codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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ALINROM 91/12A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX ALIMENTARIUS COMMISSION Nineteenth Session Rome, 1–10 July 1991

REPORT OF THE TWENTY-THIRD SESSION OF THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINATS

The Hague, The Netherlands, 4–9 March 1991

Note: This report incorporates Codex Circular Letter CL 1991/10-FAC.

CX 4/30.2 CL 1991/10-FAC April 1991

TO: - Codex Contact Points

- Interested International Organizations

FROM: Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme

di Caracalla, 00100 Rome, Italy

SUBJECT: <u>Distribution of the Report of the Twenty-third Session of the Codex</u>

Committee on Food Additives and Contaminants (ALINORM 91/12A)

The report of the Twenty-third Session of the Codex Committee on Food Additives and Contaminants is attached. It will be considered by the Nineteenth Session of the Codex Alimentarius Commission to be held in Rome from 1–10 July 1991.

A. MATTERS OF INTEREST TO THE COMMISSION ARISING FROM THE REPORT OF THE TWENTY-THIRD SESSION OF THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

The following matters will be brought to the attention of the Nineteenth Session of the Codex Alimentarius Commission:

- 1. Proposed Amendments to the International Numbering System at Step 8; para. 105 and Appendix IV, ALINORM 91/12A.
- 2. Sampling Plan for Mercury, Cadmium and Lead at Step 8; para. 189, ALINORM 91/12A.
- 3. Methods of Analysis for Aflatoxins at Step 8; para. 121, 123 and Appendix VI, ALINORM 91/12A.

Governments wishing to propose amendments or to comment on the above revisions to the International Numbering System, the draft sampling plan for mercury, cadmium, and lead, or the methods of analysis for aflatoxins, should do so in writing in conformity with the Guide to Consideration of Standards at Step 8 (see Codex Alimentarius Procedural Manual, Seventh Edition) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, 00100 Rome, Italy, not later than 31 May 1991.

- 4. Codex Advisory Specifications for the Identity and Purity of Food Additives Arising from the 35th JECFA Session at Step 3; para. 98 and Appendix III (Categories I and II), ALINORM 91/12A.
- 5. Guideline Levels for Radionuclides in Foods Dilution Factors Applied and Treatment of Minor Dietary Components; paras. 139 and 142, respectively, ALINORM 91/12A.
- 6. Permanent Guideline Levels for Radionuclides in Foods; para. 147, ALINORM 91/12A.
- 7. General Procedures for the Establishment of Guideline Levels for Contaminants; paras. 22, 27-28 and 157, ALINORM 91/12A.
- 8. Lead Levels in Sugars; paras. 158-159, ALINORM 91/12A.

B. <u>DOCUMENTS OF INTEREST TO BE ELABORATED FOR DISTRIBUTION AND/OR GOVERNMENT COMMENT PRIOR TO THE 24TH SESSION OF THE CCFAC</u>

- 1. Proposed Draft Codex General Standard for Food Additives (United States); see paras. 30-37, ALINORM 91/12A.
- 2. JECFA Specifications Not Adopted as Codex Advisory Specifications (United States), see paras. 89-91, ALINORM 91/12A.
- Codex Advisory Specifications for the Identity and Purity of Food Additives
 Arising from the 37th JECFA Session (United States), see paras. 92-99,
 ALINORM 91/12A.
- 4. Revised Inventory of Processing Aids (United States), see paras. 106-108, ALINORM 91/12A.
- 5. Proposed Draft General Procedures for the Establishment of Guideline Levels for Contaminants (Denmark and the Netherlands); see paras. 22, 27-28 and 157, ALINORM 91/12A.

C. REQUEST FOR COMMENTS AND INFORMATION

1. <u>Proposed Amendments to the International Numbering System - para. 105.</u> ALINORM 91/12A

The Committee decided to include amendments to the International Numbering System through the solicitation of government comments as a standing agenda item.

2. <u>Proposed Amendments to the Inventory of Processing Aids - para. 108.</u> <u>ALINORM 91/12A</u>

The Committee agreed that a revised inventory of processing aids would be presented by the United States at its next Session (see point B.4 above), with the understanding that additional proposals would be solicited.

- 3. <u>Draft Guideline Levels for Methylmercury in Fish para. 151. ALINORM 91/12A</u>
 - The Committee agreed to seek additional information from governments and the CCFFP as to other predatory species of fish which were creating problems in international trade.
- 4. <u>Proposed Draft Guideline Levels for Cadmium and Lead in Foods para. 156.</u> ALINORM 91/12A

The Committee agreed to collect intake data and proposals for guideline levels for specific commodities causing problems in international trade.

5. <u>Proposed Draft Guideline Levels for Polychlorinated Biphenyls (PCBs). PBB</u> sand Ugilec in Foods - para. 169. ALINORM 91/12A

As indicated in paragraph 169, the Committee agreed to solicit government comments and information on matters including the control, national strategies and guideline levels for these contaminants.

6. <u>Proposed Draft Guideline Levels for Dioxins in Foods - para. 174. ALINORM 91/12A</u>

As indicated in paragraph 174, the Committee decided to solicit information and comments on matters including national strategies and guideline levels for this contaminant in foods.

7. Proposed Draft Guideline Levels for Benzo-(a)-pyrene. Hydrogen Cyanide.
Phthalates and Ethylcarbamate in Foods - paras. 178.180. 183 and 187.
respectively. ALINORM 91/12A

As indicated in the referenced paragraphs, the Committee decided to solicit information and comment on several issues concerning these contaminants in foods.

8. <u>Proposals for the Priority Evaluation of Food Additives and Contaminants by</u> <u>JECFA - para. 192 and Appendix VII. ALINORM 91/12A</u>

The Committee agreed that governments should be requested to submit proposals for the priority evaluation of food additives and contaminants by JECFA.

9. <u>Proposed Draft Maximum Levels for Aflatoxins in Foods - para. 118. ALINORM</u> 91/12A

The Committee decided to solicit information and comments from governments on those issues related to aflatoxin contamination in foods, as summarized in paragraph 118.

10. <u>Proposed Draft Guideline Level for Aflatoxin M₁in Milk - para. 122 and Appendix</u> VI. ALINORM 91/12A

The Committee decided to seek government comments on proposed draft guideline levels for aflatoxin M_1 in milk at Step 3 (see Appendix VI) .

11. Proposed Draft Maximum Level for AflatoxinB₁in Supplementary Feed for Milk Producing Animals - para. 127 and Appendix VI. ALINORM 91/12A

The Committee decided to send the proposed draft maximum level, as contained in Appendix VI, to governments for comments at Step 3.

12. <u>Proposed Draft Maximum Levels for Ochratoxin A and the Trichothecene Group in Foods - para. 135. ALINORM 91/12A</u>

The Committee agreed to solicit additional information on the subject contaminants for discussion at its next Session.

13. Sampling Plans for Aflatoxins - para. 131. ALINORM 91/12A

The Committee decided to solicit government comments on sampling plans and confidence limits for those commodities which were items of concern to governments.

For points C.1 to C.8 above:

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Nutrition and Quality Affairs
Ministry of Agriculture, Nature Management and Fisheries
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For points C.9 through C.13 above:

Mr. W.J. de Koe Ministry of Welfare, Health and Cultural Affairs General Inspectorate for Health Protection P.O. Box 5406 2280 H.K. Rijswijk (ZH) The Netherlands

In addition, please forward a copy of the comments to: Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy.

SUMMARY AND CONCLUSIONS

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

- concluded that the issues of food additives and contaminants should continue to be examined by one Committee, although it was suggested that the agenda for the next CCFAC meeting should be clearly divided between these subjects to expedite the Committee's work, (paras. 19-29);
- agreed that an *ad hoc* working group would elaborate a Codex General Standard for Food Additives under specific terms of reference, for circulation and government comment prior to the next session of the Committee, (paras. 30-37);
- agreed to circulate for comment a list of JECFA Specifications not yet adopted as Codex Advisory Specifications, (paras. 89-91);
- agreed to forward certain specifications for the identity and purity of food additives arising from the 35th JECFA Session to the Commission for adoption as Codex Advisory Specifications, (paras. 92-99);
- agreed to forward additional proposed amendments to the International Numbering System to the Commission for endorsement, with the understanding that further proposals would be solicited, (paras. 100-105);
- agreed to solicit comment and to consider a revised inventory of processing aids at its next session, (paras. 106-108);
- agreed to discontinue the consideration of amendments to Codex List B with the understanding that it would be reinstated if necessary, (paras. 109-111);
- agreed to solicit information and comment concerning the establishment of guideline levels for aflatoxins in specific foodstuffs, (paras. 113-118);
- agreed to request additional information from the CCCPL concerning proposed draft guideline levels for aflatoxins in peanuts as to data and stage of processing, (paras. 119-120);
- agreed to circulate proposed draft guideline levels for aflatoxin M₁ in milk and aflatoxin B₁ in supplementary feed for milk producing animals for government comment, (paras. 121-127);
- agreed to circulate methods of analysis for aflatoxins for comment and endorsement by the CCMAS, and adoption by the Commission, (paras. 121 and 123);
- agreed to solicit government comment on sampling plans and confidence limits for aflatoxins in specific commodities, (paras.128-131);
- agreed to solicit information concerning the establishment of maximum levels and sampling plans for aflatoxin ochratoxin A and the trichothecene group, (paras. 132-135);
- agreed to recommend to the Commission the application of guideline levels for radionuclides in foods to the reconstituted product and to maintain the current text as to minor dietary components, (paras. 137-142);

- recommended that the current Codex guideline levels for radionuclide contamination in foods be extended for an indefinite period, (paras. 143-147);
- reaffirmed its decision to forward draft guideline levels for methylmercury in fish to the Commission for adoption, (paras. 148-151);
- agreed to solicit information on intake data and proposed guideline levels for cadmium and lead in specific commodities, (paras. 152-156);
- agreed to elaborate a general philosophy paper on the establishment of guideline levels for contaminants for consideration at its next session, (paras. 22, 27-28, 157);
- agreed to recommend to the Commission the alignment of draft guideline levels for lead in sugars with the level of 0.5 mg/kg in fructose, (paras. 158-159);
- agreed to solicit government comment and information on the control and establishment of proposed draft guideline levels for polychlorinated biphenyls, PBBs, dioxins, benzo-(a)-pyrene, hydrogen cyanide, phthalates and ethylcarbamate, (paras. 160-187);
- agreed to await a decision of the CCMAS concerning the elaboration of a simple sampling plan for mercury, cadmium and lead, with a view towards its adoption by the Commission, (paras. 188-189), and;
- proposed a list of food additives and contaminants for priority evaluation by JECFA, (paras. 190-192).

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CCFAC FOR PRIORITY EVALUATION BY JECFA

OPENING OF THE SESSION (Agenda Item 1)

- 1. The Codex Committee on Food Additives and Contaminants held its 23rd Session in The Hague, the Netherlands, from 4-9 March1991, 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 186 participants, representing 35 member countries and 34 international organizations (see Appendix I for the List of Participants, including the Secretariat).
- 2. The State Secretary for Agriculture, Nature Management and Fisheries of the Netherlands, Mr. J.D. Gabor, stated that some countries were attending the Committee meeting for the first time, and he especially warmly welcomed these new Delegations. The State Secretary remarked that the large attendance indicated the value attached to the activities of the Codex Alimentarius by member governments.
- 3. The State Secretary emphasized the growing importance of general Codex objectives in relation to the GATT negotiations. The State Secretary stated that it was his view that if the GATT negotiations did not succeed, there would be nothing but losers and therefore, he predicted that the GATT negotiations would succeed. This success would increase the status and importance of the Codex Alimentarius significantly.
- 4. The State Secretary noted that food quality and environmental matters were becoming more and more intertwined and could no longer be seen apart from each other. It was his opinion that food additives and contaminants should be dealt with in one Committee.
- 5. The State Secretary pointed out that food additives and contaminants were still on the minds of consumers. With regard to food additives, today's consumers seemed to be developing an ever more sophisticated opinion. From a Dutch study, it was shown that many consumers, for example, acknowledged the usefulness of and the need for preservatives. However, views on colours and flavourings were less favourable. Consumers were increasingly anxious about food contaminants, which were beyond their powers of perception and assessment.
- 6. The State Secretary remarked that The Hague was a fascinating, beautiful city with an old and rich history as the seat of the Dutch Government.
- 7. The State Secretary ended his remarks by wishing the Committee a good and successful meeting.

ADOPTION OF THE AGENDA (Agenda Item 2)

8. The Committee adopted the Provisional Agenda (CX/FAC 91/1) as proposed. There were no suggestions from the floor for items to be discussed under Agenda Item 13 (Other Business and Future Work). In order to facilitate discussions concerning the priority evaluation of compounds by JECFA, the Committee appointed an informal working group to propose a priority list of food additives and contaminants under the chairmanship of Mr. R. Top (The Netherlands).

APPOINTMENT OF RAPPORTEURS (Agenda Item 3)

9. The Committee <u>agreed</u> with the proposal of the Chairman to appoint Mr. R. Ronk (U.S.A.) as rapporteur.

CONSIDERATION OF THE REPORT OF THE THIRTY-SEVENTH MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA) (Agenda Item 4 (a))

- 10. The Thirty-Seventh Report of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was introduced by the Joint Secretariat of JECFA, Dr. J.L. Herrman (WHO) and Dr. J. Weather wax (FAO). The report had been published by WHO as Technical Report Series No. 806. The toxicological monographs from the Thirty-Seventh Meeting of JECFA would be published by WHO as WHO Food Additives Series No. 28. The specifications would be published in the Compendium of JECFA Food Additive Specifications by FAO.
- 11. A large number of food additives and two contaminants were evaluated. Thirteen substances were evaluated for specifications only.
- 12. A number of enzyme preparations were evaluated, including several from genetically modified microorganisms. These were evaluated in the traditional way, with the addition that the genetic modification procedures were reviewed and a great deal of attention was paid to the characterization of the producing organisms and the fermentation process. ADIs "not specified" were established for all of these preparations. To assist in the evaluation of enzymes from genetically modified sources, JECFA prepared a document entitled, "Principles Governing Consideration of Enzyme Preparations from Genetically Modified Organisms" (Compendium of JECFA Food Additive Specifications, 1991), which described the JECFA approach to the safety assessment of these types of products. This document was considered to be tentative at present and comments were invited by JECFA from interested parties involved in enzyme manufacture.
- 13. Three allyl esters (hexanoate, heptanoate, and isovalerate) used as flavouring agents were evaluated on the basis of the method used in setting priorities for the safety evaluation of food flavouring ingredients. A group ADI was established on the basis of the allyl alcohol moiety, because the esters were rapidly hydrolysed and the allyl group appeared to be the most toxic. JECFA recommended that, in the future, all members of a chemically-related group should be placed on the agenda, even if some of them were not in the highest-priority group.
- 14. Two contaminants, benzo [a] pyrene and ochratoxin A, were evaluated. Because benzo [a] pyrene is a potent genotoxic carcinogen, a tolerable intake could not be established. A provisional tolerable weekly intake (PTWI) of 112 ng/kg of body weight was established for ochratoxin. A which is a contaminant of poorly stored grains. JECFA recommended that, in the future, compounds such as benzo [a] pyrene, which were members of larger groups of toxic compounds, be considered as a group.
- 15. In a general item, JECFA stressed the importance of pharmacokinetic studies for assessing the safety of food additives and contaminants. The generation of such data was encouraged.
- 16. The FAO publication, "Guide to JECFA Specifications", had been revised by Mrs. H. Wallin (Finland) and was reviewed and accepted by the 37th JECFA. The revision included new instrumental and microbiological methods and consolidated analysis methods from various JECFA publications. It would be published in 1991 as FAO Food and Nutrition Paper 5, Revision 2. The "General Notices" section, regarding preparation of monographs, would be made available to organizations providing specifications data for JECFA review.

REPORT OF THE JOINT UNEP/FAO/WHO FOOD CONTAMINATION MONITORING PROGRAMME (GEMS/FOOD) (Agenda Item 4 (b))

17. A progress report of the Joint UNEP/FAO/WHO Food Contamination Monitoring Programme, or GEMS/Food, was available (CX/FAC 91/2). The Delegation of Norway stated that the monitoring programme was very useful, and would also like to participate in the future. The Delegation of Italy stated that their government also wished to participate in the programme.

MATTERS OF INTEREST TO THE COMMITTEE ARISING FROM OTHER CODEX SESSIONS (Agenda Item 4 (c))

18. The Committee had before it document CX/FAC 91/3, which highlighted those matters arising from other Codex Committees directly applicable to the CCFAC. The Committee noted that a number of items appeared later on the agenda and therefore, agreed to defer discussions of these items until that time.

Proposals for the Expedited Review of Food Additives and Contaminants

- 19. The Coordinating Committee for North America and the South-West Pacific (CCNASWP) suggested that the CCFAC request the Commission and JECFA to examine the need for the expedited review of food additives considered to be generally recognized as safe (GRAS). CCNASWP also asked the Commission to examine means to provide expedited guidance on contaminants and in this regard, recommended the possible separation of CCFAC into two Committees. The Coordinating Committee for Europe (CCEURO) noted that the Commission had discussed this issue at its 17th Session, where it was agreed that a new committee did not need to be formed at that time. The CCEURO supported a proposal to increase the number of JECFA meetings in order to expedite CCFAC work. The Executive Committee (CCEXEC) agreed that the CCFAC and JECFA should discuss these issues (i.e., the review of GRAS additives, splitting the Committee, additional JECFA sessions) while noting that these subjects would also be discussed at the FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade.
- 20. The Delegation of the U.S.A., speaking as the chair of CCNASWP, reported that at the meeting of CCNASWP the discussion had been initiated by a need to expedite the review of GRAS additives by JECFA. The Delegation also noted that although food additive and contaminant evaluations were closely related, the approach to their evaluation could be quite different, which in turn might reflect a need for the participation of different experts and different procedures. He stressed that this proposal was not an indication of dissatisfaction with CCFAC, -but a suggestion for developing an evaluation system beneficial to both approaches.
- 21. The Delegation of Sweden agreed and noted that since food additives and contaminants had different philosophies and approaches, and in view of the workload, a split of the Committee might be warranted. This position was supported by Norway.
- 22. The Delegation of the U.K. expressed its appreciation for the explanation given by the chair of the CCNASWP, and noted that there was a distinct difference in the approach to the evaluation of food additives and contaminants but they were connected through JECFA, which discussed both. However, it was stated that at the national government levels different experts were involved. It was argued that where a philosophy on food additives existed, the Committee might need to develop a philosophy on contaminants. It was suggested that this could be accommodated by dividing the

agenda so that discussions of these issues within the CCFAC itself occurred at separate times of the same session.

- 23. The Delegation of Belgium noted that this issue had been discussed before (i.e. the 17th CAC) and that no new arguments were heard. At this time, it was felt there was no justification for separation of the Committee, however, an increased workload and new directions outlined by the FAO/WHO Conference could change this decision.
- 24. The Delegation of Germany called the attention of the Committee to a comparable dilemma in the EC Scientific Committee for Food (SCF). The SCF was divided into several working groups, one of which dealt with food additives and one with contaminants.
- 25. The Delegation of the Netherlands agreed that there were differences in philosophies toward the evaluation of food additives and contaminants, but also noted that there were also similarities, e.g. risk assessment procedures and intake data. The Delegation admitted that the workload was considerable. However, it could be handled under current procedures and the Netherlands were not in favour of a separation.
- 26. The Delegations of Canada, France, Poland, Spain and Switzerland supported the opinions expressed by Belgium, the Netherlands and the U.K.
- 27. The Delegation of the U.S.A. reserved its position pending the outcome of discussions at the FAO/WHO Conference. The Delegation of the U.S.A. indicated that the establishment of general provisions for the elaboration of Codex contaminant levels in foods could be very important in solving the present dilemma.
- 28. The Chairman summarized the discussion and stated that this would be an important issue at the Rome Conference and invited delegates to express their opinions on that occasion. Some suggestions would be taken into account at the next CCFAC meeting, such as a reorganization of the agenda by separating these two issues. In addition, the idea of elaborating a separate philosophy and procedure for examination of contaminants by the CCFAC could also be examined. The general conclusion of the Committee was that there were more similarities than differences in the evaluation of food additives and contaminants, and that the Committee could deal with the two items in one Committee.
- 29. The JECFA Secretariat noted that the GRAS additive issue would be discussed at the Rome Conference. The Joint Secretariat also indicated that both FAO and WHO were of the opinion that no new expert committees (i.e., specific to contaminants) should be formed. In addition, it was also noted that the present number of JECFA meetings could be increased, depending on extra-budgetary support.

PROPOSED DRAFT CODEX GENERAL STANDARD FOR FOOD ADDITIVES (Agenda Item 5)

- 30. The Committee had before it document CX/FAC 91/4, as well as Conference Room Documents 1, 20 and 23, which summarized government comments submitted concerning this subject in response to CL 1990/26-FAC.
- 31. The Chairman recalled discussions held at its previous session regarding this issue (paragraphs 29-37, ALINORM 91/12), where government comments on proposals made in the paper of Dr. W.H.B. Denner in document CX/FAC 89/16 were deliberated. The Committee noted that the document had been elaborated in view of, among other issues, the difficulties in endorsing provisions for food additives in Codex standards

without considering food additive provisions in other standards, or food additive use in non-standardized foods.

- 32. At its 22nd Session, the Committee <u>agreed</u> to request the Secretariat to prepare a document on the use of antioxidants and preservatives in Codex standards by grouping together the present Codex uses of these additives in the format proposed by Dr. Denner. This document was circulated for government comment and information on food additive usage in foods not covered by Codex standards.
- 33. The Secretariat noted that similar food additives which were permitted for use at corresponding maximum use levels were grouped together in the Circular Letter for ease of reference. Compounds with maximum levels of use established under "good manufacturing practice" had also been included. The Secretariat also noted that comments submitted in response to the Circular Letter continued to support the establishment of a general food additive standard, although differences of opinion existed as to the format for such a standard. Many Delegations provided information on national provisions for food additives used in non-standardized foods in their countries. The Committee decided that this information provided an excellent basis for continued work on the general standard.
- 34. The Delegation of the Netherlands, as supported by the Delegations of Belgium, Canada, Denmark, Egypt, Finland, Germany, Sweden, Thailand and the U.S.A., agreed with the importance of continuing this activity, although it was noted that the first step should be the examination of the general principles, scope and format of such a standard. The Committee noted that this would include discussions concerning food additive categories, restrictions on the use of food additives, and food additive provisions in Codex standards. The Delegation of Denmark, supported by Finland, stressed the need to define specific food groups, to examine information concerning technological need, and to examine the basis of maximum use levels (i.e., examination ingoing or residual amounts). The Delegation of Belgium also emphasized the need to examine all sources of food additive intake when establishing use levels, especially for those compounds with a low acceptable daily intake.
- 35. The observer of the European Community indicated that its member states were also elaborating a global food additive directive based on a "horizontal" approach, which also took into account parameters concerning assurances as to compound safety, technological need and consumer information (e.g., labelling). The observer suggested that this information could be used to provide valuable input to the Committee. The observer of the International Organization of Consumers Unions (IOCU), while expressing their general support for the establishment of a general food additive standard, cautioned the Committee as to the importance of establishing good control parameters for the use of food additives in such a standard. The observer noted that this included, among other issues, the establishment of technological need at minimum use levels based on a thorough safety evaluation.
- 36. In the interest of facilitating the Committee's work in this area, it was agreed that a Working Group should be formed under the Chairmanship of the United States to begin deliberations at the current session on the establishment of a Codex General Standard for Food Additives, with a view towards the circulation of a document for government comment and input prior to the next Session of the Committee. The Working Group should take government comments concerning this issue into account as well as information provided by other Codex Committees and international organizations. It was also emphasized that the Codex General Principles for the Use of Food Additives

(CAC/MISC.1-1989) should be strictly followed. In this regard, the Committee was reminded that specific procedures existed in the Codex Alimentarius Procedural Manual (pages 131-135, Seventh Edition) concerning the relationship between the CCFAC and Commodity Committees. These procedures not only included toxicological evaluation, but also encompassed justification concerning technological functions and need for a food additive. Specifically, the Committee established the following terms of reference for the Working Group, which would include the recommendations of the "Denner" paper as a basis for its deliberations:

- should establish general principles for such a standard, which would include a discussion of the proposed format and scope;
- elaborate a Proposed Draft General Standard for Food Additives for all foods, which at the present time should be restricted to antioxidants and preservatives; and,
- complete the document in time to allow governments to study and comment prior to the next session.
- 37. The Committee also <u>agreed</u> that the Working Group under the chairmanship of the U.S.A. would consist of the following members: Australia, Belgium, Canada, Denmark, Finland, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, Switzerland, Thailand, the U.K., the U.S.A., EEC, IOCU, IFAC, ILSI, IDF, CIAA and IFGMA. It was also agreed that the Working Group would meet immediately prior to the next CCFAC to analyze government comments submitted and to provide a progress report to the plenary session.

CONSIDERATION OF INTAKE OF INTENSE SWEETENERS (Agenda Item 6)

- 38. The Committee had before it Conference Room Document 2 (CX/FAC 91/5), which summarized comments received from Egypt, the Netherlands and the U.K. to CL 1990/ 17-FAC in which governments were invited to submit information on the intake of intense sweeteners.
- 39. The Delegations of Egypt, the Netherlands, and the U.K. further explained their written comments. The Committee agreed that the data submitted indicated that special attention needed to be directed to the evaluation of intense sweetener intake for special population groups (i.e. children and diabetics). It was noted that this was especially relevant when considering intense sweeteners which have been assigned a low ADI, such as saccharin. The Delegation of the U.K. stated that actual intake surveys were the only way to obtain accurate intake figures, as hypothetical models resulted in misleading figures.
- 40. The Committee <u>concluded</u> that useful information on food additive intake had been collected, and that this information would be considered when elaborating the Codex General Standard for Food Additives.

ENDORSEMENT OF FOOD ADDITIVE PROVISIONS IN CODEX COMMODITY STANDARDS (Agenda Item 7 (a))

41. The Committee had before it document CX/FAC 91/6-Part I, which summarized those food additive provisions in Codex Standards forwarded for endorsement, as follows:

CODEX COMMITTEE ON PROCESSED MEAT AND POULTRY PRODUCTS (ALINORM 91/16)

- <u>Draft Revised Codex Standards for Luncheon Meat (Appendix VI). Cooked Cured Ham (Appendix VII). Cooked Cured Pork Shoulder (Appendix VIII) and Cooked Cured Chopped Meat (Appendix IX)</u>
- 42. The Secretariat explained that the CCPMPP had restricted the use of erythrosine to replace lost colour in luncheon meat and cured chopped meat products produced with binders. The Delegations of Finland, Japan, Poland, Sweden and Switzerland expressed reservations about the use of erythrosine, while the Delegations of Germany, the Netherlands, Norway and the U.K. requested the deletion of erythrosine entirely. The observer of the EEC advised against the endorsement of erythrosine because of its low ADI, and in view of possible intake from other food sources. The Delegation of Denmark reserved its position on nitrite, stating that an ingoing amount of 150 mg/kg was adequate.
- 43. With reference to phosphates, the Delegation of Switzerland, with support from the Delegation of Denmark, suggested that Codex should only deal with added phosphates. However, it was noted that a provision for naturally occurring phosphates had been included by the CCPMPP at the request of the CCFAC at its last session. The JECFA Secretariat also confirmed that iso-ascorbic acid had an ADI Not Specified whereas the MTDIs for added and naturally occurring phosphates were identical at 0-70 mg/kg bw. In addition, it was stated that iso-ascorbic acid was the same as erythorbic acid as evaluated by JECFA. The Committee agreed to these amendments.
- 44. The Delegation of Germany reserved its position on erythorbic acid. The Delegation of Finland asked whether metabolic competition between ascorbic acid and iso-ascorbic acid could cause toxicological problems, but the JECFA Secretariat said this was not seen as an issue.
- 45. The Committee <u>decided</u> to endorse those provisions forwarded by the CCPMPP, with the exception of erythrosine, which was not endorsed.

JOINT ECE/CODEX ALIMENTARIUS GROUP OF EXPERTS ON STANDARDIZATION OF FRUIT JUICES. (ALINORM 91/14)

- Draft Standard for Vegetable Juices (Appendix II)
- Draft Guidelines for Mixed Fruit Juices (Appendix III)
- Draft Guidelines for Mixed Fruit Nectars (Appendix IV)
- 46. The Delegation of the U.S.A. questioned whether carbon dioxide was an extraction solvent or a processing aid. The Secretariat and the Chairman of the Joint ECE/Codex Alimentarius Group of Experts on Standardization of Fruit Juices were of the opinion that in this case it was used as a carbonating agent and therefore, should be treated as a food additive.
- 47. The Committee <u>agreed</u> to endorse the food additive provisions in all three standards, which included a corrected classification of carbon dioxide as a carbonating agent.

JOINT FAO/WHO COMMITTEE OF GOVERNMENT EXPERTS ON THE CODE OF PRINCIPLES CONCERNING MILK AND MILK PRODUCTS (CX 5/70 - 22nd Session)

- <u>Draft Standard for Low Fat Dairy Spreads (A-16) (Appendix III)</u>
- 48. The observer of OFCA noted that both methylcellulose and carboxymethyl cellulose and its sodium salts were allocated an ADI not specified, and the Committee <u>accepted</u> these changes. The Delegation of Italy expressed its reservations concerning the levels of thickening agents proposed. The Delegation of Spain reserved its position on Annato.
- 49. The Committee agreed to endorse the food additive provisions of this standard, as amended above.
- Cheese Standards for Saint Paulin (C-13), Svecia (C-14), Herrgardost (C-21), Hushallost (C-22) and Norvegia (C-23). Cheddar Cheese (C-I), Other Cheeses (where applicable), Butter (A-I), Cottage Cheese (C-16), Processed Cheese Preparations (A-8c), Cream Cheese (C-31) and Flavoured Yoghurt and Products Heat-Treated After Fermentation (A-IIb)
- 50. Several comments were made concerning apparent confusion between the terms natamycin and nisin. The Committee concluded that nisin should be deleted from the text, and that the ADI listing for natamycin would read as 0-0.3 mg/kg bw.
- 51. The Delegations of Austria, Denmark, Japan, Switzerland and the U.K. reserved their position about natamycin, as it was felt to be undesirable to have antibiotics in food. This view was supported by the observer of IOCU. The observer of the IDF stated that natamycin was only applied on the surface of the cheese and that consumption of this food additive was negligible.
- 52. The Committee <u>agreed</u> to endorse those food additive provisions as forwarded by the CCMDS, and as amended above.
- Standard for Butteroil and Anhydrous Butteroil and Anhydrous Milkfat (A-2) -Antioxidant Provisions Only
- 53. The Committee did not endorse the use of TBHQ. All other antioxidant provisions of the standard were endorsed as presented. However, the Delegation of Germany reserved its position on dilauryl thiodipropionate and isopropyl citrate mixture.
- Draft International Group Standard for Cheeses in Brine (Appendix IX)
- 54. The JECFA Secretariat indicated that the ADI of "not allocated" was assigned to Patent Blue V and therefore, the Committee concluded that since there was no ADI, the food additive could not be endorsed.
- 55. The Delegations of Egypt, Germany, Greece, Italy, Norway, Sweden and Switzerland expressed their reservations concerning the use of any colours in this standard. The observer of IOCU noted that it had reservations about the use of colours in any basic foods. Consumers were especially concerned about what they perceived to be safety, deception and nutritional aspects. The observer of IDF pointed out that the main objective of colour use was to adjust for seasonal variations in milk production.
- 56. The Delegation of Australia, as supported by the Delegation of the U.K. and the observer of the IOCU, supported the view that in general terms CCFAC needed more information on technological need and justification for food additive use.

- 57. The Secretariat stressed that specific instructions existed which outlined procedures for cooperation between Codex Committees, which included providing technological information and justification for review by the CCFAC. It was agreed that the principles might need to be reviewed and reemphasized to all Codex Committees. These items were in fact scheduled for discussion at the FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade (18-27 March 1991 in Rome). It was agreed that the results of these discussions as well as discussions at the Commission concerning this subject would be forwarded to the Committee at its next session.
- 58. The Committee <u>agreed</u> to endorse the standard as proposed with a temporary endorsement for Brilliant Blue FCF subject to further information on technological justification, and no endorsement for Patent Blue V.
- <u>Draft International Group Standard for Uncured/Unripened Cheeses (Appendix X)</u>
- 59. The Secretariat noted that alpha and gamma carotenes should be deleted since the ADI of 0-5 mg/kg was based on beta carotene only. The Committee also noted that the ADI of sodium carboxymethyl cellulose should be listed as not specified. The Committee <u>agreed</u> to these amendments.
- 60. The observer of the IDF pointed out that calcium chloride was missing from the standard as a coagulating agent at a level of 200 mg/kg milk. The Secretariat agreed to the correction.
- 61. Several Delegations pointed to the fact that some substances such as starch, dextrose and gelatin were normally not considered as food additives. The observer of the IDF offered to obtain additional information on this point. The Delegation of Canada also asked whether carriers for stabilizers should be endorsed by the CCFAC. It was agreed to ask the Milk Committee for clarification concerning these issues, although the Secretariat pointed out that the Milk Committee had explained its view concerning the classification of food additives and processing aids in Annex I of CX/FAC 91/6-Part I.
- 62. The Delegation of Germany stated that stabilizers were not needed in cheese but only in cheese preparations. The Delegations of Belgium, Finland, Sweden and the observer of IOCU requested a limit for all colours and a technological justification for their use.
- 63. The Delegation of Iceland noted that Furcelleran was identical to Carrageenan, and therefore, the Committee decided to omit the term Furcelleran.
- 64. The Committee <u>decided</u> to endorse the food additive provisions as proposed and amended above, with a temporary endorsement for all colours pending an explanation of technological justification and proposed use levels and to remove those substances not normally considered to be food additives (e.g., starch, dextrose, gelatin) from the standard.
- Revised Standard for Sweetened Condensed Milk. Sweetened Condensed Skimmed Milk. Sweetened Condensed Partly Skimmed Milk and Sweetened Condensed High-Fat Milk (Standard A-4) (Appendix V)
- Revised Standard for Evaporated Milk. Evaporated Skimmed Milk. Evaporated
 Partly Skimmed Milk and Evaporated High-Fat Milk (Standard A-3) (Appendix IV)

65. The Committee <u>decided</u> to endorse the food additive provisions of both standards, and added the technological justification for the salts of the acids listed as stabilizers.

<u>Classification of Permitted Additions in Milk Product Standards as Food Additives or</u> Processing Aids

- 66. The Secretariat noted that the IDF statement, as forwarded by the CCMDS (Annex 1, CX/FAC 91/6-Part I), was presented to the Committee for information and comment as opposed to a request for a specific endorsement. The observer of the IDF pointed out that the list should be seen as an inventory indicating how food additives in milk products should be labelled. The observer of AMFEP pointed out that he could not agree with the statement that all enzymes except coagulating enzymes were considered as food additives and that with a few exceptions, all enzymes were normally considered as processing aids. The Delegation of the United Kingdom noted that this was merely a labelling question, and those enzymes used as food additives would need to be labelled.
- 67. The Delegation of Malaysia questioned the need for flavour enhancers. The Delegation of Germany also noted that added salts could not be considered as processing aids. The Delegation of Finland requested that the Committee should focus on categorizing enzymes as processing aids or food additives by following the INS classification.
- 68. The Committee concluded it would bring these issues to the attention of the CCMDS with a recommendation to reconsider the statement in view of CCFAC work on the elaboration of the International Numbering System.

<u>Enzyme Preparations Used in Cheese Manufacture and the Use of Lysozyme in the Prevention of Late Blowing in Cheese</u>

- 69. The Committee had before it Annex 2 of CX/FAC 91/6-Part I (Enzymes Used in Cheesemaking) which had been forwarded by the CCMDS to the CCFAC for advice and possible endorsement. The Delegation of The Netherlands reminded the Committee of the preceding discussion of the Milk Committee statement contained in CX/FAC 91-6/Part I, Annex 1 (see above). The Committee was requested to decide which enzymes were food additives and which were processing aids. The Milk Committee was requested to supply a more precise explanation of technological justification for use. Information was also requested on the toxicological status as well as specifications. This view was supported by many Delegations, which also noted that the list of enzymes was incomplete. The use of hydrogen peroxide in cheesemaking was questioned since JECFA had recommended against its use for the preservation of milk, except in very special cases.
- 70. The Delegation of Finland supported the Dutch view while adding that it should also be clarified as to which enzymes were originating from genetically modified microorganisms.
- 71. The Delegation of the U.K. reminded the Committee that the distinction between food additives and processing aids was only relevant for labelling purposes. Their safety and function were the only relevant aspects to be considered by this Committee. In this regard, JECFA was encouraged to continue its work in the evaluation of enzymes. The Delegation of the U.K. further stated that it had objections to the use of enzymes mentioned in Groups 4 and 5 in the annex because of a lack of technological justification. The Delegation of Egypt pointed out that enzymes from animal sources had

to be declared in many countries for religious reasons. The observer of IOCU stated that the use of enzymes should be declared on the label and that CCFL should consider this.

72. The Delegation of the Netherlands stated that the CCMDS should follow the nomenclature developed by JECFA if enzymes produced by genetically modified organisms were included in their revised proposals. The observer of the EEC also called attention to inconsistencies in the list. Coagulating enzymes were listed as processing aids only, when in fact, other functions were also assigned to the group of enzymes concerned. The Committee decided to refer the document back to the Milk Committee in order to focus its attention on the food additive and processing aid problem, especially as regards lysozyme, catalase, hydrogen peroxide and enzymes produced by genetically modified organisms.

Status of Endorsement of Food Additive Provisions

73. The results of the Committee's decisions regarding their endorsement of food additive provisions in Codex standards are contained in Appendix II, Part I to this report.

ENDORSEMENT OF FOOD CONTAMINANT PROVISIONS IN CODEX COMMODITY STANDARDS (Agenda Item 7 (b))

74. The Committee had before it document CX/FAC 91/6-Part II, which summarized those food contaminant provisions forwarded for endorsement, as follows:

CODEX COMMITTEE ON PROCESSED MEAT AND POULTRY PRODUCTS (ALINORM 91/16)

- <u>Draft Revised Codex Standards for Luncheon Meat (Appendix VI). Cooked Cured Ham (Appendix VII). Cooked Cured Pork Shoulder (Appendix VIII) and Cooked Cured Chopped Meat (Appendix IX)</u>
- 75. Several Delegations (Canada, Denmark, Finland, Germany, Norway, Sweden, Switzerland) and the observer of IOCU were opposed to the endorsement of the proposed levels for lead and tin stating that they were too high, and therefore, the contaminant provisions for these metals should not be endorsed by the Committee. Contamination of canned products through lead soldering or even the use of tin containers could be avoided due to improved technological procedures.
- 76. The Committee <u>decided</u> to temporarily endorse these provisions, with a view towards their reconsideration by the CCPMPP.
- Draft Revised Codex Standard for Corned Beef (Appendix V)
- 77. The Committee <u>decided</u> to temporarily endorse the provisions and to ask the CCPMPP to review the levels, as indicated above.

CODEX COMMITTEE ON CEREALS. PULSES AND LEGUMES (ALINORM 91/29)

- General Proposed Draft Guideline Levels for Contaminants in Cereals. Pulses and Legumes (para. 24)
- 78. The Delegation of the U.S.A. indicated that new data concerning cadmium were not available to the CCCPL, and that regardless of levels proposed, levels differed from foodstuff to foodstuff for several reasons, (e.g. naturally occurring metals in soil) and therefore, levels should be based on individual commodities with a related sampling plan.

- 79. The Committee agreed with the Delegation of the U.S.A. in that the establishment of single levels for cadmium and lead for all cereals, pulses and legumes was not in accordance with the variation that occurred between species and in different countries and regions. The Delegation of Japan supported the view of the U.S.A. by saying that more data on the distribution of cadmium in the natural environment in different regions and toxicological evaluations should be performed. Several Delegations thought that the proposed level for cadmium was too low and the level for lead too high. As the Committee also noted that arsenic and mercury based pesticides were no longer commonly used, it questioned the need for these contaminant provisions. The Delegation of Switzerland indicated that these levels were based on a contaminant questionnaire elaborated through the CCCPL, but that government responses were limited.
- 80. The observer of the IOCU expressed the growing concern among consumers concerning contaminants in western as well as other countries of the world, and noted that if contamination was preventable, high maximum levels should not be established.
- 81. The Committee <u>decided</u> to temporarily endorse the levels of arsenic, mercury and lead in cereals, pulses and legumes and to postpone endorsement of cadmium. Furthermore, it decided to ask the CCCPL to review the levels of lead as well as cadmium and to comment on the necessity to include levels for arsenic and mercury. The CCFAC also expressed the need for CCCPL to consider differentiating levels established for various types of cereals, pulses and legumes.

JOINT FAO/WHO COMMITTEE OF GOVERNMENT EXPERTS ON THE CODE OF PRINCIPLES CONCERNING MILK AND MILK PRODUCTS (CX 5/70 - 22nd Session)

- Draft Standard for Low Fat Dairy Spreads (A-16) (Appendix III). Draft Standard for Food Grade Sweet and Acid Whey Powders (A-15) (Appendix XII). Draft Standard for Edible Rennet Casein (A-14) (Appendix XI)
- 82. Several Delegations (Denmark, Finland, Norway and Sweden) were of the opinion that the level of lead in these standards was too high and that in normal situations the lead levels in milk were very low. Therefore, lead would only be present at very low levels in the products concerned.
- 83. The Committee <u>decided</u> to endorse the levels as proposed with the understanding that Delegations of the Nordic countries listed above reserved their position concerning this matter.

JOINT ECE/CODEX ALIMENTARIUS GROUP OF EXPERTS ON STANDARDIZATION OF FRUIT JUICES (ALINORM 91/14)

- <u>Draft General Standard for Vegetable Juices (Appendix II). Draft Guidelines for Mixed Fruits Juices (Appendix III) and Mixed Fruit Nectars (Appendix IV)</u>
- 84. The Committee was of the opinion that the proposed levels for arsenic, lead and tin were too high, although it was noted that identical levels for arsenic had been endorsed by the Committee in the past for similar fruit juice products. In answer to a question from the Delegation of Finland, the Chairman of the Joint ECE/Codex Alimentarius Group of Experts on Standardization of Fruit Juices explained that sulphur dioxide was a naturally occurring contaminant in fruit and vegetable juices.
- 85. The Chairman of the Joint ECE/Codex Alimentarius Group of Experts on Standardization of Fruit Juices noted that because of technical improvements in processing and packaging, levels of tin and lead should decrease in the near future.

86. The Committee <u>decided</u> to temporarily endorse the levels for arsenic, lead and tin and to endorse the other contaminant levels as proposed.

Status of Endorsement of Food Contaminant Provisions

87. The results of the Committee's decisions regarding their endorsement of food contaminant provisions in Codex standards are contained in Appendix II, Part 2 to this report.

ACTION REQUIRED BY THE CCFAC AS A RESULT OF CHANGES IN API STATUS OF FOOD ADDITIVES (Agenda Item 7 (c))

88. The Committee did not have any comments on the list in Part III of document CX/FAC 91/6 and accepted the list as presented. It was noted that the recommended changes might need to be reviewed by the individual Commodity Committees concerned, and that the Secretariat would facilitate this procedure. The food additives in question are included in this report as Appendix II, Part III.

<u>UPDATED INDEX OF CODEX SPECIFICATIONS</u> (Agenda Item 8 (a))

- 89. The Committee had before it Conference Room Document 3 (CX/FAC 91/7) containing the response of the U.S.A. to CL 1990/17-FAC. The Circular Letter requested governments to review the Updated Index of Codex Specifications (CX/FAC 90/7-Revised Annex) and to suggest food additives that should be considered for establishing Codex Advisory Specifications. The Delegation of the U.S.A. reported that of the 540 total food additives for which JECFA had established specifications, 505 had been reviewed by the Committee with 280 having been adopted as Codex Advisory Specifications. Thirty-five specifications had been elaborated by JECFA and published prior to 1971 and had not been reviewed by the Committee.
- 90. The JECFA Secretariat stated that comments had been requested on which of the remaining 260 food additives that have not been adopted as Codex Advisory Specification should be given priority for evaluation and updating by JECFA. He stressed the importance of replying and commenting to such circular letters. This was supported by the delegate from IOCU who stated that food additive specifications were very important to the consumer.
- 91. The Committee <u>decided</u> to circulate for comment a list of JECFA Specifications not adopted as Codex Advisory specifications for discussion by the Working Group on Specifications prior to the next CCFAC Session.

CONSIDERATION OF SPECIFICATIONS ARISING FROM THE 35TH JECFA SESSION (Agenda Item 8 (b))

- 92. The Committee had before it Conference Room Document 17 (Report of the Working Group on Specifications). The Working Group was chaired by Mr. D. Dodgen (U.S.A.) with Mrs. H. Wallin (Finland) serving as rapporteur.
- 93. The JECFA Secretariat reported that the combined Compendium of JECFA Food Additives Specifications had now been completed and was undergoing final minor editing prior to publication. This Compendium had been prepared by Dr. Kenji Ishii and supported by his colleagues in the Japan Food Additives Association. The JECFA Secretariat informed the Committee that the forthcoming Compendium of JECFA Food Additive Specifications would have several indexes and would indicate "CXAS" in the upper right-hand corner of each specification to show that they were Codex Advisory. In addition, the alphabetical index of the Compendium would give the year a specification had been adopted as CXAS; the index by functional class would have CXAS identified

by an asterisk (*); and there would be a separate index listing only those specifications which were CXAS. The Committee expressed its appreciation for these considerable efforts.

- 94. Two other related key JECFA references were also undergoing final editorial review before publication. The Food Additives Data System had been updated with the assistance of the International Life Sciences Institute (ILSI) and would be published as FAO Food and Nutrition Paper (FNP) 30, Revision 2. Also, the Guide to JECFA Specifications had been updated and expanded by Mrs. H. Wallin and her colleagues from the Food Research Laboratory of the Technical Research Centre of Finland. The Guide provided the analytical methods and other tests used in JECFA specifications and would be published as FAO FNP 5, Revision 2. The Committee commended both organizations and Mrs. Wallin for their efforts in preparing these important documents.
- 95. The Working Group reviewed all of the specifications contained in FAO FNP 49 which had been prepared following the 35th meeting of JECFA. The Working Group also considered the comments regarding these specifications received in response to CL 1990/21-FAC.
- During the review, the specifications were divided into five categories: I. recommended for adoption without changes; II. recommended for adoption with editorial or minor technical changes; III. referred to JECFA for further review because of necessary substantive changes; IV. specifications presently scheduled for JECFA review; and V. specifications which were classed by JECFA as tentative and could not be considered as Codex Advisory. Much of the discussion concerned the specification for Gum Arabic. Questions were raised as to the identity of the substance tested toxicologically and the specifications prepared by JECFA. It was reported that the International Association for Development of Natural Gums (AIDGUM), and the producing countries Chad, Mauritania, Senegal and Sudan maintained that the new JECFA specification did not represent the gum arabic of commerce. The article of commerce included various species of Acacia, not just Acacia senegal. The Working Group placed the Gum Arabic specification in category III. The JECFA Secretariat made it clear that any reevaluation of Gum Arabic by JECFA would be based only on a clearly defined test substance that had been chemically characterized and toxicologically tested. Specifications for such a substance should include tests to detect the presence of other gums which were not Gum Arabic and which would be considered as adulterants. The Committee agreed with the suggestions of the JECFA Secretariat.
- 97. The Delegation of Canada questioned the need for the Committee to review JECFA specifications. Several national Delegations and the EEC stated that such review was not only desirable, but they felt it was necessary as JECFA did not always have all of the relevant data and there was no provision for government review of the specifications.
- 98. The Committee <u>agreed</u> to send categories I and II (see Appendix III) forward to the CAC for adoption as Codex Advisory Specifications. The Committee also <u>agreed</u> that JECFA should be requested to review the use of toxic solvents required in the test procedures listed in specifications.
- 99. The Committee expressed its appreciation for the efforts of the Working Group and reinstated it under the chairmanship of Mr. D. Dodgen (U.S.A.). The following countries and organizations attending this Working Group were invited to participate in the reinstated group: Chad, Denmark, Finland, France, Germany, Japan, the

Netherlands, Senegal, Sudan, Switzerland, U.K., U.S.A., AIDGUM, ASPEC, EEC, FAO, IFG, ISO, Marinalg, SNPA.

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

- 100. The Committee had before it Conference Room Documents 4 (CX/FAC 91/8) and23 which summarized comments from Canada, Thailand and the U.S.A. submitted in response to CL 1990/17-FAC. The Committee was reminded that at its previous session specific criteria had been defined for the inclusion of a compound in the INS list (ALINORM 91/12, para. 90). The Committee was also reminded that the proposed Foreword, Table of Functional Class Titles and Definitions of the INS System, as agreed to at the last CCFAC Session, were being forwarded to the Commission for adoption at Step 8.
- 101. The Delegation of Canada submitted a list of several compounds to be included in the INS list. The observer from FIVS, supported by the Delegations of Germany, Italy and Spain, stated that saffron was not a food additive but rather a spice and therefore should not be included in the INS. The Chairman informed the Committee that flavours did not belong on the list.
- 102. The Delegation of the U.S.A. proposed the addition of edible gelatin as a thickener, stabilizer or glazing agent and gum ghatti and sodium caseinate as thickeners, stabilizers or emulsifiers. These substances were approved for use in foods by the U.S.A. and were required to be declared on the final product label.
- 103. The Delegation of Belgium stated that gelatine and sodium caseinate were considered food ingredients as opposed to food additives and for this reason should not be included in the INS list. It was noted that this discussion had also taken place at a previous session of the Committee (ALINORM 89/12 A, para. 77), whereby a request to include sodium caseinate on the list was denied. The Delegation of the United States recalled that the criteria for the inclusion of a compound in the INS list was that it be approved as a food additive by a member country. Therefore, edible gelatin and sodium caseinate should receive INS numbers. However, the Delegation of the U.S.A. stated that it was willing to withdraw the proposals, but would make the proposal again next year.
- 104. The Committee <u>agreed</u> that only gum ghatti would be included in the INS list. The Committee also <u>agreed</u> with the proposals of Canada concerning the inclusion of several compounds in the INS list. The proposals of Thailand were already included in the INS system except for sodium calcium silicoaluminate (anticaking agent) which should be resubmitted at the next session with additional information provided by the Thai authorities.
- 105. The Committee <u>decided</u> to include revisions to the INS list as a standing agenda item, which would be coordinated by the Delegation of Australia, based on responses to a circular letter. The proposed amendments to the INS list, which are included in the report as Appendix IV, were being forwarded to the Commission for endorsement.

PROPOSED AMENDMENTS TO THE INVENTORY OF PROCESSING AIDS (Agenda Item 9 (b))

106. The Committee had before it Conference Room Document 5 (CX/FAC 91/8 - Add.1) containing the response of the U.S.A. to CL 1990/17-FAC, which proposed to add Chymosin Enzyme Preparation derived from *E. coli* K-12 to the inventory,

- 107. The Delegation of the U.S.A. stated that the inventory was an information document and that some of the substances on the inventory had been evaluated by JECFA. The Chymosins produced by three different microorganisms were evaluated by JECFA and would be added to the inventory. The Delegation of the U.S.A. offered to revise the inventory for presentation at CCFAC's session next year. The observer of EEC indicated that the inventory would be helpful to their member states when preparing legislation on the control of processing aids. Several Delegations pointed out that an inventory list of processing aids should not contain substances which were normally considered as food ingredients or food additives.
- 108. The Committee <u>agreed</u> that a revised inventory of processing aids would be presented by the U.S.A. at the next session, with the understanding that additional proposals would also be obtained through a circular letter.

PROPOSED AMENDMENTS TO CODEX LIST B (Agenda Item 9 (c))

- 109. The Committee had before it document CX/FAC 91/8-Add.2A containing suggested changes to Codex List B.
- 110. The Secretariat pointed out that the last full text of list B had been published in 1987 and asked whether there was a need to continue updating the list. The Committee noted that although in the past the list had been useful, in the future it would have limited relevance.
- 111. The Committee concluded that the updating of List B should be discontinued with the understanding that it might be reinstated if necessary. The current proposals for updating Codex List B, as agreed to by the Committee, are appended to this report as Appendix V.

MYCOTOXINS IN FOOD AND FEED (Agenda Item 10)

112. The Committee had before it documents CX/FAC 91/10, CX/FAC 91/10-Add. 1, CX/FAC 91/10-Add. 2, CX/FAC 91/10-Add. 3, and Conference Room Documents 6, 7 and22, which provided a summary of government comments submitted, as well as the report of the Working Group on Mycotoxins (Conference Room Document 18). The Chairman reminded the Committee that at its 22nd Session proposed maximum levels for aflatoxins in food and feed were circulated for comments (CL 1990/17-FAC) on these levels as well as on a proposed sampling plan. The CL also requested information on the relationship between aflatoxin B_1 in feed and aflatoxin M_1 in milk.

PROPOSED DRAFT MAXIMUM LEVELS FOR AFLATOXINS IN FOOD (Agenda Item 10 (a))

- 113. The Chairman of the Working Group reported that the proposed level of $10\mu g/kg$ total aflatoxins for all foods had been extensively discussed at the meeting of the Working Group. It was noted that the importing and exporting countries were moving further apart on the acceptability of the proposed maximum levels for all foods. Several countries mentioned that maximum levels for aflatoxins in food should be established on a commodity by commodity basis as it was very difficult to establish a single level applicable to all foodstuffs. The Working Group noted that using the terms such as raw and processed for commodities could lead to confusion, as these terms needed to be accurately defined.
- 114. The Secretariat explained that the status and application of guidelines, as opposed to statutory levels in Codex Standards would be dealt with at the FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade in Rome, and

consequently by the CAC. The Committee noted that normal procedures for the application of maximum levels applied to food ready for consumption, with emphasis placed on control by the importing country. Nevertheless, the CAC had encouraged the exporting country to establish measures to guarantee that a certain foodstuff did not exceed a limit applied at point of import.

- 115. The Delegation of Denmark stated that in consideration of aflatoxin toxicity, the lowest possible level should be set in order to protect the consumer. The level of 4 μ g/kg as proposed by Denmark was supported by several Delegations.
- 116. Several Delegations agreed that levels for aflatoxins should be set on a commodity by commodity basis, and these commodities should include the establishment of a level for aflatoxin M_1 in milk as well. It was noted that levels for commodities that would undergo further processing could be higher than the level for the product ready for human consumption, because processing or sorting could in some circumstances reduce these levels. The Committee also noted that JECFA was not likely to reevaluate aflatoxins in the near future or establish a tolerable daily intake, and therefore, a numerical limit for these toxins would be difficult, if not impossible, to establish.
- 117. The Delegation of Egypt, supported by France and Switzerland, stated that special care should also be directed to infant food. The Delegation of the Netherlands, as supported by the Delegation of the U.K., stated that levels should be set for raw products that moved in international trade which were ready for processing into foods for human consumption. The Delegation of Denmark stated that it was clear that more information on this subject was needed and that governments should be invited to submit more data to the Committee.
- 118. The Committee <u>decided</u> to solicit information and comment from governments on the following issues:
 - i) identify specific foodstuffs that could be contaminated with aflatoxins and which moved in or caused problems with international trade (e.g. figs, tree nuts, dried fruits, corn, peanuts and maize);
 - ii) provide technological and intake data on individual commodities, and also give information as to the stage or effects of processing;
 - iii) provide information on the identification of the target (human or animal) consumer of the commodity;
 - iv) provide information on national regulations concerning aflatoxins;
 - v) provide suggestions for suitable sampling plans.

As a result of these discussions, the Committee <u>decided</u> not to establish a maximum level for total aflatoxins in foods at the present time.

Proposed Draft Guideline Levels for Aflatoxins in Peanuts

119. The Secretariat reported that the Codex Committee on Cereals, Pulses and Legumes had proposed maximum levels for total aflatoxins in peanuts for circulation and government comment at Step 3 (ALINORM 91/29, Appendix II). The proposed levels were 15 μ g/kg for raw peanuts and 10 μ g/kg for processed peanuts. The Committee noted that although it was not being asked to endorse the proposed levels at this time, it nevertheless would make comments to CCCPL.

120. Several Delegations stated that the proposed levels were too high, while others said that more information should be requested from CCCPL concerning the basis on which these levels were elaborated. The Delegations of Denmark, Germany and the U.K. supported a level of $4\mu g/kg$ b.w. for ready-to-eat peanuts. The CCCPL would also be requested to indicate at which stage of processing the proposed levels would apply (i.e., ready for processing, ready for consumption, etc.). The Committee <u>decided</u> to submit to the CCCPL the different opinions expressed above concerning requests for information on the data underlying the levels, as well as the stage of processing.

Proposed Draft Guideline Levels for Aflatoxin M₁ in Milk

- 121. The observer of the IDF called the attention of the Committee to the IDF-statement (CX/FAC 91/10-Add. 1), in which information was summarized concerning aflatoxin in milk and feed and analytical methods as requested by the CCFAC (para.141, ALINORM 91/12). This information had been discussed by the Milk Committee for forwarding to the CCFAC. The observer of the AOAC suggested that a document distributed to the Working Group on Mycotoxins which listed methods of analysis for aflatoxins should be circulated for comment and endorsement by the CCMAS, and adoption by the Commission at Step 8. The Delegation of Egypt also noted that care should be taken when discussing baby foods.
- 122. The representative of IDF explained that it was proposing a guideline level of $0.05\mu g/kg$ for bulk milk and $0.01~\mu g/kg$ for milk for baby food for aflatoxin M₁ The Committee noted that several Delegations supported the levels to be forwarded 0to the Milk Committee and <u>decided</u> to seek government comments on these levels, (also see paras. 124-127).
- 123. The proposed draft guideline level for aflatoxin M_1 in milk and the AOAC methods of analysis for aflatoxins are included in this report as Appendix VI.

PROPOSED DRAFT MAXIMUM LEVELS FOR AFLATOXIN IN FEED (Agenda Item 10 (b))

- 124. The Committee had before it document CX/FAC 91/10-Add.1, as well as Conference Room Documents 6 and 22, which summarized government comments submitted in response to CL 1990/17-FAC. The Report of the Working Group on Mycotoxins was also presented to the Committee in Conference Room Document 18. The Committee also noted the IDF statement in document CX/FAC 91/10-Add. 1 as forwarded by the CCMDS, which provided information requested by the CCFAC at its last session (para. 141, ALINORM 91/12).
- 125. The Committee noted from the Working Group report that an increasing number of countries based their policy towards aflatoxin B_1 in feed on a maximum level of aflatoxin M_1 in milk of 0.05 μ g/kg. It was recognized that in order to maintain the maximum level of 0.05 μ g/kg in milk, a maximum level of 5 μ g/kg (aflatoxin B_1) in supplementary feed for milk producing animals should be established. The Delegation of Egypt also expressed a need to take feed ingredients into account.
- 126. The Working Group proposal was supported by the Delegations of Canada, Denmark, the Netherlands and Switzerland, while the Delegation of the U.S.A. reserved its position.
- 127. The Committee <u>decided</u> to send the proposed draft maximum level of [5 μ g/kg] aflatoxin B₁ in supplementary feed for milk producing animals to governments for comments at Step 3 based on the information submitted by the Milk Committee

concerning the relationship between aflatoxin M_1 in milk and aflatoxin B_1 in feed, (also see paras. 121-123). The proposed level is included in the report as Appendix VI.

SAMPLING PLANS FOR AFLATOXINS (Agenda Item 10 (c))

- 128. The Chairman of the Working Group noted the two sampling plans for aflatoxins in peanuts as circulated for comments at Step 3 by the CCCPL, and as included in document CX/FAC 91/10-Add.2. In addition, other government comments submitted in response to CL 1990/17-FAC were summarized in Conference Room Document 6.
- 129. The Working Group, while noting that sampling plans should be established only when tied to a specific commodity, suggested that the sampling plan proposed at its last session should not be considered for the time being.
- 130. The Committee <u>agreed</u> that sampling plans should be established on a commodity by commodity basis. Several Delegations suggested that the Committee should establish a confidence limit for the sampling plan.
- 131. The Committee <u>decided</u> to send out a circular letter seeking comment and information on sampling plans and confidence limits for those commodities which were items of concern to governments. The Committee also agreed in principle with the CCCPL to request the Commission to consider holding an expert: consultation to examine those issues regarding sampling plans for aflatoxins.

PROPOSED DRAFT MAXIMUM LEVELS FOR PATULIN AND OCHRATOXIN IN FOODS (Agenda Item 10 (d))

- 132. The Committee had before it document CX/FAC 91/10-Add.3 and Conference Room Document 7, which summarized government comments submitted in response to CL 1990/17-FAC and the Report of the Working Group on Mycotoxins (Conference Room Document 18). The Committee recalled that at its previous session it had decided to gather information concerning national strategies, regulations, methods of compliance and problems experienced in international trade regarding this subject.
- 133. The Chairman of the Working Group informed the Committee that several countries had established guideline levels for patulin at 50 μ g/kg in apple products. It was generally recognized that good manufacturing practices would be sufficient to avoid patulin contamination, and that problems in international trade related to patulin were nonexistent. The Delegation of Denmark maintained that there was not a need for the establishment of patulin levels. However, the Delegation noted that attention should be directed to ochratoxin A as it was a contaminant in several commodities. More information should be solicited before proposing guideline levels. The Delegations of Germany and the Netherlands also supported the need for more information on ochratoxin A. The Committee was also informed that a number of other mycotoxins, especially those produced by Fusarium species such as trichothecenes, needed further attention.
- 134. The JECFA Secretariat informed the Committee that a PTWI had been established for ochratoxin A at a level of 112 μ g/kg body weight by the 37th JECFA. In addition, the International Programme on Chemical Safety (IPCS) had recently published an Environmental Health Criteria (EHC) document (No 105) on selected mycotoxins, including the ochratoxins. The Committee also noted that the AOAC had adopted a new validated chromatographic method with a detection limit of 10 μ g/kg for ochratoxin A. The Delegation of Sweden reported that a recent toxicological evaluation by an expert

Nordic group had concluded that 5 μ g/kg b.w. was a tolerable daily intake. It was noted that the group's report would be made available to the Committee.

135. The Committee <u>agreed</u> that more information should be requested on ochratoxin A and the trichothecene group for discussion at its next session.

REPORT OF THE WORKING GROUP OF MYCOTOXINS (Agenda Item 10 (e))

136. The Committee reinstated the Working Group on Mycotoxins under the Chairmanship of the Netherlands. The Working Group membership included: Australia, Belgium, Canada, Denmark, France, Germany, the Netherlands, Portugal, Sweden, Switzerland, Thailand, U.K., U.S.A., AOAC, IDF, IPCS and IPF.

INDUSTRIAL AND ENVIRONMENTAL CONTAMINANTS IN FOOD

The Chairman introduced this Agenda Item by explaining the approach of the Netherlands. The Netherlands had several legal limits for environmental and industrial contaminants, among which were heavy metals, PCBs and dioxins. The general policy was that legal limits should ensure that heavy contaminated food did not enter the market and that the food consumed was safe. These were the effect directed measures. Furthermore, there were source directed measures to prevent contaminants entering the environment and, as a result, the food chain. The Chairman expressed the need for a basic philosophy on contaminants.

GUIDELINE LEVELS FOR RADIONUCLIDES IN FOODS (i.e. dilution factors applied. treatment of minor dietary components) (Agenda Item 11 (a))

- 137. The Committee had before it document CX/FAC 91/11, as well as Conference Room Documents 8 and 22, which summarized government comments submitted in response to CL 1990/17-FAC. The Committee was reminded that Guideline Levels for Radio nuclides in Foods were adopted at the 18th Session of the CAC and published in Supplement 1 of Codex Alimentarius Volume XVII. As requested by the CAC, the CCFAC agreed that the application of dilution factors and minor dietary components should remain under review, and decided to seek additional government comments.
- 138. The majority of Delegations stated that their countries would apply maximum permitted levels established for foodstuffs to concentrated or dried products on the basis of the product as prepared for consumption. Dilution factors as provided by the manufacturers would be taken into consideration. The Delegation of Egypt directed the attention of the Committee to the use of milk powder for children. They expressed the need for assessment of the risk arising from dilution factors applied in the preparation of milk which represented a major portion of a child's diet. The Delegation of the U.S.A. recommended that the guideline level should apply to the commodities in the form in which they were offered in international trade, as opposed to the food as prepared for consumption. In the latter case there would be a proliferation of different standards for the same commodities which were dependent on their stage of preparation. The observer of IOCU stated that it favoured the ready for consumption approach.
- 139. The Committee <u>decided</u> to inform the CAC of its discussion, which included its decision to apply the guideline levels for radionuclides in food to the reconstituted product (i.e., ready for consumption).
- 140. The Committee considered the comments received on minor dietary components. The observer of the EEC informed the Committee that the Community had adopted regulations establishing maximum permitted levels of radionuclide contamination in minor foodstuffs following a nuclear accident and a list of foodstuffs

considered to be of minor importance in the diet. It was noted that the maximum permitted contamination levels for these minor dietary products were ten times higher than those applicable to commonly consumed foodstuffs.

- 141. The observer of the IOCU commented that the list of foodstuffs considered of minor importance in the EEC's regulation included several commodities which represented important products for the diet in some regions of the world. The observer of IOCU emphasized the need to treat all foods with a uniform approach when applying guideline levels for radionuclides. Other Delegations also expressed strong reservations to the EEC list in view of different diets and habits in diverse regions of the world.
- 142. The Committee noted that it was not its task to define minor dietary components. It noted that the Codex Guideline Levels for Radionuclides in Food emphasized the need for special consideration for certain classes of food which were consumed in small quantities, such as spices. The Chairman concluded that the existing text in the Standard was supported by the Committee.

ESTABLISHMENT OF GUIDELINE LEVELS FOR RADIONUCLIDES IN FOOD SUBSEQUENT TO THE ACCIDENT YEAR (Agenda Item 11 (b))

- 143. The Committee had before it document CX/FAC 91/11-Add.1 and 91/11-Add.1A as well as Conference Room Documents 9, 22 and 23 which summarized government comments submitted in response to CL 1990/33-FAC. The Committee was reminded that the CCEXEC had requested the CCFAC to examine the application of levels for radionuclide contamination on a permanent basis, with a view towards providing advice to the Commission.
- 144. The observer of the EEC informed the Committee that two main factors should be considered in the establishment of permanent guideline levels subsequent to the accident year. These included contamination of foods up to 5 years after an accident and the total exposure of a population to radionuclides. For these reasons, the observer of the EEC recommended that the Codex guideline levels should apply not only to the accident year, but also to the whole period during which contamination could exceed the guideline levels.
- 144. The Delegation of Norway, as supported by the Nordic countries, recalled its position as presented at the 17th Session of the Codex Coordinating Committee for Europe, which had given extensive reasons for establishing levels for radionuclides on a permanent basis (paras. 119-128, ALINORM 91/19). The Delegation of Switzerland stated that the Committee should consider establishing lower levels for radionuclides in foods after the first year, in view of the decreasing contamination of agricultural products. The Delegation of the U.K. supported the extension of the existing guideline levels for a longer period, but opposed a level established on a permanent basis, because it was unnecessary for international trade. The Delegation of Egypt, supported by Malaysia and Thailand, speaking on behalf of the CCASIA, expressed their concern and reservations to the extension of current Codex guideline levels in foods for a period subsequent to the accident year, as these levels were felt to be too high. It was felt that permanent guideline levels needed to be established on a completely different basis.
- 146. The observer of the IOCU supported the point of view of Switzerland, and expressed its concern for consumer protection in view of the extension of the original guideline levels for radionuclides in food for a longer period of time.
- 147. The Committee <u>agreed</u> that the current Codex guideline levels for radionuclide contamination in foods should be extended for an indefinite period, especially when

considering that there was no additional risk for consumers, but that the need for it would be regularly reviewed. The Committee also noted that in the future, information provided by the International Commission on Radiation Protection might also be an excellent basis to decide on the extension of the guideline levels. The Committee <u>decided</u> to forward this information to the CAC for its consideration.

DRAFT GUIDELINE LEVELS FOR METHYLMERCURY IN FISH (Agenda Item 11 (c))

- 148. The Committee had before it document CX/FAC 91/11-Add. 2 and Conference Room Documents 10 and 23, which summarized government comments submitted in response to Circular Letter 1990/28-FAC. The Committee recalled its earlier discussions concerning this issue, whereby the advice of the Codex Committee on Fish and Fishery Products (CCFFP) was sought concerning CCFAC proposals for the establishment of guideline levels for methylmercury in fish (Appendix VIII, ALINORM 91/12). The CCFFP, while opposing the establishment of guideline levels in general, had noted that more work would need to be undertaken to determine to which predatory species the levels would apply. In any case, the CCFFP favoured the measurement of total mercury as opposed to methylmercury.
- 149. Several Delegations (Australia, Belgium, Denmark, Finland, France, Germany, the Netherlands, Sweden and Switzerland) were in favour of relating maximum levels to total mercury as opposed to methylmercury as the analysis for total mercury was considered easier, cheaper and more readily available. The Delegation of the U.S.A. indicated its preference for the analysis of methylmercury.
- 150. Several Delegations (Australia, Belgium, Denmark, Finland, France, Germany, the Netherlands and Sweden) supported the previously proposed two guideline levels of 1.0 mg/kg for certain specified predatory fish and a level of 0.5 mg/kg for all other species. The Delegations of Canada and the U.S.A. did not see the need for two guideline levels. The Delegation of the U.S.A. favoured one limit (1.0 mg/kg methylmercury) for all fish. New Zealand stressed that some kinds of predatory fish like marlin contained more than 1.0 mg mercury/kg and that in these cases, recommendations for consumers were necessary.
- 151. The Committee <u>agreed</u> on two levels, one high level for predatory fish such as sharks, swordfish, tuna and pike, and one lower level for other fish as proposed at its last session to remain as elaborated for forwarding to the CAC for endorsement at Step 8. The Committee also a <u>greed</u> to seek additional information from governments and the CCFFP as to other predatory species which were creating problems in international trade.

NATIONAL STRATEGIES FOR CONTROL OF CADMIUM AND LEAD IN FOOD (Agenda Item 11 (d))

- 152. The Committee had before it document CX/FAC 91/II-Add.3 and Conference Room Documents 11 and 23, which summarized government comments submitted in response to CL 1990/17-FAC. The Committee noted that existing guideline levels for lead in Codex Standards were contained in Volume XVII of the Codex Alimentarius, and that provisions for cadmium had not been established, (see also Agenda Item 7 (b), above). The Committee also recalled that general guideline levels for certain food groups were established at its 21st Session and circulated for government comments at Step 3 (CL 1989/16-FAC and Appendix IX, ALINORM 89/12A).
- 153. The Delegation of Sweden stated that lead contamination of wine could be decreased by prohibiting the use of lead capsules on wine bottles, which was in line with

- a recent recommendation elaborated by the Office International de la Vigne et du Vin. The Committee <u>agreed</u> to recommend to the Commission that the use of lead capsules on wine bottles should be phased out by the end of 1993.
- 154. Several Delegations stated that improved technological processes made the use of lead soldered cans unnecessary. Additionally, the phasing out of the use of lead in shot used in hunting, clay pigeon shooting, in food contact materials and in petrol were also important in the elimination of lead contamination. The Committee <u>agreed</u> to encourage the elimination of the use of lead soldered cans. The Delegation of Australia pointed out that developing countries which may still be using lead soldered cans should receive technological assistance towards this end.
- 155. The importance of controlling source orientated operations to reduce the contamination of the environment with cadmium and lead was emphasized. This would result in lower levels of these contaminants in food. The Delegation of the U.S.A. stated that cadmium was present naturally in many soils. The Committee recommended reducing the cadmium content of fertilizers and the phasing out of lead containing petrol.
- 156. The Delegation of the Netherlands noted that the establishment of guideline levels could prevent highly contaminated food products from being traded or sold. The Delegation of Denmark also agreed that international guideline levels are needed to prevent international trade problems. The Committee <u>decided</u> to continue Its deliberations on setting levels based on the need to protect consumers and to prevent trade problems. The Committee <u>agreed</u> to collect intake data and proposals for guideline levels for those commodities causing problems in international trade.
- 157. In addition, the Committee expressed a need for a general philosophy to facilitate its deliberations concerning the establishment of guideline levels for contaminants. The Committee accepted the offer of the Delegations of Denmark and the Netherlands to prepare a paper for discussion at the next CCFAC meeting. The Secretariat also reminded the Committee that discussions to be held at the FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade in Rome and CAC concerning this issue should be taken into consideration.
- 158. The Committee noted that a proposal for the reduction of lead levels in all sugar standards from 2 mg/kg to 1 mg/kg, (except for white sugar which was already at 1 mg/kg and fructose which was 0.5 mg/kg) had been circulated for government comments at Step 3, (CL 1989/27-S). These reductions had been temporarily endorsed at the 19th CCFAC Session and were currently scheduled for adoption by the CAC at Steps 5 and 8 (using the accelerated elaboration procedure).
- 159. The Committee, while noting the above proposals, concluded that the lead levels could be lowered significantly. The Committee <u>decided</u> to recommend to the CAC that the lead levels in sugars should be lowered even further to 0.5 mg/kg, which would align all of the sugar standards with the current lead levels in the fructose standard.

NATIONAL STRATEGIES FOR CONTROL OF POLYCHLORINATED BIPHENYL (PCBs) IN FOOD (Agenda Item 11 (e))

- 160. The Committee had before it document CX/FAC-90/20-Add.1 as prepared by the Netherlands and Conference Room Documents12, 21 and 22, which summarized government comments.
- 161. The Delegation of the Netherlands stated that reliable tolerable daily intake levels had not yet been established for PCBs and that in view of the difficulty in establishing

such levels, it was not likely they would be established in the near future. However, it was expected that tolerable intakes would be below 1 μ g/kg bw/day. The Delegation of the Netherlands also noted that PCBs were banned in most countries but that their presence in the environment, and therefore in the food chain, would persist for a long time. The Delegation noted that two different approaches in PCB analysis existed, i.e. one measuring total PCBs, and one focusing on individual congener PCBs. It was stated that national strategies tended to be source oriented and included PCB monitoring. Several countries had already established legal maximum levels for PCBs in foodstuffs. The Delegation of the Netherlands recommended guideline levels for PCBs in foodstuffs for the consideration of the Committee.

- 162. The Delegation of Germany stated that German policy was directed toward the control of contamination sources and followed EEC directives in this area. The Delegation also noted that maximum levels for specific congeners and food items also existed.
- 163. The Delegations of Norway and Denmark stated that only isolated cases of PCB contamination were known. It was noted that a national survey on dioxin, including coplanar PCBs, was underway in Norway. The Delegation of Denmark expressed its preference for a method of analysis exclusively based on those congener PCBs that were toxicologically the most significant.
- 164. The IOCU observer expressed his concurrence with the safety factor of 100 applied to the no-observed-effect level (NOEL) for monkeys as highlighted in the working paper. He asked whether PBBs, which were used as fire retardants, could also be included, especially due to concerns regarding their accumulation. The Delegation of the Netherlands explained that as PBBs were far less known than PCBs, more research in this field was needed. He stated that PBBs were scheduled to be banned in the Netherlands.
- 165. The Delegation of Sweden stated that PCBs, PBBs and dioxins should be considered together. The Swedish approach was also source orientated and included a total prohibition of PCBs.
- 166. The JECFA Secretariat stated that JECFA did not provide tolerable daily intakes for PCBs due to a lack of reliable data. It was pointed out that an Environmental Health Document on PCBs would probably be finalized within the next year, but that the information provided would also be limited. PBBs had not been evaluated by JECFA, but based on their chemical properties, one would expect accumulation.
- 167. The Delegation of the U.S.A. pointed out that there was a need for a PCB guideline level for fish only, as levels for other products were becoming increasingly lower with effective source contamination controls.
- 168. The Delegations of Canada, Denmark, Germany, the Netherlands, Norway and Sweden expressed a preference for the establishment of guideline levels for specific congeners. However, this could cause difficulties as not every country could perform these analyses, and there would also need to be agreement on which congeners would be analyzed.
- 169. The Committee <u>agreed</u> to the following conclusions concerning this issue:
 - 1. The Committee expressed its general opinion that the preferred approach to the control of PCBs was at their source, which included a ban on PCB use and a control of waste incinerators.

- 2. A circular letter would request governments for comments on establishing guideline levels for PCB congeners for fish as proposed in document CX/FAC-90/20-Add.l. Information on toxicologically significant congeners and on the necessary methods of analysis would also be requested.
- 3. Further data on intake, legislation and monitoring of PCBs, PBBs and Ugilec, would also be collected.
- 4. The above discussion would also be forwarded to the CCFFP for information and comment.

NATIONAL STRATEGIES FOR CONTROL OF DIOXINS IN FOOD (Agenda Item 11 (f))

- 170. The Committee had before it document CX/FAC-91/II-Add.4, as well as Conference Room Documents 13 and 22, containing the responses of governments concerning this subject (CL 1990/17-FAC).
- 171. The JECFA Secretariat explained that there had been a WHO expert consultation on dioxins, held in the Netherlands in December 1990, where data from both animal experiments and human exposure to dioxins were compared. The consultation concentrated its deliberations on 2, 3, 7, 8-TCDD as this was the most toxic congener and was carcinogenic in animals. Human data on 2, 3, 7, 8-TCDD were inconclusive and there appeared to be no evidence of genotoxicity. A tolerable daily intake of 10 picogr/kg b.w. was established by the consultation.
- 172. The Delegation of Canada pointed out that Canada had considerable experience related to dioxins. It explained that a general regulation existed in Canada in which foods were considered adulterated if they contained any level of dioxins. Due to improved analytical methodology, application of this regulation had become impractical and was under review. In light of this, Canada had taken an approach which was source oriented and was aimed at providing consumer consumption advisories if necessary (e.g., fish and shellfish in the vicinity of pulp mills) and reducing or eliminating by technological means sources of dioxins. In this context, the Delegation of Canada pointed out the recent technological changes in the manufacture of bleached paper board which had led to the elimination of this as a source of dioxins in milk packaged in cardboard containers.
- 173. The Delegations of Denmark, the Netherlands, Norway and the U.S.A. supported the Canadian approach as related to source control aspects. Waste incinerating plants and metal industries were indicated as other major sources of contamination. The Delegation of Germany indicated how their source orientated approach was translated into limit setting regulations for various sources of contamination. However, it was noted that there was not enough data to establish guideline levels at the present time. The observer of the EEC also pointed out that several relevant EEC-directives existed concerning dioxins that could provide a good source of information for the CCFAC. The Committee concluded that as the major sources of dioxin emission were known, the first objective should be the reduction, avoidance or control of dioxin contamination. The CCFAC also noted that the affected commodities apparently were the fat portions of animal and milk products and fatty fish. The Committee also decided that the establishment of guideline levels was premature, but that the collection of information should continue in view of national surveys undertaken in several countries, (e.g. Denmark, the Netherlands, Norway).
- 174. The Committee decided to solicit additional information through a CL, as follow:

- 1. identification of contamination sources and national control strategies;
- commodities affected (e.g. animal fat, fatty fish, milk);
- 3. information concerning harmonized methods of analysis, and
- 4. the need for the establishment of guideline levels which included the identification of international trade problems.

NATIONAL STRATEGIES FOR CONTROL OF BENZO-(A)-PYRENE. HYDROGEN CYANIDE. 2-DIETHYLHEXYLPHTHALATE AND ETHYLCARBAMATE (Agenda Item 11 (g))

175. The Committee had before it document CX/FAC-Add.5 and Conference Room Documents 14, 22 and 23 which summarized government comments submitted in response to CL 1990/17-FAC. The Committee <u>agreed</u> to discuss these substances on a case-by-case basis.

Benzo-(a)-pyrene

- 176. Several Delegations introduced their comments and reported that the benzo-(a)-pyrene content of food could be greatly reduced by good manufacturing practices (GMP). The way food was prepared, e.g. smoking, influenced the level of this compound in food. Foodstuffs could also be contaminated from environmental sources.
- 177. The Delegation of Sweden, supported by Denmark and the Netherlands, stated that more information was needed on this compound, as well as on other polycyclic aromatic hydrocarbons and suggested to maintain this subject as an item for discussion for next year.
- 178. The Committee <u>agreed</u> with this suggestion, and <u>recommended</u> that the level of benzo-(a)-pyrene should be kept as low as possible by applying GMP and by processing foodstuffs in an appropriate matter. It was also recommended that environmental pollution with benzo-(a)-pyrene should be avoided.

Hydrogen cyanide

- 179. The Delegation of the UK suggested that the Committee examine cyanogenic glycosides in general, instead of considering hydrogen cyanide only. Several Delegations noted that this substance occurred naturally. The Delegation of Switzerland stated that the levels occurring in spirits such as kirsch did not pose a problem to health. The JECFA Secretariat also noted that hydrogen cyanide and glycosides were on the JECFA priority list for evaluation.
- 180. The Committee <u>decided</u> to discuss hydrogen cyanide next year and to ask for more toxicological data, data on occurring levels, national regulations and national control measures to reduce contamination.

2-diethylhexylphthalate (DHP)

- 181. The Delegation of Denmark said that DHP was not only a contaminant of food due to migration from plastic wrappings, but it was also an environmental pollutant. It biodegraded slowly and since additional data would be forthcoming, it should be kept on the agenda for future CCFAC sessions.
- 182. The observer of the EEC mentioned that there was an EEC directive on maximum permitted levels of DHP in food migrating from plastics. Several Delegations suggested that contamination of food with DHP could be avoided by only permitting its use for packaging used for non-fatty foods.

183. The Committee <u>decided</u> to request information through a CL on phthalates in general and to recommend against the use of DHP in plastics that came into contact with fatty foodstuffs. Furthermore, governments would be requested to submit to the Committee any information on regulations, levels of contaminants and of possible trade problems.

Ethylcarbamate

- 184. The Committee noted that some countries had set guideline levels for ethylcarbamate in commodities like distilled spirits and wines. Other countries had made recommendations to the industry to lower this contamination, in conjunction with control monitoring programs.
- 185. The observer of the EEC mentioned the results of four studies undertaken in different EEC member countries and reported that they had taken into account the goals set by the U.S. Food and Drug Administration.
- 186. The Delegation of Sweden reported that a toxicological evaluation had been performed by a Nordic expert group on ethylcarbamate. The results would be made available to the Committee.
- 187. Recommendations should be given to the industry to reduce the ethylcarbamate level in those foodstuffs concerned. The Committee <u>decided</u> to continue work in this field. Information would be requested on analytical and toxicological data, technological improvements and national regulations.

SAMPLING PLANS FOR CONTAMINANTS (Agenda Item 11 (h))

- 188. The Committee had before it Conference Room Document 15 (CX/FAC 91/II-Add.6) which summarized government comments submitted concerning this issue in response to CL 1990/17-FAC.
- 189. The Secretariat explained that the CCEXEC had temporarily endorsed (para. 67-68, ALINORM 91/3) the simple sampling plan for mercury, cadmium and lead as proposed by CCFAC at its last session (para. 28, ALINORM 91/12). As this sampling procedure was expected to be discussed and fully endorsed by the forthcoming Codex Committee on Methods of Analysis and Sampling, the Committee decided to await their decision, with a view towards its adoption by the Commission at Step 8.

PROPOSALS FOR PRIORITY EVALUATION OF FOOD ADDITIVES AND CONTAMINANTS BY JECFA (Agenda Item 12)

- 190. The Committee had before it Conference Room Document 16 (CX/FAC 91/12) which summarized government proposals for priority evaluation, as well as Conference Room Document 24, the Report of the Informal Group on Priorities. The Group met to consider the status of the substances listed for priority evaluation at the Twenty second meeting of CCFAC, and to consider new additions to the priority list. Mr.R. Top of The Netherlands chaired the meeting.
- 191. The Group reviewed the previous CCFAC priority list (Appendix VII, ALINORM 91/12) and received information from the JECFA Secretariat regarding the substances scheduled for evaluation at the 39th meeting of JECFA scheduled for February 1992. Those substances already proposed by CCFAC for evaluation were combined with several substances proposed at this session and were recommended for JECFA evaluation.

192. The Committee <u>agreed</u> with the recommendations of the Group, as included in this report under Appendix VII. The Delegations were encouraged to send toxicological information and data when requested, especially as related to cadmium and lead.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 13)

- 193. The Committee noted that at its next session it would consider the following matters:
 - Proposed Draft General Codex Standard for Food Additives;
 - Endorsement and/or Revision of Maximum Levels for Food Additives and Contaminants in Codex Standards;
 - Consideration of Specifications for the Identity and Purity of Food Additives;
 - Proposed Amendments to the International Numbering System;
 - Proposed Amendments to the Inventory of Processing Aids;
 - Proposed Draft General Principles for the Elaboration of Contaminant Levels in Food:
 - Proposed Draft Maximum Levels for Aflatoxins in Food;
 - Proposed Draft Maximum Levels for Aflatoxins in Feed;
 - Proposed Draft Sampling Plans for Aflatoxins;
 - Proposed Draft Maximum Levels and Methods of Analysis and Sampling for Ochratoxin A and Trichothecenes;
 - Establishment of guideline levels for cadmium and lead in food;
 - Establishment of guideline levels for polychlorinated biphenyls and dioxins in foods:
 - Establishment of guidelines levels for benzo-(a)-pyrene, hydrogen cyanide, 2-diethylhexylphthalate and ethylcarbamate;
 - Proposals for the Priority Evaluation of Food Additives and Contaminants by JECFA.

DATE AND PLACE OF NEXT SESSION (Agenda Item 14)

194. The Committee noted that its Twenty-fourth Session would be held in The Hague from 23-28 March 1992, with the understanding that the Working Group Sessions would meet on 20 March.

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Summary Status of Work

<u>January Jacas of Work</u>					
Subject	Step	For Action by:	Document Reference		
Guideline Levels for Methylmercury in Fish	8	19th CAC	ALINORM 91/12A, paras. 148-151, ALINORM 91/12, App. VIII		
Guideline Levels for ACN and VCM in Food and Food Packaging Materials	8	19th CAC	ALINORM 91/12, App. VIII		
International Numbering System	3 & 8	19th CAC Governments 24th CCFAC	ALINORM 91/12A, App. IV ALINORM 91/12, App. III		
Sampling Plan for Contaminants	8	17th CCMAS 19th CAC	ALINORM 91/12A, paras. 188-189		
Methods of Analysis for Aflatoxins	8	17th CCMAS 19th CAC	ALINORM 91/12A, App. VI		
Proposed Draft Codex General Standard for Food Additives	2, 3	United States Governments 24th CCFAC	ALINORM 91/12A, paras. 30-37		
Proposed Draft General Procedures for the Establishment of Guide-line Levels for Contaminants	1, 2	Denmark/ Netherlands 24th CCFAC	ALINORM 91/12A, paras. 22, 27-28 & 157		
Consideration of Specifications for the Identity and Purity of Food Additives	1	19th CAC Governments WG on Speci- fications 24th CCFAC	ALINORM 91/12A, paras. 92-99 & App. III		
Updated Index of Codex Specifications	3	Governments WG on Speci- fications 24th CCFAC	ALINORM 91/12A, paras. 89-91		
Proposed Draft Maximum Levels for Aflatoxins in Foods	3	Governments 24th CCFAC	ALINORM 91/12A, paras. 113-118		
Proposed Draft Guide-line Levels for Aflatoxins in Milk	3	Governments 24th CCFAC	ALINORM 91/12A, App. VI		
Proposed Draft Guideline Levels for Aflatoxins in Peanuts	3	8th CCCPL 25th CCFAC	ALINORM 91/29, App. II		
Proposed Draft Maximum Levels for Aflatoxins Ochratoxin A and the trichothecene group	3	Governments 24th CCFAC	ALINORM 91/12A, paras. 132-135		
Proposed Draft Maximum Levels for Aflatoxins in Feed	3	Governments 24th CCFAC	ALINORM 91/12A, App. VI		
Sampling Plans for Aflatoxins	3	Governments	ALINORM 91/12A,		

National Stategies and Proposed Draft Guideline Levels for:		24th CCFAC	paras. 128-131
a) Cadmium and Lead	3	Governments 24th CCFAC	ALINORM 91/12A, para. 156
b) Polychlorinated Bi-phenyls (PCBs), PBBs and Ugilec	3	Governments 24th CCFAC	ALINORM 91/12A, para. 169
c) Dioxins	3	Governments 24th CCFAC	ALINORM 91/12A, para. 174
d) Benzo-(a)-pyrene, hydrogen cyanide, phthalates and ethylcarbamate	3	Governments 24th CCFAC	ALINORM 91/12A, paras. 178, 180, 183 & 187
Inventory of Processing Aids	3	Governments United States 24th CCFAC	ALINORM 91/12A, paras. 106-108
Food Additives and Contaminants Proposed for Priority Evaluation by JECFA	-	Governments 24th CCFAC	ALINORM 91/12A, App. VII

ALINORM91/12A Appendix I

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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 suppleants, conseillers et consultants sont énumérés par ordre alphabétique.
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ENDORSEMENT OF MAXIMUM LEVELS FOR FOOD ADDITIVES IN CODEX COMMODITY STANDARDS

This Appendix summarizes all food additive provisions as forwarded by those Codex Committees listed below which were considered by the Codex Committee on Food Additives and Contaminants at its 23rd Session.

Abbreviations Used

E - Endorsed

TE - Temporarily Endorsed

EP - Endorsed Postponed for reasons given in the footnotes

Limited by GMP - Limited by Good Manufacturing Practice

NE - Not Endorsed

	Committee/Commodity	<u>Session</u>	<u>Document</u>
l.	Processed Meat and Poultry Products	15th	ALINORM 91/16
II.	Fruit Juices	19th	ALINORM 91/14
III.	Milk and Milk Products	22th	CX 5/70-22nd Session

I. PROCESSED MEAT AND POULTRY PRODUCTS

DRAFT REVISED CODEX STANDARD FOR LUNCHEON MEAT (APPENDIX VI)
DRAFT REVISED CODEX STANDARD FOR COOKED CURED HAM (APPENDIX VII)

DRAFT REVISED CODEX STANDARD FOR COOKED CURED PORK SHOULDER (APPENDIX VIII)

DRAFT REVISED CODEX STANDARD FOR COOKED CURED CHOPPED MEAT (APPENDIX IX)

Food Additive	Maximum Level in the Finished Product	Paragraph	Status of Endorsement
Potassium and/or Sodium Nitrite	200 mg/kg (ingoing) (total nitrite expressed as sodium nitrite) 125 mg/kg (residual)	42, 45	E
Ascorbic acid and Na salt Iso-ascorbic acid and Na salt	500 mg/kg (expressed as ascorbic acid) singly or in combination	43, 44, 45	EE
Phosphates (naturally present plus added) 1	8000 mg/kg (expressed as P205)	43, 45	Е
Added phosphates (mono-, diand poly-) sodium and potassium salts ²	3000 mg/kg (expressed as P205) singly or in combination	43, 45	E
Erythrosine (CI 45430) to replace loss of colour (for product with binder only) ³	15 mg/kg	42, 45	NE
Disodium guanylate Disodium inosinate	Limited by GMP	45	Е

Natural phosphate (mg/kg P₂0₅) is calculated as 250 x % protein.

² Having INS Nos. 339, 340, 450, 451 and 452.

For luncheon meat and cooked cured chopped meat only.

II. FRUIT AND VEGETABLE JUICES DRAFT GENERAL STANDARD FOR VEGETABLE JUICES (APPENDIX II)

Food Additive	Maximum Level in the Finished Product	Paragraph	Status of Endorsement
L-Ascorbic acid	400 mg/kg		
Citric acid	GMP		
Lactic acid (not in products having undergone lactic acid fermentation)	GMP		
Malic acid	GMP	46, 47	E
Glutamic acid and its sodium or potassium salts	GMP	40, 47	<u> </u>
Natural flavour obtained from seasonings, spices, herbs and fruit juices	GMP d		
Carbon dioxide	GMP		

DRAFT GUIDELINES FOR MIXED FRUIT JUICES (APPENDIX III)

Food Additive	Maximum Level in the Finished Product	Paragraph	Status of Endorsement
Citric acid	GMP		
Malic acid	GMP	46, 47	Ε
Carbon dioxide	GMP		

DRAFT GUIDELINES ON MIXED FRUIT NECTARS (APPENDIX IV)

Food Additive	Maximum Level in the Finished Product	Paragraph	Status of Endorsement
Citric acid	GMP		
Malic acid	GMP	46. 47	F
L-ascorbic acid	400 mg/kg	40, 47	□
Carbon dioxide	GMP		

III. MILK AND MILK PRODUCTS DRAFT STANDARD FOR LOW FAR DAIRY SPREADS (A-16). (APPENDIX III)

Food Additive	Maximum Level in the Finished Product	Paragraph	Status of Endorsement
Betacarotene Annatto extracts	25 mg/kg 20 mg/kg (calculated as total bixin or norbixin)	49 48, 49	E E
Natural butter flavours and flavouring substances and natureidentical flavouring substances as defined for the purpose of the Codex Alimentarius (see Codex Guide to the Safe Use of Food Additives (CAC/FAC 5-1979))	Limited by GMP	49	E
Lecithins	Limited by GMP	49	Е
Mono and diglycerides of fatty acids	Limited by GMP	49	E
Pectins Agaragar Carrageenan Guar gum Locust bean gum Xanthan gum Methyl cellulose Carboxymethyl cellulose and its sodium salts Sodium, potassium, calcium and ammonium alginates Propylene glycol alginate	10 g/kg individually or in combination	48, 49	E
Sorbic acid and its sodium and calcium salts	2500 mg/kg	49	E
Benzoic acid and its sodium and potassium salts	1000 mg/kg	49	E
If used in combination, the comb exceed 2500 mg/kg of which the shall not exceed 1000 mg/kg Lactic acid and its calcium, potassium and sodium salts Citric acid and its calcium, potassium and sodium salts Sodium hydrogen carbonate Sodium carbonate Sodium hydroxide Sodium monophosphates		49	E

CHEESE STANDARDS FOR SAINT PAULIN (C-13). SVECIA (C-14). HERRGARDOST (C-21) HUSHALLOST (C-22) AND NORVEGIA (C-23)

Food Additive	Maximum Level in the Finished Product	Paragraph	Status of Endorsement
Natamycin	2 mg/dm2 (maximum penetration of 5 mm)	50, 51, 52	E

STANDARDS FOR CHEDDAR CHEESE (C-1). OTHER CHEESES (where applicable) AND BUTTER (A-I)

Food Additive	Maximum Level in the Finished Product	Paragraph	Status of Endorsement
Annatto (Cheddar) 1	25 mg norbixin/kg		
Annatto (Other Cheeses)	10 mg norbixin/kg	52	E
Annatto (Butter)	20 mg norbixin/kg		

While most Cheddar is made with less than 10 mg/kg, a small amount of coloured Cheddar is made, requiring up to 25 mg/kg.

STANDARDS FOR COTTAGE CHEESE (C-16). PROCESSED CHEESE PREPARATIONS (A-8c). CREAM CHEESE (C-31) AND FLAVOURED YOGHURT AND PRODUCTS HEAT TREATED AFTER FERMENTATION (A-IIb)

Food Additive	Maximum Level in the	Paragraph	Status of
	Finished Product		Endorsement
Karaya gum	GMP	52	E

STANDARD FOR BUTTEROIL AND ANHYDROUS BUTTEROIL AND ANHYDROUS MILKFAT (A-2) - ANTIOXIDANTS PROVISIONS ONLY

-			
Food Additive	Maximum Level in the	Paragraph	Status of
	Finished Product		Endorsement
Propyl gallate	100 mg/kg		
Butylated hydroxytoluene (BHT)	7/20/200675 mg/kg	53	Ε
Butylated hydroxyanisole (BHA)	200 mg/kg	00	
Tertiary butyl hydro – quinone	0 0		NE
(TBHQ)	120 mg/kg	53	NE
Any combination of Propyl gallate,	200 mg/kg (individual	53	Е
BHT, BHA or TBHQ	limits not to be		
,	exceeded		
Natural and synthetic tocopherols	500 mg/kg	53	Е
Ascorbyl Palmitate	500 mg/kg		
Ascorbyl Stearate	(individually or in	53	E
7.000.037. 0.000.0	combination)		_
Dilauryl thiodipropionate	200 mg/kg	53	E
Citrus acid	3 3		_
Sodium citrate	GMP	53	E
Isopropyl citrate mixture	100 mg/kg individually	1	
Phosphoric acid	or in combination	53	Е
Monoglyceride citrate		00	_
worldgryddriad diliald			

DRAFT INTERNATIONAL GROUP STANDARD FOR CHEESES IN BRINE (APPENDIX IX)

Food Additive	Maximum Level in the Finished Product	Paragraph	Status of Endorsement
Calcium chloride	200 mg/kg milk used	58	E
Lactic acid	GMP	58	E
Gluconodelta lactone	10 mg/kg milk used	58	E
Chlorophyll and chloro-phyllin copper complex	15 mg/kg cheese	55, 58	Е
Patent blue V		54,55,58	NE
Brilliant blue FCF	2 mg/kg cheese	55,58	TE

DRAFT INTERNATIONAL GROUP STANDARD FOR UNCURED/UNRIPENED CHEESES (APPENDIX X)

Food Additive*	Maximum Level in the Finished Product	Paragraph	Status of Endorsement
Lactic acid			
Citric acid			
Acetic acid	GMP	64	E
Hydrochloric acid			
Phosphoric acid	000 // '!!	00.04	_
Calcium chloride	200 mg/kg milk	60, 64	E
Gluconodelta lactone	10 mg/kg milk		E
Cuar gum			
Guar gum			
Karaya gum			
Tragacanth gum			
Carrageenan or its salts			
Xanthan gum	5 g/kg of finished	62, 63, 64	_
Agaragar	product wt (total)	- , , -	E
Calcium sulphate	ļ (,		
Gelatin			
Alginic acid or its salts			
Propylene glycol esters of alginic			
acid			
Sodium carboxymethyl cellulose		59	
Pectins	GMP	61, 62, 64	TE
Starches and modified starches			
Microcrystalline cellulose			
Mono-and diglycerides			
Lecithin			
Sucrose	GMP	61, 62, 64	TE
Dextrose	· · · · · ·	0 :, 0=, 0 :	· -
Corn syrup solids			
Dextrine			
Glycerine			
Beta carotenes	10 mg norbixin/kg	59, 64	
Annatto		,	
Betaapo-8'-carotenal			
Chlorophyll and chlorophyllin			TE
copper complex	15 mg/kg	64	TE
Lactoflavin (riboflavin) Curcumin			
Carminic acid			
Beet red			
Sorbic acid and its salts	1 g/kg	64	E

^{*} The Milk Committee is requested to review this list to decide as to which of these are food ingredients as opposed to food additives while using the INS system.

REVISED STANDARD FOR SWEETENED CONDENSED MILK, SWEETENED CONDENSED SKIMMED MILK, SWEETENED CONDENSED PARTLY SKIMMED MILK AND SWEETENED CONDENSED HIGH-FAT MILK (STANDARD A-4) (APPENDIX V)

Food Additive		Maximum Level in the Finished Product	Paragraph	Status of Endorsement
Hydrochloric acid Citric acid Carbonic acid Orthophosphoric Acid Polyphosphoric acid	sodium, potassium & calcium salts	2000 mg/kg singly 3000 mg/kg in combination expressed as anhydrous substances	65	Е

REVISED STANDARD FOR EVAPORATED MILK, EVAPORATED SKIMMED MILK, EVAPORATED PARTLY SKIMMED MILK AND EVAPORATED HIGH-FAT MILK (STANDARD A-3) (APPENDIX IV)

Food Additive		Maximum Level in the Finished Product	Paragraph	Status of Endorsement
Hydrochloric acid Citric acid Carbonic acid Orthophosphoric acid Polyphosphoric acid	sodium, potassium &calcium salts	2000 mg/kg singly 3000 mg/kg in combination expressed as anhydrous substances	65	E
Carrageenan		150 mg/kg		E

ALINORM 91/12A Appendix II-Part II

ENDORSEMENT OF MAXIMUM LEVELS FOR CONTAMINANTS IN CODEX COMMODITY STANDARDS

This Appendix summarizes all food contaminant provisions as forwarded by those Codex Committees listed below which were considered by the Codex Committee on Food Additives and Contaminants at its 23rd Session (abbreviations listed in Part I apply).

	Committee/Commodity	<u>Session</u>	<u>Document</u>
1	Processed Meat and Poultry Products	15th	ALINORM 91/16
II	Cereals, Pulses and Legumes	7th	ALINORM 91/29
Ш	Milk and Milk Products	22nd	CX 5/70-22nd Session
IV	Fruit Juices	19th	ALINORM 91/14

I. PROCESSED MEAT AND POULTRY PRODUCTS

DRAFT REVISED CODEX STANDARDS FOR LUNCHEON MEAT (APPENDIX VI)

DRAFT REVISED CODEX STANDARDS FOR COOKED CURED HAM (APPENDIX VII)

DRAFT REVISED CODEX STANDARDS FOR COOKED CURED PORK SHOULDER (APPENDIX VIII)

DRAFT REVISED CODEX STANDARDS FOR COOKED CURED CHOPPED MEAT (APPENDIX IX)

Contaminant	Maximum Level in the Final Product	Paragraph	Status of Endorsement
Lead Tin (for products in tinplate containers)	0.5 mg/kg 200 mg/kg	75, 76	TE
Tin (other containers)	50 mg/kg		

DRAFT REVISED CODEX STANDARD FOR CORNED BEEF (APPENDIX V)

Contaminant	Maximum Level in the Final Product	Paragraph	Status of Endorsement
Lead	1 mg/kg		
Tin (for products in tinplate containers) Tin (other containers)	200 mg/kg 50 mg/kg	77	TE

II. CEREALS, PULSES AND LEGUMES

GENERAL PROPOSED DRAFT GUIDELINE LEVELS FOR CEREALS, PULSES AND LEGUMES (para. 24)

Contaminant	Maximum Level in the Final Product	Paragraph	Status of Endorsement
Arsenic	0.5 mg/kg	78-81	TE
Cadmium	0.1 mg/kg		EP ¹
Mercury	0.05 mg/kg		TE
Lead	0.5 mg/kg		TE

concerning more data required.

III. MILK AND MILK PRODUCTS

DRAFT STANDARD FOR LOW FAT DAIRY SPREADS (A-16) (APPENDIX III)

Contaminant	Maximum Level in the Final Product	Paragraph	Status of Endorsement
Iron	1.5 mg/kg		
Copper	0.1 mg/kg	82-83	E
Lead	0.1 mg/kg		

DRAFT STANDARD FOR FOOD GRADE SWEET WHEY AND ACID POWDERS (A-15) (APPENDIX XII)

Contaminant	Maximum Level in the Final Product	Paragraph	Status of Endorsement
Copper Lead Iron (spray dried powder) Iron (roller dried powder)	5 mg/kg 2 mg/kg 20 mg/kg 50 mg/kg	82-83	E

DRAFT STANDARD FOR EDIBLE RENNET CASEIN (A-14) (APPENDIX XI)

Contaminant	Maximum Level in the Final Product	Paragraph	Status of Endorsement
Iron	5 mg/kg		
Copper	2 mg/kg	82-83	E
Lead	20 mg/kg		

IV. FRUIT AND VEGETABLE JUICES DRAFT GENERAL STANDARD FOR VEGETABLE JUICES (APPENDIX II)

Contaminant	Maximum Level in the	Paragraph	Status of
	Final Product		Endorsement
Arsenic	0.2		TE
Lead	0.3 1	04.06	TE
Copper	5.0		E
Zinc	5.0		E
Iron	15.0	84-86	E
Tin	200.0 ¹		TE
Sum of Copper, Zinc and Iron	20.0		E
Sulphur Dioxide	10.0		E

Mineral impurities insoluble in 10 per cent hydrochloric acid shall not exceed 100 mg/kg.

DRAFT GUIDELINES FOR MIXED FRUIT JUICES (APPENDIX III) DRAFT GUIDELINES FOR MIXED FRUIT NECTARS (APPENDIX IV)

Contaminant	Maximum Level in the Final Product	Paragraph	Status of Endorsement
Arsenic	0.2		TE
Lead	0.3 1	84-86	TE
Copper	5.0		E
Zinc	5.0		E
Iron	15.0	04-00	E
Tin	200.0 ¹		TE
Sum of Copper, Zinc and Iron	20.0		Е
Sulphur Dioxide	10.0		Е

¹ These levels remain under review, taking into account a sampling plan.

ALINORM 91/12A Appendix II-Part III

Mineral oil (food grade)

CHANGE IN STATUS OF ENDORSEMENT OF FOOD ADDITIVES RESULTING FROM CHANGE IN ADI STATUS

Food Additive	Paragraph
Butylated hydroxytoluene (BHT) Tertiarybutyhydroquinone (TBHQ) Erythorbic acid and its sodium salt	88
Alpha-amylase from B. stearothermophilus Alpha-amylase from B. subtilis	
Alpha-amylase from B. stearothermophilus expressed in B. subtilis Alpha-amylase from B. megaterium expressed in B. subtilis	
Chymosin A produced from E. coli K-12 containing a calf prochymosin A gene	
Chymosin B produced from A. niger var. awamori containing a calf prochymosin B gene	
Chymosin B produced from K. lactis containing a calf prochymosin B gene	
Allyl heptanoate Allyl hexanoate Allyl isovaleratetrans	
trans-Anethole	
<u>d</u> -Carvone <u>1</u> -Carvone	
Erythrosine Acesulfame potassium	
Trichlorogalactosucrose Dimethyldicarbonate	
Dioctyl sodium sulfosuccinate Gellan gum	

SPECIFICATIONS FOR IDENTITY AND PURITY OF CERTAIN FOOD ADDITIVES (FAO FNP 49) ARISING FROM THE 35TH JECFA SESSION

Category I: (recommended for adoption to the Commission)

Ethyl vanillin

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

Citric and fatty acid esters of glycerol

Ferrous lactate

Fumaric acid

General specifications for enzyme preparations used in food processing

Modified starches

Paprika oleoresin

Quinine hydrochloride

Sodium percarbonate

Sucrose esters of fatty acids

Turmeric oleoresin

Category III: (substantive changes required)

Carob bean gum (Ignition temperature for total ash content)

Gum arabic (identification of the commercial gum and the substance tested toxicologically)

Iron oxides (limit for content of nickel)

Category IV: (There were no substances in Category IV)

Category V: (specifications designated by JECFA as tentative)

Carotenes (algae)
Carotenes (vegetable)
Dihydrocoumarin
2-Nitropropane
Tannic acid

ALINORM 91/12A Appendix IV

PROPOSED AMENDMENTS TO THE INTERNATIONAL NUMBERING SYSTEM

The following new INS numbers were allocated to food additives, as proposed by the countries listed:

NUMBER	FOOD ADDITIVES	FUNCTIONS
Proposals of Canada		
407	Carrageenan and its Na, K, NH4 and Ca salts (includes furcellaran)	Thickener, gelling agent, stabilizer
181	Tannins	Colour, emulsifier, stabilizer, thickener
344	Lecithin citrate	Preservative
345	Magnesium citrate	Acidity regulator
336	Potassium tartrates (i) Monopotassium tartrate (ii) Dipotassium tartrate	Stabilizer, sequestrant
164	Saffron	Color
Proposal of the United States	1	
419	Gum ghatti	Thickener, stabilizer, emulsifier

ALINORM 91/12A Appendix V

UPDATING CODEX LIST B

Addition to Codex List B	<u>Status</u>	JECFA Ref.1
<u>Antioxidants</u>		
Buytlatedhydroxytoluene (BHT)	B1	16
Tertiary butyl hydroquinone (TBHQ)	B1	16
Miscellaneous food additives		
Dioctyl sodium sulfosuccinate	B1	3, 6, 16
Mineral Oil (food grade)	B1	16
Change of Status		
Flavouring agents	Old status	New status
1 Carvone	B2	B1

JECFA-References

JECFA-Reference 3, Evaluation of Certain Food Additives, (21st Report of the Report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series No. 617, 1978.>

JECFA-Reference 6, Evaluation of Certain Food Additives, (24th Report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series No. 653, 1981.

JECFA-Reference 16, Summary and Conclusions of the 37th Meeting of the Joint FAO/WHO Expert Committee on Food Additives, Geneva 5-14 June 1990.

Proposed Draft Guideline Levels for Aflatoxin M₁ in Milk

Bulk milk: 0.05 μ g/kg Aflatoxin M₁ Milk destined for baby foods: 0.01 μ g/kg Aflatoxin M₁

$\frac{\text{Proposed Draft Maximum Levels for Aflatoxin B}_1 \text{ in}}{\text{Supplementary Feeding Stuffs for Milk Producing Animals}}\\ \underline{\text{[5 $\mu\text{g}/\text{kg}] Aflatoxin B}_1}$

Methods of analysis for aflatoxins

(All references are to be official methods of analysis of the AOAC, 15th Ed., 1990)

Type II Methods Aflatoxin M1 in dairy products (1974)	(TLC)	974.17, p. 1199
Aflatoxin M1 in Milk and Cheese (1980) (Stubblefield method)	(TLC)	980.21, p. 1200
Aflatoxins M1and M2 in Fluid Milk (1986)	(LC)	986.16, p. 1203
Aflatoxin M1 in Milk and Dried Milk (IDF/ISO/AOAC group E 33) (modified Stubblefield method)	(TLC/HPL C)	IDF Bulletin 207, 1986
Aflatoxins in Corn (1972)	(TLC)	972.26, p. 1191
Aflatoxins in Cottonseed Products (1980)	(TLC)	980.20, p. 1192
Aflatoxin B1 in Cottonseed and Mixed Feed (1989)	ELISA screening	989.06, P. 1193 *
Aflatoxins in Coconut, Copra and Copra Meal (1971)	(TLC)	971.24, p. 1191
Aflatoxins in Pistachio Nuts (1974)	(TLC)	974.16, p. 1195
Aflatoxins in Peanuts and Peanut Products (1970)	(TLC)	970.45, p. 1190
Aflatoxins in Soybeans (1972)	(TLC)	972.27, p. 1195
Aflatoxin B1 in Corn and Roasted Peanuts AOAC-IUPAC	ELISA screening	990.32, suppl. *
Aflatoxins B1, B2, G1 and G2 in Corn and Peanut Butter AOAC-IUPAC	(LC)	990.33, suppl.
Aflatoxins BI, B2 and G1 in Corn, Cottonseed, Peanuts and Peanut Butter AOAC-IUPAC	ELISA screening	990.34, suppl. *
Aflatoxins in Corn, Raw Peanuts and Peanut Butter (AOAC-IUPAC) (B1, B2, G1, G2 at > 10 ng total afl/g	Imm. Aff. (Aflatest)	991.31, Suppl. *

^{*} Fully validated screening methods

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aflatoxin levels

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

Food additives	Functional effect	Proposed by
Carrageenans (immunological aspects) Acidulant in soft drinks	
Adipic acid Fumaric acid	Acidulant in soft drinks	Cormany
Sucroseoctaacetate	Bittering agent	Germany
Patent blue V	Food colour	
Konjac flour	Stablilizer	United States
Nitrogen (specifications only)		
Pectins (specifications only)		Denmark
Sorbitan tristearate (specifications only	')	
Cyclodextrins		Dem. Peoples'
		Rep. of Korea
<u>Contaminants</u>		Proposed by
Nitrite		
Nitrate		
Nitrosamines		The Netherlands
Phthalates		
Trichothecenes		
1,3-Dichloro-2-propanol		Germany
3-Chlorol, 2-propanediol		Germany
Dioxins		CCFAC
Ethyl carbamate		Informal group on
		priorities
Lead		United States
Cadmium		
Polycyclic aromatic hydrocarbons		Denmark
Paralytic shellfish toxins		Canada
<u>Others</u>		Proposed by
Safety of food and feed products after ammoniation to reduce		Secretariat