codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX ALIMENTARIUS COMMISSION

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REPORT OF THE
SIXTEENTH SESSION OF THE CODEX COMMITTEE
ON FOOD ADDITIVES
The Hague, 22nd - 28th March, 1983

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

The Hague, 22nd - 28th March, 1983

INTRODUCTION

1. The Codex Committee on Food Additives held its Sixteenth Session in The Hague, The Netherlands, from 22nd to 28th March, 1983, by courtesy of the Government of the Netherlands. Mr. A. Feberwee (The Netherlands) acted as Chairman. The Session was attended by 190 participants. They represented 40 countries and observer countries and 34 international organizations (see Appendix I for the List of Participants, including the Secretariat).

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

2. The Sixteenth Session was opened by Mr. A. Ploeg, State Secretary of the Netherlands' Ministry of Agriculture and Fisheries. His welcoming address is given as Appendix II to this report.

GENERAL REMARKS

3. The Chairman and Dr. L. Ladomery of the FAO spoke in memory of Professor G.L. Gatti who had died since the last Session. Professor Gatti had for many years been a prominent member of the Italian delegation in various international fora associated with Codex. His extensive knowledge and experience will be missed by many international organizations, as well as his friendly and cooperative attitude. The Session observed a moment of silence in memory of Professor Gatti.

4. The Secretariat considered it timely to remind the Session of the procedure regarding participation of international organizations at Codex Sessions. With the Chairman's permission he read Rule VII.5 of the Rules of Procedure of the Codex Alimentarius Commission as follows:

"4. Subject to the provisions of Rule VII.5, the Director-General of FAO or WHO may invite intergovernmental or international non-governmental organizations to attend as observers, the sessions of the Commission and of its subsidiary bodies.

5. Participation of international organizations in the work of the Commission, and the relation between the Commission and such organizations shall be governed by the relevant provisions of the constitution of FAO or WHO, as well as by the applicable regulations of FAO or WHO on relations with international organizations; such relations shall be handled by the Director-General of FAO or WHO as appropriate".

In defining whether an organization is international and to which category it belongs, the Secretariat explained that FAO bases its consideration on: a) information provided by the organization itself (statutes, by-laws, membership, finances, etc.) and b) its inclusion in the yearbook of international organizations edited by the Union of International Associations in Brussels. Therefore, international organizations wishing to attend CCFA sessions as observers should send their request together with the above information to The Director, International Agency Affairs, Food and Agriculture Organization of the UN, 00100 Rome, Italy with a copy to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Rome, well in advance of the session they wish to attend.

5. The delegation of Argentina repeated the request made at the Fifteenth Session that the proceedings and papers of the Codex Committee on Food Additives should be available in Spanish as well as in English and French, including simultaneous interpretation into Spanish, during the Session. The Secretariat undertook to look into the matter so that documents in Spanish would be available for the Session. The Chairman appreciated the request for simultaneous interpretation at the Session but indicated that because of financial constraints it could not be possible at the moment. The late arrival of documents combined with the lack of a Spanish version could result in the Argentinian delegation placing reservations on Agenda Items 4,6,8 and 10 to 16 which might not have otherwise been necessary.

APPOINTMENT OF RAPPORTEURS

6. Mr. T. Avigdor (Switzerland) and Mr. R. Ronk (USA) were appointed as rapporteurs.

ADOPTION OF THE AGENDA

7. The Committee adopted the provisional agenda (CX/FA 83/1) without amendments.

MATTERS OF INTEREST FOR THE COMMITTEE

REPORT OF THE 26TH SESSION OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES

8. The Committee had before it the report of the above mentioned Session of JECFA (WHO Technical Report Series 683) which was presented by the WHO Joint Secretariat of JECFA.

9. The Committee was informed that there was a general discussion at JECFA relating to principles governing: i) the toxicological evaluation of compounds, ii) the establishment and revision

of specifications, iii) significance of the occurrence of nephrocalcinosis in the toxicological evaluation of modified starches, iv) food colours extracted from foods, v) phosphates and polyphosphates in food additive use, vi) toxicological evaluation of xenobiotic anabolic agents, vii) metals occurring in foods, viii) safety aspects of Codex specifications and ix) food additive computerized databank.

10. The main groups of additives examined by the Committee included antioxidants, emulsifying agents, enzymes of micro-biological origin used in processing, flavouring agents, food colours, inorganic salts and buffering agents, sweetening agents, thickening agents and a few other miscellaneous food additives. The individual substances evaluated were selected from those included in the CCFA priority list or submitted to JECFA with proposals for amendment prior to their endorsement as Codex Advisory Specifications. The specifications had been published as Food and Nutrition Paper No. 25. The Committee was informed that the English version of the specifications had been sent to all Codex Contact Points, member governments and interested international organizations for comment.

11. The report laid down general principles which should guide the evaluation of residues of anabolics in meat and noted that the process resembled in many respects, the evaluation of pesticides, since the essential elements required in both cases were:

a) adequate relevant toxicological data, and
b) comprehensive data about the nature and level of residues.

12. The report also contained the Committee's reaction to a request formulated by the Codex Alimentarius Commission with regard to the identification of criteria in the Committee's specifications which represent "minimum safety requirements". The expression "minimum safety requirements" in relation to the Committee's chemical specifications, was taken to mean that only food additives of a food-grade quality which had full toxicological evaluations should be used. In giving this interpretation and advice to the Commission, the Committee noted that its function was to evaluate scientific and technical information, and that the obligation to accept or otherwise was a matter for Governments.

13. With regard to food contaminants, the report defined several important end-points for the evaluation of contaminants as well as of substances which were both essential nutrients and unavoidable constituents of food. The Committee decided that the allocation of an Acceptable Daily Intake (ADI) from zero to an upper limit was not appropriate for these substances; thus for copper and zinc, which are both essential to human nutrition, but caused toxicity at higher levels of intake, the Committee established provisional maximum tolerable daily intakes (PMTDI), expressed in two figures, one indicating the level essential for nutritional purposes and the other the maximum safe level. For tin, a metal contaminant, with no cumulative properties, a provisional maximum daily intake expressed in one figure was established. It should be noted that for metal contaminants with cumulative properties (e.g. cadmium, lead and mercury), the Committee had already established provisional tolerable weekly intakes expressed in one figure. Finally, since phosphorus (as phosphate) is an essential nutrient as well as an unavoidable constituent of food, the Committee established a maximum daily intake expressed in one figure for this substance; this applies to diets that are nutritionally adequate in respect to calcium - if the calcium intake were high, the intake of phosphate could be proportionally higher, and the reverse relationship would also apply. In this regard, however, the Committee noted that some concern had been expressed recently about the possibility that increasing use of phosphates and polyphosphates as food additives might disturb calcium/phosphorus ratios in the diet. After examining the evidence, the Committee decided that the question of the optimum ratio was still unresolved and recommended further studies on the consequences of high dietary intakes of phosphates.

14. The Committee noted that JECFA stressed the urgency of implementing the recommendation made in its Twentyfifth Report that a group of experts be convened as soon as possible to study the application of advances in methodology to the toxicological evaluation of food additives and contaminants and also of pesticide residues.

15. The discussion which followed centred around para.14 of the Fifteenth Report of CCFA (ALINORM 83/12) and the Committee agreed that future letters from JECFA to food additive manufacturing industry should explain the reason why data on technological and nutritional considerations are required. It was also recommended that a summary report should be issued immediately after JECFA's Session as has been the case during the past couple of years. Such a report should be distributed to all Codex Contact Points and any other interested users.

16. There was a discussion on the necessity for manufacturing data which could be proprietary in nature for JECFA to make a complete evaluation of the safety of a food additive. The Secretariat pointed out that while Circular Letter 82/17 did not require this data it was very useful in setting adequate specifications for the additive and in answering other questions the Committee had. If at all possible JECFA would like to receive the information but the review could proceed without it.

INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY (IPCS)

17. This agenda item was introduced by the representative of IPCS who noted that previous presentations of the IPCS had been made to the Thirteenth Session of the CCFA (ALINORM 79/12), the Fourteenth Session (ALINORM 81/12), and to the Fifteenth Session (ALINORM 83/12). His presentation is reproduced as Appendix III.

18. The Committee concluded that its interest in the IPCS was mainly concerned with three particular aspects: namely, that the terms of reference of JECFA as the advisory body to the Codex Alimentarius Commission in all scientific matters concerning food additives be maintained; that the JECFA/CCFA system for priority selection of compounds for evaluation by JECFA should not be changed; and that JECFA should be strengthened.

MATTERS OF INTEREST FROM CODEX SESSIONS

19. The Committee had before it documents CX/FA 83/4 and CX/FA 83/4-Add.1 on the above subject which were presented by the Secretariat.

20. 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 discussion on them until the particular agenda items were presented.

Codex Committee on Fats and Oils, 12th Session (ALINORM 83/19, paras 62-66)

21. JECFA at its Twentyfifth Session made a toxicological evaluation of 2-nitro-propane, a processing aid, which is used as a solvent for extraction of fats and oils and leaves residues as low as 0.02 ppm in the oil. JECFA recommended that the solvent should not be used in the preparation of food. France raised the question whether such low levels, 20 parts per billion, could still exert toxicity. It further asked whether the JECFA experts had taken these facts into consideration when they evaluated this compound.

22. The Committee noted that this would be discussed under Agenda Item 11 on Processing Aids and agreed to defer discussions on the subject.

Joint ECE/CODEX Alimentarius Group of Experts on Standardization of Fruit Juices, 15th Session, (ALINORM 83/14, paras 48-58).

23. The Joint Group of Experts asked CCFA to give advice about how to establish limits for Sn, Pb, Cd, and Hg in fruit juices. While Sn and Pb in fruit juices are primarily due to processing, Cd and Hg are due to environmental pollution. The Group of Experts asked CCFA to provide clear guidelines on how to proceed with the collection of data and the establishment of limits for these contaminants. The Committee agreed that this task comes under the terms of reference of the Committee but deferred discussion to Agenda Item 16 on Environmental Contaminants.

Codex Coordination Committee for Asia, 3rd Session, (ALINORM 83/15, Appendix II)

24. The Coordinating Committee for Asia proposed to change the endorsement status for the provision on tin in certain fruit and vegetable products from "temporarily endorsed" to "endorsed" and asked CCFA to consider its proposal.

25. The Committee noted that the problem of excessive levels of tin in foods such as canned fruit based beverages, was discussed by the 26th JECFA, and could result in acute manifestations of gastric irritation. The Committee agreed not to take any action until health related problems due to excessive intakes of tin are clarified by JECFA. The Committee also noted that the subject would come up for discussion before the 15th Session of CAC.

Codex Committee on Food Labelling, 15th Session (ALINORM 83/22), Definition of Food Additives (paras 106 and 107)

26. Some delegations attending the above Committee did not agree with the definition of Food Additives, elaborated by CCFA since the definition would encompass certain constituents like vitamins and minerals used for nutritional purposes and asked this Committee to review its definition of food additives.

27. The Committee recalled that it had discussed the same subject at its 13th Session (ALINORM 81/12, paras 24-26) and reaffirmed its opinion that the present definition of food additives which had been elaborated after several sessions of the Codex Committee on Food Additives is satisfactory and should not be modified. The Codex Committee on Food Labelling may modify the definition of "Food Ingredient" for the purposes of labelling if that is felt necessary.

28. Denmark, Argentina and Austria informed the Committee that in their countries, vitamins and minerals added to food were considered as food additives.

29. Belgium drew the attention of the Committee to the report of the 9th Session of CAC (ALINORM 72/35, para 294) where the Commission while adopting the definition of food additives elaborated by CCFA pointed out that the definition of food additives had been drafted to exclude typical ingredients such as condiments, spices, salt and nutritional substances such as vitamins, amino acids and trace elements.

Executive Committee of the Codex Alimentarius Commission, 29th Session (ALINORM 83/3)

30. The Executive Committee had noted the view of CCFA on the minimum safety requirement of specifications and the proposed procedure for elaboration of Codex advisory specifications. These questions on safety requirements and procedures had been sent to governments for comment and would be before the 15th Session of CAC for consideration.

Codex Committee on Processed Fruits and Vegetables, 16th Session (ALINORM 83/20) Contaminants in Processed Fruits and Vegetables

31. The Committee on Processed Fruits and Vegetables agreed to levels of 250 mg/kg for tin and 1 mg/kg for lead as maximum levels of contaminants that could be present in processed fruits and vegetables and expressed its opinion that it is up to the Codex Committee on Food Additives to consider the acceptability of the maximum levels from a safety point of view on the basis of appropriate intake data and toxicological guidelines.

32. The Committee, having noted that the new levels of Sn and Pb agreed to by the Codex Committee on Processed Fruits and Vegetables are at Step 3 of the Procedure, took no action but agreed to consider them at its next (17th) Session when they would be at Step 5 of the Codex procedure.

Carry-over Principle

33. The Carry-over Principle was discussed and adopted as legal texts both at the 11th and 13th Sessions of the Commission with the result that the texts were scattered in two reports. The text of Carry-over Principle adopted at the 11th Session of the Commission was reproduced in toto in the Guide to the Safe Use of Food Additives.

34. The delegation of Australia and the Secretariat attending the 16th Session of CCPFV were of the opinion that the scattered texts on the Carry-over Principle should be combined into a form suitable for publication in the Codex Alimentarius.

35. The Secretariat of CCFA prepared a modified text which the Committee agreed to discuss while considering Agenda Item 11 on Processing Aids.

Codex Committee on Meat Hygiene

36. The Committee noted that the Codex Committee on Meat Hygiene had decided to adjourn sine die but had recommended the setting up of a Working Group which would interest itself in collecting more data with a view to establishing residue levels of anaboles and antibiotics in meat. The matter will come up for consideration before the 15th Session of the Codex Alimentarius Commission.

OTHER MATTERS

General Standard for Irradiated Foods

37. The Codex Committee on Food Hygiene at its 13th Session in 1979 noted that the upper limit of 1 megarad set in the Codex Draft General Standard for Irradiated Foods raised certain concerns. These concerns included increased radiation resistance, increased pathogenicity associated with genetic changes of surviving micro-organisms and also with the destruction of vegetative cells which could prevent competititve growth of spoilage micro-organisms prior to outgrowth of C.botulinum spores.

38. At the request of the FAO and WHO, the subject was considered at a meeting of the Board of the International Committee on Food Microbiology and Hygiene of the International Union of Microbiology Societies held in Copenhagen, December 1982. The Board noted the concern of the Codex Committee on Food Hygiene but after analysing the scientific knowledge available to date, it was satisfied that there was no cause for concern and that modern techniques were adequate to control the situation.

Agenda for 27th JECFA Session

39. The Committee noted with satisfaction the quick action that had been taken by JECFA to evaluate the food additives that it had included in the priority list. The Committee was pleased to note that 14 of the 18 additives in the Codex Priority List would be considered by JECFA at its 27th Session.

IBT Studies

40. Some evaluations of food additives by JECFA were placed in doubt because some of the supporting studies had been carried out by Industrial Bio Test Laboratories. While discussing the 25th report of JECFA, the CCFA at its 15th Session accepted the offer from Canada and the USA to make available to the Committee a list of food additives which had come under question because the toxicological basis for their approval could not be validated (para.13, ALINORM 1983/12).

41. The Committee was informed by Canada that IBT involvement was not considered to be major except in the case of the compounds noted in document CX/FA 83/4, i) brominated vegetable oil, and ii) hydroxypropylcellulose.

42. The Committee took note of this but agreed to take no action since the involvement of IBT was not considered major and also since more than adequate information on the toxicology of the compounds from more reliable studies was available to it. In the case of brominated vegetable oil, no ADI had been alloted by JECFA.

Health Aspects of Residues of Anaboles in Meat

43. The Committee noted that a Working Group on health aspects of residues of anaboles in meat which met at Bilthoven, recommended that CCFA should interest itself in evaluating the available data on trenbolone acetate and zeranol, with a view to establishing their safety, and also in harmonizing national legislations on the use of anabolic agents. (See document "Health Aspects of Residues of Anabolics in Meat", Report on a WHO Working Group, Euro Reports and Studies 59, Regional Office for Europe, World Health Organization, Copenhagen).

GUIDELINES FOR THE ESTABLISHMENT OF FOOD ADDITIVE PROVISIONS IN COMMODITY STANDARDS

44. The Committee had before it the above guidelines contained in document CX/FA 83/16. The guidelines had been prepared by the Secretariat on the request of the 15th Session of the Committee, on the basis of government comments received. In introducing the document the Secretariat recalled that work on the guidelines had been initiated following a request by the 13th Session of the Commission and were intended for Codex Commodity Committees in supplying appropriate information to this Committee on the basis of which provisions for food additives can be endorsed in the light of technological justification and consumer protection.

45. The Committee decided to discuss the guidelines section by section. As a general remark the delegation of the UK expressed the opinion that the guidelines were not clear and contained information which was a duplication of existing Codex principles and guidelines on food additives. The only useful section in the guidelines was Section 4 which indicated the information to be supplied by Commodity Committees. Even this section required considerable amendments. The delegation of the UK was not convinced of the need to develop guidelines.

Sections 1,2 and 3

46. The Committee noted that 2(a) represented an approach to the setting of maximum levels for food additives which was a departure from the guidelines included in the Procedural Manual related to the endorsement of food additive provisions. A number of delegations were of the opinion that maximum levels should always be set where an ADI had been given to a particular food additive, since food additives which were self-limiting would not necessarily be used in amounts consistent with their acceptable daily intakes.

47. The Secretariat was of the opinion that Guidelines for Codex Commodity Committees on setting maximum levels for food additives might be useful to facilitate endorsement of food additive provisions by the Committee.

48. After some discussion the Committee agreed that Sections 1,2 and 3 were a duplication of what was already stated in the General Principles for the Use of Food Additives and should be deleted.

49. As regards the publication of the above General Principles, the Committee expressed regret that they had not been included in the Procedural Manual of the Commission (5th Edition) as requested at the last session of the Committee. It strongly requested the Secretariat to assure that the General Principles would be included in the Procedural Manual as Addenda pages. The Secretariat undertook to comply with the request of the Committee, but noted that it was the intention of the Secretariat to include the General Principles in Volumes 1 and 14 of the Codex Alimentarius dealing with definitions and general information and food additives, respectively.

Section 4

50. The Committee agreed that the guidelines should deal with information to be submitted by Codex Commodity Committees to this Committee to enable it to perform its endorsing function in a better way. The Committee decided to set up a small drafting group consisting of delegations from the UK, USA, Norway, Switzerland and the Federal Republic of Germany. The drafting group was requested to prepare a questionnaire type document indicating information to be supplied by Commodity Committees along the lines suggested in the Secretariat paper.

51. The Committee received a report from the Drafting Group. It agreed with the conclusions of the Group that: the Codex General Principles for the Use of Food Additives, (see CAC Procedural Manual, 4th Edition, page 19) and para.13(b) of the proposed Guidelines for Codex Committees, concerning Food Additives, Procedural Manual, 5th Edition, contained all the information which was needed by Codex Committees in establishing or endorsing food additive provisions in Codex Standards. These provisions were adequate in such a way as to protect the consumer from fraudulent practices and to protect the health of the various groups of consumers. It remained, therefore, only to stress that the General Principles should be followed and that the Codex Committee on Food Additives should receive adequate assurance that this was indeed so. Any further guidance addressing this question need not be subjected to formal procedures in their elaboration and should be regarded as an internal document for use by the Codex Committees concerned.

52. In discussing the list of the guidance for Codex Commodity Committees developed by the Drafting Group, the Committee reached the following recommendations:

(a) the definition of Good Manufacturing Practice as contained in the original paper should be included;

(b) the resulting document should be included in the Codex Alimentarius, Vol. XIV and should also be brought to the attention of Codex Commodity Committees and their Chairmen, Codex Contact Points, and other interested bodies.

53. It was understood that, as a first step, the text of the guidance to Codex Committees should be submitted to the Commission for consideration (see Appendix IV).

CONSIDERATION OF FOOD ADDITIVE INTAKE

54. The Committee had before it the report of the Working Group on Food Additive Intake, Room Document CX/FA 83/5-Add.1. In introducing the report, the Chairman of the WG, Mr. M. Fondu (Belgium) informed the Committee that the Working Group had considered with regard to contaminants (i) draft guidelines for the study of dietary intake of contaminants EFP/82.36 and (ii) levels of lead in sugar. It had also considered food additives intake and draft classification of foodstuffs. As requested by the Committee at its last Session (ALINORM 83/12, para 76, 105) the WG had given special consideration to:

- antioxidants: BHA, BHT, TBHQ, gallates
- preservatives: benzoic acid and its salts, sulphur dioxide and its derivatives
- colouring matters with an ADI less than 2 mg/kg bw
- artificial sweeteners: saccharin, cyclamate
- xanthan gum.

55. The Working Group had discussed briefly the problems of the level of 1 ppm lead for sugar. (ALINORM 83/12, para 129) and had stressed the importance of meeting the lowest possible level for lead in foodstuffs. The WG had first discussed the question of the amount of sugar ingested and secondly the level of lead in sugar. It had noted that there is a lack of data on sugar consumption from such products as confectionery, ices, chocolate and soft drinks. However, assuming a mean daily intake of 100 g of sugar, a level of 1 ppm lead would result in a daily ingestion of 100/µg lead from sugar. This value represented about a quarter of the maximum tolerable daily intake (3 mg/7 = 420 ug/day) and was considered to represent a rather high intake. With regard to the level of lead in sugar, information had been obtained from Brazil and Italy. In Brazil in the majority of cases, the level of lead in partially refined sugar (demerara), obtained from one region in the country, was lower than 0.5 ppm. In Italy mean figures for refined sugar were 0.2 ppm.

56. The Committee endorsed the proposal of the Working Group to ask the sugar producing countries to provide analytical data regarding lead levels in refined sugar. The delegation of The Netherlands pointed out the possible effect of the production method of sugar on the level of lead in the end product and therefore suggested that information on the production method as well as on the degree of refining of the samples of sugar should accompany the analytical data.

57. The WG had agreed that Codex maximum levels for contaminants should not be used for calculations and that, therefore, the use of PCDI estimates for contaminants were not relevant. If an evaluation of risk had to be made, estimates of actual intake had to be used. The WG had, therefore, recommended that the governments join the FAO/WHO Food Contamination Monitoring Programme and base their studies on the guidelines for the study of dietary intake of contaminants which will probably be available in September of this year. The draft guidelines were presented in the WG by the representative of the WHO (EFP/82.36).

58. The representative of the WHO informed the Committee that, at the moment, 22 countries participated in the Monitoring Programme and that FAO/WHO were interested in more countries participating in the programme which collected data on the amounts of substances such as heavy metals, PCB's, chlorinated pesticides and mycotoxins in a variety of foodstuffs and in the total diet. Interested delegates were invited to approach the WHO representative.

59. The delegation of Brazil emphasized that involvement in the FAO/WHO Food Contamination Monitoring Programme was highly desirable. It emphasized the value of standardization of the methodology of analysis and sampling for lead in foodstuffs to enable comparison between countries. The delegation of Cuba agreed with the comments of Brazil. It wished to participate in the FAO/WHO Monitoring Programme.

60. The Committee supported the recommendation of the WG that more governments join the FAO/WHO Food Contamination Programme.

61. The WG had concluded that, on the basis of a mean individual daily intake of visible fat of 71 g (40% of the daily fat intake) and the assumption that antioxidants are added to visible fats such as oil, fats, shortenings and margarines at a level not higher than 200 ppm, the mean daily intake of antioxidants (BHA, BHT, TBHQ) would be 14 mg per person (temporary ADI 0-0.5 mg/kg/bw/day). The WG believed, therefore, that the intake of these antioxidants, even if present at a level of 200 ppm in visible fats and fats used as ingredients in other foodstuffs would not exceed the ADI.

62. The WG had calculated the PCDI of gallates starting from the hypothesis that these antioxidants are added to all visible fats at a level of 200 ppm and were the only antioxidants to be used. The WG had concluded that the intake of gallates was unlikely to exceed the ADI.

63. The Committee noted that the WG needed more data concerning:
- preservatives: benzoic acid and its salts, sulphur dioxide and its derivatives
- food colours with an ADI less than 2 mg/kg bw
- artificial sweeteners: saccharin, cyclamate

A circular would be prepared.

64. The Chairman of the WG pointed out that the WG would like to receive data on the disappearance of SO_2 after processing of the foodstuffs or after cooking, together with intake data especially for dried fruit, wine and beer based on actual levels of SO_2.

65. The Chairman of the WG pointed out that for artificial sweeteners intake figures were needed not only from foodstuffs, but also from other sources especially in relation to persons who use these additives for weight control purposes.

66. The delegation from Finland informed the Committee that in a study in its country the total intake from all possible sources of artificial sweeteners had been estimated. The intake of cyclamate had been estimated at 12 mg/person/day and of saccharin 6 mg/person/day.

67. With regard to Xanthan gum, the Chairman of the WG asked the Committee to raise a question to JECFA regarding the use of a safety factor of 100 when setting ADI's for thickening agents. He suggested that this factor might be too high when applied to substances like thickening agents which due to their physical capacity to bind water cannot be fed to animals at a high enough level to produce a toxic effect.

68. The Committee decided to bring this problem again to the attention of the JECFA and seek its advice.

69. The Committee agreed that the draft document on classification of foods attached to the WG report (CX/FA 83/5-Add. 1) should form part of the Circular Letter needed to obtain comments from the governments.

70. 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, USA, Australia and EEC.

ENDORSEMENT OF FOOD ADDITIVE PROVISIONS IN CODEX STANDARDS

71. In introducing document CX/FA 83/10-Part 1 and Addenda 1,4,5 and 6 the Secretariat pointed out that it had followed the procedure described in the report of the 13th Session of the Codex Alimentarius Commission.

72. The decisions of the Committee concerning the endorsement, temporary endorsement or postponement of the endorsement of food additive provisions, are indicated in Appendix V of this report.

I. Processed Fruits and Vegetables

Draft Standard for Canned Chestnuts and Canned Chestnut Puree, (ALINORM 83/20, Appendix VIII)

Sodium polyphosphate

73. The Committee followed the Secretariat's recommendation to postpone the endorsement, requesting the Commodity Committee to set a maximum level, but noted that the 26th Session of JECFA had discussed phosphates and polyphosphates and had recommended a figure of 70 mg/kg body weight as maximum tolerable daily intake for phosphates. Although in this provision only small amounts of polyphosphates are involved, the Committee agreed at this point with the suggestion of the Secretariat to request the Working Group on Food Additive Intake to consider total phosphate intake. The delegation of Argentina informed the Committee that the use of polyphosphates was not allowed in the their country.

L-Ascorbic Acid and Sodium Ascorbate

74. Commenting on the Secretariat's recommendation to postpone the endorsement of this provision on the grounds that more technological justification was required, the delegation of Switzerland informed the Committee that these substances can prevent a discolouration of the product due to iron traces and that a level of 400 ppm is sufficient to achieve this aim. The Committee decided therefore to endorse this provision, provided the maximum level of 400 mg/kg is acceptable to the Fruits and Vegetables Committee.

Colours

75. The Secretariat pointed out that only very small amounts of Turmeric are used and that in this case the Committee might wish to endorse that provision. The Committee, however, postponed the endorsement of all three colours, seeking a maximum level for the colours and awaiting a toxicological evaluation by JECFA of Crocin and Carthamus yellow. The delegation of Argentina informed the Committee that the use of colours is not allowed in Argentina in this product.

Vanillin

76. The Committee accepted the proposal of the Netherlands to endorse the provision for Vanillin, since that flavour is self-limiting. It is only used in small quantities and has a relatively high ADI.

II. Fruit Juices

77. The observer of the EEC informed the Committee that the EEC had made a detailed comparison between Codex and Common Market legislation on Fruit Juices and that this document is available to interested parties on request to the Codex Secretariat. All food additive provisions were endorsed.

III. Vegetable Proteins

Draft Standard for Wheat Gluten (ALINORM 83/30, Appendix V)

78. The Committee had a detailed discussion on the proposed general processing aid provision which did not identify and list all the processing aids involved. The Secretariat proposed that the processing aids be identified by the Commodity Committee. The delegation of the Netherlands questioned the need for asking the Commodity Committee to identify and list all the processing aids necessary in the manufacture of wheat gluten, since it felt that the Committee should not embark on the endorsement of a closed list of processing aids. There was general support for the view that, since the CCFA itself had not yet decided on its approach towards regulating processing aids, it was premature to decide on the endorsement of the proposal of the Commodity Committee. Therefore the Committee decided to postpone the endorsement but emphasized that information on the use of processing aids from Commodity Committees should be obtained and recommended that these Committees list processing aids involved and submit them to the CCFA. The Committee noted that such a procedure had been followed with satisfactory results by the CCFO.

IV. Fats and Oils

Draft Standard for /Vanaspati/Vegetable Fat Mixture/, (ALINORM 83/17, Appendix V)

Colours

79. The delegation of Switzerland proposed to the Committee a level of 10 mg/kg as a maximum level for β-carotene in order to enable the Committee to make an endorsement. The Secretariat informed the Committee that Commodity Committees usually were responsible for elaborating food additive provisions in Commodity Standards. The Committee endorsed a level of 10 mg/kg of β-carotene, should the Commodity Committee consider this an appropriate level.

Natural and synthetic tocopherols

80. The delegation of Switzerland proposed a maximum level of 200 ppm for these substances in order to enable endorsement to be made. The Committee decided, in line with its previous decisions on colours and endorsed a level of 200 ppm should the Commodity Committee consider this an appropriate level.

Dilauryl thiodipropionate

81. The Committee, noting that this substance had an ADI, agreed to endorse this provision.

Dimethyl polysiloxane (DMPS), singly or in combination with silicon dioxide

82. The Secretariat pointed out that it considered this sort of substance to be a processing aid, but reminded the Committee that in the past it had endorsed DMPS provisions as food additive provisions. The delegation of Sweden was of the opinion that in this case DMPS had to be regarded as a food additive. The Committee decided to endorse the provision, noting the discussion.

Draft Standard for Minarine (ALINORM 83/17, Appendix III) and Fat Spreads/Spreadable Table Fats (ALINORM 83/17, Appendix III)

Xanthan gum

83. The delegation of Finland asked about the lower maximum level set for Xanthan gum in view of earlier endorsements in similar products at higher levels. The observer of Marinalg explained that Xanthan gum was an efficient waterbinder and the lower level was, therefore, sufficient. The provision for 5g/kg Xanthan gum, singly or in combination, was included in the overall limit for thickeners.

Polyglycerol esters of interesterified ricinoleic acid

84. The delegation of the Federal Republic of Germany felt that the maximum level set for this substance might result in a consumption figure close to the ADI and, therefore, reserved its position. Its view was supported by the delegation of France. The Committee endorsed the provision but decided

to request the Working Group on Food Additive Intake to examine this matter. The delegation of Finland expressed a reservation concerning this additive provision.

Tertiary butyl hydroquinone (TBHQ)

85. The delegations of Finland and Sweden expressed a reservation concerning this additive provision. The provision was endorsed by the Committee.

V. Draft Standard for Vinegar (ALINORM 83/19, Appendix II)

Sulphur Dioxide

86. The Committee had some discussion on the need for SO_2 in vinegar. Noting that justification had been provided by the delegations of the UK and Brazil on the use of this substance, it endorsed the provision. The delegation of France expressed a reservation.

Colours

87. The Committee discussed the use of colours in vinegar. It noted the remark of the delegation of Finland that colouring was only required in malt vinegar. However, the delegation of the Federal Republic of Germany informed the Committee that in his country the use of colour was permitted for all types of vinegar. France uses caramel to colour alcohol vinegar. The Secretariat explained to the Committee that the Coordinating Committee for Europe had proposed the use of caramel colour made by the ammonia process only for malt vinegar. Its purpose was to restore colour lost during treatment with sulphur dioxide. The other caramel colours (i.e. plain caramel and ammonium sulphite process caramel) were intended for slight colour adjustments in other types of vinegars.

88. The Committee temporarily endorsed the use of caramel colour made by the ammonium sulphite process, with reservations from the delegations of Portugal, Spain, Thailand, Italy and Sweden.

Flavours

89. The delegation of the Federal Republic of Germany informed the Committee that it did not consider natural flavours as food additives. The Committee temporarily endorsed this general provision but agreed that it be presented in the appropriate wording, used in Codex standards.

VI. Cereals, Pulses and Legumes

Draft Standard for Wheat Flour (Advanced to Step 8), (ALINORM 83/29, Appendix II)

90. The Committee had a detailed discussion on this food additive paragraph. In general it was felt that the Standard covered a fairly wide range of products, although it noted the remarks from the Secretariat that the standard was not a general one and excluded a number of wheat flours.

Bleaching Agents

91. The Committee agreed with the Secretariat's proposal to postpone the endorsement of benzoyl peroxide and chlorine. The Committee noted moreover the reservations of many delegations regarding the use of bleaching agents and, therefore, postponed the endorsement of chlorine dioxide.

Enzymes

92. The observer from AMFEP was of the opinion that the enzymes in this case were processing aids and requested that they be endorsed. The Committee agreed with the delegation of Belgium that the enzyme provisions should not be endorsed unless the origin of each of them was specified and it was also agreed that other enzymes than those evaluated by JECFA should not be endorsed.

Flour Improvers

93. The Committee endorsed the use of ascorbic acid at a level of 200 mg/kg flour and of L-cysteine hydrochloride, at a level of 90 mg/kg flour, noting a request from the delegation of France for raising the maximum level of use in the latter to 300 mg/kg flour. Finland, Italy, Greece, Norway and Sweden indicated that they would be opposed to raise the level of cysteine hydrochloride to 300 mg/kg.

94. The Committee noted the many reservations concerning the use of azodicarbonamide and, therefore, postponed its endorsement.

95. The Committee also noted the many reservations concerning the use of potassium bromate and the remarks of the delegation of Switzerland who informed the Committee that several countries had banned or restricted the use of this substance in the light of recent toxicological information. The Committee, therefore, postponed the endorsement of this food additive provision.

96. The Committee followed the suggestion of the delegation of Canada supported by Norway to limit the endorsement of the food additive provision on sulphur dioxide by restricting the use of the flour concerned to the manufacture of biscuits and pastry. Reservation was expressed by the Federal Republic of Germany, France and Finland to the use of SO_2 in flour.

97. The Committee postponed the endorsement of monocalcium phosphate since the proposed maximum level of use might result in exceeding the maximum tolerable daily intake of phosphate and since many delegations opposed the use of these flour improvers.

98. The Committee noted the remarks of the delegation of the UK that the Commodity Committee had already done a lot of supporting work for these provisions and that many types of products, regional differences and production scale differences were involved. However, the Committee was of the opinion that, in view of the many critical reactions to the proposals, it had to confirm to its conclusions.

Technological Justification for the Use of Calcium Disodium Salt of EDTA (Na_2Ca EDTA) as an Anti-oxidant Synergist in Fat Spreads/Spreadable Table Fats

99. The Committee had postponed the endorsement of this additive provision at its last Session (ALINORM 83/12, para 111). It had requested more data from the Commodity Committee on the technological function.

100. The data requested had been supplied in the form of a paper written by John M. Hasman of CPC International Inc. on behalf of the USA delegation to the Codex Commodity Committee on Fats and Oils. The paper was presented as Annex I to Room Document CX/FA 83/10 - Part I-Add. 6.

101. As a result of the arguments presented in the above paper, the Committee agreed with the Secretariat's recommendation to endorse the provision for the calcium disodium salt of EDTA in fat spreads/spreadable table fats. Reservations were expressed without discussion by the delegation of Finland, New Zealand, the Federal Republic of Germany, Italy, Switzerland, Poland and France.

Food Additives in FAO/WHO Code of Principles Standards for Varieties of Cheese

102. The Committee had previously not endorsed certain food additive provisions in cheese standards pending information on technological justification and the provision of maximum levels of use.

103. At the present Session the FAO Secretariat, having obtained the required information during the 20th Session of the Joint FAO/WHO Committee of Governments Experts on the Codex Principles concerning Milk and Milk Products held in Rome, 26th-30th April, 1982, made the recommendations recorded in Appendix V.

104. The first recommendation concerning sorbic acid or its sodium or potassium salts in extra hard grating cheese and processed cheese standards was endorsed by the Committee with reservations expressed by the Federal Republic of Germany, Finland and France.

105. Recommendation 2a (concerning the use of propionic acid and certain of its salts in processed cheese) was also endorsed by the Committee with reservation by the Federal Republic of Germany and France.

106. Recommendation 2b (re. the use of nisin in processed cheese) was endorsed with reservations by the Federal Republic of Germany, Austria, Thailand and Spain.

107. Recommendation 2c (re. the use of annatto and β-carotene in processed cheese at 600 mg/kg) led to questions as to the exact meaning of this provision in relation to the ADI for annatto expressed as bixin. The Swiss delegation also mentioned that a great part of the added colour is lost during preparation of cheese. It was pointed out by the representative of the International Dairy Federation (IDF) that the Milk and Milk Products Group would not be meeting for 3 years. However, at the request of the Committee he agreed that the IDF would clarify these points.

108. Recommendation 3 (re. the use of chlorophyll copper complex in blue-veined cheese and extra hard-grating cheese) was endorsed by the Committee with a reservation from the Federal Republic of Germany.

109. Recommendation 4 (re. the use of hexamethylenetetramine (HMT) in provolone cheese) also led to various questions such as an explanation of the technological justification concerning the use of HMT. The Committee postponed endorsement and requested further data, including the nature of the residue.

Action Needed by CCFA resulting for Change in ADI Status of Food Additives

110. The Committee had before it a paper prepared by the FAO Secretariat with the above title (CX/FA 83/10, Part I-Add. 2) concerning the action required following the JECFA's annual establishment on revision of ADIs.

111. Action taken by the 24th and 25 Sessions of JECFA and the corresponding action taken by the Committee were described in Appendix V, Part I which also lists the Secretariat's recommendations for specific changes in previous endorsements. The Committee approved these recommendations and asked the Secretariat to make the consequential changes in the Codex lists of food additives. As regards changes to endorsements these should be brought to the attention of the Commission as appropriate.

Endorsement of Maximum Levels for Contaminants in Codex Commodity Standards, Processed Fruits and Vegetables, Fruit Juices and Fats and Oils

112. The Secretariat had prepared a document (CX/FA 83/10-Part II) containing provisions for contaminants subject to endorsement by the Committee as at the end of October 1982 from a collection of Commodity Committees. These provisions, as finally endorsed by the Committee, are recorded in Appendix V, Part II. There was discussion before this agreeement was reached, as described below.

113. The maximum level of tin recommended for temporary endorsement by the Secretariat at 250 mg/kg was first discussed in connection with the Draft Standard for Canned Chestnuts and Canned Chestnut Puree. Reservations were expressed from Switzerland, Sweden, New Zealand, Finland, Belgium, the Federal Republic of Germany, Italy and Poland. The principles debated applied also to the three standards for fruit juices. There was first a general discussion of maximal levels of tin that could be present in canned foods.

114. The observer from the EEC pointed out that the recent evaluation of tin by JECFA (26th Meeting) indicated that this level of tin could lead to excessive intake if the maximum level proposed for endorsement were regularly to be found in the food. He recommended that the question of the tin content of processed fruitsand vegetables and fruit juices should be reconsidered as a matter of priority.

115. The Committee noted these concerns and that a maximum level of 250 mg/kg for tin included in Codex Standards represented a level recommended for action by governments relation to food packed in tinned containers moving in international trade. In setting maximum levels for tin, Codex gave consideration to the needs of developing countries. The Committee also noted that JECFA had set a tolerable daily intake for tin which could now be used by countries for comparison with estimates of actual daily intakes of tin carried out by them as suggested by the Working Group on Food Additive Intake. The 200 mg/kg level of tin in food quoted in the report of the JECFA was noted to be a threshhold for manifestations of acute gastric irritation observed in some epidemiological studies and did not represent a recommendation by JECFA for a legal maximum level in food.

116. The Committee agreed that more information should be made available urgently to Codex on actual levels of tin in various canned foods and on the total intake of tin from dietary studies. It was also agreed that the question of setting maximum levels for contaminants and of interpreting compliance with maximum levels of consignments moving in international trade should be considered as a general problem under a later agenda item.

117. The decision to endorse the maximum tin level of 250 mg/kg on a temporary basis was finally made with reservations from Switzerland, Sweden, New Zealand, Finland, Belgium, UK, Netherlands, Denmark, the Federal Republic of Germany, Italy and Poland.

Canned Chestnuts and Chestnut Puree

118. The Committee postponed the endorsement of lead in this product noting that the proposed maximum levels was also being considered at Step 3 of the amendment procedure for a number of processed fruits and vegetables by CCPFV.

Fruit Juices

119. In endorsing the maximum lead level in the fruit juices the Committee noted the reservation of the Canadian delegation.

120. Several delegations raised the question of the inclusion of provisions for 'non-toxic' ingredients such as iron in fruit juices (Australian delegation) and in fats and oils (Norwegian delegation). It was agreed to request Commodity Committees to indicate the basis on which maximum levels for such contaminants were proposed.

121. The Committee, at its 15th Session, had postponed endorsement of the provision for lead at a maximum level of 1 mg/kg as a contaminant in composite and filled chocolate and has asked the Commodity Committee for more information on the source of lead. The Committee on Cocoa Products and Chocolate had agreed that, while a limit of 0.5 mg/kg was acceptable for cocoa butter, it was not sufficient for composite and filled chocolate which would contain up to 55% sugar, which itself might contain up to 0.5 mg/kg of lead.

122. This argument as a basis for a limit of 1 mg/kg was contested by several delegations. The limits of lead at 1 mg/kg in chocolate and 0.5 mg/kg in cocoa butter were finally endorsed by the Committee but with reservations from Thailand, Canada, Italy and the Federal Republic of Germany.

Cereals, Pulses and Legumes and the Tin Content of Pineapple Juice

123. The Committee had before it a room document prepared by the Secretariat on the subject. It reported that "The Committee on Cereals, Pulses and Legumes at its 3rd Session had noted that, although maximum levels for contaminants in cereals were desirable, there was no information at present available by which it could identify such contaminants and decided to leave the present general text unchanged." (Para 73, ALINORM 83/29).

124. The Secretariat recommended to the Committee to temporarily endorse the contaminant provision in these Cereal Standards and to urge the Codex Committee on Cereals, Pulses and Legumes to collect more information on the type of heavy metals involved and the actual levels of heavy metals found in cereals which could be reviewed by the Committee at a later date.

125. The Committee accepted this recommendation noting the comment of the Belgium delegation that the Joint FAO/WHO Food Contamination Monitoring Programme was a valuable source of data of the required sort.

126. The Committee temporarily endorsed the maximum level of 250 mg/kg for tin in pineapple juice on the understanding that the reservations noted above in the case of the fruit juices would apply.

Consideration of Lead Levels in Recommended Codex Standards for Sugars

127. The Committee had before it a room document prepared by the UK Secretariat for sugar on this subject (CX/FA 83/10-Part II-Add. III) following the request at earlier Sessions for more data. The document summarized the replies to the questionnaire received in response to Circular Letter CL 1982/36.

128. The Committee reached similar conclusions on the proposal for a Codex maximum level for lead as for tin. However, it noted that lead was a metal with cumulative action and that it may cause serious impairment of health even at small quantities especially with children. It, therefore, recommended that care should be exercised to ensure that levels of lead in food should be kept as low as possible and that these levels should be continuously monitored.

129. After considerable discussion the Committee decided not to recommend a change in the lead levels in the sugar standards nor to change the status of those endorsements. There were reservations from the delegations of the Federal Republic of Germany, Canada, Italy, Finland, Sweden, France and Denmark.

130. The Committee requested the Secretariat to elicit more information from the countries as to the technological feasibility for reducing the lead levels from the existing ones so that a maximum level lower than 1 mg/kg could be set.

THE GUIDE TO THE SAFE USE OF FOOD ADDITIVES

131. The Committee noted that the FAO/WHO Food Additives Data Bank system for Computerization of Data on Food Additives evaluated by JECFA launched jointly by FAO and WHO in 1981 is still in the experimental phase of development and will become operational soon. Data on all the food additives so far considered by JECFA amounting to about 500 substances, had been entered in the system and edited. The system now contains up-to-date (as at April 1982) information including chemical names, synonyms, functional classes, evaluation status or ADI, and references to specifications and toxicological monographs. The permitted use of additives in different food commodities, as endorsed by CCFA and included in standards adopted by the CAC are also given. The system allows for updating and for retrieval of information by substance, by class name and by functional use. The extension of the system is being looked into.

132. The databank will be published in several sections and will include for example an alphabetical list of additives,a detailed status of each food additive as given in page 2 of document CX/FA 83/2 and a list of compounds by functional class etc. Such a publication will employ a photo-processing system. A terminal would be located in the Food Policy and Nutrition Division, FAO, Rome, and this would enable FAO to quickly respond to the request from member governments and international organizations with information about food additive status. The data bank would be updated at the end of each JEFCA and Commission Session. It was hoped to release for circulation, the first publication of the databank by the end of 1983.

133. Some of the information presently contained in the Guide to Safe Use of Food Additives will not be published as part of the FAO/WHO Food Additive Data Bank System i.e. descriptive material, the general principles for the use of food additives, various categories of food additives (Lists A1, A2, B1,B2,C1 and C2) the status of Codex specifications, and some material presently appearing as headings such as definitions. The Joint FAO/WHO Food Standards Programme intends to have the above information published as a separate volume of the Codex Alimentarius. This publication in conjunction with information from the computerized Data Bank System will provide member governments with up-to-date information on the Codex position regarding the safe use of Food Additives. The Secretariat mentioned that some cost to user might be involved.

134. The Committee congratulated FAO for launching an exercise as above and felt that the computerized print-out of the food additive provisions in Codex Standards and the status of evaluation of the food additives by JECFA would be extremely useful information. Some delegates expressed an opinion that it would be advisable to issue it as a loose leaf publication. Opinion was also expressed that it would be advisable for FAO to publish all books related to food additives and their evaluation in a series separate from the Food and Nutrition Paper Series.

International Numbering Systems for Food Additives

135. The Committee had before it documents CX/FA 83/9-Add.2 (the report of the WG, Appendix VI, CX/FA-Add.2, and CX/FA 83/4-Add.1, Attachment 1 and Add. 1A (the revised comments)). In introducing the report of the Working Group on Class Names of Food Additives, the Chairman (Mr. L. Erwin, Australia) informed the Committee that the WG had considered the discussion which covered a range of numbering systems used around the world. These included the EEC system, and the modifications of Sweden and Norway, the system as in the Codex Guide to the Safe Use of Food Additives, the Brazilian system and various others used internationally for flavours, enzymes and colours.

136. In the WG, there was a general agreement that an international system of numbering of food additives for labelling purposes should be developed and that it should be based on the EEC system. It was noted that there would be some problems. For example, the WG agreed that the use of the prefix "E" would create difficulties in adapting the EEC system for international use. Retention of the prefix could create difficulties in international trade but on the other hand the prefix "E" had a meaning for consumers in the EEC.

137. The Committee noted that the observer from the EEC would take up this matter with EEC Member States in order to obtain their views on the possible deletion of the prefix "E" if the EEC system should be used as the basis of an international system. It also noted that the present EEC system did not cover all additives listed for use in Codex Standards.

138. The WG proposed to review a procedure for the inclusion of new numbers into an international list based on the EEC system before the next Session. In order to proceed, a discussion paper would need to be prepared outlining draft procedures and identifying specific difficulties. The Committee agreed with the proposals of the WG that such a paper be prepared by Mr. L. Erwin (Australia), Mr. R. Haigh (EEC), Dr. Rao Maturu (FAO Secretariat) and Dr. G. Kouthon (JECFA Secretariat) with help of the members of the WG.

139. The Committee agreed with the conclusion of the WG that the development of an international numbering system was an urgent and important area of work.

140. In relation to labelling of food additives by a numbering system, the Committee agreed that to facilitate international trade, governments should try to be consistent. It noted the comment of the observer of CIAA on behalf of the EEC food industry that the prefix "E" was not always well understood by the consumer. The Committee in general supported the conclusions and recommendations of the WG.

Class Names of Food Additives

141. The Committee had before it the report of the ad hoc Working Group on Class Names of Food Additives (CX/FA 83/9, Add. 2) Appendix VI and a working paper prepared by Australia (CX/FA 83/9-Add. 2a). The Chairman of the WG (Mr. Erwin, Australia) informed the Committee that the Codex Committee on Food Labelling had adopted the class names suggested by the Codex Committee on Food Additives. The WG justified the retention of the class name "enzymes" since enzymes which act as processing aids in many cases, are food additives in specific cases.

142. The WG informed the Committee that UK suggested a more extensive listing of class names that would provide more detailed information to the consumer. It also informed the Committee that the list of all Codex Food Additives covered by specifications recently put in the computer had a far more extensive list of class names but that these included functional classes which were not always meaningful to the consumer.

143. The Committee noted the view of the WG that the list of class names as contained in the revised draft General Standard for the Labelling of Prepackaged Foods (ALINORM 83/22, Appendix VI) is adequate for its purposes for the time being but that the WG also felt that it might work out a more extensive list of class names for the Committee's use. The Committee also noted that flavours may be qualified as "natural", "nature identical", "artificial" or in combination of these as appropriate but agreed with the WG's view that this classification although useful to experts might possibly be confusing to the consumer. Nevertheless it decided that it would be premature to take a decision on this matter since flavours and definitions for them were currently being considered by the Working Group on Flavours.

144. The Committee had some discussion on the proposed provisions. The delegation of Norway noted that the class names had to be used in all cases together with the specific name or recognized numerical identifications, according to the draft standard. The delegation of the UK felt that as the numbering system developed there would be a need for additional class names.

145. The delegation of Italy and the observer of AMFEP expressed reservation concerning the inclusion of enzymes in the list of class names because enzymes very seldom act as additives. The

observer of EEC informed the Committee that enzymes were not included in the EEC numbering system. The delegation of the Netherlands felt that enzymes should be declared by their specific name. The delegation of the USA felt that a system should first be developed and that a decision concerning deleting or adding class names should be postponed. The Secretariat expressed the opinion that not all additives are covered by class names in the Draft Standard for the Labelling of Prepackaged Foods. In the absence of a permitted class name the specific name has to be used because the draft standard only permits code numbers for food additives for which a class name has been included in the standard.

146. The delegate of France expressed reservation concerning the qualification of flavours by "nature identical" and the combination of the words "natural", "nature identical" and "artificial" as appropriate.

147. The observer of the EEC asked that para. 5 in CX/FA 83/9-Add. 2a should be deleted because this remark of the observer of the EEC related to something else.

148. The Secretary of the WHO noted that there were additives which are multi-functional. However, the ADI belongs not to the use of the additives as a specific category. It should be noted that the toxicological evaluation of a food additive carried out by JECFA is not necessarily linked only to one specific function or use in food. It might not however apply to its use or uses in applications other than in food.

149. The Committee thanked the ad hoc Working Group for its double task and agreed to its reinstatement with Mr. Erwin (Australia) as Chairman. The membership is Canada, UK, USA, New Zealand, Arab Republic of Egypt, Brazil, Italy, Sweden, Switzerland, Thailand, Netherlands, EEC, CIAA, AMFEP and IFGMA.

Codex List B

150. The Committee had before it the document CX/FA 83/2 Add. 1 (revision) listing food additives on Codex List B, updated following the 26th Meeting of JECFA (Appendix VII). No proposals were made by member governments and international organizations for additions to the list, at the session.

151. The Committee agreed with the suggestion of the representative from WHO to change the definition of Codex List B to read as list of food additives that contain those substances in which the member states and/or industry has shown interest and evaluation of which by the Joint FAO/WHO Expert Committee on Food Additives is still pending.

152. The Committee requested the Secretariat to prepare a paper on the "Philosophy behind the preparation on Codex List B" for discussion at the next Session and also solicit comments from governments and international organizations for their continued interest in the food additives listed in Codex List B and for additions if any.

Amendments to the International General Standard for Irradiated Foods and the Recommended International Code of Practice for the operation of Irradiation Facilities used for the treatment of foods

153. The Committee had before it revised versions of the General Standard for Irradiated Foods and of the Code of Practice for the Operation of Irradiation Facilities used for the Treatment of Foods (Appendix VI, ALINORM 83/12). It also had before it the report of the Working Group on Food Irradiation (CX/FA 83/14.Add. 1).

154. The report of the Working Group was introduced by Dr. J.P. Modderman (USA) Chairman of the Group. He indicated that comments on the revised drafts had been received from France, Federal Republic of Germany and the USA. In addition, comments previously received too late for consideration from Mexico had also been available. He gave an outline of the issues discussed by the Group, as recorded in the report of the Group given in Appendix VIII.

155. The Committee discussed the revised General Standard and the Recommendations of the Working Group for further changes.

Section 2.2

156. The delegation of Italy was of the opinion that the standard should also provide for a "maximum value of absorbed dose" since the "overall average absorbed dose" did not provide sufficient information.

Section 3 - Wholesomeness of Irradiated Foods

157. Several delegations were of the opinion that Section 3.1 contained statements concerning the safety of irradiated foods which could be taken for granted. Such statements were not appropriate for inclusion in a standard. The representative of WHO was of the opinion that reference to microbiological aspects should be more accurate by using the wording in the report of the Joint FAO/IAEA/WHO Expert Committee.

158. It was agreed that Section 3.1 should be included as a footnote to Section 2.2 giving also the relevant reference to the FAO/WHO/IAEA publication on Wholesomeness of Irradiated Foods. Section

3.1 was deleted and the title of the Section 3 changed to "Hygiene of Irradiated Foods".

159. The Committee discussed whether the Codex General Principles of Food Hygiene and Codes of Hygienic Practice should be attracted to the General Standard as mandatory provisions. The Working Group had proposed the use of the word "shall" rather than "should" in referring to the above Codex recommendations on food hygiene. The delegation of the USA strongly supported the recommendations of the Working Group. In its opinion there was a need for more binding provisions on food hygiene with irradiated foods. Other delegations were of the opinion that Codex Codes of Hygienic Practice, which were very detailed, should remain advisory for all foods. The Committee noted that, by requiring the mandatory application of the General Principles of Food Hygiene and of the Codes of Practice, the Committee was, in fact, recommending that for irradiated foods the appropriate Codex Principles and Codes concerning Food Hygiene should be subject to acceptance by Governments.

160. The Committee adopted the recommendation of the Working Group. The delegations of Norway, Finland, Thailand, UK, Sweden and Denmark reserved their position. It was also noted that the Working Group had recommended changing "should" to "shall" in further sections. The Committee accepted those changes and decided that this question related to Section 3 be brought specifically to the attention of the Commission.

Treatment of foods by chemicals and irradiation

161. The delegation of France proposed to include a provision prohibiting treatment of foods by chemicals either before or after irradiation. The Committee noted that the Working Group had considered this matter and had concluded that there was no reason for such a prohibition. The Committee decided not to introduce a provision such as suggested by France.

Section 4.1 - Conditions for Irradiation

162. The delegation of the Federal Republic of Germany proposed that there should be a requirement for the submission of all necessary information to the relevant national authority as a basis for a food by food authorization of the process, at least during the initial stages. The Committee noted that the Working Group had discussed this matter but had not accepted the proposal, since it considered that this was a matter entirely for governments.

Section 6 - Labelling

163. The delegation of Italy was of the opinion that all irradiated foods at all steps of the food chain should be labelled as having been irradiated indicating also the purpose of the irradiation. This included irradiated foods used as components in other foods.

164. The delegation of the Federal Republic of Germany was of the opinion that all labelling provisions for irradiated foods should be included in one standard and not, as is the case at present, partly in the General Standard for Irradiated Foods and partly in the General Standard for the Labelling of Prepackaged Foods.

Status of the Standard and the Code

165. The Committee agreed that, as it had considered two sets of Government comments on the Draft General Standard and Code (one at Step 3 and another at Step 6), the Draft General Standard for Irradiated Foods and the Draft Code of Practice on Irradiation Facilities included in Appendix IX to this report, should be advanced to Step 8 of the Procedure and the Commission be requested to adopt the standard and the Code at Step 8 of the Procedure.

Establishment of an ad hoc Working Group on Food Irradiation

166. The Committee thanked the Chairman of the Working Group, Dr. J. Modderman (USA) and the members of the group for their work and decided to re-establish the Working Group with the same membership as before plus IFGMA. The delegation of the USA indicated that, tentatively, it was willing to reassume Chairmanship of the Working Group.

CONSIDERATION OF FLAVOURS

167. The Chairman of the ad hoc Working Group on Flavours, Mr. J.P. Goddijn of the Netherlands, presented his WG's report CX/FA 83/6 (Room document).

General Requirements for Natural Flavours

168. Mr. Goddijn reminded the Committee that during its 15th Session it had asked the WG to elaborate specifications for natural flavourings. During its discussions on the matter the WG had considered the possibility of elaborating a Standard, but the idea was rejected by the majority of the members. The report of the Working Group contained an Annex "General Specifications for Natural Flavourings" to illustrate the sort of approach which might be followed. The Committee endorsed this approach in general terms. The FAO representative pointed out that confusion might arise by the use of the term "specification", since this might be associated with a specific JECFA activity. The Committee decided to use the description suggested by the UK delegation, namely "General Requirements for Natural Flavourings".

169. Mr. Goddijn pointed to difficulties in defining and translating terms and proposed that the "Definition" section in the General Requirements should be revised, using the existing IOFI multilingual terminology, before the next Session. There were various other revisions proposed both by Mr. Goddijn and by delegations and the Committee accepted the WG's proposal to prepare a new version for the next Session of the Committee.

Priority Setting of Flavouring Substances

170. The Committee noted the publication of the first volume of a series which contained quantitative data on volatile substances in food (sponsored by IOFI and issued by CIVO-INO). A second volume is expected by the end of 1983. Such data were considered essential for the estimation of the consumption ratios of individual flavouring substances. The consumption ratio number is a valuable tool in setting priorities. The Committee took note of this information, encouraged this work and solicited the participation and contribution of others. The representative for IOFI and FIVS agreed to provide any available data to the Working Group.

Articificial Flavouring Substances

171. Mr. Goddijn reported that the Working Group had discussed the artificial flavouring substances included in Codex List B of Food Additives (CX/FA 83/2, Add. 1). A suggestion to delete these substances from List B had not been supported: on the other hand the WG had accepted the offer of IOFI to update the list. The Committee noted these comments.

Inventory of Source Materials for Natural Flavours

172. The representative of FIVS suggested the preparation of an inventory of source materials for natural flavours. He offered to provide information and to prepare a list of existing inventories of such materials. After a discussion the Committee suggested that the list of the Council of Europe should be updated on the basis of further information received. Suggestions on how this might best be done and information should be directed to the ad hoc Working Group on Flavourings. An offer was made during the Session by the delegation of the USA to provide information. The Committee accepted this offer and asked to bring the information in front of the Working Group on Flavours.

Setting Up an Ad Hoc Working Group

173. The Committee thanked the Working Group for its work and decided to reinstate it under the Chairmanship of Mr. J.P. Goddijn. The membership of the Working Group is Austria, Belgium, Denmark, Egypt, France, the Federal Republic of Germany, Finland, Italy, Switzerland, Thailand, The Netherlands, United Kingdom, USA, Council of Europe, EEC, IOFI, FIVS, FAO, WHO and CIAA.

CONSIDERATION OF PROCESSING AIDS

174. The Committee had before it the report of the Working Group on Processing Aids (CX/FA 83/12 Add. 2), which is reproduced as Appendix X. In introducing the report, the Chairman of the Working Group (Mr. R. Ronk, USA) described the procedure followed in the preparation of the inventory list, explaining that interested parties could submit new substances for inclusion in the list. About 40-50 new substances had been submitted this year and will be included in a revised inventory. He also indicated that the definitions of food additives and contaminants were inclusive of the definition of processing aids. Therefore he suggested that the USA should redraft the inventory attempting to apply the definition of processing aids to each compound and including them in one of the four categories mentioned in para. 2 of the Working Group's report. The criteria used to decide upon the character of each substance will be included in the document. As the next step he envisaged that JECFA might evaluate all processing aids which leave significant residues. The Committee decided to circulate the updated inventory to all Codex Contact Points and the sub-divided inventory to the members of the Working Group soliciting their comments. The Committee agreed that this should be an open list.

175. The Chairman of the Working Group informed the Committee on the situation regarding 2-nitropropane. JECFA had recommended in its 25th report that this substance should not be used in food processing. There had been wide support for this point of view in the Codex Committee on Fats and Oils, however some of the delegations had felt that it should be referred back to JECFA, since only very low residues were involved. The WG had agreed with the deletion of this substance and had therefore, proposed a procedure for the removal of substances from the inventory list. The Committee agreed with this deletion and with the establishment of such a procedure and decided to list 2-nitropropane in List C (1) of the Guide to the Safe Use of Food Additives.

176. The Committee had some further discussion on the JECFA recommendation on 2-nitropropane. It was informed by JECFA Secretariat that evaluation was based on a risk analysis of the inhalation of the substance during its manufacture. It also informed the Committee that JECFA was not likely to reach a different conclusion in reconsidering the recommendation. The Chairman of the Working Group, however, felt it desirable to have a risk assessment from JECFA of the health significance of a residue level of 2-nitropropane in food. He also suggested that JECFA be requested to advise the Committee on specific questions of this sort if such advice was sought. The Committee agreed with this view and requested the Secretariat to seek JECFA's response on this issue.

177. The WG responding to a request from Sweden recommended the removal of asbestos from the inventory and proposed placing it on the Committee's priority list. This recommendation was supported by the delegations of France and the UK. The Secretariat of the JECFA informed the Committee that JECFA, at its 22nd Session, had confirmed its conclusions on asbestos made at the 18th Session that there was unequivocal evidence relating to ingestion of asbestos fibres to cancer and, therefore, had discouraged its use in food. The Committee, therefore, considered it premature to refer asbestos back to JECFA and requested the WG to collect information on the type(s) of asbestos used and other relevant data available.

178. The Chairman of the WG drew the Committee's attention to the view of the group that it required more information on the justification of the proposed changes in order to decide on a proposed draft revision of the carry-over principle. The Secretariat informed the Committee that it intended to re-draft the carry-over principle in order to make the text more suitable for inclusion in Vol. XIV of the Codex Alimentarius incorporating the decision of the 13th Session of the Commission. It did not intend to change the essentials of the principle. The Committee agreed that a re-draft should be made by the Secretariat and that it should be sent to the Working Group members for their comments prior to discussion at the next session.

Appointment of an Ad Hoc Working Group on Processing Aids

179. The Committee thanked the Chairman and decided to reinstate the Working Group under the Chairmanship of Mr. R. Ronk (USA). The membership of the Working Group is as follows: Australia, Austria, Belgium, Brazil, Denmark, France,Federal Republic of Germany, Italy, New Zealand, Netherlands, Spain, Switzerland, United Kingdom, USA, Thailand, AFCA, CIAA, IFGMA, AMFEP, CEFIC, ILSI, EEC.

Consideration of Food Grade Salt

180. The technological justification for the additives in salt and the draft standard for Food Grade Salt were discussed by a Working Group chaired by Dr. (Mrs.) M.A. Perinelli (Italy),the report of which CX/FA 83/13 Part 1 -Add. 1 (Room Document) was available to the Committee.

181. The Committee decided to discuss the standard in 3 parts i) Technological justification for the Additives in Salt and Endorsement ii) Methods of Analysis and iii) Standard.

TECHNOLOGICAL JUSTIFICATION FOR THE USE OF FOOD ADDITIVES IN FOOD GRADE SALT

182. The Committee had before it document CX/FA 83/13 which was introduced by Mrs. M.A. Perinelli, Chairman of the Working Group on Salt Standard.

183. The Committee was satisfied with the view of the Working Group that the provision of all the food additives which fell into 3 categories i) anticaking agents, ii) emulsifiers and iii) processing aids in the standard for Food Grade Salt was technologically justified. The provision for ammonium citrate, the inclusion of which could not be justified technologically was deleted from the list of food additives. Ferric ammonium citrate which acts as a crystal modifier was added to the existing list of food additives.

Endorsement of Food Additive Provisions in the Standard for Food Grade Salt

184. In introducing document CX/FA 83/10, Part 1-Add. 3, the Secretariat pointed out that the document included food additive provisions in the standard for food grade salt. The decisions of the Committee concerning the endorsement, temporary endorsement or postponement of the endorsement of food additive provisions are indicated in Appendix V of this report.

Anticaking Agents

185. The delegation of France expressed its wish for a lower level, 5 mg/kg, of ferrocyanides except for dendritic salt.

Emulsifiers

186. The delegations of Federal Republic of Germany and France expressed reservation concerning this additive provision.

187. The Committee decided to postpone endorsement of additives in the standard which had not been evaluated by JECFA. These food additives had been deleted from the standard since it had been advanced to Step 8.

Methods of Analysis and Sampling of Salt

188. The Committee had before it the report of the Working Group on Methods of Analysis and Sampling of Salt (CX/FA 83/13-Part II, Room Document). Dr. Mignon of CEES presented the report of the Working Group.

189. The Committee noted that the following methods for the determination of arsenic, lead, cadmium and mercury in salt had been the subject of collaborative studies by 19 laboratories. An assessment of the results of the collaborative study had shown that those methods were sensitive enough for the necessary determinations of the contaminants in salt.

ECSS/SC 311-1982:	Determination of Arsenic content Silver diethyldithiocarbamate photometric method
ECSS/SC 312-1982:	Determination of total mercury content Cold vapour atomic absorption spectrometric method
ECSS/SC 313-1982:	Determination of total lead content Flame atomic absorption spectrometric method
ECSS/SC 314-1982:	Determination of total cadmium content Flame atomic absorption spectrometric method

190. The delegation of the Federal Republic of Germany expressed reservation concerning the methods of analysis.

191. The Committee requested the Working Group to provide more specific details concerning the sampling methods for salt. The WG is seeking advice from the Codex Committee on Methods of Analysis and Sampling.

192. The Committee agreed to reinstate the ad hoc Working Group under the Chairmanship of Dr. Rocamora (Spain) with the participation of Austria, Brazil, Egypt, France, Greece, Italy, Japan, The Netherlands, Spain, Switzerland, Thailand, USA and the European Committee for the Study of Salt (CEES).

Consideration of the Draft Standard for Food Grade Salt

193. The Working Group on the Salt Standard analysed the government comments as contained in CX/FA 83/13-Parts 1 and 1a and prepared a new draft standard for Food Grade Salt.

194. The following modifications were made in the existing standard (ALINORM 83/12, Appendix III) which was at Step 7 of the Codex Procedure.

195. The WG agreed with Norway for the inclusion in the Scope, a categoric statement about the general character of the standard, which will not preclude the establishment of specific requirements necessary for either local reasons or for special food manufacturing and expanded the existing Scope by adding to the Scope section "subject to the provisions of this standard more specific requirements for special needs may be applied".

196. The Working Group agreed with Finland (ALINORM 83/12, para.178) that date marking may be needed in the case of iodized salt, because of slow evaporation (sublimation) of potassium iodide. Iodized salt, a special food salt, is, however, not fully covered by the general standard for Food Grade Salt. Food Grade Salt as such is quite stable, and the Working Group felt, that there would not be a need for any date marking.

197. Mexico and Thailand had wanted the sodium chloride content for sea salt to be reduced below the existing figure of 97% in the standard. Reduction of sodium chloride content below the existing figure of 97% in the standard would result in a possible increase in magnesium salts which makes the product more hygroscopic. Also increased levels of magnesium salts may pose health hazards. The Working Group did not change the existing figure of 97% for the content of sodium chloride in food grade salt.

198. The WG had lowered the existing provisions for cadmium from the existing 0.5 mg/kg level to 0.2 mg/kg. The action of the WG had been mainly based on health considerations and the results of analysis of only a few samples of salt which were available to the Working Group.

199. The Committee accepted all the changes proposed by the WG, except the provision for cadmium which had been lowered to 0.2 mg/kg. The Committee based its decision on the fact that the WG had not evaluated enough samples on the basis of which to assess whether cadmium in salt represented a health problem. The Committee suggested that more data should be collected on the cadmium content of salt from member governments as well as from the Joint FAO/WHO Food Monitoring Programme for a future review and reinstated the cadmium provision of 0.5 mg/kg in the standard.

200. France, Finland, Sweden, UK, Switzerland, Italy, Federal Republic of Germany, Greece and Austria reserved their position on the adoption of a provision of 0.5 mg/kg for cadmium in the standard. The UK also requested lower levels for lead and mercury.

201. UK queried that part of the Scope section which related to the non-applicability of the standard to salts from origins other than those mentioned in Section 2, namely salt which is a by-product of the chemical industries and expressed its reservation.

202. Thailand reserved its position concerning the adoption of 97% as the minimum sodium chloride content for sea salt.

203. The Committee agreed with the suggestion of the UK and made minor changes to the labelling section in Section 7.1.3 which referred to dendritic salt and to Japan's suggestion to include the

silver nitrate method (which is under study by the WG on Methods of Analysis and Sampling of Salt) as an alternative method for determination of halogèns in the section on Methods of Analysis and Sampling.

Status of the Draft Codex Standard for Salt

204. The revised Draft Codex Standard for Food Grade Salt attached as Appendix XI was advanced to Step 8 of the Codex Procedure.

205. UK, Thailand, Federal Republic of Germany and France expressed their reservation concerning the action of the Committee to advance the standard to Step 8.

206. The Committee thanked the ad hoc Working Group for the quality and quantity of its work and agreed to its reinstatement with Mrs. M.A. Perinelli (Italy) as Chairman. The membership is Austria, Brazil, Greece, USA, Switzerland, Japan and European Committee for the Study of Salt (CEES).

Consideration of the Working Group on Specifications

207. The Committee had before it the report of the ad hoc Working Group on Specifications (CX/FA 83/7 - Conference Room Document attached as Appendix XII). In introducing the report, the Chairman of the Working Group, Dr. J. Modderman (USA) informed the Committee that the Working Group had considered the JECFA 26th Report (WHO/TRS 683) in relation to safety aspects of the Expert Committee and Codex Specification. It also reviewed comments received from governments on JECFA specifications for identity and purity of food additives and contaminants in FAO Food and Nutrition Paper No. 19.

208. The Working Group noted the convergence of opinion between the Executive Committee, JECFA and the 15th Session of the CCFA on the problem of "minimum safety requirements". This opinion was expressed in para 6 of ALINORM 83/12, Appendix X and reads: "The Working Group stresses that food grade quality is achieved by compliance with the specifications as a whole and not merely with industrial 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".

209. The Working Group followed the same procedure as at the last Session of CCFA in assigning the specifications of document FAO Food and Nutrition Paper No. 19 to five categories. General comments were made on these specifications and are presented in the report of the Working Group.

210. The Working Group recommended 21 substances contained in Food and Nutrition Paper No. 19 for adoption by the Commission as advisory Codex specifications, 5 substances for adoption by the Commision after editorial corrections, and referred 30 substances back to JECFA for further consideration. In this latter group proposals for amendments were also provided in the reports of the Working Group. In addition, 8 substances were not reviewed for reasons given in the report and another group of 11 substances having tentative specifications were reviewed to a feasible extent.

211. The Working Group did not find it appropriate to consider all the specifications contained in Food and Nutrition Paper No. 25, which was published following JECFA 26th Session. The reasons for this decision are given in the report of the Working Group.

212. During the discussions the observer from AMFEP explained that the provision for a specification on glutaraldehyde in isomerized syrup was advisable since this was the relevant parameter for the use of glucose isomerase immobilized with glutaraldehyde. From the two possibilities to provide for a glutaraldehyde limit as indicated by the Working Group, he proposed to delete this criterion from all specifications for the immobilized enzymes under discussion and make it part of a separate standard on isomerized syrup. The representative from the UK explained the need for all criteria in a specification to apply to the substance being evaluated. The two options proposed in the report appeared to have equal weight but on practical grounds it would be preferable to apply the glutaraldehyde limit to the enzyme preparation rather than the final product for which there might not be a Codex Standard.

213. The representatives of Canada and the USA expressed their support for the above view. Furthermore the representative of the US informed the Committee that information was available in the US Code of Federal Regulations (CFR) on the removal of glutaraldehyde from the enzymes and offered to put this information at the disposal of the Working Group. The Committee did not feel it was competent to comment on the FAO Joint Secretary at JECFA's request for a recommendation to lower the level of glutaraldehyde from 5 to 1 mg/kg at this stage. This decision was also based on the information that the evaluation of glutaraldehyde would be made by JECFA at its 27th Session in April 1983. would be made by JECFA at its 27th Session in April 1983.

214. The representative of the Federal Republic of Germany inquired whether action was taken by FAO on the Committee's recommendations to publish JECFA's specifications in a loose leaf form (15th Session). The FAO Joint Secretary of JECFA informed the meeting that it was not possible to implement this recommendation for obvious reasons which may be related to financial as well as practical aspects. This recommendation as well as others will further be brought to the attention of his supervisors in FAO and necessary follow-up action will be taken to the extent feasible.

215. The observer from OFCA proposed the deletion of a reference to an Atomic Absorption Spectrophotometric method (AAS) as a replacement for the uranyl method which was deleted by the Working Group. This recommendation which was recommended by the Working Group referred to the specifications for sodium carboxymethylcellulose (see category III of the report of the Working Group). These changes were acceptable to the Committee since an alternative method was available. The deletion of reference to the AAS method was accepted by the Committee since an alternative method is available.

216. The Committee noted that the future task of the Working Group on Specifications would be to review JECFA specifications as contained in the FAO Food and Nutrition Paper Series.

217. The Chairman thanked Dr. Modderman for his valuable contribution to the work of the Working Group and Dr. Modderman expressed his appreciation to the WG and to Mrs. Meyland and Dr. Hofstetter for their assistance in preparing the report of the Working Group, which is included as Appendix XII.

218. 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, Finland, France, Federal Republic of Germany, Greece, Guyana, Italy, Switzerland, UK, Thailand, EEC, CEFIC , IFGMA, IPPA, IOFI and OFCA.

SAMPLING PLANS FOR THE DETERMINATION OF CONTAMINANTS IN FOOD

219. The Chairman reminded the Committee of the origin of its concern for this subject: guidance was needed on what was meant by the maximum contaminant level (MCL) and also on how to deal with its enforcement. The Committee had before it, for background information, document CX/FA 82/8, with the above title prepared by the USA and FAO from its last Session. CX/FA 82/8 had been the subject of a Circular Letter asking governments for comments. The replies had been collated and analysed by the USA in document CX/FA 83/8 (Room Document). This is reproduced as Appendix XIII with minor editorial changes.

220. Dr. Modderman of the USA introduced his paper informing the Committee that he had additional reactions from Canada and the Federal Republic of Germany following its preparation.

221. Key concerns were governments' reactions to the two recommendations of CX/FA 82/8 which are reproduced here for convenience:

1. The CCFA should define 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 consignment 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 suitable number of replicate analysis of the composite to assure precise results and provide for check analysis by a second enforcement official.

222. The reactions of those governments who had replied to the Circular Letter had been generally positive apart from strong French opposition to recommendation No. 1. However, there had been minor reservations from all of the Governments and organizations that commented. Dr. Modderman suggested that the Committee should revise the original recommendations on the basis of the comments received (this should involve a formal statement as to what is meant by the term maximum contaminant level); give general advice on sampling procedures and advise Commodity Committees that it would require detailed sampling plans in connection with any contaminant levels proposed in commodity standards.

223. The Committee was unable to accept these recommendations since discussion revealed them to be based on several fundamental issues on which there was no consensus.

224. There was also considerable discussion as to whether the definition in recommendation No. 1 might be understood to apply retroactively to commodity standards already endorsed by CCFA, an interpretation the commentators could not agree with. The view was expressed that the lot average should be compared by Governments to the ratios obtained by more extensive sampling which could establish "lot" variation. Neither view was adopted.

225. The Committee finally decided that its best course of action would be to formulate alternative approaches to determining compliance with MCL, based on the working paper and the comments received from governments and to offer these views to governments for their reactions. The Committee accepted Dr. Modderman's suggestion that a questionnaire might be suitable for this exercise and he agreed to assist the Secretariat in devising this approach.

CONSIDERATION OF PRIORITY AREAS FOR FOOD ADDITIVES AND CONTAMINANTS

226. The Committee had before it the report of the Working Group, CX/FA 83/11 Add. 1, and the Working Documents 83/11, Part 1 , (including Add. 1 and 2) and CX/FA 83/4 Add. 1. The report is

included as Appendix XIV.

227. In introducing this part of the report of the Working Group, its Chairman, Mr. L. Erwin (Australia), informed the Committee that the WG had considered packaging materials, environmental contaminants, residues of veterinary chemicals in foods, soft drinks and some other possible areas for future work. Many comments had been received.

Packaging Materials

228. The Committee had a detailed discussion on the possibilities of initiating work in this area. It recognized that this area of work is very wide and complex and might lack the expertise to deal with it adequately. It noted the objections of the EEC, New Zealand, CIAA, Belgium, The Netherlands, and the UK along these lines. The Committee also noted the recommendations of the Working Group that it should, as a first approach, restrict its involvement to only four specific substances of immediate public health concern; viz.: vinyl chloride, styrene, acrylonitrile and di-ethylhexylphthalate. In this report it noted the observation made by the Canadian delegation, that the Working Group was not proposing an assessment of all packaging materials as such, but only certain components as contaminants which could be evaluated by JECFA.

229. The Working Group's proposal was supported by the delegations of Thailand, Australia, Canada, Brazil and Norway. The WHO representative also expressed his satisfaction with the proposal and explained that in his view, the Committee had, by selecting four substances provided sufficient guidance to JECFA to start work in this important area. He felt, however, that the establishment of maximum levels should be a task for CCFA.

230. The Secretariat drew the attention of the Committee to the wide range of non-toxicological data required and doubted if it was able to provide much assistance in this field.

231. The Committee decided not to indicate packaging materials per se as a priority area for the present but to add the four substances mentioned to the priority list for JECFA's evaluation.

232. The Committee also decided to distribute a Circular Letter requesting data on:
- actual levels of these substances in foods due to migration from packaging materials
- the actual foods packaged in materials which may contain these substances
- the extent of use and nature of packaging materials which may contain these substances
- any other component of packaging materials which could be a publication concern. The delegation of Canada offered to collect and coordinate the information for the CCFA.

Environmental Contaminants

233. The recommendations of the WG were considered in conjunction with the discussion on paper on contaminants in food, approaches by governments and possible action by CCFA (Ref. para.246).

Residues of Veterinary Chemicals in Food

234. The Chairman of the Working Group informed the Committee that the WG had agreed that this was an area of great concern and that action was required. The WG however, was divided in its opinion as to how this work should be handled. Some members had felt that the CCFA should involve itself in the area, others however, had felt that the required expertise was so specific that another Committee should deal with it.

235. The Committee noted that the Committee on Meat Hygiene, which has adjourned sine die, had appointed a Working Group to provide advice on the matter at the next Commission meeting. The Working Group had recommended that a consultant be appointed to make a detailed study of this subject and to advise the Commission as to how the Codex Alimentarius should handle the problem.

236. The Committee proposed the following as possible terms of reference for such a consultant: "To advise the Codex Alimentarius Commission as to how to handle the question of residues of veterinary chemicals in foods. This may include the following: (a) To identify residues, in foods of animal origin, of veterinary chemicals such as chemo-therapeutic agents, antibiotics, growth promotants, and other feed additives that give rise to public health concern and/or cause difficulties in food trade; (b) to obtain from governments and other sources data on levels of such residues; (c) to obtain information about regulations and conditions for use of such veterinary chemicals; ways and means of administering such regulations; control mechanisms; data on possible "waiting periods" after application, etc. (d) to obtain information on which specific residues should be regulated in food; available toxicological data; and analytical methods being used".

237. The Committee agreed to put this proposal before the Commission and to offer to consider the consultant's report if the Commission wished.

Soft Drinks

238. The Chairman of the Working Group reminded the Committee that it had adopted an advisory list of food additives in soft drinks at its 11th Session. It had noted the work done by the Working Group on Food Additive Intake which indicated that in most cases the amounts of additives ingested

from soft drinks did not exceed 20% of the ADI. It has further noted that there was not much international trade in soft drinks and had therefore concluded that there was no need for setting maximum levels on food additives in soft drinks. The Committee agreed with this recommendation.

Other areas for possible future work

239. The Committee agreed with the Working Group's opinion that it was not possible for CCFA to get involved in the following areas, although they are considered as important areas for possible future work:

- drinking water treatment agents
- analysis of foods for food additive content
- sampling of foods for food additives and contaminants

Priority List of Food Additives and Contaminants

240. The Chairman of the Working Group informed the Committee that the WG had reviewed the priority list prepared at previous Sessions. The WG had noted that most of the substances presently on the list had been included on the agenda of the forthcoming 27th Session of JECFA. The group had retained only three substances. It had further included additives proposed at the current Session of the Committee, additives endorsed by CCFA but not yet evaluated by JECFA and additives proposed by the ad hoc Working Group on Salt. The Chairman of the Working Group further suggested to include the additives proposed by the ad hoc Working Group on Future Work.

241. There was some discussion on the inclusion of nitrogen, carbon dioxide and nitrous oxide on the list. The delegation of Canada informed the Committee that some members of the Working Group felt that JECFA's statements needed some clarification. After some discussion it was decided to delete nitrogen from the list but to retain carbon dioxide and nitrous oxide, requesting a clarification from JECFA. The observer from OFCA informed the Committee that carboxymethylcellulose could be deleted from the list, since this name was actually used as a synonym for NaCMC, which was already evaluated by JECFA.

242. The delegation of the USA agreed to specify for the next Session the salts of capric, caprylic, lauric and oleic acids actually used by the salt industry.

243. The Committee accepted to include at the request of the delegation of the USA for glucose isomerases from the following four micro-organisms:
- Streptomyces rubiginosus
- Actinoplanes missouriensis
- Streptomyces olivaceus
- Streptomyces olivochromogenes

An updated priority list is included as Annex I to Appendix XIV.

244. The Chairman thanked the members of the Working Group and its Chairman, Mr. Erwin, for their valuable contribution.

245. The Committee reinstated the Working Group with Mr. Erwin as its Chairman, noting its double task. The membership of the Working Group is as follows; Austria, Australia, Brazil, Canada, Federal Republic of Germany, Thailand, United Kingdom and USA.

CONTROL MEASURES OF INDUSTRIAL AND ENVIRONMENTAL CONTAMINANTS IN FOODS

246. The Committee had before it document CX/FA 83/18 on "Contaminants in Food: Approaches by Governments and Possible Actions by CCFA", prepared and presented by H.P. Mollenhauer, FAO Consultant.

247. According to the mandate outlined by CCFA at its 15th Session (ALINORM 83/12, para. 190), the main objectives of the paper are to (i) supply information on contaminants in food of public health concern and/or creating hindrance to trade (ii) describe Government control measures and (iii) advise the Committee on what its task in this field could be, taking into account, inter alia, available resources.

248. In Sections I and II, the paper contains a chronology of Codex actions on contaminants, leading up to a description of on-going programmes and activities on contaminants. As information to the Codex Alimentarius in general, detailed description is given of many of the relevant programmes of FAO, WHO and UNEP. These included JFCMP, IRPTC, and other subject programmes which register toxic chemicals, collect and compile national legislation and monitor the environment. The valuable results of such work could best be put to use by CCFA by establishing close links between those programmes, the CCFA and the Codex Secretariat. Section III deals with the second major objective of the paper, to take stock of the contaminant situation at the national level, especially concerning various control measures, including administrative and policy questions. Concern of governments over certain contaminants in food can be judged by the number of legislative provisions on permissible maximum levels for individual contaminants and, of course, from Government comments received. The results of a brief study are compiled in Annexes I and III of that paper.

249. Major environmental contaminants of concern appear to be mercury, lead, cadmium and aflatoxin. Reasons for contaminants causing difficulties to the trade are (i) losses through spoilage, (ii)

differing legal limits in various countries, and (iii) rather low legal limits which are difficult to maintain, to sample and to analyse some in the order of parts per trillion.

250. A further problem appears to be the fact, that legal limits are set for contaminants in raw materials, but not for follow-up products, considering that the carry-over principle applies to additives only and not to contaminants. Annex IIIe, p. 23,of CX/FA 83/18 is indicative of differing national legal limits for mercury in fish.

251. In Section IV the commonly used approaches to control measures concerning contaminants in food are described along with measures of environmental protection at the source.

252. Governments have either set legal limits which must be enforced, or guideline levels which indicate control measures should be instituted, but does not require removal of the product from trade.

253. The recommendations put forward in the Working Paper were discussed by the Committee in the light of the report of WG on Priorities and Future Work. The recommendations (a) government policy on setting limits for contaminants; (b) monitoring; (c) cooperation between CCFA and JFCMP; (d) flow of information between JFCMP and CCFA; (g) strengthening food control facilities in developing countries; (i) subsection (i):IRPTC to gather information on legislation of contaminants, were approved. They are reproduced as Appendix XV to this report.

254. The substance of recommendations (j) subsection (1) monitoring of "technical" contaminants by Commodity Committees and subsection (ii) establishment of a WG on Contaminants are taken up in the Report.

255. Major points in the discussion concerned the importance of close cooperation between various programmes and CCFA, as raised by Australia, and the need for assistance to developing countries in their efforts to participate in food control included monitoring of contaminants, as raised by Brazil. The numerous activities of FAO and WHO in this field were explained.

256. The Committee also discussed the choice of terms for a "guideline" level as different from a legal maximum level. The "guideline" level was to be the amount of contaminant in a food which would indicate that control measures should be taken to avoid the possibility that the contaminant level might rise to a level which could endanger public health. It was decided that the task to find a suitable term would depend on a suitable definition. Following the recommendation of the Working Group on Priorities and Future Work the Committee decided to establish a new Working Group on Contaminants. The following countries declared their interest in participating in the WG; Australia, Brazil, Belgium, Canada, Denmark, Finland, Federal Republic of Germany, The Netherlands, New Zealand, Norway, Thailand, USA and IFGMA. The Chairman of the WG would be chosen at a later date. Establishing a definition for "Guideline levels for Contaminants" was considered as an agenda item for a new WG on Contaminants which the Committee decided to set up. Further tasks for the WG should be the organizing of cooperation with various programmes according to recommendation. The WG was also charged with the subject of "application of the carry-over principle to contaminants".

257. Regarding document CX/FA 83/4 which had been dealt with under items 4(c) and 4(d), the Committee discussed the following items in connection with contaminants:

(i) With reference to a request from the Joint ECE/Codex Alimentarius Group of Experts on Fruit Juices(ALINORM 83/14, paras 48-58) the advice from CCFA would be that the Group should collect their data similar to the CCPFV, but should leave the monitoring of environmental contaminants such as Cd and Hg to the JFCMP.
Fruit Juice being one of the food items dealt with by JFCMP, information on levels of contaminants could be obtained from there. Concerning the collection of data on technical contaminants the Group could approach the Chairman of the former group on collecting such data by the CCPV (Mr. L. Erwin). Pertinent information on validity and comparability of data and on analytical quality assurance studies are contained in "Summary and assessment of data received from the FAO/WHO collaborating centres for food contamination monitoring". (page 9), issued by JFCMP, Uppsala, 1982; the JFCMP have also a questionnaire for collecting such data, that would be useful to the Group.

(ii) Concerning a statement by CCPFV (ALINORM 83/20) on Endorsement of Levels for Tin and Lead by CCFA, the Committee agreed with the procedure outlined in that statement.

258. The Chairman thanked Mr. Mollenhauer for the excellent paper that he had prepared on environmental contaminants for discussion at the Session.

DATE AND PLACE OF NEXT SESSION

259. The Committee noted that its next Session would take place in The Hague, from 10-16 April, 1984 pending approval of the Codex Alimentarius Commission.

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OPENING SPEECH AT THE 16TH SESSION OF THE CODEX COMMITTEE ON FOOD ADDITIVES

by

Mr. A. Ploeg, State Secretary
of the Netherlands Ministry of
Agriculture and Fisheries

The Hague, March 22nd 1983

Ladies and Gentlemen,

Those of you that were present at the previous - the 15th - session of the Codex Committee on Food Additives will remember that Mr. van Dinter, Secretary General of the Ministry of Agriculture, opened that session. That meeting, marking as it did a lustrum, offered an appropriate reason to look back at what had been accomplished and to look forward to future tasks.

I do not wish to repeat his words, but even so I should like to emphasize again the value the Government of the Netherlands, and I personally as State Secretary of the Ministry of Agriculture and Fisheries, attach to the work of your Committee.

To illustrate this I should like, instead of confining myself to remarks of a more general nature, to refer to some specific items on the agenda - it would be too time-consuming to treat them all. But making a selection certainly does not imply that the rest of your agenda should be considered to be of less importance ...

First a few words on: "Guidelines for the establishment of food additive provisions in commodity standards".

I do feel that the guidance your Committee provides for in relation to the use of food additives will help clarify where such use is - and where it is not - justified and useful. Scrutiny of the justification of such use is not restricted to the health aspects of the relevant additive (although of primary importance). Other quality-aspects should also be taken into consideration; for instance if the use of certain additives might pose the risk of consumer deception about the true quality of the product or serve to cover up the lack of "Good Manufacturing Practice". All of us agree that additives do perform important functions in food, but questions such as I have mentioned - and were raised by your Committee - should be dealt with.

Secondly: "The irradiation of foods".

In recent years we have seen considerable progress in this process which now seems at the brink of acquiring a much broader significance in food preservation - including such foods which might otherwise be lost by decay. I do not have to stress the need to prevent such loss in our world. The standard your Committee is developing - and has nearly completed - clearly defines how this method can be applied safely and successfully. I am guilty of no over-estimation when I say that this standard will be used widely in national and international food regulations.

Under "Future work" I discovered the attention you are - among other subjects - going to devote to "Residues in food of chemotherapeutic agents, anaboles, antibiotics and possible metabolites in animal husbandry and in veterinary medicine". This is an activity which, in my view, Codex Alimentarius should certainly embark upon. International harmonisation of regulations on these residues is urgently needed: to protect the consumer and to prevent barriers in international trade. On the other hand the complexity of the matter necessitates a careful approach for which, I feel, you are eminently suited.

The last item I want to touch upon briefly is "Industrial and Environmental Contaminants in Food". In many parts of the world food production has problems with such - unintentional but often harmful - contamination. I do not want to anticipate your discussions on this subject. But I feel your conclusions on how to tackle this problem will be urgently needed in the near future - and it is a good idea to start your discussion on the basis of the thorough report prepared by the FAO consultant.

Items such as those just mentioned, underline the importance of the work of your Committee - and of WHO/FAO Codex Alimentarius in general, as the highest international platform for food standards, including safety aspects. Its influence for the benefit of national and international legislation, in protecting the consumer and promoting free trade, can hardly be over-emphasized and goes far beyond the formal acceptance of Codex Standards by Governments.

Both aspects have, I repeat, the full support of the Government of the Netherlands. We are proud therefore to host your Committee as well as that on Pesticide Residues, now and in the future.

Your attendance - in growing numbers in spite of economic recession and budgetary problems in many countries - indicates that we share the same opinion on the need for your work here.

Well, this is enough for Item 1 on the Agenda; I wish you good luck with the remaining 19 items! Have a pleasant and successful stay in the Hague!

INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY

The membership of the International Programme on Chemical Safety (IPCS) has substantially increased since July 1980 when the first session of the Programme Advisory Committee (PAC) met.

There are today 26 Member States which contribute and actively collaborate with the IPCS activities. These are: Australia, Belgium, Brazil, Bulgaria, Canada, Czechoslovakia, Denmark, Federal Republic of Germany, Finland, France, India, Israel, Italy, Japan, Mexico, Netherlands, New Zealand, Norway, Sri Lanka, Sweden, Switzerland, Thailand, UK, USA, USSR, Venezuela.

The concerns voiced by this Committee regarding the terms of reference of JECFA being changed as a result of the integration of the JECFA Technical Secretariat into IPCS, were mainly due to the difficulty in properly distinguishing between managerial shifts and the charter of JECFA as the Advisory Body to the Codex Alimentarius Commission in all scientific matters concerning food additives as defined by the Second and Third Joint FAO/WHO Conferences on Food Additives and Contaminants. Today, almost five years since this integration, it can be clearly stated that not only has IPCS respected the character of JECFA, but has also given support to the implementation of the recommendations made by the Third Joint FAO/WHO Conference on Food Additives and Contaminants with a view to extending the terms of reference of JECFA to deal with food contaminants.

With regard to the JECFA/CCFA system for priority selection of compounds for evaluation the representative of IPCS noted that in the light of the JECFA tradition, the JECFA/CCFA system for priority selection has been a system which has worked well in the past, and the Director-Generals of WHO and FAO have always given serious consideration to the recommendations of the CCFA for priority selection when approving the agenda for JECFA. The last five reports of JECFA demonstrate to which extent this statistical approach has been respected.

This Committee has repeatedly expressed the desire of seeing JECFA strengthened. The representative of IPCS explained that the strengthening of JECFA has far-reaching implications which could not be comprehensively dealt with here, since FAO should be brought into the picture. He therefore had limited his presentation to the efforts made and being made by the IPCS in this area, and would like to call your attention to (1) the numbers of temporary advisers servicing the JECFA Committee in 1981 and 82: 9 in 1981 and 12 in 1982; (2) the number of compounds examined for toxicological evaluation: 46 in 1981 and 48 in 1982 (88 if we consider the separate compounds under the class of phosphates, polyphosphates and modified starches).

The representative of the IPCS explained that the activities related to JECFA on the WHO side may be defined as having three working levels: a) the level of international experts, b) the level of Temporary Advisors and c) the level of the WHO Secretariat of JECFA, and he informed the Committee that no changes have been envisaged at the first level, either in terms of organization or budget. At this level, the IPCS has made sure that provisions have been made to ensure the inclusion of JECFA in the WHO Regular Budget for 1984-85. This has been done and these provisions have been approved by the WHO Executive Board which met in January 1983. As far as the second level was concerned some restructuring and improvements were needed to overcome the financial and organizational constraints of the past which were the main difficulty in finding scientists willing to perform the task of summarizing toxicological data without remuneration as outlined above. The WHO Secretariat of JECFA, taking advantage of the flexibility of IPCS, was able to accept offers from several national government institutions to support the WHO input to JECFA and a plan of action was formulated.

Presently, the following national institutions have agreed to collaborate with WHO in the preparatory activities of JECFA:

Food Directorate, Department of National Health and Welfare, Ottawa, Canada;
National Institute of Health, Rome, Italy;
National Institute of Hygienic Sciences, Tokyo, Japan;

Department of Health and Social Security, Division of Toxicology, Environmental Pollution and Prevention, London, England; and
Food and Drug Administration, Washington, DC, USA.
Other countries, such as Australia, Brazil, Denmark, Federal Republic of Germany, Israel and The Netherlands have expressed the desire to enter into such an agreement in the near future.
This valuable contribution from national institutions represents the most promising aspect for strengthening this second operational level of JECFA.

The representative of IPCS explained that the strengthening of the third level namely the WHO Secretariat of JECFA still requires careful study as the workload at WHO incurred by JECFA has grown in inverse proportion to the financial support available. The participation of organizations or associations which have expressed the desire to become more involved in the organizational work (preparatory, follow-up, distribution of JECFA documents, etc.) on the WHO's side, by contributing manpower and financial support could be profitable taken up at this level by IPCS in its work in supporting JECFA in order to overcome the present constraints and to ensure its role in the JECFA/CCFA system. He further stated that one of the most pressing problems apart from the shortage of manpower, facing the WHO Secretariat of JECFA is the timely production and the majority of the distribution of documents resulting from each JECFA meeting, and steps were presently taken by the IPCS to seek new ways and means to reach satisfactory solutions. He informed the Committee that since 1981, the IPCS has taken on the responsibility of issuing a short information document after each JECFA meeting, including the summary and conclusions of the meeting for the use of national food regulatory officers and industrial concerns interested in pursuing the further toxicological work indicated by JECFA (and JMPR). It was hoped that this fast dissemination which will continue in the future of JECFA (and JMPR) information,will prove useful.

ALINORM 83/12A
APPENDIX IV

GUIDANCE TO CODEX COMMITTEE CONCERNING THE ESTABLISHMENT OF PROVISIONS FOR FOOD ADDITIVES

1. In providing for the use of food additives in Codex Standards, Codex Committees should strictly follow the General Principles for the Use of Food Additives (see Annex 2) in order to ensure that the interest of all consumers are safeguarded both from a point of view of the protection of their health and of ensuring that Good Manufacturing Practices are followed. The General Principles should be available to Codex Committees at the time of establishing or endorsing provisions for food additives, as appropriate.

2. In setting or endorsing maximum levels for food additives, para 13(b) of the Guidelines to Codex Committees concerning food additives included in the Procedural Manual of the Codex Alimentarius Commission (page 69, 5th Edition) should be followed. Full explanation should be provided of any departure from the above guidelines governing the setting of maximum levels for food additives or their limitation by GMP (see Annex 1), to the Codex Committee on Food Additives.

3. Maximum levels for food additives should, as far as possible, be set on the final product, i.e. on the product covered by the draft Codex Standard. Departure, from this practice, e.g. the setting "maximum levels for use", should be explained to the Codex Committee on Food Additives.

4. Provisions for food additives should be drafted clearly so as to leave no doubt as to their exact meaning, particularly with regard to the identity of the additive and the maximum levels set and whether these apply to the use of the additive singly or in combination.

5. The use of each additive or functional group of additives should be justified by providing a concise explanation of the technological functions of and need for the additive(s) and of the consequence if the additive provided for, were not to be endorsed. Where colours and flavours are needed to make good losses arising from processing, the Commodity Committee should so indicate. In providing for food additives and in justifying their use, Codex Committees should indicate where these have been included to meet the special manufacturing needs or storage conditions in developing countries.

ANNEX I

DEFINITION OF GOOD MANUFACTURING PRACTICE IN RELATION TO THE USE OF FOOD ADDITIVES

Good Manufacturing Practice means that:

(a) the quantity of the additive added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritional or other technical effect in food;
(b) the quantity of the additive that becomes a component of food as a result of its use in the manufacturing, processing or packaging of a food and which is not intended to accomplish any physical, or other technological effect in the food itself, is reduced to the extent reasonably possible;
(c) the additive is of appropriate food grade quality and is prepared and handled in the same way as a food ingredient.

ANNEX 2

GENERAL PRINCIPLES FOR THE USE OF FOOD ADDITIVES

1. All food additives, whether actually in use or being proposed for use, should have been or should be subjected to appropriate toxicological testing and evaluation. This evaluation should take into account among other things, any cumulative, synergistic or potentiating effects of their use.

2. Only those food additives should be endorsed, which so far as can be judged on the evidence presently available, present no hazard to the health of the consumer at the levels of use proposed.

3. All food additives should be kept under continuous observation and should be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information.

4. Food additives should at all times conform with an approved specification, e.g. the Specifications of Identity and Purity recommended by the Codex Alimentarius Commission.

5. The use of food additives is justified only where they serve one or more of the purposes set out from (a) to (d) and only where these purposes cannot be achieved by other means which are economically and technologically practicable and do not present a hazard to the health of the consumer:

(a) to preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified in the circumstances dealt with in subparagraph (b) and also in other circumstances where the food does not constitute a significant item in a normal diet;
(b) to provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;
(c) to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not so change the nature, substance or quality of the food as to deceive the consumer;

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

6. Approval or temporary approval for the inclusion of a food additive in an advisory list or in a food standard should:

(a) as far as possible be limited to specific foods for specific purposes and under specific conditions;
(b) be at the lowest level of use necessary to achieve the desired effect;
(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 those groups.

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 16th 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

I FRUITS AND VEGETABLES

Draft Standard for Canned Chestnuts and Canned Chestnut Puree

(ALINORM 83/20, Appendix VIII)

FOOD ADDITIVES	Maximum level in the final product	Paragraph	Status of Endorsement
Chelating Agent			
Sodium polyphosphate	Limited by Good Manufacturing Practice	81	EP[1]
Firming Agent			
Alum	Limited by Good Manufacturing Practice		EP[2]
Antioxidants			
L-Ascorbic acid) Sodium ascorbate)	400 mg/kg expressed as ascorbic acid, singly or in combination	82	E
Acidifying Agents			
Citric acid) Malic acid) L-Tartaric acid)	Limited by Good Manufacturing Practice		E E EP[1]
Bleaching Agent			
Sulphur dioxide	30 mg/kg, calculated as SO_2		E
Natural Colouring Agents			
Tumeric (CI 75300)) Crocin (CI 75100)) Carthamus Yellow (CI75140)	Limited by Good Manufacturing Practice	83	EP[1] EP[2] EP[2]
Natural Flavours			
Extract of Vanilla Vanillin	Limited by Good Manufacturing Practice	84	TE E
Thickening Agents			
Pectin and Amidated Pectin	10 g/kg, singly or in combination		E

1 Maximum level should be set since ADI exists

2 Has not been evaluated by JECFA

II FRUIT JUICES

Draft Standard for Guava Nectar preserved exclusively by physical means

(ALINORM 83/14, Appendix III)

FOOD ADDITIVE	Maximum level in the final product	Paragraph	Status of Endorsement
Citric Acid	Limited by GMP	85	E
Malic Acid	Limited by GMP	85	E

Draft Standard for Mango Juice preserved exclusively by physical means

(ALINORM 83/14, Appendix IV)

Citric Acid	Limited by GMP	85	E
Malic Acid	Limited by GMP	85	E

Draft Standard for Pulpy Mango Nectar preserved exclusively by physical means

(ALINORM 83/14, Appendix V)

Citric Acid	Limited by GMP	85	E
Malic Acid	Limited by GMP	85	E

III VEGETABLE PROTEINS

Draft Standard for Wheat Gluten

(ALINORM 83/30, Appendix V)

	Paragraph	Status of Endorsement
May contain those processing aids necessary for the efficient manufacture of gluten	86	EP[1]

IV FATS AND OILS

Draft Standard for /Vanaspati /Vegetable Fat Mixture/,

(ALINORM 83/17, Appendix IV)

Draft Standard for /Mixed Vanaspati /Substitute Ghee/,

(ALINORM 83/17, Appendix V)

FOOD ADDITIVE	Maximum Level in the final product	Paragraph	Status of Endorsement
Beta Carotene	10 mg/kg	87	E[3]
Annatto extracts	Limited by GMP		EP[2]
Curcumin	Limited by GMP		EP[2]
Turmeric	Limited by GMP		EP[2]
Canthaxanthine	Limited by GMP		EP[2]
Beta-apo-8' carotenol	Limited by GMP		EP[2]
Methyl and ethyl esters of beta-apo-8' carotenoic acid	Limited by GMP		EP[2]

1 CCFA has not yet decided on its approach towards the regulatory of processing and therefore considers it premature to decide on endorsement proposals. However CCFA is highly interested in receiving information from the Commodity Committees on the processing aids involved

2 A maximum level should be set since an ADI exists

3 CCFA proposes a level of 10 mg/kg

FATS AND OILS (cont.)

FOOD ADDITIVE	Maximum levels in the final product	Paragraph	Status of Endorsement
Propyl gallate) Octyl gallate) Dodecyl gallate)	100 mg/kg individually or in combination		E
Butylated hydroxy-toluene) Butylated hydroxy-anisole) Tertiary butyl hydroquinone)	200 mg/kg individually or in combination		TE
Any combination of gallates with BHA or BHT and/or TBHQ	200 mg/kg but gallates not to exceed 100 mg/kg		
Natural and synthetic tocopherols	Limited by GMP	88	E[1]
Dilauryl thiodipropionate	200 mg/kg	89	E
Ascorbyl palmitate) Ascorbyl stearate)	500 mg/kg singly or in combination		E
Citric acid and sodium citrate	Limited by GMP		E
Isopropyl citrate) mixture) Phosphoric acid) Monoglyceride citrate)	100 mg/kg singly or in combination		E
Dimethyl polysiloxane) singly or in combination with silicondioxide)	10 mg/kg	90	E[2]

1 ... proposes a level of 200ppm

2 Considered to be a processing aid

FATS AND OILS (cont.)

FOOD ADDITIVE	Maximum levels in the final product	Paragraph	Status of Endorsement
Natural flavours and flavouring substances and nature-identical flavouring substances as defined for the purpose of Codex Alimentarius	Limited by GMP		E

Draft Standard for Minarine (ALINORM 81/17, Appendix III) and Fat Spreads/Spreadable Table Fats (ALINORM 83/17, Appendix III)

Xanthan gum	5g/kg	singly or in combination	91	E
Polyglycerol esters of Interesterified ricinoleic acid	5 g/kg	singly or in combination	92	E
	Maximum level in the fat			
Tertiary Butyl hydroquinone	100mg/kg	singly or in combination with other oxidants	93	E

Draft Standard for Fat Spreads/Spreadable Table Fats (Alinorm 83/17, Appendix III)

Calciumdisodium EDTA	100 mg/kg	107-109	E

V DRAFT STANDARD FOR FOOD GRADE SALT

ALINORM 83/12 APPENDIX III

FOOD ADDITIVE	Maximum Level in the final product	Paragraph	Status of Endorsement
Calcium Carbonate Magnesium Carbonate Magnesium Oxide Tricalcium Phosphate Silicon Dioxide, Amorphous Calcium Silicate Magnesium Silicate Sodium Alumino Silicate Sodium Calcium Alumino Silicate Aluminium, Calcium, Magnesium Potassium or Sodium Salts of Myristic Acid, Palmitic Acid or Stearic Acid	20 g/kg singly or in combination		E
Calcium, Potassium or Sodium Salts of Ferrocyanides	10 mg/kg (20 mg/kg in Dendritic Salt)		E
Polisorbate (80)	10mg/kg		E
Dimethylpolysiloxane	10 mg/kg		E

VI Draft Standard for Vinegar

(ALINORM 83/19, Appendix II)

	Maximum Level in the Final Product		
Sulphur dioxide	70 mg/kg	94	E
L-Ascorbic Acid	400 mg/kg		E
Caramel Colour (Ammonium Sulphite Process)	1 g/kg	95	TE
Caramel Colour (Ammonia Process)	1 g/kg	95, 96	EP[1]
Natural Flavouring Substances	Limited by GMP	97	TE

1 Has not been evaluated by JECFA

VII CEREALS, PULSES AND LEGUMES

Draft Standard for Wheat Flour

ALINORM 83/29 Appendix II

Food Additive	Maximum Level of Use	Paragraph	Status of Endorsement
Bleaching Agents			
Benzoyl peroxide	100 mg/kg	99	EP[1 2]
Chlorine dioxide	30 mg/kg	99	EP[1]
Chlorine	2500 mg/kg	99	EP[1 2]
Enzymes			
Fungal amylase	GMP	100	EP[3]
Suitable proteolytic enzymes	GMP	100	EP[3]
Flour Improvers			
L-ascorbic acid	200 mg/kg	101	E
Azodicarbonamide	45 mg/kg	102	EP[4]
Potassium bromate	50 mg/kg	~~103~~ 95	EP[2 4]
L-cysteine hydroehloride	90 mg/kg	101	E
Sulphur dioxide	200 mg/kg	104	E
Mono-calcium phosphate	2500 mg/kg	105	EP[4]

1 Many delegations were opposed to the use of bleaching agents
2 The proposed maximum level of use exceeds the Usage level recommended by JECFA
3 Information on the origin of teh enzyme is absent
4 Many delegations were opposed to the use of these flour improvers

VIII MILK AND MILK PRODUCTS

	Paragraph	Status of Endorsement
Extra Hard Grating Cheese (Standard C 35) and Processed Cheese Standards A-8		
Provision of sorbic acid or its sodium or potassium salts, maximum 1,000 mg/kg calculated as sorbic acid in the final product	112	E
Processed Cheese, Standards A-8		
Provision of Propionic acid and its sodium and calcium salts, maximum 3,000 mg/kg calculated as propionic acid in the final product	113	E
Provision of Nisin, maximum 12.5 mg/kg	114	E
Provision of colours		
Annatto B-Carotene, maximum 600 mg/kg	115	EP[1]
Chlorophyll including Copper Chlorophyll) Oleoresin of Paprika) Riboflavin) Curcumin)		E
Blue veined cheese (C-32) and Extra Hard Grating Cheese (C-35) Provision of Chlorophyll Copper Complex maximum 15 mg per kg		E
Provolone Cheese (C-15)		
Provision of hexamethylene tetramine, maximum 25 mg/kg expressed as formaldehyde in the final product	117	EP

1 Pending clarification on the maximum level in the cheese

Change in status of endorsement of food additives resulting from JECFA evaluation

Carob bean gum (Locust bean gum)

Commodity	Maximal Level of Use	Earlier Status	Present Status of Endorsement
Processed cheese products	8g/kg singly or in combination with other thickeners	TE	E
Pickled cucumbers	Limited by GMP	TE	E
Canned carrots	10g/kg singly or in combination with other thickeners	TE	E
Cream cheese	5g/kg singly or in combination with other thickeners	TE	E
Minarine	10g/kg singly or in combination with other thickeners	TE	E
Canned Baby foods	2g/kg of the ready to eat product	TE	E

Pectin (Amidated and Non-Amidated)

Commodity	Maximal Level of Use	Earlier Status	Present Status of Endorsement
Processed cheese products	8g/kg singly or in combination with other thickeners	TE	E
Minarine	10g/kg singly or in combination with other thickeners	TE	E
Canned mushrooms) Canned asparagus) Canned green peas)	10g/kg singly or in combination with other thickeners when the commodities contain butter or other fats or oils	TE	E
Canned sardines and sardine type products	20g/kg, packing medium, singly or in combination: agar, modified starches, carageenan, guar gum, carob bean gum, alginic acid and its salts	TE	E
Canned mackeral or Jack mackeral	20g/kg singly or in combination with other permissible thickeners or jellifying agents	TE	E

Dodecylgallate, Octylgallate and Propygallate

Commodity	Maximal Level of Use	Earlier Status	Present Status of Endorsement
Edible fats and oils Edible palm oil Edible palm kernel oil Edible grape seed oil Edible coconut oil Edible babassu oil Low Erucic acid rape seed oil Minarine Margarine Butter oil and anhydrous milk fat not intended for direct human consumption nor for use in recombined milk or recombined milk products	100mg/kg of fat singly or in combination	TE	E

Fast Green FCF

Commodity	Maximal Level of Use	Earlier Status	Present Status of Endorsement
Edible ices	100 mg/kg	E	TE
Canned mature processed peas	200mg/kg singly or in combination with other colours	E	TE
Canned apple sauce			
Canned peas (in speciality packs)			
Jams (Fruit preserves) and jellies			
Citrus marmalade (in lime marmalade only)	100 mg/kg singly or in combination with tartrazine	E	TE
Pickled cucumbers	300mg/kg singly or in combination with other colours.	E	TE

ENDORSEMENT OF MAXIMUM LEVELS FOR CONTAMINANTS IN CODEX COMMODITY STANDARDS

	Committee	Session	Document
I	Processed Fruits and Vegetables	15th	ALINORM 83/20
II	Fruit Juices	15th	ALINORM 83/14
III	Fats and Oils	12th	ALINORM 83/17
IV	Cocoa Products and chocolate	15th	ALINORM 83/10
V	Cereals, Pulses and Legumes	3rd	ALINORM 83/29

I PROCESSED FRUITS AND VEGETABLES

DRAFT STANDARD FOR CANNED CHESTNUTS AND CANNED CHESTNUT PUREE
(ALINORM 83/20, Appendix VIII)

Contaminant	Maximum Level	Paragraph	Status of Endorsement
Tin	250 mg/kg	121 -125	TE
Lead	1 mg/kg	126, 127	EP

II FRUIT JUICES

DRAFT STANDARD FOR GUAVA NECTAR PRESERVED EXCLUSIVELY BY PHYSICAL MEANS
(ALINORM 83/14, Appendix III)

Contaminant	Maximum Level	Paragraph	Status of Endorsement
Arsenic	0.2 mg/kg		E
Lead	0.3 mg/kg		E
Copper	5.0 mg/kg		E
Zinc	5.0 mg/kg		E
Iron	15.0 mg/kg	128	E
Tin	250.0 mg/kg		TE
Sum of Copper, Zinc and Iron	20.0 mg/kg		E
Sulphur Dioxide	10.0 mg/kg		E

(Levels proposed by the Commodity Committee were similar to those endorsed for other juices)

FRUIT JUICES (cont.)

DRAFT STANDARD FOR MANGO JUICE PRESERVED EXCLUSIVELY BY PHYSICAL MEANS
(ALINORM 83/14, Appendix IV)

Contaminant	Maximum Level	Paragraph	Status of Endorsement
Arsenic	0.2 mg/kg		E
Lead	0.3 mg/kg		E
Copper	5.0 mg/kg		E
Zinc	5.0 mg/kg		E
Iron	15.0 mg/kg		E
Tin	250.0 mg/kg		TE
Sum of Copper, Zinc and Iron	20.0 mg/kg		E
Sulphur Dioxide	10.0 mg/kg		E

(Levels proposed by the Commodity Committee were similar to those endorsed for other juices)

DRAFT STANDARD FOR PULPY MANGO NECTAR PRESERVED EXCLUSIVELY BY PHYSICAL MEANS
(ALINORM 83/14, Appendix V)

Contaminant	Maximum Level	Paragraph	Status of Endorsement
Arsenic	0.2 mg/kg		E
Lead	0.3 mg/kg		E
Copper	5.0 mg/kg		E
Zinc	5.0 mg/kg		E
Iron	15.0 mg/kg		E
Tin	250.0 mg/kg		TE
Sum of Copper, Zinc and Iron	20.0 mg/kg		E
Sulphur Dioxide	10.0 mg/kg		E

(Levels proposed by the Commodity Committee were similar to those endorsed for other juices)

DRAFT STANDARD FOR PINEAPPLE JUICE

tin	250.0 mg/kg	134	TE

III FATS AND OILS

DRAFT STANDARD FOR /VANASPATI /VEGETABLE FAT MIXTURE/ (ALINORM 83/17, Appendix IV)

DRAFT STANDARD FOR /MIXED VANASPATI /SUBSTITUTE GHEE/ (ALINORM 83/17, Appendix V)

Contaminant	Maximum Level	Paragraph	Status of Endorsement
Matter Volatile at 105°C	0.2% m/m		E
Insoluble impurities	0.05% m/m		E
Soap content	0.005% m/m		E
Iron	1.5 mg/kg		E
Copper	0.1 mg/kg		E
Lead	0.1 mg/kg		E
Arsenic	0.1 mg/kg		E

(Levels proposed by the Commodity Committee were similar to those endorsed for other fats)

IV Cocoa Products and Chocolate

Draft Standard for Composite and Filled Chocolate (ALINORM 83/10 Appendix III)

Contaminant	Maximum Level		Paragraph	Status of Endorsement
	Chocolate	Cocoa Butter		
Lead	1 mg/kg	0.5 mg/kg	129-130	E

V Cereals, Pulses and Legumes ALINORM 83/29

Wheat flour, Maize, Whole maize meal, Degermed maize meal and Maize grits shall be free from heavy metals in amounts which may represent a hazard to health.

131-133 E

REPORT OF THE AD-HOC WORKING GROUP ON CLASS NAMES OF FOOD ADDITIVES

1. The Working Group convened on 21st March 1983 and representatives from the following countries attended: Australia, Brazil, Canada, Fed. Rep. of Germany, New Zealand, Netherlands, Switzerland, Thailand, United Kingdom and USA. Observers from Asociación Española de Aditivos Alimentarios (AFCA), Confédération des Industries Agro-Alimentaires de la CEE (CIAA), Grocery Manufacturers of America, the EEC Commission and FAO also participated. Mr. Laurie Erwin (Australia) acted as Chairman and Dr. G.D. Kouthon (FAO) was the Rapporteur.

Class Names

2. The Working Group reviewed the working paper on Class Names (CX/FA 83/9-Add. 2a). Particular attention was given to the decisions taken by the 16th Session (May 1982) of the Codex Committee on Food Labelling in regard to the declaration of food additives in food labelling. The class names proposed for labelling purposes as given in the revised Draft General Standard for the Labelling of Prepackaged Foods (ALINORM 83/22, Appendix VI, Section 4.2.2.4) were again discussed.

3. Dr. Kouthon of the JECFA Secretariat advised that all Codex food additives covered by specifications had been recently listed on computer and that a far more extensive range of class names had been used. It was decided that JECFA and CCFA may find it practical to use a wider range of groupings for administrative purposes.

4. The delegation of the UK expressed the view that a more extensive list of class names would be useful to inform consumers. It was noted that the policy of the Food Labelling Committee was that the list should be kept to a minimum and that such class names should describe the technological function in terms which could be easily understood by consumers. The Working Group endorsed the present list of class names without change. It was agreed, however, that it could be appropriate to propose a limited number of additional class names,should experience suggest,this would be worthwhile.

5. The Working Group discussed the proposed labelling provision that the expression "flavours" may be qualified by "natural", "nature identical", "artificial" or a combination of these words as appropriate. While some members considered that this was meaningful information for consumers, others considered that it would be misleading or not easily understood particularly the distinction between "natural" and "nature identical". It was decided that it would be premature to take a decision on this matter since flavours and definitions for them were being considered simultaneously by the Working Group on Flavours.

Proposed International Numbering System for Food Additives

6. Consideration was given to the working paper on the International Numbering System for Food Additives (CX/FA 83/9-Add.1) prepared by Australia and written comments submitted by Australia, Finland, France, New Zealand, Norway, Spain, Sweden, EEC, Brazilian Food Industry Association, International Organization of the Flavour Industry (IOFI) and the Asociación Española de Aditivos Alimentarios (AFCA).

7. The Chairman explained that the paper attempted to review the systems presently used in the EEC, the Codex Guide to the Safe Use of Food Additives (CAC/FAL 5-1979), Brazil, Norway, Sweden and various systems used internationally for flavours, enzymes and colours.

8. The observer from the EEC distributed a draft annex to the list of EEC numbers as given in Attachment II to the working paper CX/FA 83/9-Add.1. This document extended the list of EEC numbers to other categories of additives used for the purposes of labelling

under the EEC legislation. The EEC class names were, in general, comparable to the Codex List of Class Names.

9. It was noted that the letter "E" did not prefix these numbers. The Working Group agreed that the use of the prefix "E" would create difficulties in adapting the EEC system for international use. Further, the numbers alone would be adequate to identify specific food additives. The observer from the EEC was requested to take up this matter with EEC Member States in order to obtain their views on the possible deletion of the prefix should the EEC system be used as the basis of an international system. It was pointed out that the retention of the prefix within the EEC could create trading difficulties should Codex adopt a system using the EEC numbers without the prefix. On the other hand the prefix "E" had a meaning for consumers in the EEC.

10. The various numbering systems presently in use were reviewed. It was noted that the EEC system was already in wide use and had been shown to be very suitable for labelling purposes.

11. The delegation of the USA advised that present regulatory requirements in his country required specific declaration of food additives. However, in view of the need for an international numbering system the USA could, in principle, support the development.

12. There was general agreement that an international system of numbering of food additives for labelling purposes should be developed and that it should be based on the EEC system. It was noted that there would be technical and procedural problems. For example, the present EEC system did not cover all additives listed for use in Codex standards. Dr. Kouthon advised that the computerized list of Codex additives would facilitate a rapid comparison of the two lists.

13. A procedure for the inclusion of new numbers into an international list based on the EEC system would need to be developed. This would presumably require close liaison between the EEC and the CCFA and JECFA Secretariats. The observer from the EEC was of the opinion that there were a number of issues involved that could not be decided upon at this time. He would need to consult with EEC Member States on the various issues involved before and final decisions could be taken.

14. Since only food additives required label declaration, the numbering system would only need to cover food additives used as ingredients and not processing aids.

15. The Working Group felt that it would be premature to give detailed consideration to specific procedural arrangements. It accepted the Chairman's proposal that a discussion paper be prepared outlining draft procedures and identifying specific difficulties. It was agreed that this paper be prepared by Mr. Erwin (Australia), Mr. Haigh (EEC), Dr. Rao Maturu (FAO Secretariat) and Dr. Kouthon (JECFA Secretariat).

16. Mr. Haigh (EEC) noted that in order to identify procedural requirements and difficulties it would be helpful if members of the Working Group could consider the matter in greater depth. Views could then be obtained in response to a questionnaire distributed within two or three months. These replies would assist in the preparation of the discussion paper for the next meeting of the Working Group.

17. There was unanimous agreement that this work was important and of an urgent nature. This was due to its extensive implications in facilitating international trade and advising consumers. It was,therefore,agreed that the Working Group should continue this work and convene prior to the next meeting of the Committee.

18. In closing the meeting, the Chairman thanked all participants for their constructive and cooperative approach. This had resulted in extensive and valuable progress being made particularly in the developments of an international numbering system for food additives.

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UP-DATED CODEX LIST B OF FOOD ADDITIVES

Codex List B of Food Additives contains those substances in which the member states and/or industry has shown interest, and evaluation of which by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), is pending.

Some of the food additives in the list B had been evaluated by JECFA at some of its sessions but no ADI could be allocated mainly because of a lack of adequate data. Such of the food additives which fall in the above Category are given a Status of B1. The rest of the food additives which had never been considered by JECFA are given a Status of B2.

APPENDIX VII

1. ACIDS, BASES, SALTS	Status	JECFA Ref.
dihydrogen orthophosphate, ammonium (ammonium phosphate, monobasic)	B2	
diphosphate, dicalcium (calcium pyrophosphate)	B1	8
diphosphate, tetrapotassium (potassium pyrophosphate)	B1	8
Fumarate, calcium	B2	
Fumarate, potassium	B2	
1,4-Heptanolactone, calcium and sodium salts	B2	
hydrogen orthophosphate, diammonium (ammonium phosphate, dibasic)	B1	8
hydrogen orthophosphate, magnesium (magnesium phosphate, dibasic)	B2	
dl-malate, sodium hydrogen	B2	
Metabisulphate, calcium	B2	
Phosphate, bone	B1	8
Phytate, calcium	B2	
Polyphosphate, ammonium	B1	8
Polyphosphate, calcium	B1	8
Polyphosphate, potassium	B1	8
Succinate, ammonium	B2	
Succinate, calcium	B2	
Succinate, magnesium	B2	
Succinate, potassium	B2	
Succinic acid	B2	
Sulphate, aluminium-ammonium	B2	
Sulphate, aluminium-potassium	B1	1, 2
Sulphate, aluminium-sodium	B1	2
Sulphate, aluminium	B1	1, 2
Sulphate, ammonium, potassium and sodium	B2	
Sulphate, hydrogen, potassium and sodium	B2	
Suphuric acid	B2	
dl-Tartaric acid and its salts	B1	3
L(+)Tartrate, ammonium	B2	
L(+)Tartrate, calcium	B2	
L(+)Tartrate, magnesium	B2	
Triphosphate, pentapotassium	B2	
2. ANTIOXIDANTS		
4-Hydroxymethyl-2,6-di-tert-butylphenol	B2	
3. CARRIER SOLVENTS		
Diethylene glysol monoethyl ether	B1	4, 5, 6
Diethylene glysol monopropyl ehter	B1	5
Diethyl tartrate	B1	5, 7
Dipropylene glycol	B1	5
Hexylene glycol	B2	
Isopropyl myristate	B1	5
Paraffins (not defined)	B2	
Synthetic triglycerides	B1	5, 7

	Status	JECFA Ref.
4. COLOURS		
Beet Red	B1	8
Alkanet	B1	3
Alkanin	B1	3
Anthocyanins (incl. anthocyanine)	B1	3, 8
Black 7984	B1	3
Brown FK	B1	3
Capsanthine	B1	3
Capsorubine	B1	3
Caramel colour (ammonia process)	B1	3
Caramel colour (caustic sulphite)	B2	
Carothene (natural)	B1	3
Carthamus (yellow and red)	B1	3
Chrysoine	B1	3
Fast Red E	B1	3
Fast Yellow AB	B1	3
Green S	B2	
Indanthrene Blue	B2	
Lithol Rubine BK	B1	3, 8
Lycopene	B1	1, 3
Orange GGN	B1	1, 3
Orange G	B2	
Orange RN	B1	1, 3, 4
Patent Blue V	B1	1, 8
Ponceau SX	B1	1, 6
Ponceau 6R	B1	1, 3
Quercetin and quercitron	B1	3
Saffron	B1	3
Scarlet GN	B1	3
Silver	B1	3
Ultramarines	B1	3
Xanthophylls	B1	1
Yellow 2G	B1	1, 3, 5
5. EMULSIFIERS AND STABILIZERS		
Benzoin gum	B1	3
Bleached lecithins	B2	
Dioctyl sodium sulphosuccinate	B2	
Ethyl hydonethyl cellulose	B2	
Esters of glycerol and thermally oxidized soybean fatty acids	B1	4, 6
Gum ghatti	B1	8
Hydroxylated lecithin	B1	3, 6
Karaya gum	B1	3, 6, 7
Oat gum	B1	3
Oxidized hydroxypropyl distarch glycerol	B1	4
Quillaia extract	B1	8
Sodium carboxymethyl distarch glycerol	B2	
Starch aluminium octenyl succinate	B2	
Starch sodium succinate	B1	8
Stearoyl monoglyceridyl citrate	B1	8
Stearoyl propylene glycol hydrogen succinate	B2	
Succinylated monoglycerides	B1	8
Tragacanth gum	B1	3, 6

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6. ENZYMES

	Status	JECFA Ref.
Carbohydrase (Aspergillus oryzae varieties)	B2	
Catalase (Aspergillus niger varieties)	B2	
Catalase (Micrococcus lysodeikticus)	B2	
Ficin	B2	
Micorbial carbohydrase (Aspergillus awamori)	B2	
Microbial carbohydrase (Arthrobacter)	B2	
Microbial glucose oxidase (Penicillium amagasakiense)	B2	
Microbial rennet (Bacillus cereus)	B2	
Microbial rennet (Irpex lacteus)	B2	
Ficin	B2	
Micorbial carbohydrase (Aspergillus awamori)	B2	
Microbial carbohydrase (Arthrobacter)		
Butane	B1	5
Cyclohexane	B1	5
Di-isopropyl ether	B1	5
1,1-Dichloroethane	B1	5
Dichlorofluoromethane	B2	
1,2-dichlorotetrafluoroethane	B1	5
Diethyl ether	B1	5
Furfural	B1	5
Iso-butanol	B1	5
Isopropanol	B1	6, 7
Isopropyl acetate	B1	5
Methyl ethyl ketone	B1	5
Methylated spirit (industrial)	B2	
Naphta (Medium petroleum fraction)	B2	
n-Propanol	B1	5, 7
Tetrachloroethylene	B1	5
1,1,1-Trichloroethane	B1	5, 7
1,1,2-trichloro-trifluoroethane	B1	5
1,1,2-Trichloroethylene	B1	5

8. FLAVOURS

	Status	Council of Europe No.	FEM No.	JECFA Reference
Acetaldehyde benzyl methoxyethyl acatal		523	2148	
3-Acetyl-2,5-dimethylfuran		-	3391	
Acetyl isovaleryl		-	3190	
Acetyl nonanoyl		155	3090	
Allyl acetic acid		2004	2843	
Allyl anthranilate	B2	254	2020	
Allyl cinnamate		344	2022	
Allyl cyclohexylacetate		2070	2023	
Allyl cyclohexylbutyrate		283	2024	
Allyl cyclohexylhexanoate		2180	2025	
Allyl cyclohexylpropionate		2223	2026	
Allyl cyclohexylvalerate		474	2027	
Allyl 2-ethylbutyrate		281	2029	
Allyl furoate		360	2030	
Allyl heptanoate	B2	369	2031	
Allyl hexanoate		2181	2032	
Allyl hexenoate		610	-	

8. FLAVOURS (Cont.)	Status	Council of Europe No.	FEM No.	JECFA Reference
Allyl-a-ionone		2040	2033	
Allyl isovalerate	B2	2098	2045	
Allyl phenoxyacetate		228	2038	
Allyl sorbate		2182	2041	
Allyl thiopriopionate		-	3329	
Allyl tiglate		2183	2043	
Allyl undecen-10-oate	B2	441	2044	
Amylheptin carbonate	B2	2172	-	
a-Amylcinnamaldehyde dimethyl acetal	B2	47	2062	
a-Amylcinnamaldehyde	B2	128	2061	
a-Amylcinnamal acetate	B2	216	2064	
a-Amylcinnamal alcohol	B2	79	2065	
a-Amylcinnamal formate	B2	357	2066	
a-Amylcinnamal isovalerate	B2	463	2067	
2-Amyl-5 or 6-keto-1,4-dioxane	B2	2205	2076	
Anisylacetone	B2	163	2672	
Benzaldehyde propylene glycol acetal	B2	2226	2130	
Benzilidene methyl acetone	B2	161	2734	
2-Benzofurnacarboxaldehyde	B2	2247	3128	
Benzoin	B2	162	2132	
Benzyl butyl ether	B2	520	2139	
Benzyl-2,3-dimethyl crotonate	B2	2187	2143	
Benzyl-4-heptanone	B2	2140	2146	
Benzyl isobutyl carbinol	B2	2031	2208	
Benzyl isobutyl ketone	B2	159	2740	
Benzyl isoeugenol	B2	522	-	
Benzyl propyl carbinol	B2	83	2953	
Beta propyl anisole	B1			5
Benzyl ethyl carbinol	B2	2137	-	
Butan-2-one-2-yl butanoate	B2	-	3332	
2-Butyl-2-butenal	B2	-	3392	
2,3-Butanedithiol	B2	-	3477	
Butyl butytylglycollate	B2	2188	-	
Butyl butyryllactate	B2	2107	2190	
2-sec-Butylcyclohexanone	B2	-	3261	
2-Butyl-5 or 6-keto-1,4-dioxane	B2	2206	2204	
a-Butylcinnamaldehyde	B2	127	2191	
Carvacryl ethylether	B2	2057	2246	
Cinnamaldehyde ethyleneglycol	B2	48	2287	
Cinnamyl anthranilate	B2	255	2295	
Cinnamyl phenylacetate	B2	235	2300	
Citral propylene glycol acetal	B2	4064	-	
Citronellyl oxyacetaldehyde	B2	2012	2310	
Cinnamyl formate	B2	352	2299	
Cinnamyl propionate	B2	414	2301	
Cyclohexyl butyrate	B2	2082	2351	
Cyclohexyl formate	B2	498	2353	
Cyclohexyl hexanoate	B2	528	-	
Cyclohexyl isovalerate	B2	459	2355	
Cyclohexyl propionate	B2	421	2354	

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8. FLAVOURS (Cont.)	Status	Council of Europe No.	FEM No.	JECFA Reference
Cyclohexylacetic acid	B2	34	2347	
Cyclohexyl anthranilate	B2	257	2350	
Cyclohexyl cinnamate	B2	337	2352	
Cyclohexylethyl acetate	B2	218	2348	
Cyclohexyl mercaptan	B2	529	-	
Cyclopentanethiol	B2	-	3262	
Dehydrodihydroionone	B2	-	3447	
Diethyl sebacate	B2	623	2376	
Dihydroanethole	B2	2026	2930	
Dimethylbenzylcarbinyl acetate	B2	2077	2392	
Dimethylbenzylcarbinyl isobutyrate	B2	2084	2394	
3,7-Dimethyl-2,6-octadienyl 2-ethylbutyrate	B2	-	3339	
Dehydrodihydroionol	B2	-	3446	
Dibenzyl disulfide	B2	4077	-	
Dibenzyl ketone	B2	2054	2397	
Dibenzyl ether	B2	2150	2371	
Di-(butan-3-one-1-yl) sulfide	B2	-	3335	
4,4-Dibutyl-y-butyrolactone	B2	2231	2372	
Dibutyl sebacate	B2	622	2373	
Dicyclohexyl disulfide	B2	-	3448	
5,7-Dihydro-2-methylthiano (3,4-D)pyrimidine	B2	-	3338	
2,4-Dimethyl-5-acetylthiazole	B2	-	3267	
2,4-Dimethylbenzaldehyde	B2	-	3427	
2,5-Dimethyl-2,5-dihydroxy-1,4-dithiane	B2	-	3450	
2,5-Dimethyl-3-furanthiol	B2	-	3451	
bis-(2,5-Dimethyl-3-furyl)disulfide	B2	-	3476	
2,5-Dimethyl-3-thiofuroylfuran	B2	-	3481	
2,5-Dimethyl-3-thioisovalerylfuran	B2	-	3482	
2,6-Dimethyl-4-heptanol	B2	4030	3140	
2,6-Dimethyl-5-heptenal	B2	2006	2389	
2,6-Dimethyloctanal	B2	112	2390	
2,4-Dimethyl-2-pentenoic acid	B2	4081	3143	
Dimethyl phenyl carbinyl isobutyrate	B2	4240	2388	
Dimethyl phenylethyl carbinyl acetate	B2	219	2735	
Diphenyl disulfide	B2	4085	3225	
spiro-(2,4-Dithia-1-methyl-8-oxabicyclo(3.3.0) octane-3,3-(1'-oxa-2'-methyl)cyclopentane) and spiro (2,4-dithia-6-methyl-7-oxabicyclo(3.3.0) octane-3,3'-(1'-oxa-2'-methyl)cyclopentane)	B2	-	3270	
2,2-Dithiodithiophene	B2	-	3323	
Dodeca-3,6-dional	B2	2121	-	
Estragole	B1			5
p-Ethoxybenzaldehyde	B2	626	2413	
7-Ethoxy-4-methyl-coumarine	B2	2193	-	
o-(Ethoxymethyl)phenol	B2	-	3485	
2-Ethoxythiazole	B2	-	3340	
Ethyl 2-acetyl-3-phenylpropionate	B2	2241	2416	
Ethyl benzoylacetate	B2	627	2423	
Ethyl butyryllactate	B2	2242	-	
Ethyl cresoxyacetate	B2	2243	3157	
Ethyl cyclohexylpropionate	B2	2095	2431	
Ethyl 2,4-dioxohexanoate	B2	-	3278	
Ethyl N-ethylanthranilate	B2	629	-	
Ethyl 2-ethyl-3-phenylpropanoate	B2	-	3341	

8. FLAVOURS (Cont.)	Status	Council of Europe No.	FEM No.	JECFA Reference
Ethyl furfuracrylate	B2	545	-	
Ethyl furylpropionate	B2	2091	2435	
2-Ethyl-2-heptenal	B2	120	2438	
Ethyl-iso-eugenol	B2	190	2472	
Ethyl 2-mercaptopropionate	B2	-	3279	
Ehtyl methyl phenylglycidate	B2			
Ethyl nitrite	B2	2190	2446	
Ethyl octine carbonate	B2	480	2448	
Ethyl 4-phenylbutyrate	B2	307	2453	
Ethyl phenyl carbinyl butyrate	B2	628	2424	
Ethyl 3-phenyl glycidate	B1	2097	2454	3
Ethyl thioacetate	B2	-	3282	
2-Ethylthiophenol	B2	-	3345	
Ethyl 10-undecenoate	B2	2102	2461	
Ethylene tridecanedioate	B2	4094	-	
3-Ethyl-2-hydroxy-4-methyl-cyclopent-2-en-1-one	B2	-	3453	
5-Ethyl-2-hydroxy-3-methyl-cyclopent-2-en-1-one	B2	-	3454	
N-Ethyl-2-isopropyl-5-methyl-cyclohexanecarboxamide	B2	-	3455	
Ethyl-2-methyl-3-pentenoate	B2	-	3456	
2-Ethyl-1,3,3-trimethyl-2-norbornanol	B2	-	3491	
Ethyl methyl phenylglycidate	B1	-	-	5
Eugenyl methylether	B1			5, 7
2-Furanmethanethiol formate	B2	4112	3158	
2-Furfurylidene butanal	B2	2251	2492	
Furfuryl isopropyl sulphide	B2	2248	3161	
Furfuryo thiopropionate	B2	-	3347	
Geranyl acetoacetate	B2	243	2510	
Guaiyl acetate	B2	552	-	
4-Heptanol	B2	555	-	
3-Heptyp-5-methyl-2(3H)furanone	B2	-	3350	
trans-3-Heptenyl-2-methylpropanoate	B2	-	3494	
a-Hexylcinnamaldehyde	B2	129	2569	
2-Hexylidene cyclopenthanone	B2	167	2573	
Hydroxycitronellal	B2	100	2583	
Hydroxycitronellal diethyl acetal	B2	44	2584	
Hydroxycitronellal dimethyl acetal	B2	45	2585	
Hydroxycitronellol	B2	559	2586	
2-Hydroxy-2-cyclohexen-1-one	B2	-	3458	
2-Hydroxy-3,5,5-trimethyl-2-cyclohexenone	B2	-	3459	
6-Hydroxy-3,7-dimethylocatnoic acid lactone	B2	-	3355	
3-(Hydroxymethyl)-2-octanone	B2	-	3292	
Isobornyl butyrate	B2	564	-	
Isobutyl benzyl carbinol	B2	2031	2208	
Isobutyl N-methylanthranilate	B2	649	-	
beta-Isomethyl ionone	B2	650	-	
Isopropyl cinnamate	B2	325	2939	
y-Ionone	B2	4139	3175	
Isoamyl furylbutyrate	B2	2080	2070	
Isoamyl furylpropionate	B2	2092	2071	
Isobornyl formiate	B2	565	2162	
Isobornyl isovalerate	B2	452	2166	
Isobornyl propionate	B2	412	2163	
Isobutyl furylpropionate	B2	2093	2198	
Isoegenyl butylether	B2	2151	-	
Isoegenyl formate	B2	356	2474	
Isoegenyl phenylacetate	B2	237	2477	
Iso-a-methylionone	B2	169	2714	

8. FLAVOURS (Cont.)	Status	Council of Europe No.	FEM No.	JECFA Reference
p-Isopropyl phenyl acetaldehyde	B2	132	2954	
3-(p-Isopropyl)-phenyl propanal	B2	2261	2957	
Isoquinoline	B2	4871	2978	
2-Keto-4-butanethiol	B2	-	3357	
Licorice	B2			
3-Mercapto-2-butanol	B2	-	3502	
2-Mercapto thiophene	B2	478	-	
4-Methyl-5-(beta-acetoxy ethyl)thiazole-3-methyl-5-ethylpheno	B2	580	-	
Methyl thiazol acetate	B2	-	3205	
2-Mercapto-3-butanol	B2	-	3502	
3-Mercapto-2-butanone	B2	-	3298	
3-Mercapto-2-pentanone	B2	-	3300	
2,3 or 10-Mercaptopinane	B2	-	3503	
2-Mercaptopropionic acid	B2	4156	3180	
1-(p-Methoxyphenyl)-1-penten-3-one	B2	164	2673	
Methoxypyrazine	B2	-	3302	
p-Methylbenzyl acetone	B2	160	3074	
Methylbenzyl disulphide	B2	-	3504	
Methyl p-tert-butylphenylacetate	B2	577	2690	
d-Methylcinnamaldehyde	B2	578	2697	
6-Methylcoumarin	B2	579	2699	
Methyl decine carbonate	B2	2111	2751	
Methyl-beta-naphthyl Ketone	B1			7
2-Methyl-3-furanthiol	B2	4172	3188	
Methyl furfuracrylate	B2	2267	-	
2-Methyl-3,5 or 6-furfuryl-thiopyrazine	B2	(2287)	3189	
3-(5-Methyl-2-furyl)butanal	B2	-	3307	
bis(2-Methyl-3-furyl)disulfide	B2	-	3259	
bis(2-Methyl-3-furyl)tetrasulfide	B2	-	3260	
Methyl heptine carbonate	B2	481	2729	
5-Methyl-5-hexen-2-one	B2	-	3365	
a-Methyl-beta-hydroxypropyl-(a-methyl-beta-mercaptopropyl)sulphide	B2	-	3509	
Methyl-iso-butylcarbinyl acetate	B2	2073	-	
Methyl-beta-ionone	B2	144	2712	
Methyl-delta-ionone	B2	2145	2713	
a-Methyl-p-methoxy-cinnamaldehyde	B2	584	3182	
2-Methyl-5-methoxythiazole	B2	4034	3192	
Methyl 4-(methylthio)butyrate	B2	-	3412	
2-Methyl-4-(methylthio)furan	B2	-	3366	
2-Methyl-3,5 or 6-methylthio-pyrazine	B2	(2290)	3208	
2-Methyloctanal	B2	113	2727	
Methyl octine carbonate	B2	479	2726	
2-Methyl-4-pentenoic acid	B2	-	3511	
2-Methyl-4-phenylbutanal	B2	134	2737	
3-Methyl-2-phenylbutanal	B2	135	2738	
Methyl 4-phenylbutyrate	B2	308	2739	
3-Methyl-5-propyl-2-cyclohexen-1-one	B2	4178	3577	
2-(2-Methylpropyl)pyridine	B2	-	3370	
3-(2-Methylpropyl)pyridine	B2	-	3371	

8. FLAVOURS (Cont.)	Status	Council of Europe No.	FEM No.	JECFA Reference
2-(1-Methylpropyl)thiazole	B2	-	3372	
Methyl styryl carbinol	B2	2032	2880	
3-Methylthiobutanal	B2	-	3374	
4-Methylthiobutanal	B2	-	3414	
4-Methylthio-2-butanone	B2	-	3375	
Methyl thiofuroate	B2	-	3311	
3-Methylthio-1-hexanol	B2	-	3438	
4-Methylthio-4-methyl-2-pentanone	B2	-	3376	
2-Methyl-3-tolyl-propanal	B2	587	2748	
Musk ambrette	B2	495	2758	
Musk ketone	B2	2147	-	
Musk xylol	B2	2218	-	
2-Naphthalenthiol	B2	-	3314	
beta-Naphtyl anthranilate	B2	2170	2767	
beta-Naphtyl ethylether	B2	2058	2768	
beta-Naphtyl methyl ketone	B1	147	2723	5
beta-Naphtyl isobutyl ether	B2	2273	-	
1,9-Nonanedithiol	B2	-	3513	
Nonanoyl 4-hydroxy-3-methoxybenzylamide	B2	590	2787	
1,3-Nonanediol acetate	B2	2075	2783	
3-Nonanon-1-yl acetate	B2	2076	2786	
Octanon-1-ol	B2	592	2804	
2-trans-6-trans-Octadienal	B2	-	3466	
1,8-Octanedithiol	B2	-	3514	
6-Octenal	B2	664	-	
Phenylethyldimethylcarbinyl isobutyrate	B2	2086	2736	
Phenylpropyl propionate	B2	419	2897	
1-Phenyl-3(5)-propylpyrazole	B2	2277	-	
Piperonyl formate	B2	2154	-	
Paraldehyde	B2	594	-	
Pentyl 2-furyl ketone	B2	-	3418	
Phenoxyethyl isobutyrate	B2	2089	2873	
4-Phenyl-2-butyl acetate	B2	671	2882	
2-Phenyl-3-carbethoxy-furan	B2	-	3468	
Phenylethyl methyl carbinol	B2	85	2879	
Phenylethyl methyl ethyl carbinol	B2	86	2883	
5-Phenylpentanol	B2	674	-	
3-Phenyl-4-pentenal	B2	-	3318	
2-Phenyl-4-pentenal	B2	-	3519	
2-Phenyl-1-propanol	B2	2257	2732	
2-Phenylpropanal dimethyl acetal	B2	2017	2888	
1,2-Propanedithiol	B2	-	3520	
2-Phenylpropionaldehyde	B2	126	2886	
1-Phenyl-2-propyl butyrate	B2	2276	3197	
2-Phenylpropyl butyrate	B2	285	2891	
3-Phenylpropyl cinnamate	B2	597	-	
2-Phenylpropyl isobutyrate	B2	2087	2892	
2-(3-Phenylpropyl) tetrahydrofurane	B2	489	2898	
Piperonyl acetate	B2	2068	2912	
Piperonyl acetone	B2	165	2701	
Piperonyl isobutyrate	B2	305	2913	
Propenylguaethol	B2	170	2922	
p-Propyl anisole	B1	2026	2930	5
Propylene glycol dibenzoate	B2	-	3419	

8. FLAVOURS (Cont.)	Status	Council of Europe No.	FEM No.	JECFA Reference
Propyl furylacrylate	B2	2090	2945	
3-Propylidenephtalide	B2	494	2952	
o-Propylphenol	B2	-	3522	
Propyl thioacetate	B2	-	3385	
Pseudocyclocitral	B2	2133	-	
Pyrazine ethanethiol	B2	(2285)	3230	
Pyrazine methanethiol	B2	-	3299	
Pyrazinyl methyl sulfide	B2	(2288)	3231	
2-Pyridine methanethiol	B2	2279	3232	
Resorcinol dimethyl ether	B2	189	2385	
Sucroseoctaacetate	B2	4219	FDA/GRAS	
1,5,5,9-tetramethyl-13-oxatri-cyclo(8,3,0,$0^{4,9}$) tridecane	B2	-	3471	
p-Tolylacetaldehyde	B2	130	3071	
Trideca-4,7-dienal	B2	684	-	
Tetrahydrofurfuryl butyrate	B2	2081	3057	
Tetrahydrofurfuryl cinnamate	B2	4224	3320	
Tetrahydrofurfuryl propionate	B2	2096	3058	
Tetrahydrolinaloöl	B2	77	3060	
Tetrahydro-pseudo-ionone	B2	2053	3059	
Tetramethyl ethylcyclohexenone	B2	168	3061	
Thiogeraniol	B2	-	3472	
Thioguaiacol	B2	2219	-	
2-(p-Tolyl)-propanal	B2	131	3078	
2,6,6-Trimethyl-1-cyclohexen-1-acetaldehyde	B2	-	3474	
3,5,5-Trimethylhexanal	B2	-	3524	
3,5,5-Trimethyl-1-hexanol	B2	-	3324	
9-Undecenal	B2	123	3094	
10-Undecenal	B2	122	3095	
Vanillin acetate	B2	225	3108	
Vanillidene acetone	B2	691	-	
9. FLAVOUR ENHANCERS				
Aspartate, monosodium	B2			
Glutamate, L-Arginine	B2			
Glutamate, L-Lysine	B2			
10. MISCELLANEOUS				
Acesulfame potassium	B1			7
Acetone peroxide	B2			
Beexwax	B2			
Carnauba wax	B2			
Chlorine	B2			
Condensed tannins	B2			
Diethyline glycol manoethyl ether	B1			6
Dioctyl sodium sulphosuccinate	B1			3, 6
Glycerol esters of wood rasin	B1			1, 4
Hydrogenated glucose syrup (Lycasin R)	B1			6
Lactitol	B2			
Licorice	B2			
Saccharate of lime	B2			
Shellac	B2			

10 MISCELLANEOUS (Cont.)	Status	JECFA Reference
Sorbitol	B1	8
Sorboyl palmitate	B1	1, 4
Sucrose acetate isobutyrate	B1	3, 8
Thaumatin	B2	
Thermally oxidized soyabean oil	B2	
Wood flour	B2	
Xylitol	B1	3, 2
11. PROCESSING AIDS		
Asbestos	B2	
Bentonite	B1	4
Diatomaceous earth	B1	3
Perlite	B2	
12. PRESERVATIVES		
Benzoate, calcium	B2	
Parahydroxybenzoate, butyl	B2	

REFERENCES

1. Evaluation of Certain Food Additives (Eighteenth Report of the Expert Committee). FAO Nutrition Meeting Report Series No. 54, 1974; WHO Technical Report Series No. 557, 1974 and Corrigendum.

2. Evaluation of Certain Food Additives (Twenty-second Report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series No. 631, 1978.

3. Evaluation of Certain Food Additives (Twenty-first Report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series No. 617, 1978.

4. Evalution of Certain Food Additives (Twentieth Report of the Expert Committee). FAO Food and Nutrition Series No. 1, 1976; WHO Technical Report Series No. 599, 1976.

5. Evaluation of Certain Food Additives (Twenty-third Report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series No. 648, 1980.

6. Evaluation of Certain Food Additives (Twenty-fourth Report of the Joint FAO/WHO Committee on Food Additives). WHO Technical Report Series No. 653, 1980.

7. Evaluation of Certain Food Additives (Twenty-fifth Report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series No. 669, 1981.

8. Evaluation of Certain Food Additives (Twenty-sixth Report of the Joint FAO/WHO Expert Committee on Food Additives) WHO Technical Report Series No. 683, 1982.

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APPENDIX VIII

REPORT OF THE AD HOC WORKING GROUP ON FOOD IRRADIATION

The Ad hoc Working Group (WG) met prior to the 16th Session of CCFA under the Chairmanship of Dr. J. Modderman, assisted by Dr. L. Ladomery and Mr. J. van Kooy as Joint Secretaries. Delegates from Belgium, Canada, Fed. Rep. of Germany, France, Italy, The Netherlands, Thailand, United Kingdom and USA participated in the work of this WG. Of the international organisations FAO and IAEA were represented in the WG.

The WG discussed in detail comments received on the draft revised Recommended International General Standard for Irradiated Foods and on the draft revised Recommended International Code of Practice for the operation of Radiation Facilities for the Treatment of Foods, both at Step 5, from the Fed. Rep. of Germany, France and USA. Also the comments from Mexico received at Step 3 on these Codex documents were taken into account, where applicable.

The WG noted also a communication from the Danish Codex Alimentarius Committee that it had no comments on the draft revised Standard at Step 5.

As suggested in the comment of USA the WG had a general discussion on the consistency in the standard regarding mandatory and recommended provisions. At a number of instances the WG changed the word "should" into "shall" to clarify what is permitted, recommended, or required. In particular the WG considered a proposal to make the maximum absorbed dose specified in the Standard (2.2)* mandatory by changing "should" into "shall". After a discussion, it was agreed not to introduce such a change noting that 10 kGy represented an overall average dose of radiation. The limit of 10 kGy would be regarded as an expression of the results of wholesomeness testing rather than that of a legal upper limit. Much lower upper limits of absorbed dose would be dictated in the majority of the practical applications by the self-limiting nature of good irradiation practice. It was noted, however, that international agreement would be desirable on the wholesomeness of irradiated food up to an overall average absorbed dose of 10 kGy as recommended in the Standard. With reference to the wholesomeness of irradiated foods and in particular their microbiological safety, the Secretariat drew attention to a meeting of the Board of the International Committee on Food Microbiology and Hygiene of the International Union of Microbiological Societies, held in Copenhagen in December 1982.

This Board, after analysing the scientific knowledge available to date, reconfirmed the view of the 1980 Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food that the irradiation of food up to an overall average dose of 10 kGy introduces no special microbiological problems. This Board concluded that food irradiation is an important addition to the methods of control of food borne pathogens and would

* This and other figures between brackets refer to the numbering of the paragraphs of the Standard.

not present any additional hazards from shifts in the microflora or changes in the attributes of microorganisms.

The WG considered a proposal to raise the energy level of X-rays from 5 to 10 MeV (2.1.). It emphasized that this matter should be reviewed when conclusive data on the appropriateness of increasing the maximum energy level of X-rays were available and appropriate action should be taken to amend the standard if necessary. The WG discussed a proposal to prohibit the treatment of food using chemicals either prior to or following irradiation. The WG considered that any such restriction could only be contemplated for those cases where both the chemical treatment and the irradiation process served identical purposes and were, therefore, alternatives. It also noted that the irradiation of food, which complies with the provisions of (4.2) of the Standard, would be acceptable from a health point of view, and, therefore, the WG agreed that there were no valid reasons for restricting the irradiation of such foods.

In reviewing the cases where the full irradiation dose would be given in two or more instalments the WG agreed to improve the text of this paragraph (5.2 c) by replacing "as part of one process" by "as part of processing for a specific technological purpose".

Another improvement of the text was introduced in paragraph (5.3) by replacing the word "total" by "cumulative".

The WG considered proposals to include further information to the Standard relating to packaging materials used during irradiation and details of the irradiation process. In this respect the WG distinguished between two types of information required by national authorities:

a) detailed information on the basis of which governments may wish to authorize the application of the process to given foods or to foods generally, and

b) information required in the shipping documents for the purpose of checking compliance with the relevant Standard.

It was noted that an irradiated food would be subject to the relevant Standard and regulations governing foods generally, and to any specific food standards relating to individual foods. Good irradiation practice would be best checked by direct control of the irradiation facility. For these reasons the inclusion of detail other than already specified under (6.1) would not be particularly useful. The WG decided only to change the word "date" to "date(s)" in order to take care of any possibility of authorized re-irradiation. As regards the draft revised Code of Practice only some editorial improvements were included.

The revised documents are attached to this report.

Conclusion

Considering that the attached draft revised documents have now been subjected to two rounds of government comments, which have considerably contributed to an improvement of the technical matters therein contained, and taking into account the accelerated procedure decided upon at the 15th Session of CCFA, the WG recommends CCFA at its present Session, to advance these Codex documents to Step 8.

APPENDIX IX

DRAFT CODEX GENERAL STANDARD FOR IRRADIATED FOODS

(Advanced to Step 8 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(*). (**)

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.

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

(**) 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 10 kGy introduces no special nutritional or microbiological problems (Wholesomeness of Irradiated Foods, Report of a Joint FAO/IAEA/WHO Expert Committee, Technical Report Series 659, WHO, Geneva, 1981).

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 incude 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. (Ref. No. ...).

3. HYGIENE OF IRRADIATED FOODS

3.1. The food shall comply with the provisions of the Recommended International Code of Practice - General Principles of Food Hygiene (Ref. No. CAC/RCP 1-1969, Rev. 1, 1979) and, where appropriate, with the Recommended International Code of Hygienic Practice of the Codex Alimentarius relative to a particular food.

3.2. 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.

4.2. Food Quality and Packaging Requirements

The doses applied shall be commensurate with the technological and public health purposes to be achieved and shall be in accordance with good radiation processing practice. 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.

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.

(*) The utility of the irradiation process has been demonstrated for a number of food items listed in Annex B to the Recommended International Code of Practice for the Operation of Radiation Facilities used for the Treatment of Foods.

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 processing for a specific technological purpose.

5.3. The cumulative 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(s) of treatment and lot identification.

6.2 Prepackaged foods intended for direct consumption

The labelling of prepackaged irradiated foods shall be in accordance with the relevant provisions of the Codex General Standard for the Labelling of Prepackaged Foods (Ref. No. ...).

6.3. Foods in bulk containers

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

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

(Advanced to Step 8 of the Codex Procedure)

1. INTRODUCTION

This code refers to the operation of irradiation facilities based on the use of either a radionuclide source (^{60}Co or ^{137}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.

3. GOOD RADIATION PROCESSING PRACTICE

Facility design should attempt to optimalize 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

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* see Annex A to this Code.

** detailed in the Manual of Food Irradiation Dosimetry, IAEA, Vienna, 1977, Technical Report Series No. 178.

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.

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* see Annex B to this Code.

ANNEX A

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, z)
- 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 ($\bar{D}$min) and maximum ($\bar{D}$max) dose will be a good estimate of the overall average dose.

i.e. in these cases

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

2. Effective and limiting dose values

Some effective treatment e.g. the elimination of harmful micro-organisms, or a particular shelflife extension, or a disinfestation 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 when the overall average dose is 10 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 can be made and a record of product movement and placement can be kept to provide a control of the process in support of routine dosimetry measurements.

In a machine facility a continuous record of beam parameters, e.g. 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 B

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 Reports of the Joint FAO/IAEA/WHO Expert Committees on Food Irradiation (WHO Technical Report Series, 604, 1977 and 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.

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ALINORM 83/12A
APPENDIX X

REPORT OF THE WORKING GROUP ON PROCESSING AIDS

1. The Chairman, Mr. R.J. Ronk (USA) called the meeting to order and outlined the business for the meeting. The Working Group would discuss CX/FA 83/12 Add. 1 Government Comments with a special focus of adding new items to the processing aids inventory. In addition the group would be asked to adopt a procedure for removing materials from the processing aids inventory which could be recommended to CCFA. Finally the Chairman wished to discuss a new draft of the carry-over principle.

2. Uses of the Inventory

Many comments from Governments have been received which question the definition of processing aids and the eventual use of the inventory. It was decided that the USA would:

a) re-draft the inventory adding any materials which had been proposed by governments and other interested parties;
b) attempt to apply the definition of processing aid to each compound on the re-drafted inventory with the following categories in mind:
   i) processing aids which clearly fit the definition of processing aid
   ii) those materials which are both food additive and processing aid (e.g. different functions in different foods)
   iii) those compounds which because of carry-over residues would seem to be usually considered only as food additives
   iv) and those which might actually have simultaneous functions as processing aids and functionality in the finished food.

This re-drafting would be submitted to the Chairman CCFA, the FAO Secretariat and members of the Working Group for their comments and revisions within three months of the close of the Fifteenth Session. After the CCFA reviews the information that would result from this evaluation of the inventory it should be possible to make some decisions about the eventual use of the inventory by the Committee. For example the Committee might decide that all significant residues will eventually be evaluated by JECFA.

3. At the 25th Session of JECFA the Committee recommended that 2-nitropropane should not be used in the processing of food. It has been recommended by some governments and by some of the members of the Committee on Fats and Oils that 2-nitropropane be deleted from the inventory of processing. In order to accomplish this the WG recommends to CCFA that the procedure for deleting materials from the inventory be the following:

> Where Governments or interested parties call to the attention of the WG information which raises significant health concerns about the use of processing aid on the inventory, that information will be referred to JECFA for advice and if the problems are confirmed the WG will recommend to CCFA the removal of that material from the inventory.

Since in the case of 2-nitropropane JECFA has already made a decision the WG recommends that 2-nitropropane be deleted from the inventory. In addition Sweden has questioned asbestos on the inventory and the WG recommends that this will be placed on the priority list for JECFA review.

4. The Fruits and Vegetables Committee has felt that carry-over principle needs classification and re-definition. A draft of the revision was considered but there were many questions about the necessity for changes in the present definition that the WG decided it was not worth the effort. Unless greater justification for change is demonstrated the WG recommends that carry-over principle remain as it is.

5. The following countries and organizations were represented at the WG.

Thailand	Federal Republic of Germany
New Zealand	Belgium
Brazil	France
Germany	Austria
UK	
Spain	
Switzerland	
USA	
Denmark	
The Netherlands	
The EEC Commission	
AMFEP	
IFMA	
CEFIC	
ILSI	
CIAA	
IFGDA	
FAO	

DRAFT CODEX STANDARD FOR FOOD GRADE SALT
(Advanced to Step 8 of the 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. Subject to the provisions of this standard more specific requirements for special needs may be applied. 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 of calcium, potassium, magnesium chlorides as well. 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 stabilize such additions.

4. FOOD ADDITIVES

4.1 All additives used shall be of food grade quality.

4.2 Anticaking Agents

	Maximum Level in the Final Product
4.2.1 Coating agents; Carbonates, calcium and/or magnesium; Magnesium oxide; Phosphate, tricalcium; Silicon dioxide,amorphous; Silicates, calcium, magnesium, sodium alumino, or sodium calcium alumino	20 g/kg singly or in combination
4.2.2 Coating hydrophobic agents; Aluminium, calcium, magnesium, potassium or sodium salts of myristic, palmitic or stearic acids	

		Maximum Level in the Final Product
4.2.3	Crystal modifiers; Ferrocyanides, calcium, potassium* or sodium*	10 mg/kg* singly or in combination expressed as $[Fe(CN)_6]^{4-}$
4.3	Emulsifiers	
	Polysorbate 80	10 mg/kg
4.4	Processing Aid	
	Dimethylpolysiloxane	10 mg of residue/kg

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
5.2	Copper	- not more than	2 mg/kg expressed as Cu
5.3	Lead	- not more than	2 mg/kg expressed as Pb
5.4	Cadmium	- not more than	0.5 mg/kg expressed as Cd
5.5	Mercury	- not more than	0.1 mg/kg expressed as Hg

6. HYGIENE (To be endorsed 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 (To be endorsed by the Codex Committee on Food Labelling)

In addition to Sections 1, 2, 4 and 6 of the Codex 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 may be designated as a dendritic salt on the label.

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 "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 para. 2, or the method of production may be declared on the label, provided such indication does not mislead or deceive the consumer.

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*Sodium and potassium ferrocyanides, maximum level may be 20 mg/kg when used in the preparation of dendritic salt.

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 ingredients shall be declared in descending order of proportion in accordance with Section 3.2(b) and 3.2(c) of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1981). Food additives shall be declared by the use of both class names and specific names or recognized numerical identification.

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

Each container shall be embossed or otherwise permanently marked in code or in clear to identify the producing factory and/or the packer and the lot.

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 Sections 7.1 to 7.6 shall either be placed on the non-retail container or be given in accompanying documents.

8. METHODS OF ANALYSIS AND SAMPLING (To be endorsed by the Codex Committee on Methods of Analysis and Sampling)

8.1 Sampling (To be elaborated) 1/

8.2 Determination of Sodium Chloride Content

This method allows the calculation of sodium chloride content, as provided for in Section 3.1, on the basis of the results of the determinations of sulphate (Method 8.4), halogens (Method 8.5), calcium and magnesium (Method 8.6), potassium (Method 8.7) and loss on drying (Method 8.8). Convert sulphate to $CaSO_4$ and unused calcium to $CaCl_2$, unless sulphate in sample exceeds the amount necessary to combine with calcium, in which case convert calcium to $CaSO_4$, and unused sulphate first to $MgSO_4$ and any remaining sulphate to Na_2SO_4. Convert unused magnesium to $MgCl_2$. Convert potassium to KCl. Convert unused halogens to NaCl. Report the NaCl content on a dry matter basis, multiplying the percentage NaCl by 100/100-P, where P is the percentage loss on drying.

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".

1/ Method being developed by the Ad-Hoc Working Group on Methods of Analysis and Sampling of Salt.

8.5 Determination of Halogens 1/

According to ISO 2481-1973 "Determination of halogens, expressed as chlorine. Mercurimetric method" (for the recovery of mercury from the laboratory waste, see Annex of ECSS/SC 183-1979).

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 183-1979 "Determination of potassium content by sodium tetraphenylborate volumetric method" or alternatively according to ECSS/SC 184-1979 "by 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. Zincdibenzyldithiocarbamate photometric method".

8.10 Determination of Arsenic Content

According to method ECSS/SC 311-1982 "Determination of arsenic content. Silver diethyldithiocarbamate photometric method".

8.11 Determination of Mercury Content

According to method ECSS/SC 312-1982 "Determination of total mercury content. Cold vapour atomic absorption spectrometric method".

8.12 Determination of Lead Content

According to method ECSS/SC 313-1982 "Determination of total lead content. Flame atomic absorption spectrometric method".

8.13 Determination of Cadmium Content

According to method ECSS/SC 314-1982 "Determination of total cadmium content. Flame atomic absorption spectrometric method".

1/ An alternative method for the estimation of halogens by using silver nitrate is being studied.

APPENDIX XII

REPORT OF THE WORKING GROUP ON SPECIFICATIONS

The Working Group, chaired by Dr. J. Modderman (USA), had the following task to perform: Consideration of Specifications for the Identity and Purity of Food Additives in the light of comments received (CL 1982/8-FA and CL 1982/33-FA).

1. The Working Group noted with satisfaction that the position of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), expressed at the 26th Session, on "minimum safety requirements" agreed with the position of the CCFA adopted at its 15th Session.

2. The Working Group noted that the Executive Committee of the Codex Alimentarius Commission thought the approach of the CCFA, on the status of Codex Advisory Specifications and the procedures for elaboration of Codex Advisory Specifications, was a reasonable one. The Executive Committee requests comments from Governments on these two matters in CL 1982/42-FA. The Working Group encourages national governments and interested international organizations to respond to this Circular Letter in every case.

3. The Working Group concluded that Food and Nutrition Paper No. 19, containing specifications developed at the 25th JECFA, would be evaluated at this meeting. However, Food and Nutrition No. 25, containing specifications developed at the 26th JECFA, had not been available for sufficient time for all governments to comment. Therefore, the Working Group evaluated comments on only those specifications in Paper No. 25 which will be under review at the next JECFA, and made recommendations on these specifications to the FAO Joint Secretary of JECFA.

4. The Working Group concluded that review of specifications in Food and Nutrition Paper No. 19 would be on the basis of the "advisory status" recommended by the 15th CCFA.

5. The Working Group assigned specifications to five categories based on the technical comments received in reply to CL 1982/8-FA requesting comments on Paper No. 19. These categories are the same as those used at the 15th CCFA. The categories are:

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.

6. Review of specifications in FAO Food and Nutrition Paper No. 19 in light of comments received.

General Comments

i) Some governments commented on the format of JECFA specifications. They specifically recommended: (a) a distinct separation of Identity and Purity Tests; and (b) placement of longer methods at the end of a monograph. The Working Group noted with pleasure that the FAO had already started work on revising the book of General Methods (FAO Food and Nutrition Paper No. 5).

ii) The Working Group noted that there were significant differences between the "functional uses" specified in JECFA monographs and the "class names" being developed by the Codex Alimentarius for the purposes of labelling. The Working Group recommends the more systematic use of the class names approved by Codex to identify functional uses in JECFA specifications.

iii) There were considerable comments on specifications for food colours. The Working Group recommends that all chemically synthesized food colours should be reviewed as a group by JECFA. The Working Group specifically requests JECFA to consider comments on:

- modernization of test methods for assay and impurities especially of high performance liquid chromatography (HPLC);
- provision for "lakes" of food colours in the specification monographs;
- develop Purity Tests for specific impurities in each food colour;
- revise trace metal limits to make them more uniform, for example, arsenic 3 mg/kg, lead 10 mg/kg, mercury 1 mg/kg and limits on chromium and zinc were appropriate;
- revise specification limits on volatile matter, chlorides and sulphates to indicate they are determined by difference of 100% minus dyes and impurities.

iv) The Working Group discussed the JECFA specifications on enzyme preparations. Specifically some governments expressed concern with the specificity of microbial sources in light of the new biotechnology of gene splitting and development of novel microbial strains. Most of the members of the Working Group agreed that JECFA specifications for enzyme preparations in Paper No. 19 were sufficient for the present situation. When methodology to detect new microbial strains is developed, the Working Group will study the matter further. Several specification monographs on glucose isomerases have limits on glutaraldehyde, which is actually a requirement for isomerized syrup. The Working Group recommends that JECFA revise the glutaraldehyde requirement to apply to the enzyme preparation, or apply the present JECFA limit to isomerized syrup, when a food standard or food additive specification monograph on isomerized syrup is developed.

v) The Working Group reminded the FAO of their previous recommendation to publish JECFA specifications in a loose-leaf format.

Category I (Recommended for Adoption by the Commission)

Aspartame
Aspergillus niger var - glucose oxidase and catalase
Aspergillus oryzae var -α- amylase and glucoamylase
Aspergillus oryzae var - protease
Butan-2-ol
Calcium ascorbate
Cinnamaldehyde
Cyclohexane
Ethyl Phenylglycidate
Ficin
Glucono delta-lactone
Isopropyl myristate
Klebsiella aerogenes - pullulanase
Maltol
Micrococcus lysodeicticus-catalase
Octanal
Polydextroses
Polyoxyethylene (20) sorbitan monostearate
Polyoxyethylene (20) sorbitan tristearate
Streptomyces rubiginosus - glucose isomerase
Toluene

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

	Correction
Bacillus licheniformis -α-amylase	- Delete cheese on the list of typical applications
d (+)-Carvone l (-)-Carvone	- Angular rotation, change name
Light petroleum	- Synonym
Magnesium di-L-glutamate	- Specific rotation, misprint

Category III (not recommended for adoption)

	Recommended change
Actinoplane missouriensis - glucose isomerase	- Gluteraldehyde limit
Allura Red AC	- Consider addition of UV- identity test and limit for "organic compounds, which are not colouring substances"
Amidated pectin	- Delete identity test F. Consider the comments made by IPPA.
Azorubine	- Misprints. Consider the limit for zinc.
Bacillus coagulans var - glucose isomerase	- Gluteraldehyde limit.
Brilliant Black PN	- Change the title , check the synonyms, decrease the limit for primary amines to 0.01% and consider the limit for zinc.
Brown HT	- decrease the limit for assay to 70%.
Butan-1-ol	- add limit for butyl ether
Calcium stearoyl lactate	- Consider the definition. Decrease the lower limit for total lactic acid to 15%
Canthaxanthin	- Method of assay: incorporate foot-note 2 in the text for water dispersible products and give the formulae for calculations.

Beta-apo-8'-Carotenal	- Check the code numbers, NATCOL should provide some technical justifications for changes.
Beta-Carotene, Synthetic	- Check the code numbers. NATCOL should provide some technical justifications for changes.
Beta-apo-8'-Carotenoic acid ethyl ester	-Check the code numbers.NATOL should give technical justifications for changes.
Erythrosine	- CEFIC and USA will provide further information . Consider the limit for fluorescein.
Ethyl methyl ketone	- Add limit for hexane-2-one and criteria for specific gravity at 25°C.
Hydroxypropyl cellulose	- Consider the Chemical formula. Loss on drying: bring the method in consistency with the method for other celluloses. Add a pH-test.
Hydroxypropyl methyl cellulose	- Consider the Chemical formula . Add a pH-test.
Indigotine	- Increase limit for water insoluble matter to 0.4% and the limit for subsidiary dyes to 5%.
Methyl cellulose	- Consider the "Chemical formula". Add a pH-test and a limit for hydroxyethoxyl groups.
Paprika oleoresin	- Add limit for capsaisin relative to colour intensity. Residual solvent, delete one of the names for CH_2Cl_2.
Pectins	- Delete the identity test F. Consider the comments made by IPPA.
Ponceau 4R	- See general comments
Red 2G	- See general comments
Riboflavin-5'-phosphate sodium	- Check criteria for specific rotation. Change the procedure for fluorescence measurement. Consider the relevance of a test for lumiflavin.
Sodium carboxymethyl cellulose	- Check degree of substition. Add limit for sodium. Delete the uranyl method or replace it by an AAS-method.
Sodium sesquicarbonate	- Assay: change the ratio of the two components. Change the limits for water content. Revise the method for sodium bicarbonate.

Sodium stearoyl lactate	- Definition: consider the description. Decrease the lower limit for "total lactic acid" to 15%. Increase the upper limit for "acid value" to 130. Decrease the lower limit for "ester value" to 90.
Streptomyces olivaceous - glucose isomerase Streptomase olivochromogenes - glucose isomerase Streptomyces violaceoniger - glucose isomerase	Gluteraldehyde limit

Category IV (not reviewed because of recent JECFA revision)

Acesulfame potassium

Annatto extracts

Carmines

Diethyl tartrate

Estragole

Eugenyl methyl ether

Isopropyl acetate

1,1,2-Trichlorotrifluoroethane

Category V (tentative specifications, reviewed if possible)

Bacillus cereus - microbial rennet	- Information on "secondary enzyme activity" and "typical application" are given by IDF.
Diethylene glycol monoethyl ether	- no information
Ethanol	- no information
Isobutanol	- Add criteria for specific gravity at 25°C. Use IR-spectrum from FCC III.
Isomaltitol	- Consider the specific name. Add limit for nickel and reducing sugar.
Methanol	- Increase the water content to 0.1%
Methyl beta-naphtyl ketone	- Use IR-spectrum from FCC III, delete UV-test.
Polyvinyl polypyrrolidone (PVPP)	- no information.
Propan-1-ol	- no information
Propan-2-ol	- limit for heavy metals seems low compared to the limit for arsenic.
Para-Propylanisole	- Use IR-spectrum from FCC III.

SAMPLING PLANS FOR THE DETERMINATION OF CONTAMINANTS IN FOODS - REPLIES RECEIVED IN RESPONSE TO CL 1982/14 - FA

Response from Governments:

Ten governments commented on CL 1982/14-FA: Australia, Chile, Denmark, Finland, France, Italy, New Zealand, Norway, Thailand, and the United States of America (USA). Three Commodity Committees considered the CL: Fats and Oils (CCFO), Processed Fruits and Vegetables (CCPFV) and Special Dietary (CCSD). These three Commodity Committees provided comments from individual national delegations but they did not provide a Committee response. Three other Commodity Committees met after the 15th CCFA but there is no indication that these Committees considered the CL: Cereals, Pulses and Legumes, Cocoa Products and Chocolate, and Milk and Milk Products. The Codex Committee on Methods of Analysis and Sampling decided to comment on CX/FA 82/8 at a later meeting. One international organization, the International Food Additives Council (IFAC), provided comments.

Most of the Government responses commented on both the two recommended guidelines in CX/FA 82/8 and on the factors to consider in developing sampling plans presented in CX/FA 82/8. One government (Chile) commented on the sampling approach of the CCPR, which was included in CL 1982/14-FA, but did not comment on CX/FA 82/8. Government responses on the two recommended guidelines on page 9 of CX/FA 82/8 were specific in their acceptance or rejection of the recommendations. However, their reasons for rejection of the recommendations and their additional comments on other aspects of sampling discussed in CX/FA 82/8 are numerous. The Commodity Committees did not respond specifically to the recommendations. All three Commodity Committees that considered CL 1982/14-FA deferred to comments from their national governments.

Because the individual comments in each Government's response are so varied, this report will categorize and analyze the comments rather than quote each comment verbation.

Analysis of comments on the Recommendations on page 9 of CX/FA 82/8

With respect to Recommendation 1, i.e., define Maximum Contaminant Level (MCL) as the average contaminant concentration in a lot, nine governments were in general agreement (Australia, Chile [agreed to same principle in the CCPR approach], Denmark, Finland, Italy, New Zealand, Norway, Thailand, USA) and one government, France, opposed the recommendation. Some of the nine governments who agreed with the recommendation also had reservations that the principle could be applied to all foods: Australia, Denmark, Italy, Thailand, USA. Italy stated that Recommendation 1 should only apply to contaminants with a "delayed risk." Italy noted this approach can be used because the acceptable risk to the consumer of some units within a lot exceeding an MCL where considered in setting the MCL. The USA proposed new wording for this recommendation to say that consignments which are usually non-homogeneous should be treated differently. Norway observed that the recommendation should be written to say that the MCL is compared to the measured value for average-of-a-lot rather than the MCL is defined as the average-of-a-lot. The IFAC also observed that the Recommendation was worded to indicate the CCFA set MCLs rather than Commodity Committee. France was opposed to the principle of enforcing MCLs by measuring the average-of-a-lot because they favor a sampling plan which provides an estimate of the actual contaminant frequency distribution in each lot. Australia and France suggest that a different kind of upper limit could be set - one which defines the maximum level of contaminant for any sample taken and analyzed.

With respect to Recommendation 2, i.e., measure average-of-a-lot by blending samples from a lot to obtain a composite sample and analyzing the composite sample, seven governments were in favor (Australia, Denmark, Finland, New Zealand, Norway, Thailand, USA) while France and Italy opposed this Recommendation. Nearly all governments who agreed with Recommendation 2 did so only as a general principle and expressed reservations that the composite sample approach could apply to all contaminant situations. Some of the reservations on composite sampling by the seven governments in general agreement with Recommendation 2 are:

- preparing a composite sample may be impractical for certain foodstuffs (New Zealand, Norway).
- Recommendation 2 should not be written so that it is a directive to the Commodity Committees to prepare composite-sampling plans (Australia, USA). Furthermore, Australia recommends that other relevant Codex Committees should examine the composite approach and comment on its suitability.
- composite sampling can be applied to foodstuffs which are homogeneous, but the recommendation should be broad in scope so as to include sampling plans for foodstuffs which are non-homogeneous (Australia, Denmark, New Zealand, Thailand, USA).

Italy concludes that some information on the variability of contaminant concentration within a lot is needed to enforce MCLs. Italy proposes the sampling plan which they sent to CCFA in reply to CL 1979/39. This plan includes random selection and blending of primary samples to produce five composite samples. (The author of this report concludes that the Italian sampling plan should not result in an estimation of the variability of contaminant within a lot. The Italian plan does give a more reliable estimate of the average contaminant concentration than the plan in CX/FA 82/8 which uses one composite sample. However, to estimate the variability of contaminant concentration within a lot, one would have to analyze a set of primary samples drawn from the lot without blending of the primary samples.)

France desires a sampling plan in which sufficient primary samples are analyzed to statistically estimate the actual distribution curve for contaminant concentration within a lot.

Analysis of other comments on the General Content of CX/FA 82/8

Several governments observed that a composite sampling approach is of value at the selling point or at international borders rather that at the manufacturering point for foodstuffs (New Zealand, France, USA). However, composite sampling should not be used at the retail level or for portions of a lot (Australia, France). Some governments had reservations on average-of-a-lot and composite sampling approaches for consignments within which the number of lots is unknown (France, Thailand, USA).

Some governments had questions on which contaminants are within the responsibility of the CCFA. New Zealand observed that the composite approach may not be appropriate for microbial contaminants. A comment from the last CCFO meeting is that the definition of contaminant on page 2 of CX/FA 82/8 is in conflict with the description on Page 4.

The CCFO also relates a comment that the Recommendations directly conflict with the approach suggested by the Codex Committee on Methods of Analysis and Sampling (CCMAS) in the General Principles for the Selection of Sampling Plans Appendix II (Alinorm 81/23, Appendix II). The CCMAS General Principles advise that sampling plans for health-related properties should be specific because such plans are applied to heterogeneous conditions such as sporadically occurring chemical contaminants.

The USA observes that CCFA should emphasize that recommendations from the CCFA are guidelines stating CCFA's preferred approach, but that Commodity Committees should be the organizations which actually develop specific sampling plans. Australia observes that the endorsing role of the CCFA should be emphasized, especially with respect to the "arbitrary" decisions of Commodity Committees in setting MCLs cited in IV, para. 3, of CX/FA 82/8, as well as the CCFA role of oversight with respect to setting MCLs based on Good Manufacturing Practice (GMP) and safety.

France submitted a comment which discusses in depth the principles of statistical quality control which should be included in a sampling plan for contaminants. This government observes that comparing MCL with the average contaminant concentration, where the contaminant has an exponential-like distribution in a lot, results in consumer ingestion of portions of the lot in which the contaminant level is greater than the MCL. France notes the many sources of variation in enforcing contaminants: variation in quality of raw material, variation due to processing and variation in the method of analysis, and concludes that a sampling plan to measure these variations would be preferrable. They argue for enforcing MCLs by analyzing fewer lots with a more efficacious sampling plan. France also notes that some sampling terms in CX/FA 82/8 do not agree with those of other organizations.

Other nations, in addition to France, observe that more sophistocated sampling plans may be needed for contaminants which are significant public health hazards (Thailand), imminent risks (Italy), a quality factor-such as histamine in fish (Finland) or where the public health significance of an MCL is in doubt (Australia). On the other hand, the USA observes that MCLs are endorsed as "safe," i.e., without public health hazard, by the CCFA based on the average lifetime exposure of consumers to the contaminant. The USA further comments that consumers experience all of the variability of contaminant concentration in foodstuffs, cited in CX/FA 82/8, and conclude that the Recommendations provide protection to the consumer when evaluated on the long-term basis.

REPORT OF THE AD HOC WORKING GROUP ON THE PRIORITY LIST AND FUTURE WORK

1. The Working Group chaired by Mr. Laurie Erwin (Australia) had the following texts to perform:

(i) To establish a Priority List of Food Additives and Contaminants; and

(ii) To analyse the views of the Member Governments on possible Future Work for CCFA.

Priority List of Food Additives and Contaminants

2. The Working Group reviewed the priority list prepared at the previous session (March 1982) of CCFA (ALINORM 83/12, App. XI). It was noted that most of the substances had been included on the agenda for the forthcoming 27th Session (April 1983) of JECFA. Only nitrogen, carbon dioxide and nitrous oxide remained. It was noted that polyglycerol esters of fatty acids, which were also on the priority list had previously been reviewed by JECFA.

3. Nitrogen and carbon dioxide were retained on the priority list for the development of specifications and for clarification of toxicological status. Nitrous oxide was also retained.

4. It was decided that vegetable gums and resins which have been already considered by JECFA but for which an ADI has not yet been established should be listed as a group in conjunction with other gums such as dammar gum. These gums were considered to be of particular interest to developing countries and should be accorded high priority. The JECFA Secretariat advised that provision of adequate data for the evaluation of these substances was difficult to obtain since the producing countries were often not in a position to provide such extensive data. It was agreed that all Member Countries be requested to provide any data they may have on these gums. The delegate of the USA advised that, because of a lack of biological information, the USA had recently required some of the food gums to undergo 90 day toxicological testing. For example, gum tragacanth was presently being tested in the FDA Laboratory.

5. Consideration was then given to additives proposed by Governments for inclusion on the priority list. The following were included:

- Chlorine: proposed by the UK. It is used in some flours destined for cake making and is included in the Draft Standard for Wheat Flour.

- Thiocyanate: proposed by Sweden for use in the preservation of raw milk by activation of the natural occurring antibacterial system in the milk (lactoperoxidase).

- Alpha amylase from Bacillus lichenformis: proposed by Denmark.

- Immobilized glucose isomerase from Bacillus coagulans: proposed by Denmark.

6. In regard to the enzymes glucose isomerase from Streptomyces violaceoniger (proposed by France), and protease from Streptomyces fradiae (proposed by Spain), it was noted that both had been considered by the 26th Session (April 1982) of JECFA.

7. The Working Group also had before it a list of additives (mainly salts) that had been endorsed by the CCFA for use in certain commodities but which had not been evaluated by JECFA. It was agreed that these be added to the priority list except for potassium L (+) tartrate (which had already been evaluated), and paprika which was regarded as an ingredient rather than a food additive.

8. In regard to the L (+) tartrates of ammonium, calcium and magnesium which were included on the list, it was noted that the forthcoming session of JECFA would review the DL (∓) tartrates of calcium and magnesium. The Working Group questioned whether all the isomers were used in food manufacture and proposed that advice be sought on which substances are actually used.

9. The Revised Priority List of Food Additives and Contaminants is given in Annex 1.

Possible Future Work

10. The Working Group had before it the Working Paper on Possible Future Work (CX/FA 83/11 Part 1) prepared by Australia.

11. It was noted that at its previous session (March 1982) the CCFA identified the following as possible items of future work:
    - packaging materials
    - environmental contaminants
    - residues of veterinary chemicals in foods
    - maximum levels of food additives in soft drinks

12. In Codex CL 1982/18 - FA comments had been requested on the above items and other possible future work. The Working Group had before it comments submitted by Australia, Barbados, Belgium, Canada, Cyprus, Denmark, Ecuador, Finland, Hungary, Mexico, New Zealand, Norway, Sweden, Thailand, United Kingdom, the Council of Europe and Dr. J.G. Davis, Reading, UK. A draft paper on Future Work of the CCFA prepared by Dr. Rao Maturu was also considered.

Packaging Materials

13. Some members of the Working Group expressed the view that this subject was outside the terms of reference of the CCFA. After due consideration, there was a consensus that the CCFA was the appropriate Codex Committee to handle this matter.

14. It was noted that this was a very broad and complex topic and the extensive work involved would be beyond the resources of the CCFA. The Council of Europe had advised that it would not commence new work on packaging materials. It was noted that the USFDA and some European countries are heavily involved in this work and the EEC is studying monomers and other starting substances for plastics used in food packaging materials.

15. It was finally agreed that the CCFA should undertake work on packaging materials but for the present should restrict its involvement to specific substances of possible and immediate public health concern. In the first instance four substances which might migrate from packaging materials into foods were identified as priority areas

- vinyl chloride
- styrene
- acrylonitrile
- di-ethylhexylphthalate

16. The Working Group agreed that Governments and Commodity Committees should be requested to advise on what regulations presently exist in respect to these substances. Further, the following information would also be of assistance:

- data on actual levels of these substances in foods due to migration from packaging materials
- the actual foods packaged in materials which may contain these substances
- the extent of use and nature of packaging materials which may contain these substances

In addition, comments could be sought on any other components of packaging materials which could be a cause for concern as regard public health.

17. The delegate of the USA advised of the work being done in that country and offered to assist the CCFA in this work to the extent of available resources.

Environmental Contaminants

18. The Working Group noted that the last session (March 1982) of the CCFA had considered information supplied by Governments on maximum levels for industrial and environmental contaminants (CX/FA 82/18). The CCFA had considered this to be a wide field and that priorities should be set for those contaminants of public health concern. It was therefore recommended that a consultant prepare a paper on this work (Alinorm 83/12, paras 188 - 190).

19. There was general agreement that the CCFA should pay attention to environmental contaminants in future work. However, because of the extent of the topic priority areas would need to be identified. Further, there would be a need to establish procedures on how this work should be handled including the involvement of JECFA and the nature of the levels which should be established.

20. The Working Group noted that the report of the consultant (H.P. Mollenhauer), entitled "Contaminants in Food - Approaches by Governments and Possible Actions by the Codex Committee on Food Additives", had just become available and would be considered under Agenda Item 16 at the plenary session.

21. It was decided that the recommendations in the paper (CX/FA 83/18, pages 12 and 13) should be briefly reviewed by the Working Group.

22. In regard to Recommendation (a), the Working Group agreed that Governments should carefully consider the specific problems connected with the control of environmental contaminants in foods before deciding upon legal limits. In addition, any system should be supported by a suitable monitoring programme. There was an extended discussion on the consultant's proposal that in the first instance it would be appropriate for Governments to establish "Guideline levels" or "action levels". After considering various alternatives the Working Group decided that perhaps a useful level to establish would be a "defect action level". This would not be intended as a level at which the food would be rejected but rather one which would trigger immediate follow-up action including investigatory and control procedures, as appropriate.

23. The Working Group expressed strong support for recommendation (b) that CCFA request the Codex Alimentarius Commission to (i) encourage international programmes on monitoring and control of environmental pollution, and (ii) encourage Governments to participate in the Joint FAO/WHO Food Contamination Monitoring Programme (JFCMP).

24. There was also general support for Recommendation (c) that (i) the work of JFCMP be closely coordinated to the requirements of the CCFA, and (ii) that the Chairman of the CCFA attends meetings of the JFCMP Technical Advisory Committee. It was noted that to date no formal arrangements existed between CCFA and JFCMP and consequently there was some misunderstanding as to the type and extent of work being undertaken by each. Therefore, it was extremely important that a close working relationship be developed as soon as possible.

25. Recommendation (d) that JFCMP keep CCFA informed of the type and extent of contamination of specific foods was seen as an extension of the previous recommendation.

26. The Working Group did not discuss in any detail the remaining Recommendations as these outlined procedures and initiatives which could only be taken as follow-up action when adequate data becomes available.

27. In view of the workload envisaged, the Working Group decided to recommend that the CCFA, at this meeting, establish a new Working Group to deal with environmental contaminants.

Residues of Veterinary Chemicals in Foods

28. The Working Group agreed that priority shpuld be given to the establishment of maximum limits for residues in food of chemotherapeutic agents, anaboles and antibiotics, and possible metabolites of veterinary chemicals used in animal husbandry and veterinary medicine.

29. It was noted that JECFA and the CCFA had already given some consideration to this work. Various views were expressed on how this work should be handled in the future. While some members of the Working Group considered that the work was appropriate to the CCFA and could be handled by it, others considered that a new committee was necessary.

30. This latter viewpoint was on the basis that development of such levels necessitated expertise in the use of veterinary chemicals on the farm. In this regard it was noted that the 5th Session (October 1982) of the Codex Committee on Meat Hygiene (CCMH) had decided that,although it had niether the responsibility nor the expertise to establish such residue limits, it did have the expertise in the use of veterinary chemicals (draft Alinorm 83/15, para. 213).

The CCMH had therefore decided that in view of the Committee being adjourned sine die it would recommend to the Commission that if considered necessary it could establish an Expert Working Group to provide advice on antibiotics, anaboles and other veterinary chemicals to the relevant Codex Committee (draft Alinorm 83/15, para 133).

31. The Working Group was advised that it may be possible for FAO to appoint a consultant to investigate the whole question of how this work could be handled. This approach was endorsed by the Working Group which proposed the following as possible terms of reference for the consultant:

"a) to identify residues, in foods of animal origin, of veterinary chemicals such as chemo-therapeutic agents, antibiotics, growth promotants, and other feed additives that give rise to public health concern and/or cause difficulties in the food trade.

b) To obtain from governments and other sources data on levels of such residues.

c) To obtain information about regulations and conditions for use of such veterinary chemicals; ways and means of administering such regulations; control mechanisms; data on possible "waiting periods" after application; etc.

d) to obtain information on which specific residues should be regulated in food; available toxicological data; and analytical methods being used.

e) To advise the Codex Alimentarius Commission on how to handle these matters and how the different tasks should be handled including the toxicological evaluations.

Maximum Levels of Food Additives in Soft Drinks

32. The Working Group noted that the 11th Session (May 1977) of CCFA adopted an advisory list of food additives in soft drinks (Alinorm 78/12, paras 116 - 119) and that this is published in CAC/FAL 5 - 1979, The Guide to the Safe Use of Food Additives. The CCFA, at its 13th Session (September 1979) had also considered a report of the Working Group on Food Additive Intake (CX/FA 79/5) which indicated that in most cases the amounts of additives ingested from soft drinks did not exceed 20% of the ADI.

33. The Working Group was advised that the intake of food additives from soft drinks had been under review by the Working Group on Food Additive Intake

for many years and that there were no specific areas of concern. It was also pointed out that soft drinks were not a significant item in international trade.

34. In view of the above, the Working Group recommends that at this time the establishment of maximum levels for food additives in soft drinks is not a priority item for CCFA.

Other Possible Future Work

35. The Working Group discussed a range of other possible future work including:

- - drinking water treatment agents
- analysis of foods for food additive content
- sampling for food additives and contaminants in foods

36. Although the Working Group considered these additional proposals to be important, it agreed that in view of the decisions already taken it would not be possible for CCFA to handle any further work in the immediate future.

PRIORITY LIST ESTABLISHED BY 16th SESSION OF CCFA

Additives retained from previous list for clarification of safety-in-use

- Carbon dioxide
- Nitrous oxide

Additives Endorsed by CCFA but not yet evaluated by JECFA 1)

- Aluminum ammonium sulphate
- Ammonium phosphate
- Ammonium succinate
- Ammonium L(+) tartrate
- Calcium adipate
- Calcium fumarate
- Calcium hydrogen carbonate
- Calcium succinate
- Calcium L(+) tartrate
- Calcium triphosphate
- Clarifying enzymes
- Diammonium hydrogen phosphate
- Guanylic acid
- Inosinic acid
- Magnesium acetate
- Magnesium adipate
- Magnesium citrate
- Magnesium hydrogen phosphate
- Magnesium succinate
- Magnesium L(+) tartrate
- Monomagnesium phosphate monobasic
- Monopotassium monophosphate
- Potassium fumarate
- Potassium inosinate
- Potassium guanylate
- Potassium sulphite
- Potassium saccharin
- Potassium succinate
- Potassium sulphate
- Sodium aluminium polyphosphate
- Sodium sorbate

Additives proposed at 16th Session (March 1983)

- Chlorine: proposed by UK
- Sodium thiocyanate: proposed by Sweden
- Alpha amylase from Bacillus lichenformis: proposed by Denmark
- Immobilized glucose isomerase from Bacillus coagulans: proposed by Denmark
- Streptomyces rubiginosus: proposed by USA
- Streptomyces olivaceus: proposed by USA
- Streptomyces olivochromogenes: proposed by USA
- Actinoplanes missouriensis: proposed by USA
- Bacillus coagulans: proposed by USA
- Vegetable gums: proposed by WG on Priorities

Additives Proposed by ad hoc Working Group on Salt (March 1983)

- Aluminium, calcium, magnesium, potassium and sodium salts of capric, caprylic, lauric and oleic acids 1)
- Potassium alumino silicate
- Aluminium calcium silicate
- Ferric ammonium citrate
- Magnesium ferrocyanides
- Manganese ferrocyanides
- Ferrous manganocyanide

Substances proposed by the ad hoc Working Group on Priorities (March 1983)

Vinyl chloride, styrene, acrylonitrile, diethylhexylphthalate

1) Governments and industry are requested to indicate which substances are actually used and to provide specifications to the FAO Joint Secretary of JEFCA with a copy to the Codex Secretariat.

APPENDIX XV

Recommendations on Contaminants

1(a) Governments should carefully consider the specific problems connected with controlling environmental contaminants in foods before deciding on legal maximum levels; wherever feasible, the setting-up of guideline-levels - linked with appropriate clauses of the basic food law - could be an appropriate measure for safeguarding the health of the consumer.

Such a system, however, should be supported by monitoring the level of contamination, so that Governments are kept informed of any health hazard from contaminants, that might require stronger action.

1(b) International programmes on monitoring and control of environmental pollution should be encouraged to concentrate on measures concerning contamination of the food chain.

1(c) It is recommended to governments of developed and developing countries that they participate in JFCMP.

1(d) For this purpose FAO should further strengthen food control facilities in developing countries, so that they are able to monitor the level of food contamination, assess the situation, and participate in JFCMP.

2(a) The work of JFCMP should be closely coordinated to the priorities and requirements of CCFA.

2(b) For this purpose, it would be useful if the Chairman of CCFA be represented regularly at the meetings of JFCMP Technical Advisory Committee - being a committee of government experts - as an observer.

2(c) The JFCMP should be invited to inform CCFA on type and extent of contamination of specific foods at appropriate intervals to be determined.

3 The IRPTC of UNEP should be invited to give priority to gathering information on legislation on contaminants in food. The Codex Secretariat may also collect such information from member Governments and other sources.