

**codex alimentarius commission**

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

**WORLD HEALTH  
ORGANIZATION**

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**ALINORM 93/12A**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX ALIMENTARIUS COMMISSION**

**Twentieth Session**

**Geneva. 28 June – 7 July 1993**

**REPORT OF THE TWENTY-FIFTH SESSION OF THE  
CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS  
The Hague, The Netherlands, 22–26 March 1993**

**Note:** This report incorporates Codex Circular Letter CL 1993/8-FAC.

**TO:** - Codex Contact Points  
- Interested International Organizations  
- Participants at the 25th Session of the Codex Committee on Food Additives and Contaminants

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

**SUBJECT:** Distribution of the Report of the Twenty-fifth Session of the Codex (ALINORM 93/12A)

The report of the Twenty-fifth Session of the Codex Committee on Food Additives and Contaminants is attached. It will be considered by the Twentieth Session of the Codex Alimentarius Commission to be held in Geneva from 28 June to 7 July 1993.

**PART A: MATTERS FOR ADOPTION BY THE COMMISSION ARISING FROM THE TWENTY-FIFTH SESSION OF THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS**

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

1. Proposed Draft Preamble of the Codex General Standard for Food Additives at Step 5; paras. 27–50 and Appendix II, ALINORM 93/12A.
2. Specifications for the Identity and Purity of Food Additives arising from the 39th Session of JECFA Recommended for Adoption as Codex Advisory Specifications, paras. 59–65 and Appendix V (Categories I and II), ALINORM 93/12A.
3. Proposed Amendments to the International Numbering System, paras. 66–74 and Appendix VI, ALINORM 93/12A.
4. Proposed Draft Provisional Guideline Level for Aflatoxin B<sub>1</sub> in Supplementary Feedingstuffs for Milk Producing Animals at Step 5, paras 116–121 and Appendix VII, ALINORM 93/12A.

Governments wishing to propose amendments or to comment on the above matters or any provisions thereof should do so in writing in conformity with the Procedure for the Elaboration of Worldwide Codex Standards (at Steps 5 and/or 8) (see Codex Alimentarius Procedural Manual, Seventh Edition) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, **not later than 20 June 1993.**

**PART B: REQUEST FOR COMMENTS AND INFORMATION**

1. Methods of Analysis for the Determination of Food Additives in Foods para. 14, ALINORM 93/12A

The Committee agreed to request comments on the need for methods of analysis to determine food additives in foods moving in international trade based on those methods listed in document CX/FA 87/11 - Add. 2 (document available upon request of the Codex Secretariat).

2. Food Categories Related to the Use of Antioxidants and Preservatives

paras. 34, 49 and Appendix III, ALINORM 93/12A

The Committee agreed to request comments on the GSFA food category system with a view towards reflecting global dietary patterns and food categories. The Committee also agreed to request comments on food categories where antioxidants or preservatives are not allowed, or where their use was restricted (see Appendix III), with an indication of levels that should be allowed and their technological justification.

3. Revision of Maximum Levels for Food Additives

- paras. 53–54 and Appendix IV, ALINORM 93/12A

The Committee agreed to request proposals from governments regarding levels of use of those food additives listed in Appendix IV in specific food categories, technological justification and dietary intakes with a view towards considering these proposals for inclusion in the General Standard. The Committee also agreed to request information on whether or not maximum levels for synthetic and vegetable carotenes could be applied as a group to foods.

4. Proposed Amendments to the International Numbering System

- para. 74, ALINORM 93/12A

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

5. Proposed Amendments to the Inventory of Processing Aids

- para. 80, ALINORM 93/12A

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

6. Information and Proposals for Maximum Levels of Aflatoxins in Specific Foodstuffs - para 125, ALINORM 93/12A

The Committee agreed to solicit governments comments and information, especially from exporting countries, on aflatoxins in specific foodstuffs such as peanuts, pistachio nuts and dried figs.

7. Information on Ochratoxin A and Trichothecenes- para. 133, ALINORM 93/12A

The Committee agreed to solicit specific information concerning ochratoxin A and Trichothecenes as outlined in paragraph 133.

8. Cadmium and Lead in Foods- para. 140, ALINORM 93/12A

The Committee decided to gather additional information on cadmium and lead in foods.

9. Information Concerning PCBs, PBBs and Tetrachlorobenzyltoluene in Foods- para. 145, ALINORM 93/12A

The Committee decided to solicit additional information.

10. Information Concerning Dioxins in Foods- para. 150, ALINORM 93/12A

The Committee, while expressing general support for source directed measures, decided to seek additional information.

11. Information Concerning Polycyclic Aromatic Hydrocarbons. Hydrogen Cyanide. Phthalates and Ethyl Carbamate in Foods - paras. 154, 155, 157 and 159, respectively, ALINORM 93/12A

The Committee decided to solicit additional information from governments.

12. Proposals for the Priority Evaluation of Food Additives and Contaminants by JECFA - para. 173 and Appendix VIII, ALINORM 93/12A

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

Governments and international organizations wishing to submit comments and information on the above matters are invited to do so no later than 1 October 1993 as follows: Mrs. C.G.M. Klitsie, Ministry of Agriculture, Nature Management and Fisheries, P.O. Box 20401, 2500 E.K. The Hague, The Netherlands (Telex No. 32040 LAVI NL, Telefax No. 70.347.7552), with a copy to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy.

## **SUMMARY AND CONCLUSIONS**

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

### **MATTERS FOR CONSIDERATION BY THE COMMISSION:**

- Decided that responsibility for the establishment and endorsement of methods of analysis to determine food additives in foods should be transferred to the Codex Committee on Methods of Analysis and Sampling (para. 14);
- Decided to forward the revised Preamble of the Proposed Draft Codex General Standard for Food Additives to the Commission for adoption at Step 5 (para. 49);
- Agreed to advance Specifications for the Identity and Purity of Food Additives arising from the 39th JECFA Session for adoption as Codex Advisory Specifications by the Commission (para. 62);
- Agreed to advance amendments to the International Numbering System to the Commission for endorsement (para. 74);
- Agreed to prepare a proposed draft Codex General Standard for Contaminants (para. 115); and
- Agreed to forward the proposed draft Provisional Guideline Level for Aflatoxin B<sub>1</sub> in Supplementary Feedingstuffs for Milk Producing Animals to the Commission for adoption at Step 5 (para. 121).

### **OTHER MATTERS OF INTEREST TO THE COMMISSION:**

- Agreed to admit a representative of the Press to the meeting (para. 9);
- Agreed to request comments on the need for methods of analysis to determine food additives in foods moving in international trade (para. 14);
- Agreed to request comments on the General Standard for Food Additives food category system with a view towards reflecting global dietary patterns and food categories (para. 34);
- Agreed that Schedules 1, 2 and Annex A of the Proposed Draft Codex General Standard for Food Additives would be revised based on responses to those food categories where antioxidants and preservatives are not allowed or restricted (Appendix III) and circulated for government comment (paras. 48-49);
- Agreed that the consideration of changes resulting from a change in ADI status or other toxicological recommendations would remain as standing agenda items, while specific proposals for establishing levels for additives would be requested of governments (paras. 54 and 102);
- Agreed to continue the revision of the Inventory of Processing Aids through government comments (para. 80);
- Agreed that the delegations of the Netherlands and the United States would prepare a discussion document concerning the possible elaboration of a Registry/Inventory of Additives Produced through Biotechnology for government comments (para. 90);

- Concluded that the safety evaluation of Food Additives Produced through Biotechnology would continue to be conducted by JECFA on a case-by-case basis as required (para. 93);
- Agreed that Sweden would prepare a proposed draft Code of Practice on Source Directed Measures to Reduce Contamination of Foodstuffs (para. 113) and that Switzerland would prepare a paper on the inclusion of a contaminant in the General Standard for Contaminants (para. 112) for the Committee's consideration;
- Agreed that Canada and other delegations would prepare a proposed draft Code of Practice for the Reduction of Aflatoxins in Raw Materials and Supplementary Foodstuffs for Milk Producing Animals (para. 119);
- Agreed to continue requesting information regarding the contamination of various foodstuffs with aflatoxins, while noting that Germany planned to present a report on aflatoxins in pistachio nuts and dried figs for the next CCFAC (para. 125);
- Welcomed the initiative of FAO in preparing for the FAO Consultation on Sampling Plans for Aflatoxins (para. 128);
- Agreed that Sweden would prepare a discussion paper on the aflatoxins ochratoxin A and trichothecene for consideration at its next session (para. 133);
- Agreed that the Codex Committee on Fish and Fishery Products should continue to take responsibility for the elaboration of a list of fish to which the higher guideline level for total mercury applies (para. 136);
- Agreed to continue collecting information on cadmium and lead and that a position paper on lead would be prepared by the delegations of Denmark and Sweden for consideration at the next CCFAC session (para. 140);
- Agreed to collect information on PCBs, PBBs, tetrachlorobenzyltoluene and dioxins in foodstuffs, and that the Netherlands would prepare a position paper on PCBs and dioxins prior to the Committee's next session (paras. 145, 146, 150 and 151);
- Agreed to collect additional information on poly-cyclic aromatic hydrocarbons, hydrogen cyanide, phthalates and ethyl carbamate for consideration at the next CCFAC (paras. 154, 155, 157 and 159);
- Proposed a list of food additives and contaminants for priority evaluation by JECFA (para. 173); and
- Agreed that a procedure would need to be developed for the inclusion of food additives on the priority list on the basis of the implementation of the General Standard (paras. 171-172).

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

1. The Codex Committee on Food Additives and Contaminants held its 25th Session in The Hague, The Netherlands, from 22-26 March 1993, through the courtesy of the Government of The Netherlands. Mrs. C.G.M. Klitsie of The Netherlands acted as Chairman. The Session was attended by 210 participants, representing 33 member countries and 38 international organizations (see Appendix I for the list of participants).

2. The State Secretary for Agriculture, Nature Management and Fisheries, Mr. J.D. Gabor, welcomed everyone to the 25th Session of the Codex Committee on Food Additives and Contaminants and gave a short summary of the history of the Committee while emphasizing the importance of the elaboration of general standards for food additives and for contaminants in foods.

3. The State Secretary also emphasized the importance of the involvement of consumers in the development of food legislation and policy as balanced participation by all parties would result in wider support of the Committee's initiatives.

4. In this regard, the State Secretary urged that within the Codex framework, provisions for the control of food additives and contaminants in foods should only be elaborated if there was an obvious advantage in preventing technical barriers to trade.

5. The State Secretary concluded his remarks by wishing the participants a successful session and a pleasant stay in The Hague.

6. Mr. J.R. Lupien, Director, FAO Food Policy and Nutrition Division, thanked the Government of The Netherlands for its contributions and efforts towards the convening of the Jubilee Twenty-fifth Session of the Codex Committee on Food Additives and Contaminants.

7. Mr. Lupien indicated that FAO was pleased to see the active worldwide participation in the Committee which supported important aspects of Codex work towards the facilitation of international trade in food through the development of Codex standards and other texts based on sound scientific principles of consumer protection. Mr. Lupien also referred to the International Conference on Nutrition as another way to promote better food quality, agriculture and environmental protection throughout the world.

8. Mr. Lupien stressed the increasing importance of this Committee's work, especially as the GATT Uruguay Round of Multilateral Trade Negotiations included provisions that GATT would seek the expert advice and assistance of international organizations such as FAO and Codex within its procedures.

## **ADOPTION OF THE AGENDA (Agenda Item 2)**

9. The Committee adopted the Provisional Agenda (CX/FAC 93/1) as proposed. In order to facilitate discussions concerning the priority evaluation of compounds by JECFA and amendments to the INS system, the Committee appointed informal working groups to discuss these subjects under the Chairmanship of Mr. R. Top (The Netherlands) and Mr. L. Erwin (Australia), respectively. The Committee also agreed to admit a representative of the press (Food Chemical News) to the meeting.

## **APPOINTMENT OF RAPORTEURS (Agenda Item 3)**

10. The Committee agreed with the proposal of the Chairman to appoint Mr. R. Ronk (USA) as rapporteur.

#### **MATTERS OF INTEREST ARISING FROM CODEX COMMITTEES (Agenda Item 4)**

11. The Committee had for its consideration document CX/FAC 93/2 when discussing this agenda item, which summarized matters of interest arising from other Codex Committees. It was noted that most of the items in the working paper were for information only or were scheduled for discussion elsewhere and therefore, the Committee decided to focus its discussions on the following matters.

##### **Methods of Analysis for the Determination of Food Additives in Foods**

12. The Committee was informed that the 10th Session of the Codex Committee on General Principles (CCGP) had discussed the possible overlap in the terms of reference for CCFAC and the Codex Committee on Methods of Analysis and Sampling (CCMAS). The Committee recommended that in relation to the elaboration of methods of analysis for food additives, arrangements should be made to avoid duplication of work (para. 62, ALINORM 93/33).

13. In response to this recommendation, the 18th Session of the Codex Committee on Methods of Analysis and Sampling suggested that as a practical solution, the CCFAC could establish a priority list of a small number of additives requiring action by the CCMAS, as this was a considerable task (paras. 31-33, ALINORM 93/23). The CCMAS recommended that these questions should be brought to the attention of the CCFAC and the Commission for consideration in order to clarify the respective responsibilities of the Committees in question, especially as related to procedural matters.

14. The Committee noted that the list of methods of analysis for food additives (CX/FAC 87/11-Add. 2) prepared for discussion at the 20th CCFAC was quite extensive. Therefore, the Committee decided to request government comments on the need for methods of analysis to determine food additives in foods moving in international trade based on the above document. The Committee decided, however, that responsibility for the establishment and endorsement of methods of analysis for the determination of food additives in foods should be transferred to the CCMAS.

##### **Proposals to amend the General Principles of the Codex Alimentarius**

15. The Committee was informed that the 10th Session of the Codex Committee on General Principles had decided to propose amendments to the General Principles of the Codex Alimentarius that would require application of the "free distribution" acceptance principle to Codex general and commodity standards. The CCGP also agreed that for the time being, this form of acceptance served a useful purpose in providing for transparency of government regulations (paras. 28-34, ALINORM 93/33).

16. In response to a question concerning the compatibility of the principle of "free distribution" with health safeguards, the Committee was informed that the GATT Uruguay Round text on sanitary and phytosanitary measures confirmed countries' rights to establish all measures necessary to protect human, animal and plant health under certain conditions.

#### **CONSIDERATION OF THE SUMMARY REPORT OF THE FORTY-FIRST MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA) (Agenda Item 5)**

17. The Committee had before it the summary report of the Forty-first meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (PCS/93.8), which was held in Geneva from 9 to 18 February 1993. The Committee noted that the full report

would be published by WHO in late 1993. The summary report was introduced by the Joint Secretaries of JECFA, Dr. J.L. Herman (WHO) and Dr. J. Paakkanen (FAO).

18. D-Limonene, maltitol, maltitol syrup and quinine were added to the JECFA agenda after publication of the request for data. Sodium iron EDTA was added to the agenda to provide an assessment of its safety for use in supervised food fortification programmes in populations in which iron deficiency anaemia was endemic. Alginic acid and its salts, carmines, and erythrosine were added for specifications only. Cyclodextrin- $\beta$  was evaluated under the designation  $\beta$ -cyclodextrin, while carbamide was evaluated under the designation urea.

19. JECFA had requested the submission of data by July 1992. However, most of the data were received well after that date and this created problems. The JECFA Secretariat stressed the need for the submission of data at the time requested, as failure to comply with these deadlines could result in the inability of JECFA to review those substances as requested.

20. JECFA considered the points that were raised at the 24th Session of the Codex Committee on Food Additives and Contaminants, including the request for the reconsideration of quinine (paras 12-28, ALINORM 93/12). JECFA concluded that current use levels up to 100 mg/1 (as quinine base) in soft drinks were not of toxicological concern.

21. The contaminants cadmium and lead were reassessed. The assessment of cadmium was based upon WHO Environmental Health Criteria 134, which had been recently published. The models used in that document were similar to the one used by JECFA at its Thirty-third meeting, when the previous provisional tolerable weekly intake (PTWI) of 7  $\mu\text{g}$  per kg body weight was confirmed. At the Forty-first meeting JECFA concluded that data were lacking that would permit a definitive assessment. For example, questions remained about the toxicological significance of the excretion of low molecular weight proteins and the bioavailability of cadmium from different foods. JECFA concluded that the available data supported the present PTWI of 7  $\mu\text{g}$  cadmium per kg body weight, and made recommendations for future research on cadmium which, if performed, should provide a better basis for the future reassessment of cadmium.

22. The assessment of lead was based upon the conclusions of a Task Group organized by the International Programme on Chemical Safety (IPCS) that was held shortly before the JECFA meeting. Based upon the apparent quantitative relationship between exposure to lead and the blood lead concentration in infants and children, JECFA concluded that the previous PTWI of 25  $\mu\text{g}$  per kg body weight for infants and children would result in a blood lead concentration of between 5 and 6  $\mu\text{g}$  per dl. This level was below blood lead concentrations shown to be associated with an effect on intellectual performance. Therefore, JECFA maintained the PTWI of 25  $\mu\text{g}/\text{kg}$  bw for infants and children and extended it to adults, primarily due to the need for pregnant women and women of child-bearing age to restrict their lead intake to protect the fetus. The former PTWI of 50  $\mu\text{g}/\text{kg}$  for adults was withdrawn.

23. Forty-eight substances were considered for specifications for identity and purity. New specifications, some of them tentative, were prepared for six substances that were evaluated for the first time. Twenty-five substances were considered for specifications only, eight of which had been placed in Category III at the 24th Session of the CCFAC (Appendix III, ALINORM 93/12). Several substances that had previously been given tentative specifications were on the agenda, but no data were provided. JECFA

recommended that mechanisms for encouraging the submission of data in such instances should be developed.

24. It was noted that the 39th Session of the Executive Committee had expressed concerns regarding the need for increased resources for JECFA meetings (para. 14, ALINORM 93/3). FAO and WHO responded to this concern by budgeting four JECFA meetings in the 1994-1995 biennium, as opposed to three in recent biennia. Because of the need for the assessment of a large number of veterinary drugs, three meetings on veterinary drugs were scheduled in 1994 and 1995; the next meeting on food additives and contaminants was tentatively scheduled for February 1995. It was anticipated that FAO and WHO would be in a position to hold one JECFA meeting on food additives and contaminants and one JECFA meeting on residues of veterinary drugs in food each year after the 1994-1995 biennium.

25. After the presentations by the Joint Secretaries, questions were raised as to why JECFA specified an acceptable use level for quinine in soft drinks rather than an ADI, and why the statement "normal levels of glucoalkaloids (solanine) in potatoes (20-100 mg per kg of potatoes) were not of toxicological concern" was made instead of allocating an ADI or TDI. Concern was expressed that such recommendations from JECFA could be misunderstood in that levels slightly above these "limits" might be considered to be unsafe. The WHO Joint Secretary of JECFA pointed out that these recommendations should not be seen as representing a new policy, but were made in these cases because of the lack of a history of consumption by humans and quantitative data to enable the establishment of an ADI.

26. The CCFAC stressed the importance for JECFA to establish numerical ADIs and PTWIs wherever possible and to explain its recommendations clearly.

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

27. The Committee had before it CL 1992/13-FAC containing the Proposed Draft Codex General Standard for Food Additives; CL 1992/11-FAC requesting specific comments on the CIAA Food Categorization System; CX/FAC 93/3 containing comments from Czechoslovakia, Israel, Finland, New Zealand, Switzerland, the United Kingdom, the Association of Microbial Food Enzyme Producers and the European Committee on Food Salts; Conference Room Document 4 containing comments from Australia, Canada, Denmark, France, Netherlands, Spain, CIAA, IDF, National Association of Chewing Gum Manufacturers, Grocery Manufacturers of America; Conference Room Document 15 containing the joint Comments of Iceland, Norway and Sweden; Conference Room Document 16 containing the joint Nordic comments of Denmark, Finland, Iceland, Norway and Sweden on the CIAA System; and three unnumbered documents containing comments from Japan, Thailand and the EC.

28. The Report of the Working Group, which had met on 19 March 1993 in The Hague, was presented in Conference Room Document 2. The Working Group was chaired by Mr. Richard Ronk (USA) and Mr. Durward Dodgen (USA) with Mrs. Bente Fabech (Denmark) acting as Rapporteur, and included delegations from Australia, Belgium, Canada, Denmark, Finland, France, Germany, Iceland, Italy, Malaysia, the Netherlands, New Zealand, Norway, the Philippines, Switzerland, Sweden, Thailand, United Kingdom, the United States of America, IOCU, CIAA, EC, ELC, ILSI, IDF, IFAC, IFG, BLL, CEFIC, MARINALG, GPMC, IGMFA, WHO and FAO.

29. The Chairman recalled that the 24th Session of the Committee had agreed that the General Standard for Food Additives (GSFA) would be developed on the basis of a number of principles, as indicated in CL 1992/18-FAC. The Committee agreed that these principles (with slight modifications) should be reflected in the Preamble of the GSFA. The Committee considered each section of the Preamble of the GSFA and agreed to the following revisions.

#### Section 1 - Scope

##### Section 1.1 - Permitted Food Additives

30. This Section was revised to state that the standard applied exclusively to food additives which have been evaluated by JECFA.

##### Section 1.2 - Foods In Which Additives May Be Used

31. This Section was revised to make it clear that the standard would cover all foods "whether or not they have previously been standardized by Codex". The statement that "the food additive provisions of Codex Commodity Standards shall be included in and superseded by the provisions of this Standard" (original Section 4 (a)) was also added to this Section, as was the statement that the "Basis for these provisions are set forth in Annex A" (original Section 4 (c)).

32. The Committee agreed to add a new Section 1.3 - Foods In Which Additives May Not Be Used. This Section stated that those food categories or food items where restricted was covered in this Standard. The Committee considered the list of these food categories (Appendix III), which had been prepared by a small Drafting Group on the basis of previous government comments in reply to CL 1992/11-FAC. The Committee agreed to circulate the list for further comments, with the understanding that this information would be used to complete the Schedules for antioxidants and preservatives of the standard prior to the Committee's 26th Session.

33. A new Section 1.4 Permitted Levels of Use for Food Additives was added to indicate that the levels were based either on existing provisions in Codex Standards or as decided "after subjecting the requested maximum levels to an appropriate method which to determine dietary intake which would verify the compatibility of a proposed maximum level with the ADI".

34. The Delegation of Japan, as supported by other Asian delegations, expressed concern that the GSFA was applicable only to Western dietary patterns and that the food category system should be revised to reflect other cultural dietary patterns. The Committee agreed that the GSFA food category system should be amended to reflect food categories globally and that this information would be requested from governments.

35. The Delegations of Japan and Malaysia expressed the view that the Danish Budget Method (DBM), based on Western dietary habits, was not applicable to Asian countries where consumption patterns were very different. Japan proposed to delete all reference to the DBM from the Standard. Some delegations and the observer of the EC pointed out that the DBM led to an overestimate of intake and questioned whether the Danish Budget Method was appropriate as various evaluation methods were used in other countries. The Chairman reminded the Committee that it had previously agreed to recommend this method as a first screen. The Committee agreed that food intake consumption data should be provided whenever possible, but that the DBM could be used as a screening method when no other method was available. It was also stressed that decisions of the Committee could be revised when actual evaluation data became

available., The Committee therefore agreed to add a statement to the effect that "The Danish Budget Method may be used as a first step in this regard. The submission of actual food consumption data is also to be encouraged." It was also agreed to add a reference to the DBM in a footnote to the Preamble.

#### Section 2 - Definition of Terms used in this Standard

36. This Section was unchanged.

#### Section 3 - General Principles for the Use of Food Additives

37. In Section 3.1 - Safety Evaluation it was decided to refer exclusively to JECFA evaluations. Footnote 5 to this section had the sentence "other appropriate procedures may be used to estimate the TMDI and EDI" added.

38. In Section 3.2 - Technological Need and Justification of Use the Committee agreed to indicate that the use of additives was justified "only when such use has an advantage for, does not present a hazard to the health of and does not mislead the consumer".

39. In Section 3.3 - Good Manufacturing Practice it was agreed to revise paragraph (a) to state that the quantity of additives added to food should be "limited to the lowest possible level necessary to accomplish its desired effect".

40. Section 3.3 (c) was changed to a new Section 3.4 - Specifications for the Identity and Purity of Food Additives.

#### Section 4 - Basis for Establishing Food Additive Provisions for this Standard

41. This Section was deleted as such since the provisions contained in paragraph 4 (a) and (c) had been incorporated in the Scope Section (see para. 31), and paragraph 4 (b) was moved to a new Section 6 (see para. 44). The following sections were renumbered accordingly in the revised draft of the Preamble of the GSFA, as contained in Appendix II.

#### Section 5 - Carry-Over of Food Additives into Foods

42. Some delegations were of the opinion that it would not be realistic to require compliance with the provisions in Section 5 with respect to the carry-over principle, especially since there was an increasing number of composite foods. Also, additives present in one of the ingredients of a composite food often had a functional effect in the end-product. These Delegations were of the opinion that paragraph (d) in Section 5.1 should be deleted. The Committee agreed that the whole Section would be put in square brackets for additional comments on the carryover principle, and the Section was renumbered as Section 4.

#### Section 6 - Format of the Standard

43. The Committee agreed to delete the reference to non-standardized foods in this Section and to indicate that maximum levels for food additives were set on the product as consumed. All provisions of this Section were re-numbered as Section 5.

44. The Committee agreed to add a new Section 6. Review and Revision of the Standard, to indicate that the provisions of the Standard would be revised on a regular basis and following any revision of the ADIs, and based on technological need and justification for use.

## **SCHEDULES**

45. The Committee agreed that all reference to non-standardized foods should be deleted from the Headings of both Schedules I and II, as the Standard was applicable to all foods. It was further agreed that the request for comments on the list of foods in which the use of antioxidants and preservatives were not allowed or restricted (Appendix III) would also request governments to indicate the levels that should be allowed when additives were used in food groups or food items, and their technological justification. Schedules 1 and 2 would be revised in the light of these comments and circulated for comments at Step 3 prior to the next session of the Committee.

46. It was further agreed to modify the presentation of Schedules 1 and 2 by replacing the columns "Maximum Levels and Conditions of Use" with columns for "Food Categories", "Maximum Levels" and "Conditions of Use".

### **Annex A - Guidelines for the Use of Food Additives in Non-Standardized Foods**

47. The Committee agreed to delete reference to non-standardized foods in the Guidelines which were retained as an integral part of the Standard, and to circulate them for comments at Step 3. It was further agreed to request governments to indicate the technological need for the use of additives proposed and the basis for the estimation of dietary intake.

## **STATUS OF THE PROPOSED DRAFT CODEX GENERAL STANDARD FOR FOOD ADDITIVES**

48. The Committee agreed to revise Schedules 1 and 2 using the information compiled in Appendix III based on government comments on food categories where antioxidants and preservatives were not allowed, or where their use was restricted. Governments would also be requested to indicate the levels that should be allowed when additives were used in food groups or food items, and their technological justification.

49. The Committee decided to forward the revised Preamble of the proposed draft General Codex Standard on Food Additives (Appendix II) to the 20th Session of the Commission for adoption at Step 5. The Committee also agreed that Schedules 1, 2 and Annex A (Guidelines) contained in CL 1992/18-FAC would be revised (see paras. 45-47) and circulated for comments at Step 3 prior to the next session of the Committee.

50. The Committee reinstated the Working Group (with the addition of the Delegations of Austria and Japan) under the Chairmanship of the United States and expressed its appreciation to this Delegation for the progress achieved since the Committee's last session.

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

51. The Committee had before it documents CX/FAC 93/4 and Conference Room Document 1 when discussing this agenda item, which addressed the endorsement of maximum levels for food additives in Codex standards and action required as a result of changes in ADI status arising from the 41st JECFA, respectively.

52. The Committee noted that the new horizontal approach of Codex had resulted in a significant reduction of requests for endorsement from Commodity Committees and therefore, the Committee did not review any new proposals from Commodity Committees for endorsement at the current meeting.

53. In discussing action required as a result of changes in ADI status, the JECFA Secretariat explained that at present the three different categories of carotenes (i.e., synthetic, vegetable and algae) each had their own specifications and applications. In view of this clarification, the Committee agreed that governments should be requested to provide information as to whether or not maximum levels for synthetic and vegetable carotenes as a group could be applied to foods, as it was noted that carotenes derived from algae were chemically different and had no ADI allocated.

54. The Committee, while agreeing with the Secretariat's proposals concerning action required as a result of changes in ADI status (Conference Room Document 1), decided to append the document to the report (see Appendix IV) for action by the Secretariat/Chairman of the relevant Codex Commodity Committees concerned. More importantly, the Committee agreed to request proposals from governments regarding levels of use in specific food categories, technological justification and dietary intake for those additives listed with a view towards considering these proposals for inclusion in the general standard. The Committee also agreed that the consideration of changes resulting from a change in ADI status would remain a standing agenda item.

#### **CONSIDERATION OF SPECIFICATIONS NOT ADOPTED AS CODEX ADVISORY SPECIFICATIONS (Agenda Item 8 (a))**

55. The Committee had before it documents CX/FAC 93/5 and Conference Room Documents 14 and 22 when discussing this agenda item, which summarized government comments submitted by Canada, Denmark, Finland, France, The Netherlands, Spain, Thailand and the United Kingdom in response to CL 1992/8-FAC. The Committee also considered the Report of the Working Group on Specifications, as summarized in Conference Room Document 3. The Working Group was chaired by Dr. D.F. Dodgen, while Mrs. H. Wallin (Finland) acted as Rapporteur.

56. The Committee recalled that at its previous session government comments were requested on the list of specifications contained in Appendix VII of ALINORM 93/12 as to whether or not these substances were currently used as food additives.

57. The Committee agreed that specifications for the following substances not be considered for adoption as Codex Advisory Specifications, as there was no information submitted on the present use of these substances as food additives: Distearyl thiodipropionate, Dulcin, Pepsin (avian) and Potassium chlorate. In addition, as Sodium caseinate was generally considered as a food by most Codex member governments, this substance was not proposed for consideration as a Codex Advisory Specification.

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

#### **CONSIDERATION OF SPECIFICATIONS ARISING FROM THE 39TH JECFA MEETING (Agenda Item 8 (b))**

59. The Working Group reviewed the specifications prepared by the 39th Meeting of JECFA which were published in FAO Food and Nutrition Paper 52 (1992) as Addendum I to the JECFA Compendium of Food Additive Specifications, except those designated by JECFA as "tentative" and those re-evaluated by the 41st JECFA Meeting. The Working Group also considered the comments regarding these specifications received in response to CL 1992/13-FAC.



60. The Committee praised the efforts of JECFA in publishing the JECFA Compendium of Food Additive Specifications in bound form, and noted that revisions sent to the JECFA Secretariat would be considered when the Compendium was revised in the future.

61. During the Working Group review, the specifications were divided into five Categories: I - Recommended for adoption as Codex Advisory Specifications without changes; II - Recommended for adoption with editorial or other minor changes; III - Referred back to JECFA for further review because of clarifications for necessary substantive changes; IV - Substances on the agenda of the recent (41st) JECFA Meeting and V - Substances designated by JECFA as "tentative".

62. The Committee agreed to refer the 16 substances in Categories I and II (see Appendix V) to the Commission for adoption as Codex Advisory Specifications. It was also noted that comments received on specifications assigned to Categories IV and V would be forwarded to JECFA along with those in Category III.

63. The Committee agreed to forward to JECFA for consideration general comments received from Poland and Sweden concerning limits of heavy metals. In addition, the Committee stressed that requests to JECFA to change certain criteria of the specifications should be accompanied by appropriate documentation in support of the proposed revisions.

64. The Committee noted the suggestion of the representative of the International Federation of Glucose Industries (IFG) that JECFA should make available its agenda and call for data to international organizations which could help make certain that JECFA received the available data.

65. The Committee expressed its appreciation for the efforts of the Working Group and reinstated it under the Chairmanship of Dr. D.F. Dodgen (USA). The following countries and organizations were invited to participate in the reinstated group: AMFEB, CEFIC, Denmark, Finland, Germany, IFAC, IFG, IPPA, Italy, Malaysia, MARINALG/BIOPOLYMER, Philippines, Switzerland, Thailand, UK and USA.

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

66. The Committee had for its consideration document CX/FAC 93/6, containing government comments in reply to CL 1992/8-FAC from Finland, Malaysia and Spain. The report of the informal Working Group which had met during the session was presented by the Chairman, Mr. L. Erwin (Australia).

67. The Committee agreed not to recommend for inclusion in the INS flavours caffeine, quinine hydrochloride and quinine sulphate as flavours were not subject to numerical identification.

68. The Committee considered the recommendation of the Working Group to allocate number 307a to tocopherol acetate (antioxidant) while retaining the current identification of tocopherol (307). It was pointed out that this decision, entailing a significant change in the approach to the INS System, was justified on the grounds that a change in the identification number for tocopherol would both represent a heavy burden on industry and result in consumer confusion. The view was expressed that tocopherol acetate was not an antioxidant but a nutrient (vitamin E). The Chairman recalled that any substance used as a food additive by one or more countries was eligible to be numbered according to the INS System, but that this did not result in any obligation for other

countries to use it as a food additive. The Committee decided that information should be provided by Finland to allow for the addition of tocopherol acetate as an antioxidant in the INS system under number 307a in the future.

69. The Committee agreed that it was not necessary to allocate different numbers to natural and synthetic carotenes, as this would entail the revision of all previously assigned INS numbers for similar food additive groups.

70. The Committee was informed that the Working Group had proposed to identify Processed Euchemia Seaweed (PES) as number 426 because JECFA had evaluated it at its 41st Session. The Delegation of the Philippines indicated that toxicological and technological data had been submitted to JECFA on PES and that the number allocated should reflect its similarity with carrageenan. Several countries and the Observer of Harinalg International pointed out that the ADI of PES, as well as its technological properties, were different from those of carrageenan. In reply to a question of the Delegation of the Philippines on the JECFA Guidelines for the naming of food additives, the JECFA Secretariat recalled that these Guidelines applied when descriptive names were already in common use for a specific additive, but that this was not the case with PES. The Committee agreed to assign the INS number 426 to PES and noted that governments would have the opportunity for comments on this point as well as other additions to the INS in the future, as amendments to the system would be a standing agenda item.

71. Some delegations questioned the use ascribed to 927b urea (carbamide) as a flour treatment agent, and pointed out that it was used only as a texturizer in chewing-gum; the Committee agreed to delete the reference to flour treatment.

72. The Committee agreed that as sodium iron EDTA was regarded as a nutrient and not as an additive in the countries where it was used, no number should be allocated to it. The Committee agreed that there was no need to allocate a number to konjac flour because it was considered an ingredient as opposed to a food additive in the countries where it was used.

73. The Committee also agreed to the following amendments to the INS:

275	calcium	behenatepreservative
468	croscarmellose	stabilizer, binder
642	lysine hydrochloride	flavour enhancer
459	beta-cyclodextrin	Stabilizer, binder

74. The Committee agreed to reinstate the Working Group at its next session and to include consideration of the INS as a standing item on its agenda. It also agreed that the above proposed amendments would be forwarded to the Commission for adoption at its 20th Session. The proposed amendments to the International Numbering System are attached to the present report as Appendix VI.

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

75. The Delegation of the United States presented the comments of governments in reply to CL 1992/8-FAC as contained in document CX/FAC 93/7 (France, Malaysia, Spain) and Conference Room Document 5 (Institut Européen des Industries de la Gomme de Caroube - INEC).

76. The Committee had an exchange of views on whether or not to establish separate lists for substances used as processing aids only and another list for

substances used both as processing aids and food additives. The Committee decided not to change the current presentation of the Inventory, as included in Volume I of the revised Codex Alimentarius, and as decided at previous sessions of the Committee.

77. The Committee agreed to the suggestion that countries should state the exact purpose served by new processing aids when they proposed their inclusion in the Inventory.

78. The Committee agreed to replace the term "sugar alcohols" with "polyols", and "starch syrup" with "glucose syrup". It further agreed to include sulphuric acid as a peeling agent for locust bean seeds; to the addition of glucono-delta-lactone for the pre-acidification of milk in preparing curds for cheese making; beta-cyclodextrine as a flavour adjunct and cholesterol extracting agent in butter.

79. The Committee also agreed to add:

Clarifying agents

Active carbon

Sugars/oils

Fuller's earth

Oils

Plant Derived Preparations

Lipases

Interesterification of fats and oils

Solvents. Extraction and Processing

Citric acid

Phosphoric acid

Fats and Oils

Sodium hydroxide

Others (wetting agents)

Magnesium sulphate

80. The Committee agreed to continue the revision of the Inventory on the basis of government comments submitted before its next session, as this subject would remain as a standing agenda item. The Chairman thanked the Delegation of the USA for their contribution and the Committee welcomed the Delegation of Germany taking over responsibility for maintenance and revision of the Inventory of Processing Aids in the future.

**EVALUATION OF FOOD ADDITIVES PRODUCED BY MODERN BIOTECHNOLOGY**  
**(Agenda Item 11)**

81. The Committee had before it CX/FAC 93/8 and Conference Room Documents 19 and 23 containing the comments on CL 1992/8-FAC received from Canada, the United Kingdom, The Netherlands and Japan.

82. The Committee was reminded of its previous discussions concerning this issue, whereby it was decided to gather additional information from governments on the evaluation of food additives produced through modern biotechnology (paras. 138-142, ALINORM 93/12). The Committee noted that this discussion was based on a Commission request for "General Subject" Committees to discuss issues related to biotechnology within the context of their terms of reference.

83. It was noted that data required for the safety evaluation of these substances would depend on the type of product (i.e., pure chemical substance, enzyme preparation or whole organism) and would include details on other issues such as molecular biology, history of donor and receptor organism and purity criteria. It was also stated that a food

additive produced by modern biotechnology therefore required testing on a case by case basis, needed to be listed somewhere within Codex, and needed to be reviewed for specifications if necessary. It was stressed that these substances were not inherently' less safe than other food additives.

84. The Committee agreed to restrict its work to food additives, processing aids and flavourings and that Codex should harmonize different national safety evaluation procedures for these products.

85. However, the Delegation of Japan pointed out that Codex action to harmonize evaluation systems would be premature and, for the time being, each country might use the report of the Joint FAO/WHO Consultation on Strategies for Assessing the Safety of Foods Produced By Biotechnology (1991; ISBN 92-4-156145-9) as a reference. The WHO representative also informed the Committee that as a follow-up to the above Consultation, WHO, in collaboration with the National Food Agency of Denmark, was considering the convening of a Workshop on Health Aspects of the Use of Marker Genes in Plants and Possibilities for their Use in Identification and Control of Genetically Modified Plants, tentatively scheduled to be held in Copenhagen from 21-24 September 1993. It was noted that health and safety aspects, as well as regulatory control instruments, would be discussed.

86. The Delegation of the United States informed the Committee that a Statement of Policy for New Plant Varieties, including traditional breeding, had been issued by the US Food and Drug Administration. It was noted that the Statement provided guidance to industry about safety evaluations required and how and when to involve government agencies. The Statement was based on principles elaborated by the Organization for Economic Cooperation and Development and as established at the Joint FAO/WHO Consultation. The Delegation of Norway also informed the Committee that the Nordic States had issued a publication on the safety aspects of foods originating from biotechnology.

87. The representative of the EC mentioned that an EC Directive on Novel Foods was in preparation. It was stated that this proposal provided for an approval procedure for novel foods or foods prepared by novel processes, including biotechnology. Food additives produced by novel techniques or biotechnology would be considered as a new additive requiring full evaluation by the EC Scientific Committee for Food.

88. The representative of the IOCU recognized the potential benefits of biotechnology and stated that the IOCU would consider food additives produced under biotechnology on a case by case basis. It was also noted that consumers may have different views on biotechnology based on ethical considerations or for other reasons and in this regard, the need for clear labelling as well as a Codex register/inventory for biotechnology products was stressed. Both aspects would help to improve consumer acceptance of and confidence in biotechnology.

89. In response to a statement that the evaluation of the safety of food additives produced by biotechnology was exclusively a JECFA responsibility, the Delegation of Japan questioned whether JECFA was sufficiently equipped to deal with specific biotechnological issues. The JECFA Secretariat pointed out that JECFA had sufficient flexibility to invite the experts needed for these evaluations. The Committee requested JECFA to invite those experts necessary to cover all safety aspects of biotechnological products.

90. The Delegation of the United States expressed concern about what was meant by a Codex register/inventory and made the point that there was no registry system within Codex. The Committee agreed that the Netherlands and the United States would identify what was meant by a registry/inventory with the understanding that the document would be circulated for government comments prior to the 26th CCFAC.

91. The Delegation of Japan urged the USA and The Netherlands to take account of the report of the Joint FAO/WHO Consultation as well as the report of the Organization of Economic Cooperation and Development.

92. In response to a question concerning the labelling of food additives produced through biotechnology, the Secretariat stated that labelling was exclusively within the competence of the Codex Committee on Food Labelling.

93. The Committee concluded that the safety evaluation of food additives produced through biotechnology would continue to be done by JECFA on a case by case basis as required by the prioritization of substances for JECFA review. It was further agreed that the Commission would be advised of this conclusion.

#### **THE JOINT UNEP/FAO/WHO FOOD CONTAMINATION MONITORING AND ASSESSMENT PROGRAMME (GEMS/FOOD) (Agenda Item 12)**

94. The Committee had before it document CX/FAC 93/9, which reported on the progress of GEMS/Food in providing global information on levels and trends of contaminants in food, their contribution to the total diet and their significance with regard to public health. During 1992, two important GEMS/Food documents were issued concerning monitoring data collected by the programme through 1988, including "The Contamination of Food" (UNEP/GEMS Environmental Library No. 5, UNEP, Nairobi, 1992) for general distribution and "Assessment of the Dietary Intake of Chemical Contaminants" (WHO/HPP/FOS/92.4) mainly intended for health professionals. In addition, it was stated that an assessment document on aflatoxin data collected within and outside GEMS/Food would be published during 1993.

95. Technical cooperation, mainly with GEMS/Food participating institutions in developing countries, continued during 1992. Analytical Quality Assurance (AQA) exercises for aflatoxin, organochlorine compounds and heavy metals (lead, mercury and cadmium) were carried out. Support in the form of reference standards was provided to participating countries. In addition, sub-regional training courses in Sao Paulo, Brazil and Guatemala were sponsored by GEMS/Food on the analysis of organochlorine pesticide residues in food.

96. In Europe, GEMS/Food had been greatly expanded by the establishment of GEMS/Food-Euro which was administered by the WHO European Centre for Environment and Health in Rome, and coordinated by the GEMS/Food Collaborating Centre for Food Contamination Monitoring in Berlin. It was anticipated that GEMS/Food-Euro would contribute significantly to both the quantity and quality of data reported to GEMS/Food in the future.

97. The Committee expressed appreciation to GEMS/Food for providing the report.

#### **ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR CONTAMINANTS IN CODEX STANDARDS (Agenda Item 13)**

98. The Committee had before it documents CX/FAC 93/10 and Conference Room Document 1 when discussing this agenda item, which addressed the endorsement of

maximum levels for contaminants in Codex standards and action required as a result of changes in PTWI status arising from the 41st JECFA, respectively.

99. The Committee noted that the new horizontal approach of Codex resulted in a significant reduction of requests for endorsement from Commodity Committees and therefore, the Committee did not review any new proposals for endorsement at the current meeting.

100. In discussing action required as a result of changes in PTWI, the Committee agreed with the Secretariat's proposals concerning action required as a result of changes in PTWI status of lead and cadmium. JECFA maintained the PTWI of 7 µg per kg body weight for cadmium and therefore no action was required. However, the PTWI for lead was reduced from 50 to 25 µg/kg body weight for adults and maintained at 25 µg/kg for children and infants body weight. The Committee agreed that all the Commodity Committees affected would be informed of the change in PTWI.

101. In reference to chloropropanols, 3-chloro-1,2 propanediol and 1,3 dichloro-2-propanol the Committee noted that JECFA recommended keeping levels of this contaminant in hydrolysed vegetable proteins to the lowest level technologically achievable. In view of this carcinogenicity of chloropropanols and the JECFA recommendation, the Committee agreed that the Chairman/Secretariat of the Codex Committee on Soups and Broths should be informed accordingly. The observer of the AIBP indicated that data concerning this contaminant would be brought forward for consideration by the CCFAC at its next session.

102. The Committee decided to append the revised Conference Room Document to its report (see Appendix IV) for action by the Secretariat/Chairman of relevant Codex Commodity Committees. The Committee also agreed that consideration of changes in PTWI status in contaminants would remain as a standing agenda item.

#### **PROPOSED DRAFT PROCEDURES FOR ESTABLISHING A GENERAL STANDARD FOR CONTAMINANTS IN FOODS (Agenda Item 14)**

103. The Committee had before it document CX/FAC 93/11, prepared by the Delegations of Denmark and The Netherlands, which presented a proposed draft procedure for Establishing a General Standard for Contaminants in Foods. The observer of the EC also provided information on a recently elaborated procedure which outlined a procedure for establishing maximum levels for contaminants in foods.

104. The Chairman restated the principles that formed the basis of the proposed draft procedure, as decided at the last session of the CCFAC (paras. 64-78, ALINORM 93/12). The authors of the document summarized its contents on a section by section basis.

105. A general discussion on the principles of the proposed draft procedure revealed a number of areas which required further clarification and study.

106. In this regard, the Committee agreed that the principle aim of the document was consumer protection, while priorities on future action by the Committee would be set on the basis of preventing technical barriers to trade.

107. The Committee agreed that when information on intake of contaminants from sources other than food was available, this information should be taken into consideration. However, in making this decision, the Committee also agreed that no action would be taken to gather information on intake of contaminants from sources other than food.

108. The Committee agreed that a reference to animal feedingstuffs should also be included in the scope section of the General Standard for Contaminants in Food (GSC) and that it was not appropriate at present to include inherent naturally occurring toxicants in the proposed draft procedure of a General Standard for Contaminants. It was also agreed that action would be taken by the Committee on inherent naturally occurring toxicants on a case by case basis as required. The Committee agreed that the level of a food contaminant should always be as low as reasonably achievable, and decided to include such a statement in the beginning of the GSC.

109. In order to reach maximum transparency, the Committee agreed, for the time being, to establish maximum limits wherever possible. It was noted that problems could arise from national deviations from Codex maximum limits in relation to national control. In case of future problems, the Committee agreed that other solutions should be taken into consideration.

110. The Delegation of Japan stressed the need for a careful examination of the applicability of the Danish Budget Method for different regional dietary patterns. It was suggested that the GEMS/Food Programme and the UNEP/FAO/WHO Guidelines for Predicting Dietary Intake of Pesticides should be included as alternative first intake screening methods. It was agreed that references to these documents should be included in the text of the general standard.

111. The Committee agreed to the General Principles (Section V) of CX/FAC 93/11 (pages 16-18) which outlined a procedure for Establishing a General Standard for Contaminants in Foods and to the recommendations listed on page 19, paragraphs 31-37.

112. The Committee agreed that notes should be prepared addressing the following four questions as stated on page 10 of CX/FAC 93/11 when a government requested a contaminant be included in the General Standard:

1. Are toxicological information, analytical data and intake data readily available?
2. Are there indications of potential health problems?
3. Is there information about barriers to international trade in foods or raw materials used in food production?
4. Is there information about technological possibilities or economic problems related to any initiatives to reduce exposure?

The Delegation of Switzerland agreed to prepare such a note using one contaminant as an example in order to make the procedure clear.

113. The Committee agreed that Sweden would elaborate a Code of Practice which contained recommendations on source directed measures to reduce contamination of foodstuffs with heavy metals, organochloride compounds and other contaminants, and inherent naturally occurring toxicants.

114. The Committee agreed that the Delegations of Denmark and The Netherlands would prepare a proposed draft Codex General Standard for Contaminants in Foods, consistent with the above comments and recommendations. The Committee agreed to send this document for government comments at Step 3 by at the earliest opportunity. Governments were also invited to send written comments on the current document (CX/FAC 93/11) to the Delegation of Denmark. The Committee was informed that the Commission would be notified of this procedure.

115. The Committee thanked Mr. Berg (Denmark) and Mr. Kloet (The Netherlands) for their outstanding efforts in preparing the documents for its consideration.

### **MYCOTOXINS IN FOOD AND FEED (Agenda Item 15)**

#### **PROPOSED DRAFT GUIDELINE LEVEL FOR AFLATOXIN B<sub>1</sub> IN SUPPLEMENTARY FEEDINGSTUFFS FOR MILK PRODUCING ANIMALS (Agenda Item 15 (a))**

116. The Committee had before it government comments in reply to CL 1992/8-FAC, as presented in CX/FAC 93/12-Part I (Canada, Denmark, Spain, United Kingdom), Conference Room Documents 6 (Norway and Sweden), 20 (Italy), 24 (Thailand) and 29 (The Netherlands).

117. The Delegations of Thailand and the Philippines informed the Committee that their countries were implementing programmes for the reduction of contamination by aflatoxins in raw materials used for feeds; however, the level proposed by this Committee was too low and could not be applied in view of prevailing climatic and geographic conditions and difficulties encountered at the harvest and post-harvest stages. Some countries indicated that they did not regard the establishment of a level for aflatoxin B<sub>1</sub> in supplementary feedingstuffs for milk producing animals as a major issue, as the level for aflatoxin M<sub>1</sub> in milk was of primary public health concern. Some delegations expressed the view that the methods currently used might not be reliable enough and have great variability in the detection of low levels of aflatoxins. It was also questioned whether supplementary feeding stuffs were actually traded as such and if the establishment of a level for this commodity was warranted. The Delegation of Egypt, among other delegations, indicated that they imported or exported primarily raw materials which were processed at the country level for the preparation of supplementary feedingstuffs, and that this issue could be dealt with by national authorities with regard to consumer protection.

118. The Committee was informed that two official EC methods for the determination of aflatoxin B<sub>1</sub> in feeds had been established following interlaboratory collaborative studies in member countries.

119. It was suggested that the contamination of foodstuffs could be better addressed through Codes of Practice for production and manufacture of feeds rather than by setting levels in the end-product. The Committee agreed to consider the establishment of a Code of Practice to reduce contamination in raw materials and supplementary feedingstuffs for milk-producing animals. The Delegation of Canada agreed to prepare a draft Code of Practice with the cooperation of the Delegations of The Netherlands, Sweden and the United States, as well as other interested delegations.

120. The Committee agreed to forward the provisional level of [5 µg/kg] of Aflatoxin B<sub>1</sub> in Supplementary Feedingstuffs for Milk Producing Animals in square brackets to Step 5, with the understanding that the level did not apply to individual feed components. The Delegations of Malaysia, the Philippines and Thailand reserved their position on this decision.

#### **Status of the Proposed Draft Guideline Level for Aflatoxin B<sub>1</sub> in Supplementary Feedingstuffs for Milk Producing Animals**

121. The Committee agreed to forward the Proposed Draft Provisional Guideline Level to the 20th Session of the Commission for adoption at Step 5, with the understanding that the accelerated elaboration procedure would not be initiated. The Guideline Level is attached to the present report as Appendix VII.



**PROPOSED DRAFT MAXIMUM LEVELS FOR AFLATOXINS IN SPECIFIC FOODSTUFFS (Agenda Item 15 (b))**

122. The Committee had before it government comments in reply to CL 1992/8-FAC, as presented in CX/FAC 93/12-Part II (Canada, Denmark, Finland, Poland, United Kingdom) and Conference Room Documents 7 (France, Germany, Norway, Sweden), 20 (Italy), 25 (Thailand) and 29 (The Netherlands). The Committee was also informed of the discussions held at the 10th Session of the Coordinating Committee for Africa, where concern was expressed over the CCFAC decision to discontinue the consideration of a level for Aflatoxin M<sub>1</sub> in milk destined for baby foods (para. 11, ALINORM 93/28).

123. Several delegations commented on the surveys carried out in their countries on the contamination of various commodities by aflatoxins. Some delegations further indicated that their national legislation set maximum levels for aflatoxins in foods for direct consumption, and in some cases, set guideline levels for commodities destined for further processing. Other delegations stated they were currently considering the establishment of such levels.

124. The Delegation of Egypt indicated that some exporting and/or importing developing countries had difficulties with international trade foodstuffs because they lacked resources to carry out sampling and analysis.

125. The Committee agreed to continue requesting information from governments, especially exporting countries, regarding the contamination of peanuts, pistachio nuts and dried figs, and stressed that this information should make a clear distinction between regular monitoring (surveillance) and more specific sampling to address an emergency situation or solve a compliance question. The Delegation of Germany planned to present a report on the issues involving pistachio nuts and dried figs for consideration at the next meeting.

**SAMPLING PLANS FOR AFLATOXINS (Agenda Item 15 (c))**

126. The Representative of FAO, Dr. Paakkanen, informed the Committee about the forthcoming Technical Consultation on Aflatoxin Sampling Plans, scheduled to be held at FAO Headquarters in Rome from 3-6 May 1993. He recalled that the 24th Session of CCFAC had expressed its support for such a consultation and provided the terms of reference for the Consultation (para 98, ALINORM 93/12). The 39th Session of the Executive Committee had also approved this initiative (paras. 70-71, ALINORM 93/3). It reported that the commodities concerned would be limited to peanuts and corn, and that the terms of reference for the Consultation, based on the recommendations of the CCFAC, were as follows:

- to identify the type of peanut and corn commodities moving in international trade and, most likely to be contaminated by aflatoxins, and specify their characteristics;
- to establish the mathematical models for the distribution of aflatoxins in these commodities;
- to establish Guidelines for the development of sampling plans for aflatoxin analysis;
- to recommend sampling plans for export control as well as import control;
- to evaluate the effects of sample collection and sample preparation on the results of the analysis; and

- to indicate the percentage of the commodity which should be rejected as a consequence of the application of the proposed sampling plan.

127. The Committee was informed that 15 internationally recognized experts had been invited with a responsibility to provide independent advice to FAO as technical and scientific experts, and would not represent their governments or institutions.

128. The Committee welcomed the initiative of FAO in preparing for the Consultation, and anticipated a report on the results of the Consultation at its 26th meeting.

**PROPOSED DRAFT MAXIMUM LEVELS FOR OCHRATOXIN A IN FOODS (Agenda Item 15 (d))**

129. The Committee had before it government comments in reply to CL 1992/8-FAC, as presented in CX/FAC 93/12-Part III (Canada, Denmark, United Kingdom), Conference Room Documents 8 (Norway and Sweden), 20 (Italy), and 29 (The Netherlands).

130. The representative of WHO informed the Committee that it had been recently decided that the GEMS/Foods Programme would collect information on ochratoxin A, and that further information might be available at the next session of the Committee.

131. The Secretariat of JECFA indicated that ochratoxin A was on the priority list for the next session of JECFA, scheduled to be held in February 1995.

132. The Committee was informed that an AOAC method for the determination of ochratoxin A was being further tested by the NMKL in collaboration with laboratories in the Nordic countries.

133. The Committee was also informed that the Nordic countries had carried out an evaluation of this contaminant and proposed to collect data and prepare a discussion paper on ochratoxin A. Contamination by trichothecenes would also be included in the paper. The Committee welcomed this proposal and agreed that interested countries would send relevant information to Sweden on ochratoxin A, as well as on trichothecenes, for consideration at the next session of CCFAC.

**IDENTIFICATION OF ADDITIONAL PREDATORY SPECIES OF FISH AS RELATED TO CODEX GUIDELINE LEVELS FOR MERCURY IN FISH (Agenda Item 16 (a))**

134. The Committee had before it CX/FAC 93/13-Part I and Conference Room Document 9 and 26 presenting the comments of Canada, Denmark, Malaysia, Norway, Poland, Sweden, Spain, United Kingdom and Thailand submitted in response to CL 1992/8-FAC.

135. The Committee was reminded that those levels adopted at Step 8 for methylmercury in fish at its 19th Session actually applied to total mercury. The 24th CCFAC had agreed to seek additional information on the identification of other fish to which the higher guideline level of 1 mg/kg total mercury applied (i.e., in addition to shark, swordfish, tuna and pike).

136. The Committee agreed that the Codex Committee on Fish and Fishery Products (CCFFP) should continue to take responsibility for the elaboration of a list of fish for which the higher guideline level applied and which created problems in international trade, based on common and scientific names. It was also noted that feeding patterns and other factors would need to be taken into account.

**PROPOSED DRAFT GUIDELINE LEVELS FOR CADMIUM AND LEAD IN FOODS**  
**(Agenda Item 16 (b))**

137. The Committee had before it CX/FAC 93/13-Part II and Conference Room Documents 10, 17 and 27 presenting the comments of Canada, Denmark, Finland, Spain, the United Kingdom, Norway, Sweden, Germany, Thailand and Japan submitted in response to CL 1992/8-FAC.

138. The Secretariat informed the Committee of progress made by the Codex Committee on Cereals, Pulses and Legumes (Part H of CX/FAC 93/2) concerning this subject and of the JECFA evaluation of lead and cadmium at its 41st Session. The JECFA Secretariat indicated that these evaluations were based on Environmental Health Criteria (EHC) 134 for cadmium and on the report of an IPCS Task Group for Lead.

139. Some delegations expressed concern about the high intake levels of lead and cadmium as there was a possibility that intake was approaching the PTWI. Some delegations stated that source directed measures were needed and that limits should be set on categories of foodstuffs rather than setting specific limits on a particular food. The Delegation of the United States and the observer of the EC reported on progress made in eliminating source contamination from lead capsules on wine. The representative of IOCU stressed the urgent need for maximum levels for both cadmium and lead.

140. The Committee agreed that establishing maximum levels for cadmium and lead was important and also stated that contamination should be reduced as much as reasonably achievable through source directed measures. The Committee also agreed that a position paper on lead would be prepared by Denmark and Sweden for consideration at the 26th CCFAC. The Committee also agreed to gather additional information on cadmium and lead.

**PROPOSED DRAFT GUIDELINE LEVELS FOR PCBs, PBBs AND TETRACHLOROBENZYL TOLUENE IN SPECIFIC FOODSTUFFS** (Agenda Item 16 (c))

141. The Committee had before it document CX/FAC 93/3-Part III, as well as Conference Room Documents 11 and 18, presenting the comments received from the Governments of Canada, Denmark, the United Kingdom, France, Norway, Sweden and Germany in reply to CL 1992/8-FAC.

142. Several delegations expressed their concern as to establishing limits for PCB contamination, as the analysis of individual PCB congeners was difficult and expensive. It was also indicated that it was difficult to develop maximum limits for this contaminant because JECFA had not established a provisional tolerable daily or weekly intake.

143. The Delegation of The Netherlands informed the Committee of a meeting planned in August/September 1993, organized by the WHO Regional Office for Europe and The Netherlands, on equivalence factors of dioxins, furans and dioxine-related PCBs. The Delegation of Denmark informed the Committee about the report of the Nordic Council of Ministers on Risk Assessment of PCBs, which contained valuable information on future work on this subject. The Representative of WHO informed the Committee that a WHO Environmental Health Criteria Document on PCBs was due to be published in the near future.

144. Several delegations expressed their support for source directed measures to reduce contamination of foodstuffs by PCBs, PBBs and tetrachlorobenzyltoluene as opposed to setting maximum limits for these contaminants at this time. It was also noted

that some PCB congeners were similar to dioxins in chemical structure and toxicological properties and therefore, both groups of contaminants should be evaluated at the same time.

145. The Committee agreed that there was general support for source directed measures to reduce contamination by PCBs, PBBs and tetrachlorobenzyltoluene in foodstuffs, and that additional information would be requested before its next session.

146. The Committee also agreed that the Delegation of The Netherlands would prepare a position paper on PCBs before the next session of the CCFAC. Governments were invited to send additional information to The Netherlands.

#### **PROPOSED DRAFT GUIDELINE LEVELS FOR DIOXINS IN FOODS (Agenda Item 16 (d))**

147. The Committee had before it document CX/FAC 93/13-Part IV, as well as Conference Room Documents 12 and 21, presenting comments received from Canada, Finland, the United Kingdom, Norway, Sweden and Germany in reply to CL 1992/8-FAC.

148. Several delegations supported the use of source directed measures to reduce contamination of foodstuffs by dioxins. It was noted that in the case of local and regional problems, restriction on the sale of contaminated products from affected areas could be used to control dioxin intake. However, it was also noted that dioxin contamination did not appear to cause problems in international trade.

149. The observer of the IOCU indicated that, like dioxin related PCB congeners, bromide containing dioxins showed dioxin like toxicological effects and should therefore also be included in a future toxicological evaluation.

150. The Committee agreed that there was a general support for source directed measures to reduce contamination by dioxins in foodstuffs, and that additional information would be requested before its next session.

151. The Committee also agreed that The Netherlands would prepare a position paper on dioxins and dioxin-like PCBs before the next session of the CCFAC. Governments were invited to send additional information to the Delegation of The Netherlands.

#### **POLY-CYCLIC AROMATIC HYDROCARBONS (E.G. BENZO-A-PYRENE), HYDROGEN CYANIDE, PHTHALATES (E.G. DEHP) AND ETHYL CARBAMATE IN FOODS (Agenda Item 16 (e))**

152. The Committee had before it document CX/FAC 93/13-Part V, as well as Conference Room Documents 13 and 28, presenting the comments received from Canada, Denmark, Malaysia, Poland, Spain, the United Kingdom, France, Norway, Sweden and Thailand in reply to CL 1992/8-FAC.

##### Poly-cyclic Aromatic Hydrocarbons

153. The Delegations of Sweden and France emphasized the need for source directed measures in order to reduce contamination of foodstuffs by poly-cyclic aromatic hydrocarbons. The Observer of the EC informed the Committee that it had a directive which contained maximum limits for benzo-a-pyrene in foods.

154. The Committee agreed that there was general support for source directed measures to reduce contamination by poly-cyclic aromatic hydrocarbons in foodstuffs, and that additional information would be requested before its next session, with the view towards possibly elaborating a Code of Practice on source directed measures in the future.

### Hydrogen Cyanide

155. The Committee agreed that no action on hydrogen cyanide could be taken this year and that additional information should be requested in order to decide on possible future actions needed by the Committee concerning this contaminant.

### Phthalates

156. The Delegation of Switzerland informed the Committee about a toxicological evaluation conducted by an Expert Working Group of the Council of Europe on packaging materials in contact with foodstuffs. The Delegation of Denmark and the observer of the EC also indicated that a toxicological evaluation on DEHP was available.

157. The Committee decided to continue to gather additional information on phthalates.

### Ethyl Carbamate

158. The Delegation of Denmark informed the Committee about a report of the Nordic Council of Ministers on ethyl carbamate in alcoholic beverages and foodstuffs.

159. The Committee agreed that additional information on contamination of foodstuffs by ethyl carbamate would be requested in order to decide at the next CCFAC session if a position paper on this contaminant had to be prepared. The Delegation of Denmark indicated that they were willing to prepare such a paper in the future.

### **PROPOSALS FOR THE PRIORITY EVALUATION OF FOOD ADDITIVES AND CONTAMINANTS BY JECFA (Agenda Item 17)**

160. The Committee had before it Conference Room Document 30, the report of the informal Working Group on Priorities. The Working Group had met to consider the status of the substances listed for priority attention at the Twenty-fourth Session of CCFAC (Appendix VI, ALINORM 93/12) and to consider new additions to the priority list. Mr. R. Top of The Netherlands chaired the Working Group meeting.

161. The Committee maintained nitrite, nitrate, nitrosamines, and ochratoxin A on the priority list, because new significant data should be available on each of these substances by mid-1994.

162. The Committee maintained dioxins on the priority list, pending the results of a WHO European Regional Office/IPCS project on toxic equivalency factors (TEFs), which should result in a better interpretation of the tolerable daily intake of 10 pg per kg body weight for 2,3,7,8-TCDD that was established at a WHO consultation in 1990.

163. The Committee maintained ethyl carbamate on the priority list pending the results of carcinogenicity studies that were underway under the sponsorship of the U.S. National Toxicology Programme.

164. The Delegation of the Czech Republic indicated that new toxicity information was available on certain phthalates, which would be made available. Therefore, the Committee maintained these substances on the priority list, and delegations were requested to specify which of them were of particular interest and concern at the next session of CCFAC.

165. The Committee maintained the polycyclic aromatic hydrocarbons (PAHs) on the priority list pending the results of an IPCS project to prepare an Environmental Health Criteria document on the PAHs.

166. The Committee deleted paralytic shellfish toxins from the priority list and decided not to ask for a JECFA evaluation on the safety of food and feed products after ammoniation to reduce aflatoxin levels because of a lack of information.

167. The Committee maintained the trichothecenes on the priority list because new toxicological information was expected from Canada which was conducting a study on vomitoxin.

168. The Delegation of the United Kingdom requested that patulin be placed on the priority list for reevaluation by JECFA, because new significant toxicity information had become available since the previous evaluation. The Delegation of the United States requested that 4-hexyl resorcinol be placed on the priority list, and the Delegation of New Zealand requested that alitame be placed on the priority list. The Committee agreed to add these substances. It was noted that these Delegations were responsible for ensuring that the appropriate data were submitted on the respective substances when they were considered by JECFA.

169. The Delegation of Egypt requested that tartrazine, brilliant blue, brilliant black, thaumatin, aspartame, and sorbitol be reevaluated and that monellin and miraculin be evaluated by JECFA. Because it was not known whether information was available to provide a basis for the assessment of these substances, they were not placed on the priority list. The Delegation of Egypt would inform the JECFA Secretariat of any information that they had on toxicology and the Chairman of CCFAC of any information that they had on intakes, which would provide a basis for deciding whether they should be placed on the priority list at a future session.

170. The question was raised as to the significance of short-term exposure to high levels of substances. It was noted that JECFA had included a section in the Thirty-third report (WHO Technical Report Series, No. 776) dealing with this issue. This question was related to several issues, including exposure of various age groups such as infants, children, and pregnant women. The JECFA Secretariat was asked to provide information at the next session of CCFAC on WHO and IPCS activities in this area.

171. It was drawn to the attention of the Committee that the General Standard for Food Additives had implications for JECFA in that its implementation could result in many food additives coming forward for assessment. Food additives that were included in the International Numbering System (INS) but which had not yet been assessed by JECFA would probably require assessment, and some that had been allocated an ADI of "not specified" could need to be reconsidered if they were permitted in the GSFA on the basis of GMP. It was stated that a system should be instituted that would provide for the systematic inclusion of food additives on the priority list on the basis of the implementation of the General Standard.

172. The Committee agreed that eventually more substances would be prioritized for assessment or reassessment for the above reasons. However, it would be premature to try to identify such substances before they were included in the General Standard. Therefore, the Committee agreed that this issue should be maintained as an item for future work.

173. The Committee agreed to the priority list as attached to this report as Appendix VIII.

### **OTHER BUSINESS AND FUTURE WORK (Agenda Item 18)**

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

- Proposed Draft Codex General Standard for Food Additives;
- Proposed Draft General Standard for Contaminants in Foods;
- Endorsement and/or Revision of Maximum Levels for Food Additives and Contaminants in Codex Standards;
- Action Required as a Result of Changes in ADI Status and other Toxicological Recommendations;
- Consideration of Specifications for the Identity and Purity of Food Additives;
- Consideration of methods of analysis for food additives that may be a problem in international trade;
- Proposed Amendments to the International Numbering System;
- Proposed Amendments to the Inventory of Processing Aids;
- Consideration of the Draft Maximum Level for Aflatoxin M<sub>1</sub> in Milk and the Draft Provisional Guideline Level for Aflatoxin B<sub>1</sub> in Supplementary Feedingstuffs for Milk Producing Animals;
- Proposed Draft Maximum Levels for Aflatoxins in Specific Foodstuffs;
- Proposed Draft Maximum Levels for Ochratoxin A and Trichothecenes in Foods;
- Proposed Draft Guideline Levels for Cadmium and Lead in Foods;
- Proposed Draft Guideline Levels for PCBs, PBBs and Tetrachlorobenzyltoluene in specific foodstuffs;
- Proposed Draft Guideline Levels for Dioxins in Foods;
- Consider the need for a position paper on poly-cyclic aromatic hydrocarbons, hydrogen cyanide, phthalates and ethylcarbamate;
- Proposals for the Priority Evaluation of Food Additives and Contaminants by JECFA.

### **DATE AND PLACE OF NEXT SESSION (Agenda Item 19)**

175. The Committee was informed that its 26th Session would be held from 7-11 March 1994 in The Netherlands, with the understanding that the Working Group on the General Standard for Food Additives would meet on Friday, 4 March and the Working Group on Specifications would meet on Saturday, 5 March.

**CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS**  
**Summary Status of Work**

<b>Subject</b>	<b>Step</b>	<b>For Action by:</b>	<b>Document Reference</b>
Proposed Draft Preamble of the Codex General Standard for Food Additives	5	20th CAC	Appendix II, ALINORM 93/12A
Proposed Draft Maximum Level for Aflatoxin M <sub>1</sub> in Milk	5	20th CAC	Appendix V ALINORM 93/12
Proposed Draft Provisional Guideline Level for Aflatoxin M <sub>1</sub> in Supplementary Feeding Stuffs for Milk Producing Animals	5	20th CAC	Appendix VII, ALINORM 93/12A
Specifications Recommended for Adoption by the Commission as Codex Advisory Specifications	3	20th CAC	Appendix V, ALINORM 93/12A; Appendix III ALINORM 93/12
Amendments to the International Numbering System	8	20th CAC	Appendix VI, ALINORM 93/12A; Appendix IV ALINORM 93/12
Proposed Draft Codex General Standard for Contaminants in Foods	1, 2 and 3	20th CAC Netherlands/ Denmark Governments 26th CCFAC	paras. 103-115 ALINORM 93/12A
Procedure for the Inclusion of a Contaminant in the Codex General Standard for Contaminants	2, 3	Switzerland Governments 26th CAC	paras. 103-115, ALINORM 93/12A
Food Categories where Antioxidants or Preservatives are Not Allowed or are Restricted	3	Governments Secretariat	paras. 27-50 and Appendix III, ALINORM 93/12A
Revised Schedules 1,2 and Annex A of the Proposed Draft General Standard for Food Additives	2, 3	USA/Secretariat Governments 26th CCFAC	paras. 27-50, ALINORM 93/12A
Procedure for the Inclusion of a Food Additive on the Priority List on the Basis of the Implementation of the General Standard for Food Additives	--	26th CCFAC	paras. 160-173, ALINORM 93/12A
Methods of Analysis for the Determination of Food Additives in Foods	3	Governments 26th CCFAC 19th CCMAS	paras. 12-14, ALINORM 93/12A
Registry/Inventory of Additives	1, 2	20th CAC	paras. 81-93,



Produced through Biotechnology	and 3	USA/Netherlands Governments 26th CCFAC	ALINORM 93/12A
Proposed Draft Code of Practice on Source Directed Measures to Reduce Contamination of Foodstuffs	1, 2 and 3	20th CAC Sweden Governments 26th CCFAC	paras. 103-115, ALINORM 93/12A
Proposed draft Code of Practice for the Reduction of Aflatoxins in Raw Materials and Supplementary Feedingstuffs for Milk Producing Animals	1, 2 and 3	20th CAC Canada Governments 26th CCFAC	paras. 116-121, ALINORM 93/12A
Information on Aflatoxins in Specific Foodstuffs	3	Governments 26th CCFAC	paras. 122-125, ALINORM 93/12A
Report on Aflatoxins in Pistachio Nuts and Dried Figs	- -	Germany 26th CCFAC	paras. 122-125, ALINORM 93/12A
Discussion Paper on Ochratoxin A and Trichothecene	2, 3	Governments Sweden 26th CCFAC	paras. 129-133, ALINORM 93/12A
Sampling Plans for Aflatoxins	- -	FAO Technical Consultation on Sampling Plans 26th CCFAC	paras. 126-128, ALINORM 93/12A
Information on Cadmium and Lead - Discussion Paper on Lead	2, 3	Governments Denmark/Sweden 26th CCFAC	paras. 137-140, ALINORM 93/12A
Information on PCBs PBBs, tetrachlorobenzyltoluene and dioxins in foods; Position paper on PCBs and Dioxins	2, 3	Governments Netherlands 26th CCFAC	paras. 141-151 ALINORM 93/12A
Information on polycyclic aromatic hydrocarbons, hydrogen cyanide, phthalates and ethyl carbamate	3	Governments 26th CCFAC	paras. 152-159, ALINORM 93/12A
Amendments to the Inventory of Processing Aids	3	Governments 26th CCFAC	paras. 75-80, ALINORM 93/12A
Food Additives and Contaminants Proposed for Priority Evaluation by JECFA	3	Governments 26th CCFAC	Appendix VIII, ALINORM 93/12A

## APPENDIX I

### LIST OF PARTICIPANTS\* LISTE DES PARTICIPANTS\* LISTA DE PARTICIPANTES\*

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- \* The Heads of Delegations are listed first: Alternates, Advisers and Consultants are listed in alphabetical order.
- \* Les Chefs de délégations figurent en tête et les suppléants, conseillers et consultants sont énumérés par ordre alphabétique.
- \* Figuran en primer lugar los Jefes de las delegations, los Suplentes, Asesores y Consultores aparecen por orden alfabético.

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**APPENDIX II**  
**PROPOSED DRAFT PREAMBLE,**  
**TO THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES**  
**(At Step 5)**

**1. SCOPE**

**1.1 Permitted Food Additives**

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

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

**1.2 Foods in Which Additives May Be Used**

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

**1.3 Foods in Which Additives May Not Be Used**

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

**1.4 The Permitted Levels of Use for Food Additives**

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

The food additives covered by this standard and their maximum levels of use are based in part on the food additive provisions of previously established Codex commodity standards, or upon the request of governments after subjecting the requested maximum levels to an appropriate method to determine dietary intake which would verify the compatibility of a proposed maximum level with the ADI. The Danish budget method may be used as a first step in this regard.<sup>2</sup> The submission of actual food consumption data is also encouraged.

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

**2. DEFINITIONS OF TERMS USED IN THIS STANDARD**

(a) Food additive means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include "contaminants" or substances added to food for maintaining or improving nutritional qualities.<sup>3</sup>

<sup>3</sup> Codex Alimentarius, Second Edition (1992), Volume I (General Recommendations), p. 11.

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

<sup>4</sup> Principles for the Safety Assessment of Food Additives and Contaminants in Food, World Health Organization, (WHO Environmental Health Criteria, No. 7), p. III (1987).

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

### **3. GENERAL PRINCIPLES FOR THE USE OF FOOD ADDITIVES**<sup>5</sup>

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

#### **3.1 Safety Evaluation**

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

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

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

#### **3.2 Technological Need and Justification of Use**

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

(a) to preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified in the circumstances dealt with in sub-paragraph (b) and also in other circumstances where the food does not constitute a significant item in a normal diet;

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

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

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

### **3.3 Good Manufacturing Practice (GMP)<sup>7</sup>**

<sup>7</sup> Codex Alimentarius Commission, Procedural Manual, Seventh Edition (1989), pp. 134-35

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

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

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

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

### **3.4 Specifications for the Identity and Purity of Food Additives**

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

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

## **[4. CARRY-OVER OF FOOD ADDITIVES INTO FOODS<sup>9</sup>]**

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

### **4.1 Compliance with the Carry-Over Principle**

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

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

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

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

(d) the food additive carried over is present at a level which is nonfunctional, i.e. at a level significantly less than that normally required to achieve an efficient technological function in its own right

#### **4.2 Non-Compliance with the Carry-Over Principle**

An additive carried over into a particular food in a significant quantity or in an amount sufficient to perform a technological function in that food as a result of the use of raw materials or other ingredients in which the additive was used, be treated and regarded as an additive to that food, and shall be provided for according to the general principles of this Standard.

### **5. FORMAT OF THE STANDARD**

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

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

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

<sup>11</sup> Each Codex Commodity Standard has been initially assigned to one of the food categories or subcategories of the system developed by the Confédération des Industries Agro-Alimentaires de la CEE (CIAA). Although the CIAA Food Categorization System is not reproduced in the General Standard per se, the relevant food categories and specific food items derived from the CIAA system are listed within the Schedules of this Standard. Codex Standard Numbers (CXSNS), together with the corresponding names of the Codex Commodity Standards and the CIAA food categories and subcategories to which the CXSNS have been classified, are listed in ANNEX B.

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

### **6. REVIEW AND RERVISION OF THE STANDARD**

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

### **APPENDIX III**

#### **FOOD CATEGORIES WHERE PRESERVATIVES AND/OR ANTIOXIDANTS ABE/ARE NOT USED**

+ means allowed  
- means not: allowed

	<b>Antioxidants</b>	<b>Preservatives</b>
1. Dairy products, excluding products of Category 2		
1.1 Milk and dairy based drinks	-	-
1.1.1 Milk and buttermilk		
1.1.1.1 Milk		
1.1.1.2 Sterilized milk and UHT goats milk		
1.1.1.3 Buttermilk (plain)		
1.1.2 Dairy based drinks, flavoured and/or fermented	-	+
1.2 Fermented and renneted milk products (plain), excluding drink	+	-
1.2.1 Fermented milks (plain)	+	-
1.2.1.1 Not heat-treated after fermentation	-	+
1.2.1.1 Heat-treated after fermentation	-	+
1.2.2 Renneted milk	-	+
1.3 Condensed milk (plain) and analogues		
1.3.1 Condensed milk (plain)		
1.3.2 Beverage whiteners	+	+
1.4 Cream (plain) and the like		
1.4.1 Pasteurized cream	-	
1.4.2 Sterilized, UHT, whipping or whipped and fat creams	-	-
1.4.3 Clotted cream		+
1.4.4 Cream analogues	+	+



1.5	Milkpowder and cream powder (plain)		
1.5.1	Milk and cream powder	+	
1.5.2	Powder analogues	+	+
1.6	Cheese		
1.6.1	Unripened cheese		+
1.6.2	Ripened cheese	-	+
1.6.2.1	Total cheese		
1.6.2.2	Cheese rind		
1.6.3	Processed cheese	+	+
1.6.4	Cheese analogues	+	+
1.7	Dairy based desserts incl. flavoured and composed products on basis of 1.2, 1.3, 1.4 and 1.6	+	+
2.	Fats and oils and fat emulsions (type water in oil)		
2.1	Fats and oils essential free from water	+	
2.1.1	Butter oil, anhydrous milkfat, ghee		
2.1.2	Vegetable oils and fats		
2.1.3	Lard, tallow and fishoil		
2.2	Fat emulsions mainly of type water in oil		
2.2.1	Emulsions containing at least 80% fat		
2.2.1.1	Butter and concentrated butter		-
2.2.1.2	Margarine	+	+
2.2.2	Emulsions containing less than 80% fat		
2.2.2.1	Reduced fat emulsions	+	+
2.2.2.2	Low fat emulsions	+	+
2.2.2.3	Very low fat emulsions (less than 20% fat)	+	+

2.3	Mixed and/or flavoured products based on fat emulsions	+	+
2.4	Fat based desserts	+	+
3.	Edible ices	+	+
4.	Fruits and vegetables		
4.1	Fresh fruits and vegetables		
4.1.1	Untreated fruits and vegetables		
4.1.2	Surface treated fruits and vegetables	+	+
4.1.3	Peeled and/or cut fruits and vegetables	+	+
4.2	Frozen fruits and vegetables	+	-
4.3	Processed fruits and vegetables	+	+
5.	Confectionery		
5.1	Cocoa products and chocolate products (filling excluded)		
5.2	Sugar confectionery, cocoa and nut based confectionery	+	+
5.3	Chewing gum	+	+
6.	Cereals and cereal products, excluding bakery		
6.1	Whole, broken or flaked grain, incl. rice		+ (parboiled rice) -
6.2	Flours and starch		
6.3	Breakfast cereals, incl. rolled oats	+	+
6.4	Pasta products (fillings only)	+	+
6.5	Cereal and starch based desserts	+	+
7.	Bakery wares		
7.1	Bread and ordinary bakery wares	+	+
7.2	Fine bakery wares	+	+
8.	Meat and meat products, including poultry and game		
8.1	Fresh meat, poultry and game		
8.2	Meat products in whole pieces/cuts	+	+

8.2.1	Non-cured		
8.2.1.1	Non-cooked		
8.2.1.2	Cured (incl. salted)		
8.2.1.3	Cured (incl. salted) and dried		
8.2.2	Cooked		
8.3	Comminuted meat products	+	+
8.3.1	Non-cooked		
8.3.1.1	Non cured		
8.3.1.2	Cured (incl. salted)		
8.3.1.3	Cured (incl. salted) and dried		
8.3.2	Cooked		
9.	Fish and fish products		
9.1	Fish and fish products	+	+
9.1.1	Fresh fish		
9.1.2	Fresh crustaceans, molluscs and echinoderms		
9.2	Frozen fish and fish products	+	+
9.2.1	Frozen fish, fish fillets and fish products		
9.2.2	Frozen battered and/or fried fish and fish products		
9.2.3	Frozen minced and creamed fish products		
9.3	Cooked and/or fried fish and fish products	+	-
9.3.1	Cooked fish and fish products		
9.3.1.1	Cooked fish and fish products		
9.3.1.2	Cooked crustaceans		
9.3.2	Fried fish and fish in products		

9.4	Semi-preserved fish and fish products	+	+
9.4.1	Smoked, dried and/or salted fish and fish products		
9.4.2	Fish and fish products marinated and/or in jellies		
9.4.3	Fish and fish products pickled and/or in brine		
9.4.4	Semi-preserved fish and fish products other than 9.4.1 through 9.4.4		
9.5	Preserved fish and fish products	+	+
10.	Eggs and egg products		
10.1	Fresh eggs		
10.2	Liquid egg products		+
10.3	Frozen egg products		
10.4	Dried and/or heat coagulated egg products	+	
10.5	Egg based desserts	+	+
11.	Sugars and honey		
11.1	Sugar (saccharose)	-	-
11.1.1	White and semi-white sugar		
11.1.2	Speciality sugar		
11.1.3	Brown sugar		
11.1.4	Sugar solutions and sugars, also (partially) inverted		
11.2	Other sugars and syrups	-	+
11.3	Honey	-	-
12.	Salts and spices, soups, sauces and salads, protein products, etc.		
12.1	Salt		
12.2	Herbs, spices, seasonings and condiments	+	
12.3	Vinegars	+	+
12.4	Mustards	+	+
12.5	Soups and broths	+	+
12.6	Sauces and the like products, incl. ketchup	+	+
12.7	Salads and sandwich spreads	+	+

12.8 Yeast	+	-
12.9 Protein products	-	-
13. Foodstuffs intended for particular nutritional uses		
13.1 Infant formulae and follow-on formulae	+	
13.2 Weaning foods	+	-
13.3 Dietetic foods intended for special medical purposes		
13.4 Dietetic formulae for slimming purposes and weight reduction		
13.5 Supplementary foods for dietary uses		
13.5.1 Supplementary foods for dietetic uses, solids		
13.5.2 Supplementary foods for dietetic uses, liquids		
13.6 Salt substitutes for dietetic uses		
13.7 Food supplements		
14. Beverages, excluding dairy products		
14.1 Non-alcoholic		
14.1.1 Waters	-	
14.1.2 Fruit and vegetable juices	+	+
14.1.3 Fruit and vegetable nectars	+	+
14.1.4 Water based flavoured drinks	+	+
14.1.5 Other concentrates than 14.1, 14.2	+	+
14.1.6 Coffee, coffee substitutes, tea, herbal infusions and hot cereal based beverages	-	-
14.2 Alcoholic (incl. the alcohol free and low-alcoholic counterparts)	+	+
14.3 Beer coolers	+	+
15. Ready-to-eat savouries	+	+
15.1 Savoury snacks, potato, cereal or starch base	+	+
15.2 Processed nuts, savoury coated nuts and nut mixtures	+	+
16. Food that could not be placed in any of the groups above	+	+

Evaluation for each product;

- " -

- " -

- " -

- " -

- " -

- " -

**APPENDIX IV**

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

Substance	Previous acceptable daily intake in mg/kg body weight and other toxicological recommendations	Present acceptable daily intake (ADI) in mg/kg body weight and other toxicological recommendations	Current Codex Uses	Secretariat Recommendation for Action
<b><u>Antioxidants</u></b>				
Dodecyl gallate	No ADI (30th JECFA)	0-0.05 (Temporary)	None	Committee should consider restoring the Codex uses endorsed prior to the 30th JECFA Inform Chairman/ Secretariat of Codex Committee on Fats and Oils that the ADI has been decreased - food additive provisions may require review
Octyl gallate	No ADI (30th JECFA)	0-0.1 (Temporary)	None	
Propyl gallate	0-2.5 (30th JECFA)	0-1.4	Specified vegetable, animal or mixed animal and vegetable fat products	
<b><u>Flavouring agents</u></b>				
Benzyl acetate	0-5 [Temporary (35th JECFA)]	0-5 (Group ADI with benzyl alcohol, benzaldehyde, benzoic acid and benzoate salts)	None specified	No action required - no current Codex uses specified
2-Ethyl-1-hexanol	None	0-0.5	None specified	No action required - new evaluation - no current Codex uses specified
d-Limonene	0-1.5 (39th JECFA)	Not specified	None specified	No action required - no current Codex uses specified

e-Methylbenzyl alcohol	None	0-0.1	None	No action required - new evaluation
Quinine hydro-chloride	Use up to 75 mg/1 (as quinine base) not of toxicological concern (39th JECFA)	Use up to 100 mg/1 (as quinine base) not of toxicological concern	None	No action required - no current Codex uses specified
Quinine sulfate				
<b><u>Flavour enhancers</u></b>				
5'-Disodium guanylate	Not specified (29th JECFA)	Not specified	Luncheon meat, cooked	No action required - previous ADIs are maintained
5'-Disodium inosinate	Not specified (29th JECFA)	Not specified	cured pork shoulder, cooked cured chopped meat, bouillons and consommés	
<b><u>Food colours</u></b>				
Carotenes (Algae)	No ADI (35th JECFA)	No ADI	None	No action required - previous ADI of "not allocated" is maintained
Carotenes (Vegetable)	No ADI (35th JECFA)	Acceptable (Provided level of use does not exceed that normally found in vegetables)	None	Committee should consider establishing Codex uses in view of endorsement of the use of synthetic carotenes
<b><u>Sweetening agents</u></b>				
Maltitol	Not specified (33rd JECFA)	Not specified	None	No action required - previous ADIs were maintained
Maltitol syrup	Not specified (33rd JECFA)	Not specified	None	
Saccharin	0-2.5 [Temporary group ADI for saccharin and its calcium, potassium and sodium salts (28th JECFA)]	0-5	None	No action required - previous ADI has been increased

**Thickenine agents**

Konjac flour	None	Not specified (Temporary)	None	CCFAC should request other Codex Committees to consider the establishment of use levels and justification for these compounds where appropriate
Processed <i>Eucheuma</i> seaweed	No ADI (39th JECFA)	0-20 (Temporary)	None	
Propylene glycol alginate	0-25 (17th JECFA)	0-70	Canned vegetables, canned fish, milk products, yoghurt, cheeses and minarine	No action required - previous ADI has been increased

**Miscellaneous substances**

$\beta$ -Cyclodextrin	None	0-6 (Temporary)	None	No action required - new evaluation
Sodium iron EDTA	None	Provisionally considered safe in food fortification programmes	None	Should be referred to the Codex Committee on Nutrition and Foods for Special Dietary Uses
Sucrose acetate isobutyrate	No ADI (26th JECFA)	0-10 (Temporary)	None	No action required - ADI not allocated previously
Urea	None	Use level up to 3% in chewing gum not of toxicological concern	None	No action required - new evaluation

**Contaminants**

Cadmium	0.007 mg/kg body weight (33rd JECFA)	7 $\mu$ g/kg body weight	None	No action required - previous PTWI maintained
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Lead	25 µg/kg body weight - children and infants (30th JECFA) 50 µg/kg body weight -adults (22nd JECFA)	25 µg/kg body weight	Edible oils, fruit juices and nectars, chocolate products, sugars, bouillons and consommés	Inform Chairman/ Secretariat of Codex Committees on Fats and Oils, Sugars, Soups and Broths, Cocoa Products and Chocolate and Fruit Juices that the PTWI for lead (adults) has been decreased - maximum levels for lead need to be reviewed
Chloropropanols (3-chloro-1,2-propanediol and 1,3-dichloro-2-proponal)	None	Levels in hydrolyzed vegetable proteins should be the lowest techno-logically achievable	None	Inform Chairman/ Secretariat of Codex Committees on Soups and Broths that a toxicological recommendation has been established. – maximum levels for chloropropanols may need to be elaborated

## APPENDIX V

### SPECIFICATIONS FOR IDENTITY AND PURITY OF CERTAIN FOOD ADDITIVES ARISING FROM THE 39th MEETING OF JECFA

#### Category I (recommended to the Commission for adoption)

Beeswax  
Candelilla Wax  
Cellulase from *Trichoderma longibrachiatum*  
Dammar Gum  
Diethylene Glycol Monoethyl Ether  
 $\beta$ -Glucanase from *Trichoderma harzianum*  
Sorbitan tristearate  
Thermally Oxidized Soya Bean Oil  
Thermally Oxidized Soya Bean Oil Interacted with Mono- & Diglycerides  
Titanium Dioxide

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

Ethyl vanillin  
Isomalt  
Lysozyme Hydrochloride  
Paraffin wax  
Pectins  
Tannic acid

#### Category III (referred to JECFA, substantive changes required)

Calcium Stearoyl Lactylate	Question on method for lactic acid
Carnauba Wax	Question on melting point and acid, ester & saponification values
Carob Bean Gum	Question on the need for microbiological criteria etc.
Curcumin	Question about limit for residual solvents (50 mg/kg suggested for each to be consistent with other similar products)
Microcrystalline wax	Question about colour
Nitrogen	Question on content, limits for oxygen, moisture, carbon dioxide, argon, helium, other carbon compounds
Sodium stearoyl lactylate	

#### Category IV (substances revised by recent session of JECFA)

Alginic acid, Ammonium alginate, Calcium alginate, Carotenes (algae), Carotenes (vegetable), d-Limonene, Potassium Alginate, Quinine hydrochloride and Sodium Alginate.

Category V (specifications designated as tentative)

Aluminium powder, Carthamus Red, Dichloromethane, Furfural Potasatre  
Eucheuma Seaweed, Shellac, Sorbitan

## APPENDIX VI

### PROPOSED AMENDMENTS TO THE INTERNATIONAL NUMBERING SYSTEM

The 25th Session of CCFAC agreed to allocate, amend or delete the following INS Food Additives numbers, for adoption by the 20th Session of the Codex Alimentarius Commission:

#### ADDITIONS

<u>Number</u>	<u>Food Additive</u>	<u>Functions</u>
275	calcium behenate	preservative
426	processed Euchemia seaweed	thickener, stabilizer
459	beta-cyclodextrin	stabilizer, carrier
468	croscarmellose	stabilizer, binder
642	lysin hydrochloride	flavour enhancer
927b	urea (carbamide)	

APPENDIX VII

**PROPOSED DRAFT PROVISIONAL GUIDELINE LEVEL<sup>1</sup>**  
**FOR AFLATOXIN B<sub>1</sub> IN SUPPLEMENTARY FEEDINGSTUFFS**  
**FOR MILK PRODUCING ANIMALS**  
(At Step 5)

[5 µg/kg] Aflatoxin B<sub>1</sub>

<sup>1</sup> Guideline levels are intended for use in regulating food moving in international trade. When the guideline level is exceeded, governments should decide whether and under what circumstances the food should be distributed within their territory or jurisdiction.

**APPENDIX VIII**

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

**Food additives**

Alitame  
4-Hexyl resorcinol

**Proposed by**

New Zealand  
United States

**Contaminants**

Dioxins  
Ethyl carbamate  
Nitrite, nitrate, and nitrosamines  
Ochratoxin A  
Patulin  
Phthalates  
Polycyclic aromatic hydrocarbons  
Trichothecenes

**Proposed by**

CCFAC  
CCFAC  
Netherlands  
U.K., Denmark  
U.K.  
Netherlands  
Denmark  
Netherlands