codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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ALINORM 95/12A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-first Session
Rome, 3-8 July 1995

REPORT OF THE 27TH SESSION OF THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

The Hague, 20-24 March 1995

NOTE: This report includes Codex Circular Letter CL 1995/10-FAC

TO: - Codex Contact Points
- Interested International Organizations
- Participants at the Twenty-Seventh 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-Seventh Session of the Codex Committee on Food Additives and Contaminants (ALINORM 95/12A)**

The report of the Twenty-Seventh Session of the Codex Committee on Food Additives and Contaminants (CCFAC) is attached. It will be considered by the Twenty-First Session of the Codex Alimentarius Commission to be held in Rome from 3-8 July 1995.

PART A: MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION

The following matters will be brought to the attention of the 21st Session of the Codex Alimentarius Commission for adoption:

1. **Draft Preamble to the General Standard for Contaminants and Toxins in Foods at Step 8;** paras. 80-90 and Appendix VI, ALINORM 95/12A.

2. **Codex Advisory Specifications at Step 8;** paras. 53-57 and Appendix IV (Categories I and II), ALINORM 95/12A.

Governments wishing to propose amendments or to comment on the above matters should do so in writing in conformity with the Guide to the Consideration of Codex Standards Including Consideration of Any Statements Relating to Economic Impact *(Codex Alimentarius Procedural Manual,* Eighth Edition, pp. 33-35) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, **not later than 31 May 1995.**

3. **Annex A of the Proposed Draft General Standard for Food Additives at Step 5;** para. 48 and Appendix III, ALINORM 95/12A.

4. **Annexes I, II and III of the Proposed Draft General Standard for Contaminants and Toxins in Foods at Step 5;** para. 101 and Appendix VII, ALINORM 95/12A.

Governments wishing to submit comments regarding the implications which the above matters or any provisions thereof may have for their economic interest should do so in writing in conformity with the Uniform Procedure for the Elaboration of codex Standards and Related Texts (at Step 5) *{Codex Alimentarius Procedural Manual,* Eighth Edition, pp. 27-29) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy **not later than 31 May 1995.**

PART B: REQUEST FOR COMMENTS AND INFORMATION

1. Proposed Amendments to the International Numbering System; paras. 58-62, ALINORM 95/12A.

The Committee agreed that consideration of amendments to the International Numbering System would be a standing agenda item.

2. Proposed Amendments to the Revised Inventory of Processing Aids; paras. 63-67 and Appendix V, ALINORM 95/12A.

The Committee agreed to append the revised Inventory of Processing Aids to its report for additional comments and discussion at its next Session.

3. Consideration of Methods of Analysis for the Determination of Food Additives in Foods Moving in International Trade; paras. 68-72, ALINORM 95/12A.

The Committee agreed to further develop the above list of methods on the basis of comments to be requested on document ***CX/FAC 95/9.***

4. Information on Cadmium, PCBs, Dioxins, Polycyclic Aromatic Hydrocarbons and Hydrogen Cyanide; paras. 131, 139 and 142, ALINORM 95/12A.

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

5. Proposals for the Priority Evaluation of Food Additives and Contaminants by JECFA; para. 157 and Appendix VIII, ALINORM 95/12A.

The committee agreed that additional proposals for revisions to the list would be requested.

Governments and international organizations wishing to submit comments and information on the above matters are invited to do so **no later than 1 October 1995** as follows: Mrs. A.B. 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 (Telefax No. 31.70.347.7552); 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-seventh Session of the Codex Committee on Food Additives and Contaminants reached the following conclusions:

MATTERS FOR CONSIDERATION BY THE EXECUTIVE COMMITTEE AND/OR COMMISSION:
– Agreed to forward **Annex A (Guidelines for the Estimation of Appropriate Levels of Use of Food Additives)** of the proposed draft General Standard for Food Additives to the Commission for adoption at Step 5 (para. 48);
– Agreed to forward four substances in Categories I and II to the Commission for adoption as **Codex Advisory Specifications** at Step 8 (para. 56);
– Agreed to forward the revised version of the draft **Preamble to the General Standard for Contaminants and Toxins in Foods** to the Commission for adoption at Step 8 (para. 90);
– Agreed to forward revised versions of **Annexes I, II and III of the proposed draft General Standard for Contaminants and Toxins in Foods** to the Commission for adoption at Step 5 (para. 101), and;.
– Agreed to forward the summary of its **Current Status of Work** to the Executive Committee for approval (para. 159).
OTHER MATTERS OF INTEREST TO THE COMMISSION:
– Agreed to append the table concerning **Action Required as a Result of Changes in ADI Status or Other Toxicological Recommendations** to its report for action by other Codex Committees, with the understanding that this subject would remain as a standing agenda item (para. 28 and Appendix II);
– Accepted the offer of the United Kingdom to prepare more precise proposals on **risk assessment/management procedures related to food additive intake and exposure** for consideration at its next meeting (paras. 35 and 46-47);
– Agreed that **Schedules 1 and 2 of the proposed draft General Standard for Food Additives as related to antioxidants and preservatives** should be condensed to ranges of minimum and maximum levels within food categories and sub-categories, with the understanding that current food additive levels in Codex Standards should be included (para. 40);
– Agreed to proceed with the inclusion of proposed food additive levels for **thickeners, stabilizers and sweeteners** into the proposed draft General Standard for Food Additives on the basis of government comments (para. 41);
– Requested Iceland and New Zealand to proceed with the identification of information needed to address **technological justification and need for the use of food additives** and the criteria for evaluating such data in the context of the General Standard for Food Additives (paras. 43-44 and 47);
– Agreed to **postpone endorsement of food additive provisions in Codex Standards** with the understanding that new proposals clarifying individual provisions (including technological need) would be prepared by the relevant

Codex Committees for CCFAC review based on the Codex General Principles for the Use of Food Additives (para. 51);
– Agreed that governments wishing to comment on the previous CCFAC decision to assign **International Numbering System No. 407a to Processed Eucheuma Seaweed** should do so at the Commission in accordance with Codex Rules of Procedure, and that additional proposals for amendments to the International Numbering System would be requested (paras. 61-62);
– Agreed to append the revised **Inventory of Processing Aids** to its report for additional comment and discussion at its next Session (para. 67);
– Agreed that Canada would further develop the **List of Methods of Analysis for the Determination of Food Additives in Foods Moving in International Trade** on the basis of comments, for consideration at its next Session (para. 72);
– Agreed to **temporarily endorse contaminant levels for hydrocyanic acid in Codex Standards for Gari and Edible Cassava Flour** with the understanding that the Codex Regional Coordinating Committee for Africa would be requested to clarify the levels proposed (para. 74);
– Agreed to **postpone endorsement of the proposed draft guideline level and sampling plans for aflatoxins in peanuts** pending the future JECFA evaluation (para. 79);
– Agreed that Denmark and the Netherlands would revise **Annexes IV and V of the proposed draft General Standard for Contaminants and Toxins in Foods** for circulation and comment (para. 102);
– Agreed that the United Kingdom, in cooperation with the Netherlands and the United States, would prepare a **position paper on aflatoxins** for circulation and comment (para. 104);
– Agreed to maintain the **draft maximum level for Aflatoxin M_1 in Milk** at Step 7 pending the JECFA evaluation of aflatoxins and the development of the position paper on aflatoxins by the United Kingdom (para. 106);
– Agreed that comments submitted on **Aflatoxin Levels and Sampling Plans in all Foodstuffs** would be incorporated into the position paper on aflatoxins under development by the United Kingdom (para. 107);
– Agreed that Canada should 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 comment at Step 3 prior to its next Session (para. 113);
– Agreed that Sweden should prepare a **position paper on Ochratoxin A** for consideration at its next Session (para. 116);
– Agreed that Sweden would further develop the **proposed draft Code of Practice on Source Directed Measures to Reduce the Contamination of Foodstuffs,** while also taking account of information submitted on **cadmium and lead,** for circulation and comment prior to the Committees next Session (paras. 119-120,124 and 131);

– Agreed that Denmark would revise the **proposed draft Standard for Lead** for circulation and comment prior to its next Session (para. 128);
– Agreed to request **additional information on cadmium** for consideration at its next Session (para. 131);
– Agreed that the Netherlands would revise, in part on the basis of0 additional comments to be submitted, the **discussion paper on PCBs and Dioxins** for consideration at its next Session (paras. 136-137 and 139);
– Agreed that no further action was needed on **PBBs, tetrachlorobenzyltoluene, phthalates and ethyl carbamate** at the present time, with the understanding that additional information could be requested in the future if it was decided that levels needed to be established (paras. 139 and 141);
– Agreed to collect additional information on **polycyclic aromatic hydrocarbons and hydrogen cyanide** before deciding on possible future action (para. 142), and;
– Proposed a **List of Food Additives and Contaminants for Priority Evaluation by JECFA**, with the understanding that additional proposals for revisions to the list would be requested (para. 157).

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LIST OF APPENDICES

OPENING OF THE SESSION (Agenda Item 1)

1. The Codex Committee on Food Additives and Contaminants held its 27th Session in the Hague, the Netherlands, from 20-24 March 1995, through the Courtesy of the Netherlands. Mr. H. van der Kooi of the Netherlands acted as Chairman. The session was attended by 247 participants, representing 40 member countries, and 37 international organizations (see appendix I for the List of Participants).

2. At the invitation of the Chairman, Mr. T. Joustra, the Secretary General of Agriculture, Nature Management and Fisheries welcomed everyone to the 27th session of the Codex Committee of Food Additives and Contaminants on behalf of the Netherlands.

3. The Secretary General introduced the new chairman of the Codex Committee on Food Additives and Contaminants, Mr. H. Van der Kooi. Mr. H. van der Kooi is interalia responsible for Codex affairs at the Ministry of Agriculture, Nature Management and Fisheries in the Netherlands.

4. The Secretary General reminded the Committee of the growing importance of Codex work in light of the GATT agreements which were agreed on in January 1994. The ever increasing number of participants indicates the interest of governments and international organizations.

5. The Secretary General showed great interest in the developments on risk assessment, risk management and risk communication. The Secretary General stressed that sound risk management is of outstanding importance for human, animal and plant health and the environment on the one hand, and for fair trade on the other.

6. The Secretary General 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.

7. The Chairman stressed accordingly the great importance of clear and transparent decision making processes of the Codex Committees. Therefore the horizontal approach should be further elaborated, particularly in the General Standard on Food Additives and the General Standard on Contaminants.

ADOPTION OF THE AGENDA (Agenda Item 2)

8. The Committee adopted the Provisional Agenda[1] as proposed, while documents concerning agenda item 9, Proposed Amendments to the International Numbering System[2] and agenda item 16, Proposals for the Priority Evaluation of Food Additives and Contaminants by JECFA[3] had not been prepared, as comments had not been submitted.

1 CX/FAC 95/1

2 CX/FAC 95/7

3 CX/FAC 95/23

9. In order to facilitate discussions concerning the priority evaluation of compounds by JECFA, the Committee appointed an informal working group on this subject under the Chairmanship of Mr. R. Top (The Netherlands). The Committee decided not to install the INS working group as comments had not been received (see paras. 58-62).

10. Pending the decision of the Codex Commission on the revision of the guidelines for Codex Committees concerning press and public attendance at Codex meetings, the Committee agreed to the attendance of a representative of the Press.

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.

MATTERS OF INTEREST ARISING FROM THE EXECUTIVE COMMITEE AND OTHER CODEX COMMITTEES (Agenda Item 4a)

Matters Arising from Other Codex Committees[1]

[1] CX/FAC 95/2

12. The Committee noted that the 41st Session of the Executive Committee[2] confirmed at Step 1 CCFAC proposals for new work concerning "Procedures for the Evaluation of Food Intake Data Used in Risk Analysis" (see paras. 29-35) and a "Code of Practice for All Foodstuffs Transported in Bulk" in collaboration with the Codex Committee on Food Hygiene (CCFH); the CCEXEC also adopted at Step 5 the proposed draft "Preamble to the Codex General Standard for Contaminants and Toxins in Foods" (see paras. 80-90) and agreed to the discontinuation of the establishment of a proposed draft "Guideline Level for Aflatoxin B_1 in Supplementary Feedingstuffs for Milk Producing Animals".

[2] ALINORM 95/3, para. 47 and Appendix II

13. The Committee noted that the 21st Session of the Codex Alimentarius Commission would make a decision as to which Committee (i.e., CCFAC or CCFH) was responsible for the initial elaboration of the proposed draft "Code of Practice for All Foodstuffs Transported in Bulk". However, as it was noted that such a Code should address all types of contamination (e.g., heavy metals, microorganisms and other contaminants), the importance of CCFACs participation in the drafting of the Code was emphasized (also see para. 118).

14. In discussing the request of the 27th Session of the Codex Committee on Food Hygiene for CCFAC to establish maximum levels for residues in spices fumigated with ethylene oxide[3] the Committee noted that the establishment of residue limits for fumigants appeared to be under the responsibility of the Codex Committee on Pesticide Residues and therefore, asked the CCPR to consider this matter.

[3] ALINORM 95/13, para. 81

15. In regard to the suggestion of the 23rd Session of the Codex Committee on Food Labelling[1] for the CCFAC to consider the problem of hypersensitive reactions to food additives in the context of the carry-over principle, the Committee reconfirmed its earlier decision that no specific action was required by the CCFAC in this regard, especially since JECFA took account of hypersensitive reactions when evaluating food additives. The Committee also noted the previous decision of the 19th Session of the Codex Alimentarius Commission that the Codex Committee on Methods of Analysis and Sampling was responsible for the establishment of methods of analysis for aflatoxins[2].

[1] ALINORM 95/22, para. 111

[2] ALINORM 91/40, paras. 214-215

16. The Committee agreed that the request of the 11th Session of the Codex Committee on General Principles[3] for clarification on how the CCFAC proposed to interact with the responsible commodity committees within the framework of the General Standards for Food Additives and for Contaminants should be discussed at its 28th Session on the basis of a paper to be prepared by the Codex Secretariat.

[3] ALINORM 95/33, para. 49

Progress Report on GEMS Food - the Global Food Contamination Monitoring and Assessment Programme[4]

[4] Conference Room Document 3

17. The Representative of WHO presented a progress report on GEMS/Food which provides Codex and other relevant institutions information on levels and trends of contaminants in food, their contribution to the total human exposure and significance with regard to public health and trade. GEMS/Food now includes participating institutions in 63 countries, including many developing countries.

18. Several GEMS/Food activities were presented which related to the work of the Committee, in particular the evaluation of chemical contamination of breast milk. Supporting components of GEMS/Food include on-going analytical quality assurance studies, provision of information on methodologies, training and limited material support. Two new WHO Collaborating Centres were designated in 1994 to inter alia cooperate with GEMS/Food in areas of mycotoxins and pesticide analysis and training.

19. Countries which were not currently participating in GEMS/Foods were encouraged to contact the GEMS/Food Coordinator, WHO, Geneva to obtain further information on joining the programme.

CONSIDERATION OF THE SUMMARY REPORT OF THE FORTY-FOURTH MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA) (Agenda Item 4b)

Summary Report of the 44th JECFA Meeting

20. The Committee had before it the summary report (Unnumbered) of the forty-fourth meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), which was held in Rome from 14 to 23 February 1995. The Committee noted that the full report would be published by WHO in late 1995. The summary report was introduced by the Joint JECFA Secretaries, Dr. J.L. Herrman (WHO) and Dr. J. Paakkanen (FAO).

21. The Joint Secretaries provided clarification on some of the individual evaluations that were performed, in particular, on nomenclature used for describing the mineral oils. Oils may be derived from two crude oil sources, of either naphtenic (N) or paraffinic (P) origin and are derived using either the conventional acid (oleum) treated (A) or the hydrogenation or hydrotreated (H) process. The viscosity is given in centistokes. Thus, a P100(H) oil refers to a paraffinic oil with a viscosity of 100 centistokes produced by hydrogenation process.

22. The Delegation of the United Kingdom, in commenting on the statement of JECFA that it is "inappropriate to compare exposure to nitrate from vegetables directly to the ADI and hence to derive limits for nitrate in vegetables directly from it", considered it to be inappropriate for the Codex Alimentarius Commission to establish nitrate limits in vegetables at this time (also see para. 153) .

23. Specifications for identity and purity were considered for fifty-six substances. New specifications were prepared for two substances that were evaluated for the first time. Specifications for forty-six substances were revised, for seven maintained unchanged and for one substance the existing specifications were withdrawn.

24. Work of the revision of the specifications for alginates, Processed Eucheuma Seaweed, and Gum Arabic highlighted the need for consistency in allocating limits for microorganisms in food additives from natural sources. JECFA will in future therefore require information on the microbiological status of substances prepared from natural source materials to enable the Committee to establish suitable microbiological purity criteria where needed. The information includes, but is not limited to, total plate counts, moulds and yeasts, coliforms and Salmonellae.

25. The Expert Committee also considered a paper that outlined an approach for the safety evaluation of flavouring agents that are consumed in small amounts. The approach makes use of human exposure thresholds for each of the structural classes, to which intake is compared. The integration of data on intake, in relation to thresholds, with information on structure-activity relationships, metabolism, and toxicity in the form presented in the criteria that were proposed, was considered by the Committee to provide a means of conducting evaluations consistent with principles previously elaborated by the Committee. It recommended that at a future meeting the procedure be applied to the evaluation of a number of flavouring agents from different chemical classes in order to assess its utility in practice, taking into account the effect of varying human exposure thresholds and in light of as wide a range of sources of data on intake as possible.

26. Specifications for flavouring substances will be established as these substances are placed on the agenda, taking into account the work already done by other expert bodies, like the Scientific Committee on Food of the European Union, the Committee of Experts on Flavouring Substances of the Council of Europe, and the Food Chemicals Codex of the National Academy of Sciences.

Action Required as a Result of Changes in ADI Status or Other Toxicological Recommendations Arising from the 44th JECFA Meeting[1]

[1] Conference Room Document 4

27. The Committee was informed that the above document summarized the result of changes in ADI status or other toxicological recommendations (i.e., for contaminants) arising from the 44th JECFA Session (Rome, 14-23 February 1995).

28. As at previous sessions, the Committee agreed to append the document to its report (see Appendix II) for action by the relevant Codex Commodity Committees. The Committee also noted that the consideration of changes resulting from a change in ADI or other toxicological recommendations would remain a standing agenda item, especially in view of the importance of taking this information into account when elaborating the General Standards.

CONSIDERATION OF PROCEDURES FOR THE EVALUATION OF FOOD INTAKE DATA USED IN RISK ANALYSIS (Agenda Item 5)

29. The Representative of the WHO presented a summary of the recently concluded Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues which was held at WHO Headquarters, 13-17 March 1995. The Consultation resulted in several recommendations, including a list of definitions for food

safety risk analysis terminology. Of particular importance to the Committee, the Consultation established a four step paradigm for risk analysis which was recommended for adoption across all Codex committees. The Consultation emphasized the need to separate risk assessment from risk management and communication which is required as a consequence of the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures. The Consultation endorsed the current direction of the Committee to explicitly include exposure assessment in the consideration of food additives and contaminants.

30. The Delegation of the UK introduced the working paper and comments submitted[1]. It was noted that the document described risk assessment/risk management frameworks, including definitions, in the specific context of JECFA and CCFAC in setting standards. As the vertical approach for setting standards was being changed to a horizontal one, strategic step-wise methods were proposed to set priorities for additives and contaminants of special concern for future evaluations.

[1] CX/FAC 95/3 (Codex Risk Assessment and Management Procedures: The Translation of Advice from JECFA into Codex General Standards for Food Additives and Contaminants) and comments from Australia, Canada (CX/FAC 95/3-Add. 1) and Spain, IFGMA (Conference Room Document 5)

31. The Working Group on General Standards for Food Additives, which had already discussed the paper at length, offered recommendations in order to progress.

32. The Committee welcomed the paper and thanked the Delegation of the UK for its efforts. The Committee reconfirmed that CCFAC agreed that it should continue to carry out risk assessment and risk management by developing guidelines, while JECFA should continue to perform hazard evaluations. Several delegates also supported the idea for setting up an Expert Working Group on Intakes under CCFAC.

33. Intake/exposure assessment methodology was discussed in more detail. Several delegates expressed concerns about regional and cultural differences. The Delegation of Japan observed that in certain cases it may be necessary for CCFAC to consider setting double or triple standards taking into consideration different intakes. Although general screening methods (initial assessment of *per capita* intakes or the Danish Budget Method) were advocated by some delegations, other delegations also felt that the consideration of more accurate data on exposures were required, which took account of cultural pattern(s) or "critical" non-average groups in the population. It was noted that Codex Coordinating Committees could provide information on specific regional intakes. The Committee, however, agreed not to set a specific methodology at this stage.

34. The Committee decided to accept the offer of the UK Delegation to continue its work on exposure assessment by putting forward some more precise proposals using the Danish Budget Method as an initial screening method, including examples (antioxidants and preservatives), and to provide these proposals to the CCFAC prior to the next meeting, especially on those intakes that come close to the ADI. The Committee also decided that the revised document should take account of activities of other Codex Committees on dietary intake (Codex Committee on Pesticide Residues) as well as the deliberations of the former CCFAC Working Group on Food Additive Intake.

35. The Committee agreed that it should

- continue with the development of risk assessment/management procedures, with the understanding that further action would be taken (at a later stage) when the recommendations of the Joint WHO/FAO Expert

Consultation on the Application of Risk Analysis to Food Standards Issues became available.

- postpone the decision about setting up an ad hoc Working Group on Intake under CCFAC until its next Session for the same reason.
- continue its work on exposure assessment by accepting the offer of the UK Delegation to develop more precise proposals taking account of work in this area by other Codex Committees and the previous CCFAC working group on Food Additive Intake.

CONSIDERATION OF THE PROPOSED DRAFT CODEX GENERAL STANDARD FOR FOOD ADDITIVES (Agenda Item 6)

36. The Committee had before it the first revision of Worksheets for the development of Schedules 1, 2 and Annex A[1] (on the basis of comments received in reply to CL 1994/11-FAC) and the latest revision of the Schedules[2] in the light of comments received from Bolivia, Canada, the Nordic countries (Denmark, Finland, Iceland, Norway, Sweden), Mexico, Switzerland, USA, the European Community, AMFEP, IDF, IFMA, ILSI[3].

37. Written comments were also available from the Delegation of Brazil, who informed the Committee that additive provisions were included in the current harmonization process undertaken in the framework of MERCOSUR. The Working Group meeting was chaired by Dr A. Rulis (USA) and Dr D. Dodgen (USA) acted as vice-chairman. Dr B. Fabech (Denmark) acted as rapporteur.

38. The recommendations of the Working Group[4], as presented by Dr. Rulis, were considered by the Committee, which came to the following conclusions.

[4] CRD1

Schedules 1, 2 and Annex A

39. The Committee reasserted its earlier decision to proceed with Schedule 2 (i.e., in addition to Schedule 1) in view of its usefulness, especially to identify foods that do not contain additives.

40. The Committee agreed that existing information on preservatives and antioxidants, which currently included a number of levels for each additive, should be condensed and refer only to the range of minimum and maximum levels within food categories and sub-categories, with the understanding that current food additive levels in Codex Standards would be included.

Further Work on Food Additives Classes

41. The Committee agreed that although the sections of the Schedules on antioxidants and preservatives were not completed yet, further work on other classes of additives should be initiated. After an exchange of views on the classes which should be selected and the criteria to make such a decision, it was agreed to proceed with thickeners and stabilizers in view of their widespread use, and with sweeteners, as they represented only a small list of substances. It was agreed to send a Circular Letter containing a list of additives belonging to these classes and evaluated by JECFA for government comments so as to proceed as similarly accomplished for preservatives and antioxidants (i.e., as per CL 1994/11-FAC).

42. The observer from the EC informed the Committee of the recent publication of the three EC Directives on Additives, which used a similar horizontal approach, with a

presentation along the format of Schedule 1. He noted that the Schedules did not include all additives used as antioxidants or preservatives and that this question should be addressed before the exercise was completed; this problem would also arise for other classes as many additives had several functional uses. The observer indicated that the EC Directives included all classes of additives and proposed to the Committee to use the EC schedules as a basis for further development of the standard to include all additives; he also stressed the necessity to proceed rapidly with the completion of the standard as it was urgently needed for the purposes of international trade. The Committee expressed its appreciation of the EC contribution to the development of the standard and agreed to circulate for comments the data which would be communicated by the EC, for consideration by the next session.

Technological Justification and Need

43. The Committee considered the paper prepared by the Delegations of New Zealand and Iceland on Consideration of Technological Justification and Need for the Use of Foods Additives[1] and comments from CEFIC and CESDA[2] The Committee expressed its appreciation to both delegations for the elaboration of this document which clarified the issues involved, and requested New Zealand and Iceland to proceed with the identification of information needed to address technological justification and need for the use of food additives and the criteria for evaluating such data.

1 CX/FAC 95/5

2 CRD 21

44. It was noted that differences as to technological need from one country to another should be recognized in the perspective of the overall objectives of ensuring safety and facilitating international trade. It was pointed out that the Committee would, wherever possible, have to address technological need through consideration of additive classes instead of a case-by-case approach. The Delegations of New Zealand and Iceland were also asked to elaborate on how these aspects would be incorporated into and affect the General Standard. The delegations agreed to proceed with this task and invited other interested delegations to submit information and proposals on this issue, in order to prepare a document for the consideration of the next CCFAC session.

45. The observer from Consumers International emphasized the need for a comprehensive standard developed along principles of transparency; consumers' benefit deriving from the use of additives should also be considered.

Intake Assessment

46. The Committee considered the question of exposure in the light of earlier discussions on "Codex Risk Assessment and Management Procedures: the Translation of Advice from JECFA into Codex General Standards for Foods and Contaminants" (see paras. 30-35).

47. Some delegations expressed the view that the Committee should proceed with a step-by-step approach in developing the standard and that while technological need and exposure should be addressed, this should not delay the progress of the standard.

Status of the Proposed Draft General Standard on Food Additives

48. The Committee agreed to forward Annex A of the Proposed Draft General Standard to the Commission for adoption at Step 5 (See Appendix III). 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 Committees last Session.

ENDORSEMENT AND/REVISION OF MAXIMUM LEVELS FOR FOOD ADDITIVES IN CODEX STANDARDS[1](Agenda Item 7)

1 CX/FAC 95/6

49. The Committee noted that the above document presented various food additives for endorsement in a number of Draft Standards forwarded by the Codex Committee on Fish and Fishery Products and the Committee on Milk and Milk Products.

50. Several delegations pointed out that not all of the proposed additives had been evaluated by JECFA, levels had been established for additives with an ADI of "not specified" and that specific food additives should only be considered on the basis of the Codex General Principles for the Use of Food Additives [2] In this regard, it was noted that several current proposals for food additive use did not comply with these principles. The Committee also noted that in view of its current work on the General Standard on Food Additives concerning technological need, it would be premature to fully endorse these food additive provisions at present.

2 Codex Alimentarius Volume I, pages 50-51

51. The Committee agreed to postpone endorsement with the understanding that new proposals clarifying individual provisions (including technological need) would be prepared for review on the basis of the Codex General Principles for the Use of Food Additives, and in compliance with those provisions contained in the Preamble to the General Standard on Food Additives (ALINORM 95/12, Appendix II, Section 3).

52. The Secretariat informed the Committee that the Codex Committee on Tropical Fresh Fruits and Vegetables[1] had requested the Codex Committee on Pesticide Residues to establish a provision for sulphur dioxide treatments in lychees, without specifying a maximum level. The Committee noted that although the request of the CCTFFV appeared to fall within CCFAC's terms of reference, a specific proposal for the establishment of such a level rested with the CCTFFV.

1 ALINORM 95/35, paras. 36-37

CONSIDERATION OF SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES NOT PREVIOUSLY REVIEWED BY THE COMMITTEE (Agenda Item 8)

53. The Working Group on Specifications considered government comments submitted[2] regarding the above specifications received in response to CL 1994/28-FAC as indicated in the Working Group report[3] The Chairman of the Working Group, Dr. D. Dodgen (USA) presented the Working Group's discussions and recommendations.

2 CRD 14 (Germany), 15 (Denmark) and CRD 2 (Spain, United Kingdom, United States, Dragoco, CEFIC, EFEMA and IFAC)

3 CRD 2

54. The Committee was informed that the Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) covering evaluations through its 41st Session was now available.

55. The FAO Secretary to JECFA pointed out that although benzaldehyde was a flavour it was on the JECFA priority list for its 46th meeting and therefore was included in

Category IV (substance on the agenda of a forthcoming JECFA session). The JECFA Secretariat also indicated that if appropriate, JECFA would withdraw those specifications "that were no longer necessary".

56. The Committee agreed with the recommendations of the working group to refer the four substances in Categories I and II (see Appendix IV) to the Commission for adoption as Codex Advisory Specifications.

57. The Committee expressed its appreciation for the Working Group, and especially for the efforts of its Chairman, Dr D. Dodgen, and reinstated it under the chairmanship of the US. The following countries and organizations will participate in the Working Group: Belgium, Denmark, Finland, Germany, Japan, Malaysia, Mexico, the Netherlands, New Zealand, Norway, Sweden, Switzerland, Thailand, Philippines, UK, USA, AMFEP, CEFIC, FCC, IFAC, JFAA, SIAP, Marinalg International, NACGM and the ELC.

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

58. The Committee noted that because no additional written proposals for amendments to the INS system had been received in response to CL 1994/9-FAC, document CX/FAC 95/7 was not issued.

59. The Committee agreed that proposals made during the meeting by the Delegations of Brazil and Germany should be submitted in writing for consideration at the 28th CCFAC. In taking this decision, it was noted that the INS system was exclusively restricted to food additives. Food ingredients were beyond the scope of the INS.

60. With reference to the previous decision of the Committee to assign INS number 407a to processed eucheuma seaweed (PES)[1] the Delegation of France suggested an alternative solution which would entail re-assigning the current INS number 408 for bakers yeast glycan to PES. This solution would require assigning a new INS number to bakers yeast glycan (e.g. 426). However, the Delegation of The Philippines noted that this subject should be discussed at the 21st Session of the Codex Alimentarius Commission when considering the adoption of INS number 407a as recommended by the 26th CCFAC, and as encompassed in the Codex Rules of Procedure.

1 ALINORM 95/12, paras. 66-69

61. The Committee agreed that governments wishing to comment on the previous CCFAC decision to assign INS number 407a to PES should do so at the 21st Session of the Commission in accordance with the Guide to the Consideration of Standards at Step 8 of the Procedure for the Elaboration of Codex Standards[2] and as requested under CL 1994/9-FAC (see ALINORM 95/12).

2 Codex Alimentarius Procedural Manual, eighth edition, pages 33-35

62. The Committee also agreed that the consideration of amendments to the INS system would be a standing item on its agenda, with the understanding that such amendments would be sought through circular letter.

CONSIDERATION OF THE REVISED INVENTORY OF PROCESSING AIDS[3](Agenda Item 10)

3 CX/FAC 95/8

63. The Delegation of Germany introduced the above document which contained a Revision of the Inventory of Processing Aids as requested by the Committee at its

previous session[4] The Committee noted that government comments were not submitted in response to CL 1994/9-FAC.

[4] ALINORM 95/12, paras. 73-75

64. Consumers International expressed its appreciation for the revised list and emphasized that attention should be focused on the safety of the listed processing aids from a consumer perspective, especially in regard to blood plasma and several types of solvents.

65. The Delegation of the Netherlands expressed the opinion that microbial control agents might require further attention as there were some concerns relating to their safety, especially when improperly used as a substitute for GMP. The Delegation of Denmark regretted that in the revision of the Inventory, useful information concerning areas of use, residues, interactions with food and JECFA evaluations had been omitted.

66. The Delegation of Sweden also pointed out that future revisions to the inventory should also include a revised cover page indicating that substances on the list have not been approved for use as a processing aid by Codex.

67. The Committee agreed to append the revised Inventory of Processing Aids to its report (see Appendix V) for additional comments and discussion at its next session.

CONSIDERATION OF METHODS OF ANALYSIS FOR THE DETERMINATION OF FOOD ADDITIVES IN FOODS MOVING IN INTERNATIONAL TRADE[1] (Agenda Item 11)

[1] CX/FAC 95/9

68. The Committee was informed by the Delegation of Canada of its work on the consideration of methods of analysis for the determination of food additives in foods moving in international trade as requested by the CCFAC at its 26th Session[2]

[2] ALINORM 95/12, paras. 82-83

69. Several delegations asked what future procedure should be followed regarding this document and whether it should be restricted to additives or whether it should also include contaminants.

70. The Secretariat indicated that if the document were to have official status, it would have to go to the Codex Committee on Methods of Analysis and Sampling for endorsement and subsequent adoption by the Commission. It was also noted that the terms of reference for CCFAC included the consideration of methods of analysis for both food additives and contaminants.

71. Several delegations also noted the procedure agreed to at the previous CCFAC included the prioritization of methods required for international trade, and suggested this should be included in further work. Elaboration of criteria for evaluating acceptable methods of analysis, as currently undertaken by the Codex Committee on Methods of Analysis and Sampling[3], was also seen as a valuable tool in developing this document further.

[3] ALINORM 95/23, paras. 29-33

72. The Committee expressed its appreciation for the valuable work done by Canada and agreed that the list would be further developed on the basis of comments solicited by circular letter on document CX/FAC 95/9. Governments would be requested to provide additions or amendments to the list where necessary, to select foods and food

additives to be considered as a priority because of potential problems in trade and to provide to opinions on the inclusion of methods of analysis for contaminants in the list. The Committee agreed that at its next meeting the need for the establishment of an informal WG to study this subject would be considered.

ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR CONTAMINANTS IN CODEX STANDARDS[1] (Agenda Item 12)

[1] CX/FAC 95/10

Proposed Draft Standards for Gari and Edible Cassava Flour

73. The Committee noted that the CCCPL had requested the advice of the CCFAC as to the different levels of hydrocyanic acid applied to the Gari and Cassava Flour Standards (2 mg/kg and 10 mg/kg, respectively)[2]. The JECFA Secretariat informed the Committee that at its 39th meeting JECFA had concluded that a level of up to 10 µg/kg hydrogen cyanide in the standard for Edible Cassava Flour was not associated with acute toxicity.

[2] ALINORM 95/29, para. 105

74. The Committee temporarily endorsed the above levels with the understanding that the Codex Regional Coordinating Committee for Africa would be requested to clarify the need for the lower level of Gari.

75. It was suggested that guidelines should be developed for the processing of beans containing cyanogenic glycosides, as had been similarly noted by the 24th CCFAC[3].

[3] ALINORM 93/12, paras. 40-41

Proposed Draft Guideline Level and Sampling Plans for Aflatoxins in Peanuts

76. The Committee was informed that the CCCPL had agreed to advance a proposed draft sampling plan and guideline level of 15 µg/kg (20 kg sample size) for total aflatoxins in peanuts intended for further processing for adoption at Step 5 by the 21st Session of the Commission, with the understanding that the CCFAC would be advised of this decision[4]. It was also noted that government comments had been requested at Step 5 by the CCCPL under CL 1994/35-CPL. The JECFA Secretariat indicated that aflatoxins were scheduled for review by the 46th JECFA Session in February 1996.

[4] ALINORM 95/29, paras. 12-19 and Appendix II

77. Several delegations expressed the view that 15 µg/kg was too high, especially in view of the recognized carcinogenicity of aflatoxins and the desire to lower levels as much as possible.

78. Other delegations supported the guideline level of 15 µ*g/kg,* especially since the majority of international trade was in peanuts intended for further processing as opposed to products for direct consumption. It was also noted that lower levels could have serious consequences for international trade, and that aflatoxins could be adequately controlled through good agricultural and manufacturing practices.

79. The Committee agreed to postpone endorsement of the proposed draft guideline level and sampling plans for aflatoxins in peanuts pending the future JECFA evaluation (see para. 145).

CONSIDERATION OF THE DRAFT PREAMBLE TO THE CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS AT STEP 7 (Agenda Item 13a)

80. The Committee had before it the Draft Preamble to the Codex General Standard for Contaminants and Toxins in Foods[1] s adopted by the forty-first session of the Executive Committee[2], as well as government comments received from Japan, Sweden and the United Kingdom in reply to CL 1994/20-FAC[3].

1 CX/FAC 95/11

2 ALINORM 95/3, para. 47 and Appendix II

3 CX/FAC 95/11-Add.I

81. After thanking the delegations of the Netherlands and Denmark for their work on the draft preamble, the Committee discussed the document on a section by section basis and agreed to the following changes.

Introduction

82. The introduction to the Preamble served an explanatory function only, the Committee agreed that the introduction (as well as the references at the end of the Preamble) should be deleted.

Section 1.2.2 - Contaminant

83. The Committee reaffirmed that the General Standard for Contaminants and Toxins in Foods applied to any substance that met the Codex definition for a contaminant[4]. In this regard, it was noted that processing aids in and of themselves are intentionally used in the production of foods, and therefore they are not defined as contaminants.

4 Section 1.2.2 of the Preamble

84. As residues of processing aids are substances not intentionally added to foods and therefore meet the terms of the Codex definition for a contaminant, the Committee agreed that in future, residues of processing aids may be incorporated into the Standard on a case by case basis as required.

Section 1.2.4 - Maximum level and related terms

85. As the protection of consumer health and the facilitation of international trade in food were the general objectives of Codex Alimentarius, the Committee agreed that references to these general objectives need not be duplicated in this Section.

Section 1.3.1 - General

86. With respect to the sentence that contamination should be prevented or reduced as much as possible the Committee agreed to delete this sentence, as this was adequately covered in another part of this section.

Section 1.3.3 - Specific criteria

87. With regard to the specific criteria on intake data, the Committee agreed to add an indent on data concerning the intake of contaminants for susceptible consumer groups such as pregnant women.

88. Although the Committee stressed the importance of priority action by CCFAC on existing as opposed to potential problems in trade related to food contamination, the fair

trade considerations of this section were left unchanged. However the term "foods" was changed to "commodities" for consistency.

89. With respect to the evaluation of toxicological information, the Committee agreed that in addition to information on acute and long term toxicity, relevant results of other toxicological studies should be taken into account, and revised this section accordingly.

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

90. The Committee agreed to forward the revised version of the Draft Preamble to the General Standard for Contaminants and Toxins in Foods to the twenty-first session of the Codex Alimentarius Commission for adoption at Step 8. The Preamble is attached to this report as Appendix VI.

CONSIDERATION OF THE PROPOSED DRAFT CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS (EXCLUDING PREAMBLE) AT STEP 4 (Agenda Item 13b)

91. The Committee had before it the Draft General Standard for Contaminants and Toxins in Foods (excluding the Preamble)[1] and government comments received from Finland and Poland[2].

[1] CX/FAC 95/12

[2] CX/FAC 95/12-Add.l

92. After thanking the authors from the delegation of the Netherlands and Denmark for their efforts in drafting the General Standard, the Committee discussed the document section by section and agreed to the following changes.

Annex I - Criteria for the Establishment of Maximum Levels in Foods

93. With respect to the principles and criteria outlined in the document for the establishment of maximum levels for contaminants in foods, the Committee agreed that the authors would revise the Draft General Standard so that it would be consistent with the recommendations of the Joint FAO/WHO Consultation on the Application of Risk Analysis to Food Standards Issues that took place at WHO Headquarters, Geneva from 13-17 March 1995 (see para. 29).

94. In addition, the Committee agreed that the text of the Draft General Standard must also be harmonized with the draft Preamble to the General Standard agreed upon under Agenda Item 13(a).

95. The Committee noted the need to consider potential regional variations in exposure to a contaminant when elaborating maximum levels in the General Standard.

96. The Committee reaffirmed that the criteria for inclusion of a level for a contaminant in a food in the General Standard should be that consumption of the contaminated food presents a significant risk to consumers and there are actual or expected problems in trade in the food.

97. The Committee noted that if no validated and suitable method of analysis was available for the measurement of a contaminant, risk management could not be adequately achieved by setting Codex maximum levels and other risk management options should be considered (e.g. source control measures).

Annex IVA - Annotated List of Contaminants and Toxins

98. The Committee agreed that food quality indications were not within the scope of the General Standard, and that in Annex IV priority should be given to contaminants on the basis of specifically identified food safety problems.

Annex IVB - Situation Review of Contaminants and Toxins in Foods

99. The Committee agreed that, if available, references to validated methods of analysis as well as references to information on toxicological guidance should be included in this section.

Annex V - Food Categorization System to be used in the General Standard

100. With respect to the use of the proposed food categorization system, the Committee agreed that a principle should be developed which enabled account to be taken of the carry-over of contaminants and toxins from primary products to processed products.

Status of the Proposed Draft Codex General Standard for Contaminants and Toxins in Foods (Excluding Preamble)

101. The Committee agreed that the Delegations of Denmark and the Netherlands would revise Annex I, II and III of the Draft Standard based on the above comments and recommendations made during the session, with the understanding that the revised versions of Annex I, II and III would be forwarded to the 21st session of the Codex Alimentarius Commission for adoption at Step 5. In taking this decision, it was noted that the document may need to be revised in the future depending on the recommendations of the Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues. The Annexes are attached to this report as Appendix VII.

102. The Committee also agreed that the Delegations of Denmark and the Netherlands would revise and further elaborate Annex IV and V of the Draft Standard. The Committee invited Delegations to send additional comments directly to the Delegation of the Netherlands as soon as possible and agreed that the revised and elaborated version of the Annexes would be sent for government comments at the earliest opportunity.

MYCOTOXINS IN FOOD AND FEEDS (Agenda Item 14)

103. There was general consensus on the need to elaborate a position paper to clarify a number of issues including the relation between contamination of feedstuffs and contamination of milk; intake data for aflatoxins; practical and technical aspects of contamination control, the implementation of good agricultural practices, as well as the reduction of contamination through processing; methods of analysis and sampling.

104. The Committee welcomed the offer of the Delegation of the United Kingdom to prepare a position paper on aflatoxins which would encompass all relevant issues, in cooperation with the Delegations of the Netherlands and the United States, for circulation and comments prior to the 28th CCFAC.

CONSIDERATION OF THE DRAFT MAXIMUM LEVEL FOR AFLATOXIN M, IN MILK (Agenda Item 14a)

105. The Chairman recalled the decision of the last session of the Committee to maintain the Draft Maximum Level at Step 7 pending an estimate from JECFA on the

toxicological potency of aflatoxins B_1 and M_1 and in view of the lack of agreement on the proposed level of 0.05 µg/kg[1]

[1] ALINORM 95/12, paras. 114-119

Status of the Draft Maximum Level for Aflatoxin M_1 in Milk

106. The Committee agreed to maintain the draft Maximum Level at Step 7 due to the lack of agreement, the pending JECFA evaluation of aflatoxins (see para. 145) and the development of the position paper under the direction of the United Kingdom (see para. 104).

COMMENTS AND INFORMATION OF AFLATOXIN LEVELS AND SAMPLING PLANS IN ALL FOODSTUFFS (Agenda Item 14b)

107. The Committee noted that current comments received in reply to CL 1994/9-FAC[2] would be incorporated into the position paper on aflatoxins to be prepared under the direction of the United Kingdom for its next session (see para. 104).

[2] CX/FAC 95/13 (Finland, Greece, Sweden, UK) and CRD 6 (Germany, USA)

PROPOSED DRAFT CODE OF PRACTICE FOR THE REDUCTION OF AFLATOXINS IN RAW MATERIALS AND SUPPLEMENTARY FEEDINGSTUFFS FOR MILK-PRODUCING ANIMALS (Agenda Item 14c)[3]

[3] CX/FAC 95/14

108. The Delegation of Canada presented the proposed draft Code and recalled that in view of the difficulty to set a level, the last session of the Committee had decided to focus on measures to prevent contamination by aflatoxins[4].

[4] ALINORM 95/12, paras. 128-130

109. The Committee expressed its appreciation to the Delegation of Canada for the important work accomplished and agreed that the Code should be developed independently from the establishment of maximum levels for aflatoxins, without prejudice to the decision the Committee might take at a later date, and in the light of the comments received[5]

[5] CX/FAC 95/14-Add.l (Denmark, United Kingdom) and CRD 13 (USA)

110. With reference to Section 2.5.2, several delegations and the Observer from the EC expressed the view that in conformance with EC legislation, blending of contaminated and non-contaminated feedstuffs should not be permitted as it could actually increase the risks of overall contamination.

111. Some delegations pointed out that hazards associated with decontamination of feeds should be considered carefully, as the scientific data indicated that aflatoxins were not always effectively eliminated; it was noted that additional research would be required in this area.

112. The Committee had an exchange of views on the transfer of Aflatoxin $B_1$to milk as the document referred to a percentage of 1% and some delegations felt that 2% would be more accurate, while other preferred to cite a range. The code should draw attention to the importance of maintaining B_1 levels in total feed below a critical level.

Status of the Proposed Draft Code of Practice for the Reduction of Aflatoxins in Raw Materials and Supplementary Feedingstuffs for Milk-Producing Animals

113. As no consensus could be reached at this stage on the amendments to be included in the text, the Committee agreed that further consideration should be given to the complex issues raised and that it should be further developed. The Committee welcomed the offer of the Delegation of Canada to proceed with the revision of the paper in the light of the present discussion and written comments, with a view towards its revision and circulation for additional comments at Step 3 prior to the 28th CCFAC.

INFORMATION ON OCHRATOXIN A AND TRICHOTHECENES (Agenda Item 14d)[1]

[1] CX/FAC 95/15

114. The Delegation of Sweden presented the aforesaid paper which incorporated further information received from governments in reply to CL 1994/9-FAC. The Committee noted that additional comments were available[2]; certain countries as well as the European Community had been conducting surveys of contamination and were currently considering future action, including the establishment of maximum levels for ochratoxins.

[2] CX/FAC 95/15-Add. 1 (Finland, United Kingdom), CRD 7 (USA)

115. The JECFA Secretariat informed the Committee that trichothecenes were on the priority list of JECFA; however, additional data would be required before they could be evaluated. It was also noted that Ochratoxin A had recently been re-evaluated at the 44th JECFA meeting where a PTWI of 0.1 µ*g/kg* body weight was assigned.

116. The Committee expressed its appreciation to the Delegation of Sweden for the valuable information presented and agreed that Sweden should proceed with the preparation of a position paper on Ochratoxin A for consideration by its next session.

CONSIDERATION OF THE PROPOSED DRAFT CODE OF PRACTICE ON SOURCE DIRECTED MEASURES TO REDUCE CONTAMINATION OF FOODSTUFFS (Agenda Item 15a)[1]

[1] CX/FAC 95/16 and comments from the United States (CX/FAC 95/16-Add.l)

117. The delegation of Sweden introduced the new version of the Code of Practice on Source Directed Measures, which was revised as requested by the 26th CCFAC[2]. It was recalled that the Commission had agreed that although source directed measures could not be proposed in and of themselves, they could be incorporated into Codes of Practice provided they were in conformity with the terms of reference of the CCFAC. The Committee welcomed the Code as a basis for further discussions and thanked Sweden for its efforts.

[2] ALINORM 95/12, paras. 137-140

118. The Committee had an exchange of views on the subject of cross-contamination during transport (also see para. 13). The Committee noted that the Code prohibited the transport of foods in vessels which had previously contained highly toxic cargoes. It was suggested that adequate cleaning procedures would provide adequate protection from cross-contamination from highly toxic cargoes; some delegations indicated their preference for total separation of food and non-food transport. However, the Committee maintained this paragraph as currently drafted.

119. It was also suggested that the Code should prohibit the use of toxic substances in contact with food (e.g. lead, paperboard produced from chlorine treated pulp). The Committee welcomed the offer of Sweden to further develop the Code on the basis of written comments and the above discussion for circulation and comments at Step 3 prior to the 28th Session (also see paras. 120, 124 and 131).

COMMENTS AND INFORMATION ON CADMIUM AND LEAD (Agenda Item 15b)

120. The Committee decided that comments submitted in reply to CL 1994/9-FAC[3] would be taken into consideration in the development of the proposed draft Code of Practice on Source Directed Measures to Reduce Contamination of Foodstuffs (see paras. 117-119).

3 CX/FAC 95/17 (Finland, Sweden, United Kingdom, Canada) and CRD 8 (USA, OIV)

DISCUSSION PAPER ON LEAD (Agenda Item 15c)

121. The Committee had for its consideration the Proposed Draft Standard for Lead[4] (prepared by Denmark) and the Position Paper on Lead[5](prepared by Sweden and Denmark).

4 CX/FAC 95/18 and government comments from Australia and Poland (CX/FAC 95/18-Add.l), Canada, Finland, Spain and Sweden (CRD 9), the Netherlands (CRD 22)

5 CX/FAC 95/18-Add.2

Position Paper on Lead

122. The Delegation of Sweden introduced the paper, which was revised at the request of the last session[1]. It was noted that the 41st JECFA meeting maintained the PTWI of 25 µg/kg body weight for infants and children and extended it to adults. The former PTWI of 50 µg/kg for adults was withdrawn. It was also noted that the application of source directed measures had already significantly reduced lead contamination (phasing out lead in petrol and the use of lead soldered cans).

1 ALINORM 95/12, paras. 141-145

123. The Observer from the Council of Europe indicated that they published a monograph on lead and would publish monographs on cadmium and mercury in the future. A Council of Europe resolution on lead, cadmium and mercury, including source directed measures and levels, was under preparation.

124. The Committee decided that the recommendations in the position paper, including the relevant general aspects, should be incorporated into the Proposed Draft Code of Practice on Source Directed Measures to Reduce Contamination of Foodstuffs (see paras. 117-119). Sweden agreed to undertake this work.

Proposed Draft Standard for Lead

125. The Delegation of Denmark introduced the paper, which was prepared at the request of the last session[2]. The Committee expressed its appreciation to Denmark for its efforts.

2 ALINORM 95/12, para. 143

126. The Committee had an exchange of views on the levels proposed as related to specific commodities, and noted that the levels in current Codex standards should be taken into account. However, it was recognized that these levels might need to be reviewed when incorporated into the General Standard.

127. The Committee also noted that the following suggestions should be taken into account:

- it should be clearly indicated that the maximum levels should be based on the edible portion and reconstituted products where relevant;
- as Codex levels are usually applied to average levels per lot, relevant methods of analysis and sampling would need to be developed;
- levels would only be set for commodities that contribute significantly to lead intake;
- the exposure of children to lead should be examined;
- in relation to milk, consideration should be given to possible concentration of lead in processed milk products, and;
- in relation to fruit and vegetables, washing and peeling should be taken into account.

128. The Committee decided to accept the offer of Denmark to revise the proposed draft standard in the light of written comments and the above discussion, for circulation and comments prior to the 28th CCFAC.

DISCUSSION PAPER ON CADMIUM (Agenda Item 15d)[1]

[1] CX/FAC 95/19 and comments from Spain (CRD 16)

129. The working paper on Cadmium was prepared by France as requested by the 26th CCFAC[2]. The Committee noted that cadmium was recently evaluated at the 41st JECFA session, where the PTWI of 7 µg/kg body weight was maintained. The Committee was also informed that cadmium was scheduled for JECFA re-evaluation (see para. 152) based on new data regarding its bioavailability.

[2] ALINORM 95/12, para. 150

130. It was pointed out that bioavailability of cadmium was affected by nutritional status and diet, soil conditions and crop variety. It was also noted that cadmium contamination was not a problem in some regions of the world.

131. In view of the pending JECFA evaluation, the Committee decided that it was premature to consider the establishment of specific levels for cadmium. However, it was agreed that recommendations in the paper should be incorporated into the proposed draft Code of Practice on Source Directed Measures to Reduce Contamination of Foodstuffs under development by Sweden (see paras. 117-119). It was also decided that additional information would be requested on cadmium.

DISCUSSION PAPER ON PCBs AND DIOXINS (Agenda Item 15e)

132. The Committee had before it the discussion paper on dioxins and PCBs prepared by the Netherlands[3]. Government comments and information concerning dioxins and PCBs received from Finland, Sweden and the United States in reply to CL 1994/9-FAC were also taken into account[4](see paras. 138-139).

[3] CX/FAC 95/20

[4] CX/FAC 95/21 and Conference Room Document 10

133. After the introduction of the paper, the Committee thanked the Delegation of the Netherlands for their efforts in drafting the document.

134. On the basis of the information presented in the paper, it was concluded that there were sufficient indications of both potential health hazards and trade problems. Therefore, in line with the procedure for risk management decisions as outlined in Annex II of the Draft General Standard for Contaminants and Toxins in Foods, the Committee agreed that Codex maximum levels for dioxins and PCBs in foods may eventually be developed (see para. 101 and Appendix VII).

135. With respect to the gaps and uncertainties in the knowledge concerning the toxicological evaluation of the contaminants, the Committee agreed that before Codex maximum limits would be elaborated for dioxins and PCBs, JECFA should evaluate both groups of contaminants. Therefore, the Committee agreed to maintain dioxins, dioxin-like PCBs and non-planar PCBs on the priority list for JECFA evaluation (see para. 146).

136. The Committee agreed that, for the sake of clarity, risk assessment and risk management of PCBs and dioxins, would be dealt with separately. The delegation of the Netherlands agreed to revise the discussion paper on the basis of written and verbal comments presented at the meeting and comments submitted prior to the 28th CCFAC.

137. Finally, the Committee agreed that in order to be able to establish Codex maximum levels after the JECFA evaluation, delegations would be invited to provide additional comments and information on the contaminants by circular letter (see para. 139). Information was especially needed on food intake data and validated methods of analysis and sampling.

COMMENTS AND INFORMATION ON PCBs, PBBs, TETRACHLOROBENZYLTOLUENE AND DIOXINS IN FOODS (Agenda Item 15f)

138. The Committee had before it the documents presenting government comments and information on PCBs, PBBs, tetrachlorobenzyltoluene and dioxins in foods received from Finland, Sweden and the United States in reply to CL 1994/9-FAC[1].

[1] CX/FAC 95/21 and Conference Room Document 10

139. The Committee agreed to continue to collect information on dioxins and PCBs (see para. 137). In addition, the Committee agreed that at this stage no more action was needed on PBBs and tetrachlorobenzyltoluene, with the understanding that additional information could be solicited in the future if it was decided that the establishment of levels were necessary.

COMMENTS AND INFORMATION ON POLYCYCLIC AROMATIC HYDROCARBONS, HYDROGEN CYANIDE, PHTHALATES AND ETHYL CARBAMATE IN FOODS (Agenda Item 15g)

140. The Committee had before it the documents presenting governments comments and information on polycyclic aromatic hydrocarbons, hydrogen cyanide, phthalates and ethyl carbamate in foods received from Sweden, the United Kingdom, Canada and the United States in reply to CL 1994/9-FAC[2].

[2] CX/FAC 95/22 and Conference Room Document 11

141. The Committee decided that at this stage no more action was needed by the Committee on phthalates and ethyl carbamate with the understanding that additional information could be requested in the future if it was decided that levels needed to be established.

142. In addition, the Committee agreed to continue to gather information on polycyclic aromatic hydrocarbons and hydrogen cyanide before deciding on possible future action.

PROPOSALS FOR THE PRIORITY EVALUATION OF FOOD ADDITIVES AND CONTAMINANTS BY JECFA (Agenda Item 16)

143. The Committee had before it Conference Room Document 23, 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-sixth Session of CCFAC (Appendix VI, ALINORM 95/12) and to consider new additions to the priority list. Mr R. Top of the Netherlands chaired the Working Group meeting.

144. The food additives on the previous priority list (glycerol esters of wood rosin, polydextrose (specifications only) and sucrose esters of fatty acids) were evaluated at the forty-fourth meeting of JECFA in February 1995, so they were removed from the list.

145. Aflatoxins B_1 and M_1 had been on the previous priority list. Even though the greatest potential risk is posed by these aflatoxins, and most toxicity studies have been performed on them, the Committee concluded that aflatoxins B_2, G_l and G_2 should be considered as well because they are also present in food. The Delegation of the United States will provide toxicity data and the Delegation of Sweden will provide the Nordic review to JECFA for consideration. The Delegations of Brazil and Japan will provide information on levels of aflatoxins in food commodities. The JECFA Secretariat requested other governments or organizations who have relevant information to provide it. Instructions for submitting information will be provided in the request for data that will be issued shortly.

146. Although adequate data for a full assessment of the dioxins, dioxin-like PCBs and non-planar PCBs were not now available, it was recognized that further relevant work is underway. These contaminants were maintained on the priority list.

147. Carcinogenicity studies on ethyl carbamate underway in the US National Toxicology Program will most likely not be reported for several years. These studies will be critical for the risk assessment and ethyl carbamate was maintained on the priority list.

148. The phthalates were removed from the priority list, with the understanding that they could be reinstated if new relevant information becomes available.

149. The polycyclic aromatic hydrocarbons, particularly benzo[a]pyrene, are present in many foodstuffs. The Delegation of Denmark will provide more information at the next session on the availability of relevant data on substances in this group. These contaminants were maintained on the priority list.

150. The trichothecenes were maintained on the priority list. The delegations of Finland and the Netherlands are prepared to provide analytical data and information on their presence in food commodities.

151. The Committee agreed to add salatrim (short- and long-chain acid triacylglycerol molecules), a fat substitute, and enzyme-hydrolyzed carboxymethyl cellulose (for development of specifications only) to the priority list at the request of Mexico and Finland, respectively. Stevioside (a sweetening agent) was also added to the priority list at the request of Egypt. However, it was not clear that sufficient information would be available for evaluation by JECFA. Information on the availability of data on stevioside should be provided to the next Session of the Committee.

152. In the light of new information, Cadmium was added to the priority list for re-evaluation at the request of the United States of America. Studies underway in Japan should also be available within the next two years.

153. Nitrate (from all sources) was added to the priority list at the request of the Netherlands. Studies on the bioavailability of nitrate in vegetables are underway in both the Netherlands and United Kingdom. The status of these studies will be provided at the next Session of the Committee (also see para. 22).

154. The General Standard for Food Additives specifies that food additives with ADIs "not limited" or "not specified" can be used according to GMP. The Committee recognized that re-evaluations of many of these food additives may be necessary to reflect current uses. Priorities for their re-evaluation will be established in the context of development of the General Standard.

155. It was suggested that when an additive is placed on the priority list related compounds (e.g. all gallates) should be evaluated at the same time.

156. The Delegation of the United States pointed out the increasing importance of JECFA in light of new international trade agreements. JECFAs decision making processes will inevitably come under increasing scrutiny by parties who stand to be affected by JECFAs decisions. While acknowledging the effectiveness of JECFA despite its limited resources, the Delegation stressed the importance of accelerating progress towards openness in selecting experts and in ensuring that they have the proper expertise, that conflicts of interest do not arise and that its assessments are transparent.

157. The Committee agreed to the priority list as attached to this report as Appendix VIII, with the understanding that additional proposals for revisions to the list would be requested.

OTHER BUSINESS (Agenda Item 17)

158. The Committee had no other business to discuss.

MEDIUM-TERM OBJECTIVES AND FUTURE PROGRAMME OF WORK[1] (Agenda Item 18)

[1] CX/FAC 95/24

159. The Committee agreed on its Current Status of Work (Annex 1) for forwarding to the Executive Committee for approval.

DATE AND PLACE OF NEXT SESSION (Agenda Item 19)

160. The Committee was informed that the 28th Session of the Codex Committee on Food Additives and Contaminants was tentatively scheduled to be held in The Hague from 11-15 March 1996, subject to approval by the Commission.

ANNEX 1

CODEX COMMITEE 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
Draft Preamble to the Codex General Standard for Contaminants and Toxins in Foods	8	21st CAC	Appendix VI, ALINORM 95/12A
Specifications Recommended for Adoption as Codex Advisory Specifications	8	21st CAC	Appendix IV, ALINORM 95/12 and ALINORM 95/12A
Amendments to the International Numbering System	8	21st CAC	Appendix V, ALINORM 95/12
Draft Maximum Level for Aflatoxin M_1 in Milk	7	28th CCFAC	para. 106, ALINORM 95/12A
Annex A of the Proposed Draft General Standard for Food Additives	5	21st CAC	Appendix III, ALINORM 95/12A
Revised Schedules 1 and 2 of the Proposed Draft General Standard for Food Additives	2,3	United States Governments 28th CCFAC	para. 40, ALINORM 95/12A
Annexes I, II and III of the Proposed Draft General Standard for Contaminants and Toxins in Foods	5	21st CAC	Appendix VII, ALINORM 95/12A
Annexes IV and V of the Proposed Draft General Standard for Contaminants and Toxins in Food	2,3	Denmark/Netherlands Governments 28th CCFAC	para. 102 ALINORM 95/12A
Consideration of Technological Justification and Need for the Use of Food Additives	2	Iceland/New Zealand 28th CCFAC	para. 43-44, ALINORM 95/12A
Procedures for Risk Assessment and Management Related to Food Additive Intake and Exposure	2,3	U.K. Governments 28th CCFAC	para. 35, ALINORM 95/12A
Consideration of Methods of Analysis for the Determination of Food Additives in Foods	3	Governments Canada 28th CCFAC	para. 72, ALINORM 95/12A
Proposed Draft Code of Practice on Source Directed Measures to Reduce Contamination of Foodstuffs	2,3	Sweden Governments 28th CCFAC	para. 119, ALINORM 95/12A

Proposed Draft Code of Practice for the Reduction of Aflatoxins in Raw Materials and Supplementary Feeding-stuffs for Milk Producing Animals	2,3	Canada Governments 28th CCFAC	para. 113, ALINORM 95/12A
Position Paper on Aflatoxins	2,3	United Kingdom Governments 28th CCFAC	para. 104, ALINORM 95/12A
Position Paper on Ochratoxin A	2,3	Sweden Governments 28th CCFAC	para. 116, ALINORM 95/12A
Proposed Draft Standard for Lead	2,3	Denmark Governments 28th CCFAC	para. 128, ALINORM 95/12A
Discussion Paper on PCBs and Dioxins	2,3	Netherlands 28th CCFAC	para. 136, ALINORM 95/12A
Information on Cadmium, PCBs, Dioxins, Polycyclic Aromatic Hydro-carbons and Hydrogen Cyanide in Foods	3	Governments 28th CCFAC	paras. 131,139 and 142 ALINORM 95/12A
Revised Inventory of Processing Aids	3	Governments 28th CCFAC	Appendix V, ALINORM 95/12A
Food Additives and Contaminants Proposed for Priority Evaluation by JECFA	3	Governments 28th CCFAC	Appendix VIII, ALINORM 95/12A

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ACTION REQUIRED AS A RESULT OF CHANGES IN ADI STATUS OR OTHER TOXICOLOGICAL RECOMMENDATIONS

Substance	**Previous acceptable daily intake in mg/kg of body weight and other toxicological recommendations**	**Present acceptable daily intake (ADI) in mg/kg of body weight and other toxicological recommendations**	**Current Codex Uses**	**Secretariat Notes**
Antioxidants				
Butylated hydroxytoluene (BHT)	0-0.125(temporary)	0-0.3	Edible fats and oils, mayonnaise	Previous ADI increased
tert-Butylhydroquinone (TBHQ)	0-0.2 (temporary)	0-0.2(temporary)	Edible fats and oils	Previous ADI maintained
Carrier solvent Diethylene glycol monoethyl ether	No ADI allocated	No ADI allocated	None	No change
Colour stabilizer 4-Hexylresorcinol	None	Treatment of crustaceans not of toxicological concern	None	New evaluation
Emulsifiers				
Dioctyl sodium sulfosuccinate	0-0.25(temporary)	0-0.1	None	Previous ADI lowered
Glycerol esters of wood rosin	No ADI allocated	No ADI allocated	None	No change
Sucrose esters of fatty acids	0-16(group ADI)	0-20(temporary group ADI)	Margarine, cocoa powders and dry cocoa-sugar	Previous ADI increased

			mixtures	
Flavouring agent Ethyl vanillin	0-5 (temporary)	0-3	Follow-up formula, baby/infant foods, cocoa products, cream	Previous ADI lowered
Food colours Canthaxanthin	No ADI allocated	0-0.03	Edible fats and oils, canned/quick frozen shrimps/prawns, bouillons and consommes, margarine	New ADI allocated
Curcumin	0-0.1(temporary)	0-1 (temporary)	Edible fats and oils, bouillons and consommes, mayonnaise, butter, margarine, processed cheeses	Previous ADI increased
Glazing agents Microcrystalline wax	Not specified	0-20(group ADI)	Processing Aid	New ADI established
Mineral oil (revised and divided into two specifications):				
(a) Mineral oil (high viscosity)	Not specified (temporary)	0-20	Processing Aid	New ADI established
(b) Mineral oil (medium and low viscosity)				
(i) Class I	Not specified (temporary)	0-1(temporary)	Processing Aid	New ADI established
(ii) Class II and Class III	Not specified (temporary)	0-0.01(temporary group ADI)	Processing Aid	New ADI established

Paraffin wax	Not specified	No ADI allocated	Processing Aid	New ADI established
<u>Sweetening agent</u> Alitame	None	No ADI allocated	None	No change
<u>Thickeners</u> Processed *Eucheuma* seaweed	0-20(temporary)	0-20 (temporary)	None	Previous ADI maintained
<u>Miscellaneous substances</u> ß-Cyclodextrin	0-6 (temporary)	0-5	None	Previous ADI lowered
Nitrite	0-5 (group ADI)	0-3.7 (expressed as nitrate ion)	Various varietal cheeses, cooked cured ham and pork shoulder	Equivalent ADI maintained
Nitrate	0-0.2 (temporary)	0-0.06 (expressed as nitrite ion)	Canned corned beef and other processed meats	Previous ADI lowered
Potassium bromate	Withdrawn	Use as a flour treatment agent not appropriate	None	No change
<u>Contaminants</u> Ochratoxin A	0.000112 (PTWI)	0.0001 (PTWI)	None	
Patulin	0.007 (PTWI)	0.0004 (PMTDI)	None	

CODEX GENERAL STANDARD FOR FOOD ADDITIVES
ANNEX A
GUIDELINES FOR THE ESTIMATION OF APPROPRIATE LEVELS OF USE OF FOOD ADDITIVES
(at Step 5)

Note: It is understood that all additives will be used in conformance with the General Principles for the Use of Food Additives specified in the **Preamble** of this Standard.

Additives Used in Foods Similar to Currently Specified Foods

Guideline 1 Unless otherwise noted in **Schedules 1 and 2** of this Standard, food additives will generally be regarded as suitable for use in a food of a particular food or food subcategory at approximately the same levels at which the additive is specified in **Schedules 1 and 2** for use in a similar food or food subcategory.[1]

[1] The foods identified in Schedules 1 and 2 of this Standard have been classified according to the food categorization system of the Confédération des Industries Agro-Alimentaires de la CEE (CIAA).

The following Guidelines apply to all uses of food additives not covered by Guideline 1, i.e., use of additives in foods that are not similar to the foods in which the additives are currently specified.

Additives With ADIs "Not Specified"

Guideline 2 When the ADI of an additive is "not specified" (NS), the additive should be suitable for use under conditions of good manufacturing practice (GMP) in foods generally.[2]

[2] The term "good manufacturing practice" is defined in the Preamble of this Standard.

Additives With Numerical ADIs Used in Solid Foods Only

Guideline 3 Maximum levels equivalent to **40 x ADI** should be suitable for the use of an additive in foods generally.

Guideline 4 Maximum levels equivalent to **80 x ADI** should be suitable for the use of an additive in foods when the following conditions are met: (a) cereals and milk products are kept free of the additive; or (b) cereals are the only products containing the additive; or (c) the daily consumption of the foods in which the additive is used at this level does not exceed about one-half of the total food consumed.

Guideline 5 Maximum levels equivalent to **160 x ADI** should be suitable for the use of an additive in foods when the following conditions are met: (a) cereals, milk products, and widely consumed meat, fish, and egg products are kept free of the additive; or (b) the additive is used solely in milk products; or (c) the additive is used solely in meat, fish, and egg products; or (d) the additive is used solely in ice cream products, margarine, mayonnaise, dressings, cakes, confectionery and other specialty products; or (e) the daily consumption of the foods in which the additive is used at this level does not exceed about one-fourth of the total food consumed.

Guideline 6 Maximum levels equivalent to **320 X ADI** should be suitable for the use of an additive in foods when the daily consumption of the foods in which the additive is used at this level does not exceed about one-eighth of the total food consumed.

Guideline 7 When an additive is used in more than one type of solid food, maximum levels of use in additional foods must be based on estimates of the relative contribution each type of food will make the overall intake of the additive, including its uses in foods specified in **Schedules 1 and 2.**

Additives With Numerical ADIs Used in Non-Alcoholic Beverages Only

Guideline 8 The maximum level of use of an additive in non-alcoholic beverages may be assumed to be approximately **40 x ADI**, which is based on an intake of 25 ml of beverage per kg body weight per day (or 1.5 litres for a 60-kg person). Higher or lower values may be applied when reliable and relevant beverage consumption data are available.

Guideline 9 When an additive is used in more than one type of non-alcoholic beverage, maximum levels of use in additional foods must be based on estimates of the relative contribution each type of beverage will make to the overall intake of the additive, including its uses in beverages specified in **Schedules 1** and **2.**

Additives With Numerical ADIs Used in Both Solid Foods and Beverages

Guideline 10 When an additive is used in different types of solid foods and non-alcoholic beverages, maximum levels of use in additional foods and beverages must be based on estimates of the relative contribution each type of food and beverage will make to the overall intake of the additive, including its uses in foods and beverages specified in **Schedules 1** and **2.**

Additives Currently Used at High Levels Relative to Their ADIs

Guideline 11 For an additive having one or more uses in **Schedules 1 and 2** that are higher than **320 x ADI**, maximum levels of use in additional foods and beverages should not be recommended in this Standard without further review. In such cases, appropriate further use of the additive should be determined on the basis of estimates of total consumer exposure to the additive, or other appropriate criteria.

Alternate Method of Demonstrating Compliance with Guidelines 3-11

Guideline 12 The requirements of Guidelines 3-10 may be met, alternatively, by demonstrating that the theoretical maximum daily intake (TMDI) or estimated daily intake (EDI) of an additive, calculated by appropriate procedures, does not exceed its ADI. This method may also be used to determine whether an additive whose currently specified uses exceed 320 x ADI, as in Guideline 11, may be found suitable for its proposed additional uses.[1]

[1] See "Guidelines for Simple Evaluation of Food Additive Intake", CAC/VOL XIV Ed. 1, Supplement 2 (1989).

JECFA Additives Not Currently Specified in Schedules 1 and 2

Guideline 13 Additives which have been evaluated by JECFA and have been allocated a numerical ADI, or ADI "Not Specified", but which are not currently specified in **Schedules 1 and 2**, may be found suitable for use in foods under the conditions set forth in Guidelines 2-10 or 12.

SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES NOT PREVIOUSLY REVIEWED BY THE COMMITTEE

Category I (recommended to the Commission for adoption)

Sulfuric acid

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

Potassium sodium L(+)-tartrate	(CAS number)
Sodium dihydrogen phosphate	(review the number of significant figures in the assay limit)
Sodium L(+)-tartrate	(CAS number & review the number of significant figures in the assay limit)

Category III (substantive changes required)

Flavouring agents

Butyl acetate
Decanal
Diacetyl
Ethyl acetate
Ethyl butyrate
Ethyl isovalerate
dl-Menthol
1-Menthol
Methyl phenylacetate
Methyl salicylate
γ-Nonalactone
Phenylacetaldehyde
Piperonal
γ-Undecalactone
Vanillin

Other additives

Annatto extracts	(need for taking into account new manufacturing processes)
Propylene glycol esters of fatty acids	(consider including limits for free and total propylene glycol, free fatty acids etc)
Borax	(specifications have to be drawn up)
Boric acid	(specifications have to be drawn up)
o-Phenylphenol	(consider including limits for 1-naphtol, p-phenylphenol and diphenyl ether)
Sodium o-phenylphenol	(consider including limits for 1-naphtol, p-phenylphenol and diphenyl ether)
Tartaric, acetic and fatty acid esters of glycerol, mixed and Tartaric and fatty	(specifications have to be drawn up; present monograph includes two different substances)

acids esters of glycerol	
Ammonium hydroxide	(consider revision to recognize the composition of the commercial product; review the number of significant figures in the assay limit)
Cyclohexylsulfamic acid	(consider the need for a limit for aniline; consider lowering limits for cyclohexylamine and dicyclohexylamine)
Hydrochloric acid	(consider the need for a limit for total organic (non- fluorine) compounds, benzene, fluorinated organic compounds and mercury)
Lactic acid	(review need for cyanide and methanol limits, which relate to out-dated manufacturing method)
Propylene glycol	(consider the need for limits for chlorinated organic compounds and propanediol polymers; review limit for water content)
Sodium polyphosphate, glassy	(review identity and composition of the material; consider limit for cyclic compounds)
Triacetin	(review limit for water content and its implications on the assay value)

Category IV (specifications which may be revised at forthcoming JECFA sessions)

Benzoic acid
Sodium benzoate
Benzaldehyde

Category V (specifications designated as tentative)

Acetone peroxide
Ammonium persulfate
Calcium iodate
Calcium peroxide
Calcium dihydrogen phosphate
Chlorine dioxide
Potassium persulfate
Stearyl tartrate

REVISED INVENTORY OF PROCESSING AIDS

INTRODUCTION

The inventory of processing aids (IPA) was adopted by the Codex Alimentarais Commission in 1989[1]. The IPA is subject to ongoing revision.

[1] Codex Alimentarais Volume 1, Section 5.7

As the identification of gaps or duplication in the IPA was difficult, the attached abridged version was prepared by excluding foods, food additives in the INS-system and repetitions.

The IPA is an open list of substances used during food processing. Inclusion of a substance does not imply that the CAC has endorsed its safety for any particular use.

Delegations are asked to examine the revised list, and to suggest how it may be made more complete and more precise. Information on uses, residues and reaction products, safety of the substances and safety of residues were requested.

LIST OF USUAL PROCESSING AIDS

Besides
- Usual foodstuff
- Food additives with an INS-Nr
- Mixtures and compounds of listed PA's

ANTIFOAM AGENTS

Fatty acid ester with ethylene oxide or propylene oxide
Fatty alcohols (C8-C30)
n-Butoxypolyoxyethylene polyoxypropylene glycol
Oxoalcohols C9-C30
Petroleum hydrocarbons
Petroleum wax (synthetic)
Polyacrylic acid, sodium salt
Polyethylene glycol
Polyethylene glycol dioleates
Polyoxyethylene esters of C8-C30 fatty acids
Polyoxypropylene esters of C8-C30 fatty acids
Polyoxyethylene esters of C9-C30 oxoalcohols
Polyoxypropylene esters of C9-C30 oxoalcohols
Polypropylene glycol
Tallow, oxidized or sulphated

CATALYSTS

Alloys of 2 or more listed metals
Chromium
Copper
Copper Chromate
Copper chromite
Ferrous sulfate
Manganese
Molybdium
Nickel

Palladium
Platinum
Potassium metal
Potassium methylate (methoxide)
Potassium ethylate (ethoxide)
Sodium amide
Sodium ethylate
Sodium metal
Trifluoromethane sulfonic
Zirconium

CLARIFYING AGENTS/FILTRATION AIDS

Absorbent clays (bleaching, natural, or activated earths)
Active carbon
Asbestos
Chloromethylated aminated styrene-divinylbenzene resin
Diatomaceous earth
Divinylbenzene-ethylvinylbenzene copolymer
Fuller's earth
Isinglass
Magnesium acetate
Perlite
Polyacrylamide/polysodium acrylate copolymer
Polymaleic acid and sodium polymaleate
Vegetable carbon (activated)
Wood flour/Sawdust

COLOUR STABILIZERS

(only FA)

CONTACT FREEZING AND COOLING AGENTS

Brine (eg. salt brine)
Dichlorofluoromethane
Freons (to be specified)

DESICCATING AGENT/ANTICAKING AGENTS

Octadecylammonium acetate (in ammonium chloride)

DETERGENTS (wetting agents)

Methyl glucoside of coconut oil ester
Quaternary ammonium compounds
Sodium lauryl sulphate
Sodium xylene sulphonate

ENZYME IMMOBILIZATION AGENTS AND SUPPORTS

Glutaraldehyde
Glass
Diatomaceous earth
Ceramics
Diethylaminoethyl cellulose

Ion exchange resins
Polyethylènimine

ENZYME PREPARATIONS (Including immobilized enzymes)

Animal-Derived Preparations

Alpha-amylase	(hog or bovine pancreas)
Catatase	(bovine or horse liver)
Chymosin	(calf, kid, or lamb abomasum)
Lipase	(bovine stomach) (salivary glands or forestomach of calf, kid, or lamb) (hog or bovine pancreas)
Pepsin	(hog stomach, poultry-proventicum)
Phospholipase	(pancrease)
Rennet	(bovine, calf, goat, kid, or sheep, lamb stomach)
Trypsin	(porcine or bovine pancreas)

Microbiological Origin

Alcohol dehydrogenase	*(Saccharomyces cerevisiae)*
Alpha amylase	*(Aspergillus niger)*
	(Aspergillus oryzae)
	(Bacillus licheniformis)
	(Bacillus stearothermophilus)
	(Bacillus subtilis)
	(Rhizopus delemar)
	(Rhizopus oryzae)
Alpha galactosidase	*(Aspergillus niger)*
	(Mortierella vinacea sp.)
	(Saccharomyces carlsbergensis)
Arabino-furanosidease	*(Aspergillus niger)*
Beta amylase	*(Bacillus cereus)*
	(Bacillus megaterium)
	(Bacillus subtilis)
Beta glucanase	*(Aspergillus niger)*
	(Bacillus subtilis)
	(Trichoderma harzianum)
Beta glucosidase	*(Trichoderma harzianum)*
Catalase	*(Aspergillus niger)*
	(Micrococcus lysodeicticus)
Cellobiase	*(Aspergillus niger)*
or betaglucosidase	*(Trichoderma reesei)*
Cellulase	*(Aspergillus niger)*
	(Aspergillus oryzae)
	(Rhizopus delemar)
	(Rhizopus oryzae)
	(Sporotrichum dimorphosporum)
	(Trichoderma reesei)
	(Thielavia terrestris)
Dextranase	*(Aspergillus species)*
	(Bacillus subtilis)

	(Klebsiella aerogenes)
	(Penicillium funiculosum)
	(Penicillium lilacinum)
Endo-beta glucanase	*(Aspergillus niger)*
	(Aspergillus oryzae)
	(Bacillus circulons)
	(Bacillus subtilus)
	(Penicillium emersonii)
	(Rhizopus delemar)
	(Rhizopus oryzae)
	(Trichoderma reesei)
	(Disporotrichum dimorphosphorum)
Esterase	*(Mucor miehei)*
Exo-alpha glucosidase	*(Aspergillus niger)*
Exo-alpha glucosidase (immobilized)	(same sources as above)
Glucoamylase or amyloglucosidase	*(Aspergillus awamori)*
	(Aspergillus niger)
	(Aspergillus oryzae)
	(Rhizopus arrhizus)
	(Rhizopus delemar)
	(Rhizopus niveus)
	(Rhizopus oryzae)
	(Trichoderma reesei)
Glucose isomerase	*(Actinoplanes missouriensis)*
	(Arthrobacter sp.)
	(Bacillus coagulans)
	(Streptomyces albus)
	(Streptomyces olivaceus)
	(Streptomyces olivochromogenes)
	(Streptomyces rubiginosus)
	(Streptomyces sp.)
	(Streptomyces violaceoniger)
Glucose isomerase (immobilized)	(same sources as above)
Glucose oxidase	*(Aspergillus niger)*
Hemicellulase	*(Aspergillus niger)*
	(Aspergillus oryzae)
	(Bacillus subtilis)
	(Rhizopus delemar)
	(Rhizopus oryzae)
	(Sporotrichum dimorphosporum)
	(Trichoderma reesei)
Inulinase	*(Aspergillus niger)*
	(Kluyveromyces fragilis)
	(Sporotrichum dimorphosporum)
	(Streptomyces sp.)
Invertase	*(Aspergillus niger)*
	(Bacillus subtilis)
	(Kluyveromyces fragilis)
	(Saccharomyces carlsbergensis)

	(Saccharomyces cerevisiae)
	(Saccharomyces sp.)
Isoamylase	*(Bacillus cereus)*
Lactase	*(Aspergillus niger)*
(Beta-galactosidase)	*(Aspergillus oryzae)*
	(Kluyveromyces fragilis)
	(Kluyveromyces lactis)
	(Saccharomyces sp.)
Lactoperoxidase	
Lipase	*(Aspergillus flavus)*
	(Aspergillus niger)
	(Aspergillus oryzae)
	(Brevibacterium lineus)
	(Candida lipotytica)
	(Mucor javanicus)
	(Mucor miehei) (Mucor pusillus)
	(Rhizopus arrhizus)
	(Rhizopus delemar)
	(Rhizopus nigrican or niveus)
Malic acid decarboxylate	*(Leuconostoc oenos)*
Maltase or	*(Aspergillus niger)*
alphaglucosidase	*(Aspergillus oryzae)*
	(Rhizopus oryzae)
	(Trichoderma reesei)
Melibiase	*(Mortierella vinacea sp.)*
(alphagalactosidase)	*(Saccharomyces carlsbergensis)*
Nitrate reductase	*(Micrococcus violagabriella)*
Pectinase	*(Aspergillus awamori)*
	(Aspergillus foetidus)
	(Aspergillus niger)
	(Aspergillus oryzae)
	(Bacillus licheniformis)
	(Rhizopus oryzae)
	(Trichoderma reesei)
Pectin esterase	*(Aspergillus niger)*
Pectinlyase	*(Aspergillus niger)*
Polygalacturonase	*(Aspergillus niger)*
Protease	*(Aspergillus melleus)*
	(Aspergillus niger)
	(Aspergillus oryzae)
	(Bacillus cereus)
	(Bacillus licheniformis)
	(Bacillus subtilis)
	(Brevibacterium lineus)
	(Endothia parasitica)
	(Lactobacillus casei)
	(Micrococcus caseolyticus)
	(Mucor miehei)
	(Mucor pusillus)
	(Streptococcus cremoris)
	(Streptococcus lactis)

	(Bacillus acidopullulyticus)
Pullulanase	*(Bacillus subtilis)*
	(Klebsiella aerogenes)
Serine proteinase	*(Streptomyces fradiae)*
	(Bacillus licheniformis)
Tannase	*(Aspergillus niger)*
	(Aspergillus oryzae)
Xylanase	*(Aspergillus niger)*
	(Sporotrichum dimorphosporum)
	(Streptomyces sp.)
	(Trichoderma reesei)
β-xylosidase	*(Trichoderma reesei)*

SOLVENTS (extraction and processing)

Acetone (dimethyl ketone)
Amyl acetate
Benzyl alcohol
Benzyl benzoate
Butane-1,3-diol
Butan-1-ol
Butan-2-ol
Butyl acetate
Cyclohexane
Dibutyl ether
1,2-Dichlororethane (Dichloroethane)
Dichloromethane, Methylenchloride
Dichlorotetrafluoroethane
Diethyl citrate
Diethyl ether
Diethyl tartrate
Di-isopropylketone
Ethyl acetate
Ethyl lactate
Ethylmethylketone (butanone)
Glycerol tripropionate
Heptane
Hexane
Isoparaffinic petroleum hydrocarbons
Isopropyl myristate
Methanol
Methyl acetate
Methyl propanol-1, Isobutanol
Nitric acid
2-Nitropropane
n-Octyl alcohol
Pentane
Petroleum ether (light petroleum)
Propane-1-ol
Propane-2-ol (isopropyl alcohol)
Tertiary butyl alcohol
1,1,2-Trichloroethylene

Trichlorofluoroethylene
Trichlorofluoromethane
Tridodecylamine
Toluene

FAT CRYSTAL MODIFIERS

Sodium dodecylbenzene sulphonate
Sodium lauryl sulphate

FLOCCULATING AGENTS

Acrylamide resins, also modified
Acrylate-acrylamide resin
Complexes of soluble aluminum salt and phosphoric acid
Dimethylamine-epichlorohydrin copolymer
Fuller's earth (calcium analogue of sodium montmorillonite)
Isinglass
Dried and powdered blood plasma
Polyacrylic acid, -salts, -amides

ION EXCHANGE RESINS, MEMBRANES, AND MOLECULAR SIEVES

RESINS:

Copolymers of methyl acrylate and divinylbenzene, also
- aminolyzed with dimethylaminopropylamine
- crosslinked with diethyleneglykol
- hydrolyzed

Completely hydrolyzed terpolymers of methyl acrylate, divinylbenzene and acrylonitrile.

Cross-linked phenolformaldehyde activated with triethylenetetramine or tetraethylenepentamine.

Cross-linked polystyrene, first chloromethylated then aminated with trimethylamine, dimethylamine, diethylenetriamine or dimethylethanolamine.

Diethylenetriamine, triethylenetetramine, tetraethylenepentamine cross-linked with epichlorohydrin.

Epichlorohydrin cross-linked with ammonia.

Polystyrene-divinylbenzene reticulum with trimethylammonium groups.

Reaction resin of formaldehyde, acetone and tetraethylene-pentamine.

Copolymeres of Styrene and divinylbenzene, also
- cross-linked
- chloromethylated
- aminated with dimethylamine
- oxidized with hydrogen peroxide
- sufonated

Sulfite-modified cross-linked phenol-formaldehyde, with modification resulting in sulfonic acid groups on side chains.

Sulfonated anthracite coal meeting the requirement of American Society for Testing and Materials D388-38, Class I, Group 2.

Counter ions:

Aluminum
Bicarbonate
Calcium
Carbonate
Chloride
Hydronium
Hydroxyl
Magnesium
Potassium
Sodium
Sulfate

MEMBRANES:

Polyethylene - polystyrene base modified by reaction with chloramethyl ether and subsequent amination with trimethylamine, diethylenetriamine or dimethylethanolamine.

Polymers and Polyethylene - polystyrene base modified by reaction with chloramethyl ether and subsequent amination with trimethylamine, diethylenetriamine or dimethylethanolamine.

Polymers and copolymers containing the following components:

Cellulosics (such as cellulose diacetate, -ethers),
Polysulfone-sulfonated polysulfone,
Polyethersulfone-sulfonated polyethersulfone,
Fluoropolymers (such as polyvinylidene fluoride),
Polysulfoneamides, aliphatic/aromatic,
Polyamide and copolyamides (such as polypiperazineamides, phenylenediamine trimesamide polymer),
Polyesters (such as polyethyleneterephalate),
Polyolefins (such as polypropylene, polyethylene),
Polyacrylonitriles,
Polystyrene-sulfonated polystyrene,
Chitin/chitosan and derivatives,
Polyureas-polyurethanes,
Polyethers, and Polyamines.

LUBRICANTS, RELEASE AND ANTI-STICK AGENTS, MOULDING AIDS

Bentonite
Butyl stearate
Castor oil
Ethoxylated mono- and diglycerides
Hydrogenated sperm oil
Waxes

MICRO-ORGANISM CONTROL AGENTS

Disodium cyanodithioamidocarbonate
Disodium ethylene bis dithiocarbamate
Ethylenediamine
Hydrogen peroxide
Hypochlorites
Iodophors
Lactoperoxide system (lactoperoxidase, glucose oxidase, thiocyanate salt)
N-alkyl (C12-C16) dimethyl benzylchloride
Nitric acid
Peracetic acid
Potassium N-methyldithiocarbamate
Propylene oxide
Quaternary ammonium compounds
Sodium chlorite
Sodium dimethyldithiocarbamate

PROPELLANT AND PACKAGING GASES

Argon
Chloropentafluoroethane
Helium
Octafluorocyclobutane
Oxygen
Trichlorofluoromethane

WASHING AND PEELING AGENTS

Alkylene oxide adducts of alkyl alcohols and fatty acids
Aliphatic acid mixture consisting of valeric, caproic, enanthic, caprylic, and pelargonic acids.
Alpha-alkyl-omega-hydroxy-poly (oxyethylene)
Dialkanolamine
Dithiocarbamate
Ethylene dichloride
Ethylene glycol monobutyl ether
Hydrogen peroxide
Hypochlorites
Linear undecylbenzenesulfonic acid
Monoethanolamine
Organophosphates
Polyacrylamide
Potassium bromide
Sodium dodecylbenzene sulfonate
Sodium 2-ethylhexyl sulphate
Sodium -methyl naphthalene sulfonates
Sodium n-alkylbenzene-sulfonate
Triethanolamine

YEAST NUTRIENTS

B-Complex vitamins
Biotin
Ferrous ammonium sulphate
Ferrous sulphate
Inositol
Niacin
Pantothenic acid
Yeast autolysates
Zinc sulphate

OTHER PROCESSING AIDS

Acrylic resin with primarily tertiary amino groups
Alkylene oxide adduct
Allyl isothiocyanate
Aluminum oxide
Ammonium nitrate
Amyl acetate
Benzyl alcohol
Ethylene oxide-propylene oxide copolymers and blockpolymeres
Fatty alcohol-glycol ether
Gibberellic acid
Glycerol ester of adipic acid
Glycerol tripropionate
Hydrogen
Hydrophillic fatty acyl esters, linked to a neutral carrier
Isopropyl alcohol
Magnesium tartrate
Methyl glycoside water
Modified higher alcohol
Non-ionogenic alkylene oxide adduct with emulgatorv
Oxalic acid
Paraffin
Polyalkylene oxide, in combination with special fatty alcohols
Polyethoxylated alcohol, modified
Polyacrylate
Polyethylene glycol
Polyglycol copolymer
Potassium gibberellate
Sodium
Sodium hypochlorite
Sodium polyacrylate
Sodium polyacrylate-acrylamide resin
Sulphonated copolymer of styrene and divinylbenzene
Tannic acid with quebracho extract
Vegetable fatty acyl (hydrophillic)
Xylose

DRAFT PREAMBLE TO THE CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS (at Step 8)

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 substance that meets the terms of the Codex definition for a contaminant, including contaminants in feed for food-producing animals, <u>except</u>:

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, and 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 mis 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 in a food or feed commodity is the maximum concentration of that substance recommended by the CAC to be legally permitted in that commodity.

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]

[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 level.

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.

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 broad 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
- data on intake by susceptible groups

Fair trade considerations

- existing or potential problems in international trade
- commodities 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 level management 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.

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 Annex IV). The Codex standards are 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. See 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 JECFA 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 Levels.

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

ANNEX I	-	Criteria for the Establishment of Maximum Levels in Foods
ANNEX II	-	Procedure for Risk Management Decisions
ANNEX III	-	Format of the Standard

ANNEX I

CRITERIA FOR THE ESTABLISHMENT OF MAXIMUM LEVELS IN FOODS

INTRODUCTION

In this Annex criteria are mentioned regarding information which is considered necessary for evaluating contaminant problems in foods and for the establishment of maximum levels. It is therefore important that these criteria are taken into account when information is supplied to JECFA and/or to the CCFAC.

The criteria mentioned here are elaborated in more detail than in section I.3.3. of the Preamble. Only those aspects are mentioned that need further clarification, so criteria or aspects that are not mentioned here should not be ruled out in the evaluation process.

Toxicological information

Integrated toxicological expert advice regarding a safe/tolerable intake level of a contaminant is essential when decisions about maximum levels in foods are considered. A recommendation from JECFA regarding the maximum allowable or tolerable intake, based on a full evaluation of an adequate toxicological data base, shall be the main basis for decisions by CCFAC. In urgent cases, it may be possible to rely on less developed evaluations from JECFA or on toxicological expert advice from other international or national bodies.

When toxicological information is presented in relation to proposals for maximum levels for contaminants in foods, indications are desirable about the following aspects:

- identification of the toxic substance(s)
- metabolism in humans and animals, as appropriate
- toxicokinetics and toxicodynamics
- information about acute and long term toxicity in humans and animals and other relevant toxicity data
- conclusions and advice of toxicological expert(s) (groups), with references, including information on specially vulnerable population groups or animals.

Analytical data

Validated qualitative and quantitative analytical data on representative samples should be supplied. Information on the analytical and sampling methods used and on the validation of the results is desirable. A statement on the representativity of the samples for the contamination of the product in general (e.g. on a national basis) should be added. The portion of the commodity that was analyzed and to which the contaminant content is related should be clearly stated and preferably should be equivalent to the definition of the commodity for this purpose or to existing related residue regulation.

Appropriate sampling procedures should be applied. Special attention to this aspect is necessary in the case of contaminants that may be unequally distributed in the product (e.g. mycotoxins in some commodities).

Intake data

It is desirable to have information about the contaminant concentrations in those foods or food groups that (together) are responsible for at least half and preferably 80 % or more of the total dietary intake of the contaminant, both for average consumers and for high consumers.

Information about the **presence of the contaminant in foods that are widely consumed** (staple foods) is desirable in order to be able to make a satisfactory assessment of the contaminant intake and of risks associated with food trade.

Food consumption data for average, most exposed and susceptible consumer groups are desirable for evaluations of (potential) intake of contaminants, both on a national and on an international scale. It is therefore important to have information about both average and high consumption patterns regarding a wide scale of foodstuffs, so that for every contaminant the most exposed consumer groups may be identified. Detailed information about high consumption patterns is desirable, both regarding group identification criteria (e.g. age or sex differences, vegetarian or regional dietary customs, etc.) and statistical aspects.

Dietary intake of contaminants: Reference is made to the Guidelines for the study of dietary intake of chemical contaminants (WHO). It is important to supply all relevant details, such as the type of study (duplicate diet, total diet or market basket study, selective study), and statistical details. Calculated contaminant intake data from food consumption models may also be useful. When results about food groups and about effects of preparation and cooking etc. are available, these should also be supplied.

Fair trade considerations

Existing, expected or potential problems in international trade: In order to assess the urgency of a problem to be discussed by CCFAC it is important to have information about the magnitude of existing or expected problems, both regarding the amount and the source of the food or feed that is at stake and the concerned parties and economic aspects involved. Potential problems should also be indicated.

Foods concerned moving in international trade: The main exporting and importing countries for commodities which are involved in the issue should be identified and it is essential that information is available about contaminant concentrations in the commodities originating from the main exporting countries.

Information about national regulations: It is desirable that details are made available by countries (especially the main exporting and importing countries) about their national regulations regarding the contaminant in question, in particular on the data and the considerations on which these regulations are based. For a good evaluation of the problem it is essential that not only the data base is clear, but also the risk assessment and risk management policy which is used for making decisions regarding maximum levels in foods.

Technological considerations

Information about the source of the contaminant and the way in which the food is contaminated is essential for assessing the possibilities to control the contamination process and to be able to guarantee a desired product quality. Where possible **Source-related measures** should be proposed. **Good Manufacturing Practice (GMP)** and/or **Good Agricultural Practice (GAP)** should also be formulated to control a contamination

problem. When this is possible, maximum levels may be based on GMP or GAP considerations and may thus be established at a level as low as reasonably achievable. Considerations regarding the technological possibilities to control a contamination problem should also be taken into account when a primary risk assessment model (theoretical maximum daily intake) shows possible intakes exceeding the toxicological maximum intake recommendation. In such a case the possibilities of lower contamination levels need further careful examination. Then a detailed study about all the aspects involved is necessary, so that decisions about maximum limits can be based on a thorough evaluation of both the public health arguments and the possibilities and problems to comply with the proposed standard.

Risk assessment and risk management considerations

A tiered approach, involving risk assessment and risk management procedures, is recommended for developing a consistent policy regarding public health risks related to contaminants in foods.

Risk assessment is defined as the process of assessing the probability of the occurrence of particular hazards. The first step is **hazard evaluation.** This involves the evaluation of toxicological information about possible effects of the contaminant, including dose/response relationships, and when possible the establishment of a safety standard (ADI, TDI or comparable toxicological recommendation) for the intake of the contaminant. In the **risk characterisation** step the hazard evaluation results are combined with the **intake estimation** of the contaminant, based on food consumption data and occurrence assessments. Potential public health risks can be considered to exist when there is evidence that the contaminant intake of (groups of) consumers may exceed (on a long term basis for long term recommendations) the toxicological recommendation about the maximum acceptable or tolerable intake level. More specific estimation and description of the risks will be necessary to deal adequately with cases when intakes exceeding the toxicological standard occur in practice and cannot easily be reduced. This also applies when it has not been possible to establish a safe dose level of the contaminant.

Risk management involves decisions about policies and actions to manage and reduce public health risks, including the establishment and enforcement of maximum levels of contaminants in foods. It is based on adequate risk assessment and on information about policy options and strategies to deal with contamination problems and involves **risk communication** with other relevant authorities and with those affected by risk management measures. Responsible risk management is based on consistent application of an appropriate policy regarding the protection of public health, but also involves taking into account other relevant criteria, such as the available analytical data, the technological possibilities to control the contamination of products, economic factors and fair trade criteria.

In short, the risk assessment shall establish how many consumers possibly exceed the toxicological standard, and for how long time and how much, and what this implies as real health risks. Risk management involves, in a consistent way, deciding what is acceptable in this respect and what is not, to what extent other factors can be taken into account, and decisions and actions to achieve sufficient public health protection and control of the contamination.

Risk management evaluations may lead to the conclusion that maximum levels should be established for foods. In the process leading to such a decision, the

consequences, costs and benefits should be presented and evaluated in relation to other policy options.

Establishment of maximum levels for contaminants

The **establishment of maximum levels of contaminants in foods** involves several principles, some of which have already been mentioned. Briefly stated, the following criteria will help in maintaining a consistent policy in this matter:

- MLs shall be set only for those contaminants which are or may be a hazard to public health.
- MLs shall be set only for those foods that are significant for the total exposure of the consumer to the contaminant, and for foods, of which the contaminant level presents known or expected problems in international trade.
- MLs shall be set as low as reasonably achievable. Providing it is acceptable from the toxicological point of view, MLs shall be set at a level which is (slightly) higher man the normal range of variation in levels in foods that are produced with current adequate technological methods, in order to avoid undue disruptions of food production and trade. Where possible, MLs shall be based on GMP and/or GAP considerations in which the health concerns have been incorporated as a guiding principle to achieve contaminant levels as low as reasonably achievable. Foods that are evidently contaminated by local situations or processing conditions that can be avoided by reasonably achievable means shall be excluded in this evaluation, unless appreciable economic aspects are at stake and a higher ML can be shown to be acceptable from a public health point of view.
- Proposals for MLs in products shall be based on data from at least various countries and sources, encompassing the main production areas/processes of those products, as far as they are engaged in international trade. When there is evidence that contamination patterns are sufficiently understood and will be comparable on a global scale, more limited data may be enough.
- MLs may be set for product groups when sufficient information is available about the contamination pattern for the whole group, or when there are other arguments that extrapolation is appropriate.
- Numerical values for MLs shall preferably be regular figures in a geometric scale (0.01, 0.02, 0.05, 0.1, 0.2, 0.5, 1, 2, 5 etc.), unless this may pose problems in the acceptability of the MLs.
- MLs should not be lower than a level which can be analyzed with methods of analysis that can be readily applied in normal product control laboratories, unless public health considerations necessitate a lower detection limit which can only be controlled by means of a more elaborate method of analysis. In all cases, however, a validated method of analysis should be available with which a ML can be controlled.
- The contaminant as it should be analyzed and to which the ML applies should be clearly defined. The definition may include important metabolites when this is appropriate from an analytical or toxicological point of view. It may also be aimed at indicator substances which are chosen from a group of related contaminants.

- The product as it should be analyzed and to which the ML applies, should be clearly defined. MLs shall in general preferably be expressed as a level of the contaminant related to the product as it is, on a fresh weight basis. In some cases, however, there may be valid arguments to prefer expression on a dry weight basis. Preferably the product shall be defined as it moves in trade, with provisions where necessary for the removal of inedible parts that might disturb the preparation of the sample and the analysis. The product definitions used by the CCPR and contained in the Classification of foods and feeds may serve as guidance on this subject; other product definitions should only be used for specified reasons.
- For fat soluble contaminants which may accumulate in animal products, provisions should be applied regarding the application of the ML to products with various fat content (comparable to the provisions for fat soluble pesticides).
- Guidance is desirable regarding the possible application of MLs established for primary products to processed products and multi-ingredient products. When products are concentrated, dried or diluted, use of the concentration or dilution factor is generally appropriate in order to be able to obtain a primary judgment of the contaminant levels in these processed products. The maximum contaminant concentration in a multi-ingredient food can likewise be calculated from the composition of the food. Information regarding the behaviour of the contaminant during processing (e.g. washing, peeling, extraction, cooking, drying etc.) is however desirable to give more adequate guidance here. When contaminant levels are consistently different in processed products related to the primary products from which they are derived, and sufficient information is available about the contamination pattern, it may be appropriate to establish separate maximum levels for these processed products. This also applies when contamination may occur during processing. In general however, maximum levels should preferably be set for primary agricultural products and may be applied to processed, derived and multi-ingredient foods by using appropriate factors. When these factors are sufficiently known, they should be added to the data base about the contaminant and mentioned in connection to the maximum level in a product.
- MLs shall preferably not be set higher man is acceptable in a primary (theoretical maximum intake and risk estimation) approach of their acceptability from a public health point of view. When this poses problems in relation to other criteria for establishing MLs, further evaluations are necessary regarding the possibilities to reduce the contaminant levels, e.g. by improving GAP and/or GMP conditions. When this does not bring a satisfactory solution, further refined risk assessment and contaminant risk management evaluations will have to be made in order to try to reach agreement about an acceptable ML.

Procedure for risk assessment in relation to (proposed) MLs for contaminants

It will be evident that in the case of contaminants, it is more difficult to control food contamination problems than in the case of food additives and pesticide residues. Proposed MLs will inevitably be influenced by this situation. In order to promote acceptance of Codex contaminant MLs, it is therefore important that assessments of the acceptability of those MLs are done in a consistent and realistic way. The procedure

involves assessment of the dietary intake in relation to the proposed or existing MLs and the maximally acceptable intake from the toxicological point of view.

For pesticide residues, Guidelines (WHO, 1989) have been prepared for predicting the dietary intake, involving a three-tiered approach with increasingly realistic predictions of intake. In the crude and intermediary estimate phase, hypothetical global and cultural diets are used to calculate the theoretical maximum daily intake (TMDI) and the estimated maximum daily intake (EMDI) (based on proposed or existing MRLs). The best estimate involves the national dietary pattern and corrections for known residue level in foods as consumed, etc. It is recommended to be cautious in using other than average food consumption values, although it is considered appropriate to use relevant average food consumption data for identifiable subgroups of the population. The procedure is used to assess the acceptability of proposed MRLs and to promote international acceptance of Codex MRLs.

For contaminants and natural toxins in food, essentially the same procedure is recommended to be used. Food consumption patterns with a higher intake of critical foods may be used in the intake calculations when this is part of an accepted national or international health protection and risk management policy. Calculated data should where possible always be compared with measured intake data. Proposals for Codex MLs should be accompanied by intake calculations and risk assessment conclusions regarding their acceptability and use. Statements from Governments about the (non-) acceptance of (proposed) Codex MLs should refer to specified intake calculations and risk assessment conclusions which support this position.

ANNEX II

PROCEDURE FOR RISK MANAGEMENT DECISIONS

INTRODUCTION

The recommended procedure for risk management decisions in the CCFAC is presented here as a simple decision scheme based on the main criteria, mentioned in the Preamble, I.4.2.. Criterion (1), basic information about the contaminant (problem) is not further mentioned, because it is considered a prerequisite, without which no sensible discussion can take place. Criterion (5), technological and economic aspects, is an essential tool for making recommendations about the management of the contaminant problem and for developing MLs, and when this information is not adequate, further data shall be requested. Bearing this in mind, it need not be further mentioned in the decision scheme, which is shown below. Decisions can be based on me availability of information (- or + or ?) on the following criteria:

(2a) Tox toxicological information,
(2b) A/In analytical and intake data,
(3) PHP potential health problems,
(4) TB international trade barriers.

The question mark ? was used in the column PHP, to indicate that only toxicological information is sufficiently available, or only intake data, so that there is no sufficient basis to decide whether there are potential health problems. Obviously, in practice there will be many situations which are not so clear cut as it is presented in the scheme. Information may be considered sufficient by some, and inadequate by others. Decisions will have to be taken on a case by case basis, considering the criteria mentioned in Annex I. Further quantification of the criteria for the necessary data base for making decisions may become inevitable when serious problems are encountered in practice regarding this aspect.

Risk management decision scheme for CCFAC

	Criterion				
Case	(2a) Tox	(2b) A/In	(3) PHP	(4) TB	CCFAC Action
1.	-	+	?	-	Request Tox data/evaluation by JECFA
2.	-	+	?	+	Request Tox data/evaluation by JECFA, national risk assessment. In urgent cases, CCFAC statement
3.	+	-	?	-	Request analytical/intake data
4.	+	+	-	-	No further action
5.	+	+	-	+	Request national risk assessment. After evaluation (in urgent cases, after a preliminary assessment) a CCFAC statement
6.	+	+	+	-	Development of MLs by CCFAC
7.	+	+	+	+	Development of MLs by CCFAC, with priority (in urgent cases, if necessary, temporary MLs)

ANNEX III

FORMAT OF THE STANDARD

INTRODUCTION

The format for Schedule I shall contain the following elements:

Name of the contaminant
Symbols, synonyms, abbreviations, scientific descriptions and identification codes that are commonly used shall be mentioned too.

Codex number of the contaminant
Number according to the list described in Annex IV.

Reference to JECFA meetings
(in which the contaminant was discussed).

ADI, TDI, PTWI or similar toxicological intake recommendation
When the situation is complex a short statement and further references may be necessary here.

Residue definition
Definition of the contaminant as it shall be analyzed and to which the maximum level applies.

List of Codex standards for the contaminant in foods
This list shall be composed by the following elements, in columns:

- Classification number of food commodity or food category
- Name of food commodity/category
- Numerical value of maximum level
- Suffix accompanying a ML, to specify the application of the ML
- Code for type of maximum level: maximum level, ML; guideline level, GL; or else, when appropriate (e.g. temporary maximum levels).
- Step in Codex procedure (only in CCFAC working documents)
- References to documents
- References to methods of analysis
- References to methods of sampling
- Notes/remarks

When appropriate, instead of a maximum level a (note referring to a) statement regarding the contaminant in the mentioned food (category) may be inserted.

The format of Schedule II shall contain the following elements:

Name of food commodity/category

Classification number of food commodity or food category

List of Codex standards for contaminants in that food commodity/category

This list shall be composed by the following elements, in columns:

- Name of the contaminant
- Numerical value of maximum level
- Code for type of maximum level
- Step in Codex procedure (only in CCFAC working documents)
- References, remarks and notes (shorter than in Schedule I).

FOOD ADDITIVES AND CONTAMINANTS PROPOSED FOR PRIORITY EVALUATION BY JECFA

Food Additives	Proposed by
Enzyme-hydrolyzed carboxymethyl cellulose (specifications only)	Finland
Salatrim (short- and long-chain acid triacylglycerol molecules)	Mexico
Stevioside	Egypt
Condaminants	**Proposed by**
Alfotoxins B, G, and M	CCFAC
Cadmium	USA
Dioxins and dioxins-like PCBs	CCFAC
Ethyl carbamate	CCFAC
Nitrate	Netherlands
Polycyclic aromatic hydrocarbons	Denmark
Trichothecenes	Netherlands