany (level of 321), Greece, Poland (320 only).

55. The Observer from the EEC informed the Committee that TBHQ and Dilauryl thiodipropionate were not allowed under present legislation and that these additives were currently under consideration following the same horizontal approach as the Committee.

- **Proposed Draft Standard for Animal Fats**

- Synthetic gamma-tocopherol and delta-tocopherol (308/309): Japan
- TBHQ (319): Germany, Finland, Japan, Poland

- **Proposed Draft Standard for Fat Spreads**

- Beta-apo-8'-carotenal (160e): Japan
- Polyoxyethylene Sorbitan Monolaurate, Monooleate, Monopalmitate, Monostearate and Tristearate (432 to 436): Germany, Japan
- Sucroglycerides (474): Japan
- Sorbitan monostearate, tristearate, monolaurate, mpnooleate, monopalmitate (491 to 495): Japan
- Dilauryl thiodipropionate (389): Finland, Sweden, Poland, EEC
- Octyl gallate/Dodecyl gallate (311/312): Japan, Sweden
- Synthetic gamma tocopherol (308): Japan
- Synthetic delta tocopherol (309): Japan

- **Proposed Draft Standard for Mayonnaise**

- Beta-apo-8'-carotenal and Beta-apo-8'-carotenic acid (160e/160f) : Japan
- Synthetic gamma-tocopherol and delta-tocopherol (308/309): Japan
- EDTA (385): Japan, Poland
- BHA/BHT (320/321): Poland
- Oxystearin (387): Japan

- **Proposed Draft Amendment to the Canned Crab Standard**

- EDTA (385): Poland

CONSIDERATION OF SPECIFICATIONS ARISING FROM THE 41ST JECFA MEETING (Agenda Item 8)

56. The Working Group reviewed specifications prepared by the 41st Meeting of JECFA,. which were published in Addendum 2 to FAO Food and Nutrition Paper 52 (Compendium of Food Additive Specifications), with the exception of those designated by JECFA as "tentative". The Working Group also considered comments regarding these specifications received in response to CL 1993/23-FAC, as indicated in the report of the Working Group meeting (Conference Room Document 2).

57. During the Working Group review, the specifications were divided into five Categories: I - Recommended for adoption as Codex Advisory Specifications without changes; II - Recommended for adoption with editorial or other minor changes; III - Referred back to JECFA for further review because of clarifications for necessary substantive changes; IV - Substances on the agenda of the recent JECFA Meeting (not applicable) and V - Substances designated by JECFA as "tentative".

58. The Committee agreed to refer the 22 substances in Categories I and II (see Appendix IV) to the Commission for adoption as Codex Advisory Specifications. It was also noted that comments received on specifications assigned to Category V would be forwarded to JECFA along with those in Category III. The Committee was informed that all 11 substances referred back to JECFA by this session of the Committee would be on the agenda of the 44th meeting of JECFA scheduled to be held in Rome, February 1995.

59. The Committee requested JECFA to conduct a general review of contaminant levels, in particular, of lead and other heavy metals, in food additives used in foods at high levels.

60. The JECFA Joint Secretariat informed the Committee that from 1995 two meetings of JECFA would be convened annually, one for food additives and one for veterinary drugs. The Committee expressed its appreciation for these efforts.

61. The Committee was informed that the second printing of the JECFA Compendium of Food Additive Specifications, published as FAO Food and Nutrition Paper 52/1 (Vol. 1) and 52/2 (Vol. 2), was now available from the FAO Distribution and Sales Unit in Rome. The Committee was also informed that the Food Additives Data System, which was previously published as FAO Food and Nutrition Paper 30, would be revised within three months. The data system, which contained all JECFA evaluations from the 1st through 41st Session of the Expert Committee, including food additives, contaminants and veterinary drugs, would be published as a Joint FAO/WHO document later this year.

62. The Committee was advised that the fourth edition of the. Food Chemicals Codex was scheduled to be published in March 1996. The Committee was also informed that the English version of the sixth edition of the Japanese Standard for Food Additives would be published in 1994.

63. The Committee reaffirmed its earlier decision (para 58, ALINORM 93/12A) that in view of the fact that there would be no new JECFA specifications available for review by this Committee at its 27th Session in 1995 (because a JECFA meeting for the review of food additives was not scheduled in 1994), the remaining substances in Appendix VII of ALINORM 93/12 should therefore be scheduled for review in 1995.

64. The Committee expressed its appreciation for the efforts of the Working Group and reinstated it under the Chairmanship of Dr. D.F. Dodgen (USA). The following

countries and organizations were invited to participate in the reinstated group: Denmark, Finland, Germany, Japan, Malaysia, Norway, Philippines, Sweden, Switzerland, Thailand, UK, USA, AMFEP, CEFIC, FCC, IFAC, JFAA, SIAP, Marinalg International, Kelco International, WHO and FAO.

PROPOSED AMENDMENTS TO THE INTERNATIONAL NUMBERING SYSTEM (Agenda Item 9)

65. The Chairman of the Informal Working Group on the International Numbering System (INS), Mr. L. Erwin (Australia) presented its discussions and recommendations as contained in Conference Room Document 12 (CX/FAC 94/6). Representatives of Australia, Canada, Denmark, Finland, France, Germany, Indonesia, Italy, Malaysia, New Zealand, Philippines, Switzerland, Thailand and observers from the EEC, Biopoloymer International, Industrial Food Additives and Food Enzymes, IFAC and Marinalg International attended the meeting.

Processed Eucheuma Seaweed

66. It was recalled that the 20th Session of the Commission (paras. 204-207, ALINORM 93/40) had requested the Committee to reexamine its decision to allocate number 426 to Processed Eucheuma Seaweed (PES). The following options had been considered by the Working Group: 1) retain number 426; 2) allocate 407(i) to carrageenan and 407(ii) to PES; 3) reconfirm 407 for carrageenan and allocate 407a to PES; 4) defer a decision pending the consideration of PES by JECFA. The Working Group proposed the third option in order to achieve a compromise, with the understanding that this matter could be revisited by the next session of the Committee after the JECFA meeting.

67. Several delegations were in favor of deferring a decision pending the review of PES by JECFA, and pointed out that the allocation of numbers 407 and 407a might not conform to the usual numbering procedure. Several other delegations stressed that the Committee had enough information at this stage to reach a decision, especially as the allocation of numbers was not dependent on the conclusions of JECFA, and that such a decision was needed so as not to jeopardize the economic interests of producing countries and to facilitate international trade.

68. While acknowledging the difficulties in reaching a decision in view of the different opinions expressed, the Chairman stressed that the allocation of an INS number was not related to the JECFA evaluation but was only needed for identification and labelling purposes. Moreover, exporters would still have to comply with the regulations of the importing countries to gain entry to their markets. Insofar as problems related to the identification of PES were of a commercial nature, the interested parties were encouraged to come to a satisfactory agreement.

69. The Committee agreed with the proposal of the Chairman to allocate number 407a to PES as a compromise solution.

Calcium behenate

70. The Committee noted that calcium behenate was a salt of fatty acid and as such it was probably covered under number 470. In view of this fact, the Committee agreed that a separate number for this substance was not required pending the receipt of additional information from Finland, which had proposed this additive.

Alitame

71. The Committee noted that this sweetener was now approved for use in some countries and agreed with the proposal of the Working Group to allocate INS number 956.

Status of Amendments to the International Numbering System

72. The Committee agreed to reinstate the informal Working Group at its next session and to include consideration of proposed amendments to the INS as a standing item on its agenda. It also agreed that the above amendments to the INS would be forwarded to the 21st Session of the Commission for adoption. The amendments to the INS are attached to this report as Appendix V.

PROPOSED AMENDMENTS TO THE INVENTORY OF PROCESSING AIDS (Agenda Item 10)

73. The Delegation of Germany introduced Conference Room Document 11 (CX/FAC 94/7) presenting the aforesaid amendments proposed in reply to Circular Letter CL 1993/8-FAC.

74. The Committee agreed that there should be no reference to the use of microorganism control agents used in the treatment of drinking water, as drinking water was covered by the WHO Guidelines for Drinking Water Quality. The Secretariat also confirmed that only substances used exclusively as processing aids were listed in the inventory, and that compounds that function as processing aids and food additives should not be included in the Inventory *perse.*

75. The Committee agreed with the proposal of the Delegation of Germany to revise the inventory on the basis of current proposals and future comments for consideration at its 27th Session.

REGISTRY/INVENTORY OF FOOD ADDITIVES PRODUCED THROUGH BIOTECHNOLOGY (Agenda Item 11)

76. The Committee had before it document CX/FAC 94/8 concerning the above subject, as prepared by the Delegations of the Netherlands and the United States. Mr. Top of the Netherlands introduced the paper.

77. The Committee recalled its previous discussions concerning this issue (paras. 81-93, ALINORM 93/12A) , whereby it was noted that the safety evaluation of food additives produced through biotechnology would continue to be done by JECFA on a case-by-case basis as required. It was also noted that the labelling of food additives produced through biotechnology was exclusively within the competence of the Codex Committee on Food Labelling.

78. The Committee questioned the establishment of such a list as it could be misinterpreted, and because there was no need to differentiate between food additives produced by means of biotechnology and those produced by conventional methods once they had been evaluated by JECFA and an ADI allocated. Therefore, it was agreed not to pursue the establishment of the registry/inventory at the present time.

Safety Assessment of Foods Produced by Modern Biotechnology

79. A representative of WHO informed the Committee of their activities related to the above subject. The WHO Representative noted that the objective of these activities was to develop, in collaboration with FAO, guidelines for the evaluation of foods produced from biotechnology, as identified in the Commission's Medium-Term Programme of Work (Appendix 3, ALINORM 93/40).

80. To meet this objective, a consultation will be held mid-1995, jointly sponsored by FAO/WHO in collaboration with OECD, to develop draft guidelines. The Consultation will build upon existing initiatives undertaken, such as:

- Joint FAO/WHO Consultation on "Strategies for Assessing the Safety of Foods Produced by Biotechnology" (1991);
- WHO Workshop on "Health Aspects of Marker Genes in Genetically Modified Plants" (1993), and;
- OECD Guidelines on the Safety Assessment of Foods Produced by Modern Biotechnology.

81. It was noted by the representative of WHO that the above Consultation would also take account of recent scientific developments and the results of activities planned by other international agencies during the period. These activities were anticipated to include:

- Workshop to examine the commercialization of agricultural products derived through modern biotechnology planned for June 1994 in Washington, sponsored by OECD;
- Workshop on the safety evaluation of foods for which the principle of substantial equivalence cannot be applied planned for September 1994 in Oxford, sponsored by OECD in collaboration with WHO, and;
- Workshop to explore the application of the principle of substantial equivalence to food safety planned for late 1994/early 1995 in Copenhagen and convened by WHO in collaboration with OECD and possibly FAO.

GOVERNMENT COMMENTS ON THE NEED FOR METHODS OF ANALYSIS TO DETERMINE FOOD ADDITIVES IN FOODS MOVING IN INTERNATIONAL TRADE (Agenda Item 12)

82. The Committee had before it documents CX/FAC 94/9 and Conference Room Document 4 containing comments on the above subject from Canada, Finland, Sweden, the United Kingdom and the International Sweeteners Association in response to CL 1993/8-FAC.

83. The Committee, while recalling its previous discussions concerning this issue (paras. 12-14, ALINORM 93/12A), reaffirmed the following course of action concerning the establishment of methods of analysis for food additives:

- CCFAC will continue to consider methods of analysis for the determination of food additives in food for forwarding to the CCMAS for endorsement;
- Canada will update and prioritize the list of methods of analysis for food additives prepared for discussion at the 20th CCFAC (CX/FAC 87/11-Add. 2) in cooperation with the AOAC, and while taking the expertise of other international organizations, including ISO and CEN, into account;
- CCFAC will prioritize those additives or classes of additives that require the establishment of methods for purposes of international trade, and;
- the updated list will be forwarded to the CCMAS for endorsement after consideration by the 27th CCFAC.

The Chairman thanked Canada for its willingness to undertake this effort. The Chairman also invited governments and international organizations to send information directly to Canada.

REPORT OF THE JOINT UNEP/FAO/WHO FOOD CONTAMINATION MONITORING AND ASSESSMENT PROGRAMME (GEMS/FOOD) (Agenda Item 13)

84. The Committee had before it document CX/FAC 94/10, which reported on progress of GEMS/Food in providing global information on levels and trends of contaminants in food, their contribution to the total diet and their significance with regard to public health. The programme, which now included institutions in 59 countries, was an important part of national and international efforts to provide assurance regarding the safety of the food supply and provides the basis, where appropriate, for remedial actions, for food control, for industry and public education and for resource management. Supporting components of GEMS/Food included technical cooperation, analytical quality assurance and information exchange.

85. During 1993, work was started on reviewing the basic project document which had supported GEMS/Food for the past several years. Special consideration was being given to the role of GEMS/Food in responding to the recommendations of the UN Conference on the Environment and Development and the International Conference on Nutrition, both of which recognized contaminated food as a significant hazard. A number of global and regional activities had been carried out in 1993-1994, which were summarized in the paper.

ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR CONTAMINANTS IN CODEX STANDARDS (Agenda Item 14)

86. The Committee had before it document CX/FAC 94/11, which presented the contaminant levels for lead, arsenic, iron and copper in fats and oils as proposed by the Codex Committee on Fats and Oils for endorsement. The Committee was informed that, with the exception of the palm olein and stearin standards, the proposed levels had previously been endorsed by the CCFAC. It was also noted that the maximum levels proposed for iron and copper were listed as quality characteristics in the revised fat and oil standards.

87. The proposed lead and arsenic levels were 0.1 mg/kg for all types of edible fats and oils, while the levels for iron and copper were differentiated according to the different stages of processing and types of fats and oils.

88. Some delegations suggested postponing the endorsement of the levels so that they would be considered within the framework of the General Standard for Contaminants. These delegations preferred to deal with the levels through the horizontal approach instead of through the endorsement of specific contaminant levels in commodity standards.

89. Several delegations expressed the view that as the levels for iron and copper were not related to safety, but were proposed as quality characteristics to prevent lipid oxidation, these should not be considered as contaminants *perse.* The Committee therefore decided not to discuss the iron and copper levels and to leave the establishment of such levels to the Codex Committee on Fats and Oils.

90. It was also pointed out that it might be useful at a later stage to consider different levels for inorganic and organic arsenic compounds.

91. The Committee endorsed the levels of 0.1 mg/kg for lead and arsenic in fats and oils, as contained in document CX/FAC 94/11, with the understanding that these levels would be subject to further review when incorporated into the General Standard on Contaminants and Toxins in Foods.

CONSIDERATION OF THE PROPOSED DRAFT CODEX GENERAL STANDARD FOR CONTAMINANTS IN FOODS (Agenda Item 15 (a))

92. The Committee had before it document CX/FAC 94/12, prepared by the Delegations of Denmark and The Netherlands, which presented a proposed draft General Standard for Contaminants in Foods (GSC). Government comments from Spain were presented in CX/FAC 94/12-Add.1.

93. The Chairman briefly summarized the history leading to the current document, as outlined in Background section of the working paper. The authors introduced the document on a section by section basis.

94. The Committee agreed to change the title of the General Standard into "Codex General Standard for Contaminants and Toxins in Foods" to more accurately reflect the scope of the standard. The Committee, in discussing the Standard point-by-point, agreed to the following changes.

PREAMBLE

Section 1.1 - Scope

95. The Committee agreed to delete the reference to residues of processing aids from this Section.

Section 1.2.2 - Contaminant

96. Taking into consideration that a broad definition of contaminants had already been adopted by the Codex Alimentarius, the Committee agreed to use this general definition as a basis for the GSC. However, it was also agreed that for the purpose of this standard, a working definition for contaminants would be elaborated.

Section 1.2.3 - Natural Toxins

97. In view of decisions taken at the last meeting of the Committee (para. 108, ALINORM 93/12A), it was agreed that natural toxins would be included in the GSC. The Committee reaffirmed this decision and also agreed that inherent naturally occurring toxicants would only be considered by the Committee for inclusion in the GSC on a case' by case basis as required. Therefore, this Section was changed to reflect these conclusions.

98. With regard to the inclusion of bacterial toxins, the Committee agreed that these should not be included in the GSC as this matter appeared to lie within terms of reference for the Codex Committee on Food Hygiene.

Section 1.2.4 - Maximum Level and Related Terms

99. With regard to the status of guideline levels, maximum levels and maximum limits within Codex, it was noted that the Commission had already indicated that the status of all Codex texts should be considered as mandatory. In order to obtain maximum transparency and with regard to the CCFAC terms of reference, the Committee agreed to use the term "maximum level" throughout the entire GSC.

Section 1.3 - General Principles Regarding Contaminants in Foods

100. The Committee agreed that in establishing maximum levels for contaminants and toxins in foods regional consumption patterns and/or highly exposed consumer groups should be taken into account. The Committee agreed that it would discuss this matter at its next session.

Section 1.4.2 - Procedure for Preliminary Discussion about Contaminants in the CCFAC

101. The Committee agreed with the proposal of the Delegation of Switzerland to include a reference for a procedure for the inclusion of a contaminant in the GSC, an example of which was given in document CX/FAC 94/13 (Agenda Item 15 (b)). It was also agreed that document CX/FAC 94/20 (Agenda Item 17 (b)) would be used in this regard.

102. In setting maximum levels for contaminants and toxins in foods, the Committee agreed that it may consider expected future effects on international trade. The Committee agreed to adjust the text of this section accordingly.

Annex 1 - Criteria for the Establishment of Maximum Levels in Foods and Feeds

103. The Committee agreed that information concerning contaminant concentrations in those foods or food groups that were responsible for at least half, but preferably 80 to 85%, of the total dietary intake of the contaminant, both for average consumers and highly exposed consumers, was desirable.

104. The Committee requested that JECFA consider the feasibility of providing advice on risk assessment in situations where numerical tolerable intakes could be established for contaminants (as with aflatoxins). An estimate of the toxicological potency of such contaminants might be considered by JECFA as part of the risk assessment process.

105. The Committee agreed that horizontal standards such as the GSC should only address public health issues and therefore, all references to quality matters in the entire standard would be removed. The Committee also agreed that its objective should be to establish standards for contaminants at the lowest levels reasonably achievable through principles of good agricultural and manufacturing practice.

Annex 3 - Format of the Standard for Contaminants in Foods and Feeds

106. The Committee agreed that the proposed food categorization system should include primary food commodities as well as processed foods.

Annex 4 - Numbering System for Contaminants to be used in the Codex GSC

107. With regard to the introduction of an international numbering system for contaminants in the GSC, the Committee agreed that the introduction of a numbering system for contaminants was premature at this stage. However, it was suggested that a structured list of contaminants would facilitate a logical approach in the development of the GSC.

SCHEDULES I and II

108. The authors informed the Committee that Schedules 1 and 2 were elaborated at this stage for information only as an example of the format of the Standard. It was agreed that the standard should be condensed and simplified as much as possible in the context of the horizontal approach.

Status of the Codex General Standard for Contaminants and Toxins in Foods

109. The Committee agreed to forward the preamble of the proposed draft General Standard for Contaminants and Toxins in Foods to the Executive Committee for adoption at Step 5. The Preamble is attached to this report as Appendix III.

110. The Committee also agreed that the Delegations of Denmark and the Netherlands would revise the remaining sections of the proposed draft General Standard for Contaminants and Toxins in Foods based on the comments and recommendations made during this session and on additional comments which were requested to be submitted directly to the Delegation of the Netherlands as soon as possible. The Committee agreed to send the revised document, excluding the Preamble, for government comments at Step 3 at the earliest opportunity.

PROCEDURE FOR THE INCLUSION OF A CONTAMINANT IN THE CODEX GENERAL STANDARD FOR CONTAMINANTS IN FOODS (Agenda Item 15 (b))

111. The Committee had before it document CX/FAC 94/13, prepared by the Delegation of Switzerland, which presented a draft procedure for the inclusion of a contaminant in the Codex General Standard for Contaminants in Foods (GSC). The Committee had requested the Delegation of Switzerland to prepare a discussion note using one contaminant as an example in order to make the procedure clear (para. 112, ALINORM 93/12A).

112. In their introduction of the document, Switzerland noted the difficulty of identifying existing problems in trade caused solely by contaminants. The Committee noted that while significant problems concerning contaminants in trade did exist, these were normally dealt with on a commercial level.

113. The Committee thanked the Delegation of Switzerland for their outstanding efforts in drafting the document and agreed that contaminants would be included in the GSC on the basis of the example given in the subject working paper (see para. 101).

CONSIDERATION OF THE DRAFT MAXIMUM LEVEL FOR AFLATOXIN M_1 IN MILK (Agenda Item 16 (a))

114. The Committee had before it government comments in reply to CL 1993/22-FAC as presented in documents CX/FAC 94/14 (IDF) and Conference Room Documents S (Ivory Coast, Sweden) and 10 (USA), as well as comments from Brazil (unnumbered).

115. The Committee was informed that the Commission had adopted the proposed draft maximum level of 0.05 μg/kg for Aflatoxin M_1 in liquid milk at Step 5, on the understanding that a review of available methods of analysis and sampling and a thorough risk analysis would be carefully considered by the Committee before the maximum levels were forwarded for final adoption (paras 195-198, ALINORM 93/40).

116. Several delegations did not favour the proposed maximum level, as the relationship to aflatoxins in feedingstuffs was not clear, the level could not be achieved without losing significant quantities of milk and that aflatoxins in milk were controlled through the establishment of levels for feed. Source related measures for the control of aflatoxins were also highlighted. It was also noted by the United States that a level of 0.5 μg/kg provided adequate consumer protection.

117. Several other delegates favoured the proposed maximum level, as it was felt that such could be met by proper source directed measures. The availability of proper methods of analysis to detect such levels was also highlighted.

118. The JECFA Secretariat indicated that irreducible aflatoxin levels were defined, and that this determination did not imply that commodities needed to be destroyed. The

Delegation of Sweden also suggested that JECFA should be asked to provide an estimate of the health risks associated with different aflatoxin intakes.

119. The Committee decided to request JECFA to provide estimates on the toxicological potency of aflatoxins B_1 and M_1 Pending such an evaluation, the Committee also agreed to maintain the draft maximum level for aflatoxin M_1 in milk at Step 7.

CONSIDERATION OF THE PROPOSED DRAFT PROVISIONAL GUIDELINE LEVEL FOR AFLATOXIN B_1 IN SUPPLEMENTARY FEEDING STUFFS FOR MILK PRODUCING ANIMALS (Agenda Item 16 (b))

120. The Committee had before it government comments in reply to CL 1993/22-FAC as presented in documents CX/FAC 94/14-Part I (Malaysia, Spain, IDF) and Conference Room Documents 5 (Ivory Coast, Sweden) and 10 (USA).

121. The Committee was informed that the Commission had returned the proposed draft provisional guideline level of 5 *µ*g/kg for supplementary feeding stuffs for milk producing animals for further examination of problems in international trade and risk analysis aspects (paras. 216-220, ALINORM 93/40).

122. The Committee noted that the relationship between aflatoxins in milk and feeds was not clear, and that there was not much trade in supplementary feeding stuffs *per se.* It was also indicated that international trade mostly concerned individual feed components.

123. In view of the above discussion, the Committee decided to discontinue the establishment of guideline levels for aflatoxin B_1 in supplementary feedingstuffs for milk-producing animals, with the understanding that the control of such contamination should be achieved through source-directed measures (see Agenda Item 16 (e)). It was also noted that the Executive Committee would be informed of this decision.

GOVERNMENT COMMENTS AND INFORMATION ON AFLATOXINS IN SPECIFIC FOODSTUFFS (Agenda Item 16 (c))

124. The Committee had before it government comments in reply to CL 1993/8-FAC, as presented in document CX/FAC 94/14 Part II (Finland, Greece, Canada) and Conference Room Document 10 (USA).

125. In discussing this issue, the Committee emphasized the importance of adequate sampling plans to ensure the proper examination of products.

126. The Committee decided to solicit additional comments and information on aflatoxin levels and sampling plans in all types of foods for consideration by the 27th CCFAC.

REPORT ON AFLATOXINS IN PISTACHIO NUTS AND DRIED FIGS (Agenda Item 16 (d))

127. The Committee agreed that information on the above commodities would also be solicited as outlined above (see paras. 124-126).

PROPOSED DRAFT CODE OF PRACTICE FOR THE REDUCTION OF AFLATOXINS IN RAW MATERIALS AND SUPPLEMENTARY FEEDING STUFFS FOR MILK PRODUCING ANIMALS (Agenda Item 16 (e))

128. The Committee had before it document CX/FAC 94/16, as prepared by the Delegation of Canada at the request of the 25th CCFAC (para. 119, ALINORM 93/12A).

129. The Committee expressed its appreciation to Canada for the excellent work and emphasized its importance as a basis for the control of aflatoxin contamination in foods. It was also noted that several additional matters could be further emphasized, such as pre-harvest and post-harvest treatments, decontamination processes, the use of fungicides and the handling of food by farmers.

130. The Committee accepted the offer of Canada to revise the document with the assistance of the Netherlands and Thailand for circulation and government comment at Step 3 well before the 27th CCFAC Session.

DISCUSSION PAPER ON OCHRATOXIN A AND TRICHOTHECENES (Agenda Item 16 (f)).

131. The Committee had before it document CX/FAC 94/17 (prepared by Sweden) and additional information submitted in reply to CL 1993/8-FAC as summarized in Conference Room Documents 8 (China) and 9 (USA). The Committee was informed that Ochratoxin A would be evaluated by JECFA in February 1995.

132. The Committee expressed its appreciation to Sweden for the working paper, as it offered an excellent evaluation of available data. It was also felt that the paper could serve as a useful model for the collection and analysis of data and for the eventual inclusion of these contaminants in the General Standard.

133. The Committee agreed that a level may need to be set for ochratoxin A after the receipt of additional information and the JECFA evaluation. In regard to trichothecenes, it was decided to collect additional information. It was agreed that information should be sent directly to Sweden, and that the Codex Committee on Cereals, Pulses and Legumes would be notified of the Committee's activities in this regard.

SAMPLING PLANS FOR AFLATOXIN ANALYSIS IN PEANUTS AND CORN (Agenda Item 16 (g))

134. The Committee had before it CX/FAC 94/18, which summarized the background, conclusions and recommendations of a FAO Technical Consultation on Sampling Plans for Aflatoxin Analysis in Peanuts and Corn (Rome, 3-6 May 1993). The full report of the Consultation (FAO Food and Nutrition Paper 55) was also made available for the Committee. The Representative of FAO, Dr. J. Paakkanen, informed the Committee of the results of the Consultation.

135. The Consultation emphasized the importance of aflatoxin contamination and its effects on international trade. The Consultation developed and evaluated sampling plans for aflatoxin analysis in peanuts and corn using two sample sizes, TLC as an analytical method and guideline levels of 5, 10, 15, 20 and 30 µg/kg for aflatoxin. The Consultation also gave advice on sample collection and sample preparation.

136. The Committee expressed its gratitude and appreciation to FAO and the group of experts for preparing the report, which would be directed to the Codex Committee on Cereals, Pulses and Legumes for action when establishing maximum levels for aflatoxins in peanuts. It was also noted that the report would be brought to the attention of the Codex Committee on Methods of Analysis and Sampling.

PROPOSED DRAFT CODE OF PRACTICE ON SOURCE DIRECTED MEASURES TO REDUCE CONTAMINATION OF FOODSTUFFS (Agenda Item 17 (a))

137. The Committee had before it document CX/FAC 94/19, prepared by the Delegation of Sweden, presenting the major elements of a proposed draft code of

practice on source directed measures to reduce contamination of foodstuffs as requested by the 25th CCFAC (para. 113, ALINORM 93/12A).

138. The Committee welcomed the document as a general framework on source directed measures and complimented the Delegation of Sweden for their excellent work.

139. The Committee agreed that the document should take account of other international initiatives in this area as well as possible source directed measures for transport by road, rail and sea (see para. 19).

140. The Committee agreed that the Delegation of Sweden would revise the document based on the Committee's discussions for circulation and government comment at Step 3 prior to the 27th CCFAC. Governments were also invited to send written comments on the current document directly to the Delegation of Sweden.

DISCUSSION PAPER ON LEAD (Agenda Item 17 (b))

141. The Committee had before it document CX/FAC 94/20, prepared by the Delegations of Sweden and Denmark, which presented a discussion paper on lead as decided by the 25th CCFAC (para. 140, ALINORM 93/12A).

142. In introducing the paper, the authors gave special attention to those sections on hazard identification, risk, assessment and risk management. The authors advised that in regard to establishing maximum levels for lead in foodstuffs, source directed measures to reduce contamination were important.

143. The Committee welcomed the document and complimented the authors on its preparation, and agreed that the paper was an excellent starting point for the elaboration of maximum levels for lead by the Committee at its next session.

144. The Committee agreed that the Delegations of Sweden and Denmark would further develop the paper for the next session on the CCFAC according to the recommendations and comments made during the session and taking account of available intake data from different regions in the world, from the GEMS/Food Programme, and from other international bodies.

145. The Committee agreed to send this document for government comments at Step 3 at the earliest opportunity. Governments were also invited to send written comments on the current document to the Delegation of Sweden.

GOVERNMENT COMMENTS AND INFORMATION ON CADMIUM AND LEAD (Agenda Item 17 (c))

146. The Committee had before it document CX/FAC 94/21 and Conference Room Documents 6 and 10, presenting comments and information on cadmium and lead received from Finland, Canada and the United States of America in reply to CL 1993/8-FAC. Comments from Thailand (unnumbered) were also considered.

147. The Delegation of Thailand informed the Committee that cadmium contamination in certain food commodities, particularly rice, had been monitored and found in the range lower than 0.05 mg/kg. The total dietary intake of cadmium had been found to be 0.03 mg/kg body weight per week. The high intake data on cadmium in Thailand, as presented in the latest report of the GEMS/Food Monitoring Programme, was due to the fact that these data represented a small group of highly exposed consumers.

148. The Committee was also informed that the proposed draft maximum level for cadmium in cereals, pulses and legumes was under consideration by the Codex Committee on Cereals, Pulses and Legumes.

149. The Committee reiterated the importance of establishing maximum levels for cadmium and lead, as well as the reduction of contamination as much as reasonably achievable through source directed measures.

150. The Committee agreed that a position paper on cadmium, similar to the paper on lead presented at the current session, would be prepared by the Delegation of France for consideration by the 27th CCFAC, Governments were invited to send additional information directly to France. The Committee also agreed to gather additional information on cadmium and lead.

DISCUSSION PAPER ON PCBs AND DIOXINS (Agenda Item 17 (d))

151. The Committee noted that the above paper would be prepared by the Netherlands for discussion at the 27th Session of the CCFAC. Governments were invited to send additional information to the Delegation of The Netherlands.

GOVERNMENT COMMENTS AND INFORMATION ON PCBs, PBBs, TETRACHLOROBENZYLTOLUENE AND DIOXINS IN FOODS (Agenda Item 17 (e))

152. The Committee had before it document CX/FAC 94/23 and Conference Room Document 9, presenting government comments and information on the above contaminants in foods received from Finland, Canada and the United States in reply to CL 1993/8-FAC. Comments from Thailand (unnumbered) were also considered.

153. The Committee agreed that the comments on PCBs and dioxins should be taken into consideration by the Delegation of the Netherlands in preparing their position papers on PCBs and dioxins (see para. 151).

154. The Committee decided to continue to gather additional information on the above contaminants before deciding on possible future action.

GOVERNMENT COMMENTS AND INFORMATION ON POLYCYCLIC AROMATIC HYDROCARBONS, HYDROGEN CYANIDE, PHTHALATES AND ETHYL CARBAMATE IN FOODS (Agenda Item 17 (f))

155. The Committee had before it document CX/FAC 94/24 and Conference Room Document 10, presenting government comments and information on the above contaminants in foods received from Canada and the United States in reply to CL 1993/8-FAC. Comments from Thailand (unnumbered) were also considered.

156. The Committee decided that no action on the above contaminants could be taken at this stage and that additional information should be collected by the Committee.

PROPOSALS FOR THE PRIORITY EVALUATION OF FOOD ADDITIVES AND CONTAMINANTS BY JECFA (Agenda Item 18)

157. The Committee had before it Conference Room Document 13 (CX/FAC 94/25), the report of the informal Working Group on Priorities. The Working Group had met to consider the status of the substances listed for priority attention at the Twenty-fifth Session of CCFAC (Appendix VIII, ALINORM 93/12A) and to consider new additions to the priority list. Mr. R. Top of the Netherlands chaired the Working Group meeting.

158. Of the substances on the previous priority list, the JECFA Secretariat have placed the food additives alitame and 4-hexyl-resorcinol and the contaminants nitrite, nitrate, nitrosamines, ochratoxin A, and patulin on the agenda of the forty-fourth meeting of JECFA, which will be held in February 1995.

159. The Committee was aware that WHO and the International Programme on Chemical Safety (IPCS) were involved with various assessment activities with dioxins. However, it was considered to be important that JECFA also reviewed these contaminants to assess the safety of their oral intake and residues in food. Therefore, the Committee maintained dioxins and dioxin-like PCBs on the priority list.

160. The Committee was aware that carcinogenicity studies sponsored by the U.S. National Toxicology Program were underway on ethyl carbamate. Their progress should be monitored so that this substance could be placed on the agenda of JECFA at the earliest opportunity. In the meantime, the Committee maintained ethyl carbamate on the priority list.

161. It was not clear what data were available on the phthalates. The Delegation of the Netherlands would take the lead in making this determination. In the meantime, these contaminants were maintained on the priority list.

162. Studies were being performed on the polycyclic aromatic hydrocarbons (PAHs) in Denmark and the Netherlands. Delegations from these countries made commitments to ascertain their progress and report back to CCFAC next year. In the meantime, the Committee maintained these contaminants on the priority list.

163. The trichothecenes were considered to be important contaminants, and that they should be reviewed by JECFA as soon as relevant data became available. A long-term study in mice on deoxynivalenol (DON, vomitoxin) was presently underway in Canada. The trichothecenes were maintained on the priority list pending the results of this study.

164. The Committee agreed to add glycerol ester of wood rosin and polydextrose (specifications only) to the priority list at the request of the delegation of the United States of America and to add sucrose esters of fatty acids at the request of the Delegation of Japan.

165. In view of the discussion that was held under Agenda Item 16 (paras. 114-123), the Committee agreed to add aflatoxins B_1 and M_1 to the priority list. The FAO Joint Secretary of JECFA informed the Committee that specifications for all of the substances placed in Category III (Appendix VI) at the present session of the CCFAC would be placed on the agenda at the forty-fourth meeting of JECFA. In addition, a number of other substances will be placed on the agenda for review of specifications because they were either placed in Category III at earlier sessions of CCFAC or requests for their review had been sent directly to FAO.

166. The representative of the EEC noted that mineral oil (food-grade) was on the agenda of the forty-fourth meeting of JECFA, and suggested that microcrystalline wax and petroleum jelly, two other substances which were on the agenda for speci-fications only, be added for toxicological evaluation since they were closely related to mineral oil. The WHO Joint Secretary of JECFA agreed that this would be reasonable since they formed part of a continuum, and that the JECFA Secretariat would consider doing so.

167. In view of the fact that FAO and WHO planned on convening one JECFA meeting per year on food additives and contaminants beginning in 1995 and the small number of food additives now on the priority list, the JECFA Secretariat encouraged delegations to submit new food additives for priority attention at future sessions of CCFAC.

168. The Committee agreed to the priority list as attached to this report as Appendix VI.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 19)

Medium-Term Objectives and Future Programme of Work

169. The Committee was informed that the Commission had requested all Codex Committees to consider their medium-term objectives as a standing agenda item (paras. 75-79, ALINORM 93/40), and that a report on the Committee's current status of work (see Annex 1) should be made to the Executive Committee on a regular basis, to be reviewed in light of the medium-term objectives.

170. The Committee concurred with a suggestion of the Secretariat that the current CCFAC medium-term objective concerning the "Establishment of General Procedures for the Review of Contaminant Levels in Foods" should be changed to reflect the Committee's work regarding the establishment of the general standard for contaminants.

Future Work

171. The Committee agreed that the following matters would be discussed at its Twenty-seventh Session:

- Proposed Draft Codex General Standard for Food Additives;
- Proposed Draft Codex General Standard for Contaminants and Toxins in Foods ;
- Endorsement and/or Revision of Maximum Levels for Food Additives and Contaminants in Codex Standards;
- Action Required as a Result of Changes in ADI Status and other Toxicological Recommendations ;
- Consideration of Specifications for the Identity and Purity of Food Additives ;
- Consideration of Methods of Analysis for Food Additives in Foods;
- Proposed Amendments to the International Numbering System;
- Proposed Amendments to the Inventory of Processing Aids;
- Consideration of the Draft Maximum Level for Aflatoxin M_1 in Milk;
- Consideration of Aflatoxin Levels and Sampling Plans in all Foodstuffs ;
- Consideration of Ochratoxin A and Trichothecenes in Foods;
- Consideration of Cadmium and Lead in Foods;
- Code of Practice for the Reduction of Aflatoxins in Raw Materials and Supplementary Feedingstuffs ;
- Code of Practice on Source Directed Measures to Reduce Contamination of Foodstuffs;
- Consideration of PCBs, PBBs, tetrachlorobenzyltoluene, dioxins, polycyclic aromatic hydrocarbons, hydrogen cyanide, phthalates and ethylcarbamate;
- Procedures for the Evaluation of Food Intake Data Used in Risk Analysis;
- Consideration of Technological Justification and Need for the Use of Food Additives;
- Proposals for the Priority Evaluation of Food Additives and Contaminants by JECFA.

DATE AND PLACE OF NEXT SESSION (Agenda Item 20)

172. The Committee was informed that its 27th Session would be held from 20-24 March 1995 in the Netherlands, with the understanding that the Working Group on the General Standard for Food Additives would meet on Friday, 17 March and the Working Group on Specifications would meet on Saturday, 18 March.

Annex 1

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS
Current Status of Work

SUBJECT	STEP	FOR ACTION BY:	DOCUMENT REFERENCE
Revised Draft Preamble to the Codex General Standard for Food Additives	8	21st CAC	Appendix II, ALINORM 95/12
Proposed Draft Preamble to the Codex General Standard for Contaminants and Toxins in Foods	5	41st EXEC Governments 27th CCFAC	Appendix III, ALINORM 95/12
Specifications Recommended for Adoption as Codex Advisory Specifications	8	21st CAC	Appendix IV, ALINORM 95/12
Amendments to the International Numbering System	8	21st CAC	Appendix V, ALINORM 95/12
Draft Maximum Level for Aflatoxin M_1 in Milk	7	27th CCFAC	para. 119, ALINORM 95/12
Revised Schedules 1, 2 and Annex A of the Proposed Draft General Standard for Food Additives	2, 3	Governments USA/Secretariat Governments 27th CCFAC	paras. 39-47, ALINORM 95/12
Consideration of Technological Justification and Need for the Use of Food Additives	2	Iceland/ New Zealand 27th CCFAC	para. 43, ALINORM 95/12
Procedures for the Evaluation of Food Intake Data Used in Risk Analysis	2, 3	U.K. Governments 27th CCFAC	para. 30, ALINORM 95/12
Proposed Draft Codex General Standard for Contaminants and Toxins in Foods (excluding Preamble)	2, 3	Netherlands/ Denmark Governments 27th CCFAC	paras. 103-110 ALINORM 95/12
Consideration of Methods of Analysis for the Determination of Food Additives in Foods	2. 3	Canada 27th CCFAC 20th CCMAS	paras. 82-83, ALINORM 95/12
Proposed Draft Code of Practice on Source Directed Measures to Reduce Contamination of Foodstuffs	2, 3	Sweden Governments 27th CCFAC	paras. 137-140, ALINORM 95/12
Proposed Draft Code of Practice for the Reduction of Aflatoxins in Raw Materials and Supplementary Feedingstuffs for Milk Producing Animals	2, 3	Canada Netherlands Thailand Governments 27th CCFAC	paras. 128-130, ALINORM 95/12
Information on Aflatoxin Levels and Sampling Plans in all foodstuffs	3	Governments 27th CCFAC	paras. 124-126, ALINORM 95/12
Information on Ochratoxin A and Trichothecenes	3	Governments Sweden 27th CCFAC	paras. 131-133, ALINORM 95/12
Discussion Paper on Lead	2, 3	Sweden/Denmark Governments 27th CCFAC	paras. 141-145, ALINORM 95/12
Discussion Paper on Cadmium	2, 3	France 27th CCFAC	paras. 146-150, ALINORM 95/12

Discussion Paper on PCBs and Dioxins	2, 3	Netherlands 27th CCFAC	para. 151, ALINORM 95/12
Information on lead, cadmium, PCBs, PBBs, tetrachlorobenzyltoluene, dioxins, polycyclic aromatic hydro-carbons, hydrogen cyanide, phthalates and ethyl carbamate in foods	3	Governments 27th CCFAC	paras. 150, 154 and 156, ALINORM 95/12
Amendments to the Inventory of Processing Aids	3	Governments Germany 27th CCFAC	paras. 73-75, ALINORM 95/12
Food Additives and Contaminants proposed for priority evaluation by JECFA	3	Governments 27th CCFAC	Appendix VI, ALINORM 95/12

REVISED DRAFT PREAMBLE TO THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES (At Step 8)

1. SCOPE

1.1 Permitted Food Additives

Only the food additives listed herein are permitted for use in foods in conformance with the provisions of this Standard.[1] Only food additives which have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and found acceptable for use in foods are included in this Standard.

[1] This provision does not apply to food additive classes not included in the General Standard as currently drafted. The statement refers only to antioxidants and preservatives.

1.2 Foods in Which Additives May Be Used

This Standard shall set forth the conditions under which permitted food additives may be used in all foods, whether or not they have previously been standardized by Codex. The food additive provisions of Codex Commodity Standards shall be included in and superseded by the provisions of this Standard. The general basis for the provisions of this Standard are set forth in Annex A. These provisions should also comply with the other requirements of the Preamble.

1.3 Foods in Which Additives May Not Be Used

Food categories or individual food items where the use of food additives are not allowed or are restricted shall be defined by this Standard.

1.4 The Permitted Levels of Use for Food Additives

The primary objective of establishing permitted levels of use of food additives in various food groups is to ensure that the intake of additives does not exceed the acceptable daily intake.

The food additives covered by this standard and their maximum levels of use are based in part on the food additive provisions of previously established Codex commodity standards, or upon the request of governments after subjecting the requested maximum levels to an appropriate method which would verify the compatibility of a proposed maximum level with the ADI.

The Danish budget method may be used as a first step in this regard[2]. The submission of actual food consumption data is also encouraged.

[2] Consensus Document on the Danish Budget Method" , Nordic Working Group on Food Toxicology and Risks Evaluation, Report No. 4/90.

2. DEFINITIONS OF TERMS USED IN THIS STANDARD

(a) Food additive means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise

affecting the characteristics of such foods. The term does not include "contaminants" or substances added to food for maintaining or improving nutritional qualities.[3]

(b) Acceptable Daily Intake (ADI) is an estimate by JECFA of the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (standard man - 60 kg). [4]

(c) Acceptable Daily Intake "Not Specified" (NS) is a term applicable to a food substance of very low toxicity which, on the basis of the available data (chemical, biochemical, toxicological, and other), the total dietary intake of the substance arising from its use at the levels necessary to achieve the desired effect and from its acceptable background in food does not, in the opinion of JECFA, represent a hazard to health. For that reason, and for reasons stated in individual JECFA evaluations, establishment of an acceptable daily intake expressed in numerical form is not deemed necessary by JECFA. An additive meeting this criterion must be used within the bounds of good manufacturing practice as defined in sub-paragraph 3.3 below.

[3] Codex Alimentarius, Second Edition (1992), Volume I (General Recommendations), p. 11.

[4] Principles for the Safety Assessment of Food Additives and Contaminants in Food, World Health Organization, (WHO Environmental Health Criteria, No. 70), p. 1Il (1987).

3. GENERAL PRINCIPLES FOR THE USE OF FOOD ADDITIVES[5]

[5] General Principles for the Use of Food Additives were originally adopted by the Ninth Session of the Codex Alimentarius as a Codex Advisory Text (para. 295, ALINORM 72/35) and were reprinted in the Second Edition of the Codex Alimentarius, Vol. 1 (General Requirements), pp. 49-51 (1992). Pertinent portions of the Text have now been incorporated as an integral part of this Standard, suitable modifications having been made as necessary with respect to the present context.

3.1 Safety Evaluation

(a) Only those food additives shall be endorsed and included in this Standard which, so far as can be judged on the evidence presently available from JECFA, present no hazard to the health of the consumer at the levels of use proposed.

(b) The inclusion of a food additive in this Standard shall have taken into account any Acceptable Daily Intake, or equivalent assessment, established for the additive and its probable daily intake[6] from all sources. Where the food additive is to be used in foods eaten by special groups of consumers, account shall be taken of the probable daily intake of the food additive by consumers in those groups.

[6] "Guidelines for Simple Evaluation of Food Additive Intake," CAC/VOL. XIV Ed. 1, Supplement 2 (1989), gives procedures for calculating the theoretical maximum daily intake (TMDI) and the estimated daily intake (EDI) of food additives; other appropriate procedures may be used to calculate the TMDI and EDI.

3.2 Technological Need and Justification of Use

The use of food additives is justified only when such use has an advantage, does not present a hazard to health and does not mislead the consumer, and serves one or more of the purposes and needs set out from (a) through (d) below, and only where these objectives cannot be achieved by other means which are economically and technologically practicable:

(a) to preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified in the circumstances dealt with

in sub-paragraph (b) and also in other circumstances where the food does not constitute a significant item in a normal diet;

(b) to provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;

(c) to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer;

(d) to provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food; provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities.

3.3 Good Manufacturing Practice (GMP)[7]

[7] Codex Alimentarius Commission, Procedural Manual, Seventh Edition (1989), pp. 134-35

All food additives subject to the provisions of this Standard shall be used under conditions of good manufacturing practice, which include the following:

(a) the quantity of the additive added to food shall be limited to the lowest possible level necessary to accomplish its desired effect;

(b) the quantity of the additive that becomes a component of food as a result of its use in the manufacturing, processing or packaging of a food and which is not intended to accomplish any physical, or other technical effect in the food itself, is reduced to the extent reasonably possible; and,

(c) the additive is prepared and handled in the same way as a food ingredient.

3.4 Specifications for the Identity and Purity of Food Additives

Food additives used in accordance with this Standard should be of appropriate food grade quality and should at all times conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission[8] or, in the absence of such specifications, with appropriate specifications developed by responsible national or international bodies. Food grade quality is achieved by compliance with the specifications as a whole and not merely with individual criteria in terms of safety.

[8] Food additive specifications endorsed by the Codex Alimentarius Commission are included in the JECFA "Compendium of Food Additive Specifications," Volumes 1 and 2 (1992), and in addenda thereto, published by FAO.

4. CARRY-OVER OF FOOD ADDITIVES INTO FOODS[9]

[9] The principle relating to the carry-over of food additives into foods (the "Carry-Over Principle") addresses the presence of additives in food as a result of the use of raw materials or other ingredients in which these additives are used. The Codex Alimentarius Commission at its 17th Session (1987) adopted a revised statement of the principle as a Codex Advisory Text. The Text is printed in its entirety in Codex Alimentarius, Second Edition, Vol. 1 (General Requirements), pp. 85-88, 1992. The Carry-Over Principle applies to all foods covered by Codex Standards, unless otherwise specified in such standards.

4.1 Compliance with the Carry-Over Principle

Other than by direct addition, an additive may be present in a food as a result of carry-over from a food ingredient, subject to the following conditions:

(a) the additive is permitted in the raw materials or other ingredients (including food additives) according to this General Standard;

(b) the amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum amount so permitted.

(c) the food into which the additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the ingredients under proper technological conditions or manufacturing practice.

5. FORMAT OF THE STANDARD

The food additives listed herein have been grouped into the 23 major functional classes of the Codex International Numbering System (INS) for Food Additives.[10] Schedule 1 of this Standard specifies, for each food additive (or food additive group) within each major functional class, the foods in which the additives may be used, together with their maximum levels of use.

[10] Although the General Standard as currently drafted covers only antioxidants and preservatives, the complete Standard will eventually cover the uses of food additives in all 23 INS functional classes; see Codex Alimentarius, Second Edition (1992), Volume I (General Recommendations), Section 5.1.

Schedule 2 of this Standard contains essentially the same information as that provided in Schedule 1 but is arranged by CIAA food category[11] and specifies which food additives may be used in foods covered by each category, as well as the maximum levels and conditions of use for each.

[11] Each Codex Commodity Standard has been initially assigned to one of the food categories or subcategories of the system developed by the Confederation des Industries Agro-Alimentaires de la CEE (CIAA). It is expected that the CIAA categorization system will form the basis of a new food classification scheme that will be eventually proposed for adoption by the CAC. Codex Standard Numbers (CXSNs), together with the corresponding names of the Codex Commodity Standards and the CIAA food categories and subcategories to which the CXSNs have been classified, are listed in ANNEX B.

Unless otherwise specified, maximum levels for food additives are set on the final product as consumed.

6. REVIEW AND REVISION OF THE STANDARD

The food additive provisions for this Standard shall be reviewed on a regular basis and revised as necessary in light of revisions of Acceptable Daily Intakes by JECFA or of changing technological need and justification for use.

ALINORM 95/12
APPENDIX III

PROPOSED DRAFT PREAMBLE TO THE CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS (at Step 5)

INTRODUCTION

This Standard is developed on the basis of previous discussion papers in which the problems and the Codex approach and procedure to deal with contaminants in food were elaborated. For a more comprehensive description of the reasoning behind the decisions that were taken, reference is made to these papers, listed in I.7., and to the reports of the Codex sessions in which these papers were discussed and the policy was decided. In order to present an easy overview of the issues involved, all principles and aspects that are involved in the Codex approach to contaminants are mentioned in a short and systematic way, with references, where necessary, to Annexes and other papers in which a more elaborated description can be found. Cursive typing is used when reference is made to Annexes and for text parts which are not meant to be part of the GSC in definitive form, but which are included in this version to introduce aspects which need further discussion.

I. PREAMBLE

I.1 SCOPE

This Standard contains the main principles and procedures which are used and recommended by the Codex Alimentarius in dealing with contaminants and toxins in foods and feeds, and lists the maximum levels of contaminants and natural toxicants in foods and feeds which are recommended by the CAC to be applied to commodities moving in international trade.

I.2 DEFINITION OF TERMS

I.2.1 General

The definitions for the purpose of the Codex Alimentarius, as mentioned in Volume 1, are applicable to the GSC and only the most important ones are repeated here. Some new definitions are introduced, where this seems warranted to obtain optimal clarity. When reference is made to foods, this also applies to animal feed, in those cases where this is appropriate.

I.2.2 Contaminant

Volume 1 of the Codex Alimentarius defines a contaminant as follows:

> "Any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter".

This standard applies to any contaminant that meets the terms of the Codex definition for a contaminant, including contaminants in feed for food-producing animals, except:

1) Contaminants having only food quality significance, but no public health significance, in the food(s).

2) Pesticide residues, as defined by the Codex definition that are within the terms of reference of the CCPR. Pesticide residues arising from pesticide uses not associated with food production may be considered for inclusion in the General Standard for Contaminants if not dealt with by the CCPR.

3) Residues of veterinary drugs, as defined by the Codex definition, that are within the terms of reference of the CCRVDF.

4) Microbial toxins, such as botulinum toxin and staphylococcus enterotoxin, that originate from microorganisms that are within the terms of reference of the CCFH.

5) Processing aids (that by definition are intentionally added to foods).

I.2.3 Natural toxins included in this standard

The Codex definition of a contaminant implicitly includes naturally occurring toxicants such as are produced as toxic metabolites of certain microfungi that are not intentionally added to food (mycotoxins).

Microbial toxins that are produced by algae and that may be accumulated in edible aquatic organisms such as shellfish (phycotoxins) are also included in this standard. Mycotoxins and phycotoxins are both subclasses of contaminants.

Inherent natural toxicants that are implicit constituents of foods resulting from a genus, species or strain ordinarily producing hazardous levels of a toxic metabolite(s), i.e. Phytotoxins are not generally considered within the scope of this standard. They are, however, within the terms of reference of the CCFAC and will be dealt with on a case by case basis.

I.2.4 Maximum level and related terms

The Codex maximum level (ML) for a contaminant or naturally occurring toxicant in a food or feed commodity is the maximum concentration of that substance recommended by the CAC to be legally permitted in that commodity. The ML is intended to ensure free movement of food in international trade.

A Codex guideline level (GL) is the maximum level of a substance in a food or feed commodity which is recommended by the CAC to be acceptable for commodities moving in international trade. When the GL is exceeded, governments should decide whether and under what circumstances the food should be distributed within their territory or jurisdiction [1]. (Ref. 18th CAC)

[1)] Because the CAC has decided that the preferred format of a Codex standard in food or feed is a maximum level, the present existing or proposed guideline levels shall be reviewed for their possible conversion to a maximum limit.

I.3. GENERAL PRINCIPLES REGARDING CONTAMINANTS IN FOODS

1.3.1 General

Foods and feeds can become contaminated by various causes and processes. Contamination generally has a negative impact on the quality of the food or feed and may imply a risk to human or animal health. Contamination shall therefore be prevented or reduced as much as possible.

Contaminant levels in foods shall be as low as reasonably achievable. The following actions may serve to prevent or to reduce contamination of foods and feeds:

- preventing food contamination at the source, e.g. by reducing environmental pollution.
- applying appropriate technology in food production, handling, storage, processing and packaging.
- applying measures aimed at decontamination of contaminated food or feed. and measures to prevent contaminated food or feed to be marketed for consumption.

To ensure that adequate action is taken to reduce contamination of food and feed a Code of Practice shall be elaborated comprising source related measures and Good Manufacturing Practice as well as Good Agricultural Practice in relation to the specific contamination problem.

The degree of contamination of foods and feeds and the effect of actions to reduce contamination shall be assessed by monitoring, survey programs and more specialized research programs, where necessary.

When there are indications that health hazards may be involved with consumption of foods that are contaminated, it is necessary that a risk assessment is made. When health concerns can be substantiated, a risk management policy must be applied, based on a thorough evaluation of the situation. Depending on the assessment of the problems and the possible solutions, it may be necessary to establish maximum levels or other measures governing the contamination of foods. In special cases; it may also have to be considered to give dietary recommendations, when other measures are not sufficiently adequate to exclude the possibility of hazards to health.

National measures regarding food contamination should avoid the creation of unnecessary barriers to international trade in food or feed commodities. The purpose of the Codex General Standard for Contaminants in Food is to provide guidance about the possible approach of the contamination problem and to promote international harmonization through recommendations which may help to avoid the creation of trade barriers.

For all contaminants, which may be present in more than one food or feed item, a general approach shall be applied, taking into account all relevant information that is available, for the assessment of risks and for the development of recommendations and measures, including the setting of maximum levels.

I.3.2 Principles for establishing maximum levels in foods and feeds

Maximum levels shall only be set for those foods in which the contaminant may be found in amounts that are significant for the total exposure of the consumer. They shall be set in such a way that the consumer is adequately protected. At the same time the technological possibilities to comply with maximum levels shall be taken into account. The principles of Good Manufacturing Practice, Good Veterinary Practice and Good Agricultural Practice shall be used. Maximum levels shall be based on sound scientific principles leading to levels which are acceptable worldwide, so that international trade in these foods is facilitated. Maximum levels shall be clearly defined with respect to status and intended use.

I.3.3 Specific criteria

The following criteria shall (not preventing the use of other relevant criteria) be considered when developing recommendations and making decisions in connection with

the Codex General Standard for Contaminants in Food: (Further details about these criteria are given in Annex I)

Toxicological information

- identification of the toxic substance(s)
- metabolism by humans and animals, as appropriate
- toxicokinetics and toxicodynamics
- information about acute and long term toxicity
- integrated toxicological expert advice regarding the acceptability and safety of intake levels of contaminants, including information on any population groups which are specially vulnerable

Analytical data

- validated qualitative and quantitative data on representative samples
- appropriate sampling procedures

Intake data

- presence in foods of dietary significance for the contaminant intake
- presence in foods that are widely consumed
- food intake data for average and most exposed consumer groups
- results from total diet studies
- calculated contaminant intake data from food consumption models

Fair trade considerations

- existing or potential problems in international trade
- foods concerned moving in international trade
- information about national regulations, in particular on the data and considerations on which these regulations are based

Technological considerations

- information about contamination processes, technological possibilities, production and manufacturing practices and economic aspects related to contaminant levelmanagement and control.

Risk assessment and risk management considerations

- risk assessment
- risk management options and considerations
- consideration of possible maximum levels in foods based on the criteria mentioned above.
- consideration of alternative solutions

I.4 CODEX PROCEDURE FOR ESTABLISHING STANDARDS FOR CONTAMINANTS IN FOOD

I.4.1 General

The Procedure for the elaboration of Codex Standards, as contained in the Procedural Manual, is applicable. Further details are mentioned here regarding the procedure to be followed and the criteria for decision making, in order to clarify and to facilitate the process of the elaboration of Codex Standards for contaminants.

I.4.2 Procedure for preliminary discussion about contaminants in the CCFAC

Suggestions for new contaminants or new contaminant/commodity combinations to be discussed in the CCFAC and to be included in the GSC may be raised by delegates or by the secretariat. An initial discussion may be held based on oral contributions, but preferably on the basis of a note containing relevant and adequate information. For a satisfactory preliminary review the following information is essential:

(1) Identification of the contaminant and concise information about the background of the problem.

(2) Indications about the availability of toxicological information and analytical and intake data, including references.

(3) Indications about (potential) health problems.

(4) Indications about existing and expected barriers to international trade.

(5) Information about technological possibilities and economic aspects related to the management of the contaminant problem in food.

(6) Preferably a proposal for action by the CCFAC.

When a delegation wishes that the Committee shall consider a request for action concerning a specific contaminant this delegation shall, as far as possible, supply information as stated above to serve as the basis for a preliminary review and request the Secretariat to include the matter on the agenda of the next meeting of the Committee.

I.4.3 Procedure for risk management decisions in the CCFAC regarding contaminants

An evaluation by JECFA of the toxicological and of other aspects of a contaminant and subsequent recommendations regarding the acceptable intake and regarding maximum levels in foods shall be the main basis for decisions to be discussed by the CCFAC. In the absence of recommendations by JECFA, decisions may be taken by CCFAC when sufficient information from other sources is available to the Committee and the matter is considered urgent.

The CCFAC procedure for risk management decisions is further described in Annex II (along the lines of CX/FAC 93/11, paras. 16-22).

I.5 FORMAT OF THE STANDARD FOR CONTAMINANTS IN FOODS

The General Standard for Contaminants in Foods contains two types of presentation for the Standards: Schedule I in which the standards are listed per contaminant in the various food categories, and Schedule II in which the contaminant standards are presented per food (category).

The format of the presentation is according to the provisions described in the Procedural Manual, in so far they are applicable. In order to obtain maximal clarity, explanatory notes shall be added where appropriate. The format contains all elements necessary for full understanding of the meaning, background, application and scope of the standards and contains references to the relevant documents and discussion reports on which the standard is based.

A full description of the format is given in Annex III.

The listing of the Codex Standards for the different contaminants may be according to a numbering system for contaminants (see proposal in Annex IV). The list is summarized in a list of contents, and an alphabetical listing of the contaminants shall be added for easy reference.

For each session of the CCFAC, a working document shall be prepared in which the complete list of Codex Standards for contaminants in foods (both proposed and agreed) is presented in the form of Schedule I.

The list of Codex contaminant standards for individual foods or food categories shall be presented according to an agreed food categorization system. Some options are discussed in Annex V.

I.6 REVIEW AND REVISION OF THE STANDARD

The contaminant provisions for this Standard shall be reviewed on a regular basis and revised as necessary in the light of revisions of toxicological advice by JEGFA or of changed risk management views, residue management possibilities, scientific knowledge or other important relevant developments.

Specific attention shall be given to the review of existing Maximum Levels and Guideline Levels and to their possible conversion to Maximum Limits.

I.7 REFERENCES

I.7.1 Codex Alimentarius Commission: Procedural Manual, 8th Edition, 1993.

I.7.2 Berg, Torsten and Kloet, David: Proposed Draft Procedures for establishing a General Standard for Contaminants in Foods (CX/FAC 93/11, January 1993).

I.7.3 Bal, Aat and Berg, Torsten: Contaminants in Food - towards a Codex Approach (CX/FAC 92/10), December 1991.

I.7.4 Mollenhauer, H.P.: Contaminants in Food, Approaches by Governments and possible actions by the CCFAC (CX/FAC 83/18), January 1983.

SPECIFICATIONS FOR IDENTITY AND PURITY OF CERTAIN FOOD ADDITIVES ASPIRING FROM THE 41ST MEETING OF JECFA

Category I (recommended to the Commission for adoption)

Ammonium polyphosphate
β-glucanase from *Aspergillus niger*
5'-Disodium guanylate
5'-Disodium inosinate
Disodium pyrophosphate
Dodecyl gallate
Erythrosine
Lecithin
d-Limonene
α-Methylbenzyl alcohol
Octyl gallate
Quinine hydrochloride
Quinine sulfate
Sucralose
Sucrose acetate isobutyrate
Tetrasodium pyrophosphate
Urea
Xanthan gum

Category II (recommended for adoption after editorial changes, including technical revisions)

α-amylase from Bacillus stearothermophilus (systematic name)
α-amylase from Bacillus subtilis (systematic name)
2-Ethyl-l-hexanol (solubility)
Propyl gallate (CAS number)

Category III (substantive changes required)

Alginic acid	(definition, formula weight, functional use, pH range, ash, microbiological criteria, lead and heavy metals limits)
Ammonium alginate	(definition, formula weight, functional use, pH range, ash, microbiological criteria, lead and heavy metals limits)
Calcium alginate	(definition, formula weight, functional use, pH range, ash, microbiological criteria, lead and heavy metals limits)
Carmines	(CAS number, heavy metals limit, method of assay, methanol limit)
Carotenes (Algae)	(INS number, extraction solvents, residual solvents, heavy metals limit, need to differentiate between algae and vegetable carotenes)
Carotenes (Vegetable)	(raw materials, INS number, extraction solvents, residual solvents, heavy metals limit, need to differentiate between algae and vegetable carotenes)
Cochineal extracts	(description, protein limit, assay, method of assay,

	methanol content, heavy metals limit)
Maltitol syrup	(INS number and error in calculation formula under method of assay)
Potassium alginate	(definition, formula weight, functional use, pH range, ash, microbiological criteria, lead and heavy metals limits)
Processed Euchema seaweed	(name, synonyms, solubility, sulfate, acid insoluble matter, pH criterion, test for galactose and anhydrogalactose, limits for cadmium, mercury and lead, extract from *E. spinosum* heavy metals, microbiological criteria)
Sodium alginate	(definition, formula weight, functional use, pH range, ash, microbiological criteria, lead and heavy metals limits)

Category IV (substances revised by recent sessions of JECFA)

None.

Category V (specifications designated as tentative)

Alpha-amylase and glucoamylase from *Aspergillus oryzae* var.
ß-Cyclodextrin
Konjac flour
Propylene glycol alginate
Sodium iron EDTA.

PROPOSED AMENDMENTS TO THE INTERNATIONAL NUMBERING SYSTEM

The 26th Session of the CCFAC agreed to allocate the following INS Food Additive numbers for adoption by the 21st Session of the Codex Alimentarius Commission.

ADDITIONS

Number	Food Additive	Functions
407a	Processed Eucheuma Seaweed	thickener, stabilizer
956	Alitame	sweetener

FOOD ADDITIVES AND CONTAMINANTS PROPOSED BY CCFAC FOR PRIORITY EVALUATION BY JECFA

Food additives	Proposed by
Glycerol ester of wood rosin	United States
Polydextrose (specifications only)	United States
Sucrose esters of fatty acids	Japan

Contaminants	Proposed by
Aflatoxins B_1 and M_1	CCFAC
Dioxins and dioxin-like PCBs	CCFAC
Ethyl carbamate	CCFAC
Phthalates	Netherlands
Polycyclic aromatic hydrocarbons	Netherlands
TrichothecenesDenmark	