

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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ALINORM 83/12

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Fifteenth Session

Rome, 4-15 July 1983

REPORT OF THE
FIFTEENTH SESSION OF THE
CODEX COMMITTEE ON FOOD ADDITIVES

The Hague, 16-22 March 1982

INTRODUCTION

1. The Codex Committee on Food Additives held its 15th session in The Hague, The Netherlands, from 16 to 22 March 1982, by courtesy of the Government of The Netherlands. Mr. A. Feberwee (The Netherlands) acted as Chairman. The Session was attended by 175 participants. They represented 38 countries and observer countries, and 29 international organizations (see Appendix I for List of Participants, including Secretariat).

OPENING SPEECH BY THE SECRETARY GENERAL OF THE MINISTRY OF
AGRICULTURE AND FISHERIES OF THE NETHERLANDS

2. The 15th Session was opened by Mr. G.J. van Dinter, Secretary-General of the Netherlands Ministry of Agriculture and Fisheries. His welcoming address is given as Appendix II to this report.

APPOINTMENT OF RAPPORTEURS

3. Mr. I. Avigdor (Switzerland) and Mr. R. Ronk (USA) were appointed as rapporteurs.

ADOPTION OF THE AGENDA

4. The Committee adopted the provisional agenda (CX/FA 82/1) with the addition of one item put forward by FAO, viz. Item 10(a)(i) "Action needed by CCFA resulting from change in ADI status of Food Additives".

5. The delegate of Argentina explained that her government had been unable to decide on its position on various agenda items because of a lack of documents and the fact that they were not available in the Spanish language. The Codex Secretariat confirmed that, as was the case with most other Codex Committees, the working documents of the Codex Committee on Food Additives were only produced in French and English, but that the final report was also published in Spanish. The delegate from Argentina entered a formal reservation against agenda items 6, 8, 10 to 15, and 17 to 19 because of inadequate time to study these documents.

REPORT OF THE 25th SESSION OF THE JOINT FAO/WHO EXPERT COMMITTEE
ON FOOD ADDITIVES

6. The Committee had before it the report of the above-mentioned session of JECFA (WHO Technical Report Series No. 669) which was presented by the representative of FAO.
7. The Committee was reminded about the objectives followed by JECFA during its 25 years of existence i.e. "To consider chemical, toxicological and other aspects of additives and contaminants in food, related to safety for human consumption and to report thereon", The Director-General of WHO had addressed the Committee on the occasion of its silver jubilee and had expressed his appreciation as well as that of the Director-General of FAO of the high level of scientific judgement and integrity of the JECFA.
8. The Committee was informed that the general discussions of JECFA related to principles governing the toxicological evaluation of food additives; principles concerning the establishment of specifications; relevance of the work of the Committee to developing countries; international liaison for greater conformity in the evaluation of food additives; validation of toxicological data; data required for technological and safety considerations; extraction solvents used in food processing; herbs, spices and natural product food additives; plastic materials in food packaging; antibiotics as direct food additives; hormones in animal production and enzyme preparations used as food additives. The importance of data on technological and safety considerations in the evaluation of food additives and the type of assistance that JECFA expected from governments and industry was underlined.
9. The Committee was informed that the 25th session of JECFA responded to the request of the 13th and 14th sessions of CCFA by reviewing the present knowledge of Fast Green FCF and discussing the problems arising from the presence of potentially toxic substances like β -asarone, cumarin, safrole, thujones and HCN in foods and beverages as a consequence of the use of herbs and spices in their preparation. The firm ADI of 12.5 mg/kg body weight for Fast Green FCF has been changed to a temporary ADI. As regards the potentially toxic substances present in herbs and spices, JECFA felt that at this stage it was difficult to make international recommendations concerning acceptable levels of toxic substances present in herbs and spices and lay down principles for their use.
10. The main groups of additives examined by the Committee comprised food colours, flavouring agents, extraction and carrier solvents. Many of the individual substances evaluated were selected from those included in the CCFA priority lists or submitted to JECFA with proposals for amendment prior to their endorsement as Codex Specifications. JECFA had also responded to specific requests by the CCFA to review the status of certain compounds. The specifications had been published as FAO Food and Nutrition Paper No. 19. The Committee was informed that copies of the specifications had been sent to all Codex Contact Points, member governments and interested international organizations for comment.
11. The Committee noted that JECFA had recommended to call two meetings of experts which would consider advances made in mutagenicity testing as screening tools for setting priorities in carcinogenicity testing and to study advances in methodology for the toxicological evaluation of food additives and contaminants. It had also requested the Codex Alimentarius Commission to provide information on residue levels of solvents (and impurities, additives, etc.) in foods processed using solvents.

12. The discussions which followed the report centered around the sections of the report relating to the validation of toxicological data, data required for technological and safety considerations, and plastic materials in food packaging.

13. Regarding the issue, about the validation of toxicological data, the Committee accepted the offer from Canada and the USA to make available to the Committee a list of additives which have come under question because the toxicological basis for their approval could not be validated.

14. The representatives of Belgium and of the CIAA felt that it will not always be possible to provide all the data requested by JECFA and expressed some concern as to the attitude that may be taken by JECFA in cases where these data were not provided in its entirety. The Secretariat indicated that, if made available to JECFA in a convenient form, such data would help to achieve a more satisfactory evaluation of food additives. Governments and industry had the option of providing such data in full or in part. FAO and WHO Secretariats and JECFA also promised to keep industry data as confidential as was practicable.

15. The delegations of Australia and Italy expressed interest in any future work on plastic materials in food packaging which JECFA had planned. In this respect the work of the Council of Europe and the EEC was noted along with that of other countries with national legislation.

Report of the Joint FAO/IAEA/WHO Expert Committee on Irradiated Foods

16. The Committee had before it the report of the above Expert Committee (WHO Techn. Rep. Ser. No. 659). The Report was introduced by the Joint Secretary of IAEA to JECFI.

17. In introducing the report the Joint Secretary of IAEA to JECFI informed the Committee of the conclusions of the Expert Committee. Among the most salient decisions of the Expert Committee were (a) the inclusion of X-rays at an energy level of 5 Mev as a permitted source of radiation, (b) the recognition that under certain conditions repeated irradiation was to be regarded as good irradiation practice, (c) the general toxicological clearance of food irradiated at levels not exceeding 10 KGy expressed as an average overall radiation dose and (d) that it would not be necessary on scientific grounds to declare the fact of irradiation. The Expert Committee had also discussed various questions relating to the efficacy of the process, nutritional aspects, microbiological questions and dosimetry. In addition, the Expert Committee had completed a number of individual clearances as additional data were available, but had recommended that no further testing was required in order to establish the safety of the process from a toxicological point of view.

18. The Committee thanked the representative of IAEA for his report but decided to discuss the recommendations of the Expert Committee in relation to the revision of the Codex General Standard for Irradiated Foods and the accompanying Code (see paras 64-70).

International Programme on Chemical Safety (IPCS)

19. The representative of WHO, commenting on this agenda item, noted that the Joint FAO/WHO Secretariat of the CCFA made available to the delegates a room document (CX/FA 82/17) containing the report of an Ad Hoc Working Group on Strengthening WHO's Contribution to JECFA and JMPR Activities within the IPCS. The report covered the WG's meeting in Geneva on 28-30 October, 1981.

20. The Working Group had identified and examined a number of organizational, operational and budgetary issues. These issues were examined by the Working Group in terms of their current arrangements under the JECFA-CCFA system, while also taking into account the organizations and operational framework of IPCS and the relevant recommendations from past sessions of the Programme Advisory Committee (PAC) of the IPCS. The recommendations of this Working Group were useful guidelines for the Central Unit to plan future activities to strengthen WHO'S input to JECFA and related areas.

21. Recently the IPCS's attention had been focussed on the issue of handling unpublished proprietary data for the JECFA's evaluations. As a result of a discussion held at the sixty-ninth session of the World Health Organizations's Executive Board, an information document on the subject (EB 69/INF. Doc./3) had been developed by the manager of IPCS; this document highlighted the specific arrangements which had been made in WHO to protect such data from misuse. Copies of this document were made available to interested delegates.

22. The WHO representative further explained to the Committee how some of the recommendations made by previous JECFA meetings had been proposed to be implemented by the IPCS. Budget proposals were being made to include in the WHO Regular Budget for 1984/85 provisions for an interdisciplinary group of Experts as recommended by the twenty-second report of JECFA (TRS-631, 1978, p.29). This group of experts (which should operate jointly with FAO) should establish an inventory of compounds that have not yet been fully evaluated and to classify them in terms of their potential hazard to health on the basis of existing toxicological knowledge and extent of use. During the biennium 1982/83, a meeting of experts will be convened by the IPCS on the updating of methodology for testing and evaluating chemicals in food. This activity had been recommended by the twenty-fifth report of JECFA (TRS-669, 1981, p. 35). Provisions were also made by the IPCS to disseminate JECFA's evaluations and make them available soon after each meeting.

23. The representative of FAO drew the Committee's attention to paragraphs 5 to 8 of the report (CX/FA 82/17) of the ad hoc Working Group on Strengthening WHO'S contribution to JECFA and JMPR activities within the IPCS. In these paragraphs FAO's position concerning questions such as FAO being associated with the IPCS, the terms of reference of JECFA and JMPR, the establishment of subject priorities, selection of experts, consultants and temporary advisers, organizational questions, funding, etc., were clearly stated. The FAO representative expressed his satisfaction at the assurances given by IPCS concerning the smooth, continued operation of JECFA including the priority setting procedures, which had been followed in the past.

24. The Committee reaffirmed the necessity that JECFA should continue to have the same responsibilities, organizational arrangements and scope as before in order to support its work and that WHO'S and FAO's regular budget should provide the source of funding.

Matters of interest from the Commission and other Codex Sessions

25. The Committee had before it documents CX/FA 82/4 and CX/FA 82/4-Add. 1 on the above subject which were presented by the Secretariat.

26. The Committee noted that a number of matters of interest reported in the documents would be discussed under other agenda items and agreed to defer discussions on them until the particular agenda items were presented.

Matters arising from the 14th Session of the Codex Alimentarius Commission Procedure for the Elaboration of Codex Specifications

27. As directed by the Commission (ALINORM 81/38, para. 208), the new procedure proposed by the UK for the elaboration of Codex Specifications was studied by JECFA and CCFA secretariats. The secretariats felt that the proposed UK procedure would involve considerable procedural delays and hence would delay the elaboration of Codex specifications and showed a preference for the earlier procedure outlined in the 5th Edition of the Procedural Manual, with some amendments.

28. The Committee noted that the Commission had adopted the definition of "Smoke" submitted by it without any amendment (ALINORM 81/39, paras 209-212).

Matters arising from Codex Committees:

Coordinating Committee for Europe (ALINORM 81/19, para 144)

29. The delegation of Spain to the above session had considered it very important for the CCFA and JECFA to embark on a study of substances coming directly into contact with food (packaging materials) and oral mucus (for ex. mouth pieces of musical instruments, toys and trick games) and suggested a limit for the vinylchloride monomer of 1 mg/kg.

30. The Committee felt that, while packaging materials came directly under the terms of reference of CCFA and agreed to discuss the subject under a future agenda item, materials coming directly in contact with membrane of the mouth mucus did not.

31. The Committee noted that EEC had studied the problem of toys and other plastic materials coming into contact with membrane of the mouth mucus and agreed that the Secretariat should bring the question raised by Spain to the attention of such bodies as may have expertise in the subject.

Codex Committee on Meat Hygiene (ALINORM 81/15)

Residue levels of antibiotics, sulphonamides and anaboles in meat

32. The Codex Committee on Meat Hygiene, while elaborating an International Code of Practice for Ante-mortem and Post-mortem judgement of slaughter animals and meat, sought the advice of CCFA on residue levels of antibiotics, chemotherapeutic agents such as sulphonamides and anabolic steroids that could be present in meat.

33. The Committee expressed its opinion that the subject comes directly under its purview and agreed to discuss it under a future agenda item but felt that the expertise of the Committee was not presently sufficient to recommend levels of antibiotics, sulphonamides and anaboles in meat that would be internationally acceptable. The question was raised whether the residue levels of antibiotics in meat recommended by JECFA at its 12th Session were still valid as they had been established on the basis of the then available methods of detection.

Trace metals and other trace contaminants in meat

34. The Committee noted that this question on levels of trace metals and contaminants which would normally be posed to the Codex Committee on meat has been referred to CCFA since that Committee on meat had adjourned sine die.

35. The opinion was expressed that it would not be possible to arrive at maximum levels of metals and contaminants in meat based on maximum levels established for lard, pork fat or edible tallow (CAC/FAL 2-1973), since the levels of trace metals in meat

were significantly influenced by environmental effects and depended also on the nature of the animal tissue or organs which could be derived from slaughter animals.

36. The Committee, however, felt that it would be possible to arrive at meaningful maximum levels of trace metals present in meat on the basis of information on actual levels of trace metals determined by analysis.

37. The Committee directed the Secretariat to refer the question back to the Codex Committee on Meat Hygiene asking for more information on

- (i) The nature of trace metals and trace contaminants involved,
- (ii) The actual levels of trace metals and trace contaminants in meat determined by analysis, and
- (3) A definition of meat.

Guidelines for the Establishment of Food Additive Provisions in Codex Standards

38. The Committee had before it documents CX/FA 82/16, Add. 1 and Add. 1A. It noted that in document CX/FA 82/16 Add. 1 the opinion of CEFIC had been wrongly attributed to Belgium. These documents contained draft guidelines prepared by The Netherlands and Codex Secretariats on the request of the 14th Session of the CCFA and comments on the draft from a number of governments and international organizations.

39. In introducing the guidelines the Secretariat noted that support for the guidelines was rather divided and that a number of comments had been received indicating that the text of the guidelines required considerable amendment. The Secretariat pointed out that it was not their intention to duplicate or to amend the General Principles for the Use of Food Additives. Rather the guidelines were meant to supplement the General Principles in providing guidance to Codex Commodity Committees in drawing up provisions for food additives in Codex Standards.

40. The Committee first discussed the need to proceed with the elaboration of the guidelines. A number of delegations felt strongly that the General Principles for the Use of Food Additives already provided adequate guidance to Codex Committees and that the difficulties of CCFA are caused by the failure of Commodity Committees to provide adequate explanations of their recommendations. For this reason the elaboration of guidelines was not necessary but the Commodity Committees had to be re-manned of the information required by the CCFA. Other delegations were not convinced of the real need of guidelines but could go along with their preparation provided they were revised in an appropriate manner. A number of delegations expressed their support for the development of guidelines as a matter of urgency.

41. The Committee also addressed the question of the exact nature of the request for Guidelines. It noted that the Commission had agreed that the Guidelines should ensure that Codex Committees provide information such as would assure the CCFA that the use of additives had been justified from a technological and other points of view. In this respect some delegations were of the opinion that it was only technological justification which Codex Committees should be expected to provide. The delegation of Norway recalled that the need for the guidelines arose out of a consideration by the 14th Session of the CCFA of the philosophy behind the use of additives and that the Guidelines would also be of help to the CCFA in endorsing food additives in Codex Standards. It was his feeling that endorsement required consideration which went beyond technological justification and toxicological evaluation and that consumers' attitude should be adequately provided for in the case of additives such as colours.

42. The question also arose as to whether the Committee should develop formal Guidelines for adoption by the Commission and inclusion in the Procedural Manual or whether a less formal approach should be adopted.

43. A number of delegations expressed their regret that the General Principles for the Use of Food Additives had not been included in the 5th Edition of the CAC Procedural Manual. The Secretariat informed the Committee that the General Principles were still operative and that they, together with other similar non-procedural texts, would be included in Volume I of the 'Codex Alimentarius' which was under preparation.

44. The Committee agreed that the Secretariat should redraft the Guidelines in the light of comments received during the present session. The Committee agreed to the suggestion that paras 1 (b), 2, 3(c) and (e), should be deleted and para 4 should be redrafted in the light of written comments. The revised Guidelines should be reconsidered by the Committee at its next session at which time the Committee would discuss the status of the Guidelines.

Consideration of the Draft Standard for Food Grade Salt

45. The Committee had before it documents CX/FA 82/13-Part I and Part IA, containing a summary of the comments received on the Draft Standard for Food Grade Salt as contained in Appendix VIII of ALINORM 81/12 and the report of the Working Group on "Salt Standard" (CX/FA 82/12 - Part I - Addendum I).

46. The Working Group had analysed the comments received from Governments and International Organizations and had prepared a new draft standard for food grade salt.

47. The Working Group had preferred to elaborate one general standard for food grade salt which would not preclude the establishment of other requirements deemed necessary with particular kind of salts and with special food manufacturing methods.

48. The list of food additives which would be permitted in the standard was quite extensive. The Working Group had realized that a long list of additives was not an invitation for manufacturers to use all of the additives on the list at the same time, but that rather a list of optional additives was necessary to make salts which would meet technological needs under a variety of climatic conditions. The point was also made that a comprehensive list of additives was needed to enable countries to continue to produce suitable salt at a low price. The Chairman of the Working Group also presented justification of technological need for individual additives where it was requested by the delegation. It was agreed that the use of potassium ferrocyanides at levels higher than 10 mg/kg should be restricted to the manufacture of dendritic salts. In this case the maximum is 20 mg/kg.

Minimum NaCl content

49. The delegate from India informed the Committee that his national legislation allowed for levels of NaCl which may vary from 96-97%. Other delegations also suggested that such limits would be more acceptable to them. The Committee modified the text to read as "The content of NaCl shall not be less than 97% on a dry matter basis, additives excluded".

Use of new additives not included in the list

50. The delegate from France supported by Greece and Egypt, asked for the inclusion of sodium thiosulphate in the list of additives to protect iodide in iodized salts. The Committee noted that iodized salt is a special salt, but agreed to accommodate the

proposal made by modifying section 3.3 (use as a carrier) to read as follows: "Food grade salt shall be used if salt is used as a carrier for food additives of nutrients for technological or public health reasons. Examples of such preparations are mixtures of salts with nitrate and/or nitrite (curing salt) and salt mixed with small amounts of fluoride, iodide, iron, vitamins, etc. and additives used to carry or protect such additions".

51. The Committee noted inclusion in the draft standard of the statement "Codex specifications of identity and purity apply whenever available". As this conveyed the meaning that Codex Specifications were mandatory, the Committee agreed to the deletion of the statement from section 4.1.

52. The Committee agreed to rearrange the list of additives into (i) Anticaking agents, (ii) free-flowing agents and (iii) Processing aids and to accommodate the use of sodium and potassium ferrocyanides as free-flowing agents at higher levels (20 mg/kg) for use in the manufacture of dendritic salt by means of a suitable footnote. In the view of the Federal Republic of Germany, the processing aids mentioned above do not fall under the definition of processing aids.

53. The Committee noted that the limits for contaminants were tentative and should be put in square brackets.

54. The Committee requested the Secretariat to have the labelling section of the standard discussed by the Codex Committee on Food Labelling meeting later this year.

55. Switzerland supported by UK, Norway, Australia, Greece, France, Federal Republic of Germany, Finland, Sweden and Denmark suggested that it would be difficult to enclose such a long list of additives in the standard without adequate information available on the technological justification and the levels of use of the additives. The Committee agreed to request this information.

56. The Secretariat suggested that, since the Committee would meet again before the next session of the Commission, another round of discussions at the next session would not delay the adoption of the standard by the Commission.

57. The Committee agreed that the ad hoc Working Group should continue its work under the chairmanship of Dr. (Mrs.) M.A. Perinelli with the participation of Austria, Brazil, Egypt, Greece, Italy, Spain, Switzerland and USA.

Status of the Standard for Salt

58. The revised draft standard for Food Grade Salt (see Appendix III) was returned to Step 6 of the Codex Procedure.

Methods of Analysis and Sampling Salt

59. The Committee had before it the report of the Working Group on Methods of Analysis and Sampling of Salt (CX/FA 82/13 - Part II, Room Document). Dr. J.M. Rafols, the delegate of Spain acted as chairman of the Group and introduced the document attached as Appendix IV.

60. The Committee noted the progress in the development of methodology for the analysis of salt and expressed its appreciation to the Working Group for the way it handled this difficult work assignment.

61. The delegation of Canada raised the question about the need for the development of methodology for distinguishing food grade salt from by-products of the chemical industries. The Committee, however, felt that there was no such need since such a possibility is precluded by labelling provisions indicating the origin included in

section 7.1.5 of the Draft Standard for Food Grade Salt (see Appendix IV).

62. The Committee requested the Working Group to consider its methods of analysis in the light of the report of the Codex Committee on Methods of Analysis and Sampling (ALINORM 79/23) and to identify those methods which were "Defining Methods".

63. The Committee agreed to reinstate the ad hoc Working Group under the chairmanship of Mr. J.M. Rafols (Spain) with the participation of Austria, Brazil, Egypt, Greece, Italy, Netherlands, Spain, Switzerland, USA and the European Committee for the Study of Salt (CEES).

AMENDMENTS TO THE CODEX GENERAL STANDARD AND CODE FOR IRRADIATED FOODS

64. The Committee had before it document CX/FA 82/14 containing a revised version of the above general standard and code and government comments at Step 3 in Addenda 1 and 1A to CX/FA 82/14 as well as the report of the ad hoc Working Group on Irradiated Foods (CX/FA 82/14-Add. 2). The Chairman of the Working Group, Mr. R.J. Ronk (USA), introduced the report of the Working Group and indicated that to facilitate approval, changes to the revised general standard had been kept to a minimum. The revised Code of practice for the operation of irradiation facilities had also been improved but not substantially changed. The Working Group also made certain recommendations about labelling to the plenary of CCFA, for the consideration of the Codex Committee on Labelling.

65. The Committee considered the report of the Working Group and the revised standard and Code prepared by the Group. It was agreed that in para 2 of Annex I to the code a clarification be inserted to indicate that not only wholesomeness considerations but also considerations of statistical dose distribution had led to the inclusion of the requirement that at least 97.51 of the mass fraction of the product could receive an absorbed dose less than 15 KGy. That stated statistical distribution would narrow the specification of the Codex so that far fewer units of the irradiated items would actually receive a dose radiation over the 10 KGy level. It was agreed to change the title of Annex 2 to indicate that the foods listed had been specifically examined by the Joint FAO/IAEA/WHO Expert Committee. In addition the title was changed to include the concept that Annex 2 was not a full guideline of technological process consideration but merely examples.

66. The Committee had detailed discussion concerning the need to declare the fact of irradiation on the label. In fact, the Joint FAO/IAEA/WHO Expert Committee (JECFI) had concluded that it was not necessary on scientific grounds to envisage special requirements for the labelling of irradiated foods. The representative of WHO speaking as the Joint FAO/IAEA/WHO Expert Committee (JECFI), took issue with the conclusion that labelling was not required on scientific grounds under certain circumstances. There might in fact be certain special situations where epidemiological follow-up might be required.

67. The Committee considered the recommendations of the Working Group in the light of clarification presented by the FAO Secretariat. The Secretariat explained that considering the scientific information available at this time, warning labels would be inappropriate for irradiated foods since they would warn the consumer against a hazard that did not exist. This would be misleading and should not be done for this reason. It was, however, possible that the fact that a food had been irradiated might be something that the consumer might want to know as a material fact about how the food had been

processed.

68. The delegations which responded to the question of labelling indicated that, in the interest of consumer information, the fact of irradiation should be declared on the label. A number of delegations, however, expressed the opinion that only the 'first generation' irradiated products should be so labelled.

69. The Committee noted that the Codex Committee on Food Labelling would be considering a Revised General Labelling Standard for Prepackaged Foods in which provisions were included for the labelling of irradiated foods.

70. The general feeling of the Committee was that only 'first generation' irradiated foods should be subject to a declaration of the fact of irradiation and that this conclusion together with the remarks made at the session should be brought to the attention of the Codex Committee on Food Labelling.

Status of the Standard and Code

71. The delegate from Norway reminded the Committee of a new procedure adopted by the Commission for advancing standards to Step 6. The procedure would allow for a new round of government comments at Step 6 prior to the next meeting of CCFA in March 1983. These then could be considered again by this Committee before the next Commission meets. Thus, there seemed little to be gained by not following this procedure. The Secretariat concurred with this interpretation that the draft standard and Code be sent to governments for comments prior to the Commission meeting.

72. The Committee agreed that there was a need to ensure that the standard and Code for irradiated foods be amended as speedily as possible through the Codex procedure. It therefore adopted Norway's suggestion. The report of the Working Group is attached as Appendix V. The Revised Draft Recommended International General Standard which has been advanced to Step 5 is given in Appendix VI.

Consideration of Food Additive Intake

73. The Committee had before it the report of the ad hoc Working Group on Food Additive Intake, Room Document CX/FA 82/5 - Add. 1, which was introduced by the Chairman of the WG, Mr. M. Fondu (Belgium).

74. The Committee noted that the task of the WG was to prepare guidelines to assist governments to determine the intake of specific food additives.

75. The Committee also noted the fundamental importance of such work in providing a sound basis for its own decisions.

76. The Committee agreed with the WG's suggestion that in view of their ADI the following additives should be given special consideration:

- anti-oxidants: BHA, BHT, gallates, TBHQ
- preservatives: benzoic acid and its salts, sulphur dioxide and its derivatives
- colouring matters with an ADI less than 2 mg/kg bw
- artificial sweeteners: saccharine, cyclamate

77. The Committee noted the WG's advice that the study of the following additives naturally present in foods should be postponed:

- nitrates, nitrites, phosphoric acid and its salts and tartaric acid.

78. The Working Group's proposed guidelines were discussed, amended and in this edited form are presented as Appendix VII. The original version contained a number of

examples of methods in use by various governments by way of illustration; these are not included in Appendix VII.

79. With reference to Section III of the guidelines the WHO representative reminded the Committee of the danger of treating the ADI on a strictly mathematical basis, i.e. without considering the factors which led to its establishment. This was noted by the Committee.

80. The WG had pointed out the different concepts involved in assessing the intake of contaminants as compared to the intake of additives. The Committee agreed that the WG should examine a forthcoming document (FAO/WHO/UNEP Monitoring Programme on Food Contaminants) on approaches to the estimation of intake of chemical contaminants in food and report back to the Committee.

81. There were comments from the Secretariat and from several delegations concerning the considerable amount of work and practical difficulties involved in some of the proposals contained in the guidelines. For example the classification of foods was a task which could be quite large, although various methods of classifying foods were already in existence. Methods of analysis were put forward as another complex area. Although the Committee agreed, it appeared that the WG would essentially act as a post-office in this connection; moreover, the whole basis of the Guidelines was to avoid sample analysis at this point and concentrate on data submitted from governments as to actual amounts, added to food of substances. These then could provide rough estimates of actual consumption figures versus ADI's.

82. The Committee thanked the ad hoc Working Group for the amount and quality of its work and agreed to its reinstatement with Mr. Fondu as Chairman. The membership is Belgium (Chairman), Brazil, Canada, Denmark, Finland, France, Federal Republic of Germany, Israel, Italy, Japan, Spain, Switzerland, Thailand, Arab Republic of Egypt, United Kingdom, U.S.A., Australia and EEC. In summary its tasks were seen to be the following:

- (1) Digest the data received from governments
- (2) Study FAO/WHO/UNEP ideas on intake of contaminants and supply these to the Committee
- (3) Make proposals on the classification of foodstuffs.

Mr. Fondu accepted the role of compiling the data and if sufficient new information was forthcoming to present it to the next meeting of the WG.

ENDORSEMENT OF FOOD ADDITIVE PROVISION IN CODEX STANDARDS

83. In introducing document CX/FA 82/10 - Part I and Add. I the Secretariat pointed out that it had followed the procedure described in the report of the 13th session of the Codex Alimentarius Commission. Included in the document were food additive provisions at Step 5 or 7.

84. The decisions of the Committee concerning the endorsement, temporary endorsement or postponement of the endorsement of food additive provisions are indicated in Part I of Appendix VIII of this report.

I. FRUIT JUICES

Draft Standard for Mango Juice Preserved Exclusively by Physical Means (ALINORM 81/14, Appendix II)

Acids

85. The observer from IPPA speaking as Chairman of the Joint ECE/Codex Group of Experts on Fruit Juices drew the attention of the meeting to the fact that the Commodity Committee had recently discussed these provisions. The Commodity Committee had acknowledged the need for acidification of this type of fruit juice. However, it was still soliciting information on the use of fumaric acid. Therefore, the Committee postponed endorsement of this acid but did endorse the provisions for citric and malic acids. The delegations of the Fed. Rep. of Germany and of Switzerland expressed their reservation.

β -carotene

86. Following the proposal of the Chairman of the Joint ECE/Codex Group of Experts on Fruit Juices, the Committee decided to postpone the endorsement of this provision, pending more information on the technological justification of this substance.

II. COCOA PRODUCTS AND CHOCOLATE

Draft Standard for Composite and Filled Chocolate (ALINORM 81/10, Appendix II)

Mono- and diglycerides of edible fatty acids

87. The Committee agreed to the reservations expressed by the delegations of Austria, Argentina and the observer of the EEC and postponed the endorsement of these substances in relation to the products in question, awaiting more information from the Commodity Committee as to the technological justification of these glycerides. It was noted that this decision might affect the Codex standard on chocolate.

Ammonium salts of phosphatidic acids

88. The Committee discussed the level of these substances in food. The observer from the EEC informed the Committee that its regulations would allow a level of 5 g/kg of either this substance or lecithin singly or in combination. The delegate of Switzerland, speaking as Chairman of the Codex Committee on Cocoa Products and Chocolate, explained the technological need for emulsifiers and emphasized that this provision had already been endorsed in the General Standards for Chocolate. The Committee, therefore, agreed to endorse this provision.

Polyglycerol polyricinoleate

89. The delegation of the Federal Republic of Germany opposed the high level of this additive. In its view, the ADI could easily be exceeded. The delegation of Argentina also reserved its position on this provision. The Committee, however, endorsed this provision since it was already endorsed in the chocolate standard. The Committee accepted the view of the delegation of the UK that the correct name for this substance was "polyglycerol esters of interesterified ricinoleic acid".

Sorbitan esters of stearic acid

90. The Committee had a detailed discussion on the use of these esters. A number of delegations opposed this provision. The Committee noted the formal problem explained to it by the Secretariat that the Chocolate standard had already been adopted by the Codex Alimentarius Commission and in postponing the provision and returning it to the Commodity Committee, the Committee was, in fact, recommending to the CAC to amend the standard for chocolate. The Chairman of the Committee on Cocoa Products and Chocolate emphasized that it was undesirable to propose changes to the chocolate standards. The delegation of the USA, supported by the delegation of the UK, stressed that the task of Codex was also the facilitation of international trade as much as possible

and these emulsifiers should be provided for. In view of these considerations, the Committee decided to endorse the provision, noting the reservations of Argentina, Austria, Federal Republic of Germany, Greece, France, Italy, Poland, Spain, Switzerland and the observer of the EEC. It also noted the reservation of Sweden on sorbitan tristearate only.

Vanillin and Ethyl-vanillin

91. The Committee noted that, in view of the guidelines concerning the endorsement of food additives, temporary endorsement had been recommended by the Secretariat, requesting information on the quantities needed. After some discussion the Committee decided to follow this recommendation.

III. FATS AND OILS

A. Draft Standard for (Fat Spreads) Spreadable Table Fats (ALINORM 81/17, Appendix V)

Annatto extracts

92. The delegation of Austria expressed its reservation concerning this additive provision.

Turmeric and Curcumin

93. The delegations of Austria, Fed. Rep. of Germany, Poland and Portugal expressed reservation concerning these additive provisions. Endorsed temporarily because of their temporary ADI status.

Emulsifying agents

94. The delegation of Finland expressed the opinion that since spreadable fats and minarine differed significantly in their fat composition, they may not need the same additives at the same maximum levels and expressed a reservation for the provisions.

Polyglycerol esters of fatty acids

95. The delegations of Argentina, Austria, and the Federal Republic of Germany expressed reservation concerning this additive provision.

Polyglycerol esters of interesterified ricinoleic acid

96. The Committee postponed the endorsement of this additive. It wished to draw the attention of the Commodity Committee to the fact that in view of the low ADI of this additive there is a possibility the ADI may be exceeded, if used at a level permitted in the standard. It requested the Commodity Committee to reconsider the maximum level suggested.

Sorbitan Salts

97. The delegations of Argentina, France, Austria, the Federal Republic of Germany, Italy, and Poland expressed reservation concerning this additive provision.

Polyoxyethylene Sorbitan Salts

98. The delegations of Argentina, Austria, Federal Republic of Germany, France, Italy, Japan, Poland, Portugal and Sweden expressed reservation concerning this additive provision.

Pectin

99. The delegations of Austria and Italy expressed reservation concerning this additive provision.

Amidated Pectin

100. The Committee noted that JECFA had recommended a firm ADI for this additive and agreed to endorse its use. The delegations of Austria, Argentina, and Poland expressed reservation concerning the additive provision.

Agar-Agar and Guar Gum

101. The delegation of Austria expressed reservation concerning this additive provision.

Carrageenan

102. The delegations of Austria and Finland expressed reservation concerning the provision.

Locust Bean Gum

103. The observer from the INEC drew the attention of the Committee to the fact that JECFA, at its 25th Session had recommended a firm ADI for this additive. The Committee, therefore, endorsed the additive provision with a reservation of the delegation of Austria.

Tragacanth gum

104. The Committee postponed the endorsement of this additive provision, since there is no ADI set by the JECFA.

Xanthan Gum

105. The Committee agreed with a proposal from the delegation of Belgium to postpone the endorsement of this additive provision, since it felt that on one hand the maximum level suggested was too high in relation to the ADI and on the other hand the few numbers of endorsement already granted by CCFA. It referred the matter to the Working Group on Food Additive Intake and requested more information from the Commodity Committee on the required maximum level.

Methylcellulose and Carboxymethyl Cellulose and its Sodium Salts

106. The delegations of Austria and Poland expressed reservation concerning these additive provisions.

Alginates, Sorbic and Benzoic Acid and their Salts

107. The delegation of Austria expressed reservation concerning these additive provisions. The delegation of Argentina expressed its wish for a lower level viz. 1000 mg/kg of sorbic acid.

Gallates

108. The Committee endorsed this additive provision, since JECFA had removed the temporary status of the ADI.

BHA and BHT, Ascorbyl Palmitate/Stearate

109. The delegations of Austria and Poland expressed reservation concerning these additive provisions. The delegation of the Federal Republic of Germany expressed its reservation for all and was especially concerned about the provision for BHT. Endorsed

temporarily because of the temporary status of their ADI.

L-Ascorbic Acid and Natural and Synthetic Tocopherols

110. The delegation of Austria expressed reservation concerning these additive provisions.

Calcium Disodium Salt of EDTA

111. The Committee agreed with the delegation of Belgium to postpone the endorsement of this additive provision and request more data from the Commodity Committee on the technological function, noting that this additive is not included in similar standards.

Sodium Hydrogen Carbonate

112. The delegation of Poland expressed a reservation for this additive provision.

Sodium carbonate, Sodium hydroxide, Sodium monophosphate

113. The delegations of Argentina and Poland expressed reservation for these additive provisions.

B. Draft Standard for Minarine (ALINORM 81/27, Appendix III)

114. The Secretariat drew the attention of the Committee to the fact that this Committee at its XIVth Session, had referred these provisions to the Committee on Fats and Oils requesting more information on the technological justification. The Commodity Committee had supplied this information, which is contained in document CX/FA 82/10-Part I-Add. I. The Committee took similar action as that for food additive provisions in spreadable table fats (ALINORM 81/17, Appendix V). The Committee postponed endorsement of Xanthan Gum and endorsed the rest of the thickening agents. The delegation of Switzerland expressed a reservation for the methyl cellulose provision.

ENDORSEMENT OF CONTAMINANT PROVISIONS IN CODEX STANDARDS

115. The decisions of the Committee concerning the endorsements, temporary endorsements or postponement of the endorsement of contaminant provisions are indicated in Part II of Appendix VII of this report.

A. Draft Standard for Canned Palmito (ALINORM 81/20, Appendix VI)

116. The Committee had an extensive discussion on the level of tin. Several delegations felt that the maximum level proposed was too high. The Committee also noted that a worldwide survey is being carried out by Australia on the tin content of canned foods. In view of these considerations it decided to temporarily endorse this provision. The delegations of Austria, the Arab Republic of Egypt, the Federal Republic of Germany, Japan, New Zealand and Poland felt that the level of tin in this product could be lowered.

B. Draft Standard for Mango Chutney (ALINORM 81/20, Appendix VIII)

117. There was some concern in the Committee about the proposed contaminant levels in this standard. The delegation of India informed the Committee that in its country the figures for levels of contaminants in mango chutney were different viz.: As - 1.1 ppm; Pb - 0.5 ppm; Cu - 30 ppm; Zn - 50 ppm and Sn - 250 ppm. The Committee postponed

the endorsement for lead, since it considered that the level of 2.0 ppm is higher than other fruit products and requested the Codex Committee on Fruits and Vegetables to reconsider the provision for lead. The Committee decided to temporarily endorse the other provisions and noted reservations from the delegations of the Arab Republic of Egypt, Austria, the Fed. Rep. of Germany, Italy and Japan for the tin provision.

II. FRUIT JUICES

Draft Standard for Mango Juice Preserved Exclusively by Physical Means (ALINORM 81/14, Appendix II)

118. The delegations of the Arab Republic of Egypt, Austria, the Fed. Rep. of Germany, Japan and Switzerland made a reservation on the provision for tin.

119. The Committee had some doubts if sulphur dioxide was really a contaminant. The observer from IPPA, speaking as Chairman of the Codex Committee on Fruit Juices, explained that even with a slight yeast activity some sulphur dioxide is produced from natural sulphates.

III. COCOA PRODUCTS AND CHOCOLATE

A. Draft Standard for [Composite Cocoa Butter] [Cocoa Butter Confectionery] (ALINORM 81/10, Appendix III)

120. The delegation of Argentina was of the opinion that the maximum levels proposed for arsenic, copper and lead were too high.

121. The Committee followed the suggestion of Canada and postponed the endorsement for the lead provision, requesting clarification about the source of the lead and suggesting that a lower level might be feasible.

B. Draft Standard for Composite and Filled Chocolate (ALINORM 81/10, Appendix II)

122. The delegation of Poland proposed a maximum level for As of 0.5 mg/kg. The Committee agreed that it required information on the relatively high maximum level for copper and postponed its endorsement.

123. The Committee also postponed the endorsement of the lead provision as it did with regard to the Draft Standard mentioned under III A.

IV. FATS AND OILS

Draft Standard for [Fat Spreads/Spreadable Table Fats] (ALINORM 81/17, Appendix V)

124. The Committee agreed with the delegation of Australia that the provision for copper represented a quality criterion rather than a contaminant provision. The Committee endorsed the provision for copper.

V. CEREALS AND CEREAL PRODUCTS (CX/FA 82/10 - Part II-Add. 2)

125. The Committee had some discussion on the proposed provisions. The delegation of Norway felt that contaminant provisions, where they are needed, should be precise; however, if they are not needed for health reasons they should not be established. The representative of WHO drew the attention of the Committee to the 22nd JECFA report which states that the presence of trace amounts to a toxic substance is not in itself a health hazard. He also emphasized JECFA's definition of an irreducible level of a

contaminant as a concentration of a substance which cannot be eliminated from food without involving the discarding of that food altogether. After some discussion the Committee agreed that it required more information from the Commodity Committee on the type of heavy metals involved, such as the actual levels found in maize and wheat flour and on the origin of these metals.

VI. CONSIDERATION OF LEAD LEVELS IN RECOMMENDED CODEX STANDARDS FOR SUGARS

126. The Committee had before it document CX/FA 82/10-Part II-Add. 1 prepared by the UK Secretariat for Sugars and additional comments of USA as contained in CX/FA 82/10- Part II-Add. 1a. In its paper the UK Secretariat elicited information from Governments regarding their views to reduce the existing level of 1.0 mg/kg of lead for sugars other than fructose to 0.5 mg/kg and recommended, based, on the replies received, that the level of lead in sugars be reduced to 0.5 mg/kg.

127. The delegation from UK informed the Committee that some producing countries have not commented to the questionnaire sent by the UK Secretariat for Sugars, and expressed the opinion that the recommendation to lower the lead levels of all sugars to 0.5 mg/kg is difficult to achieve. The lead levels of sugars are equated with sulphated ash and levels of 0.5 mg/kg of lead could be achieved only when the sulphated ash content does not exceed 0.25%. While the lead content of lactose and glucose syrup is about 1.0 mg/kg that in soft sugars could exceed 5.0 mg/kg. The UK delegation suggested that the Committee should seek more information before taking a decision.

128. The delegation from Brazil pointed out to the Committee that it was only last year that the Commission lowered the level of lead in sugars to 1.0 ppm. Brazil is presently carrying out an extensive survey to assess the compliance possibility of this level. If the lead level is reduced further at this stage it would pose many problems to this country.

129. The Committee agreed that it should not lower the maximum level of lead in sugars from the existing level of 1.0 ppm and that it needed more information on the intake of lead from sugars as compared to the overall intake from all sources. It noted the activities of the UNEP/WHO/FAO monitoring programme on contaminants and expressed its opinion that it could obtain the required information from this programme and other sources. It also requested the Working Group of Food Additive Intake to study the question and referred the matter back to the UK Secretariat on Sugars to elicit more views from the producing countries.

CONSIDERATION OF CODEX LISTS OF FOOD ADDITIVES

Revision of the Guide to the Safe Use of Food Additives (CAC/FAL 5-1979)

130. The Committee had before it document CX/FA 82/2-Add. 1(Room document), prepared by the Secretariat. The Committee was informed that there was a continued need to update this publication after every session of JECFA and of the Codex Alimentarius Commission. This difficulty in updating could be overcome by issuing the guide as a loose leaf system or by computerizing the data contained therein.

131. The Secretariat informed the Committee that a computerized data bank system was being developed by FAO and WHO which would include all the information presently contained in "The Guide to the Safe Use of Food Additives". The exercise was still not fully operational. A sample computerized data sheet was made available to the Committee. A consultant, to be appointed by FAO shortly, would work out on the final lay-out of the information for publication. It is expected that the exercise would be

completed by the end of 1982.

132. The Committee expressed its appreciation of the efforts being made by FAO/WHO to computerize the data and hoped that an index, which would help in rapidly referring to the additives, would be included in future publications.

Action needed by CCFA resulting from Change in ADI Status of Food Additives

133. The Secretariat introduced the paper CX/FA 82/2-Add. 2 (Room document). The Committee noted that JECFA at each of its sessions reevaluates food additives in the light of additional data received and may take four types of action. It may (i) change the existing ADI, (ii) change a firm ADI to temporary ADI, (iii) change a temporary ADI to firm ADI or (iv) withdraw a firm or temporary ADI.

134. The Committee noted that such action by JECFA would call for action by CCFA to (i) move additives between Codex lists A1, A2, B and C, and (ii) make appropriate changes to previous endorsement.

135. The Committee agreed to carry out such a review at the next session on the basis of a paper prepared by the Secretariat.

Codex List B

136. The Committee had before it the paper CX/FA 82/2 "Revision of Codex List B of Food Additives". The purpose of this paper is to bring the 1979 Codex List B as amended at the 14th CCFA session, up to date in the light of the conclusions of the 25th session of JECFA. The Committee deleted Carob (locust) bean gum from the list since it had an ADI. It was confirmed that the Secretariat would subdivide List B into two parts as agreed during the last session (ALINORM 81/12, para 105).

Class Names

137. The Working Group on Class Names for Food Additives did not meet at this session since its recommendations for class names had not yet been considered by the Codex Committee on Food Labelling and since it had no other business to discuss.

138. The Chairman of the Working Group suggested that the Committee should develop an international numbering system for food additives. This could be regarded as a consumer oriented numbering system which would provide information to consumers who for various, medical or other reasons wished to be informed of the exact nature of the additives included in foods. He also suggested that the existing EEC system could form a basis for such an exercise. The delegation of Norway asked that it be clear that the purpose of any food additive numbering system was to provide more complete labelling information to consumers with food allergy problems.

139. The Committee was informed by EEC that this organization was prepared to help in any activity that the Committee may undertake to develop an international numbering system for food additives but did not consider it to be an easy task.

140. The proposal of Australia to develop an international numbering system for food additives received active support from other delegations and international organizations all of which felt that development of such a system would facilitate communication and would overcome certain problems that exist in Codex Committees which do not use uniform nomenclature.

141. The Committee expressed the opinion that an international numbering system for food additives be developed taking into account all existing numbering systems (future task for the Working Group on Class Names) and agreed that, as a first step, comments

be collected from governments regarding their interest in such an activity.

142. The Committee reinstated the Working Group on Class Names under the Chairmanship of Mr. M.P. Jackson (Australia) with participation of Canada, UK, USA, New Zealand, Arab Republic of Egypt, Brazil, EEC and CIAA.

CONSIDERATION OF FLAVOURS

Consideration of certain botanicals

143. The Chairman of the *ad hoc* Working Group on Flavours, Mr. J.P. Goddijn of the Netherlands, presented his WG's report CX/FA 82/6, Add. 1 (Room Document) on this subject. The conclusion of the WG had been that use of the six botanicals in question (see para 132 (c), ALINORM 81/12) in the manufacture of alcoholic beverages - if they were used at all - was insignificant. It was in any case known that there was no interest in them for the flavouring of food. Rather than add these botanicals to the "List of plants unsuitable as a source of natural flavours" including in the Guide to the Safe Use of Additives (CAC/FAL 5-1979, page 85) the WG had recommended the complete withdrawal of that list.

144. The Committee endorsed this view of the WG and requested the secretariat to take appropriate action in relation to future editions of the guide.

Endorsement of Provisions for Natural Flavours and Nature-Identical Flavouring Substances in Codex Standards

145. The Committee noted that the Working Group had considered whether natural flavours could be fully endorsed by separating them from nature-identical flavouring substances in Codex standards. This question arose since certain artificial flavouring substances which had been given an ADI by JECFA had been fully endorsed in the past. Some delegations felt that it was an undesirable situation in the endorsement procedure. The Committee noted that the Working Group had not been able to resolve this question and it had concluded that the present procedure of temporarily endorsing natural and nature-identical flavours should be continued.

146. The FAO Joint Secretary of JECFA expressed the opinion that this problem should be tackled in an endeavour to arrive at an evaluation of natural and nature-identical flavours from a point of view of safety. In this respect it would be desirable for JECFA to be advised of a suitable approach so that the large number of flavourings involved could be evaluated. The Codex Secretariat recalled previous action taken by the Committee concerning the endorsement of the various types of flavours and flavouring substances. For example, the Committee had fully endorsed natural flavours such as essences, extracts and essential oils obtained from food sources. However, the Committee had given only a temporary endorsement to general provisions for the use of natural flavours and nature-identical flavouring substances. In view of the fact that toxicological information on many of these substances and preparations were not likely to be forthcoming in the foreseeable future, temporary endorsements by the Committee were likely to remain for a considerable length of time.

147. A number of delegations were of the opinion that a practical approach should be adopted in relation to the clearance of flavours and that a system of priorities should be established as soon as possible in order to reduce the duration of temporary endorsement. As a start it was essential to have a list of flavouring substances used in the preparation of food in order to appreciate the magnitude of the problem.

148. The Committee took note of the conclusions of the Working Group and the

remarks expressed by the delegations and by the Secretariat.

Establishment of Specifications for Natural Flavours

149. The Committee noted that the Working Group had discussed the desirability of elaborating general specifications or requirements for natural flavour and that the group had decided that it would be useful to elaborate such requirements for the next session.

150. The Committee agreed with the conclusion of the Working Group and decided to await further developments in this field.

Setting Priorities for the Evaluation of Flavouring Substances

151. The Committee was informed that the Working Group had considered ways and means of setting priorities for those substances with a view to tanking them in order of possible future examination from a point of view of safety. In this connection the Group had discussed an approach developed by Dr. J. Stofberg (Perfumer and Flavorist 6, 69-72 (1981)) which involved an examination of the contribution of added flavours to the daily intake of flavour components already contained in traditional foods.

152. The Working Group had welcomed this new approach as a valuable tool in priority setting, particularly in combination with the decision tree approach (para 120 ALINORM 79/12) and had been informed by IOFI that this organization would supply all necessary information in cooperation with an independent institute.

153. In discussing the need for setting priorities for flavouring substances and the methods to be adopted to achieve this, delegations questioned as to what body might undertake this work and how soon the necessary information would be forthcoming.

154. The representative of WHO indicated that his organization had already budgeted for a working group to be convened in 1984/85 to consider this matter, including a review of methodologies of toxicity testing. The FAO Joint Secretary of JECFA was of the opinion that the priority setting procedure, including the decision tree approach, would result in the establishment of three categories of flavouring substances from a point of view of safety and that such a procedure as, therefore, to be considered as a screening procedure for deciding which substances should be tested toxicologically. The question was also posed that, if the procedure for priority setting served the purposes of future toxicity testing, who would sponsor the testing of such a large number of substances.

155. The Committee was informed that FAO was greatly interested in taking part in any activities leading to setting priorities for flavouring substances and would explore ways of arranging for an appropriate body to consider this question jointly with WHO.

156. The Committee noted that the Council of Europe had done much work in the area of flavours and that a third edition of the "Blue Book" had recently been issued by that organization.

157. The Committee noted with satisfaction that work was envisaged on the establishment of priorities for and screening of flavouring substances and expressed the hope that rapid progress would be made. It thanked the Working Group on Flavours and decided to reinstate the Working Group under the Chairmanship of Mr. J.P. Goddijn. The membership of the Working Group is Belgium, Denmark, Egypt, France, Fed. Rep. of Germany, Italy, Netherlands, Switzerland, United Kingdom, USA, Council of Europe, EEC, IOFI, FIVS, FAO, WHO, Austria and CIAA.

Consideration of Processing Aids

158. The Committee had before it the report of the ad hoc Working Group on

Processing Aids (CX/FA 82/12-Add. 1), which is reproduced as Appendix IX. In introducing the report, the Chairman of the Working Group (R. Ronk, USA) informed the Committee that after the last session of the CCFA the Secretariat had prepared a new inventory of processing aids, which was sent to governments for comments. A considerable number of comments had been received and a new inventory had been prepared on this basis.

159. The Working Group had been confronted by several problems, one of them, being that many substances suggested as processing aids were actually food additives. The Working Group had, therefore, considered it necessary to reclassify the processing aids and to update the inventory, the USA was prepared to undertake this exercise. The revised inventory would be sent to the Secretariat, which should solicit further comments from governments.

160. Another problem for the Working Group had been the lack of information on the substances provided to the Working Group. Information is required on concentration levels in food, on residue levels and on methods of analysis to determine the residue levels.

161. The Chairman of the Working Group suggested that the precise purpose of the inventory was not yet clear and that this should be established at some future session of the CCFA. However, in his view the main purpose would appear to be to find out which processing aids left relatively substantial residues in food which might have to be referred to JECFA for evaluation.

162. The delegation of Belgium suggested that information should also be solicited about possible interaction between the processing aids and food. This was accepted by the Committee.

163. The Working Group's proposals were endorsed by the Committee. The Committee thanked the Working Group for its valuable contribution to the work of the Committee.

164. The Committee decided to reinstate the ad hoc Working Group under the Chairmanship of Mr. R. Ronk (USA). The membership of the Working Group is as follows: Australia, Austria, Belgium, France, Fed. Rep. of Germany, Italy, New Zealand, United Kingdom, Brazil, Thailand, USA, CIAA, EEC, IFMA and AMFEP.

Consideration of the Working Group on Specifications

165. The Committee had before it the report of the ad hoc Working Group on Specifications (CX/FA 82/7-Add. 1). In introducing the report, the Chairman of the Working Group, Dr. J. Modderman (USA) informed the Committee that the Working Group had considered (i) the status of Codex specifications and (ii) the procedure for the elaboration of Codex specifications, referred to it by the 14th session of the Codex Alimentarius Commission and by the 9th session of the Codex Committee on General Principles. It also reviewed in the light of comments received from governments JECFA specifications for identity and purity of food additives as contained in FAO Food and Nutrition Papers Nos 12 and 17.

166. The Working Group discussed in detail the procedures concerning the elaboration and acceptance of specifications, and proposed a new procedure, after having reviewed three proposals tabled respectively by the UK, EEC and the Secretariat of Codex. This new procedure was agreed to by the Committee. It is presented in the Annex to the report of the Working Group.

167. The Working Group recommended 20 substances contained in Food and Nutrition Paper No. 12 for adoption by the Commission, 5 substances for adoption by the Commission after editorial correction, and referred 15 substances back to JECFA for further consideration. In this latter group proposals for amendments were also provided in the report of the Working Group. In addition 25 specifications were not reviewed for reasons given in the same report.

168. From Food and Nutrition Paper No. 17 the Working Group recommended 5 specifications for adoption by the Commission, 23 substances to be referred back to JECFA together with the proposed amendments, while it was decided not to review 33 other specifications for the reasons given in the report.

169. The Chairman of the Working Group drew the attention of the Committee to the need of governments and food additive manufacturers to comment on all specifications including the tentative ones, because otherwise JECFA may never receive the information needed to change their tentative status.

170. The Committee endorsed the report of the Working Group which appears as Appendix X of this report. It was agreed that specific comments of the Working Group on Specifications in category II and III, which are included in the Working Group's report, should be submitted to the Secretariat of JECFA for action.

171. The Committee concurred with the recommendation of the Working Group to publish JECFA's specifications in a loose leaf form and requested the Secretariat to investigate its feasibility. The same specification sheet could later be used after modification as Codex Specifications.

172. The delegation of Australia suggested that JECFA specifications should be issued in an easily identifiable separate series and the Committee agreed that JECFA Secretariat should look into this possibility.

173. The Committee agreed that action should be taken by the Secretariat as stated below:

- The views of the Committee on the advisory status of Codex specifications should be submitted to the Codex Committee on General Principles for consideration.
- The opinion of the Committee on the safety aspects of Codex Specifications should be referred to JECFA for discussion at its 26th session.
- The new procedure for elaboration of Codex specifications and the changes proposed by the Committee in the format for Codex Commodity Standards should be brought to the attention of the Commission at its 15th session.

174. The Committee noted that the future tasks for the Working Group on Specifications would be to (i) review JECFA specifications as contained in FAO Food and Nutrition Paper No. 19 and (ii) consider the opinion of JECFA on the Safety Aspects of JECFA Specifications.

175. The Chairman thanked Mr. Dodgen (USA) for his past years' valuable contribution to the Working Group.

176. The Committee reinstated the Working Group with Dr. Modderman (USA) as its Chairman. The membership of the Working Group is as follows: Austria, Brazil, Canada, Denmark, France, Greece, Guyana, Switzerland, UK, Thailand and IOFI.

Consideration of the Report of the Working Group on the Codex Priority List

177. The Committee had before it the report of the ad hoc Working Group on Priority List (CX/FA 82/11-Add. 1). In introducing the report, the Chairman of the Working Group, Dr. S.W. Gunner (Canada) reminded the Committee of the decision taken at its last session to examine all additives previously put on the list, but on which no action had been taken by JECFA. These had been sent to governments for comments and document CX/FA 82/11 summarized the comments received.

178. The Working Group had discussed the changes resulting from the decisions of JECFA at its 25th session and noted that JECFA will review substances at its forthcoming 26th session in April 1982. Consequently only 37 additives remained on the list out of the original 95. The report of the Working Group is attached as Appendix XI to this report. Lactitol and ethylmethylphenylglycidate have been added to the Priority List at the request of Netherlands.

179. The Chairman of the Working Group pointed out that they had felt that there was a lack of general understanding regarding the criteria and procedures for Priority List selection. The Working Group had felt that the Committee should formally recognize the type of information deemed necessary in this regard and proposed to the Committee to accept the JECFA recommendations contained in the 25th report (Section 2.7 TRS No. 669) as to the criteria to be fulfilled before selecting compounds for the Priority List. The Committee in general accepted the proposal of the WG that information provided to JECFA should be consistent with the guidelines established at the 25th meeting of JECFA with the exception of substitute additives.

180. The representative of the CIAA expressed his concern about the data requested by JECFA. He felt that it would be difficult for industry to submit all the data required by JECFA. As a result JECFA might not feel itself to be in a position to evaluate the additive concerned. However, CIAA felt that these compounds should in any case receive an evaluation. The Chairman of the Working Group and the Committee recognized the difficulty but suggested that the JECFA requirement was an ideal to be striven for.

181. However, the Committee accepted the Working Group's recommendation that action was needed on some substances and accepted the recommendation of the WG regarding substances to be included in the priority list. In the case of substances which had been reviewed by JECFA and for which additional data had been requested, such substances would normally be placed before JECFA upon receipt of this information.

182. The Chairman of the Working Group pointed out to the Committee that the Working Group felt that it had concluded its work of cleaning up all previous Priority Lists and that the Committee should consider broadening the scope of the Working Group to cover new priority areas in general. The Committee had some discussion on this proposal and concluded that it was indeed desirable to disband the present ad hoc Working Group and establish a new one, to be named "Working Group on Priorities for Food Additives and Contaminants". The Committee agreed that the task for this Working Group would be to look into the priority areas to be considered by the Committee in the general field of food additives and contaminants.

183. The delegate of Australia, Dr. M. Jackson accepted to act as Chairman of the new ad hoc Working Group, which would consist of Canada, Australia, Federal Republic of Germany, Italy, United Kingdom, USA, WHO, FAO and IOFI.

Consideration of Sampling Plans for the Determination of Contaminants in Food

184. The Committee had before it conference room document CX/FA 82/8 prepared jointly by the USA and FAO. It was introduced by Dr. Modderman (USA) who explained

that the paper went further than examining the factors involved in developing sampling plans for contaminants: it also contained recommendations for further action. Dr. Modderman reviewed the conclusions of the working paper (CX/FA 82/8, sections IX and X) which had led to two recommendations as follows:

- (1) The CCFA should define maximum contaminant level (MCL) as the average value for the contaminant concentration in a lot or consignment of a food commodity. Enforcement officials should attempt to apply MCLs to individual lots of a food commodity, if it can be determined that a quantity of a commodity was produced under uniform conditions. If it cannot be determined whether multiple lots are in a consignment, enforcement officials can apply MCL to consignments of food commodities.
- (2) To measure the average-of-a-lot (or consignment) the CCFA should direct Commodity Committees to develop sampling plans which blend an appropriate number of primary samples to make a composite sample representative of the lot (or consignment). The sampling plan should provide for a suitable number of replicate analyses of the composite to assure precise results and provide for check analysis by a second enforcement official.

185. The SEFEL representative took issue with the statement in the working paper that "the reason for recommending compositing of primary samples is solely practical". He pointed out that the "tolerable weekly intake" concept applied by WHO to contaminants was also more in line with the composite sample approach.

186. The delegation of The Netherlands questioned the concept of average value in defining MCL (recommendation 1). Mr. Modderman described a number of factors that had led to the development of this idea: it would be the most likely route for establishing MCL, especially on a long term basis; it fitted in with ideas of promoting consumer safety; it would assist in minimizing sampling. The Secretariat pointed out that the same concept was used with pesticide residues whose distribution was expected to be similar to that of contaminants, with some exceptions (e.g. aflatoxin).

187. Many delegations agreed with the Australian delegation which felt that it needed more time to consider some of the technical aspects of the paper before accepting its recommendations. The Committee, therefore, agreed to submit the paper both for general comment, and for specific comment on the recommendations, to governments and to those Commodity Committees which would be meeting between the present and next sessions. The Secretariat agreed to write a covering note in the relevant circular letter which would describe the approach worked out by the Codex Committee for Pesticide Residues and would also provide appropriate information to governments so as to generate the information needed by the Committee for a fruitful discussion of the recommendations contained in the US paper.

Codex Maximum Levels for Industrial and Environmental Contaminants in Food

188. The Committee had before it document CX/FA 82/18 on the above subject. It was introduced by the FAO Secretariat. This document had been prepared by the Secretariat, as directed by the Committee at its last session, on the basis of information supplied by governments on legal maximum levels for industrial and environmental contaminants in food in national legislation. Information received from 9 countries had been analyzed by the Secretariat. The information obtained was scarce and varied so significantly that the Secretariat had found it difficult to arrive at meaningful conclusions concerning legal maximum levels for industrial and environmental contaminants. The

Secretariat expressed the opinion that it would be difficult to arrive at internationally acceptable maximum levels for contaminants on the basis of national figures which varied so significantly.

189. The document contained inventories on (i) chemical contaminants in foods and (ii) trace elements on their organic and inorganic derivations which came under the purview of the Committee. The Committee noted that chemical contaminants that had chemical or other similarities with pesticide residues would be considered by the Codex Committee on Pesticide Residues.

190. The Committee noted that, since collection and evaluation of data of all the chemical and inorganic contaminants listed in the inventories, would take several years, it should establish its priorities before embarking on work in this field. The Committee agreed that, as a first step, it should interest itself in certain heavy metals like As, Cd, Pb and Hg and mycotoxins, like aflatoxin, and to collect data on those contaminants which are of public health concern in different countries in order to identify the problem first and to review the approaches made by different governments to set up limits. The Committee felt that this was a task which should be undertaken by a consultant. The Codex Secretariat was requested to take steps to hire such a consultant if possible. The Committee agreed that the terms of reference of the Consultant would be:

- (1) To obtain information from governments and from other sources in order to identify contaminants of public health concern and those causing difficulties in the food trade.
- (2) As a first step in this work, contaminants should be chosen from among trace elements such as Hg, Cd, Pb, and As, and from among mycotoxins such as aflatoxin.
- (3) Study approaches adopted by governments in setting limits for or otherwise controlling levels of contaminants in foods and
- (4) Advise CCFA on what its role should be in making recommendations in this field in the light of (a) the aims of the CAC, (b) ongoing work by other bodies and (c) available resources.

It was hoped that the report prepared by the FAO consultant would be discussed by the Committee at its next session.

Possible Future Work of the Codex Committee on Food Additives and Consideration of Priority Areas

191. The Committee had before it document CX/FA 82/19 which had been prepared jointly by The Netherlands and Codex Secretariats. The document contained in a tabulated form (i) work already completed, ongoing activities, agreed future activities and suggested, possible future activities of the CCFA and (ii) possible and agreed future work of the CCFA indicating inputs from other bodies. In introducing the paper, the Secretariat expressed the opinion that since the evaluation of intentional food additives, other than flavouring substances, has been practically completed and in consideration of future work and priorities for JECFA and CCFA should be seen in terms of global areas of projected activity rather than lists of single substances. The Joint Secretariat of JECFA expressed reservation to the statement and informed the Committee that JECFA had still an appreciable work to carry out for the evaluation and reevaluation of single additives.

192. The Committee noted that certain of its activities relating to flavours, processing

aids and guidelines for estimation of intake of food additives and contaminants were ongoing activities. The Committee agreed that it should not embark on analysis of food additives in food since appropriate methodology was not available.

193. The activity on sampling, the Committee felt, is highly statistical in character and that it may not provide the right forum to justify embarking on this activity. The other activities (1) packaging materials, (2) environmental contaminants, (3) residues in food of chemo-therapeutic agents, anaboles and antibiotics and possible metabolites in animal husbandry and in veterinary medicine and (4) maximum levels for food additives in soft drinks, were suggested as possible areas of future work on which it might embark, and proposed that these should be referred to the governments to elicit their interest in such activities. Governments would also be asked if there were other important areas for future work than those listed above.

194. The comments that may be received from the different governments will be collated by the Secretariat and made available to the plenary as well as to the Working Group on Priority for Evaluation of Food Additives and Contaminants. The report of the Working Group as well as the comments received from governments would be discussed at the next session. The Committee asked the Secretariat to formulate a suitable questionnaire when seeking comments from governments on its suggested future activities (see para 193).

OTHER BUSINESS

General Principles for the Use of Food Additives

195. The Committee expressed the opinion that the "General Principles for the Use of Food Additives" is a useful reference for all Codex Committees and contains certain clauses which are procedural and expressed regret for the removal of this section from the 5th Edition of the Procedural Manual.

196. The Secretariat informed the Committee that the General Principles for the Use of Food Additives which had been taken out of the Procedural Manual were still operative and would now be published in Vol. I - General Principles of the Codex Alimentarius. These general principles are also set forth in the present edition of the Guide to the Safe Use of Food Additives. The text will be reinstated in the next edition of the Procedural Manual.

197. The Committee proposed that since the 5th Edition of the Procedural Manual has been issued in a loose leaflet form, the section on General Principles for the Use of Food Additives could be reintroduced without much problem and asked the secretariat to take the needed action.

Natural Mineral Waters

198. The delegation from Australia informed the Committee that expressing radio-activity as 226_{RA} or 228_{RA} in the standard for Natural Mineral Waters was creating problems in his country and proposed that this question be discussed at the next session of CCFA.

199. The Secretariat informed the Committee that it would refer the question raised by Australia to the Coordinating Committee for Europe which is handling the standard on the Natural Mineral Waters and also make available to that Committee the background information to be provided by Australia.

Date and Place of Next Session

200. The Committee noted that its next session would be held in The Hague, in March 1983 at a date to be agreed between the Government of The Netherlands and the Codex Secretariat.

Appendix I

LIST OF PARTICIPANTS*
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LISTA DE PARTICIPANTES

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

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OPENING SPEECH AT THE
15TH SESSION OF THE
CODEX COMMITTEE ON FOOD ADDITIVES

by

Mr. G.J. van Dinter, Secretary General
of the Netherlands Ministry of
Agriculture and Fisheries

The Hague, March 16th 1982

Ladies and Gentlemen,

At this 15th meeting of the Codex Committee on Food Additives I would like to convey to you a hearty welcome here in The Hague. Such a lustrum also offers an appropriate reason to look back at what has been accomplished but especially to look forward to future tasks. But before doing so I want to emphasize the importance The Netherlands Government attaches to the growing participation in the meetings of this Committee - from developed as well as from developing countries.

It is striking that even at times of economic recession countries and international organizations alike feel that the work of the Codex Alimentarius should not be curtailed - and justifies investments and efforts.

The Netherlands, as the host country both of this Committee and the Committee on Pesticide Residues, feels the same way.

Already now, but increasingly in future, the work of your committee will be of importance to:

- the safety of food for the consumer
- the promotion of fair trade
- modernization of national food laws: new regulations or the amelioration of existing ones - in countries all over the world.

The safety of food additives has to be scrutinized very carefully. And I dare to say: they are! National governments as well as the Expert Committees together with your Committee perform a careful and thorough job here - the safety record on food additives is a good one! So there is reason to be content but - as you are well aware - no reason to rest on our laurels.

New additives will have to be scrutinized and existing ones will have to be re-examined on the basis of new facts. Besides, the scope of your committee extends beyond that of the "real" additives, to include such subjects as food irradiation and salt. And this trend to include more and more subjects in the agenda of your meetings continues. I am referring to such subjects as food contaminants from the environment and residues of medicines or growth promoters in products from animal husbandry. There is no doubt that work in these fields is highly useful and necessary and that there certainly is reason for concern about the effects of environmental pollution on the health of our foodstuffs. It also goes without saying that Codex Alimentarius as the highest international platform for food standards (including safety), forms the right forum for such problems and should tackle them. It is up to you, however, to discuss for each item whether the Committee on Food Additives, within Codex, forms the right forum.

Not only should food be safe, but also there may not exist uncertainty about the true quality of the product - in relation to its name. Often the name of a foodstuff implies that for instance its flavour and colour originate from certain ingredients. An example: the taste and colour of chocolate originate from cacao. The use of food additives in such traditional products has to be limited in order to avoid any misconception by the consumer about the true quality of the product. This is primarily the responsibility of the different Commodity Committees - but in dialogue with you. Additives perform important functions in food, but we have to be careful about the fairness in trade.

At the 14th session of your committee Mr. Van der Meijs, in his opening speech - on behalf of the Minister of Agriculture and Fisheries - made some very valuable remarks about the importance The Netherlands attaches to the work of the Committee on Food Additives and of the Codex Alimentarius in general.

The food standards that have been developed have not yet been accepted formally by many countries, but they do exercise great influence on national laws all over the world. Codex meetings thereby serve as an excellent and stimulating encounter of specialists and administrators from all over the world.

If I open the session now, we have to bear in mind that the work has been started earlier. I am referring here to the valuable preparatory work of the Working Groups, and their Chairmen, long before the meeting and especially in the last few days. I have been informed that one Working Group even skipped the possibility to tour Holland in early spring (or late winter) during the weekend and instead did their homework! It is in this spirit that I wish you a very fruitful meeting and a pleasant stay in The Hague.

DRAFT STANDARD FOR FOOD GRADE SALT
(At Step 6 of Codex Procedure)

1. SCOPE

This standard applies to salt used as an ingredient of food, both for direct sale to the consumer and for food manufacture. It applies also to salt used as a carrier of food additives and/or nutrients. It does not apply to salt from origins other than those mentioned in item 2, notably the salt which is a by-product of chemical industries.

2. DESCRIPTION

Food grade salt is a crystalline product consisting predominantly of sodium chloride. It is obtained from the sea, from underground rock Salt deposits or from natural brine.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Minimum NaCl Content

The content of NaCl shall not be less than 97% on a dry matter basis, additives excluded.

3.2 Naturally present Secondary Products and Contaminants

The remainder comprises natural secondary products, which are present in varying amounts depending on the origin and the method of production of the salt, and which are composed mainly of calcium, potassium, magnesium and sodium sulphates, carbonates, bromides and chlorides. Natural contaminants may also be present in amounts varying with the origin and the method of production of the salt.

3.3 Use as a carrier

Food grade salt shall be used if salt is used as a carrier of food additives or nutrients for technological or public health reasons. Examples of such preparations are mixtures of salt with nitrate and/or nitrite (curing salt) and salt mixed with small amounts of fluoride, iodide, iron, vitamins, etc. and additives used to carry or protect such additions.

4. FOOD ADDITIVES

4.1 All additives used shall be of food grade quality. (Additives appearing on the list indicated by means of an asterisk have not yet been evaluated by the Joint FAO/WHO Expert Committee on Food Additives).

4.2. Anticaking agents

- 4.2. 1. Carbonate, calcium
- 4.2. 2. Carbonate, magnesium
- 4.2. 3. Magnesium oxide
- 4.2. 4. Phosphate, tricalcium
- 4.2. 5. Silicon dioxide, amorphous
- 4.2. 6. Silicate, calcium
- 4.2. 7. Silicate, magnesium
- 4.2. 8. Silicate, sodium alumino
- 4.2. 9. Silicate, potassium alumino*

Maximum level

20 g/kg singly or in combination

- 4.2.10 Silicate, aluminium calcium*
- .
- 4.2.11 Silicate, sodium, calcium alumino
- .
- 4.2.12 Stearate, aluminium
- .
- 4.2.13 Stearate, calcium
- .
- 4.2.14 Stearate, magnesium
- .
- 4.2.15 Stearate, potassium
- .
- 4.2.16 Stearate, sodium
- .
- 4.2.17 Citrate ammonium
- .
- 4.2.18 Aluminium, Calcium, magnesium, potassium or sodium salts of capric*, caprylic*, lauric*, myristic, oleic* or palmitic acids

4.3. Free-flowing agents

- 4.3.1. Ferrocyanide, sodium +
- 4.3.2. Ferrocyanide, potassium +
- 4.3.3. Ferrocyanide, calcium 10 mg/kg,⁺ singly or in combination, expressed as Fe(CN)₆
- 4.3.4. Ferrocyanide, magnesium*
- 4.3.5. Ferrocyanide, manganese*
- 4.3.6. Manganocyanide, ferrous*
- 4.3.7. Polysorbate 80 10 mg/kg

4.4. Processing Aids

- 4.4.1. Dimethylpolysiloxane 10 mg/kg

+ Sodium and potassium ferrocyanides, maximum level may be 20 mg/kg when used as crystal modifiers in the preparation of dendritic anit.

5. CONTAMINANTS

Food grade salt may not contain contaminants in amounts and in such a form that may be harmful to the health of the consumer. In particular the following maximum limits, shall not be exceeded.

- 5.1 Arsenic not more than [1] mg/kg, expressed as As ^{1/}
- 5.2 Copper not more than [2] mg/kg, expressed as Cu ^{1/}
- 5.3 Lead not more than [2] mg/kg, expressed as Pb ^{1/}
- 5.4 Cadmium not more than [0.5] mg/kg, expressed as Cd ^{1/}
- 5.5 Mercury not more than [0.1] mg/kg, expressed as Hg ^{1/}

^{1/} The maximum levels are provisional pending information on actual levels and the establishment of appropriate methods of analysis.

6. HYGIENE (Subject to endorsement by the Codex Committee on Food Hygiene)

In order to ensure that proper standards of food hygiene are maintained until the product reaches the consumer, the method of production, packaging, storage and transportation of food grade salt shall be such as to avoid any risk of contamination.

7. LABELLING (Subject to endorsement by the Codex Committee on Food Labelling)

In addition to section 1, 2, 4 and 6 of the General Standard for the Labelling of Prepackaged Foods, reference No. Codex STAN 1-1981, the following specific provisions apply:

7.1 The name of the product

- 7.1.1 All products conforming to this standard shall be designated "salt".
- 7.1.2 The designation shall include, on the label a declaration of either "Food grade" or "Cooking salt" or "Table salt".
- 7.1.3 Only when salt contains one or more ferrocyanide salts, added to the brine during the crystallization step, the name of the product as declared on the label may be "Dendritic salt".
- 7.1.4 Where salt is used as a carrier of one or more nutrients, and sold as such for public health reasons, the name of the product should be declared properly on the label for example "fortified salt", "fluoridated salt", "iodated salt", "iodized salt", "iron fortified salt", "Vitamin fortified salt" and so on, as appropriate.
- 7.1.5 An indication of either the origin, according to the description in paragraph 2, or the method of production may be declared on the label, provided such indication does not mislead or deceive the consumer.

7.2 List of Ingredients

If one or more food additives or nutrients are present in the product sold as such, a complete list of both the group and each single ingredient shall be declared on the label in descending order of proportion. The provisions of sub-sections 3.2(b) and 3.2(c) of the General Standard for the Labelling of Prepackaged Foods (ref. No. CODEX STAN 1-1981) shall also apply.

7.3 Net Contents

The net contents at packaging shall be declared by weight in either the metric ("Système, International" units) or avoirdupois or both systems of measurement as required by the country in which the product is sold.

7.4 Name and Address

The name and address of either the manufacturer or packer or distributor or importer or exporter or vendor of the product shall be declared.

7.5 Country of Origin

The country of origin of the product shall be declared if its omission would mislead or deceive the consumer.

7.6 Lot Identification

- 7.6.1 Each container shall be marked in code or in clear to identify the producing factory.
- 7.6.2 Prepackaged salt sold by retail shall be also given a "lot" or "batch" number.

7.7 Bulk packs (To be amended following the report of the Codex Committee on Food Labelling on Non-Retail Containers)

In the case of salt in bulk, the information required in 7.1 to 7.6.1 shall either be placed on the container or be given in accompanying documents.

8. METHODS OF ANALYSIS AND SAMPLING (Subject to endorsement by the Codex Committee on Methods of Analysis and Sampling)
- 8.1 Sampling
(to be elaborated) ^{1/}
- 8.2 Determination of Sodium chloride Content
According to method of calculation of sodium chloride content in food grade salt proposed by the Working Group on Methods of Analysis for Salt.
- 8.3 Determination of Insoluble Matter
According to ISO 2479-1972 "Determination of matter insoluble in water or in acid and preparation of principal solutions for other determinations".
- 8.4 Determination of Sulphate Content
According to ISO 2480-1972 "Determination of sulphate content. Barium sulphate gravimetric method".
- 8.5 Determination of Halogens
According to ISO 2481-1973 "Determination of halogens, expressed as chlorine. Mercurimetric method".
- 8.6 Determination of Calcium and Magnesium Contents
According to ISO 2482-1973 "Determination of calcium and magnesium contents. EDTA complexometric methods".
- 8.7 Determination of Potassium Content
According to ECSS/SC 183 "Determination of Potassium Content by Sodium Tetraphenyl-borate Volumetric Method" or alternatively according to ECSS/SC 184 "Flame atomic absorption spectrophotometric method".
- 8.8 Determination of the Loss on Drying (Conventional Moisture)
According to ISO 2483-1973 "Determination of the loss of mass at 110°C".
- 8.9 Determination of Copper Content
According to method ECSS/SC 144-1977 "Determination of copper content. Zincdibenzyl-dithiocarbamate photometric method".
- 8.10 Determination of Arsenic Content
(to be elaborated) ^{1/}
- 8.11 Determination of Mercury Content
(to be elaborated) ^{1/}
- 8.12 Determination of Lead Content
(to be elaborated) ^{1/}
- 8.13 Determination of Cadmium Content
(to be elaborated) ^{1/}

^{1/} Methods being developed by the ad hoc Working Group on Methods of Analysis and Sampling of Salt.

REPORT OF THE MEETING OF THE
WORKING GROUP ON METHODS OF ANALYSIS AND SAMPLING OF SALT

The Working Group was informed that the following methods for the determination of Arsenic, Lead, Cadmium and Mercury in Salt are being subjected to collaborative studies by 19 laboratories.

ECSS/SC 238	Determination of Arsenic Content Silver diethyldithiocarbamate photometric method
ECSS/SC 239	Determination of Mercury Content Flameless atomic absorption spectrometric method
ECSS/SC 255	Determination of Lead Content Flame atomic absorption spectrometric method
ECSS/SC 256	Determination of Cadmium Content Flame atomic absorption spectrometric method

The collaborative studies are still in progress and it is hoped that these would be completed by the end of 1982 so that the Working Group would be in a position to recommend methodology for determination of contaminants (As, Hg, Pb and Cd) in salt to the CCFA at its next session. The group agreed to propose to the plenary the following methods for the determination of potassium in food grade salt.

ECSS/SC 183	Determination of Potassium Content Sodium tetraphenylborate volumetric method
-------------	--

The Group felt that the ECSS/SC 184 Flame atomic absorption spectrophotometric method for determination of potassium in food grade salt which has been subjected to collaborative studies can be proposed as an alternate method. The Group learnt that the Codex Committee on Methods of Analysis and Sampling which is meeting end of this year is elaborating general principles on sampling, which may be adopted by the 15th session of the Commission. The Group agreed that a method of Sampling of Salt should be elaborated only after the adoption of the general principles on sampling and hence postponed working on this exercise to a later date. The Group noted that the standard for food grade salt contains limits for minimum NaCl content and proposed to the plenary a method of calculation of sodium chloride content in food grade salt. The Group agreed to develop in the future methodology for determination of food additives and processing aids in salts if such is required.

REPORT OF WORKING GROUP ON FOOD IRRADIATION

The Working Group was informed by the Secretariat that it was hoped to present the revised General Standard and Code of Practice after adoption by the CCFA to the Codex Alimentarius Commission at their session in 1983, for adoption at Step 9. It was therefore important not to change those sections which had already been adopted by the Codex Alimentarius Commission at earlier sessions except where the recommendations of the 1980 JECFI warranted modifications.

The Working Group decided to deal separately with modifications of the General Standard and the Code of Practice with Appendices I and II, because the latter required specialist knowledge of experts in radiation technology and dosimetry.

- (A) Revised Draft - Recommended (at Step 3) International General Standard for

Irradiated Foods CX/FA 82/14

- 2.1(c) The term "machine sources" was correct, being more general and required appropriate translation into French.
- 2.2 It was important not to confuse "overall average dose" with "average dose" as it appears in Appendix II of the Code of Practice. Retention of the guidelines in Appendix II of CX/FA 82/14 was considered useful but a small introductory paragraph should be added. This would explain the usefulness of the information for national authorities wishing to give clearance to these and other irradiated foods. The examples listed were fully documented regarding their wholesomeness and the "average doses" described the technological utility of the process.
- 2.3.5 At the suggestion of France the word "national" was added.
- 3.1 The Working Group accepted the suggestion of the Federal Republic of Germany and WHO to replace the paragraph by a wording more closely reflecting the 1980 JECFI opinion. Thus wholesomeness covered acceptability of toxicological safety and recognized that no special nutritional or microbiological problems were being introduced through irradiation.
- 3.3 It was considered that "relevant national public health requirements" covered the uncertainties of the USA regarding the safety of low acid, high moisture perishable foods pasteurized by irradiation.
- 4.2 To eliminate the objection that irradiation could be used to prolong the shelf life of poor quality food the word "Food" was added in the heading.
5. The section on reirradiation caused some confusion. It was pointed out that 5.3, limited irradiation to the general overall average dose of 10 KGy. Moreover low moisture foods were not very likely to be irradiated for insect disinfestation more than once because of the expense and the fact that GMP demanded maintenance of nutritional quality. Scientifically there was no ban to repeated irradiation within the limits of 5.3 some rephrasing of 5.2 was required.
6. The Working Group discussed at length the problem of labelling. The Secretariat stated that so far only prepackaged foods had been dealt with by the Codex Committee on Food Labelling. It was considered that prepackaged "First Generation Foods" might be labelled if national authorities so required, although JECFI did not consider it required on scientific grounds, labelling should be informative but not warn of non-existent danger nor be misleading. Putting "irradiated" before the name of the food would mean to the consumer, that the food was endowed with some special property or danger. Yet irradiation merely added a property useful to the food industry e.g. non-sprouting, better shelf life but not to the consumer except where salmonella was removed from e.g. chicken. If anything it should not be a mandatory requirement of a standard but a recommendation to leave it to the discretion of the national authority. Bulk foods required labeling on the shipping documents and not on the containers nor the consumer package as it would be confusing and misleading. "Second Generation Foods" should not be labelled as this mislead consumers because not all "Second Generation. Foods" derived

from irradiated material. It would be wrong to have the label as a warning because there was no health hazard and it would assign more importance to irradiation compared to chemical or other processes. The Working Group suggested to make 6,3 into 6.1, 6.1 into 6.2 and 6.2 into 6.3 and to modify the text to fit the above proposals.

The Working Group then discussed comments and amendments referring to the Code of Practice and its annexes. Most of the suggested amendments were already covered by statements in the General Standard. The following amendments were made:

- | | |
|---------------|--|
| 1.2.3 and 4.3 | Change "plant" to "facility" |
| 2.1 | Change "conveyor speed" to "transportation speed of the product" |
| 2.1.1 | Change "source strength" to "source activity" |
| 2.1.2 | Delete the parenthesis and the rest of the sentence after "Average beam- power" and replace by "shall be adequately recorded". |
| 2.2 | Change "conveyor" to "transportation". |
| 3. | Delete the whole first paragraph as it does not constitute elements of a Code of Practice. |

Appendix I

Para 1. Delete the rest of the sentence after "volume fractions" in the explanation of dV.

Para 2. Place the first sentence of the second paragraph at the end and change "shall" to "should" and 95% to 97.5%.

Para 4. Replace "conveyor" by "transport". Add "and placement" in the second paragraph after "product movements".

With these amendments a new version of CX/FA 82/14 was prepared.

APPENDIX VI

REVISED DRAFT RECOMMENDED INTERNATIONAL GENERAL STANDARD FOR IRRADIATED FOODS (at Step 5 of the Codex Procedure)

1. SCOPE

This standard applies to foods processed by irradiation. It does not apply to foods exposed to doses imparted by measuring instruments used for inspection purposes.

2. GENERAL REQUIREMENTS FOR THE PROCESS

2.1. Radiation Sources

The following types of ionizing radiation may be used:

- (a) Gamma rays from the radionuclides ^{60}Co or ^{137}Cs ;
- (b) X-rays generated from machine sources operated at or below an energy level of 5 MeV.
- (c) Electrons generated from machine sources operated at or below an energy level of 10 MeV.

2.2. Absorbed Dose

The overall average dose absorbed by a food subjected to radiation processing should not exceed 10 kGy*.

* For measurement and calculation of overall average dose absorbed see Annex I of Revised Draft Recommended International Code of Practice for the Operation of Radiation Facilities used for Treatment of Foods (see Annex I).

2.3. Facilities and Control of the Process

- 2.3.1. Radiation treatment of foods shall be carried out in facilities licensed and registered for this purpose by the competent national authority.
- 2.3.2. The facilities shall be designed to meet the requirements of safety, efficacy and good hygienic practices of food processing.
- 2.3.3. The facilities shall be staffed by adequate, trained and competent personnel.
- 2.3.4. Control of the process within the facility shall include the keeping of adequate records including quantitative dosimetry.
- 2.3.5. Premises and records shall be open to inspection by appropriate national authorities.
- 2.3.6. Control should be carried out in accordance with the Recommended International Code of Practice for the Operation of Radiation Facilities used for the Treatment of Foods.

3. WHOLESOMENESS OF IRRADIATED FOODS

- 3.1. The wholesomeness of foods irradiated so as to have absorbed an overall average dose of up to 10 kGy is not impaired. In this context the term wholesomeness refers to safety for consumption of irradiated foods from the toxicological point of view. The irradiation of foods up to an overall average dose of 10kgy introduces no special nutritional or microbiological problems.
- 3.2. The food should comply with the provisions of the General Principles of Food Hygiene and, where appropriate, with the Code of Hygienic Practice relative to a particular food.
- 3.3. Any relevant national public health requirement affecting microbiological safety and nutritional adequacy applicable in the country in which the food is sold should be observed.

4. TECHNOLOGICAL REQUIREMENTS

4.1. Conditions for Irradiation

The irradiation of food is justified only when it fulfils a technological need or where it serves a food hygiene purpose* and should not be used as a substitute for good manufacturing practices.

* The utility of the irradiation process has been demonstrated for a number of food items listed in Annex II to the Revised Draft Recommended International Code of Practice for the Operation of Radiation Facilities used for the Treatment of Foods (CX/FA 82/14).

4.2. Packaging and Food Quality Requirements

Foods to be irradiated and their packaging materials shall be of suitable quality, acceptable hygienic condition and appropriate for this purpose and shall be handled, before and after irradiation, according to good manufacturing practices taking into account the particular requirements of the technology of the process. The doses applied should be commensurate with the technological and public

health purposes to be achieved and should be in accordance with good radiation processing practice.

5. RE-IRRADIATION

- 5.1. Except for foods with low moisture content (cereals, pulses, dehydrated foods and other such commodities) irradiated for the purpose of controlling insect reinfestation, foods irradiated in accordance with sections 2 and 4 of this standard shall not be re-irradiated.
- 5.2. For the purpose of this standard food is not considered as having been re-irradiated when: (a) the food prepared from materials which have been irradiated at low dose levels e.g. about 1 kGy, is irradiated for another technological purpose; (b) the food, containing less than 5% of irradiated ingredient, is irradiated, or when (c) the full dose of ionizing radiation required to achieve the desired effect is applied to the food in more than one instalment as part of one process.
- 5.3. The total overall average dose absorbed should not exceed 10 kGy as a result of re-irradiation.

6. LABELLING

6.1. Inventory control

For irradiated foods, whether prepackaged or not, the relevant shipping documents shall give appropriate information to identify the registered facility which has irradiated the food, the date of treatment and lot identification.

6.2. Prepackaged foods intended for direct consumption

The labelling of irradiated foods shall be in accordance with the provisions of the Codex Standard relating to labelling of prepackaged foods.

6.3. Foods in bulk containers

The declaration of the fact of irradiation shall be made clear on the relevant shipping documents.

REVISED DRAFT

RECOMMENDED INTERNATIONAL CODE OF PRACTICE FOR THE
OPERATION OF IRRADIATION FACILITIES USED FOR THE TREATMENT
OF FOODS

1. INTRODUCTION

This code refers to the operation of irradiation facilities based on the use of either a radionuclide source (Co or Cs) or X-rays and electrons generated from machine sources. The irradiation facility may be of two designs, either "continuous" or "batch" type. Control of the food irradiation process in all types of facility involves the use of accepted methods of measuring the absorbed radiation dose and of the monitoring of the physical parameters of the process. The operation of these facilities for the irradiation of food must comply with the Codex recommendations on food hygiene.

2. IRRADIATION PLANTS

2.1. Parameters

For all types of facility the doses absorbed by the product depend on the radiation parameter, the dwell time or the transportation speed of the product, and the bulk density of the material to be irradiated. Source-product geometry, especially distance of the product from the source and measures to increase the efficiency of radiation utilization, will influence the absorbed dose and the homogeneity of dose distribution.

2.1.1. Radionuclide sources

Radionuclides used for food irradiation emit photons of characteristic energies. The statement of the source material completely determines the penetration of the emitted radiation. The source activity is measured in Becquerel (Bq) and should be stated by the supplying organisation. The actual activity of the source (as well as any return or replenishment of radionuclide material) shall be recorded. The recorded activity should take into account the natural decay rate of the source and should be accompanied by a record of the date of measurement or recalculation. Radionuclide irradiators will usually have a well separated and shielded depository for the source elements and a treatment area which can be entered when the source is in the safe position. There should be a positive indication of the correct operational and of the correct safe position of the source which should be interlocked with *the product movement* system.

2.1.2. Machine sources

A beam of electrons generated by a suitable accelerator, or after being converted to X-rays, can be used. The penetration of the radiation is governed by the energy of the electrons. Average beam power shall be adequately recorded. There should be a positive indication of the correct setting of all machine parameters which should be interlocked with the product movement system. Usually a beam scanner or a scattering device (e.g. the converting target) is incorporated in a machine source to obtain an even distribution of the radiation over the surface of the product. The product movement, the width and speed of the scan and the beam pulse frequency (if applicable) should be adjusted to ensure a uniform surface dose.

2.2. Dosimetry and Process Control

Prior to the irradiation of any foodstuff certain dosimetry measurements* should be made, which demonstrate that the process will satisfy the regulatory requirements. Various techniques for dosimetry pertinent to radionuclide and machine sources are available for measuring absorbed dose in a quantitative manner **.

Dosimetry commissioning measurements should be made for each new food, irradiation process and whenever modifications are made to source strength or type and to the source product geometry.

Routine dosimetry should be made during operation and records kept of such measurement. In addition, regular measurements of facility parameters governing the process, such as transportation speed, dwell time, source exposure time, machine beam parameters, can be made during the facility operation. The records of these measurements can be used as supporting evidence that the process satisfies the regulatory requirements,

- * see Annex I
- ** detailed in the Manual of Food Irradiation Dosimetry, IAEA, Vienna, 1977, Technical Report Series No. 173.

3. GOOD RADIATION PROCESSING PRACTICE

Facility design should attempt to optimize the dose uniformity ratio, to ensure appropriate dose rates and, where necessary, to permit temperature control during irradiation (e.g. for the treatment of frozen food) and also control of the atmosphere. It is also often necessary to minimize mechanical damage to the product during transportation, irradiation and storage, and desirable to ensure the maximum efficiency in the use of the irradiator. Where the food to be irradiated is subject to special standards for hygiene or temperature control, the facility must permit compliance with these standards.

4. PRODUCT AND INVENTORY CONTROL

- 4.1. The incoming product should be physically separated from the outgoing irradiated products.
- 4.2. Where appropriate, a visual colour change radiation indicator should be affixed to each product pack for ready identification of irradiated and non-irradiated products.
- 4.3. Records should be kept in the facility record book which show the nature and kind of the product being treated, its identifying marks if packed or, if not, the shipping details, its bulk density, the type of source or electron machine, the dosimetry, the dosimeters used and details of their calibration, and the date of treatment.
- 4.4. All products shall be handled, before and after irradiation, according to accepted good manufacturing practices taking into account the particular requirements of the technology of the process*. Suitable facilities for refrigerated storage may be required.

* see Annex II

ANNEX 1

DOSIMETRY

1. The overall average absorbed dose

It can be assumed for the purpose of the determination of the wholesomeness of food treated with an overall average dose of 10 kGy or less, that all radiation chemical effects in that particular dose range are proportional to dose.

The overall average dose, \bar{D} , is defined by the following integral over the total volume of the goods

$$\bar{D} = \frac{1}{M} \int \rho(x, y, z) \cdot d(x, y, z) \cdot dv$$

- where M the total mass of the treated sample
- ρ the local density at the point (x, y, a)
- d the local absorbed dose at the point (x, y, z)
- dv = dx dy dz the infinitesimal volume element which in real cases is represented by the volume fractions

The overall average absorbed dose can be determined directly for homogeneous products or for bulk goods of homogeneous bulk density by distributing an adequate number of dose meters strategically and at random throughout the volume of the goods. From the dose distribution determined in this manner an average can be calculated which is the overall average absorbed dose.

If the shape of the dose distribution curve through the product is well determined the positions of minimum and maximum dose are known. Measurements of the distribution of dose in these two positions in a series of samples of the product can be used to give an estimate of the overall average dose. In some cases the mean value of the average values of the minimum (D_{min}) and maximum (D_{max}) dose will be a good estimate of the overall average dose.

i.e. in these cases

$$\text{overall average dose} \approx \frac{\bar{D}_{max} + \bar{D}_{min}}{2}$$

2. Effective and limiting dose values

Some effective treatment e.g. the elimination of harmful micro-organisms, or a particular shelflife extension, or a disinfection requires a minimum absorbed dose. For other applications too high an absorbed dose may cause undesirable effects or an impairment of the quality of the product.

The design of the facility and the operational parameters have to take into account minimum and maximum dose values required by the process. In some low dose applications it will be possible within the terms of section 3 on Good Radiation Processing Practice to allow a ratio of maximum to minimum dose of greater than 3.

With regard to the maximum dose value under acceptable wholesomeness considerations and because of the statistical distribution of the dose a mass fraction of product of at least 97.5% should receive an absorbed dose of less than 15 KGy.

3. Routine Dosimetry

Measurements of the dose in a reference position can be made occasionally throughout the process. The association between the dose in the reference position and the overall average dose must be known. These measurements should be used to ensure the correct operation of the process. A recognized and calibrated system of dosimetry should be used.

A complete record of all dosimetry measurements including calibration must be kept.

4. Process Control

In the case of a continuous radionuclide facility it will be possible to make automatically a record of transportation speed or dwell time together with indications of source and product positioning. These measurements can be used to provide a continuous control of the process in support of routine dosimetry measurements.

In a batch operated radionuclide facility automatic recording of source exposure time and a record of product movement and placement can be made to provide a control of the process in support of routine dosimetry measurements.

In a machine facility a continuous record of beam parameters (voltage, current,

scan speed, scan width, pulse repetition) and a record of transportation speed through the beam can be used to provide a continuous control of the process in support of routine dosimetry measurements.

ANNEX 2

EXAMPLES OF TECHNOLOGICAL CONDITIONS FOR THE IRRADIATION OF SOME INDIVIDUAL FOOD ITEMS SPECIFICALLY EXAMINED BY THE JOINT FAO/IAEA/WHO EXPERT COMMITTEE

This information is taken from the Report of the Joint FAO/IAEA/WHO Expert Committee on Food Irradiation (WHO Technical Report Series, 659, 1981) and illustrates the utility of the irradiation process. It also describes the technological conditions for achieving the purpose of the irradiation process safely and economically.

1. CHICKEN (Gallus domesticus)

1.1 Purposes of the Process

The purposes of irradiating chicken are:

- (a) to prolong storage life
and/or
- (b) to reduce the number of certain pathogenic microorganisms, such as Salmonella from eviscerated chicken.

1.2 Specific Requirements

Average dose: for (a) and (b), up to 7 kGy

2. COCOA BEANS (Theobroma cacao)

2.1 Purposes of the Process

The purposes of irradiating cocoa beans are:

- (a) to control insect infestation in storage
- (b) to reduce microbial load of fermented beans with or without heat treatment.

2.2 Specific Requirements

2.2.1 Average dose: for (a) up to 1 kGy
for (b) up to 5 kGy

2.2.2 Prevention of Reinfestation: Cocoa beans whether prepackaged or handled in bulk, should be stored as far as possible, under such conditions as will prevent reinfestation and microbial recontamination and spoilage.

3. DATES (Phoenix dactylifera)

3.1 Purpose of the Process

The purpose of irradiating prepackaged dried dates is to control insect infestation during storage.

3.2 Specific Requirements

3.2.1 Average dose: up to 1 kGy

3.2.2 Prevention of Reinfestation: Prepackaged dried dates should be stored under

such conditions as will prevent reinfestation.

4. MANGOES (Mangifera indica)

4.1 Purposes of the Process

The purposes of irradiating mangoes are:

- (a) to control insect infestation
- (b) to improve keeping quality by delaying ripening
- (c) to reduce microbial load by combining irradiation and heat treatment.

4.2 Specific Requirement

Average dose: up to 1 kGy

5. ONIONS (Allium cepa)

5.1 Purpose of the Process

The purpose of irradiating onions is to inhibit sprouting during storage.

5.2 Specific Requirement

Average dose: up to 0.15 kGy

6. PAPAYA (Carica papaya L.)

6.1 Purpose of the Process

The purpose of irradiating papaya is to control insect infestation and to improve its keeping quality by delaying ripening.

6.2 Specific Requirements

6.2.1 Average dose: up to 1 kGy

6.2.2 Source of Radiation: The source of radiation should be such as will provide adequate penetration.

7. POTATOES (Solanum tuberosum L.)

7.1 Purpose of the Process

The purpose of irradiating potatoes is to inhibit sprouting during storage.

7.2 Specific Requirement

Average dose: up to 0.15 kGy

8. PULSES

8.1 Purpose of the Process

The purpose of irradiating pulses is to control insect infestation in storage.

8.2 Specific Requirement Average dose: up to 1 kGy

9. RICE (Oryza species)

9.1 Purpose of the Process

The purpose of irradiating rice is to control insect infestation in storage.

9.2 Specific Requirements

9.2.1 Average dose: up to 1 kGy

9.2.2 Prevention of Reinfestation: Rice, whether pre-packaged or handled in bulk, should be stored as far as possible, under such conditions as will prevent reinfestation.

10. SPICES AND CONDIMENTS, DEHYDRATED ONIONS, ONION POWDER

10.1 Purposes of the Process

The purposes of irradiating spices, condiments, dehydrated onions and onion powder are:

- (a) to control insect infestation
- (b) to reduce microbial load
- (c) to reduce the number of pathogenic microorganisms.

10.2 Specific Requirement

Average dose: for (a) up to 1 kGy
for (b) and (c) up to 10 kGy.

11. STRAWBERRY (Fragaria species)

11.1 Purpose of the Process

The purpose of irradiating fresh strawberries is to prolong the storage life by partial elimination of spoilage organisms.

11.2 Specific Requirement

Average dose: up to 3 kGy

12. TELEOST FISH AND FISH PRODUCTS

12.1 Purposes of the Process

The purposes of irradiating teleost fish and fish products are:

- (a) to control insect infestation of dried fish during storage and marketing
- (b) to reduce microbial load of the packaged or unpackaged fish and fish products
- (c) to reduce the number of certain pathogenic microorganisms in packaged or unpackaged fish and fish products.

12.2 Specific Requirements

12.2.1 Average dose: for (a) up to 1 kGy
for (b) and (c) up to 2.2 kGy

12.2.2 Temperature Requirement: During irradiation and storage the fish and fish products referred to in (b) and (c) should be kept at the temperature of melting ice.

13. WHEAT AND GROUND WHEAT PRODUCTS (Triticum species)

13.1 Purpose of the Process

The purpose of irradiating wheat and ground wheat products is to control insect infestation in the stored product.

13.2 Specific Requirements

13.2.1 Average dose: up to 1 kGy

13.2.2 Prevention of Reinfestation: These products, whether pre- packaged or handled in bulk, should be stored as far as possible under such conditions as will prevent reinfestation.

APPENDIX VII

GUIDELINES FOR FOOD ADDITIVE INTAKE STUDIES

I. Introduction

The examination by JECFA of toxicological studies, the determination of ADI s and the proposition for identity and purity criteria constitute the first step in the authorization of use of a food additive. This sequence of steps is followed by the Working Group discussion in the framework of the Codex Committee on Food Additives on the propositions of use made by the Commodity Committees. The endorsement of a proposal of use in a foodstuff will be done in accordance with the General Principles for the use of Food Additives (Procedural Manual of the Codex Alimentarius Commission, 4th ed. p. 7). At point 6 of those General Principles, the following is stated:

- "c) as far as possible take into account any Acceptable Daily Intake, or equivalent assessment, established for the food additive and the probable daily intake of it from all sources. Where the food additive is to be used in foods eaten by special groups of consumers, account should be taken of the probable daily intake of the food additive by consumers in these groups."

To give the Committee all the criteria needed to make a decision regarding endorsements, the daily intake figures for additives remains necessary information.

II. Definitions

Acceptable Daily Intake; ADI

The acceptable daily intake for man, expressed on a bodyweight basis, is the amount of a food additive that can be taken daily in the diet over a lifetime without appreciable risk to the health of the consumer. (17th Report of the Joint FAO/WHO Expert Committee on Food Additives, 1973)

Per Capita Daily Intake (PCDI)

The per capita daily intake of a food additive is the amount of the additive which would be ingested by the average person if the additive were used at authorized levels foreseen by:

- a) Codex Standards
- b) Maximum levels authorized for the foodstuffs not covered by a Codex Standard
- c) The mean values of the amount used by the industry according to G M P (estimation of the intake of food additives - computerized study of the potential daily intake 1969-1970 FAD/FA 70/30 (a) Appendix II modified).

For the purpose of the Committee the PCDI will be expressed in mg/kg bw/day. It has to be remembered that the ratio PCDI: ADI should not be taken as a measure of the actual exposure of people to chemicals used in food but only as a relative indication - very likely an overestimate -of such exposure. In fact, the "per capita daily intake" is a

hypothetical figure based upon the extreme theoretical case that:

- a) all foods in which an additive is permitted actually do contain that additive
- b) the additive is always present at the maximum permitted level
- c) the foods in question containing the additive are consumed by people each day of their lives
- d) some additives do not undergo a decrease in their level in food on cooking, etc.

When the ADI is exceeded, before a decision is made, the CCFA should ask for data which approximates the actual intake (potential daily intake).

Potential Daily Intake (PDI)

The potential daily intake of a food additive is the amount of an additive which would be ingested by the average consumer (eaters only) based on the actual use of the additives by the industry, according to G M P , or an approximation as close to the actual use level as possible.

III Proposed Approach

For a complete view of how authorized additives, in the framework of the Codex Standards, are ingested on a worldwide basis the CCFA must obtain from as many countries as possible data on the ingestion of foodstuffs. This information can be used to further guide authorizations of use.

The methodologies already described as in use by various countries should allow a given Government the possibility to choose the most suitable for its own purpose. It should also be possible to obtain complementary information from the members of the Working Group on Intake of Food Additives which might help in developing survey methods suited to the needs of individual countries.

It must be remembered that, to reach the goal of accurate intake measurements, it is not necessary to obtain exact ingestion figures of foodstuffs but to come as close as possible to the actual intake figures considering financial resources and the availability of well-trained people.

Values on additive intake obtained from many countries should give the ad hoc Working Group on Food Additive Intake the information required to prepare for the Codex Committee on Food Additives a paper which could help in the endorsement procedure. Each country will therefore have to choose the method which is best adapted to its problems and means. However, whatever method is used, the values presented to the ad hoc Working Group would have to follow a standardized scheme to facilitate their compilation and comparison. It is perceived that the consideration of availability of data has been and will be the primary determinant for the approach finally used by the CCFA to calculate additive intake. In view of this consideration, it is recommended that CCFA obtain data from national governments on the disappearance of food commodities by category or type, into the human food supply. Food Disappearance is equal to the production plus the amount imported minus the amount exported. When the calculation indicates that the intake exceeds the ADI using this technique, further inquiries into possible intake levels are required.

An intermediate method would be the development of probability factors on a national or regional basis because this type of information may be readily obtained by panels of experts. These probability factors could be used to convert the food disappearance data into potential additive intakes. The computation of additive intakes obtained by

multiplication of upper limit values for food intake by permitted maximum levels for additives in food sometimes lead to overestimations relative to the per capita approach. Therefore, it is strongly recommended that the governments develop the information required to calculate the potential daily intake, which means the intake of additives or groups of additives for a lifetime of food consumption by a representative consumer. Practically, these additive intakes should be derived from dietary surveys of actual intake of food products. Additive intakes should consider total intake of food over the lifetime of a typical consumer and typical concentrations of additives used in food products.

IV Recommended methods

The following data should be included:

1. Description of the working method used.
2. Classification of the foodstuffs which have been used (see note 1).
3. Intake of the additive according to the following table.

Foodstuff			Additive		
Kind of Foodstuff	Ingestion g/day		Authorisation ppm	Ingestion mg/day (see note 2)	
	per capita daily intake	potential daily intake		per capita daily intake	potential daily intake

Notes

1. In order to properly use the intake figures presented by a number of countries, and to be able to compare them, classification of foodstuffs is required. This classification need not necessarily be a complete one, but it should, however, be sufficiently open to allow the possibility that foods common to particular countries and certain areas may be included. The Working Group will submit at a later date a proposed classification scheme based on lists already in existence in the U.K., U.S.A., E.E.C. and WHO.
2. When an ADI has been given for a group of additives (acid and salts, cellulose derivatives) it would be easier, when possible, to indicate the mean value of ingestion for the group of additives having received an ADI together.

APPENDIX VIII - Part I

ENDORSEMENT OF MAXIMUM LEVELS FOR FOOD ADDITIVES IN CODEX COMMODITY STANDARDS

This Appendix summarizes all provisions which were considered by the Codex Committee on Food Additives at its 14th Session.

Abbreviations used

E	=	Endorsed
TE	=	Temporarily Endorsed
EP	=	Endorsement Postponed for reasons given in the footnotes
Limited by GMP	=	Limited by Good Manufacturing Practice
NE	=	Not Endorsed

Contents

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II Cocoa Products and Chocolate
III Fats and Oils

14th
11th

ALINORM 81/10
ALINORM 81/17

I. FRUIT JUICES

Draft Standard for Mango Juice Preserved Exclusively by Physical Means (ALINORM 81/14, Appendix II)

<u>FOOD ADDITIVE</u>	<u>Maximum Level in the final product</u>	<u>Paragraph</u>
<u>Acidifying Agents</u>		
Citric acid	Limited by GMP	85
Malic acid		
Fumaric acid		
<u>Natural colour</u>		
Beta Carotene	Limited by GMP	86

^{1/} The Commodity Committee is reconsidering its views for the additive provision.

II. COCOA PRODUCTS AND CHOCOLATE

Draft Standard for Composite and Filled Chocolate (ALINORM 81/10, Appendix II)

For Composite Chocolate and Coating of Filled Chocolate:

<u>FOOD ADDITIVE</u>	<u>Maximum Level in the final product</u>	<u>Paragraph</u>
(a) Mono- and diglycerides of edible fatty acids	15 g/kg	87
Lecithin	5 g/kg of the acetone insoluble component of the lecithin	
Ammonium salts of phosphatidic acids	7 g/kg	88
Polyglycerol polyricinoleate	5 g/kg	89
Sorbitan monostearate	10 g/kg	
Sorbitan tristearate	10 g/kg	90
Polyoxyethylene (20) sorbitan monostearate	10 g/kg	
Total emulsifiers	15 g/kg singly or in combination	
Natural flavours as defined in the Codex Alimentarius, and their synthetic equivalents, except those which would imitate natural chocolate or milk flavours	in small quantities to balance flavour	91
Vanillin		
Ethyl vanillin		
(b) Alkalizing and neutralizing agents carried over in proportion to the maximum quantity as provided for in the Standard for Cocoa (Cacao) Beans, Cocoa (Cacao) Nib, Cocoa (Cacao) Mass, Cocoa Press Cake and Cocoa Dust (Cocoa Fines)		
(c) The centre in the filled chocolate will contain additives to the extent permitted in the ingredients which constitute the centre		

^{2/} Awaiting information of the Commodity Committee on its technological need and maximum level in the final product.

III. FATS AND OILS

A. Draft Standard for [Fat Spreads] Spreadable Table Fats
(ALINORM 81/17, Appendix V)

<u>FOOD ADDITIVE</u>	<u>Maximum Level in the final product</u>	<u>Paragraph</u>
<u>Colours</u>		
Beta-carotene	25 mg/kg	
Annatto extracts	20 mg/kg (calculated as total bixin or norbixin)	92
Turmeric or curcumin	5 mg/kg (calculated as total curcumin)	93
<u>Flavours</u>		
Natural flavours and flavouring substances and nature-identical flavouring substances as defined for the purpose of the Codex Alimentarius (see Codex Guide to the Safe Use of Food Additives, (CAC/FAL 5-1979))	Limited by GMP	
Artificial flavouring substances as defined for the purpose of the Codex Alimentarius and included in List A (see Codex Guide to the Safe Use of Food Additives, (CAC/FAL 5-1979))		
<u>Emulsifiers</u>		
<u>Lecithins</u>		
Mono- and diglycerides of fatty acids	Limited by GMP Limited by GMP	94
Polyglycerol esters of fatty acids	10 g/kg individually or in combination	95
Polyglycerol esters of interesterified ricinoleic acid		96
Esters of fatty acids with polyalcohols other than glycerol: Sorbitan monopalmitate Sorbitan monostearate Sorbitan tristearate		97
^{1/} Polyoxyethylene (20) sorbitan monolaurate	10 g/kg individually or in combination	98
Polyoxyethylene (20) sorbitan monopalmitate		
Polyoxyethylene (20) sorbitan monostearate		
Polyoxyethylene (20) sorbitan tristearate		
Polyoxyethylene (20) sorbitan monooleate		
<u>Thickening agents</u>		
Pectin, amidated pectin		99, 100
Agar-agar		101
Carrageenan		102
Guar gum		101

Requesting the Commodity Committee to reconsider the maximum level in view of its low ADI.

Locust bean gum		103
Tragacanth gum		104
Xanthan gum		105
Methyl cellulose		106
Carboxymethyl cellulose and its sodium salts		106
Sodium, potassium, calcium and ammonium alginates		107
Propylene glycol algi alginate		107
<u>Preservatives</u>		
Sorbic acids and its sodium, potassium and calcium salts	2000 mg/kg	107
^{1/} EP, requesting the Commodity Committee to reconsider the maximum level in view of its low ADI.		
^{2/} EP, since there is no ADI given by JECFA for this additive.		
Benzoic acid and its sodium and potassium salts	1000 mg/kg	107
If used in combination, the combined use shall not exceed 2000 mg/kg of which the benzoic acid portion shall not exceed 1000 mg/kg		
<u>Antioxidants</u>		
Propyl, octyl, and odecyl gallates	100 mg/kg of the fat content individually or in combination	108
Butylated hydroxytoluene (BHT)		109
Butylated hydroxyanisole (BHA)		109
Ascorbyl palmitate/stearate	500 mg/kg of the fat content	109
L-ascorbic acid	300 mg/kg of the fat content	110
Natural and synthetic tocopherols	Limited by GMP	110
<u>Antioxidant Synergist</u>		
Calcium disodium salt of EDTA	100 mg/kg	111
<u>pH Correcting Agents</u>		
Lactic acid and their calcium, potassium and sodium salts	Limited by GMP	
Citric acid		
Sodium hydrogen carbonate	Limited by GMP	112
Sodium carbonate		113
Sodium hydroxide		113
Sodium monophosphates (orthophosphates)		113
^{1/} EP, requesting the Commodity Committee more information on its technological function.		

B. Draft Standard for Minarine (ALINORM 81/27, Appendix III)

<u>FOOD ADDITIVE</u>	<u>Maximum Level in the final product</u>	<u>Paragraph</u>
<u>Thickening Agents</u>		
Pectin, amidated pectin	10 g/kg individually or in combination	114
Agar-agar		
Carrageenan		
Guar gum		
Locust bean gum		

Tragacanth gum
 Xanthan gum
 Methyl cellulose
 Carboxymethyl cellulose and its sodium salts
 Sodium, potassium, calcium and ammonium alginates
 Propylene glycol alginate

^{1/}

EP requesting the Commodity Committee to reconsider the maximum level in view of its low ADI.

^{2/}

EP since there is no ADI given by JECFA for the additive.

APPENDIX VIII-Part II

Endorsement of Maximum Levels for Contaminants in
 Codex Commodity Standards

<u>Committee</u>	<u>Session</u>	<u>Docu</u>
Processed Fruits & Vegetables	15th	ALINOR
Fruit Juices	14th	ALINOR
Fats and Oils	11th	ALINOR
Cocoa Products and Chocolate	14th	ALINOR

I. PROCESSED FRUITS AND VEGETABLES

A. DRAFT STANDARD FOR CANNED PALMITO (ALINORM 81/20, Appendix VI)

<u>Contaminant</u>	<u>Maximum Level</u>	<u>Paragraph</u>	<u>Sta</u> <u>Enc</u>
Tin	250 me/kg calculated as tin	116	

B. DRAFT STANDARD FOR MANGO CHUTNEY (ALINORM 81/20, Appendix VIII)

<u>Contaminant</u>	<u>Maximum Level</u>	<u>Paragraph</u>	<u>Sta</u> <u>Enc</u>
Arsenic	0.5 mg/kg		
Lead	2.0 mg/kg		
Copper	5.0 mg/kg	117	
Zinc	5.0 mg/kg		
Tin	250 mg/kg		

II. FRUIT JUICES

DRAFT STANDARD FOR MANGO JUICE PRESERVED EXCLUSIVELY BY
 PHYSICAL MEANS (ALINORM 81/14, Appendix II)

<u>Contaminant</u>	<u>Maximum Level</u>	<u>Paragraph</u>	<u>Sta</u> <u>Enc</u>
Arsenic	0.2 mg/kg		
Lead	0.3 mg/kg		
Copper	5.0 mg/kg		
Zinc	5.0 mg/kg		
Iron	15.0 mg/kg	118, 119	
Tin	250 mg/kg		
Sum of Copper, Zinc and Iron	20 mg/kg		
Sulphur dioxide	10 mg/kg		

^{1/} Endorsement postponed in view of the high level.

III. COCOA PRODUCTS AND CHOCOLATE

A. DRAFT STANDARD FOR [COMPOSITE COCOA BUTTER] [COCOA BUTTER CONFECTIONERY] (ALINORM 81/10, Appendix III)

<u>Contaminant</u>	<u>Maximum Level</u>	<u>Paragraph</u>
Arsenic	0.5 mg/kg	120, 121
Copper	15 mg/kg	
Lead	1 mg/kg	

B. DRAFT STANDARD FOR COMPOSITE AND FILLED CHOCOLATE (ALINORM 81/10, Appendix II)

<u>Contaminant</u>	<u>Maximum Level</u>	<u>Paragraph</u>
Arsenic	1 mg/kg	122, 123
Copper	20 mg/kg	
Lead	1 mg/kg	

IV. FATS AND OILS

DRAFT STANDARD FOR [FAT SPREADS/SPREADABLE TABLE FATS] (ALINORM 81/17, Appendix V)

<u>Contaminant</u>	<u>Maximum Level</u>	<u>Paragraph</u>
Iron	1.5 mg/kg	124
Copper	0.1 mg/kg	
Lead	0.1 mg/kg	
Arsenic	0.1 mg/kg	

^{1/} The level is considered high. Commodity Committee asked for more information on the source of lead and copper.

REPORT OF THE AD HOC WORKING GROUP ON PROCESSING AIDS

1. The meeting began with a general discussion by the Chairman. He emphasized that the task of the Working Group is to develop an inventory of processing aids. What use it is to be put to is still to be determined. He noted that in reviewing the comments received from governments it was evident that very few provided the complete data requested in CL 1981/9. Also, several mentioned that many processing aids are trade secrets and as such there is reluctance to submit them without assurance that secrecy can be maintained.
2. The committee then considered recommended additions to the inventory of processing aids. They decided that foods such as vegetable oil or margarine should not be included on the list since these are excluded in the Commissions definition of processing aids (ALINORM 81/12, Appendix VI). Also, for others sufficient data was not provided. These will be returned to the submitters asking for the missing data.
3. The Working Group recommends that the Secretariat update the Inventory of processing aids by including those additions submitted which met the stated criteria. A careful review of the criteria will be needed. Further, the Secretariat was asked to use the format submitted by France when this is done. For a number of other compounds it was not clear whether they met the definition for processing aids, therefore, the list must be reviewed at a later date to eliminate those which are not processing aids.
4. The Chairman noted and the Working Group agreed that this is an open inventory and therefore, new compounds can be submitted at any time as can new uses for existing compounds as well as other information now missing.
5. There was a great deal of discussion concerning the lack of information which has been provided on various compounds, particularly levels of use, end use in foods, residues, and analytical methodology. Also the class names need further definition since in several cases these are not clear. The Chairman noted that what is being prepared is simply an inventory whose purpose has not been defined. Only after its purpose has been defined can class names be more accurately specified.
6. There was then a discussion on possible uses of the inventory. One possibility is use as an advisory inventory for Codex Commodity Committees of which processing aids are being used. JECFA could then be asked to evaluate those substances which may present health concerns because of possible substantial residues. Commodity standards could include a section on residues of processing aids, judged to present a health risk, as they now do for food additives and contaminants.
7. The suggestion was made that any processing aid not included in a Codex Commodity Standard be dropped from the inventory. Then the remaining items could be prioritized based on data supplied by governments concerning residues. The Codex Committee on Food Additives could evaluate those and ask JECFA to review those of interest. The Secretariat noted that it is not necessary to limit compounds on the inventory to those included in Codex Standards. The

inventory could include all processing aids. Information on these could be of interest to various governments. This is a new direction which would require clarification from the CCFA.

8. The Working Group concluded that it should continue to develop the inventory. Future meetings should consider what eventual use is to be made of this inventory. Governments will be asked for comments on this key point as well as the other questions raised in this report.

APPENDIX X

REPORT OF THE WORKING GROUP ON SPECIFICATIONS

Consideration of Specifications for the Identity and Purity of Food Additives in the Light of Comments received (ALINORM 81/12, Appendix VII; CL 1981/3, Part B (4) and CL 1981/16)

Introduction

1. Two problems were raised by the Codex Committee on Food Additives at its Fourteenth Session (ALINORM 81/12, Appendix VII). These related to

i) the status of Codex Specifications

and ii) the Procedure for the Elaboration of Codex Specifications.

Both problems have subsequently been discussed by the Codex Committee on General Principles at its Seventh Session (ALINORM 81/33) and by the Codex Commission at its Fourteenth Session (ALINORM 81/39).

Status of Codex Specifications

2. The Codex Committee on General Principles "after consideration of the basis; upon which the work of the Commission, the Codex Committee on Food Additives and JECFA- namely as a matter of priority the safety-in-use of food additives- rested, was of the opinion that whilst there was no intention to replace the technical specifications developed by the manufacturers of food additives, there was clearly an obligation, in accordance with the conditions prescribed in the toxicological evaluation of an additive not to use food additives mentioned in Codex Standards unless they met the minimum safety requirements laid down in the JECFA or Codex Specifications". The Codex Committee on General Principles agreed to seek confirmation from JECFA, and the Codex Committee on Food Additives of the above opinion. The Committee also requested the Codex Committee on Food Additives to confirm that "these Codex Specifications were advisory texts intended to assist governments and food manufacturers".

3. The Commission agreed with the conclusion of the Codex Committee on General Principles and "reaffirmed that the specifications per se were advisory and not subject to government acceptance. The Commission agreed to consider the subject of the role of the specifications in relation to food additive provisions in Codex Standards at its next Session when guidance from JECFA and CCFA would be available".

4. The Working Group on specifications offers the following guidance on the status and role of Codex Specifications.

There is an obligation that food additives should at all times be of a quality grade which is safe for the intended use (i.e. food grade quality). In evaluating food additives JECFA establishes specifications to describe food grade quality. The Working Group affirms the principle that 1) food manufacturers who use food additives in foods intended to meet

Codex Standards, 2) food additive manufacturers who produce food additives for the purpose of adding them to foods conforming to Codex Standards and 3) governments officials who enforce Codex Standards are expected to ensure that the food additives are of a quality which is equivalent to or better than the standard intended by JECFA.

5. Codex Specifications have the added benefit of a round of government comments to confirm that they are both attainable and enforceable in practice. Nevertheless neither JECFA nor Codex Specifications are the only means of describing the desired standard of safety and they must therefore be regarded as advisory, and not subject to acceptance, directly or indirectly through the acceptance of Codex Commodity Standards

6. The Working Group stresses that food grade quality is achieved by compliance with the specifications as a whole and not merely with individual criteria which vary from substance to substance. For this reason the Working Group is of the opinion that it is not feasible to rank these individual criteria in terms of safety.

7. The Working Group notes that the opinion of JECFA is also being sought regarding the precise aspects of its specifications which constitute the minimum safety requirements consistent with the toxicological evaluation. The Working Group requests the Secretariat to make its opinion available to JECFA

8. A practical consequence of accepting the Working Group's opinion would be the need to amend the section of the Procedural Manual entitled "Format for Codex Commodity Standards" (p. 53 of the 5th Edition of the Manual) by replacing the first paragraph in inverted commas by: "The following provision in respect of food additives as contained in section of the Codex Alimentarius are subject to endorsement (have been endorsed) by the Codex Committee on Food Additives".

Procedure for the Elaboration of Codex Specifications

9. The Working Group once again addressed itself to the difficulties encountered with the Procedure for the Elaboration of Codex Specifications as laid down in the Procedural Manual (Fifth edition). In the opinion of the Working Group this procedure did not set out an order of events which would ensure a final outcome in all cases. In particular there was no mechanism for resolving a situation where JECFA and CCFA could not reach agreement on a specification.

10. The Working Group had before it three proposals for an amended procedure.

- i) a proposal submitted to the Codex Committee on General Principles by the UK and referred by that Committee to the CCFA,
- ii) proposal subsequently submitted directly to the CCFA by the EC Commission acting on behalf of all member States of the European Community, which superseded the UK proposal,
- iii) a proposal tabled by the Codex Secretariat.

11. In considering the relative merits of these proposals the Working Group sought to maintain the principle that CCFA was the final authority to recommend specifications to the Codex Commission for adoption as Codex Specifications. In other words, this authority resided with Governments rather than with the independent experts of JECFA and the procedure must allow Governments to act as the final arbiters of what should constitute a Codex Specification. While adhering to this principle the Working Group was very much aware of the practical difficulties that would result if Codex Specifications differed from the corresponding JECFA specifications. In practice, therefore, the Working

Group hoped that any difference of opinion between CCFA and JECFA would always be resolved. Nevertheless the procedure had to allow CCFA the option of recommending an amended JECFA specification to the Codex Commission for adoption as a Codex Specification.

12. None of the three proposed amended procedures was found to be entirely suitable. The procedure recommended by the Working Group is set out in the annex to the Working Group report. In recommending this procedure the Working Group wishes to draw attention to its advantages over the existing procedure namely:

- i) the title includes the term "Advisory" (Codex Secretariat proposal)
- ii) CCFA is empowered to break out of "the procedural loop" between CCFA and JECFA if it so decides (Working Group proposal)
- and iii) a categorical statement is included to the effect that specifications are not subject to government acceptance (EEC proposal)

Approach to the Consideration of Specifications

At the last Session, the Working Group had defined five categories to which specifications might be assigned based on the situation pertaining at that time. The advisory status of specifications has now been confirmed and therefore the categories have been redefined as follows:

- Category I - Specifications which are suitable for submission to the Commission for final adoption as Codex Advisory Specifications.
- Category II - Specifications which will be suitable for submission to the Commission for final adoption as Codex Advisory Specifications when minor editorial corrections have been made.
- Category III - Specifications which require substantive changes before they are considered suitable as Codex Advisory Specifications and which should be held at step 2 pending further advice from JECFA.
- Category IV - Specifications not considered at the present Session since they have been revised by recent Sessions of JECFA.
- Category V - Specifications which are incomplete and have been designated by JECFA as tentative.

A list of specifications and the categories to which they have been assigned together with comments is given below:

General comments

The Working Group had the following general comments:

- i) There should be a more consistent use of IUPAC nomenclature in the chemical names and a more consistent presentation of the structural formulae. The translation of chemical names in the French publication as not always accurate
- ii) There is a need to provide more directions to the analyst in some of the methods of analysis. This is particularly so for chromatographic methods where verification that the chromatographic system is operating satisfactorily is required
- iii) The move by JECFA towards greater use of IR spectroscopy as an identity test was approved especially in the case of flavouring compounds. However, in many cases the conditions under which the spectra are to be produced is

not stated

- iv) FAO should investigate the possibility of publishing JECFA specifications in loose-leaf form so that those approved as Codex Advisory Specifications could be readily collected in a compendium. In addition it would facilitate publication of corrections.

Specifications from FAO Food and Nutrition Paper No. 12.

Category I (recommended for adoption by the Commission)

Ammonium chloride
Amyl acetate
Benzyl alcohol
Benzyl benzoate
Butane-1, 3-diol
Ethyl laurate
Furfural
Geranyl acetate
Iron oxide (black, red and yellow)
Isoamyl butyrate
Isobutanol
Methyl anthranilate
Methylene chloride
Methyl n-methyl anthranilate
Nonanal
Potassium gluconate
Potassium chloride
Sodium gluconate
Triethyl citrate
Yellow 2G

Category II (recommended for adoption by the Commission after editorial correction)

	<u>Correction</u>
Citral	Structural formula
Ethyl formate	Structural formula
Ethyl heptanoate	Structural formula (english version of JECFA specifications only)
Linalool	Structural formula
Linalyl acetate	Structural formula

Category III (not recommended for adoption)

	<u>Recommended change</u>
trans-Anethole	- Analysis of cis-isomer requires precise procedure as reference standard difficult to obtain
dl-Calcium malate	- Add maleic acid limit (0.05%)
Castor oil	Raise acid value to 4
Diethyl ether	- Raise acidity (to 0.3 ml of 0.02 N NaOH)
Ethyl nonanoate	- Raise acid value to 3
	- Select one specific gravity range
Eugenol	- Improve mineral hydrocarbonstest
Magnesium chloride	Microbiological criteria not necessary except for

Magnesium hydroxide carbonate	- Magnesium lactate.
Magnesium lactate	
Magnesium gluconate	
Polyethylene glycols	
Potassium dihydrogen citrate	- Substitute numerical limit for oxalate - Raise arsenic limit to 3 mg/kg - Delete readily carbonisable substances
Sodium dihydrogen citrate	- Substitute numerical limit for oxalate - Raise arsenic limit to 3 mg/kg - Delete readily carbonisable substances - Recognise existence of monohydrate
Sodium fumarate	- Substitute IR identification - Delete ash - Consider addition of maleic acid limit
Triammonium citrate	- Not consistent with other citrate salts.

Category IV (not reviewed because of recent JECFA revision)

Allura Red AC
 Butan-]-ol
 Butan-2-ol
 d(+)-Carvone
 l(-)-Carvone
 Chocolate Brown HT
 Cinnamaldehyde
 Cyclohexane
 Diethylene glycol mono ethyl ether
 alpha-Ionone
 beta-Ionone
 Isopropyl myristate
 Light petroleum
 Methyl ethyl ketone
 Methyl β -naphthyl ketone
 Octanal
 Propan-1-ol
 Red 2G
 Toluene

Category V (tentative specifications not reviewed)

Citronellol
 Dimethylpolysiloxane
 Ethyl lactate
 4-Hydroxymethyl-2,6 -ditertiary butylphenol
 dl-Potassium malate solution
 dl-Sodium malate

The Working Group did not review the specification for 2-nitropropane as this had been withdrawn at the 25th Session of JECFA.

Specifications from FAO Food and Nutrition Paper No. 17

Category I (recommended for adoption by the Commission)

Calcium cyclamate
Diammonium orthophosphate
Dicalcium pyrophosphate
Ethyl cellulose
beta-Ionone (correct total ionone content to read 95% in French version only)
Monoammonium orthophosphate
Sodium cyclamate
Stearoyl monoglyceridyl citrate
Succinylated monoglycerides

Category II (recommended for adoption by the Commission after editorial correction)

	<u>Correction</u>
Nitrogen	- "note" wrongly indented
Polyvinylpyrrolidone	- chemical name - relate functional use to appropriate molecular weight range
Quinine hydrochloride	- correct "ester" to "ether" in solubility - correct chloroform-ethanol insoluble substance to read "1 g of the sample...."
Quinine sulfate	- limit omitted from Chloroform-ethanol insoluble substances
Turmeric	- amend "V" to "L" in Definition and add statement on presence of other curcuminoid compounds

Category III (not recommended for adoption)

	<u>recommended change</u>
Butylated hydroxyanisole	- add 85% minimum limit for 3-isomer
Butylated hydroxytoluene	- replace assay method with UV method
Calcium saccharin	- consider raising assay to 99%
Carob bean gum	- raise OTS limit to 75 mg/kg - specify galactomannan content (75%) - amend loss on drying to 14% - amend Acid-insoluble matter to 4% - amend Protein to 7% (Nx6.25) - revise total ash method
Curcumin	- correct identity test E (Guar gum) - correct structural formula - specify melting point more closely - insert assay limit and consider method with absorption at 420 nm
Diocetyl sodium sulfosuccinate	- investigate presence of bis-(2-ethylhexyl)-malate - use of test solution B omitted from procedure
Disodium pyrophosphate	- add P ₂ O ₅ content (63.0-64.0%) - consider increasing water-insoluble matter limit to 1%
alpha-ionone	- reduce α-ionone to 85%

Pentapotassium triphosphate	- add P ₂ O ₅ content (46.5-48.0%) - increase loss on ignition
Potassium nitrate	- reduce nitrite limit to 30 mg/kg and substitute more accurate method
Potassium polyphosphate	- add cyclic phosphate limit (8%)
Propyl gallate	- reduce lower assay limit to 98.0% - add UV criterion - raise loss on drying to 1.0% - raise Ash to 0.1%
Saccharin	- delete Chlorinated organic compounds - raise OTS limit to 200 mg/kg