codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME Tel.: 52251 Telex: 625825-625853 FAO I Cables: Foodagri Rome Facsimile: (6)5225.4593

ALINORM 97/12

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-second Session
Geneva, 23 - 28 June 1997

REPORT OF THE TWENTY-EIGHTH SESSION OF THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS
Manila, the Philippines, 18 - 22 March 1996

NOTE: This report includes Codex Circular Letter CL 1996/11 - FAC.

W/W1362

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CX 4/30.2

CL 1996/11-FAC
May 1996

TO:
- Codex Contact Points
- Interested International Organizations
- Participants at the Twenty-eighth 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-eighth Session of the Codex Committee on Food Additives and Contaminants (ALINORM 97/12)

The report of the Twenty-eighth Session of the Codex Committee on Food Additives and Contaminants (CCFAC) is attached. It will be considered by the Twenty-second Session of the Codex Alimentarius Commission in Geneva from 23-28 June 1997.

MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION OR EXECUTIVE COMMITTEE

1. **Draft Annexes I, II and III of the General Standard for Contaminants and Toxins in Foods at Step 8;** ALINORM 97/12, paras. 63-65 and Appendix VI.

2. **Codex Advisory Specifications at Step 8;** ALINORM 97/12, paras. 49-51 and Appendix V.

3. **Amendments to the International Numbering System at Step 8;** ALINORM 97/12, paras. 52-54.

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 Standards at Step 8 of the Procedure for the Elaboration of Codex Standards Including Consideration of Any Statements Relating to Economic Impact (*Codex Alimentarius Procedural Manual*, Ninth Edition, pages 33-35) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, not later than 1 April 1997.

4. **Proposed Draft Annexes IV and V of the General Standard for Contaminants and Toxins in Foods at Step 5;** ALINORM 97/12, paras. 66-70 and Appendix VII.

5. **Proposed Draft Code of Practice for the Reduction of Aflatoxin B1 in Raw Materials and Supplemental Feedingstuffs for Milk Producing Animals at Step 5;** ALINORM 97/12, paras. 84-87 and Appendix IX.

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*, Ninth Edition, pages 27-29) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, **not later than 20 May 1996**.

REQUEST FOR COMMENTS AND INFORMATION

1. **Carry-Over of Sulphur Dioxide;** ALINORM 97/12, para. 7.

The Committee agreed to collect additional information on the carry-over of sulphur dioxide from raw material to the end product in the revised Codex Standard for Canned Shrimp and Prawns and related products.

2. **Maximum Level for Sulphur Dioxide in the Codex Standard for Dried Apricots;** ALINORM 97/12, para. 8.

The Committee agreed to seek additional information on a proposal to raise the maximum level for sulphur dioxide in the above Codex Standard from 2000 to 2500 mg/kg.

3. **Methods of Analysis for the Determination of Food Additives and Contaminants in Foods;** ALINORM 97/12, paras. 26-30.

The Committee agreed to request comments on additional methods of analysis for the determination of food additives and contaminants in foods based on specific criteria (see para. 28).

4. **Proposed Amendments to the International Numbering System;** ALINORM 97/12, paras. 52-54.

The Committee agreed to request comments on amendments to the INS on a continuing basis.

5. **Proposed Amendments to the Inventory of Processing Aids;** ALINORM 97/12, paras. 55-56.

The Committee agreed to request comments on amendments to the Inventory of Processing Aids on a continuing basis.

6. **Guideline Levels and Sampling Plans for Total Aflatoxins in Peanuts;** ALINORM 97/12, paras. 80-83 and Appendix VIII.

The Committee decided to return the draft guideline level and sampling plan to Step 6 for additional comment, especially as related to the scientific basis for a lower limit.

7. **Position Paper on Ochratoxin A;** ALINORM 97/12, paras. 88-90.

The Committee agreed to request comments on the position paper (CX/FAC 96/21), particularly in regard to those issues outlined in para. 90.

8. **Proposed Draft Maximum Levels for Lead;** ALINORM 97/12, paras. 93-95 and Appendix X.

The Committee agreed to circulate the revised proposed draft maximum levels for lead for additional comment.

9. **Draft Guideline Levels for Cadmium and Lead in Cereals, Pulses and Legumes;** ALINORM 97/12, paras. 96-97 and Appendix VIII.

The Committee agreed to return the above draft guideline levels to Step 6 for additional comment.

10. **Information on Cadmium;** ALINORM 97/12, para. 102.

The Committee agreed to collect additional information on cadmium for consideration at its next Session.

11. **Proposals for the Priority Evaluation of Food Additives and Contaminants by JECFA;** ALINORM 97/12, paras. 103-104 and Appendix XI.

Additional proposals for amendments and/or additions to the above list are requested.

Governments and international organizations wishing to submit comments and information on the above matters are invited to do so **no later than 1 November 1996** as follows: Mr. H. Van der Kooi, Ministry of Agriculture, Nature Management and Fisheries, Department for the Environment, Quality and Health, P.O. Box 20401, 2500 EK The Hague, The Netherlands, (Telefax No. 0031.70.347.7552), 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-eighth 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 amend the current text in the Preamble of the General Standard for Food Additives relating to the **carry-over of food additives into foods** as requested by the 21st Session of the Commission (para. 44);

- Agreed to refer thirteen substances in Categories I and II to the Commission for adoption as **Codex Advisory Specifications** (para. 51 and Appendix V);

- Agreed to forward proposals for amendments to the **International Numbering System for Food Additives** to the Commission for adoption (para. 54);

- Agreed to forward **Annexes I, II and III** of the General Standard for Contaminants and Toxins in Food to the Commission for adoption at Step 8 (para. 65 and Appendix VI);

- Agreed to forward **Annexes IV and V** of the General Standard for Contaminants and Toxins in Food to the Executive Committee for adoption at Step 5 (para. 70 and Appendix VII);

- Agreed to forward the proposed draft **Code of Practice for the Reduction of Aflatoxin B1 in Raw Materials and Supplemental Feedingstuffs for Milk Producing Animals** to the Executive Committee for adoption at Step 5 (para. 87 and Appendix IX);

- Agreed to discontinue the consideration of the **Code of Practice on Source Directed Measures to Prevent Contamination of Foodstuffs** in view of similar initiatives undertaken by the Codex Committee on Food Hygiene (para. 92);

- Agreed to discontinue the collection of information and/or the development of position papers on **PCB's , dioxins, polycyclic aromatic hydrocarbons and hydrogen cyanide** (para. 101), and;

- Agreed on proposals for the **priority evaluation of food additives and contaminants by JECFA** (para. 103 and Appendix XI).

OTHER MATTERS OF INTEREST TO THE COMMISSION:

- Agreed to forward proposed amendments to the Codex Alimentarius Procedural Manual concerning **Guidelines for Codex Committees** to the Codex Committee on General Principles for consideration (para. 25 and Appendix III);

- Agreed to forward **Methods of Analysis for the Determination of Food Additives and Contaminants in Foods** for endorsement by the Codex Committee on Methods of Analysis and Sampling (para. 29 and Appendix IV);

- Agreed that the United Kingdom would continue developing **exposure assessment methods** in support of the Codex General Standard for Food Additives for future consideration (para. 34);

- Agreed to incorporate data collected on **stabilizers, thickeners and sweeteners** into the General Standard on Food additives on the basis of principles developed previously for antioxidants and preservatives (para. 38);

- Agreed that the United Kingdom should redraft **Annex A** of the General Standard for Food Additives (para. 39);

- Agreed that Belgium, in co-operation with the CIAA, would draft explanatory notes on the use of the **Codex Food Identification System** for inclusion into the Preamble of the General Standard for Food Additives (para. 41);

- Agreed that New Zealand, Australia and Iceland would prepare a paper providing a step-wise procedure for the evaluation of **technological justification and need** within the General Standard for Food Additives (para. 42);

- Agreed that the United States would establish procedures for **amending the General Standard for Food Additives** in the Preamble to the Standard (para. 45);

- Agreed to initiate work on **colours, colour retention agents, bulking agents and emulsifiers** on the basis of previous requests (para. 46);

- Agreed to maintain the format of the **Inventory of Processing Aids** as previously adopted by the Commission (para. 56);

- Agreed that Denmark, the Netherlands and the United Kingdom would elaborate a paper to provide guidance on the **methodology and principles for exposure assessment** in the context of the General Standard for Contaminants and Toxins in Foods (para. 62);

- Agreed that discussion papers would be prepared on **arsenic, patulin and tin** for circulation, comment and consideration at its next Session (para. 67);

- Agreed that the United Kingdom would revise their **position paper on aflatoxins** for consideration at its next Session (para. 75);

- Decided to maintain the draft **maximum level for aflatoxin M1 in milk** at Step 7 pending the revaluation of aflatoxins by JECFA (para. 79);

- Decided to return the draft **guideline levels and sampling plans for total aflatoxins in peanuts** to Step 6 for additional comment (para. 83);

- Agreed to request comments on a position paper concerning **ochratoxin A** for consideration at its next Session (para. 90);

- Agreed to circulate revised proposed draft maximum levels for **lead** for additional comment at Step 3 (para. 95 and Appendix X);

- Decided to return the draft guideline levels for **cadmium and lead in cereals, pulses and legumes** to Step 6 for additional comment (para. 97 and Appendix VIII), and;

- Agreed to collect additional information on **cadmium** for consideration at its next Session (para. 102).

TABLE OF CONTENTS

LIST OF APPENDICES

INTRODUCTION AND OPENING OF THE SESSION (Agenda Item 1)

1. The 28th Session of the Codex Committee on Food Additives and Contaminants was held in Manila, the Philippines from 18 - 22 March 1996 at the kind invitation of the Governments of the Netherlands and the Philippines. Mr. Hans van der Kooi, Netherlands Department of Agriculture, Nature Management and Fisheries chaired the meeting. The meeting was attended by 145 delegates representing 35 member nations of the Commission and by 44 persons representing 31 international organizations.

2. Remarks were made by Mr. Eric T.J.T. Kwint, *Ambassador of the Netherlands to the Philippines;* Mr. V. Sibal, *FAO Representative to the Philippines;* Mr. A. Basaran, *Regional Adviser in Environmental Health, WHO;* and, Ms. M.R. Castillo, *Assistant Secretary, Philippines Department of Agriculture.*

3. Mr. M.M. Lantin, keynote speaker and *Undersecretary, Philippines Department of Agriculture*, stressed the importance and interest of the work of Codex to developing countries, especially in the context of the World Trade Organization Agreements related to the quality and safety of foods. Mr. Lantin noted the importance of harmonized international standards to increase market access. He expressed his deep gratitude to the Government of the Netherlands for its willingness to hold the 28th Session in Manila.

ADOPTION OF THE AGENDA[1] (Agenda Item 2)

4. The Committee adopted the Provisional Agenda as proposed. The Committee agreed to hold informal Working Groups to discuss proposed amendments to the International Numbering System, Proposals for the Priority Evaluation of Food Additives and Contaminants and Methods of Analysis for the Determination of Food Additives and Contaminants in Foods.

APPOINTMENT OF RAPPORTEUR (Agenda Item 3)

5. The Committee agreed with the suggestion of the Chairman to appoint Dr. Simon Brooke-Taylor of Australia as Rapporteur.

MATTERS REFERRED FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES[2] (Agenda Item 4a)

6. The Committee noted matters arising from the 21st Session of the Codex Alimentarius Commission and/or other Codex Committees related to the Implementation of the Medium-Term Plan, the adoption of proposals to Base Codex Standards and Other Recommendations on Scientific Principles and the Code of Practice for All Foodstuffs Transported in Bulk. The Committee also noted that general methods of analysis for contaminants developed or endorsed by the Codex Committee on Methods of Analysis and Sampling[3] would need to be considered when establishing the General Standard on Contaminants and Toxins in Foods.

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1 CX/FAC 96/1.

2 CX/FAC 96/2.

3 CX/FAC 96/2 - Annex II.

Carry-Over of Sulphur Dioxide

7. In discussing the request of the 21st Session of the Codex Committee on Fish and Fishery Products[4] for advice on the carry-over of sulphur dioxide from raw material to the end product in the revised Codex Standard for Canned Shrimp and Prawns and other related products, the Committee agreed to request additional information by circular letter.

8. The Committee also agreed to seek additional information on a request from the Delegation of Turkey to raise the maximum level for sulphur dioxide in the Codex Standard for Dried Apricots from 2000 to 2500 mg/kg. The delegation of Turkey also agreed to provide additional information and justification for their proposal at the 29th CCFAC.

Codex Standard for Food Grade Salt

9. In discussing the request of the 19th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses[5] to examine a proposal to lower the sodium chloride content in the Codex Standard for Food Grade Salt, the Committee discussed the proposal and since the product was mainly for domestic consumption no action was taken.

CONSIDERATION OF THE REPORT OF THE JOINT FAO/WHO EXPERT CONSULTATION ON THE APPLICATION OF RISK ANALYSIS TO FOOD STANDARDS ISSUES[6] (Agenda Item 4b)

10. The Committee was informed that the 21st Session of the Codex Alimentarius Commission, while endorsing the recommendations of the above Consultation in principle, noted that there was a need for further clarification of terms and definitions used for risk analysis.[7] Comments were therefore requested under CL 1995/40-CAC for eventual consideration by the Codex Committee on General Principles. The Commission also agreed that the report and recommendations of the Consultation should be examined by relevant Codex Committees.

11. The Committee was informed of recent activities related to risk analysis undertaken by the Codex Coordinating Committee for Asia.[8] The Committee also noted the importance of harmonized assessments for veterinary drugs, pesticides, food additives and contaminants as discussed at the Joint FAO/WHO Consultation for the Revision of Guidelines for Predicting Dietary Intake of Pesticide Residues[9].

CONSIDERATION OF THE SUMMARY REPORT OF THE FORTY-SIXTH MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES[10] (Agenda Item 5a)

12. The Summary Report of the forty-sixth meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), held in Geneva from 6 to 15 February 1996, was introduced by the Joint Secretaries, Dr J.L. Herrman (WHO) and Dr J. Paakkanen (FAO).

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4 ALINORM 95/18, para. 93.

5 ALINORM 95/26, paras. 37-42.

6 WHO/FNU/FOS/95.3.

7 ALINORM 95/37, paras. 27-30.

8 ALINORM 97/15, paras. 65-66.

9 WHO/FNU/FOS/95.11.

10 PCS/96.11.

13. JECFA confirmed that the occurrence of proliferative lesions in the adrenal medulla of rats fed polyols and lactose is a species-specific phenomenon not relevant to the toxicology of polyols and lactose in humans and therefore, the previous evaluations of the polyols were maintained.

14. Nearly 50 flavouring agents in three chemical groups were evaluated using the approach developed at the forty-fourth meeting of the Committee (WHO Technical Report Series No. 859) and described in Annex 5 of WHO Food Additives Series No. 35. JECFA concluded that there were no safety concerns at current levels of intake.

15. Aflatoxins B_1, B_2, G_1, G_2, M_1 and M_2 were evaluated following a request from CCFAC for an assessment of their carcinogenic potency and estimates of the risks from exposure. A large number of toxicity and epidemiological studies were considered, as well as biochemical markers of exposure and levels of contamination of foodstuffs. However, the evaluation was not completed at the meeting, and therefore JECFA recommended that it be continued at its next meeting devoted to food additives and contaminants.

16. Specifications for identity and purity were considered for 95 substances. New specifications were prepared for 37 substances, revised for 56 existing specifications and maintained for one substance. No specification was prepared for one substance. These specifications will be published in FAO Food and Nutrition Paper (FNP) 52 - Addendum 4.

17. General matters considered by JECFA included the harmonization of its specifications with those of other internationally recognized bodies, the lowering of existing general limits for lead and heavy metals in food additives where possible, the withdrawal of arsenic limits except where the nature and source of the substance or the level of consumption indicated that limits were necessary and the avoidance of the use of solvents and reagents in specification methods of analysis which were known or suspected carcinogens or are environmentally undesirable.

18. The *Joint FAO/WHO Expert Consultation on Application of Risk Analysis to Food Standards Issues*, held in Geneva in March 1995, recommended that exposure assessments, being primarily a scientific task, should continue to be carried out by Expert Committees such as JECFA. Therefore, a group of experts on intake participated in the forty-sixth meeting of JECFA to provide advice on aflatoxin intakes. At the next JECFA meeting, the membership of the group will be expanded to include experts from other countries.

19. JECFA noted that many data to be considered were submitted long after the deadline specified in the request for data, making it difficult to produce adequately reviewed working papers in time for the meeting. JECFA emphasized the importance of timely data submissions.

ACTION REQUIRED AS A RESULT OF CHANGES IN ADI STATUS AND OTHER TOXICOLOGICAL RECOMMENDATIONS[11] (Agenda Item 5b)

20. The Committee was informed that no action was required as a result of toxicological evaluations arising from the 46th JECFA Session as previous ADIs were maintained and no new ADIs were established for additives with current Codex uses.

21. Although JECFA had requested additional studies on the pharmacokinetics and metabolism of dodecyl, octyl and propyl gallates as a group, the Committee noted that the ADI for propyl gallate was maintained and therefore, no action was required. However, as the temporary ADIs for dodecyl and

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11 Conference Room Document 1.

octyl gallate were revised to "not allocated" ADIs, the Committee noted that unless ADIs were established in the future by JECFA, they should not be included in the General Standard for Food Additives. The report was appended (see Appendix II) for information.

CONSIDERATION OF REVISIONS TO THE CODEX ALIMENTARIUS PROCEDURAL MANUAL CONCERNING THE FORMAT OF STANDARDS AND RELATIONS BETWEEN CODEX COMMITTEES[12] (Agenda Item 6)

22. Following the request of the Codex Committee on General Principles[13] (CCGP) for clarification on the interaction between the CCFAC and commodity committees in the framework of the General Standard for Food Additives (GSFA), the Committee considered a number of proposals for inclusion in the Procedural Manual (Guidelines for Codex Committees). The 21st Session of the Commission had also confirmed that endorsement of additive provisions should continue according to current procedures pending completion of the GSFA. With regard to the format of standards, the Commission had reasserted that the additives section should be included as an integral part of Codex Standards until such time as the General Standard for Food Additives was finalized.[14]

23. The Committee agreed with the general recommendations proposed in the paper (para. 12), as follows:

- to support the introduction of Section K in the Procedural Manual concerning references to general provisions in Codex standards, and especially the GSFA;
- to continue its endorsement function on the basis of safety evaluation, technological justification and intake provided by JECFA and/or Codex committees; and,
- to continue with the development of the GSFA for the use of additives in all foods.

24. In order to integrate these objectives into current procedures and to clarify the endorsement process, the Committee agreed to propose the following amendments to the Guidelines for consideration by CCGP:

- a reference to the inclusion of additive provisions in the GSFA;
- transfer of the provisions on the setting of additive levels to the General Principles for the Use of Food Additives;
- presentation of additive provisions; and
- working procedures between the CCFAC and commodity committees, whether active or adjourned.

Status of the Amendments to the Procedural Manual (Guidelines for Codex Committees)

25. The Committee agreed to forward the amendments, as included in Appendix III, to the Committee on General Principles for consideration, with the understanding that governments would have the opportunity to comment in the framework of the CCGP.

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12 CX/FAC 96/3.

13 ALINORM 95/33, para 49.

14 ALINORM 95/37, para 58.

CONSIDERATION OF METHODS OF ANALYSIS FOR THE DETERMINATION OF FOOD ADDITIVES AND CONTAMINANTS IN FOODS[15] (Agenda Item 7)

26. The Delegation of Canada introduced a List of Methods of Analysis for the Determination of Food Additives and Contaminants in Foods, which it had revised and updated based on comments submitted in response to CL 1995/10-FAC. The Committee expressed its appreciation to Canada for its comprehensive work.

27. An informal working group (Canada, Finland, Netherlands, United States, AOAC) considered the document to prioritise substances for which methods were required to facilitate international trade.

28. The Committee agreed that methods for food additives and contaminants should be prioritized and selected according to the following criteria:

- full ADI established by JECFA;
- provisions for additives or contaminants established by Codex;
- proposed methods should have been validated;
- the use of the additive is causing or has the potential to cause problems in international trade, and;
- the additive is used in a major food or major food ingredient.

Status of Methods of Analysis for the Determination of Food Additives and Contaminants in Foods

29. The Committee agreed to forward the Methods of Analysis for the Determination of Food Additives and Contaminants in Foods (see Appendix IV) for endorsement by the Codex Committee on Methods of Analysis and Sampling, with the understanding that the methods will eventually be included in a future revision of Codex Alimentarius Volume 13 (Methods of Analysis and Sampling).

30. The Committee also agreed that governments would be invited by circular letter to provide additional methods for food additives or contaminants based on the above criteria on a continuing basis.

ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR FOOD ADDITIVES IN CODEX STANDARDS[16] (Agenda Item 8)

31. The Committee noted that no maximum levels for food additives had been submitted for endorsement since its 27th Session and therefore, no action was taken.

CODEX RISK ASSESSMENT AND MANAGEMENT PROCEDURES: EXPOSURE ASSESSMENT METHODS IN SUPPORT OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES[17] (Agenda Item 9)

32. Following the recommendations of the Commission on the integration of risk assessment procedures in the work of Codex Committees (see para. 10), and the decision of the last CCFAC session to address issues related to exposure assessment[18], the Committee considered the proposals of the Delegation of the United Kingdom on exposure estimation methods.

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15 CX/FAC 96/4 and comments from Thailand (CRD 11).

16 CX/FAC 96/5.

17 CX/FAC 96/6 and comments from Canada, France, Spain, United Kingdom and United States (CX/FAC 96/6-Add.1).

18 ALINORM 95/12A, paras. 30-35.

33. The Committee agreed that the 4-tiered approach proposed was acceptable in principle, although the limitations of the methodology was recognized. It was recognized that at the 4th tier it will be necessary to identify the major sources of uncertainty and assessments should be made on the most efficient way to include additional information. This may include national food intake data to estimate the exposure to additives where this may approach the ADI. In this regard, it was stressed that cooperation between JECFA and CCFAC was required.

34. The Committee agreed that the Delegation of the United Kingdom would provide exposure assessments in a timely manner in order to support the USA in developing the General Standard on Food Additives prior to the 29th CCFAC and should also continue developing the methodology for exposure assessment thereafter. It was agreed that comments, including comments related to body weight and regional diets, should be taken into account, and that JECFA should be consulted on future developments in this area.

CONSIDERATION OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES

35. The meeting of the Working Group on the Codex General Standard for Food Additives was chaired by Dr. A. Rulis (USA). Dr. D. Keefe (USA) acted as Vice Chairman and Mrs. B. Fabech (Denmark) acted as rapporteur.

36. After thanking the delegations involved for their outstanding efforts, the Committee considered the report of the Working Group[19] and agreed with the following recommendations.

CONSIDERATION OF COMPRESSED WORKSHEETS FOR ANTIOXIDANTS AND PRESERVATIVES[20] (Agenda Item 10a)

37. The Committee recalled that the compressed worksheets had been established to summarise data received from Member countries and that different levels of compression had been applied. The Committee agreed that these compressed schedules would be a useful tool, although it was recognized they were not intended to be the final standard.

CONSIDERATION OF STABILIZERS, THICKENERS AND SWEETENERS[21] (Agenda Item 10b)

38. The Committee agreed that the data collected on these classes of additives would be incorporated into the final Standard on the basis of the principles developed previously for antioxidants and preservatives. The Delegation of the United States agreed to perform this task.

CONSIDERATION OF GOVERNMENT COMMENTS TO ANNEX A[22] (Agenda Item 10c)

39. In view of the Committee's discussion concerning exposure assessment, the Committee decided that the United Kingdom should redraft Annex A in light of their paper for circulation, comment and further consideration by the next session.

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19 Conference Room Document 2.

20 CX/FAC 96/7.

21 CX/FAC 96/8 and comments from Spain (CX/FAC 96/8-Add.1); Brazil, Philippines, South Africa, Spain, United States, Uruguay, Zimbabwe, EACGI, EU, IFAC (CRD 4); and Mexico (CRD 11).

22 Comments from Denmark, Egypt, South Africa, Spain, United States, Uruguay and ICGMA (CX/FAC 96/9).

CONSIDERATION OF THE CODEX FOOD IDENTIFICATION SYSTEM[23] (Agenda Item 10d)

40. Several Delegations pointed out that the present system did not list foods which were widely consumed in some regions, such as Asia, and the Committee agreed that categorization should include all foods consumed world-wide. It was however recalled that a clear distinction should be made between food consumption and food categorization as the latter is only a technical description of foods for the purpose of establishing food additives provisions.

41. The Committee agreed that the Belgian Delegation, in cooperation with the CIAA, would draft explanatory notes on the use of the Food Identification System for inclusion into the GSFA Preamble. It was also agreed that a revision by the United States of the categorization system would take into account the comments received at the current meeting and future submissions in order to prepare the proposed draft Standard.

CONSIDERATION OF TECHNOLOGICAL JUSTIFICATION AND NEED FOR THE USE OF FOOD ADDITIVES (Agenda Item 10e)

42. The Committee confirmed its decision from its last session[24] that technological justification and need was one of the criteria to be taken into account in the elaboration of the standard. It was therefore agreed that the Delegations of New Zealand, Australia and Iceland would draft a paper providing a step-wise procedure for the evaluation of technological justification and need for the use of food additives, to be circulated prior to the next Session for eventual inclusion into the Preamble of the GSFA.

43. The Committee also noted that a clear distinction should be made between issues relating to exposure assessment and technological justification.

REPORT OF THE WORKING GROUP ON THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES[25] (Agenda Item 10 f)

Consideration of the carry-over principle

44. Following the request of the 21st Session of the Commission to reconsider those provisions in the Preamble relating to the carry-over of additives into foods, the Committee agreed to amend the current text of the carry-over principle by adding a new paragraph as follows:

> "An additive is permitted in a raw material or other ingredient if the raw material or ingredient is used exclusively in the preparation of a food which is in conformity with the provisions of the standard."

Procedure for the amendment of the GSFA

45. In order to facilitate future revisions to the Standard, the Committee agreed with the offer of the United States to establish draft procedures for amending the GSFA in the Preamble of the Standard. Situations requiring amendment would include the addition or deletion of additives, new use levels for an existing additive in a given food category, new food categories for a listed additive, and an updated or new JECFA ADI.

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23 CX/FAC 96/10 and comments from Canada, Denmark, France, Italy, Spain, Sweden, United Kingdom, Uruguay, CLITRAVI, ESPA, IDF (CX/FAC 96/10-Add.1); Australia (CRD 10) and Thailand (CRD 11).

24 ALINORM 95/12A, paras. 43-45.

25 Conference Room Document 2.

Food Additive Classes to Study Next

46. The Committee agreed that work should be initiated on colours, colour retention agents, bulking agents and emulsifiers on the same basis as previous requests. The Committee also reaffirmed that additives with an ADI "not specified" should be included in the standard on a class by class basis.

Future Work

47. The observer of the EC and other delegations suggested that the United States might consider all additives with an ADI "not specified" in a separate list in accordance with principles of good manufacturing practice as well as a negative list of foods where additives were not allowed. However, the Committee did not support this proposal.

48. The Committee accepted the offer of the US to apply the principles and tools already established to the data collected on antioxidants and preservatives, and if possible, stabilizers, thickeners and sweeteners and to prepare a proposed draft standard as soon as possible for circulation, comment and consideration by the Working Group next year. The Committee also requested that the US support the document with explanatory notes on the application of the principles and tools as well as information on the procedures used to develop the General Standard. The United States agreed to do so. The Committee reinstated the WG under the Chairmanship of the USA.

CONSIDERATION OF SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM 44TH JECFA MEETING BASED ON THE REPORT OF THE WORKING GROUP ON SPECIFICATIONS[26] (Agenda Item 11)

49. The Working Group on Specifications considered government comments submitted in response to CL 1995/41-FAC on Specifications for the Identity and Purity of Food Additives Arising from the 44th JECFA Meeting (FAO FNP 52-Addendum 3). The Chairman of the Working Group, Dr. P.M. Kuznesof (USA), presented the report. Mrs. Harriet Wallin (Finland) acted as rapporteur.

50. Notwithstanding a JECFA recommendation that potassium bromate was not appropriate for use as a flour treatment agent, the substance was retained on the list in view of its other minor food uses, e.g in the malting for beer.

51. The Committee agreed to refer the thirteen substances in Categories I and II (see Appendix V) to the Commission for adoption as Codex Advisory Specifications. The Committee reinstated the working group under the Chairmanship of the USA.

PROPOSED AMENDMENTS TO THE INTERNATIONAL NUMBERING SYSTEM[27] (Agenda Item 12)

52. The Chairman of the informal Working Group on the International Numbering System, Dr Simon Brooke-Taylor (Australia), presented a verbal report of the Group's discussions. Representatives of Australia, Denmark, Finland, Germany, Malaysia, Netherlands, New Zealand, Philippines, Thailand, United States, Biopolymar, IFAC, Marinalg, OFCA and SIAP attended the meeting.

53. The Committee agreed that proposals made by the Delegation of Brazil during the current meeting should be submitted in writing for consideration at the 29th CCFAC.

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26 Report of the Working Group on Specifications (CRD 3). The report of the Working Group also includes Categories III, IV and V for information.

27 Comments from Malaysia (CX/FAC 96/12).

54. The Committee agreed to assign INS 469 to Carboxy Methyl Cellulose, enzymatically hydrolysed and INS 907 to Hydrogenated Poly-1-Decenes for adoption by the Commission. The Committee also agreed that requests for amendments to the INS would be a standing agenda item.

PROPOSED AMENDMENTS TO THE REVISED INVENTORY OF PROCESSING AIDS[28] (Agenda Item 13)

55. The Committee considered the revised condensed version of the Inventory (ALINORM 95/12A, Appendix V) as presented by the Delegation of Germany at the 27th CCFAC. Comments on the revised version were requested under CL 1995/10-FAC.

56. The Committee decided to maintain the format of the Inventory of Processing Aids[29] as adopted by the Codex Alimentarius Commission in 1989. The Committee also agreed to solicit amendments to the Inventory on a standing basis for consideration under "Other Business" at future CCFAC meetings.

ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR CONTAMINANTS IN CODEX STANDARDS[30] (Agenda Item 14)

57. The Committee noted that no maximum levels for contaminants had been submitted for endorsement since its 27th Session and therefore, no action was taken.

CODEX RISK ASSESSMENT AND MANAGEMENT PROCEDURES: METHODS TO ENSURE PUBLIC SAFETY WHILE DEVELOPING THE CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD[31] (Agenda Item 15)

58. The Delegation of the United Kingdom gave a short introduction to the paper which presented a proposed methodology and recommendations for setting contaminant standards. The United Kingdom suggested that the proposed methodology should be further developed and incorporated into the General Standard for Contaminants and Toxins in Foods. It was also suggested that such work could be undertaken in cooperation with Denmark and the Netherlands prior to the 29th CCFAC.

59. The United States stressed that exposure and risk assessment was primarily a JECFA responsibility whereas risk management was under the responsibility of CCFAC. They further stated that the establishment of maximum levels for contaminants should only be justified in cases of significant risks to public health as related to exposure and only for known problems in international trade.

60. Several delegations and the representative of WHO supported the recommendation that the GEMS Food Programme should be further developed to provide a reliable source of data which could be used as a basis for establishing contaminant levels. The importance of taking account of regional variations in diets and body weight was also stressed.

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28 Comments from Spain and AMFEP (CX/FAC 96/13).

29 Codex Alimentarius Volume 1A, Section 5.8.

30 CX/FAC 96/14.

31 CX/FAC 96/15 and comments from Canada, Denmark, France, Netherlands, Spain, Uruguay (CX/FAC 96/15-Add.1) and Thailand (CRD 11).

61. The Committee thanked the Delegation of the United Kingdom for their outstanding work, and agreed that future work on exposure assessment should be carried out within the context of the Codex General Standard on Contaminants and Toxins in Food. The Committee also stressed the importance of clearly defining the respective responsibilities of JECFA and the CCFAC.

62. The Committee concluded that the Delegations of Denmark, the Netherlands and the United Kingdom would produce a paper to provide guidance on the further development of methodology and principles for exposure assessment for comments and consideration at the 29th CCFAC and in consultation with JECFA.

CONSIDERATION OF THE CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS

CONSIDERATION OF GOVERNMENT COMMENTS ON ANNEXES I, II AND III TO THE CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS (Agenda Item 16a)

63. The Committee thanked the Delegations of Denmark and the Netherlands for their work on the General Standard and noted that the Annexes were adopted at Step 5 by the 21st Session of the Commission[32]. The authors reflected on comments received at Step 6 in reply to CL 1995/37-FAC[33].

64. The Committee stressed that levels for contaminants should only be established for substances which present a significant risk to public health and a known or expected problem in international trade.

Status of the Draft Annexes I, II and III of the Codex General Standard for Contaminants and Toxins in Foods

65. After discussing the recommendations and comments made by several Delegations during the Session, the Committee agreed that the authors would revise Annexes I, II and III of the Draft General Standard for forwarding to the 22nd Session of the Commission for adoption at Step 8. The revised Annexes are attached to this report as Appendix VI.

CONSIDERATION OF ANNEXES IV AND V TO THE CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD[34] (Agenda Item 16b)

66. The Committee thanked the Delegations of Denmark and the Netherlands for their work on the revised Annexes IV and V of the General Standard. The authors presented a background and summary of the comments submitted.

Annex IV - Annotated List of Contaminants and Toxins

67. The Committee recognized the need to prioritize its work in developing the General Standard and decided to focus on arsenic, tin and patulin. The Committee accepted the offers of a number of delegations to prepare discussion papers on arsenic (Denmark), patulin (France, with data from the United Kingdom) and tin (Australia, Indonesia and Thailand) for circulation and comment prior to the 29th CCFAC.

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32 ALINORM 95/37, para. 55 and Appendix 4.

33 CX/FAC 96/16 (comments from Egypt, South Africa, Spain and Uruguay).

34 CX/FAC 96/17 and comments from Malawi (CX/FAC 96/17-Add.1) Canada, Poland, Spain, United Kingdom (CRD 6) Germany (CRD 8) and Thailand (CRD 11).

68. The Committee recognized the value of maintaining Annexes IV(A) and IV(B) as a source of general information, but noted that their integral incorporation in the General Standard was not necessary. The authors stated that they would aim at presenting an updated version of the Annexes as an information document to the 29th CCFAC and requested all interested parties to submit contributions for improvements to the text.

Annex V - Food Categorization System to be Used in the GSC

69. The Committee discussed Annex V (including sections A and B). It was agreed that wherever possible the food categorization system used for contaminants should be consistent with systems already developed for food additives and pesticides residues. The Committee also recognized that additional classes and product descriptions may be needed in the food categorization system to be used in the GSC.

Status of the Proposed Draft Annexes IV and V to the Codex General Standard for Contaminants and Toxins in Foods

70. After discussing the recommendations and comments made by several delegations during the Session, the Committee agreed that the authors would revise Annexes IV and V of the General Standard for forwarding to the 43rd Session of the Executive Committee for adoption at Step 5 and would continue to take responsibility for further action as necessary on this subject. The revised Annexes are attached to this report as Appendix VII.

MYCOTOXINS IN FOOD AND FEED

POSITION PAPER ON AFLATOXINS[35] (Agenda Item 17a)

71. The United Kingdom introduced the position paper which focused on the reduction of aflatoxin contamination in food and feed to the lowest reasonably achievable levels based on sound risk management principles. It also considered methods of analysis and sampling, practical aspects of contamination control, source directed measures and potential trade problems. The Committee noted that other specific studies on aflatoxins were being carried currently out by other bodies and that these may be taken into account in the future.

72. The Committee thanked the Delegation of the United Kingdom for its valuable work in clarifying complex issues, and had an exchange of views on exposure estimates and overestimates and the difficulties pertaining to harmonization, the relation between contamination of feedstuffs and milk, and the cost effectiveness of prevention measures as related to consumer protection.

73. The Committee also noted the activities of FAO and WHO on the prevention and control of mycotoxins contamination, especially through workshops and training programmes in developing countries.

74. The Committee was informed that JECFA was scheduled to assess the carcinogenetic potency and estimates of the risks presented by aflatoxins at its next meeting.

75. The Committee welcomed the offer of the UK to revise the paper and to incorporate the comments made at the current meeting in the context of the principles set out in the General Standard for Contaminants and Toxins in Foods.

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35 CX/FAC 96/18 and comments from Canada, Spain and Uruguay (CX/FAC 96/18-Add.1).

CONSIDERATION OF THE DRAFT MAXIMUM LEVEL FOR AFLATOXIN M_1 IN MILK[36] (Agenda Item 17b)

76. The 27th CCFAC agreed 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 the lack of consensus on the proposed level of 0.05 µg/kg.

77. Some countries were of the opinion that the proposed limit would be difficult to reach, was not required for the protection of consumers, and that methods of analysis and sampling were difficult to reproduce. Other countries supported the proposed level as necessary for consumer protection in view of existing trade in milk and milk products.

78. The Representative of WHO pointed out that it was the responsibility of the Committee to decide on the level of acceptable risk as part of its risk management tasks.

79. The Committee decided to maintain the draft maximum level at Step 7 pending the re-evaluation of aflatoxins by JECFA.

CONSIDERATION OF GOVERNMENT COMMENTS ON THE DRAFT CODEX GUIDELINE LEVELS AND SAMPLING PLANS FOR TOTAL AFLATOXINS IN PEANUTS[37] (Agenda Item 17c)

80. The draft guideline level and sampling plan for total aflatoxins in peanuts recommended by the CCCPL was adopted by the 21st Session of the Commission at Step 5. Comments were requested under CL 1995/37-FAC.

81. The countries supporting the proposal to advance the guideline level and sampling plan to Step 8 pointed out that the level was the lowest practical limit necessary to protect consumers, and that lower levels did not significantly increase consumer protection. It was noted that the level was for unprocessed products in international commerce.

82. Other delegations were of the opinion that a lower level was necessary for consumer protection.

83. The Committee deferred a decision on the sampling plan and guideline level of 15 µg/kg for total aflatoxins in peanuts intended for further processing because of a lack of consensus. The Committee decided to return the draft level and sampling plan to Step 6 (see Appendix VIII) for additional comment, particularly as related to the scientific basis for a lower limit.

CONSIDERATION OF THE CODE OF PRACTICE ON THE REDUCTION OF AFLATOXINS IN RAW MATERIALS AND SUPPLEMENTARY FEEDING STUFFS FOR MILK PRODUCING ANIMALS[38] (Agenda Item 17d)

84. The Delegation of Canada introduced the proposed draft Code, which it had revised at the request of the 27th CCFAC. The Committee expressed its appreciation to Canada for its work.

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36 ALINORM 95/12A, para. 106.

37 CL 1995/37-FAC and comments from the Netherlands, South Africa, Spain, Uruguay (CX/FAC 96/19), United States (CRD 5) and Senegal (CRD 11).

38 CX/FAC 96/20 and comments from Spain, Uruguay (CX/FAC 96/20-Add.1) and Denmark (CRD 9).

85. The Committee agreed to delete the specific feed to milk ratio in Section 1.3 as this may vary according to milk yield. The Committee also agreed to delete the reference to the "risks of sun drying in high humidity" in Section 2.2.3 in view of prevailing conditions in some countries.

86. The Committee had an exchange of views on the risks inherent in blending of contaminated feeds and decontamination and decided to delete Sections 2.5.3.3 and 2.5.3.4.

87. The Committee agreed to advance the proposed draft Code of Practice, as included in Appendix IX, to Step 5 for adoption by the Executive Committee. The need to clarify the legal position of advisory documents such as a code of practice was stressed by several delegations.

POSITION PAPER ON OCHRATOXIN A[39] (Agenda Item 17e)

88. The Delegation of Sweden introduced the position paper on Ochratoxin A, which followed up its earlier work on the subject at the request of the last session[40]. The paper reviewed toxicological evaluations and intake data as well as maximum limits currently applied and made specific recommendations, especially for establishing a maximum level for ochratoxins in cereals and the development of a code of practice to minimise exposure to Ochratoxin A. It was also noted that no barriers to trade had been reported.

89. The Committee expressed its appreciation to the Delegation of Sweden for its work. The Committee discussed issues related to methods of analysis and sampling, potential problems in trade and the possible development of a code of practice. It was noted that the carcinogenicity of Ochratoxin A had been evaluated twice by JECFA (37th and 44th meetings).

90. The Committee decided to request comments on the recommendations in the working paper, particularly in regard to economic problems in countries if a level of 5 µg/kg was established, as well as potential trade barriers and levels found in different commodities.

INDUSTRIAL AND ENVIRONMENTAL CONTAMINANTS IN FOOD

CONSIDERATION OF THE CODE OF PRACTICE ON SOURCE DIRECTED MEASURES TO REDUCE CONTAMINATION OF FOODSTUFFS (Agenda Item 18a)

91. The Committee was informed that the last session of the Codex Committee on Food Hygiene had completed the revision of the Recommended International Code of Practice - General Principles of Food Hygiene (ALINORM 97/13, Appendix II), advanced to Step 8 for adoption by the 22nd Session of the Commission.

92. As the Code included a section on Primary Production setting general provisions to avoid environmental and other contamination, the Committee agreed that the intended scope of a general Code of Practice on Source Directed Measures was covered by the GPFH and that no further action of CCFAC was required at this time.

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39 CX/FAC 96/21.

40 ALINORM 95/12A, paras. 114-116.

PROPOSED DRAFT MAXIMUM LEVELS FOR LEAD[41] (Agenda Item 18b)

93. The working paper and proposed draft levels for lead amended as requested by the 27th CCFAC were presented by the Delegation of Denmark. The paper included a summary of toxicological data and evaluations, potential health problems, intake and consideration of Codex and national maximum limits.

94. Discussions concerned the need to pay particular attention to infants and children, analytical methods, laboratory qualification, conversion factors between raw and processed products, the need for levels and/or revision of existing levels and the importance of dietary exposure in relation to total exposure. The importance of taking account of regional diets and body weights as well as the establishment of levels for specific commodities was also stressed.

95. The Committee agreed to circulate the revised proposed draft maximum levels for comment at Step 3, with the understanding that they will be included in Schedule 1 of the GSC. The levels are attached to this report as Appendix X.

CONSIDERATION OF GOVERNMENT COMMENTS ON DRAFT GUIDELINE LEVELS FOR CADMIUM AND LEAD IN CEREALS, PULSES AND LEGUMES[42] (Agenda Item 18c)

96. The Committee noted that the 20th Session of the Commission agreed with the decision of the 9th Session of the Codex Committee on Cereals, Pulses and Legumes (CCCPL) to request additional comments at Step 6 (CL 1994/35-CPL) on the draft guideline levels for cadmium (0.1 mg/kg) and lead (0.5 mg/kg) in cereals, pulses and legumes. As the 21st Session of the Commission adjourned the CCCPL *sine die*, the CCFAC was responsible for their further consideration.

97. As it was noted that the levels of lead and cadmium varied widely in different commodities, further consideration was required. The Committee decided to return the draft guideline levels for cadmium and lead in cereals, pulses and legumes to Step 6 (see Appendix VIII) for comment, and further information from JECFA.

DISCUSSION PAPER ON PCBS AND DIOXINS[43] (Agenda Item 18d)

98. The Netherlands briefly introduced the revised version of the working paper as requested by the 27th CCFAC[44]. The Committee thanked the Delegation of the Netherlands for its efforts.

99. The paper included information on indications of potential health problems, methods of analysis, risk assessment and management of dietary exposure and conclusions and recommendations.

100. In view of the Committee's decision not to proceed with the collection of information on dioxins and PCB's (see para. 101), it was agreed that an information paper may need to be prepared for consideration at a future meeting, in view of the expected forthcoming assessments from several national and international bodies.

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41 CX/FAC 96/23 and comments from France, Indonesia, Japan, OIV (CX/FAC 96/23-Add.1), Australia, Belgium, Canada, Japan, Poland, Romania, Spain, United Kingdom, Uruguay (CRD 7) Mexico and Thailand (CRD 11).

42 CL 1994/35-CPL and comments from Czech Republic, Poland (CX/FAC 96/24) and Thailand (CRD 11).

43 CX/FAC 96/25.

44 ALINORM 95/12A, paras. 132-137.

GOVERNMENT COMMENTS ON CADMIUM, PCBS, DIOXINS, POLYCYCLIC AROMATIC HYDROCARBONS AND HYDROGEN CYANIDE IN FOODS [45] (Agenda Item 18e)

101. In view of other priorities, the Committee decided to suspend the collection of information on PCB's, Dioxins, Polycyclic Aromatic Hydrocarbons and Hydrogen Cyanide. This decision was taken with the understanding that action could be taken by the Committee at a future meeting if new information became available on potential health or trade problems.

102. The Committee agreed to collect additional information on cadmium for consideration at its 29th Session.

PROPOSALS FOR THE PRIORITY EVALUATION ON FOOD ADDITIVES AND CONTAMINANTS BY JECFA[46] (Agenda Item 19)

103. The Committee had before it the report of the informal working group on priorities for JECFA. The Committee agreed to the priorities proposed by the working group as set out in Appendix XI.

104. The Committee noted that while there was a need for JECFA to review some substances with ADIs "not specified" or "not limited" in the context of the development of the GSFA, this task should not take priority over other proposals for JECFA work, and should be duly justified by CCFAC.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 20)

105. The Committee had no other business to discuss.

DATE AND PLACE OF NEXT SESSION (Agenda Item 21)

106. The Committee was informed that the 29th Session of the Codex Committee on Food Additives and Contaminants was tentatively scheduled to be held in The Hague from 17 - 21 March 1997.

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45 Comments from Norway and Spain (CX/FAC 96/26).

46 Conference Room Document 12.

ANNEX

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

CURRENT STATUS OF WORK

SUBJECT	STEP	FOR ACTION BY	DOCUMENT REFERENCE
Annexes I, II and III of the General Standard for Contaminants and Toxins in Foods	8	22nd CAC	ALINORM 97/12, Appendix VI
Codex Advisory Specifications	8	22nd CAC	ALINORM 97/12, Appendix V
Amendments to the International Numbering System	8	22nd CAC	ALINORM 97/12, para. 54
Annexes IV and V of the General Standard for Contaminants and Toxins in Foods	5	43rd EXEC Governments 29th CCFAC	ALINORM 97/12, Appendix VII
Code of Practice for the Reduction of Aflatoxin B1 in Raw Materials and Supplemental Feedingstuffs for Milk Producing Animals	5	43rd EXEC Governments 29th CCFAC	ALINORM 97/12, Appendix IX
Amendment to the Codex alimentarius Procedural Manual (Guidelines for Codex Committees)	——	12th CCGP Governments 22nd CAC	ALINORM 97/12, Appendix III
Methods of Analysis for the Determination of Food Additives and Contaminants in Foods	——	21st CCMAS Governments 22nd CAC	ALINORM 97/12, Appendix IV
Exposure Assessment Methods in Support of the General Standard for Food Additives	2/3	United Kingdom Governments 29th CCFAC	ALINORM 97/12, para. 34
Revised Annex A to the General Standard for Food Additives	2/3	United Kingdom Governments 29th CCFAC	ALINORM 97/12, para. 39
Explanatory Notes to the Codex Food Identification System	2/3	Belgium/CIAA 29th CCFAC	ALINORM 97/12, para. 41
Technological Justification and Need	2/3	AUL/ICE/NZE Governments 29th CCFAC	ALINORM 97/12, para. 42
Procedures for Amending the General Standard for Food Additives	2/3	United States Governments 29th CCFAC	ALINORM 97/12, para. 45

SUBJECT	STEP	FOR ACTION BY	DOCUMENT REFERENCE
Colours, Colour Retention Agents and Bulking Agents	2/3	USA/Secretariat Governments 29th CCFAC	ALINORM 97/12, para. 46
Amendments to the Inventory of Processing Aids	3	Governments 29th CCFAC	ALINORM 97/12, para. 56
Methodology and Principles for Exposure Assessment - General Standard for Contaminants and Toxins in Foods	2/3	DEN/NET/UK Governments 29th CCFAC	ALINORM 97/12, para. 62
Discussion Papers on Arsenic, Patulin and Tin	2/3	DEN/FRA/AUL Governments 29th CCFAC	ALINORM 97/12, para. 67
Position Paper on Aflatoxins	2/3	United Kingdom 29th CCFAC	ALINORM 97/12, para. 75
Maximum Level for Aflatoxin M1 in Milk	7	29th CCFAC	ALINORM 97/12, para. 79
Guideline Levels and Sampling Plans for Total Aflatoxins in Peanuts	6	Governments 29th CCFAC	ALINORM 97/12, para. 83
Position Paper on Ochratoxin A	3	Governments 29th CCFAC	ALINORM 97/12, para. 90
Maximum Levels for Lead	3	Governments 29th CCFAC	ALINORM 97/12, Appendix X
Guideline Levels for Cadmium and Lead in Cereals, Pulses and Legumes	6	Governments 29th CCFAC	ALINORM 97/12, Appendix VIII
Cadmium	----	Governments 29th CCFAC	ALINORM 97/12, para. 102
Food Additives and Contaminants Proposed for Priority Evaluation by JECFA	3	Governments 29th CCFAC	ALINORM 97/12, para. 103

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

Substance	Previous acceptable daily intake (ADI) 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				
Dodecyl gallate	0-0.05 (temporary)	No ADI allocated[a]	None	ADI not extended
Octyl gallate	0-0.1 (temporary)	No ADI allocated[a]	None	ADI not extended
Propyl gallate	0-1.4	0-1.4	Edible fats and oils	Previous ADI maintained
Emulsifier Glycerol ester of wood rosin	No ADI allocated	0-25	None	New ADI established
Sweetening agent Alitame	No ADI allocated	0-1[b]	None	New ADI established
Thickening agent Konjac flower	Not specified (temporary)	Not specified[C] (for food additive uses)	None	Previous ADI maintained
Miscellaneous substances				
Benzyl acetate Benzyl alcohol Benzaldehyde Benzoic acid and its salts	0-5 (group ADI)	0-5 (group ADI)	Margarine, minarine, table olives, pickled cucumbers, conc. Pineapple juice	Previous ADI maintained
Sucrose acetate isobutyrate	0-10 (temporary)	0-20	None	Previous ADI maintained
Contaminants				
Aflatoxins	Lowest level practically attainable	Evaluation not completed[d]	None	No action required

a) The temporary ADI was not extended because the additional studies on the pharmacokinetics and metabolism of dodecyl, octyl and propyl gallate requested at the forty-first meeting of the Committee (WHO Technical Report Series No. 837) were not available.

b) The results of an ongoing study of tolerance to repeated doses of alitame in diabetic subjects should be submitted for assessment when available.

c) Includes uses as a thickener, emulsifier, stabilizer, gelling agent, texturizing and glazing agent.

d) The evaluation could not be completed at the present meeting. The Committee recommended that assessment of the carcinogenic potency and estimates of the risks presented by aflatoxins be continued at the next meeting of the Expert Committee when food additives and contaminants are evaluated.

PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL (GUIDELINES FOR CODEX COMMITTEES)

Relations between Commodity Committees and General Committees
Food Additives

1) Sections (i) to (iii) (pages 114 - 115), and definition of Good Manufacturing Practice (pages 116 - 117), relating to the actual setting of additive levels, should be removed from the Manual and integrated into the General Principles for the Use of Food Additives. Sections (i) to (v) on pages 115 - 116 should be replaced by a short section giving only the principles of what the CCFAC is expected to accomplish.

2) (a) The paragraph after (iii) on page 115 should end as "additives provisions are subject to endorsement by the CCFAC and to incorporation into the GSFA".

(b) The last paragraph on page 114 should end "... should make a report ... on the basis of the General Principles for the Use of Food Additives. Provisions for food additives should indicate the INS Number, when it exists, the ADI, technological justification, proposed level, and whether the additives were previously endorsed (or temporarily endorsed). (Exact wording to be clarified)".

(c) In the section which is to replace pages 115 - 116 (or the introductory paragraphs on pages 113 - 114), there should be a paragraph clarifying the endorsement procedure, to this effect:

> "When an active commodity committee exists, proposals for the use of additives in any commodity standard under consideration should be prepared by the committee concerned, and forwarded to the CCFAC for endorsement. (Insert language similar to (ii) on page 115). When the CCFAC decides not to endorse specific additive provisions (use of the additive, or level in the end-product), the reason should be clearly stated. The section under consideration should be referred back to the Committee concerned if further information is needed, or for information if the CCFAC decides to amend the provision."
>
> "When no active commodity committee exists, proposals for new additive provisions or amendment of existing provisions, should be forwarded directly by member countries to the CCFAC".

PROPOSED METHODS OF ANALYSIS FOR THE DETERMINATION OF FOOD ADDITIVES AND CONTAMINANTS IN FOODS

(For Endorsement by the Codex Committee on Methods of Analysis and Sampling)

1. BHA, BHT, TBHQ, NDGA, propyl gallate in fats and oils; AOAC 983.15

2. cyclamates in foods; NMKL # 123, 1987

3. saccharin in beverages and sweets; NMKL # 122, 1987

4. benzoic acid and its salts
5. sorbic acid and its salts

} in foods; NMKL # 103, 1984; AOAC 983.16

6. nitrites in cured meats; AOAC 973.31

7. sulphites in foods; AOAC 990.28; AOAC 990.29 and AOAC 990.31

SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 44TH JECFA MEETING*

Category I (recommended to the Commission for adoption)

Carmines
Curcumin
Nitrogen
Phosphoric acid
Polydextrose
Potassium bromate
Potassium nitrate
Potassium nitrite
Sodium nitrate
Sodium nitrite

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

J-Cyclodextrin	- Change formula weight from 1135 to 1135.00
Mineral oil (High Viscosity)	- Change CAS number
Sodium thiocyanate	- Correct formula weight

* Specifications under Categories III, IV and V are included in the Report of the Working Group on Specifications (Conference Room Document 3).

ANNEXES I, II AND III TO THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS
(At Step 8)

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 animals and humans, including epidemiological data on humans 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. This problem, however, has to be addressed differently 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, possibly including information, if it is available, about contamination being present n parts only of the product, 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, e. g. by cleaning, 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 scientific evaluation of the probability of occurrence of known or potential adverse health effects resulting from human exposure to foodborne hazards. The process consists of the following steps: **hazard identification, hazard characterization, exposure assessment and risk characterization.** (The definition includes quantitative risk assessment, which emphasizes reliance on numerical expressions of risk , and also qualitative expressions of risk, as well as an indication of the attendant uncertainties.

The first steps are **hazard identification** and **hazard characterization. Hazard identification** is the identification of known or potential health effects in humans , produced by a contaminant which may be present in a particular food or group of foods. **Hazard characterization** is the qualitative and, if possible, quantitative evaluation of the nature of the adverse effects associated with the food contaminant, including a dose/response assessment and, when possible, the establishment of a safety standard (ADI, TDI or comparable toxicological recommendation) for the intake of the contaminant. The **exposure assessment** is the qualitative and, when possible, quantitative evaluation of the likely intake of the contaminant via food, as well as exposure from other sources if relevant. In the **risk characterization** step, the hazard identification, hazard characterization and exposure assessment are combined into an estimation of the severity and occurrence of known or potential health effects likely to occur in a given population, including attendant uncertainties.

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 is defined as the process of weighing policy alternatives in the light of the risk assessment and, if required, to select and implement appropriate control options, 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.**

Risk communication is the interactive exchange of information and opinions concerning risk among risk assessors, risk managers and other interested parties. 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 decisions may lead to maximum levels 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 that present both a significant risk to public health and a known or expected problem in international trade.

- MLs shall be set only for those foods that are significant for the total exposure of the consumer to the contaminant

- 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 than 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 a higher ML can be shown to be acceptable from a public health point of view and appreciable economic aspects are at stake.

- 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 shall apply to representative samples per lot. If necessary, appropriate methods of sampling shall be specified.

- 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. In general, MLs are set on primary products. 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 contaminant purposes, however, analysis and consequently MLs will preferably be on the basis of the edible part of the product.

  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 than 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, revised 1995) have been prepared for predicting the dietary intake, involving a two-tiered approach with increasingly realistic predictions of intake. In the crude estimate phase, hypothetical global and cultural diets are used to calculate the theoretical maximum daily intake (TMDI) (based on proposed or existing MRLs). The best estimate involves the national dietary pattern and corrections for residue losses during transport, storage, food preparation, 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 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. A harmonized approach using an appropriate intake estimation model that is as realistic as possible is recommended. 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 management 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, hazard identification and characterization. Criterion (5), technological and economic aspects, is an essential tool for making recommendations about the risk 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 the availability of information (- or + or ?) on the following criteria:

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

The question mark ? is 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				
	(2a)	(2b)	(3)	(4)	
Case	Tox	A/In	PHP	TP	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
- Step in Codex procedure (only in CCFAC working documents)
- References to documents, including references to source-directed measures or a code of practice, if appropriate
- References to standard criteria for methods of analysis and 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
- Step in Codex procedure (only in CCFAC working documents)
- References, remarks and notes (shorter than in Schedule I).

Reference to a Code of practice for the food, if appropriate

ANNEXES IV AND V TO THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS
(At Step 5)

ANNEX IV - ANNOTATED LIST OF CONTAMINANTS AND TOXINS

INTRODUCTION

In this Annex an annotated list is presented of the contaminants and toxins that are or have been dealt with in the CCFAC. It does not only encompass the contaminants and toxins for which Codex standards exist or are being developed, but also those for which further information is sought or about which a Codex decision has been taken.

The annotated list has the purpose of providing an overview of the situation regarding Codex decisions about this subject and to give guidance about further actions required. Therefore also relevant information and references are added to the list. The information shall comprise at least the current situation regarding the criteria that are important for the decision procedure of the CCFAC.

It is thus an active list, which needs to be regularly updated. In order to provide a structure for it and to facilitate the filing and retrieval of data, a number is assigned to the contaminants and toxins in the list.

The situation regarding contaminants and toxins is very complex and many substances are or have been the subject of scientific research and discussion regarding their occurrence in foods and their significance for human and animal health. On a national level, there are many activities, sometimes implying legal measures which may affect international trade in foods and feeds. It is obviously important for the CCFAC to take note of the developments in this field and to consider the necessity of actions. In order to obtain an overview of the situation, the CCFAC shall develop and maintain a working document in which more comprehensive information regarding contaminants and toxins in foods is presented in summary form. The document shall consist of an annotated comprehensive list of contaminants and toxins (Annex IV-A), and a collection of summarized textual information to the substances on the list, with references (Annex IV-B). Annex IV-A shall be structured according to a substance categorization system, by which code numbers can be assigned to the substances on the list, to allow logical and easy filing and presentation of data. This more comprehensive list shall be the basis for the code numbers which are used in Annex IV.

ANNEX IV

ANNOTATED LIST OF CONTAMINANTS AND TOXINS, SITUATION REGARDING CODEX CRITERIA AND DECISIONS

CODE NO.	CONTAMINANT NAME	- RISK ASSESSMENT STATUS	+ RISK MANAGEMENT STATUS	* CODEX DECISIONS (PENDING)
1.3	Arsenic	- PTWI mcg/kg BW (JECFA 19988) - Situation regarding organic arsenic in foods not clear - Potential health problems?	+ Existing national MLs for inorganic arsenic + Existing Codex MLs not comprehensive + Potential trade problems	* Position paper will be elaborated by Denmark for discussion in the 1997 CCFAC
1.6.	Cadmium	- PTWI 7 mcg/kg BW (41st JECFA) - Potential health problems - New JECFA evaluation requested	+ Existing national MLs + No Codex MLs + Potential trade problems	* Position paper discussed in 1995 CCFAC * New JECFA evaluation is awaited * Additional information on cadmium requested
1.9.	Copper	- PMADI 500 mcg/kg BW (JECFA 1973, 1982) - Daily requirement 50 mcg/kg BW - Health problems by too much copper unlikely	+ Existing national MLs + Existing Codex MLs (not comprehensive) + Potential trade problems	* Risk management aspect of MLs questioned * 26th CCFAC referred MLs in fats and oils to the CCFO * More general position report desirable

CODE NO.	CONTAMINANT NAME	- RISK ASSESSMENT STATUS	+ RISK MANAGEMENT STATUS	* CODEX DECISIONS (PENDING)
1.10.	Iron	- PMTDI 800 mcg/kg BW (JECFA 19983) - Daily requirement 10 - 20 mg (men/women) - Health problems by too much iron in food unlikely	+ Existing national MLs? + Existing Codex MLs (not comprehensive) + Potential trade problems?	* Risk management aspect of MLs questioned * 26th CCFAC referred MLs in fats and oils to CCFO * CCFAC decision desirable about other MLs (More general position report desirable)
1.11.	Lead	- PTWI 25 mcg/kg BW (JECFA 1993) - Potential health problems	+ Existing national MLs + Existing Codex MLs (not comprehensive) + Potential trade problems	* Proposed draft Standard with new Codex MLs (comprehensive) will be revised for 1997 CCFAC Further information required * Proposed draft Code of Practice on Source Directed Measures for lead to be further developed
1.13.	Mercury	- PTWI 5 mcg/kg BW (total Hg) - Potential health problems	+ Existing national MLs (not only for fish) + Existing Codex MLs for fish + Potential trade problems?	* Definition of Codex MLs to be reviewed * CCFAC decision desirable about risk management justification of MLs in other products than fish. Position paper desirable.

CODE NO.	CONTAMINANT NAME	- RISK ASSESSMENT STATUS	+ RISK MANAGEMENT STATUS	* CODEX DECISIONS (PENDING)
1.16.	Tin	- PTWI 14 mg/kg BW (inorganic Sn) - Potential health effects by high tin levels in canned products	+ Existing national MLs in canned products + Existing Codex MLs in canned products	* 1988 JECFA recommended efforts to keep levels of tin in canned foods as low as practicable (GMP). * CCFAC action desirable on GMP-levels in canned foods. Position paper will be developed for discussion in the 1997 CCFAC.
1.18.	Zinc	- PMTDI 1 mg/kg BW (JECFA 19973, 1982) - Daily requirement ca 15-22 mg/person - Potential health problems by too much Zinc in foods unlikely	+ Existing national MLs? + Existing Codex MLs in fruit juices and nectars + Potential trade problems?	* CCFAC decision desirable about risk management justification of MLs for Zn. Position paper desirable.
2.5.1.	Nitrate	- ADI of 5 mg/kg BW established for Sodium nitrate as food additive - Potential health problems due to ADI being exceeded? - Further studies are under way Nitrate remains on the JECFA priority list	+ Existing national MLs + No Codex MLs + (Potential) trade problems + The 1995 JECFA stated that it is inappropriate to compare exposure to nitrate directly to the ADI and hence to derive limits from it	* Further toxicological guidance is awaited before Codex MLs can be developed

CODE NO.	CONTAMINANT NAME	- RISK ASSESSMENT STATUS	+ RISK MANAGEMENT STATUS	* CODEX DECISIONS (PENDING)
3.4.	PCBs	- The JECFA did not establish an explicit toxicological recommendation on a safe intake level - Potential health problems - TEFs to be established for dioxin-like PCBs	+ Existing national MLs + No Codex MLs + Potential trade Problems	* Revised discussion paper on dioxins and PCBs discussed by 1996 CCFAC * Elaboration of Codex MLs awaits toxicological guidance
3.8.	Dioxins	- A 1992 WHO expert meeting established a TDI of 10 pg/kg BW for 2,3,7,8-TCDD - Further guidance is desirable on the use of TEFs to include other dioxins and PCBs. - Dioxins remain on priority list of JECFA - Potential health problems	+ Existing national MLs + No Codex MLs + Potential trade Problems	* Revised discussion paper on dioxins and PCBs discussed by 1996 CCFAC * Elaboration of Codex MLs awaits further toxicological guidance
4.3.	Polycyclic aromatic hydrocarbons (PAHs)	- PAHs are acknowledged carcinogens - PAHs remain on the JECFA priority list - Potential health problems?	+ Existing national MLs + No Codex MLs + Potential trade Problems?	* No further CCFAC action required until new information comes available which shows need for a decision

CODE NO.	CONTAMINANT NAME	- RISK ASSESSMENT STATUS	+ RISK MANAGEMENT STATUS	* CODEX DECISIONS (PENDING)
4.7.1.	Phthalate esters	- No specific JECFA tox. recommendation - The 1995 CCFAC removed phthalates from the priority list of JECFA - Potential health Problems?	+ National MLs? + Migration limits are established in relation to phthalate esters in food packaging materials + Potential trade problems?	* The 1995 CCFAC decided that at this stage no further action was needed.
4.12.1	Ethylcarbamate	- Ethylcarbamate is on the priority list of the JECFA; carcinogenicity studies that are under way are awaited. - Potential health problems?	+ Existing national MLs? + No Codex MLs + Potential trade problems	* The CCFAC awaits toxicological guidance
5.1.	Aflatoxins	- Aflatoxins are carcinogenic (JECFA 1987) - Risk assessment of aflatoxins is being reviewed by JECFA - (Potential) health problems	+ Existing national MLs + Codex MLs for peanuts and milk in procedure + Trade problems + Existing national MLs + Codex MLs for peanuts and milk in procedure	* Draft Code of Practice for reduction of aflatoxins in feedingstuffs for lactating animals to be revised (Canada) * Position paper on alfatoxins to be revised for 1997 CCFAC (UK) * The CCFAC awaits the JECFA evaluation of the risk of alfatoxins

CODE NO.	CONTAMINANT NAME	- RISK ASSESSMENT STATUS	+ RISK MANAGEMENT STATUS	* CODEX DECISIONS (PENDING)
5.2.	Ochratoxins	- PTWI 0.1 mcg/kg BW (44th JECFA) - Potential health problems	+ Existing national MLs + Potential trade problems	* Revised position paper to be developed for 1997 CCFAC (Sweden)
5.3	Trichothecenes	- No JECFA evaluation yet; trichothecenes are on JECFA priority list, but additional data are required - Potential health problems?	+ Existing national MLs? + No Codex MLs + Potential trade problems?	* Specific contributions desirable on toxicity and occurrence
5.4.	Patulin	- PMTDI 0.4 mcg/kg BW (1995 JECFA lowered the previous PTWI of 7 mcg/kg BW) - Potential health problems?	+ Existing national MLs in apple products + No Codex MLs + Potential trade problems?	* CCFAC evaluation will be developed for the 1997 CCFAC
7.3.	Cyanogenic glycosides (natural toxins)	- No safe intake level established by 1992 JECFA; 10 mg/kg level in food not associated with acute toxicity - (Potential) health problems!	+ National MLs? + Proposed draft Standards for Gari and edible cassava flour contain MLs for hydrogen cyanide. + Potential trade problems?	* The 1995 CCFAC requested clarification on the proposed ML for Gari (95-74) * Development suggested of guidelines for the processing of beans (95-75) * CCFAC awaits the outcome of the 1995 requests

CODE NO.	CONTAMINANT NAME	- RISK ASSESSMENT STATUS	+ RISK MANAGEMENT STATUS	* CODEX DECISIONS (PENDING)
8.	Radionuclides	- There is no safe threshold level for radionuclides; MLs are based on risk assessment calculations	+ Existing national MLs + Existing Codex GLs	* The 1991 CCFAC identified the need to review the GLs regularly. Also, the application to minor dietary components seemed unnecessarily restrictive. No action has yet been taken on these issues. A CCFAC decision desirable.
		- (Potential) health problems	+(Potential) trade problems	

ANNEX V

FOOD CATEGORIZATION SYSTEM TO BE USED IN THE GSC

INTRODUCTION

The food categorization system of the Codex General Standard for Contaminants and Toxins in Foods is constructed to perform the following functions:

It has a logical structure which enables a clear and systematic presentation of the (proposed) MLs. It contains (references to) product definitions and definitions of the part of the product which is analyzed and to which the ML refers. It contains codes for the food categories and the individual foods, so that data can be stored and retrieved in a convenient way.

To achieve as much harmonization as possible, an existing agreed categorization system is used.

The GSC uses the system which is developed in the framework of the CCPR as it is also suitable for contaminants. It is adopted for characterizing the various food and feed groups and the individual commodities. This system is especially elaborated regarding primary agricultural commodities, but needs further extension regarding processed products. Where necessary, new (sub)group codes or commodity codes are therefore introduced. These are described in Annex V-A. Annex V-A will also contain product descriptions as far as they are different from those contained in the existing system described by the CCPR.

Where appropriate and possible, the descriptive texts accompanying the food categories do or should also contain indications about the concentration or dilution factor in the processed commodities mentioned, in relation to the primary product(s) involved. In that way a first estimate can be made of the possible carry-over of contaminants from primary products to the various processed products. It has to be borne in mind however that the specific distribution of a contaminant in the primary product and the behavior during processing is a complicating factor here. Further advice may be necessary in those cases. See also the general indications in Annex I and possible specific information mentioned in relation to the contaminant.

Description of the food categorization system of the GSC

The first part contains the categorization system as developed and maintained by the CCPR. It consists of 5 classes, covering primary food commodities of plant, resp. animal origin, primary feed commodities and processed commodities of plant, resp. animal origin. The classes are subdivided in 19 types and 93 groups, which are identified by code numbers and letters.

[Reference is made to Vol. 2 of the Codex Alimentarius, section 2 (1993), in which this system is described, and to CX/PR 92/6 (in which a different kind of group numbering was introduced)].

Annex V-A is the other part of the food categorization system for the GSC. It is developed and maintained by the CCFAC, and is complementary to the system described in the first part. It is mainly directed to processed, derived and multi-ingredient foods and encompasses all those types and groups and commodity descriptions that are necessary to assign food categorization codes to existing or planned Codex MLs for contaminants.

ANNEX V-A

COMPLEMENTARY FOOD CATEGORIZATION SYSTEM FOR THE GSC

INTRODUCTION

The following additions to the food categorization system described in Annex V-A will serve the need of assigning a food code number to commodities that are not covered by Annex V-A. The commodities involved are mainly processed, derived and multi-ingredient foods.

The system has been designed as a comprehensive list (on a general level), in order to be able to accommodate possible future needs.

In this phase no individual product definitions and codes are given. It seems sufficient to go no further than a type or group level in judging the acceptability of the system. The classification can be developed in further detail as the need arises.

The system used in the GSFA for food classification has been utilized as far as it is compatible with the existing Codex classification system described in Annex V-A.

See the annexed list of proposed new food categories. Some explanations are added, and also some existing related food categories, for a better insight in the proposed system.

Commodity descriptions can often be derived from existing Codex Standards.

Information regarding concentration and dilution factors, in relation to contaminant carry-over from primary products, will be added where appropriate and available.

Definitions for the part of the product that shall be analyzed and to which the ML of a contaminant will apply, that are different from existing definitions in Annex V-A, may also be mentioned in this Annex.

CLASS	TYPE	GROUP	LETTER CODE	PRODUCT GROUP DESCRIPTION
D				**PROCESSED FOODS OF PLANT ORIGIN** (existing)
D	01			**Secondary commodities of plant origin** *(5 existing groups)*
D	01	06	TF	Treated fruit products (peeled, cut, frozen etc.) *(New proposed group; commodity codes can be derived from existing fruit codes)*
D	01	07	TV	Treated vegetable products (cleaned, cut, frozen etc.) *(New proposed group; commodity codes can be derived from existing vegetable codes)*
D	02			**Derived products of plant origin** *(7 existing groups)*
D	02	08	JV	Vegetable juices and purees *(New proposed group; commodity codes can be derived from the existing vegetable codes)*
D	02	09	SH	Sugars, syrups and honey *(New proposed group; commodity codes to be developed)*
D	03			**Manufactured foods of plant origin (multi-ingredient)** *(1 existing group)*
D	03	01	CP	Manufactured multi-ingredient cereal products (e.g. bread and other cooked cereal products) *(existing group)*
D	03	02	CB	Beverages derived from cereals (e.g. beer) *(New proposed group; commodity codes to be developed when the necessity arises)*
D	03	03	NF	Fruit nectars *(New proposed group; commodity codes can be derived from the existing fruit codes)*
D	03	04	FF	Fermented fruit beverages (wine, cider) (New proposed group; commodity codes can be derived from the existing fruit concerned)
D	03	05	DA	Distilled alcoholic beverages *(New proposed group; commodity codes to be developed when the need arises)*

CLASS	TYPE	GROUP	LETTER CODE	PRODUCT GROUP DESCRIPTION
D	03	06	FJ	Fruit jams, jellies, marmalades etc. *(New proposed group; commodity codes to be derived from the existing fruit codes)*
D	03	07	SF	Fruit chutneys and comparable preparations *(New proposed group; commodity codes to be derived from the existing fruit codes)*
D	03	08	SV	Vegetable chutneys and comparable preparations *(New proposed group; commodity codes to be derived from the existing vegetable codes)*
D	03	09	PS	Preparations from nuts, oil seeds and other seeds *(New proposed group; commodity codes to be derived from the existing product codes)*
D	03	10	PP	Other manufactured plant products *(New proposed group; commodity codes to be developed when the need arises)*
E				**PROCESSED FOODS OF ANIMAL ORIGIN** *(existing class)*
E	01			**Secondary commodities of animal origin** *(2 existing groups)*
E	01	03	MS	Secondary meat products (e.g. cooked meat) *(New proposed group; commodity codes to be derived from the existing meat codes)*
E	01	04	ES	Secondary egg products (e.g. egg powder) *(New proposed group; commodity codes to be derived from the existing egg codes)*
E	02			**Derived animal products of animal origin** (4 *existing groups)*
E	02	05	MC	Derived meet products (e.g. meet extract) *(New proposed group; commodity codes to be derived from existing meat codes)*
E	02	06	ED	Derived egg products (e.g. egg white, yolk) *(New proposed group; commodity codes to be derived from existing meat codes)*
E	03			**Manufactured food (single ingredient), animal origin** *(1 existing group)*

CLASS	TYPE	GROUP	LETTER CODE	PRODUCT GROUP DESCRIPTION
E	03	01	LI	Manufactured milk products (single ingredient) *(existing group)*
E	03	02	MT	Manufactured meat products (e.g. cured meat) *(New proposed group; commodity codes to be derived from existing meat codes)*
E	03	03	EM	Manufactured egg products (e.g. egg white powder) *(New proposed group; commodity codes to be derived from existing egg codes)*
E	04			**Manufactured food (multi-ingredient) of animal origin** *(1 existing group)*
E	04	01	LM	Manufactured milk products (multi-ingredient) *(existing group)*
E	04	02	MP	Manufactured meat products (multi-ingredient) (e.g. sausage) *(New proposed group; commodity codes to be developed in relation to commodity description)*
E	04	03	EP	Manufactured egg products (multi-ingredient) *(New proposed groups; commodity codes to be developed in relation to commodity description)*
F				**MULTI-INGREDIENT MANUFACTURED FOODS** *(New proposed class)*
F	01			**Beverages (multi-ingredient)** *(New proposed type)*
F	01	01	BS	Beverages (soft drinks end comparable preparations) *(New proposed group; commodity codes to be developed when the necessity arises)*
F	01	02	BA	Alcoholic multi-ingredient beverages *(New proposed group; commodity codes to be developed when the necessity arises)*
F	02			**Sauces, salad dressings, soups, bouillons etc.** *(New proposed type)*
F	02	01	SP	Seasonings and condiments *(New proposed group; commodity codes to be developed when the necessity arises)*

CLASS	TYPE	GROUP	LETTER CODE	PRODUCT GROUP DESCRIPTION
F	02	02	PV	Vinegars (multi-ingredient) *(New proposed group; commodity codes to be developed when the necessity arises)*
F	02	03	PM	Mustards *(New proposed group; commodity codes to be developed when the necessity arises)*
F	02	04	BS	Soups and broths *(New proposed group; commodity codes to be developed when the necessity arises)*
F	02	05	ME	Sauces and comparable products *(New proposed group; commodity codes to be developed when the necessity arises)*
F	02	06	BC	Salads and sandwich spreads *(New proposed group; commodity codes to be developed when the necessity arises)*
F	03			**Chocolate & other confectionery** *(New proposed type)*
F	03	01	CC	Chocolate products *(New proposed group; commodity codes to be developed when the necessity arises)*
F	03	02	CS	Sugar confectionery, including nut based and comparable multi-ingredient confectionery *(New proposed group; commodity codes to be developed when the necessity arises)*
F	03	03	CG	Chewing gum *(New proposed group; commodity codes to be developed when the necessity arises)*
F	04			**Margarines & other multi-ingredient fatty foods** *(New proposed type)*
F	04	01	FF	Margarines > 80 % fat *(New proposed group; commodity codes to be developed when the necessity arises)*
F	04	02	LF	Margarines < 80 % fat *(New proposed group; commodity codes to be developed when the necessity arises)*

CLASS	TYPE	GROUP	LETTER CODE	PRODUCT GROUP DESCRIPTION
F	04	03	OF	Other products based on fat emulsions *(New proposed group; commodity codes to be developed when the necessity arises)*
F	05			**Multi-ingredient bakery wares** *(New proposed type)*
F	05	01	BF	Fine bakery wares *(New proposed group; commodity codes to be developed when the necessity arises)*
F	05	02	BS	Savoury snacks (potato, cereal or starch base) *(New proposed group; commodity codes to be developed when the necessity arises)*
F	05	03	NS	Savoury coated nuts, other nut snacks, nut mixtures *(New proposed group; commodity codes to be developed when the necessity arises)*
F	06			**Multi-ingredient foods for special dietary uses** *(New proposed type)*
F	06	01	ID	Infant and follow-on formulae *(New proposed group; commodity codes to be developed when the necessity arises)*
F	06	02	CD	Weaning foods *(New proposed group; commodity codes to be developed when the necessity arises)*
F	06	03	HD	Dietetic foods intended for special medical purposes *(New proposed group; commodity codes to be developed when the necessity arises)*
F	06	04	TD	Dietetic formulae for slimming purposes and weight reduction *(New proposed group; commodity codes to be developed when the necessity arises)*
F	06	05	SD	Supplementary foods for dietetic uses (New *proposed group; commodity codes to be developed when the necessity arises)*
F	06	06	AD	Food supplements (New *proposed group; commodity codes to be developed when the necessity arises)*

CLASS	TYPE	GROUP	LETTER CODE	PRODUCT GROUP DESCRIPTION
G				**OTHER EDIBLE PRODUCTS** *(New proposed class)*
G	01			**Water, minerals and organic compounds** *(New proposed type)*
G	01	01	DW	Drinking water, mineral water, table waters *(New proposed group, commodity codes to be developed when the necessity arises)*
G	01	02	SW	Salt, salt substitutes, mineral preparations *(New proposed group; commodity codes to be developed when the necessity arises)*

DRAFT GUIDELINE LEVELS FOR CADMIUM AND LEAD IN CEREALS, PULSES AND LEGUMES
(At Step 6)

Cadmium	0.1 mg/kg
Lead	0.5 mg/kg

DRAFT GUIDELINE LEVEL AND SAMPLING PLANS FOR TOTAL AFLATOXINS IN PEANUTS
(At Step 6)

GUIDELINE LEVEL

Maximum of 15 µg/kg for total aflatoxins for peanuts intended for further processing, based on a sample size of 20 kg as referenced in the following material obtained from FAO Food and Nutrition Paper 55 (Rome, 1993), "Sampling Plans for Aflatoxin Analysis in Peanuts and Corn".

SAMPLE COLLECTION

Wherever possible, it is most appropriate (and convenient) to collect the sample when the selected lots are mobile. The estimation of the true mean aflatoxin content of a stack of sacks, for example, will be facilitated when representative samples are collected during the construction or dismantling of the stack. Similarly, sampling of large shipments of groundnuts can best be performed during the loading/unloading operation. In this situation, it is recommended that representative samples be collected from representative lots from, for example, ships holds, conveyer belts, dockside weighing towers, trucks or barges.

For unprocessed material, each sample should be composed of at least one hundred incremental samples, taken in a representative manner (using a systematic random sampling method), from locations throughout the lot.

Sample Preparation - A hammer mill with a #14 screen (3.1 mm diameter hole in the screen) similar to the type used by the U.S. Department of Agriculture to prepare samples for aflatoxin analysis is specified for peanuts. This choice represents a compromise in terms of cost and precision.

A minimal test portion size of 100 g for comminuted peanuts is recommended. If larger test portions or mills that produce a finer grind are used to prepare the sample, a lower sample preparation variance will result.

Analytical Methods - TLC analytical methods to quantify aflatoxin in the subsample extract are recommended. An extensive survey by Horwitz et al. (1993) suggested that TLC represents the most common type analytical method used by analytical laboratories.

The analytical variability, as measured by the coefficient of variation, ranges from about 9 to 82 percent. The variability associated with TLC methods reflects a compromise in the precision capabilities of the various analytical laboratories. If different analytical methods are used or more aliquots are analyzed per extract, the analytical variability can be reduced.

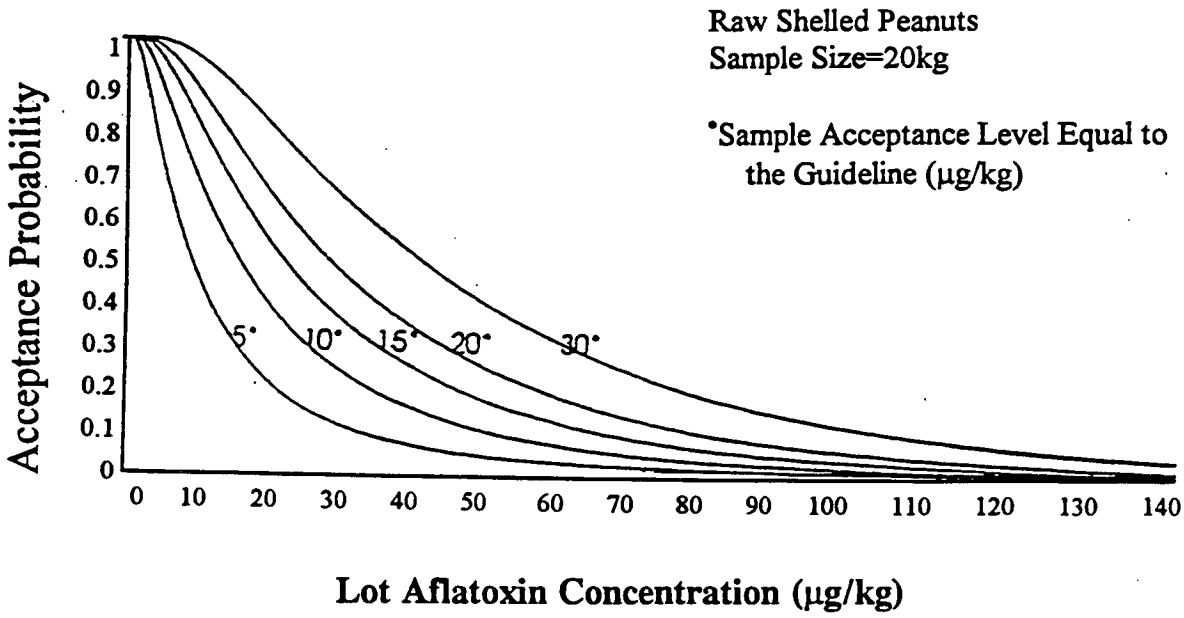

Figure 2.2 Five operating characteristic curves showing the probability of accepting raw shelled peanut lots when using 20 kg sample kernels, hammer mill for comminution, 100 g test portion, TLC analytical methods, and five sample acceptance levels.

Table I.1. Critical Factors for the Design of Aflatoxin Sampling Plans

Raw Shelled Peanuts Number Plans

Guidelines (µ/kg) - 5, 10, 15, 20, 3010
Sample Size (kg) - 5, 20 (kernels
Comminution - Hammer Mill (#14 screen)
Test Portion Size (g) - 100
Analytical Method - TLC

Inshell Peanuts

Guidelines (µ/kg) - 5, 10, 15, 20, 3010
Sample Size (kg) - 7, 27 (pods)
Comminution - Hammer Mill (#14 screen)
Test Portion Size (g) - 100
Analytical Method - TLC

PROPOSED DRAFT CODE OF PRACTICE FOR THE REDUCTION OF AFLATOXIN B_1 IN RAW MATERIALS AND SUPPLEMENTAL FEEDINGSTUFFS FOR MILK PRODUCING ANIMALS

(At Step 5)

1. BACKGROUND

1.1 Aflatoxin B_1 contamination of animal feedingstuffs can be a very serious problem, occurring in part due to inadequate storage conditions. Contamination may also occur at the preharvest stage and be exacerbated by inadequate storage conditions. Good cropping practices, use of seed varieties bred for resistance to seed-infecting fungi and insect pests as well as the use of appropriate approved pesticides represent reasonable preventive measures to control contamination in the field. Even with application of these practices, conditions created by the environment and/or traditional agricultural procedures may defeat any preventative measures.

1.2 Practices that reduce aflatoxin B_1 contamination in the field and after harvest should be an integral part of animal feedingstuff production, particularly for the export market because of the additional handling and transport steps required to get the product to the final destination. The factors most amenable for prevention of fungal infection and aflatoxin B_1 production involve proper drying and storage of the feedingstuff prior to transport. The problems created by too much moisture are magnified greatly by deficient post-harvest crop handling techniques.

1.3 Investigations concerning the biological fate of aflatoxin B_1 (AFB_1) in lactating dairy cattle have demonstrated the transmission of residues into milk, occurring as the metabolite aflatoxin M_1 (AFM_1). Although AFM_1 is considered to be less carcinogenic than AFB_1 by at least an order of magnitude, its presence in dairy products should be limited to the lowest level practicable. The amount of daily ingested AFB_1 which is transferred into milk is in the range of 0.17 to 3.3%.

1.4 CODEX has proposed a guideline level of 0.05 ug/kg (50 ppt) for AFM_1 in milk. To ensure that AFM_1 does not exceed this level in milk, attention should be given to residues of AFB_1 in the lactating dairy animal's daily feed ration.

1.5 To date there has been no widespread government acceptance of any decontamination treatment intended to reduce aflatoxin B_1 levels in contaminated animal feedingstuffs. Ammoniation appears to have the most practical application for the decontamination of agricultural commodities, and has received limited regional (state, country) authorization for its use with animal feed under specified conditions (i.e. commodity type, quantity, animal). Also, preliminary research suggests that the addition of the anticaking/binding agent "hydrated sodium calcium aluminosilicate" to aflatoxin contaminated feeds may reduce AFM_1 residues in milk, depending on the initial concentration of AFB_1 in the feed.

2. RECOMMENDED PRACTICES

2.1 Crop Production

2.1.1 Prepare seed bed for new crop by destroying or removing the seed heads or fruits (e.g. corn ears, peanuts, etc.) of aflatoxin susceptible crops.

2.1.2 Utilize soil tests if possible to determine fertilizer needs and apply fertilizer and soil conditioners to assure adequate soil pH and plant nutrition to avoid plant stress, especially during seed development.

2.1.3 When available use seed varieties bred for fungal resistance and field tested for resistance to Aspergillus flavus.

2.1.4 As far as practicable, sow and harvest crops at times which will avoid high temperature and drought stress during the period of seed development/maturation.

2.1.5 Minimize insect damage and fungal infection by the proper use of appropriate approved insecticides and fungicides and other appropriate practices within an integrated pest management program.

2.1.6 Use good agronomic practice, including measures which will reduce plant stress. Such measures may include: avoidance of overcrowding of plants by sowing at the recommended row and intra-plant spacings for the species/varieties grown, maintenance of a weed free environment in the growing crop by the use of appropriate approved herbicides and other suitable cultural practices, elimination of fungal vectors in the vicinity of the crop and crop rotation.

2.1.7 Minimize mechanical damage to crops during cultivation.

2.1.8 Irrigation is a valuable method of reducing plant stress in some growing situations. If irrigation is used ensure that it is applied evenly and individual plants have an adequate supply of water.

2.2 Harvest

2.2.1 Harvest crops at full maturity unless allowing the crop to continue to full maturity would subject it to extreme heat, rainfall or drought conditions.

2.2.2 As much as possible avoid mechanical damage during harvest.

2.2.3 Where applicable dry crops to a minimum moisture content as quickly as possible.

2.2.4 If crops are harvested at high moisture levels dry immediately after harvest.

2.2.5 Avoid piling or heaping wet freshly harvested commodities for more than a few hours prior to drying or threshing to lessen the risk of fungal growth.

2.2.6 Ensure adequate protection from rain during sun drying.

2.3 Storage

2.3.1 Practice good sanitation for storage structures, wagons, elevators and other containers to ensure that stored crops will not be contaminated. Proper storage conditions include dry, well ventilated structures that provide protection from rain or seepage of ground water.

2.3.2 For bagged commodities, ensure that bags are clean and dry and stack on pallets or incorporate a water impermeable layer between the sacks and the floor.

2.3.3 Ensure that crops to be stored are free of mould and insects and are dried to safe moisture levels (ideally crops should be dried to a moisture content in equilibrium with a relative humidity of 70 %).

2.3.4 Prevent insect infestation by the use of appropriate approved insecticides.

2.3.5 Ensure that the storage facilities are free of insects and mould by good housekeeping or the use of appropriate approved fumigants.

2.3.6 Prevent access by rodents and birds.

2.3.7 Store at as low a temperature as possible. Where possible aerate commodities stored in bulk through continuous circulation of air through the storage vessel to maintain proper temperature and moisture.

2.3.8 Use of a suitable authorized preservative e.g. an organic acid such as proprionic acid, may be beneficial in that such acids are effective in killing moulds and fungi and preventing the production of mycotoxins.

2.4 Transport

2.4.1 Make sure that transport containers and vehicles are free of mould, insects and any contaminated material by thoroughly cleaning before use or re-use. Periodic disinfestation with appropriate approved fumigants or other pesticides may be useful.

2.4.2 Protect shipments from moisture by appropriate means such as airtight containers, covering with tarpaulins, etc. Care must be taken in the use of tarpaulins to avoid sweating of the commodity that could lead to local moisture and heat build up which are prime conditions for fungal growth.

2.4.3 Avoid insect and rodent infestation during transport by the use of insect resistant containers or insect and rodent repellent chemical treatments.

2.5 Feed Production and Disposition of AFB_1 Contaminated Animal Feeds

2.5.1 Ensure that milling equipment is kept clean, free of dust and feed accumulation.

2.5.2 Use an appropriate sampling and testing program to monitor outbound and inbound shipments for the presence of AFB_1. Because AFB_1 concentration in shipments may be extremely heterogeneous refer to FAO recommendations for sampling plans. Adjust frequency of sampling and testing to take into account conditions conducive to aflatoxin B_1 formation, the regional source of the commodity and prior experience within the growing season.

2.5.3 If aflatoxin B_1 is detected, consider one or more of the following options. In all cases ensure that the aflatoxin B_1 level of the finished feed is appropriate for its intended use (i.e. maturity and species of animal being fed) and is consistent with national codes and guidelines or qualified veterinary advice.

2.5.3.1 Consider the restriction of AFB_1 contaminated feed to a percentage of the daily ration such that the daily amount of AFB_1 ingested would not result in significant residues of AFM_1 in milk.

2.5.3.2 If feed restriction is not practical, divert the use of highly contaminated feedingstuffs to non-lactating animals only.

PROPOSED DRAFT MAXIMUM LEVELS FOR LEAD
(At Step 3)

CODE NO.	FOOD	ML (MG/KG)	STEP	REMARKS
FC 1 FP 9 FS 12 FB 18 FT 26 FI 30 VA 35 VO 50 VC 45 VR 75	Fruit Vegetables except brassica (VB),leafy vegetables (VL), and mushrooms	0.1	3	
VB 40	Brassica except kale (480)	0.3	3	
VL 53	Leafy vegetables (except spinach)			
C 81	Cereal products, except bran	0.1		
VD 70	Pulses			
VP 60	Legume vegetables			
MM 97	Meat of cattle, sheep and pig	0.1	3	
PM 100	Poultry meat			
MF 97	Fats and oils: Fat from meat	0.1	3	86, milk fat
PM 111	Fat from poultry			
OC 172 OR 172	Vegetable oils			
MO 97	Edible offal of cattle, pig and poultry	0.5	3	
ML 107	Milk[1]	0.02*	3	Also secondary (82) milk products (as consumed)
WC 143	Crustaceans	2.0	3	
IM 151	Bivalve Molluscs			
JF 175	Fruit juices	0.1	3	Also nectars
FF 269	Wine	0.25	3	
LM (unspecified)	Infant formulae	0.02*	3	

* Provided appropriate methods of analysis are developed

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1 For dairy products an appropriate concentration factor applies, e.g. for cheese a factor of 10 as approximately 10 kg milk is used for 1 kg cheese.

FOOD ADDITIVES AND CONTAMINANTS PROPOSED FOR EVALUATION BY JECFA

FOOD ADDITIVES	PROPOSED BY
Alpha-acetolactate decarboxylase	Denmark
Enzyme-hydrolyzed carbozymethyl cellulose	Finland
Flavouring agents	USA/UK
Hydrogenated poly-1-decene	Finland
Maltogenic amylase	Denmark
Salatrim (short- and long-chain acid triacylglycerol molecules)	Mexico
Stevioside	Egypt

CONTAMINANTS	
Aflatoxins B, G and M	CCFAC
Cadmium	USA/Japan
Dioxins and dioxin-like PCBs	CCFAC
Ethyl carbamate	CCFAC
Nitrate	Netherlands
Polycylic aromatic hydrocarbons	Denmark/Netherlands
Trichothecenes	Netherlands