

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

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**ALINORM 99/12**

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

### **CODEX ALIMENTARIUS COMMISSION**

**Twenty-third Session**

**Rome, Italy, 28 June - 3 July 1999**

### **REPORT OF THE THIRTIETH SESSION OF THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS**

**The Hague, The Netherlands, 9-13 March 1998**

**NOTE:** This report includes Codex Circular Letter CL 1998/11-FAC.

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CX 4/30.2

CL 1998/11-FAC  
March 1998

**TO:** - Codex Contact Points  
- Interested International Organizations

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

**SUBJECT:** Distribution of the Report of the Thirtieth Session of the Codex Committee on Food Additives and Contaminants (ALINORM 99/12)

The report of the thirtieth Session of the Codex Committee on Food Additives and Contaminants is attached. It will be considered by the twenty-third Session of the Codex Alimentarius Commission in Rome from 28 June - 3 July 1999.

## MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION OR THE EXECUTIVE COMMITTEE

- 1. Draft Specifications for the Identity and Purity of Food Additives at Step 8; ALINORM 99/12, paras. 49-51 and Appendix VIII.**
- 2. Draft Maximum Level and Sampling Plans for Total Aflatoxins in Peanuts Intended for Further Processing at Step 8; ALINORM 99/12, paras. 64-72 and Appendix X.**
- 3. Draft Maximum Level for Aflatoxin M<sub>1</sub> in Milk at Step 8; ALINORM 99/12, paras. 73-75 and Appendix X.**
- 4. Amendments to the Codex International Numbering System for Food Additives at Step 5/8; ALINORM 99/12, paras. 52-54 and Appendix IX.**
- 5. Amendments to the Food Additive Provisions of the Codex Standard for Food Grade Salt; ALINORM 99/12, paras. 18-21 and appendix VII.**

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*, Tenth Edition, pages 24-25) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, **not later than 1 March 1999.**

- 6. Proposed Draft Tables for Colours, Colour Retention Agents, Bulking Agents and Emulsifiers at Step 5; ALINORM 99/12, paras. 36-39 and Appendix IV.**

- 7. Proposed Draft Tables for Acidity Regulators, Anticaking Agents, Antifoaming Agents, Firming Agents, Flavour Enhancers, Flour Treatment Agents, Foaming Agents, Glazing Agents, Humectants, Propellants and Raising Agents at Step 5; ALINORM 99/12, paras 40-41 and Appendix V.**

Governments wishing to submit comments regarding the implications which the proposed draft Guidelines or any provisions thereof may have for their economic interests 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*, Tenth Edition, pages 20-21) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy **not later than 15 May 1998**.

## REQUEST FOR COMMENTS AND INFORMATION

Governments and interested international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 1 October 1998** as follows: Mr. E.F.F. Hecker, Chairman, Codex Committee on Food Additives and Contaminants, Ministry of Agriculture, Nature Management and Fisheries, P.O. Box 20401, 2500 EK The Hague, The Netherlands (telefax No. 31.70.378.6141), with a copy to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy.

- 1. The Application of Risk Analysis for Food Additives and Contaminants; ALINORM 99/12, paras. 7-13.**

The Committee agreed to circulate recommendations arising from Joint FAO/WHO and other Consultations on risk analysis with a view to elaborating a discussion paper on the application of risk analysis for additives and contaminants for consideration by its next Session.

- 2. Proposed draft Amendments to the Codex International Numbering System for Food Additives; ALINORM 99/12, para. 55 and Appendix IX.**

The Committee agreed to circulate International Numbering System Numbers 938, 939 and 948 for Argon, Helium and Oxygen, respectively, at Step 3 of the *Accelerated Procedure* for comments, subject to confirmation by the Executive Committee.

- 3. Proposals for amendments to the Codex International Numbering System for Food Additives, including technological functions and functional classes/sub-classes; ALINORM 99/12, para. 56.**

The Committee agreed to request proposals for amendments to and on the updating of technological functions and functional classes/sub-classes in the Codex International Numbering System for Food Additives for consideration at its next meeting.

- 4. Codex Standard for Natural Mineral Waters: Health-Related Limits for Certain Substances (Section 3.2); ALINORM 99/12, paras. 57-60 and Appendix XV.**

The Committee appended Section 3.2 (Health-Related Limits for Certain Substances) of the Codex Standard for Natural Mineral Waters to its report for comment on this Section only.

- 5. Proposed draft maximum level for patulin in apple juice and the apple juice ingredient in ready made soft drinks; ALINORM 99/12, paras. 81-85 and Appendix XI.**

The Committee decided to circulate a proposed draft maximum level of 50µg/kg for patulin in apple juice and the apple juice ingredient in ready made soft drinks for comment at Step 3.

**6. Proposed draft Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals;** ALINORM 99/12, paras. 92-93 and Appendix XIV.

The Committee appended the proposed draft Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals to its report for circulation and comment at Step 3.

**7. Proposed draft maximum levels for tin;** ALINORM 99/12, paras. 105-107 and Appendix XI.

The Committee agreed to circulate proposed draft maximum levels for tin for comment at Step 3 and further consideration at its next meeting.

**8. Food Additives and Contaminants Proposed for Evaluation by JECFA;** ALINORM 99/12, paras. 108-110 and Appendix XIII.

The Committee agreed to request additional comments for additions or amendments to its Priority List, preferably well documented and in time, for consideration at the 31st CCFAC.

**9. Methods of analysis for the determination of food additives and contaminants in foods;** ALINORM 99/12, para. 111.

The Committee agreed to request comments for additional methods of analysis for the determination of food additives and contaminants in foods for consideration at its future session under Other Business.

**10. Inventory of Processing Aids;** ALINORM 99/12, para. 112.

The Committee agreed to continue inviting comments on the Inventory of Processing Aids for consideration at future sessions under Other Business.

**11. Packaging provisions for maintain the stability of iodised salt in the Codex Standard for Food Grade Salt;** ALINORM 99/12, para. 113 and Appendix XII.

The Committee agreed to append the proposal to amend the Codex Standard for Food Grade Salt to include provisions for maintaining the stability of iodised salt to its report for circulation and comment at Step 3.

## SUMMARY AND CONCLUSIONS

The Thirtieth Session of the Codex Committee on Food Additives and Contaminants reached the following conclusions:

### MATTERS FOR CONSIDERATION BY THE EXECUTIVE COMMITTEE AND/OR CODEX ALIMENTARIUS COMMISSION:

- Forwarded the draft maximum level of 15µg/kg and sampling plans for **total aflatoxins in peanuts intended for further processing** in square brackets to the Commission for adoption at Step 8 (paras. 64-72 and Appendix X);
- Forwarded the draft maximum level of 0.05µg/kg for **aflatoxin M<sub>1</sub> in milk** to the Commission for adoption at Step 8 (paras. 73-75 and Appendix X);
- Forwarded draft specifications for the identity and purity of food additives to the Commission for adoption as **Codex Advisory Specifications** (paras. 49-51 and Appendix VIII);
- Attached the table concerning the **status of the endorsement of the food additive provisions of the Codex Standard for Food Grade Salt** to its report for Commission adoption (paras. 18-21 and Appendix VII);
- Forwarded INS numbers 425 and 960 for **Konjac Flour** and **Stevioside**, respectively, to the Commission for adoption at Step 5, with a recommendation to omit Steps 6 and 7 (paras. 52-54 and Appendix IX);
- Advanced the proposed draft Schedules (Tables) for **Colours, Colour Retention Agents, Bulking Agents and Emulsifiers** to the Executive Committee for adoption at Step 5 (paras. 36-39 and Appendix IV);
- Advanced the proposed draft Schedules (Tables) for **Acidity Regulators, Anticaking Agents, Antifoaming Agents, Firming Agents, Flavour Enhancers, Flour Treatment Agents, Foaming Agents, Glazing Agents, Humectants, Propellants and Raising Agents** to the Executive Committee for adoption at Step 5 (paras. 40-41 and Appendix V);
- Agreed to circulate INS numbers 938, 939 and 948 for **Argon, Helium and Oxygen**, respectively, at Step 3 of the Accelerated Procedure for comments, subject to confirmation by the Executive Committee (para. 55 and Appendix IX);
- Agreed to append the proposal to amend the Codex Standard for Food Grade Salt to include **packaging provisions for maintaining the stability of iodised salt** to its report for circulation and comment at step 3 (para. 113 and Appendix XII), and;
- Forwarded comments concerning the draft **Code of Practice on Good Animal Feeding** for further consideration by the Executive Committee (paras 89-91).

### OTHER MATTERS OF INTEREST TO THE COMMISSION:

- Agreed to circulate recommendations arising from various Joint FAO/WHO and other Consultations concerning risk analysis for comments with a view to elaborating a **discussion paper on the application of risk analysis for additives and contaminants** (paras. 7-13);
- Attached the table concerning **Action Required as a Result of Changes in ADI Status or other Toxicological Recommendations** to its report for information (paras. 16-17 and Appendix VI);
- Agreed to several general matters, including the **proposed components** (Appendix II) of the **Codex General Standard for Food Additives** (paras. 26-28);
- Amended and agreed to request further comments on the draft Schedule (Table 3) of **Additives Permitted for Use in Food in General, Unless Otherwise Specified, in Accordance with GMP** and the list of **Food Categories or Individual Food Items Where the Use of Food Additives with GMP Limitations on Use are Not Allowed or Restricted** (Annex to Table 3) (paras. 29- 33);

- Agreed to return the draft Schedules (Tables) for **Antioxidants, Preservatives, Stabilizers, Thickeners and Sweeteners** to Step 6 for consolidation, additional comment and further consideration at its next meeting (paras. 34-35 and Appendix III);
- Accepted the offer of Denmark to prepare a discussion paper on the further consideration of the **use of colours in food** for consideration at its next meeting (para. 38);
- Agreed to return the proposed draft **Revised Annex A** to Step 2 for redrafting by Denmark and further consideration at its next meeting (paras. 42-44);
- Agreed to criteria for resolving concerns regarding the **technological justification and need for the use of food additives** (paras. 45-48);
- Agreed to request proposals for amendments to and on the updating of the **technological functions and functional classes/sub-classes** in the Codex International Numbering System for Food Additives for consideration at its next meeting (para. 56);
- Appended Section 3.2 (Health-Related Limits for Certain Substances) of the **Codex Standard for Natural Mineral Waters** to its report for comment (paras. 57-60 and Appendix XV);
- Decided to further develop the document concerning **Methodology and Principles for Exposure Assessment** in the Codex General Standard for Contaminants and Toxins in Food for circulation and comment prior to its next Session (paras. 61-63);
- Accepted the offer of Sweden to prepare an updated version of its position paper on **ochratoxin A** for circulation, comment and consideration at its next meeting (paras. 76-80);
- Decided to circulate a proposed draft a maximum level of 50µg/kg for **patulin in apple juice and the apple juice ingredient in ready made soft drinks** for comment at Step 3 and accepted the offer of France to produce an updated version of its position paper on **patulin** for further discussion at its next meeting (paras 81-85 and Appendix XI);
- Decided to circulate the current position paper on **Zearalenone** (CX/FAC 98/18) for comment and consideration at its next meeting (paras. 86-88);
- Appended the proposed draft **Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals** to its report for circulation and comment at Step 3 (paras. 92-93 and Appendix XIV);
- Agreed that Denmark would review the draft maximum levels for **lead** for circulation, comment and consideration at the next meeting (paras 94-97);
- Accepted the offer of Denmark to revise its discussion paper on **cadmium** for circulation, comment and consideration at the next meeting (paras 98-100);
- Requested Denmark to revise the position paper on **arsenic** for circulation, comment and consideration at its next meeting (paras. 101-104);
- Agreed to circulate proposed draft maximum levels for **tin** for comment at Step 3 and further consideration at its next meeting (paras. 105-107 and Appendix XI);
- Agreed on the list of **food additives and contaminants proposed for evaluation by JECFA**, and agreed to request additional comments for amendments or additions to the list for consideration by the next CCFAC (paras 108-110 and Appendix XIII);
- Agreed to request comments for additional **methods of analysis for the determination of food additives and contaminants in foods** for consideration at its future sessions under Other Business (para. 111);
- Agreed to continue inviting comments on the **Inventory of Processing Aids** for consideration at future sessions under Other Business (para. 112);
- Accepted the proposal to form an **ad hoc Working Group for Contaminants** with specific goals and terms of reference (paras. 114-116), and;

- Agreed to the offer of the Netherlands to prepare a discussion paper on **dioxins** for circulation, comment and consideration at its next meeting (para. 117).

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## **OPENING OF THE SESSION (Agenda Item 1)**

1. The 30<sup>th</sup> session of the Codex Committee on Food Additives and Contaminants (CCFAC) was held in The Hague, The Netherlands from 9-13 March 1998 at the kind invitation of the Government of the Netherlands. Mr. Edwin Hecker, Netherlands Ministry of Agriculture, Nature Management and Fisheries, chaired the meeting. The meeting was attended by 304 participants representing 54 Members of the Commission and 41 international organisations.

2. Mr. Kalden, keynote speaker and Director-General of the Netherlands Ministry of Agriculture, Nature Management and Fisheries, reflected on the interesting challenges ahead for the future and emphasised the importance of the integration of risk analysis principles into the work of Codex Committees and the changing nature of the discussion on food safety now involving both scientific and consumer concerns. Mr. Kalden also acknowledged the great importance of risk communication as an issue to be addressed by the CCFAC.

## **ADOPTION OF THE AGENDA (Agenda Item 2)<sup>1</sup>**

3. The Committee adopted the Provisional Agenda as proposed. The Committee agreed to hold an informal working group to discuss proposals for the priority evaluation of food additives and contaminants by JECFA (agenda item 14) under the chairmanship of Mr. Dornseiffen, The Netherlands.

4. The Committee heard a memorial tribute from the US delegation in remembrance of the recent death (November 1997) of Dr. Otho D. Easterday, a 25-year member and observer on the US delegation to the CCFAC. A moment of silence was observed by the Committee in honour of Dr. Easterday.

## **APPOINTMENT OF THE RAPPORTEUR (Agenda Item 3)**

5. The Committee agreed with the suggestion of the Chairperson to appoint Dr. Simon Brooke-Taylor (Australia) as rapporteur to the 30th session of the CCFAC.

## **MATTERS REFERRED FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 4a)<sup>2</sup>**

6. The Committee noted that the Codex Committee on Processed Fruits and Vegetables would consider the revision of standards under its responsibility at its 19th session (Washington, D.C., 16-20 March 1998). In reply to a comment concerning inconsistencies between current additive levels in several proposed draft standards and the provisions of the General Standard, the Secretariat recalled that in accordance with the Codex Alimentarius Procedural Manual, all additive provisions in commodity standards should be forwarded to the CCFAC for endorsement, preferably after advancement to Step 5.

## **REPORT ON ACTIVITIES RELATING TO RISK ANALYSIS IN CODEX AND OTHER BODIES (Agenda Item 4b)**

7. The Committee noted the recommendations of the Commission resulting from the Joint FAO/WHO Expert Consultation on the Application of Risk Management to Food Safety Matters,<sup>3</sup> as included in documents CX/FAC 98/2 and Addendum 1, and agreed that they should be taken into account as guidance for the orientation of its future work.

8. The WHO Representative informed the Committee of the outcome of the Joint FAO/WHO Consultation on Food Consumption and Exposure Assessment of Chemicals (Geneva, Switzerland; 10-14 February 1997), and indicated that an Executive Summary was available which presented the main conclusions and recommendations. In particular, the Consultation recommended that the principles of exposure assessment across all food chemicals in Codex should be harmonized.

9. In regard to the Joint FAO/WHO Expert Consultation on the Application of Risk Communication to Food Standards and Safety Matters (Rome, Italy; 2-6 February 1998), the WHO Representative informed the Committee that the Consultation was convened to:

- identify the elements of and recommend guiding principles for effective risk communication;

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<sup>1</sup> CX/FAC 98/1.

<sup>2</sup> CX/FAC 98/2 and CX/FAC 98/2-Add. 1.

<sup>3</sup> Rome, Italy; 27-31 January 1997 (FAO Food and Nutrition Paper 65).

- examine barriers to effective risk communication and to recommend means by which they can be overcome;
- identify strategies for effective risk communication within the risk analysis framework, and;
- to provide practical recommendations to FAO, WHO, Member Governments, the Codex Alimentarius Commission and other interested parties to improve their communication on matters related to the risk assessment and management of food borne hazards.

10. The WHO Representative drew attention to a recent WHO document issued under the auspices of the Global Environment Monitoring System/Food Contamination Monitoring and Assessment Programme (GEMS/Food) entitled “Guidelines for Predicting Dietary Intake of Pesticide Residues” which was published with the support of the Government of The Netherlands. The Guidelines provided internationally accepted methodologies for assessing exposure to pesticide residues that might result from the adoption of maximum residue limits. In addition, the WHO Representative drew attention to a newly available brochure, “Working Together for Safe Food - GEMS/Food” which described the purpose and activities of the GEMS/Food Programme.

11. The Delegation of India expressed the view that assistance provided by FAO and WHO in the area of risk analysis should be extended to cover risk communication. The WHO Representative informed the Committee that WHO, in collaboration with the Dutch Government, was undertaking a series of training courses in developing countries on the risk assessment of chemicals. While these training courses broadly addressed the safety of all chemicals, WHO was also in the process of developing a training course specifically for food borne hazards, including risk assessment, management and communication components. All developing countries that might be interested in participating in such a training course were invited to contact the WHO Programme on Food Safety and Food Aid.

12. The Committee agreed that, in order to implement the recommendations of the Commission and integrate risk analysis principles into its work, consideration should be given to specific recommendations relating to additives and contaminants. In this respect, the Committee was informed that a Workshop had been organized by the European Training and Assessment Foundation (ETAF) on behalf of the Netherlands: “Towards Internationally Acceptable Standards for Food Additives and Contaminants based on the Use of Risk Analysis” (Ede, The Netherlands; November 1997). It had considered the relationship between the CCFAC and JECFA and emphasized the importance of an interactive process for policy development as well as the risk assessment and risk management of individual additives and contaminants. The Committee agreed that the following recommendations of the Workshop should be further considered in order to provide guidance for its work:

- The CCFAC, together with JECFA, should further document the risk assessment policy for both additives and contaminants;
- As part of its overall risk analysis function, the CCFAC should clarify and document its criteria for selecting additives and contaminants for referral to JECFA for risk assessment;
- The CCFAC should clearly identify the factors considered in its decision-making process, particularly with respect to the selection of risk management options. In addition, there was a need to clarify the role of JECFA in this process;
- The CCFAC should provide guidance to JECFA on the purpose and scope of each risk assessment;
- In generating its output (risk characterisation) from the risk assessment process that is to be used in standard setting, JECFA should consider developing methods for integrating hazard characterisation and exposure assessment, and;
- Both the CCFAC and JECFA should seek timely advice from each other on matters of concern.

13. The Committee agreed to circulate these recommendations for comments with a view to elaborating a discussion paper on the application of risk analysis for additives and contaminants. The paper would also take into account the recommendations of the above mentioned Joint FAO/WHO Expert Consultations. The Committee agreed that a drafting group led by the United States, and including Australia, the Netherlands, Sweden, Thailand and the United Kingdom, should prepare the paper for consideration by the next session.

**SUMMARY REPORT OF THE FORTY-NINTH MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES** (Agenda item 5a)

14. The 49<sup>th</sup> Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated a large number of food additives, including approximately 220 flavouring agents and aflatoxins B, G, and M. The summary report was distributed soon after the JECFA meeting in June 1997.

15. A large number of flavouring agents were evaluated using the Procedure for the Safety Evaluation of Flavouring Agents that had been developed by the Committee; except for those that could not be evaluated until other chemically related substances were evaluated, no safety concerns were identified. Potency values (with uncertainty ranges) of aflatoxin B<sub>1</sub> were estimated for individuals who carry the hepatitis B virus and for those who do not. Potential population risks using hypothetical standards were estimated for illustrative purposes. Specifications of identity and purity were prepared for 40 food additives and 173 flavouring agents. The JECFA Secretariat also highlighted the risk assessment policy decisions made at the forty-ninth meeting of the Committee.

**ACTION REQUIRED AS A RESULT OF CHANGES IN ADI STATUS AND OTHER TOXICOLOGICAL RECOMMENDATIONS** (Agenda Item 5b)<sup>4</sup>

16. The Committee was informed that no action was required as a result of toxicological evaluations arising from the 49<sup>th</sup> JECFA Session.

17. The Committee agreed to amend the table by referring to the earlier recommendations of the 31<sup>st</sup> JECFA related to the evaluation of aflatoxins. The table concerning Action Required as a Result of Changes in ADI Status or other Toxicological Recommendations is attached to this report as Appendix VI for information.

**ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR FOOD ADDITIVES IN CODEX STANDARDS** (Agenda Item 6)<sup>5</sup>

18. The Committee noted that in accordance with the Codex Alimentarius Procedural Manual, all provisions in respect of food additives should be forwarded to the CCFAC for endorsement. The 22<sup>nd</sup> Session of the Codex Alimentarius Commission adopted the proposed draft revised Standard for Food Grade Salt, including the food additive provisions summarized in document CX/FAC 98/4, as a final Codex text (ALINORM 97/37, paras. 52-54). The Commission had nonetheless requested that these provisions be forwarded to the CCFAC for consideration.

19. The delegation of India observed that emulsifiers and processing aids were not technologically necessary for food grade salt intended for the final consumer, but may be necessary for industrial uses of food grade salt.

20. The Codex Secretariat clarified that the maximum level of 20 mg/kg under the functional class of anticaking agents should only apply to Tricalcium Orthophosphate, and that food additives under INS numbers 170 (i), 504 (i), 530, 551, 552, 553 (i), 554, 556 with non-specified ADIs could be used according to GMP. As the aluminium and magnesium Salts of Myristic, Palmitic or Stearic Acids had a status of no ADI allocated, the Committee agreed to recommend the removal of these specific provisions from the Standard. The remaining food additive provisions were endorsed as proposed.

21. The status of the endorsement of the food additive provisions of the Codex Standard for Food Grade Salt are contained in Appendix VII to this report.

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<sup>4</sup> CX/FAC 98/3.

<sup>5</sup> CX/FAC 98/4.

## CONSIDERATION OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES

### REPORT OF THE WORKING GROUP ON THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES (Agenda Item 7a)<sup>6</sup>

22. The meeting of the *ad hoc* Working Group on the Codex General Standard for Food Additives was chaired by Dr. Rulis (USA) and co-chaired by Dr. Keefe (USA). Bente Fabech (Denmark) acted as rapporteur. The Chairperson of the Working Group gave a comprehensive introduction of the Working Group report and thanked all delegations for their constructive input.

23. The Codex Secretariat informed the Committee that the World Trade Organization Agreement on Sanitary and Phytosanitary Measures (SPS) states:

- that Members should harmonise sanitary and phytosanitary measures on as wide a basis as possible. Members shall base these measures on international standards, guidelines and recommendations (i.e. Codex) (Article 3.1), and;
- that Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification (article 3.3).

24. The SPS Agreement recognizes, for food safety, the standards, guidelines and recommendations established by Codex relating to food additives, etc. The definition makes no distinction between standards, guidelines and recommendations, nor does it provide definitions for these terms (Annex A).

25. In relation to the GSFA, it was noted that Codex standards, guidelines or recommendations are not mandatory, that members have the option to deviate from them, and therefore, Codex work should not be constrained by such issues.

26. The Committee agreed on the proposed components of the General Standard for Food Additives. The components are attached to this report at Appendix II.

27. The Committee reaffirmed that the food category system was flexible and that Codex Members and international organizations had the opportunity to comment on any aspect of the GSFA at any time for further discussion by the CCFAC.

28. **Other Matters**

- The Committee agreed to forward Canthaxanthin, Annatto, Iron Oxides and Erythrosine for evaluation of national intake data for the 53<sup>rd</sup> JECFA in 1999 (see para. 109).
- The Committee reaffirmed the decision of the 29th CCFAC to remove the food category "Foods in General, Unless Otherwise Specified (0.0)" for additives with a numerical ADI from Tables 1 and 2 (previously referred to as Schedules 1 and 2). As this resulted in some information on additive use being omitted from the Tables, the Committee agreed that comments should be requested on specific use levels for additives contained in all the Tables under its consideration. The Committee also noted that if in exceptional situations it appeared that the use of an individual additive might exceed the ADI, such cases should be referred to JECFA for evaluation of intake data. As more information would become available, any specific cases could be discussed at the Committee's next meeting.
- The Committee further agreed that all Tables 1 and 2 under its consideration would be condensed and simplified, where appropriate, to have one entry for each food category, for each food additive with multiple functions and for additives with group ADIs. When simplifying Tables 1 and 2, numerical use levels would be retained in preference to GMP levels for additives with numerical ADIs. Where there were no numerical levels, comments would be requested on provisions with GMP levels with a view towards establishing numerical levels.

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<sup>6</sup> Conference Room Document 1.

- The Committee decided to convene the *ad hoc* Working Group prior to its next session under the chairmanship of the USA.

**ANNEX OF FOOD CATEGORIES OR INDIVIDUAL FOOD ITEMS WHERE THE USE OF FOOD ADDITIVES WITH GOOD MANUFACTURING PRACTICE LIMITATIONS ON USE ARE NOT ALLOWED OR RESTRICTED (Agenda Item 7b)<sup>7</sup>**

29. The 22nd Session of the Commission adopted the above Annex at Step 8 on an interim basis, and requested the CCFAC to review the Annex at its current meeting in light of comments received and report its findings to the next Session of the Commission (ALINORM 97/37, para. 59).

30. The Codex Secretariat had already amended Appendix IV (i.e., Table 3) to reflect correct INS numbers and food additive names for publication in a revised version of Codex Alimentarius Volume 1A. The Committee recommended the deletion of the following food additives from Appendix IV (Table 3) as these had not been evaluated by JECFA:

- INS 368: Ammonium Fumarate
- INS 349: Ammonium Malate, DL-
- INS 517: Ammonium Sulphate
- INS 505: Iron (Ferrous) Carbonate
- INS 518: Magnesium Sulphate
- INS 560: Potassium Silicate
- INS 550(i): Sodium Silicate
- INS 514: Sodium Sulphate

31. The Committee recommended the replacement of the following food additive listing in Appendix IV (Table 3):

- INS 470: Salts of Fatty Acids (Ammonium, Calcium, Potassium, Sodium) by two entries:
- INS 470: Salts of Myristic, Palmitic and Stearic Acids (Ammonium, Calcium, Potassium, Sodium)
- INS 470: Salts of Oleic Acid (Calcium, Potassium, Sodium)

The Committee recommended that the following food additives be moved from the proposed draft Worksheets for Miscellaneous Additives (CX/FAC 98/8) to Appendix IV (Table 3) as these additives had an ADI of not specified:

- INS 576: Sodium Gluconate
- INS 577: Potassium Gluconate
- INS 578: Calcium Gluconate
- INS 580: Magnesium Gluconate

32. Several delegations proposed to amend the Annex to Appendix IV (Table 3), including its title, in order to reduce the potential for misinterpretation of its contents.

33. Several delegations asked for clarification on the relationship between the Appendix and existing Codex Commodity Standards. It was reaffirmed that food additive provisions in Codex Commodity Standards take precedence over entries in the GSFA but should be consistent with the principles of the GSFA, and that the GSFA was intended to address all foods whether standardized by Codex or not. The Committee noted that food additives had been removed from Appendix IV (Table 3) and that comments would be requested. Several delegations

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<sup>7</sup> ALINORM 97/12A, Annex to Appendix IV (now referred to as the Annex to Table 3) and comments submitted in response to CL 1997/15-FAC from Denmark, France, Japan, Slovak Republic, Spain, Switzerland, United States, CEFIC, ELC, IFFJP, IPPA, Marinalg International, OIV (CX/FAC 98/5), Spain (CRD 3) and EC, IFFJP (CRD 5).

requested inclusion of fruit juices and wine in the Annex to Appendix IV (Table 3). The Committee, noting the Codex Standard for Fruit Juices, deferred a decision on these requests until its next meeting. The Committee agreed to request further comments on Appendix IV (Table 3) and the Annex to Appendix IV (Table 3) on the basis of the above discussion for further consideration at the 31<sup>st</sup> CCFAC.

**DRAFT SCHEDULES FOR ANTIOXIDANTS, PRESERVATIVES, STABILIZERS, THICKENERS AND SWEETENERS (Agenda Item 7c)<sup>8</sup>**

34. The Commission adopted the proposed draft Schedules for Antioxidants, Preservatives, Stabilizers, Thickeners and Sweeteners at Step 5 (ALINORM 97/37, para 114).

35. In view of the above discussion and as recommended by the Working Group, the Committee agreed to return the draft Schedules (i.e., Tables) to Step 6 for consolidation (see para. 28), additional comment and further consideration at its next meeting (see Appendix III).

**PROPOSED DRAFT SCHEDULES FOR COLOURS, COLOUR RETENTION AGENTS, BULKING AGENTS AND EMULSIFIERS (Agenda Item 7d)<sup>9</sup>**

36. The Committee was informed that the 29<sup>th</sup> CCFAC requested the USA to compress information previously obtained to create proposed draft schedules for circulation, comment and consideration at the current CCFAC session (ALINORM 97/12A, para. 31).

37. The representative of the OIV pointed out that there was an inconsistency between the OIV standards and the GSFA and therefore, the Committee encouraged the OIV to submit comments to eliminate these inconsistencies.

38. Several delegations expressed the need for further consideration on the use of colours in food. An offer made by the delegation of Denmark to prepare a discussion paper on this issue for consideration at the next CCFAC was accepted by the Committee.

39. The Committee decided to advance the revised proposed draft Schedules (i.e., Tables) for these food additive classes to the Executive Committee for adoption at Step 5 (see Appendix IV).

**WORKSHEETS FOR ACIDITY REGULATORS, ANTICAKING AGENTS, ANTIFOAMING AGENTS, FIRING AGENTS, FLAVOUR ENHANCERS, FLOUR TREATMENT AGENTS, FOAMING AGENTS, GLAZING AGENTS, HUMECTANTS, PROPELLANTS AND RAISING AGENTS (Agenda Item 7e)<sup>10</sup>**

40. The Committee was informed that the 29<sup>th</sup> CCFAC agreed to issue a circular letter on the remaining additives with numerical ADIs, except flavouring agents, as had been accomplished on previous requests for other food additive classes (ALINORM 97/12A, para. 37). Information and data submitted in response to CL 1997/9-FAC were used to elaborate the Worksheets contained in document CX/FAC 98/8.

41. The Committee forwarded the proposed draft Schedules (i.e., Tables) for these food additive classes to the Executive Committee for adoption at step 5 (see Appendix V).

**PROPOSED DRAFT REVISED ANNEX A (Agenda Item 7f)<sup>11</sup>**

42. The Committee was informed that the 29<sup>th</sup> CCFAC agreed to prepare a new Annex A containing a description only of the budget method and its use for prioritizing additives for JECFA review of exposure. The Committee accepted the offer of Denmark, assisted by France and the United Kingdom, to prepare a revised Annex A, containing a new version of the budget method, for circulation and comment prior to its current meeting (ALINORM 97/12A, paras. 32-34).

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<sup>8</sup> ALINORM 97/12A, Appendix V and comments submitted in response to CL 1997/15-FAC from Denmark, France, Slovak Republic, Spain, United States, CEFIC, ELC, ISA, FEDIMA (CX/FAC 98/6) and Thailand, EC (CRD 5).

<sup>9</sup> CX/FAC 98/7 and comments from Denmark, Egypt, Italy, Spain, South Africa, United States, EFEMA, IDF, ISDI, NATCOL, OIV (CX/FAC 98/7 - Add.1), IMACE (CRD 3) and Thailand, EC (CRD 5).

<sup>10</sup> CX/FAC 98/8 and comments submitted in response to same from Chile, Egypt, Uruguay, ESIA, IFCGA, CEFIC, IPPA (CX/FAC 98/8-Add. 1) and Thailand, EC (CRD 5).

<sup>11</sup> CX/FAC 98/9 and comments from Slovak Republic, South Africa, United States, CEFIC (CX/FAC 98/9-Add. 1), Norway, IFCGA (CRD 3) and EC, ILSI (CRD 5).



43. Some delegations, while generally supporting this approach (i.e., CX/FAC 98/9), pointed out that regional dietary patterns should be taken into account and that further clarification would be required concerning the percentage of the total intake allocated for some food groups and the assessment of extreme intake. The Committee recalled that this was a screening method intended for the evaluation of maximum use levels and not for intake assessment purposes. It was also agreed that the inclusion of some examples of calculation in the document would be useful.

44. The Committee agreed to return the proposed draft Revised Annex to Step 2 for redrafting by the Delegation of Denmark in light of the above discussions and comments received for further consideration by the next session.

#### **COMMENTS ON TECHNOLOGICAL JUSTIFICATION AND NEED FOR THE USE OF FOOD ADDITIVES (Agenda Item 7g)<sup>12</sup>**

45. The 29th CCFAC requested that comments on document CX/FAC 97/10 be considered at its current meeting (ALINORM 97/12A, para. 35).

46. It was noted that document CX/FAC 97/10 served to facilitate discussions on the technological justification and need for the use of food additives.

47. In the light of comments received on the paper, the following proposal put forward by Australia, with criteria for resolving concerns regarding the technological justification and need for the use of food additives in the GSFA, was agreed to by the Committee:

- Establish that at least two Codex Member States permit the use of the additive up to the maximum level proposed in Tables 1 and 2 in foods representative of the category. This establishes that trade may occur in the food containing the additive;
- Establish that the maximum level proposed is not limited to an obscure or unrepresentative food. If the maximum level is appropriate only to an obscure or unrepresentative food, consideration may be given to recognising that food and the level of additive use as a specific entry in the GSFA, and identifying a more representative level for the category as a whole;
- Where delegations continue to express concern about the proposed maximum levels of use square brackets may be appropriate, and;
- The GSFA Tables 1 and 2 are circulated for comments:
  - ◆ If a country considers that a proposed level of use is too high, data should be presented to demonstrate that use at this level presents a risk to public health, may lead to consumer deception about the nature of a food, or is otherwise technologically unnecessary, and;
  - ◆ If a country wishes to support a maximum level which has been identified as being of concern by other delegations, data should be presented to demonstrate that the product could not be made to a satisfactory quality using a lower level of additive or alternative additives that are permitted in the GSFA.

48. It was noted that this approach was consistent with the general criteria for technological justification and need in Sections 3 and 7 of the Preamble to the General Standard.

#### **CONSIDERATION OF SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES (Agenda Item 8)<sup>13</sup>**

49. The Committee noted that Specifications for the Identity and Purity of Food Additives arising from the 49<sup>th</sup> JECFA meeting (FAO FNP 52 - Add. 5) were circulated for comments under CL 1997/29-FAC.

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<sup>12</sup> Comments submitted in response to CL 1997/6-FAC from France, Spain, USA, ELC (CX/FAC 98/10) and EC (CRD 5).

<sup>13</sup> Provisional Agenda for the *ad hoc* Working Group on Specifications (CRD 2) and comments submitted in response to CL 1997/29-FAC from Denmark, Senegal, Sudan, United States, AIDGUM, AMFEP, CEFIC, CI, EUROTALC and FAO (CRD 2 - Add. 1), and the Report of the *ad hoc* Working Group on Specifications (CRD 2 - Add. 2).

Based upon recommendations made by the *ad hoc* Working Group on Specifications, the Committee forwarded substances in Categories I and II (see Appendix VIII) to the Commission for adoption as Codex Advisory Specifications.

50. The Committee noted the diverse opinions expressed by several delegations concerning the specifications for gum arabic. Some delegations expressed the opinion that gum arabic should only include gums obtained from *Acacia senegal* and separate specifications should be established for gums derived from *A. seyal*. Other delegations were of the opinion that the gums from the two *Acacia* species were related and that the specifications should remain as currently drafted. The Committee nonetheless agreed with the recommendation of the Working Group to include the substance under Category III (Substantive Changes Required). The delegation of Sudan agreed to forward the necessary data for consideration by the 1999 JECFA meeting.

51. The Committee expressed its appreciation to the *ad hoc* Working Group, which was chaired by P.M. Kuznesof (USA); H. Wallin (Finland) and I. Meyland (Denmark) acted as rapporteur and category monitor, respectively. The Committee agreed that the *ad hoc* Working Group on Specifications was an important forum for member countries and international organizations for discussing technical issues in a transparent manner unsuited for the plenary session and therefore, it reestablished the *ad hoc* Working Group under the Chairmanship of the USA, with the task of reviewing specifications arising from the 51<sup>st</sup> JECFA meeting prior to the 31<sup>st</sup> CCFAC.

#### **PROPOSED AMENDMENTS TO THE INTERNATIONAL NUMBERING SYSTEM** (Agenda Item 9)<sup>14</sup>

52. The Committee was informed that the 29<sup>th</sup> CCFAC proposed that INS numbers 425 and 960 be assigned to Konjac Flour and Stevioside, respectively, for circulation and comment at step 3 (ALINORM 97/12A, paras. 41-43). No comments were received in response to CL 1997/6-FAC.

53. The Committee noted that Konjac Flour met the following criteria established at the 22<sup>nd</sup> CCFAC (ALINORM 91/12, para. 90) for the inclusion of a compound in the INS:

- The compound must be approved by a member country as a food additive;
- The compound must be toxicologically cleared for use by a member country, and;
- The compound must be required to be identified on the final product label by a member country.

54. The Committee forwarded INS numbers 425 and 960 for Konjac Flour and Stevioside, respectively, to the Commission for adoption at step 5, with a recommendation to omit steps 6 and 7. The delegation of Japan reserved its position on the assignment of an INS number to Konjac Flour, as they considered it a food.

55. At the request of the representative of CEFIC and in view of the non-controversial nature of the amendment, the Committee agreed to circulate INS numbers 938, 939 and 948 for Argon, Helium and Oxygen, respectively, at Step 3 of the Accelerated Procedure for comments, subject to confirmation by the Executive Committee. The amendments are attached to this report as Appendix IX.

56. The Committee agreed to request comments to update the technological functions and functional classes/sub-classes assigned to individual additives in the INS system. The Committee also agreed to request proposals for amendments to the INS for consideration at its next meeting.

#### **ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR CONTAMINANTS IN CODEX STANDARDS** (Agenda Item 10)<sup>15</sup>

57. The Committee noted that no maximum levels for contaminants have been submitted for endorsement since its 29<sup>th</sup> Session.

58. The 22<sup>nd</sup> Session of the Codex Alimentarius Commission adopted the draft Revised Codex Standard for Natural Mineral Waters as a final text. Notwithstanding the concerns of several delegations at the Commission meeting that provisions related to "Health-Related Limits for Certain Substances" (Section 3.2)

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<sup>14</sup> CX/FAC 98/11 (Not issued).

<sup>15</sup> CX/FAC 98/12.

had not been subjected to CCFAC review, the Commission did not request any further CCFAC action and the Standard was adopted without change (ALINORM 97/37, paras. 85-95).

59. Several delegations stated their concerns over the provisions in the Codex Standard for Natural Mineral Waters, especially in regard to the level of 0.05 mg/l for Arsenic, which was five times higher than of the WHO Guidelines for Drinking Water Quality.

60. The Committee agreed to append Section 3.2 (Health-Related Limits for Certain Substances) of the Codex Standard for Natural Mineral Waters to its report for comment (see Appendix XV) on this Section only.

#### **METHODOLOGY AND PRINCIPLES FOR EXPOSURE ASSESSMENT IN THE CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD (Agenda Item 11)<sup>16</sup>**

61. The 29<sup>th</sup> CCFAC postponed discussions on methodology for exposure assessment to its current meeting to enable a paper to be prepared by the United Kingdom with assistance of the delegations of Denmark and the Netherlands. (ALINORM 97/12A, para.50).

62. The delegate of the United Kingdom gave a short introduction of the paper. Several delegations expressed the view that the paper served as a good basis to develop exposure assessment methodologies, and that the Joint FAO/WHO Expert Consultation on Food Consumption and Exposure Assessment of Chemicals and the advice of JECFA should also be taken into account. The importance of addressing major food groups, as well as individual foods, was stressed, as was the need to take regional dietary differences into account. Environmental contamination from air and water was also identified as an important source of exposure to be taken into account for some contaminants. Some delegations felt that the methodology should give preference to the ALARA<sup>17</sup> principle and should not be based on the highest levels of contaminants observed.

63. The Committee decided to develop the document further on the basis of the above discussions and comments submitted for circulation and comment prior to the next session of the CCFAC, and assigned this work to the UK, with the assistance of the Australia, France, Denmark, India, Italy, the Netherlands, USA and WHO.

#### **MYCOTOXINS IN FOOD AND FEED**

#### **COMMENTS ON THE DRAFT CODEX MAXIMUM LEVEL AND SAMPLING PLANS FOR TOTAL AFLATOXINS IN PEANUTS INTENDED FOR FURTHER PROCESSING (Agenda Item 12a)<sup>18</sup>**

64. The 29<sup>th</sup> CCFAC decided to maintain the draft level and sampling plan at Step 7 (ALINORM 97/12, Appendix VIII) and, pending the JECFA evaluation of aflatoxins, to collect more information on the potential economic problems from a level of 10 µg/kg and the public health implication of a level of 15, as compared to 10 µg/kg (ALINORM 97/12A, para 58).

65. The Committee noted that the 49<sup>th</sup> JECFA completed an extensive quantitative risk assessment for aflatoxins (see paras. 14-15).

66. Many delegations considered the draft level of 15 µg/kg total aflatoxins in raw peanuts sufficiently low as it applied to peanuts intended for further processing. They stated that 15 µg/kg was the lowest level that could be reasonably achieved during the production of raw peanuts and that it would facilitate international trade. A lower level was considered as a trade barrier because on the basis of the JECFA evaluation this may not offer significant improvements for public health. It was also noted that the level could be reasonably achieved by peanut producing countries.

67. Other delegations preferred 10 µg/kg and referred to the genotoxic properties of aflatoxins, uncertainties in risk assessment, the ALARA principle and the lack of data provided to show that this level would influence the availability of peanuts on the market.

<sup>16</sup> CX/FAC 98/13 and comments from Australia (CX/FAC 98/13-Add.1), USA (CRD 4) and France (CRD 5).

<sup>17</sup> As low as reasonably achievable.

<sup>18</sup> Comments submitted in response to CL 1997/6-FAC from Germany, Spain, INC (CX/FAC 98/14), Sudan, USA, IPF (CRD3) and EC (CRD 5).

68. The Committee recognised that a strong relationship existed between an aflatoxin level and an applied sampling plan.

69. A number of proposals were put forward by delegations in an attempt to reach consensus. These included a proposal for the establishment of a working group to seek a consensus on the draft maximum level and the sampling plans in the light of the final JECFA report and also a proposal that the limit of 15 µg/kg be advanced to Step 8 but the sampling plans be returned to Step 6 to enable a working group to be established to work on them for the 31<sup>st</sup> CCFAC. No consensus could be reached on these proposals.

70. The delegation of Zimbabwe requested that the Committee vote on the proposal to advance the maximum level of 15 µg/kg and the sampling plans to the Commission for adoption at Step 8. The delegation of Switzerland asked Zimbabwe to reconsider its call for a vote to enable the Committee to consider a new proposal that the maximum level and sampling plans be placed in square brackets and advanced to the Commission at Step 8. Following clarification from the Secretariat concerning the significance of square brackets, the delegation of Zimbabwe withdrew its request for a vote.

71. Despite certain reservations, the Committee accepted the proposal to forward the draft maximum level of 15µg/kg and sampling plans between square brackets to the Commission for adoption at Step 8 (see Appendix X). The Committee was further advised that the square brackets would be removed prior to final adoption at the Commission. Quantitative data supporting a lower level or alternative sampling plans should be submitted to the Commission.

72. It was also noted that in the future, and in compliance with the principles of the General Standard for Contaminants and Toxins in Foods, maximum levels for aflatoxins should be considered in the context of a quantitative risk assessment which took account of all foodborne sources.

**COMMENTS ON THE DRAFT MAXIMUM LEVEL FOR AFLATOXIN M<sub>1</sub> IN MILK** (Agenda Item 12b)<sup>19</sup>

73. The 29<sup>th</sup> CCFAC agreed to maintain the current level (0.05 µg/kg) at Step 7 and to collect more information (CL 1997/6 - FAC) on the public health implications of a higher level and the potential economic problems from the lower level as proposed (ALINORM 97/12A, para 55).

74. Many delegations supported the proposed value of 0.05 µg/kg, advocating that this level could reasonably be achieved. Other delegations drew attention to the summary report of the 49<sup>th</sup> JECFA meeting and stated that a ten fold higher level was adequate to protect public safety. The difficulties and costs associated with the use of methods of analysis for the determination of aflatoxins at the lower level were also noted. Some delegations stated that a level of 0.05 µg/kg would result in severe disruptions to international feed trade. Some delegations were of the opinion that milk for direct consumption was not widely traded internationally.

75. The delegations of Argentina, Brazil, the Philippines and the United States reserved their position and preferred a level of 0.5 µg/kg. The Committee accepted the proposal to forward the draft maximum level of 0.05 µg/kg for Aflatoxin M<sub>1</sub> in Milk to the Commission for adoption at Step 8 (see Appendix X).

**POSITION PAPER ON OCHRATOXIN A** (Agenda Item 12 c)<sup>20</sup>

76. The 29<sup>th</sup> CCFAC accepted the offer of Sweden to revise the position paper on Ochratoxin A based on the Committee's discussions and to include a proposed level for further consideration at its current meeting (ALINORM 97/12A, para. 66).

77. The delegation of Sweden briefly introduced the revised position paper. Special attention was focused on the fact that a number of *Aspergillus*-species were able to produce Ochratoxin A. Possible genotoxic carcinogenic and nephrotoxic properties were mentioned. Dietary exposure from sources other than cereals (e.g., wine, fruit juices, pig meat and coffee) was also highlighted.

Sweden recommended that:

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<sup>19</sup> Comments submitted in response to CL 1997/6-FAC from Germany (CX/FAC 98/15), USA (CRD 3) and EC (CRD 5).

<sup>20</sup> CX/FAC 98/16.

- levels need to be based on sound scientific toxicological data, using the ALARA principle and the application of all possible prevention measures;
- a code of practice for the reduction of Ochratoxin A levels in cereals should be elaborated;
- a level of 5 µg/kg for cereals and cereal products intended for direct human consumption be established, and;
- sampling plans and methods of analysis be established.

78. Many delegates appreciated the work done by Sweden and agreed that standards for commodities other than cereals needed to be considered. The use of the horizontal approach of the General Standard for Contaminants and Toxins in Foods was supported for this purpose.

79. Several delegates referred to JECFA's most recent toxicological evaluation, and stated that JECFA needed to clarify its position on the carcinogenicity of Ochratoxin A, and noted that an updated risk assessment may be necessary in the future.

80. The Committee considered that it would be premature to set a level for cereals at this time and accepted the offer of Sweden to prepare an updated version of the position paper for circulation, comment and discussion at its next meeting.

#### **POSITION PAPER ON PATULIN** (Agenda item 12d)<sup>21</sup>

81. The 29<sup>th</sup> CCFAC decided to request that additional information on Patulin be submitted to France (CL 1997/6-FAC) and accepted their offer to update the position paper based on these comments for circulation before the current meeting (ALINORM 97/12A, para. 77).

82. France noted modifications made to the earlier version of the position paper, particularly the potential to reduce patulin levels through physical, chemical and mechanical means. The paper also focused special attention on the higher risk for children who could consume large amounts of apple juice. Many delegates welcomed the clear overview given in the paper and the recommendations proposed.

83. Levels of both 25 and 50 µg/kg were discussed in relation to:

- good manufacturing and agricultural practices;
- analytical methodology availability;
- toxicological evaluations made by JECFA, and;
- difficulties in adhering to the level of 25µg/kg.

84. The Committee decided to append a maximum level of 50 µg/kg for apple juice and the apple juice ingredient in ready made soft drinks for circulation and comment at Step 3 (see Appendix XI). The Committee noted that for products containing apple juice the maximum level should be reduced proportionally to reflect the percentage of juice present in the product when consumed.

85. The Committee accepted the offer of France to produce an updated version of the paper for further discussion at its next meeting .

#### **POSITION PAPER ON ZEARALENONE** (Agenda item 12 e)<sup>22</sup>

86. The delegation of Norway introduced the position paper on Zearalenone that was prepared in close cooperation with other Nordic countries at the request of the 29<sup>th</sup> CCFAC (ALINORM 97/12A, para. 52).

87. Several delegates expressed their appreciation for the preparation of the document. The need for establishing a maximum level was questioned, as the position paper indicated that no problems in international trade had been reported.

88. The Committee decided to circulate the current position paper for comment and consideration at its next meeting.

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<sup>21</sup> CX/FAC 98/17.

<sup>22</sup> CX/FAC 98/18 and CX/FAC 98/18 - Add. 1 (not issued).

## **DRAFT CODE OF PRACTICE ON GOOD ANIMAL FEEDING (Agenda item 12f)<sup>23</sup>**

89. The 22<sup>nd</sup> Session of the Codex Alimentarius Commission noted the outcome of the FAO Consultation on Animal Feeding and Food Safety, and agreed that the Draft Code of Practice on Good Animal Feeding should be referred to the CCFAC and other Codex Committees (ALINORM 97/37, para. 129). The Draft Code of Practice was also discussed at the 30<sup>th</sup> Session of the Codex Committee on Food Hygiene (ALINORM 99/13, paras. 96-99).

90. The Committee decided to forward the following comments of delegations for further consideration by the Executive Committee:

- In general, the control procedures in the document were supported;
- A significant concern existed about the wide scope of the code of practice;
- Improvements were advocated, especially the further elaboration of codes of practice directed towards specific commodities;
- Possible conflicts with other international standards;
- Special attention was focused on the carry-over of additives/contaminants, and;
- Some delegations expressed their concerns about antibiotics and the potential hazards of antibiotic resistance.

91. The Committee noted that the Codex Code of Practice for the Reduction of Aflatoxins in Raw Materials and Supplementary Feeding Stuffs for Milk producing Animals addressed many of the issues in the Consultation report, and agreed to elaborate additional codes of practice related to specific commodities in the future if necessary. It was also noted that the CCFAC could elaborate maximum levels for animal feedingstuffs or their raw materials where necessary due to problems in trade.

## **INDUSTRIAL AND ENVIRONMENTAL CONTAMINANTS IN FOODS**

### **CODE OF PRACTICE FOR SOURCE DIRECTED MEASURES TO REDUCE CONTAMINATION OF FOODSTUFFS (Agenda Item 13a)<sup>24</sup>**

92. The 29<sup>th</sup> CCFAC accepted the offer of Sweden to elaborate the proposed draft Code of Practice for circulation, comment and consideration at the current meeting (ALINORM 97/12A, para. 85). The 22<sup>nd</sup> Commission Session accepted this proposal as new work (ALINORM 97/37, Appendix IV).

93. The delegation of Sweden presented the proposed draft Code of Practice to the Committee. As comments were not requested on the document prior to its consideration at the current meeting, the Committee agreed to append the draft Code of Practice to its report for circulation and comment at Step 3 (see Appendix XIV).

### **DRAFT MAXIMUM LEVELS FOR LEAD (Agenda Item 13b)<sup>25</sup>**

94. The 22<sup>nd</sup> Session of the Commission adopted the proposed draft maximum levels for lead at Step 5 (ALINORM 97/37, paras. 115) on the basis of recommendations arising from the 29<sup>th</sup> CCFAC (ALINORM 97/12A, paras. 68-70).

95. The delegation of Denmark briefly reviewed the comments received. It was pointed out that special attention should be paid to the impact of lead exposure on children and that there was a need for a thorough exposure assessment.

96. Several delegations suggested that the levels for fish could be lowered to 0.2 mg/kg, including a note that this figure applies to fish muscle, and to 0.05 mg/kg for meat on the basis of new data. It was further

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<sup>23</sup> CX/FAC 98/19 and comments from Australia, USA, CICALS (CX/FAC 98/19 - Add. 1), Sweden (CRD 4) and France, EC (CRD 5).

<sup>24</sup> CX/FAC 98/20 and CX/FAC 98/20 - Add.1 (not issued).

<sup>25</sup> ALINORM 97/12A, Appendix X and comments submitted in response to CL 1997/15-FAC from Poland, Slovak Republic, ISDI (CX/FAC 98/21), USA (CRD 4) and France (CRD 5).

indicated that the level for fruit juice could be lowered to 0.05 mg/kg. It was also suggested that a level of 0.3 mg/kg should be established for small fruits and berries with edible skin.

97. The Committee agreed that the delegation of Denmark would review the draft maximum levels in light of an appropriate risk assessment for children and the above discussion for circulation, comment and further consideration at the 31st CCFAC.

#### **DISCUSSION PAPER ON CADMIUM (Agenda Item 13c)<sup>26</sup>**

98. The 29th CCFAC decided to maintain the draft guideline level of 0.1 mg/kg for cereals, pulses and legumes at Step 7. It also accepted the offer of the delegation of Denmark, assisted by France and The Netherlands, to prepare a compilation of existing data on cadmium for discussion at its current meeting (ALINORM 97/12A, paras. 67 and 71).

99. The delegation of Denmark presented the discussion paper, elaborated with the assistance of the delegations of France and The Netherlands. It was pointed out that the JECFA evaluation of cadmium, scheduled in 1999, was postponed until 2000 in order to allow for the submission of data from Japan and other countries.

100. The Committee accepted the offer of Denmark to revise the discussion paper for circulation, comment and consideration at the 31<sup>st</sup> CCFAC.

#### **POSITION PAPER ON ARSENIC (Agenda Item 13d)<sup>27</sup>**

101. The 29<sup>th</sup> CCFAC accepted the offer of Denmark to further progress its position paper on arsenic for circulation, comment and consideration at its current meeting (ALINORM 97/12A, para. 74).

102. The delegation of Denmark presented the revised position paper on Arsenic and drew particular attention to the different arsenic species that occur in food. Future consideration of only the more toxic inorganic forms of arsenic instead of total arsenic was recommended.

103. Some delegations welcomed the suggestion to focus only on the arsenic species of importance. Other delegations felt that total arsenic methods and residue levels were more appropriate, although their use made additional explanations necessary because the use of total arsenic levels easily resulted in overestimations of intake. It was noted that analytical methods for the different species, especially for the organic arsenic species, were not routinely available. The Committee supported further studies on the analytical methodology, the bioavailability of the different arsenic species and their toxicological relevance.

104. The Committee requested Denmark to revise the position paper based on the above discussions and comments submitted for circulation, comment and further discussion at its next meeting.

#### **POSITION PAPER ON TIN (Agenda Item 13e)<sup>28</sup>**

105. The 29<sup>th</sup> CCFAC accepted the offer of Australia to further develop the position paper on tin, which had been developed by Australia, Indonesia and Thailand, for consideration at the current meeting (ALINORM 97/12A, para. 80).

106. The delegation of Australia presented the revised position paper on tin and drew particular attention to the recommendation for a limit of 200 mg/kg in liquid canned foods and 250 mg/kg in solid canned foods.

107. Delegations welcomed the revised paper. A number of delegations questioned the technological basis for the levels of tin proposed in the paper. The delegation of Australia explained the need for sacrificial tin coatings for acidic foods and the inadequacy of alternatives, such as lined cans. The Committee agreed to circulate the levels proposed in the paper for comments at step 3 and further consideration at its next meeting (see Appendix XI).

#### **PROPOSALS FOR THE PRIORITY EVALUATION OF FOOD ADDITIVES AND CONTAMINANTS BY JECFA (Agenda Item 14)<sup>29</sup>**

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<sup>26</sup> CX/FAC 98/22.

<sup>27</sup> CX/FAC 98/23 and comments from Australia (CX/FAC 98/23 Add. 1) and Canada, UK (CRD 3).

<sup>28</sup> CX/FAC 98/24.

108. Mr. J. Dornseiffen (the Netherlands) introduced the report of the informal Working Group on Priorities for JECFA. The Committee agreed to the priorities proposed by the Working Group except that it deleted those food additives that delegations had proposed but had not given commitments to provide information. The list of priorities agreed by the Committee is provided in Appendix XIII.

109. For intake assessments, the Committee stressed the need for countries and organizations to provide appropriate information to ensure that intakes can be assessed for food additives when used in the food categories under which they are included in the General Standard for Food Additives. The Committee agreed that, if the instructions provided in the call for data for the fifty-first meeting of JECFA are followed, appropriate information would be provided to permit such assessments (see para. 28).

110. The Committee agreed to request additional comments for additions or amendments to its Priority List, preferably well documented and in time, for consideration at the 31<sup>st</sup> CCFAC.

#### **OTHER BUSINESS AND FUTURE WORK (Agenda Item 15)**

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

111. No comments were received in response to CL 1997/6-FAC, which requested additional methods of analysis for the determination of food additives and contaminants in foods based on specific criteria (ALINORM 97/12, para. 28). The Committee agreed to continue inviting comments for consideration at future sessions under Other Business.

##### **PROPOSED AMENDMENTS TO THE INVENTORY OF PROCESSING AIDS**

112. No comments were received in response to CL 1997/6-FAC, which requested amendments to the Inventory of Processing Aids. The Committee agreed to continue inviting comments for consideration at future sessions under Other Business.

##### **PACKAGING PROVISIONS IN THE REVISED STANDARD FOR FOOD GRADE SALT**

113. The delegation of Malaysia provided a verbal summary of their proposal raised at the 29th CCFAC (ALINORM 97/12A, para. 6) to examine a proposal to include packaging provisions for maintaining the stability of iodised salt in the revised Standard for Food Grade Salt. The Committee agreed that the proposal would be appended to its report for circulation and comment at step 3 (Appendix XII).

##### **AD HOC WORKING GROUP FOR CONTAMINANTS**

114. In spite of the great amount of work the CCFAC had completed since 1988, a large number of contaminants were still on the agenda for consideration. Since the issue of contaminants presents difficulties both in regard to controlling contamination and in obtaining sufficient data for standard setting, the Chairperson proposed to install an *ad hoc* Working Group on Contaminants so sufficient progress could be made on this issue in future CCFAC meetings. The goals of the working group would be to:

- Progress the development and implementation of the General Standard for Contaminants and Toxins in Food;
- Make recommendations to the plenary session on the issue of contaminants, and;
- Ensure consistency with other international activities in the decision making approaches relating to contaminants.

115. The *ad hoc* Working Group on Contaminants would have the same status as the *ad hoc* Working Group on the General Standard for Food Additives. The terms of reference of the Working Group would be to:

- Propose refinement and implementation of the General Standard for Contaminants and Toxins in Foods, and;
- Make proposals to JECFA for contaminants to be evaluated.

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<sup>29</sup> Report of the informal Working Group on Priorities (CRD 6) and comments submitted in response to CL 1997/6-FAC from CEFIC (CRD3).



116. The Committee accepted the proposal of the Chairperson and nominated Denmark as Chair, Brazil as Vice-Chair and Australia and the Netherlands as rapporteurs.

**DIOXINS**

117. At the request of the Dutch delegation, the Committee agreed to the offer of the Netherlands to prepare a discussion paper on dioxins for circulation, comment and consideration at the 31<sup>st</sup> CCFAC. Japan informed the Committee that monitoring data was available.

**DATE AND PLACE OF NEXT SESSION** (Agenda Item 16)

118. The Committee was informed that the 31<sup>st</sup> Session of the Codex Committee on Food Additives and Contaminants was tentatively scheduled to be held in The Hague from 22-26 March 1999.

**CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS  
CURRENT STATUS OF WORK**

<b>SUBJECT</b>	<b>STEP</b>	<b>FOR ACTION BY</b>	<b>DOCUMENT REFERENCE*</b>
Draft Specifications for the Identity and Purity of Food Additives	8	23rd CAC	paras. 49-51 and Appendix VIII
Draft Maximum Level and Sampling Plans for Total Aflatoxins in Peanuts Intended for Further Processing	8	23rd CAC	paras. 64-72 and Appendix X
Draft Maximum Level for Aflatoxin M <sub>1</sub> in Milk	8	23rd CAC	paras. 73-75 and Appendix X
Proposed Draft Amendments to the Codex International Numbering System for Food Additives	5/8	23rd CAC	paras. 52-54 and Appendix IX
Draft Tables for Antioxidants, Preservatives, Stabilizers, Thickeners and Sweeteners	6	Governments 31st CCFAC	paras. 34-35 and Appendix III
Draft Maximum Levels for Lead	6	Denmark Governments 31st CCFAC	paras. 94-97
Proposed Draft Tables for Colours, Colour Retention Agents, Bulking Agents and Emulsifiers	5	45th CCEXEC Governments 31st CCFAC	paras. 36-39 and Appendix IV
Proposed Draft Tables for Acidity Regulators, Anticaking Agents, Antifoaming Agents, Firming Agents, Flavour Enhancers, Flour Treatment Agents, Foaming Agents, Glazing Agents, Humectants, Propellants and Raising Agents	5	45th CCEXEC Governments 31st CCFAC	paras. 40-41 and Appendix V
Proposed Draft Amendments to the Codex International Numbering System for Food Additives	1/2/3**	45th CCEXEC Governments 31st CCFAC	para. 55 and Appendix IX
Proposals for Amendments to the Codex International Numbering System for Food Additives, including Technological Functions and Functional Classes/Sub-Classes	3	Governments 31st CCFAC	para. 56
Codex Standard for Natural Mineral Water: Health-Related Limits for Certain Substances (Section 3.2)	3	Governments 31st CCFAC	paras. 57-60 and Appendix XV
Proposed Draft Maximum Level for Patulin in Apple Juice and the Apple Juice Ingredient in Ready Made Soft Drinks	3	Governments 31st CCFAC	paras. 81-85 and Appendix XI
Proposed Draft Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals	3	Governments 31st CCFAC	paras. 92-93 and Appendix XIV
Proposed Draft Maximum Levels for Tin	3	Governments 31st CCFAC	paras. 105-107 and Appendix XI
Food Additives and Contaminants Proposed for Evaluation by JECFA	3	Governments 31st CCFAC	paras. 108-110 and Appendix XIII

Methods of Analysis for the Determination of Food Additives and Contaminants in Foods	3	Governments 31st CCFAC	para. 111
Inventory of Processing Aids	3	Governments 31st CCFAC	para. 112
Packaging Provisions for Maintaining the Stability of Iodised Salt in the Codex Standard for Food Grade Salt	3	45th CCEXEC Governments 31st CCFAC	para. 113 and Appendix XII
Amendments to the Table of Additives Permitted for Use in Food in General, Unless Otherwise Specified, in Accordance with GMP and Food Categories or Individual Food Items Where the Use of Food Additives with GMP Limitations on Use are Not Allowed or Restricted	2/3	United States Governments 31st CCFAC	paras. 29-33
Proposed Draft Revised Annex A of the Codex General Standard for Food Additives	2	Denmark 31st CCFAC	paras. 42-44
Comments Concerning the Draft Code of Practice on Good Animal Feeding	----	45th CCEXEC	paras. 89-91
Amendments to the Food Additive Provisions of the Codex Standard for Food Grade Salt	----	23rd CAC	paras. 18-21 and Appendix VII
Discussion Paper on the Application of Risk Analysis for Additives and Contaminants	----	Governments United States 31st CCFAC	paras. 7-13
Use of Colours in Food	----	Denmark 31st CCFAC	para. 38
Methodology and Principles for Exposure Assessment in the Codex General Standard for Contaminants and Toxins in Foods	----	UK Governments 31st CCFAC	paras. 61-63
Position Paper on Ochratoxin A	----	Sweden Governments 31st CCFAC	paras. 76-80
Position Paper on Patulin	----	France 31st CCFAC	paras. 81-85
Position Paper on Zearalenone	----	Governments 31st CCFAC	paras. 86-88
Discussion Paper on Cadmium	----	Denmark Governments 31st CCFAC	paras. 98-100
Position Paper on Arsenic	----	Denmark Governments 31st CCFAC	paras. 101-104
Discussion Paper on Dioxins	----	Netherlands Governments 31st CCFAC	para. 117

\* All references refer to the report of the thirtieth Session of the Codex Committee on Food Additives and Contaminants (ALINORM 99/12).

\*\* Accelerated Procedure.

**COMPONENTS OF THE GENERAL STANDARD FOR FOOD ADDITIVES (GSFA)**

1. **Preamble**
2. **Annex A** : Guideline for the Development of Maximum Levels of Use for Food Additives with Numerical Acceptable Daily Intakes (ADIs)
3. **Annex B** : The GSFA Food Categorization System
4. **Annex C** : Cross-reference to Codex Commodity Standards and the GSFA Index of Food Additives

**List A** : JECFA “Approved” Food Additives, with ADIs and International Numbering System (INS) Numbers

**List B** : INS Numbers for JECFA “Approved” Food Additives with ADIs

5. **Table 1** : Additives Permitted for Use Under Specific Conditions in Certain Food Categories or Individual Food Items<sup>1</sup>
6. **Table 2** : Food Categories or Individual Food Items in Which the Use of Food Additives are Permitted Under Specified Conditions
7. **Table 3** : Additives with Non-Numerical ADIs Permitted for Use in Food in General in Accordance with Good Manufacturing Practice Unless Otherwise Specified (ALINORM 97/12A, Appendix IV)

**Annex to Table 3** : Food Categories and Individual Food Items Where the Use of Food Additives with Good Manufacturing Practice Limitations on Use are Not Allowed or Restricted

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<sup>1</sup> Newly formatted Schedules 1 and 2 are henceforth referred to as Tables 1 and 2, respectively.

**CODEX GENERAL STANDARD FOR FOOD ADDITIVES:  
DRAFT TABLES FOR ANTIOXIDANTS, PRESERVATIVES,  
STABILIZERS, THICKENERS AND SWEETENERS  
(At Step 6 of the Procedure)**

**NOTE:** The consolidated draft Tables of the Codex General Standard for Food Additives, which will include provisions for antioxidants, preservatives, stabilizers, thickeners and sweeteners, will be circulated for comment separately (see paras. 34-35 for details).

**CODEX GENERAL STANDARD FOR FOOD ADDITIVES:  
PROPOSED DRAFT TABLES FOR COLOURS, COLOUR RETENTION AGENTS,  
BULKING AGENTS AND EMULSIFIERS  
(At Step 5 of the Procedure)**

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

<b>Substance</b>	<b>Previous acceptable daily intake (ADI) in mg/kg of body weight and other toxicological recommendations</b>	<b>Present acceptable daily intake (ADI) in mg/kg of body weight and other toxicological recommendations</b>	<b>Current Codex Uses</b>	<b>Secretariat Notes</b>
<b>Antioxidant</b> <i>tert</i> -Butylhydroquinone (TBHQ)	0-0.2 (Temporary)	0-0.7 mg/kg bw	Edible fats and oils	Previous ADI increased
<b>Emulsifiers</b> Microcrystalline cellulose Sucrose esters of fatty acids and sucroglycerides	Not specified 0-20 (Temporary group ADI)	Not specified <sup>a</sup> 0-30 mg/kg bw <sup>b</sup>	None Magarine Cocoa powders and dry cocoa-sugar mixtures	Previous ADI maintained Previous ADI increased
<b>Enzyme preparations</b> <i>alpha</i> -Acetolactate decarboxylase Maltogenic amylase	None None	Not specified <sup>c</sup> Not specified <sup>c</sup>	None None	
<b>Flavoring agent</b> <i>trans</i> -Anethole	0-0.6 (Tempory)	0-0.6 mg/kg bw <sup>d</sup> (Temporary)	None	Previous ADI maintained
<b>Glazing agent</b> Hydrogenated poly-1-decene	None	No ADI allocated <sup>e</sup>	None	
<b>Sweetening agent</b> Maltitol syrup	Not specified	Not specified <sup>a</sup>	None	
<b>Miscellaneous substances</b> Salatrim (short- and long-chain acyltriglyceride molecules)	None	An adequate basis was not available for evaluating its safety and nutritional effects <sup>f</sup>	None	
<b>Contaminants</b> Aflatoxins B, G and M	Lowest practicable level <sup>g</sup>	See Annex 1 of 49th JECFA Summary Report	None	

<sup>a</sup> Applies to the product conforming to the revised specifications.

<sup>b</sup> Group ADI for sucrose esters of fatty acids and sucroglycerides.

<sup>c</sup> Temporary pending consideration of the "tentative" designation for the specifications. The "tentative" designation for Appendix B to Annex 1 (general specification for enzyme preparations used in food processing) of the Compendium of food additive specifications (1992) will be reviewed in 1998.

<sup>d</sup> Tempory ADI extended to 1998 to review studies underway that were requested by earlier Committees.

<sup>e</sup> Data were insufficient for establishing an ADI.

<sup>f</sup> The Committee recommended that additional appropriately designed studies be performed to assess fully both the toxicological and nutritional consequences of ingestion of salatrim.

<sup>g</sup> Presence in food should be reduced to irreducible levels. An irreducible level is defined as that concentration of a substance that cannot be eliminated from a food without involving the discarding of that food altogether, severely compromising the ultimate availability of major food supplies.

**ENDORSEMENT OF FOOD ADDITIVE PROVISIONS IN CODEX STANDARDS**  
**PROPOSED DRAFT REVISED CODEX STANDARD FOR FOOD GRADE SALT**

Food Additive	Maximum Level in Finished Product	Endorsement Status
<b><u>Anticaking Agents</u></b>		
341 (iii) Tricalcium Orthophosphate	20 mg/kg	Endorsed
	-----	
170 (i) Calcium Carbonate	}	}
504 (i) Magnesium Carbonate	}	}
530 Magnesium Oxide	}	}
551 Silicon Dioxide, Amorphous	}	}
552 Calcium Silicate	}	}
553 (i) Magnesium Silicate	} GMP	} Endorsed
554 Sodium Aluminosilicate	}	}
556 Calcium Aluminium Silicate	}	}
470 Salts of Myristic, Palmitic or Stearic Acids (calcium, potassium, sodium)	}	}
	}	}
470 Salts of Myristic, Palmitic or Stearic Acids (aluminium, magnesium)	(No ADI Allocated)	Not Endorsed
538 Calcium Ferrocyanide	-----	
536 Potassium Ferrocyanide <sup>1</sup>	10 mg/kg, singly or in combination,	}
535 Sodium Ferrocyanide <sup>1</sup>	as [Fe (CN <sub>6</sub> )] <sup>1</sup>	} Endorsed
		}
<b><u>Emulsifiers</u></b>		
433 Polyxyethylene (20) Sorbitan Monooleate	10 mg/kg	Endorsed
<b><u>Processing Aid</u></b>		
900a Polydimethylsiloxane <sup>2</sup>	10 mg of residue/kg	Endorsed

- 1 The maximum level for Sodium and Potassium Ferrocyanides may be 20 mg/kg when used in the preparation of “dendritic” salt.
- 2 Polydimethylsiloxane is listed as an antifoam agent, lubricant, release and anti-stick agent and moulding aid (as Dimethylpolysiloxane) in the Codex Inventory of Processing Aids. Polydimethylsiloxane is listed as an antifoaming agent, anticaking agent and emulsifier in the Codex International Numbering System for Food Additives.



**DRAFT SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES<sup>1</sup>**

**CATEGORY I (RECOMMENDED TO THE COMMISSION FOR ADOPTION)**

**Food additives**

Agar	Mixed carotenoids
Alginic acid	Modified starches
Ammonium alginate	Potassium alginate
Calcium alginate	Potassium propionate
Carbon dioxide	Propylene glycol
Diacetyltartaric and fatty acid esters of glycerol	Propylene glycol alginate
Ethyl hydroxyethyl cellulose	Propylene glycol esters of fatty acids
Gellan gum	Salatrim
Hydrogenated poly-1-decene	Sodium alginate
Isoamyl acetate	Sucroglycerides
Maltitol syrup	Sulfur dioxide
Microcrystalline wax	<i>tertiary</i> -Butylhydroquinone

**Flavouring agents**

No.	Name	No.	Name
13	Allyl cyclohexane propionate	127	Butyl acetate
33	Ethyl octanoate	128	Hexyl acetate
34	Ethyl nonanoate	129	Heptyl acetate
43	Isoamyl acetate	130	Octyl acetate
45	Isoamyl butyrate	131	Nonyl acetate
49	Isoamyl isobutyrate	132	Decyl acetate
50	Isoamyl isovalerate	133	Lauryl acetate
53	Citronellyl formate	134	<i>cis</i> -3-Hexenyl acetate
54	Geranyl formate	135	<i>trans</i> -3-Heptenyl acetate
55	Neryl formate	136	10-Undecen-1-yl acetate
56	Rhodinyl formate	137	Isobutyl acetate
57	Citronellyl acetate	138	2-Methylbutyl acetate
59	Neryl acetate	141	Methyl propionate
60	Rhodinyl acetate	142	Propyl propionate
61	Citronellyl propionate	143	Butyl propionate
62	Geranyl propionate	144	Hexyl propionate
63	<i>cis</i> -3,7-Dimethyl-2,6-octadien-1-yl propanoate	145	Octyl propionate
65	Citronellyl butyrate	146	Decyl propionate
66	Geranyl butyrate	147	<i>cis</i> -3 & <i>trans</i> -2-Hexenyl propionate
67	Neryl butyrate	148	Isobutyl propionate
68	Rhodinyl butyrate	149	Methyl butyrate
71	Citronellyl isobutyrate	150	Propyl butyrate
73	Neryl isobutyrate	151	Butyl butyrate
76	Neryl isovalerate	152	<i>n</i> -Amyl butyrate
79	Formic acid	153	Hexyl butyrate
		157	<i>cis</i> -3-Hexenyl butyrate

<sup>1</sup> Specifications under Categories III, IV and V are included in the Report of the Working Group on Specifications (Conference Room Document 2 - Add. 2).

80	Acetaldehyde	158	Isobutyl butyrate
81	Acetic acid	159	Methyl valerate
82	Propyl alcohol	160	Butyl valerate
83	Propionaldehyde	161	Propyl hexanoate
84	Propionic acid	162	Butyl hexanoate
85	Butyl alcohol	163	n-Amyl hexanoate
86	Butyraldehyde	164	Hexyl hexanoate
87	Butyric acid	166	Isobutyl hexanoate
88	Amyl alcohol	167	Methyl heptanoate
89	Valeraldehyde	170	n-Amyl heptanoate
90	Valeric acid	173	Methyl octanoate
91	Hexyl alcohol	174	n-Amyl octanoate
92	Hexanal	175	Hexyl octanoate
93	Hexanoic acid	179	Methyl nonanoate
94	Heptyl alcohol	180	Methyl laurate
95	Heptanal	181	Butyl laurate
96	Heptanoic acid	183	Methyl myristate
97	1-Octanol	185	Methyl isobutyrate
98	Octanal	186	Ethyl isobutyrate
99	Octanoic acid	187	Propyl isobutyrate
100	Nonyl alcohol	188	Butyl isobutyrate
101	Nonanal	189	Hexyl isobutyrate
102	Nonanoic acid	190	Heptyl isobutyrate
103	1-Decanol	191	trans-3-Heptenyl 2-methyl propanoate
104	Decanal	192	Octyl isobutyrate
105	Decanoic acid	193	Dodecyl isobutyrate
106	Undecyl alcohol	194	Isobutyl isobutyrate
107	Undecanal	195	Methyl isovalerate
108	Undecanoic acid	196	Ethyl isovalerate
109	Lauryl alcohol	197	Propyl isovalerate
110	Lauric aldehyde	198	Butyl isovalerate
111	Lauric acid	199	Hexyl 3-methylbutanoate
112	Myristaldehyde	200	Octyl isovalerate
113	Myristic acid	201	Nonyl isovalerate
114	1-Hexadecanol	202	3-Hexenyl 3-methylbutanoate
115	Palmitic acid	203	2-Methylpropyl 3-methylbutyrate
116	Stearic acid	205	Methyl 2-methylbutyrate
117	Propyl formate	206	Ethyl 2-methylbutyrate
118	Butyl formate	207	n-Butyl 2-methylbutyrate
119	n-Amyl formate	208	Hexyl 2-methylbutanoate
120	Hexyl formate	209	Octyl 2-methylbutyrate
122	Octyl formate	212	2-Methylbutyl 2-methylbutyrate
123	cis-3-Hexenyl formate	214	Ethyl 2-methyl pentanoate
125	Methyl acetate	216	Methyl 4-methylvalerate
126	Propyl acetate	217	trans-Anethole
		218	Citric acid

**CATEGORY II (RECOMMENDED FOR ADOPTION AFTER EDITORIAL CHANGES,  
INCLUDING TECHNICAL REVISIONS)**

**Food Additives**

Sodium propionate

In the description, add “or granules” after “crystals”.

**Flavouring agents**

No. Name

58 Geranyl acetate

Under “Solubility in ethanol”, for “1 L”, read “1 mL”

124 Isobutyl formate

Under “Refractive index”, verify third decimal in upper value.

**AMENDMENTS TO THE INTERNATIONAL NUMBERING  
SYSTEM FOR FOOD ADDITIVES**

**Proposals Submitted at Steps 5/8**

<b>INS NUMBER</b>	<b>COMPOUND</b>	<b>TECHNOLOGICAL FUNCTION</b>
425	Konjac Flour	Thickener
960	Stevioside	Sweetener

**Proposals Submitted at Step 3 (Accelerated Adoption)**

<b>INS NUMBER</b>	<b>COMPOUND</b>	<b>TECHNOLOGICAL FUNCTION</b>
938	Argon	Packing Gas
939	Helium	Packing Gas
948	Oxygen	Packing Gas

**DRAFT MAXIMUM LEVEL FOR AFLATOXIN IN MILK  
(At Step 8 of the Procedure)**

AFLATOXIN M<sub>1</sub> IN MILK      0.05µg/kg

**DRAFT MAXIMUM LEVEL AND SAMPLING PLANS FOR TOTAL AFLATOXINS IN  
PEANUTS INTENDED FOR FURTHER PROCESSING  
(At Step 8 of the Procedure)**

**MAXIMUM 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.

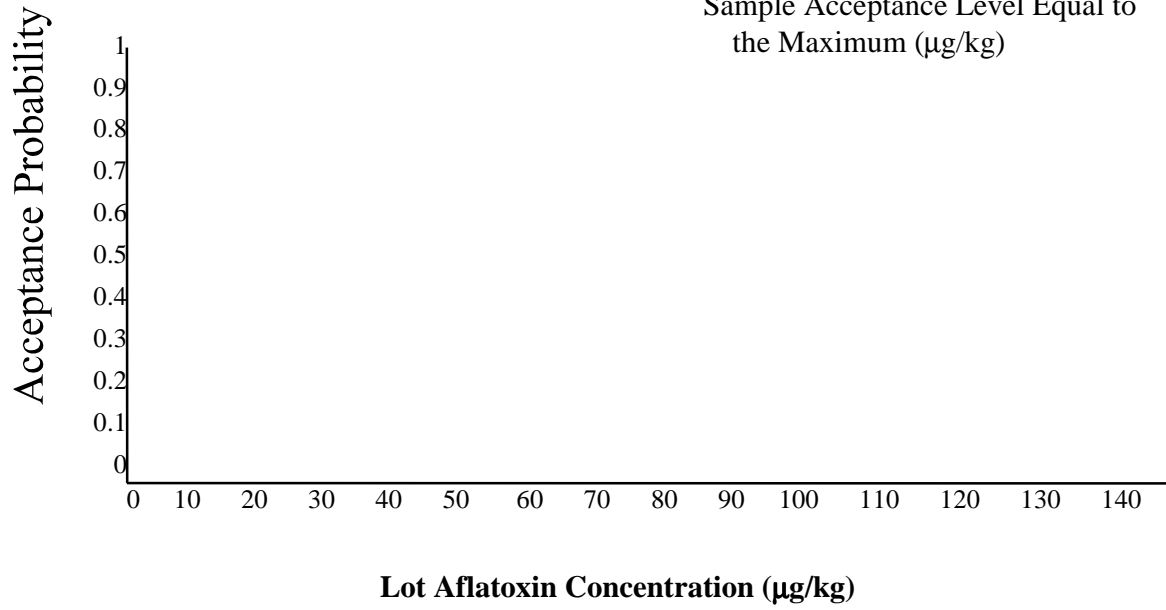
A minimal test portion size of 100 g for comminuted peanuts is recommended. If larger test portions or mills that produce a finer grind are used to prepare the sample, a lower sample preparation variance will result.

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.

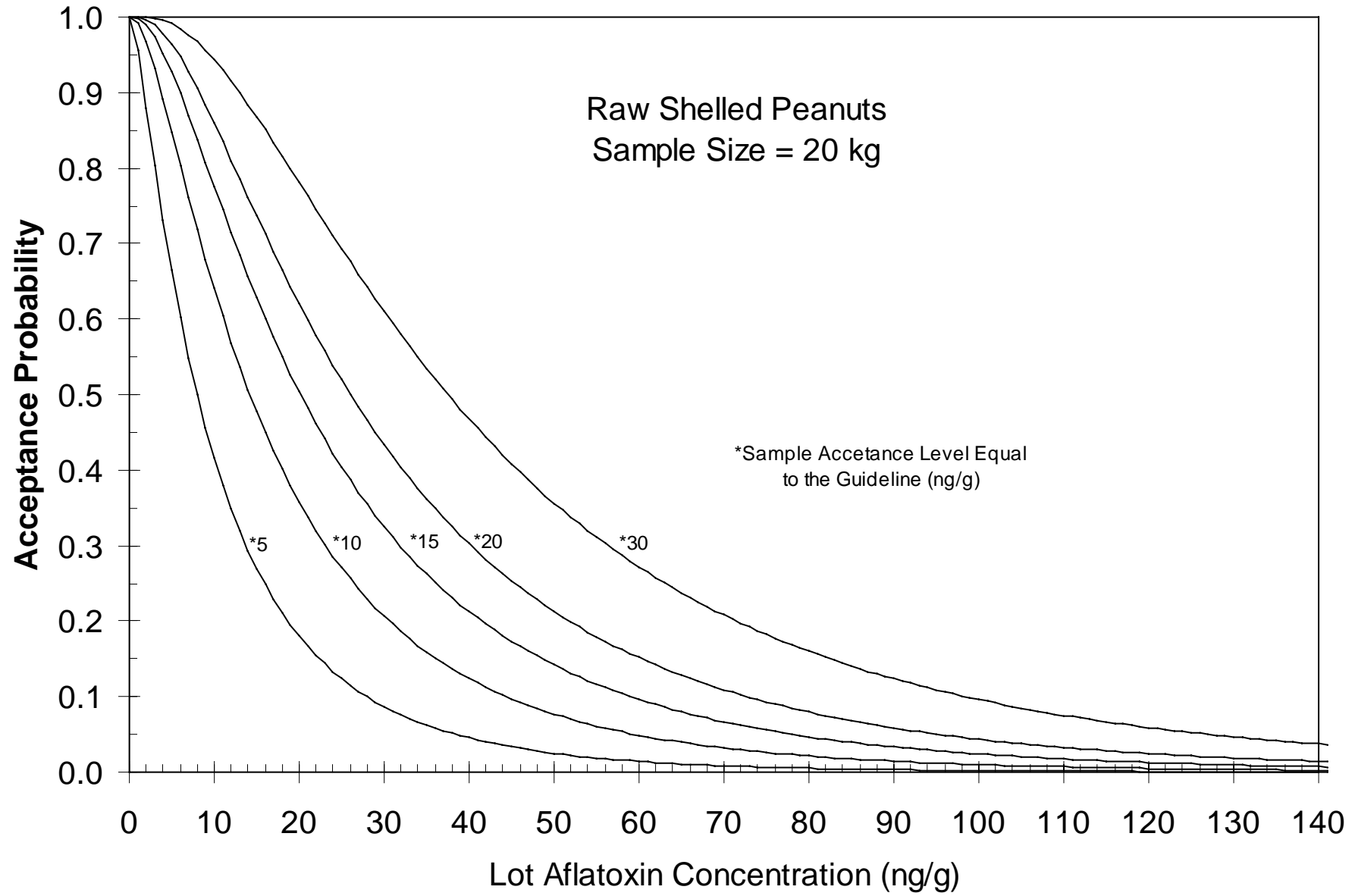
The analytical variability, as measured by the coefficient of variation, ranges from about 9 to 82 percent. The variability associated with TLC methods reflects a compromise in the precision capabilities of the various analytical laboratories. If different analytical methods are used or more aliquots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

- 68 - Raw Shelled Peanuts  
Sample Size=20kg

\*Sample Acceptance Level Equal to  
the Maximum ( $\mu\text{g}/\text{kg}$ )



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.]



**PROPOSED DRAFT AMENDMENT TO THE CODEX REVISED STANDARD  
FOR FOOD GRADE SALT (CODEX STAN 150-1985, Rev. 1)  
(At Step 3 of the Procedure)**

**8. Packaging, Transportation and Storage (New Section 8)**

- 8.1** Iodised salt should be packed in air tight bags of either high density polyethylene (HDPE) or polypropylene (PP) (laminated or non-laminated) or LDPE-lined jute bags (Grade 1803 DW jute bags lined with 150 gauge polyethylene sheet). In many countries, this may require a major switch from conventional packaging materials made of straw or jute. The cost of adding extra iodine to compensate for its loss from cheaper packaging (i.e., straw or jute) must be weighed against the cost of switching to the above expensive packing material.
- 8.2** Bulk packing units should not exceed 50 kg (in accordance with International Labour Organization (ILO) Conventions) to avoid the use of hooks for lifting the bags.
- 8.3** Bags that have already been used for packing other articles such as fertilizers, cement, chemicals, etc. Should not be reused for packing iodised salt.
- 8.4** The distribution network should be streamlined so as to reduce the interval between iodization and consumption of salt.
- 8.5** Iodised salt should not be exposed to rain, excessive humidity or direct sunlight at any stage of storage, transportation or sale.
- 8.6** Bags of iodised salt shall be stored only in covered rooms or “godowns” that have adequate ventilation.
- 8.7** The consumer should be similarly advised to store iodised salt in such a manner as to protect it from direct exposure to moisture, heat and sunlight.



**FOOD ADDITIVES AND CONTAMINANTS PROPOSED FOR  
EVALUATION BY JECFA**

**Food Additives for Toxicological Evaluation  
and Development of Specifications**

argon, helium, and oxygen  
curdlan  
erythritol  
flavouring agents  
sodium sulfate

**Proposed by**

United Kingdom  
Japan  
Australia  
United States  
European Union

**Food Additives for Intake Assessment**

canthaxanthin, annatto extracts, iron oxides, and erythrosine  
flavouring agents: consideration of comparative methods for  
estimating intake (using specific flavouring agents, to be  
identified, as examples)

CCFAC  
Norway

**Contaminants and Naturally Occurring Toxicants**

cadmium  
chloropropanols  
dioxins and dioxin-like PCBs  
ethyl carbamate  
fumonisins  
glycyrrhizic acid  
lead (risk assessment for children)  
methylmercury  
nitrate  
ochratoxin A  
phenylhydrazines, including agaritine  
polycyclic aromatic hydrocarbons  
trichothecenes  
zearalenone

Japan, United States  
United States  
CCFAC  
CCFAC  
IPCS  
Denmark  
United States  
CCFAC  
Netherlands  
United States  
Denmark  
Denmark, Netherlands  
Netherlands  
Sweden

**PROPOSED DRAFT CODE OF PRACTICE FOR SOURCE-DIRECTED MEASURES TO  
REDUCE CONTAMINATION OF FOOD WITH CHEMICALS  
(At Step 3 of the Procedure)**

1. A wide range of source-related measures to reduce chemical contamination of foodstuffs is dealt with in this Code of Practice; some of them lie outside the direct responsibility of the food control authorities. However, the national food control authorities and the Codex Alimentarius should inform the other national authorities and international organizations concerned of potential or actual food contamination problems and encourage them to take appropriate action.

2. Different approaches may be used to try and ensure that the levels of chemical contaminants in foodstuffs are as low as reasonably achievable and never above the maximum levels considered acceptable from the health point of view. Essentially, these approaches consist of a) measures to eliminate or control the source of contamination, b) processing to reduce contaminant levels and, c) measures to identify and separate contaminated food from food fit for human consumption. The contaminated food is then rejected for food use, unless it can be reconditioned and made fit for human consumption. In some cases, a combination of the above approaches must be used, for example, if emissions from a previously uncontrolled source have resulted in environmental pollution with a persistent substance, such as PCBs or mercury.

The advantages of eliminating or controlling food contamination at source, i.e. the **preventive approach**, are that this approach is usually more effective in reducing or eliminating the risk of untoward health effects, requires smaller resources for food control and avoids the rejection of foodstuffs. In many cases chemical contaminants cannot be removed from foodstuffs and there is no feasible way in which a contaminated batch can be made fit for human consumption.

Food production, processing and preparation operations should be analyzed with a view to identifying hazards and assessing the associated risks. This should lead to a determination of critical control points and the establishment of a system to monitor production at these points (i.e. the Hazard Analysis Critical Control Point or "HACCP" approach). It is important that care is exercised throughout the whole production-processing and distribution chain, since food safety and quality in other respects cannot be "inspected into" the product at the end of the chain.

### **ENVIRONMENTAL POLLUTION**

3. Pollution of air, water and soil can result in the contamination of growing food crops, food producing-animals and surface and ground waters used as sources of water for drinking and food production and processing. The relevant national authorities and international organizations should be informed about actual and potential food contamination problems and encouraged to take measures to

- control emissions of pollutants from industry, e.g. the chemical, mining, metal and paper industries, and also from weapons testing.
- control emissions from energy generation (including nuclear plants) and means of transportation.
- control the disposal of solid and liquid domestic and industrial waste, including its deposition on land, disposal of sewage sludge and incineration of municipal waste.

- control the production, sale, use and disposal of certain toxic, environmentally-persistent substances, e.g. organohalogen compounds (PCBs, brominated flame retardants etc.), lead, cadmium and mercury compounds.
- ensure that before new chemicals are introduced onto the market, and especially if they may eventually be released into the environment in significant amounts, they have undergone appropriate testing to show their acceptability from the health and environmental points of view.
- replace toxic environmentally-persistent substances by products which are more acceptable from the health and environmental points of view.

When fishing waters or agricultural land become heavily polluted due to local emissions, it may be necessary to blacklist the areas concerned, i.e. to prohibit the sale of foods derived from these polluted areas and to advise against the consumption of such foods.

## **CHEMICALS USED IN THE PRODUCTION OF RAW AGRICULTURAL COMMODITIES**

4. Properly controlled, pesticides can have a legitimate place in food production and handling by preventing pre- and post-harvest food losses. Pesticides are also used for other purposes, e.g. on non-food crops and in vector control in public health programmes. Control of the use of pesticides for such purposes is important in order to avoid contamination of foodstuffs, soil, drinking water sources and fishing waters. Within the Codex system the question of defining Good Agricultural Practice, which includes pesticide use, is the responsibility of Codex Committee on Pesticide Residues.

5. Drugs are used to prevent, diagnose, alleviate and treat diseases in food-producing animals and for certain other purposes. Strict control on access to and the use of veterinary drugs, including animal feed additives, is the most effective way of ensuring that the levels of veterinary drug residues in foods do not exceed levels considered to be acceptable from the health point of view. In addition, veterinary drugs should be used in such a way that the development of resistant strains of pathogenic bacteria is minimized. Within the Codex system, the definition of such aspects of good veterinary/agricultural practice is the responsibility of the Codex Committee on Residues of Veterinary Drugs in Foods.

6. The use of artificial, phosphate-containing fertilizers in agriculture may result in a gradual increase in the level of cadmium in the soil and thus in foodstuffs. In order to reduce this problem, measures to reduce cadmium levels in such fertilizers should be encouraged. When sludge is used on agricultural land, it should be ensured that the levels of both organic and inorganic contaminants are such that they will not result in unacceptable levels in food or fodder grown on the land or in contamination of drinking water sources.

## **MYCOTOXINS AND OTHER NATURAL TOXICANTS**

7. Because the moulds producing mycotoxins are widely distributed in the environment and other factors which influence mycotoxin production, e.g. temperature and humidity, are difficult or impossible to control, it is impossible to eliminate the possibility of mycotoxin formation in some crops. However, by the use of Good Agricultural Practice, especially during harvesting and subsequent handling (including drying) it is often possible to minimize mycotoxin contamination of animal feed and foodstuffs. FAO has issued a series of documents providing guidance on measures to reduce and control the contamination of food with mycotoxins, especially aflatoxins (e.g. FAO Food and Nutrition Paper 10). A Codex Code of Practice for the reduction of aflatoxin B1 in raw materials and supplemental feeding-stuffs for milk-producing animals has been developed and similar codes of practice aimed at reducing contamination of foods and feeds with other mycotoxins are being developed.

8. The levels of certain natural toxicants in food plants (e.g. erucic acid in rapeseed) may be reduced by plant breeding. It is important to check that plant breeding and genetic modifications produced by other means aimed at improving resistance to disease or to improve crop yields do not result in higher levels of natural toxicants in foods derived from plants (e.g. solanine in potatoes)

## **FOOD CONTACT MATERIALS AND EQUIPMENT**

9. During production, processing, transport, storage, preparation and serving foods may come into contact with a wide range of materials, e.g. metals, plastics, glazed ceramic ware, glass and paper. In some cases, depending on the nature of the food and the material and also on the contact time and temperature, this may result in contamination of the food. Such contamination should be avoided by choosing food contact materials which are appropriate for the food and contact conditions.

10. The use of lead and cadmium and compounds thereof in contact with food should be avoided. Thus the use of these metals as such in contact with food and their use in solder etc. in the manufacture or repair of containers, vessels, pipes, taps and other equipment coming into contact with food and drinking water should be avoided. If lead-containing glazes are used in the production of ceramic foodware, the manufacturing process should be so controlled that leaching of lead from the foodware in contact with food is minimized.

11. Because of their environmental persistence and toxicity, the manufacture and use of PCBs has been prohibited in many countries and the disposal of PCB-containing waste is strictly regulated. The use of PCBs in equipment or products which may inadvertently lead to contamination of food, e.g. in heat-exchangers used in the food industry and in paints used in agricultural silos, should be prohibited.

12. It is important to avoid cross-contamination of foods/food raw materials during transportation. To this end, the containers/vessels/packaging used for foods should provide adequate protection from other cargo items with which they are transported. Furthermore, when the vessels/tanks used for the bulk transportation of edible oils or other liquid foods have previously contained non-food cargoes, they should be rigorously cleaned prior to food transportation. Foods should not be transported in vessels which have immediately previously contained highly toxic products. This question has been discussed by the Codex Committee on Fats and Oils and lists of banned immediate previous cargoes have been prepared by the Federation of Oils, Seeds and Fats Associations (FOSFA International).

## **PROCESSING AIDS**

13. The nature and purity specifications of food processing aids, i.e. materials used in food processing but not intended to become part of the final food product, and the conditions under which they are used should be such that their use does not result in contamination of the food. This applies, for example to extraction solvents, catalysts, filters, flocculation aids and boiler water additives.

## **FOOD ADDITIVES**

14. It is important that the levels of contaminants e.g. heavy metals, in food additives do not exceed the maximum levels laid down in the JECFA/ Codex specifications, especially if high concentrations of the additive are used. Food additives should be used according to the principles laid down in the Codex General Standard on Food Additives.

**CODEX STANDARD FOR NATURAL MINERAL WATERS**

**Section 3.2 Health-Related Limits for Certain Substances**

Antimony	0.005 mg/l
Arsenic	0.05 mg/l, calculated as total As
Barium	1 mg/l
Borate	5 mg/l, calculated as B
Cadmium	0.003 mg/l
Chromium	0.05 mg/l, calculated as total Cr
Copper	1 mg/l
Cyanide	0.07 mg/l
Fluoride	See section 6.3.2 (Additional Labeling Requirements)
Lead	0.01 mg/l
Manganese	2 mg/l
Mercury	0.001 mg/l
Nickel	0.02 mg/l
Nitrate	50 mg/l, calculated as nitrate
Nitrite	0.02 mg/l (set as a quality limit, except for infants)
Selenium	0.05 mg/l