

codex alimentarius commission

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ALINORM 78/12

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX ALIMENTARIUS COMMISSION
Twelfth Session, April 1978

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

The Hague,
31 May - 6 June 1977

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Eleventh Session

The Hague 31 May - 6 June 1977

INTRODUCTION

1. The Codex Committee on Food Additives held its 11th session in The Hague, the Netherlands, from 31 May to 6 June 1977, by courtesy of the government of The Netherlands. Dr. G.F. Wilmink (Netherlands) acted as Chairman. The session was attended by 143 participants, including government delegations from 37 countries, observers from 20 international organizations and the Secretariat (see Appendix I for the List of Participants).

2. The session was opened by the Chairman of the Committee, who welcomed the participants on behalf of the government of The Netherlands. He expressed his regret for the long interval between the 10th and 11th sessions which was due to a variety of circumstances. Taking into account the workload for this session, he expressed the opinion that it might be useful to set up some more Working Groups during the session in order to cope with the items on the agenda in the best possible way.

APPOINTMENT OF RAPPORTEURS

3. Mr. H.U. Pfister (Switzerland) and Mr. M. Fondu (Belgium) were appointed as rapporteurs. Dr. T. Avigdor (Switzerland) assisted in the preparation of the French version of the report.

ADOPTION OF THE AGENDA

4. The Committee adopted the provisional agenda, taking into account the introduction of a new item "3(a): Appointment of Working Groups", and the deletion of items 9(c) "Specification for antioxidants and emulsifiers" and 9(e) "Specifications for thickeners and stabilizers, anti-caking agents and preservatives", due to the absence of the documents concerned.

APPOINTMENT OF WORKING GROUPS

5. In order to facilitate consideration of items 5, 6, 9, 11, 12 and 13, the Committee set up three more ad hoc Working Groups in addition to the existing ad hoc Working Groups which were established during the 10th session of the Committee.

Ad Hoc Working Group on Food Additive Intake

6. The Committee noted the composition of the ad hoc Working Group on Food Additive Intake which had been set up during the 10th session of the Committee. Under the Chairmanship of Mr. M. Fondu (Belgium) and assisted by Dr. G. Vettorazzi (WHO) as Secretary, the following countries would participate: Brazil, Canada, France, Federal Republic of Germany, Israel, Italy, Netherlands, Spain, Switzerland, the United Kingdom and the United States of America.

Ad Hoc Working Group on Flavours

7. The Committee noted the composition of the ad hoc Working Group on Flavours which had been set up during the 10th session of the Committee. Under the Chairmanship of Mr. J.P. Goddijn (Netherlands), assisted by Dr. H. van den Dool (Netherlands) as Secretary, the following countries would participate: Belgium, Denmark, France, Federal Republic of Germany, Italy, Switzerland, the U.K. and the U.S.A. In addition, the following international organizations agreed to participate in the work of the Working Group: the Commission of the EEC, IOFI and FIGVS.

Ad Hoc Working Group on Labelling of Food Additives

8. The Committee noted the composition of the ad hoc Working Group on the Labelling of Food Additives, which had been set up during the 10th session of the Committee. Under the Chairmanship of Mr. D. Maskell (U.K.), assisted by Mr. W.L. de Haas (FAO) as Secretary, the following countries would participate: Australia, Canada, France, the Netherlands, Norway and the U.S.A.

Ad Hoc Working Group on Specifications

9. The Committee agreed on the composition of the ad hoc Working Group on Specifications under the Chairmanship of Mr. D.F. Dodgen (USA), assisted by Mr. M.M. Hoover (USA) as Secretary. The following countries agreed to participate: Denmark, France, Greece, Guyana, Ireland, the Netherlands, Switzerland, and the U.K.

Ad Hoc Working Group on Food Irradiation

10. The Committee agreed on the composition of the ad hoc Working Group on Food Irradiation under the chairmanship of Dr. A. Brynjolfsson (USA) assisted by Dr. K. Vas (IAEA) as Secretary. The following countries agreed to participate: Belgium, Canada, Czechoslovakia, Federal Republic of Germany, France, Italy, the Netherlands, and Switzerland. The following international organizations would also participate: FAO, OECD, and WHO.

Ad Hoc Working Group on Priority Lists for Food Additives

11. The Committee agreed on the composition of the ad hoc Working Group on Priority List. The following countries agreed to participate: Brazil, Canada, India, Switzerland, U.K. and the U.S.A. The Chairman would be chosen by the participating members and would be assisted by Dr. G. Vettorazzi (WHO) as Secretary (see para 161).

MATTERS OF INTEREST TO THE COMMITTEE

Report of the 11th session of the Commission (ALINORM 76/44)

12. The Committee noted that (a) Codex committees had been requested by the Commission to ensure that food additive provisions included in Codex standards should be precise and should refer to the total substance in the final product, (b) Codex Food Additive Lists A and C would be brought up-to-date using consultant services and published during 1977, (c) the food additive specifications submitted to the Commission at Step 5 of the Procedure had been adopted but, for financial reasons had not yet been published as Codex specifications (paras 117-120, ALINORM 76/44).

13. The Committee was informed that the Principle relating to the Carry-over of Additives into Foods (Appendix IV, ALINORM 76/12) had been adopted by the 11th session of the Commission. As regards the question of the declaration of food additives carried over from the use of ingredients on the label, it was pointed out that this question

had been discussed at the 12th session of the Codex Committee on Food Labelling, held in Ottawa, 16-20 May, 1977. The Food Labelling Committee had concluded, consistent with part 4 of the Principle relating to the carry-over of Additives into Foods, that additives carried over into a particular food in a significant quantity or in an amount sufficient to perform a technological function in the final food product must be declared on the label. This meant that additives carried over in quantities less than those described in Part 4 of the Carry-over Principle would not have to be declared on the label. In this respect, it was noted that the judgement as to whether an additive carried over into a food was present in quantities sufficient to perform a technological function or quantities significantly below such levels rested with Codex Commodity Committees. The Committee noted the conclusions of the Codex Committee on Food Labelling and considered that it was up to that Committee to decide as to how these conclusions should be given effect. It was suggested that one way would be to include an appropriate provision in the General Standard for the Labelling of Prepackaged Foods. The Codex Committee on Food Labelling was requested to give this matter further consideration.

14. The Committee noted that the Commission had adopted the changes to the status of endorsement of food additive provisions in Step 9 standards proposed by this Committee at its last session. The Commission had decided that there was no need to follow the Codex Amendment Procedure for these changes. The Secretariat pointed out that some of the changes had been issued as corrigenda (e.g. change from temporary-endorsement to endorsement) while others were issued as amendments requiring action by governments regarding any previous acceptance of the standard (e.g. withdrawal of an additive provision).

15. The Committee was informed that the Commission had agreed with the views of the 10th session of the Committee that the question of establishing maximum levels for contaminants in Codex standards should be given more attention and had requested Codex Commodity Committees to ensure that, where necessary, Codex standards should include a section on contaminants.

16. The Committee also noted that the Commission had considered a proposal to set up a new Codex committee to deal with industrial chemicals and heavy metals in food. The Commission had decided that existing Codex committees should deal with these questions. For example, data on heavy metals and other elemental contaminants should be submitted, through Codex Commodity Committees, to this Committee (ALINORM 76/44, paras 385-391).

17. The representative of WHO informed the Committee concerning the Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme. He pointed out that the Directors-General of FAO and WHO had designated institutes in 13 countries as FAO/WHO collaborating centres for Food Contamination Monitoring. The representative of these institutes, together with experts from developing and developed countries, would meet in Geneva during June 1977 to finalize Phase II of this Programme funded by UNEP. It was envisaged that during 1977, data would be collected on the levels of organochlorine pesticides and PCBs in milk, butter and human milk and on the levels of lead in a number of vegetables and in molluscs and crustaceans. In addition, in subsequent years, data would be collected on the levels of cadmium, mercury, arsenic and aflatoxins in a number of food items. In due course, these data would be made available to all interested parties, including Codex Commodity Committees, so that maximum levels for contaminants which might be present in the food items, could be elaborated.

18. The Committee considered that there was no need to change its terms of reference in order to deal with the contaminants mentioned above and noted that some time would elapse before it would be in a position to make recommendations for maximum levels of contaminants in food on the basis of data from the FAO/WHO Monitoring Programme.

Reports of the 19th, 20th and 21st Sessions of the JECFA

19. The Committee considered the report of the 19th session of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (WHO Techn. Rep, Ser. No. 576). It noted that the Expert Committee was looking to this Committee for guidance concerning the classification of additives on the basis of technological function and their nomenclature. The Committee agreed that in up-dating Codex lists A and C of food additives, this question should be given consideration and decided to take this matter up under item 8 of the agenda.

20. The WHO representative briefly highlighted the major aspects of interest to this Committee contained in the 19th, 20th and 21st reports of JECFA. He pointed out that the 19th report contained the evaluations of some food colours, thickening agents or smoke condensates as well as of liquid smoke. The question of impurities or transformation products of intentional and unintentional food additives was discussed by the JECFA and it had been observed that in a number of instances JECFA had been faced with the task of evaluating compounds that contained unusual impurities or that gave rise to transformation products of possible toxicological significance and that, under certain circumstances, an impurity or transformation product may have to be tested separately.

21. With regard to the 20th report of JECFA, it was noted that the experts had discussed the importance of information on food additives and contaminants to developing and developed countries had called attention to the premature replacement of suspect chemicals by less tested substances and had reported on matters of concern related to modified starches. With regard to the latter question it was noted that the Experts had recommended that no new modified starches should be considered before the findings observed in long-term studies in rats fed with diets containing from 5% to 25% at different chemically modified starches were resolved.

22. With regard to the 21st report of JECFA, the WHO representative made a verbal report on the most important points contained in the draft report. He reported orally that the agenda of the 1977 session of JECFA had been modified to include consideration of the non-nutritive sweeteners saccharin and cyclamates. As regards saccharin, the previously allocated ADI had been reduced to half the former value and made temporary. In addition, the ADI for dietetic purposes had been revoked. Other aspects which had been dealt with were general principles for the evaluation of food colours, safety aspects of enzyme preparations used in food processing and the problems of exposure of infants and children to contaminants in food.

23. In answering questions regarding the availability of the toxicological monographs on food additives (WHO Food Additive Series) resulting from the evaluations of food additives carried out by JECFA at its 1975, 1976 and 1977 sessions, the WHO representative explained that the monographs resulting from the 1975 had been already published. However, those from the 1976 session, had not yet been published due to shortage of funds on the part of the two Organizations sponsoring the programme. In view of the fact of the cancellation of the WHO Food Additive Series, the WHO

representative reported that discussions were presently in process between FAO and WHO on how these monographs should be made available to interested parties.

24. A number of delegations were of the opinion that without the timely availability of summaries of the toxicological data on the basis of which the Experts had made their recommendations concerning the safe use of additives, it would not be possible for the Committee to continue its work. The Committee concurred with this view and, on the proposal of the delegation of the USA, adopted the following resolution to be brought to the attention of the Directors-General of FAO and WHO and the Codex Alimentarius Commission:

"Publication of the Reports and Monographs on the Toxicology and Specifications of the Joint Expert Committee on Food Additives

The 11th session of the Codex Committee on Food Additives, considering

- that the WHO/FAO food additive report and monographs series are an integral part of the safety assessment programme of the international community;
- that these monographs and reports serve as a template against which individual nations can compare their scientific and regulatory judgements;
- that these documents have also proved an invaluable resource to those nations which have as yet been unable to afford the material cost of sophisticated assessment systems for the judgement of the safety of ingredients added to foods;
- that, because of the publication and wide dissemination of these reports and monographs, these nations and especially developing countries are thus in a better position to use their experts and resources to upgrade the quality of their diets at home while at the same time being able to structure their exports in a fashion to be full trading partners in the international community;
- that the reports, without the monographs complete description of the supporting data, lose much of their utility;

recognizing that these ideas are major goals of FAO/WHO, requests the Directors-General of FAO and WHO:

- (1) to realign the programme priorities in order to allow for the continued publication of these monographs and reports; or
- (2) to explore ways and means to reduce the cost of publication of the monographs, in order to ensure their continued and speedy publication, possibly in an economical and simple form issued by one Organization only or, if this not possible,
- (3) to find financial resources within FAO/WHO programme limits to consider a special subscription of member nations to continue this important work."

Codex Committee on Fish and Fishery Products

25. The Committee was informed that the above committee, at its 10th session (October 1975), when considering the use of spice oils and spice extracts as an ingredient for canned mackerel, had held a discussion on what exactly constituted "additives" and what should be regarded as "ingredients" and had ultimately referred the question to this Committee (ALINORM 76/18A, para 75). It was noted that at the 11th session (October 1976), the Committee on Fish and Fishery Products had again

considered the issue - this time in relation to Canned Sardines - and had agreed that, whereas spices should be considered to be food ingredients, spice oils and spice extracts were food additives (ALINORM 78/18, para 44).

26. The Committee noted that this conclusion agreed with its opinion expressed earlier and further noted that the general question of flavour would be further discussed later during the session. The delegation of the Federal Republic of Germany stated that in its view spice oils and spice extracts were to be regarded as foodstuffs rather than as food additives.

Report of the 9th session of the Codex Committee on Foods for Special Dietary Uses (ALINORM 76/26A)

27. The Committee noted and accepted the explanation by the above Committee of the question raised concerning sections 6.2 and 7.2(c) of the Recommended International Standard for Infant Formula (see para 24, ALINORM 76/26A). In the opinion of the Dietary Foods Committee, there was no inconsistency between these two sections since section 6.2 covered substances resulting from raw materials or from processing, while section 7.2(c) referred to toxic substances arising from microbiological contamination.

Codex Committee on Food Labelling

28. The Committee was informed that the Codex Committee on Food Labelling had adopted a definition for "bulk containers", which might also be applicable to food additives when sold as such. It was agreed to consider this matter further when discussing the Revised General Standard for the Labelling of Food Additives.

29. The Committee discussed at some length a proposal of the Food Labelling Committee that the class names for food additives included in the General Standard for the Labelling of Prepackaged Foods be harmonized with the names used to designate classes of additives in the Codex List of Additives (ALINORM 76/22, paras 92-98). The Committee generally agreed that such harmonization would be useful. It was noted that at an earlier session it had been decided not to expand the list of class names. The Committee agreed, however, that the class names listed in the General Standard for the Labelling of Prepackaged Foods covered substances which varied considerably in importance from a point of view of their adequacy in informing the consumer and, moreover, that the list was incomplete. The Committee decided to consider the matter further when discussing the Codex List of Food Additives.

CONSIDERATION OF THE REPORT OF THE AD HOC WORKING GROUP ON FLAVOURS

30. At its 10th session (June 1975) an ad hoc Working Group had been set up to consider procedures for establishing positive lists and to examine the question of grouping flavouring agents (see para 7). The rapporteur of the Working Group, Mr. J.P. Goddijn, in introducing the report of the Working Group (CX/FA 77/6), stated that a pragmatic approach had been followed to resolve the question of grouping flavouring agents as, for reasons of economy, it would provisionally not be possible to test all flavouring agents.

31. The ad hoc Working Group, therefore, recommended that priority be given to:

- (1) the establishment of criteria to be used for the safety evaluation of flavouring substances irrespective of their nature;

- (2) the preparation of specifications on chemical purity of artificial and nature-identical flavouring substances; and
- (3) the toxicological evaluation of artificial flavouring substances, in order to establish a positive and open list of these substances.

32. Noting that the earlier discussion of the Committee had been based on the Council of Europe's publication "Natural Flavouring Substances, their Sources, and Added Artificial Flavouring Substances", often referred to as the "Blue Book", the Chairman requested the representative of the Council of Europe (CE) to inform the Committee on recent developments. The representative stated that a third edition of the "Blue Book" was being prepared for publication in 1978/79 under a new title: "Flavouring Substances and Sources of the Natural Flavourings". In the new edition the system adhered to in earlier editions based on open positive lists would be maintained, but the number of classes under which the natural flavouring substances were listed would be increased. The various lists of flavouring substances would be revised and smoke flavours would also be considered by the CE Working Party.

33. The representative reaffirmed the Council's interest in the work of this Committee and stressed its willingness to continue the collaboration. In turn, the Committee expressed its willingness to continue the fruitful cooperation with the Council of Europe.

34. The Committee was informed of the findings of the Joint FAO/WHO Expert Committee on Food Additives (April 1976, 20th session) which also discussed the question of priorities for the evaluation of flavouring substances (WHO Techn. Rep. Ser. No. 599, Chapter 4).

35. It was noted that the Expert Committee had felt that the best approach to the question would be to compile lists of the various flavouring substances and to estimate the likely degree of exposure of humans to each of them. These substances should then be classified in terms of possible health hazard and priorities for their evaluation should be established.

36. The Expert Committee had related the flavouring substances to their origin and occurrence and had made a division into four groups. It had stressed, however, that all flavouring substances, whether natural or not, should be evaluated for their safety. It was observed that the Expert Committee had recommended that substances deemed to be of a lower priority with regard to toxicological evaluation might be tentatively accepted for use in foods, if they were listed as acceptable by bodies such as the Council of Europe or on other acceptable advisory lists.

37. The Committee also noted that the ad hoc Working Group had recommended - next to the recommendations on priorities mentioned above in para 31 that the priorities be revised as work progressed. The report of the ad hoc Working Group is attached to this report as Appendix II.

38. The Committee expressed its appreciation for the work of the ad hoc Working Group and agreed to request the Group to continue with its work and to prepare for the next session of the Committee a priority list of artificial flavouring substances selected from those presently contained in List B and which, in due course, would be forwarded to JECFA, together with all available relevant information, for evaluation. The members of the ad hoc Working Group agreed to continue with the work. Governments and interested organizations were requested to provide such data as would help in the selection of certain substances, including natural ones, for close consideration.

REPORT OF THE AD HOC WORKING GROUP ON FOOD ADDITIVE INTAKE

39. The Committee had before it a report of the above Working Group (CX/FA 77/5 and Addendum 1) (see para 6). In introducing the report, the Chairman of the Working Group, Mr. M. Fondu informed the Committee that, as a result of a rather restricted response from governments, the report contained data only on benzoic acid from the USA, Italy and Belgium. Data from Italy and Belgium indicated that the intake, estimated on the basis of food consumption data and actual quantities of benzoic acid used, was well below the ADI. Data from the USA were in revision. The delegation of Canada reported on its screening of the consumption of food additives by estimating the potential daily intake (PDI) based on maximum use levels. Results indicated that the PDI of several food additives exceeded the acceptable daily intake (ADI) and required further in depth study. This work was currently in progress and the results would be made available to the Committee.

40. In discussing the merits of the approach used by the three countries above in estimating the daily intake of additives, the Committee noted that the PDI calculated by WHO was a useful first screening test to separate those additives where it was highly unlikely that the ADI would be exceeded. This first selection left those additives which required further examination. In this respect, the approach used by the Working Group could be regarded as a further step in arriving at a more precise estimation of daily food additive intake. This was so since, instead of using legal limits in the calculations, actual levels of the additives added to food were used in calculating the estimate of daily intake.

41. It was pointed out that should there still be, after much calculations, a problem as regards the intake of the additive in the light of the ADI, further refinements were possible, e.g. using more specific figures for food consumption. There were also other techniques such as frequency surveys of food intake, total diet studies in which the total diet of a group of individuals is analyzed chemically for food additives. The Committee also noted that it was also necessary to keep in mind high consumers of certain foods.

42. A number of countries informed the Committee that they were in the process of carrying out studies or that studies had been started on food additive intake and that the results of these studies would be submitted to the Working Group. It was pointed out that it would be desirable to extend these studies to include contaminants. In this respect, the Committee was informed of the work to be done by FAO/WHO/UNEP concerning the monitoring of certain foods for contaminants (see para 16).

43. The Committee noted that, although the 4-5 countries for which PDI had been calculated in the WHO computerized study represented a small sample of world population, it was at least indicative of what the situation might be in other countries. In any event, there was a need to extend the PDI calculations to other countries. Furthermore, there was a need to lay down a protocol according to which governments, in full collaboration with the Working Group, should address themselves to the problem of estimating total food additive intake. It was also necessary to standardize the terminology used to describe food additive intake.

44. The committee also noted that the judgement as to whether or not an estimate of intake exceeded the ADI and, therefore, represented a hazard to health should be made after having considered all factors including the basis on which the ADI had been established.

45. It was agreed that the ad hoc Working Group should continue to consider the question of food additive intake in close collaboration with WHO and governments were urged to carry out suitable food additive intake studies and submit the results to the Working Group.

ENDORSEMENT OF FOOD ADDITIVES IN CODEX COMMODITY STANDARDS

46. The Committee had before it a paper (CX/FA 77/IO-Part I and Addenda 1 and 2, distributed at the session) listing for a number of Codex standards those additive provisions which were pending endorsement.

General Remarks

47. Several delegations pointed out that, in their view, the present endorsement procedure had some shortcomings. In their opinion, food additive provisions in commodity standards should not only depend on available toxicological information on a particular substance but should also take account of the actual intake of food additives. Furthermore, some delegations were of the opinion that the technological justifications which were provided by the Commodity Committees were often insufficient.

48. In the ensuing discussion one delegation pointed out that the basis for endorsement of a food additive by this Committee should be: (i) the status of the toxicological evaluation of the additive; (ii) the technological justification for the use of the additive as presented by the commodity Committee; and (iii) individual national expertise. This delegation further held the view that the present Codex procedure provided adequately for governments to express their opinion. In view of the above arguments, the delegations of Denmark and the Federal Republic of Germany reserved their position concerning the endorsement of provisions for food additives and contaminants.

49. It was noted that for food additives with a fixed ADI the contribution of a given food could be estimated and a ratio between the PDI and ADI could be established. This exercise was considered to be of great importance in determining the priorities in evaluating food additives. Concern was, however, expressed about the ability of the Committee to keep abreast with developments in technology and toxicology.

50. The Committee concluded that the present endorsement procedure appeared to meet the requirements. In order to facilitate the work of the Committee, it was felt, however, that the Codex Secretariat, when preparing an extract of the food additives sections of Codex standards for endorsement, should identify those substances which, on the basis of their ADI, required particular attention (see also para 165).

Standard for Edible Ices and Ice Mixes (ALINORM 78/11, Appendix II)

51. The delegation of Sweden, representing the host country of the Codex Committee on Edible Ices, introduced the standard to the Committee and pointed out that the extensive list of food additives had been drawn up to accommodate all those additives presently used by one or more countries. It could be expected, however, that in a single edible ice only few of the additives would actually be used. It was also pointed out that the list as it stood provided for the possibility of substitution of additives when circumstances so required.

52. The delegation of Sweden further pointed out that the products covered by this standard were singular among commodities for which Codex standards were elaborated in that they were completely fabricated and covered a wide range of products. The Committee was informed that the Codex Committee on Edible Ices had had no

opportunity to discuss the technological justification of the individual additives in detail, but that a justification for the various groups of additives had been given.

53. The Committee held the view that it had been placed in a somewhat awkward position, as the Codex Committee on Edible Ices had adjourned sine die. Thus, it was not in a position to ask for further technological justification of the individual food additive provisions put forward. It was suggested that a working group of representatives of governments particularly interested in the products covered by the standard could be formed, which might provide the justifications needed. If the working group were to meet prior to the next session of the Commission, its findings could be presented to the Commission together with the report of the Codex Committee on Edible Ices. This procedure would thus not obstruct a possible adoption of the standard at Step 8.

54. The Committee concluded that there was a justification for the groups of additives given in the standard. It agreed to consider for endorsement the additives listed in the standard, following a justification for the use of the individual food additives by the working group of interested governments mentioned above.

Standard for Soups and Broths (ALINORM 76/9, Appendix II)

55. The delegation of Switzerland informed the Committee that the Codex Committee on Soups and Broths had altered the scope of the standard to apply only to bouillons. The Committee decided not to discuss the food additive section of this standard.

Standard for Fructose (ALINORM 76/27, Appendix II)

56. The Committee noted that the limit for sulphur dioxide in the standard for fructose was in line with similar provisions in standards for some other sugars. It was pointed out, however, that in fructose the sulphur dioxide was not added to the product as such and thus should be considered to be carried over as a contaminant. The Committee decided to endorse this provision with the understanding that the Commission would consider the deletion of the square brackets.

Standard for Low-Fat Spread (ALINORM 76/19, Appendix III)

Colours

57. The Committee noted that the present standard was closely related to the Standard for Margarine. It was observed, however, that in particular the list of additives differed.

58. The endorsement of the colours listed was postponed and the Commodity Committee was requested to set maximum levels for colours in the final product, taking into account the individual substances for which ADIs had been set. It was pointed out that only synthetic beta-carotene had been evaluated.

Emulsifiers

59. The Committee postponed the endorsement of the polyglycerol esters of fatty-acids and the polyglycerol esters of interesterified ricinoleic acid, requesting the Commodity Committees to set maximum levels.

Thickening Agents

60. In the view of the Committee, gelatine and natural starches were foods, and these substances could be listed under optional ingredients. Tracaganth gum was not

endorsed as it had not yet been cleared toxicologically and locust bean gum was temporarily endorsed.

Antioxidant Synergist

61. The endorsement of calcium, disodium salt of EDTA was postponed pending the setting of a firm maximum level by the Commodity Committee.

Standards for Edible Vegetable oils (ALINORM 76/19. Appendices VI-X and XIII)

62. Edible Coconut Oil, Edible Red Palm Oil and Edible Bleached Palm Oil, Edible Palm Kernel Oil, Edible Grapeseed Oil, Edible Babassu Oil and Edible Low-Erucic Acid Rapeseed Oil. The Committee endorsed the proposed food additive provisions in these standards.

Standard for Canned Baby Foods (ALINORM 76/26A. Appendix III)

63. The Committee endorsed the provisions for two additional thickening agents and noted that the maximum level of 6 g in 100 g of the ready-to-eat product should apply to all modified starches in the standard singly or in combination. The representative of WHO informed the Committee that modified starches were still under study and would be re-evaluated in the future.

64. The Committee postponed the endorsement of tartaric acid noting the high limit for which there appeared to be no justification. The Committee was of the opinion that the use of tartaric acid was less desirable and that other acids could better be used as pH-adjusting agents.

Standard for Follow-up Milk for Infants and Children

65. The Committee was informed that the scope of this standard Appendix IX would be enlarged to include also soya protein based products with equivalent properties. The Committee, therefore, postponed the endorsement of the food additive provisions.

Standard for Quick Frozen Green Beans (CX/QFF 75/16)

66. The Committee temporarily endorsed the provisions for flavours in this standard. The delegation of Australia was of the opinion that there was no justification for the use of flavours in these products.

Standard for Quick Frozen Fried Potato chips (CX/QFF 77/5)

67. The Committee noted that at the 11th session of the Joint ECE/Codex Group of Government Experts (March 1977) the food additive provisions in this standard had been amended. The Committee postponed the endorsement.

Standard for Small Fruit Pulpy Nectars (ALINORM 78/14. Appendix IV)

68. The Committee was informed by the Chairman of the Commodity Committee that ascorbic acid was used as a processing aid to prevent polyphenoloxidase activity. The Committee recognized that no or only very small amounts of ascorbic acid would remain in the final product and, therefore, endorsed the limitation by GMP. The delegation of Poland expressed the view that, because an ADI had been established for ascorbic acid, a maximum level should be set for this additive in this standard and also in the standard for quick frozen cauliflower.

Standard for Canned Sardines and Sardine Type Products and for canned Mackerel and jack Mackerel (ALINORM 78/18. Appendices II and III)

69. The Committee endorsed or temporarily endorsed the provisions for thickening and jellifying agents on the understanding that the maximum levels indicated applied to the packing medium and not to the final product.

Standard for Jams (Fruit Preserves) and jellies (ALINORM 76/20A. Appendix II)

Colours

70. The Committee discussed the use of colours in jams and jellies in detail. It was accepted that different consumer preferences could require differences in eye appeal of foods. Nevertheless, it was pointed out that some of the colours listed had very low ADIs. The Committee agreed to endorse the provisions for the colours which had been specifically named in the standard, but postponed the endorsement of "any safe and suitable natural food colours", because there was no approved list of such colours. The delegations of Poland, France, Sweden and Belgium expressed their reservation concerning the temporary endorsement of the colours.

71. Several delegations pointed out during the discussions on endorsement that in their countries the intake of colours was presently being studied. The Committee was of the opinion that the intake of colours through food should be a priority subject for the Working Group on Food Additive Intake and asked the governments to send results of their studies to this Working Group.

Standard for Flavoured Yoghurt (Report of the 18th session of the Committee of Government Experts on Milk and Milk Products. Appendix III)

Flavours

72. The Committee temporarily endorsed the use of flavours as listed in general terms. It was thought desirable that a more precise listing of artificial flavours be given. It was noted that the list of artificial flavours was an open list which contained, for the present, only two substances.

Colours

73. The Committee noted that the origin of colours in the product was attributed to colours "which come exclusively from flavouring substances as a result of carry-over". It was pointed out that the coloration of flavouring ingredients had as an objective to give colour to the final product. Such colours, in the view of the Committee, could not be regarded to have resulted from "carry-over". The Committee of Government Experts was requested to give a clear indication of the origin of these various colours; the endorsement of the provisions was, therefore, postponed (see Part 4 of the Principle Relating to the Carry-over of Additives into Foods, App. IV, ALINORM 76/12).

Food Additive Provisions in Codex Standards the Endorsement of which has been Postponed at Previous Sessions of the Committee

Various Additives in Cheese

74. It was agreed to request the Committee of Government Experts on Milk and Milk Products to give a justification and set a limit for the addition of phosphoric acid and hexamethylenetetramine to cheese, the use of Brilliant Blue FCF, Fast Green FCF, Indigotine and hexamethylenetetramine in provolone cheese, as well as the addition of benzoyl peroxide to extra hard grating cheese.

Nitrate in Cheese

75. The Committee noted that the Committee of Government Experts on Milk and Milk Products had had a thorough discussion on the technological necessity for the use of nitrate during cheese-making. The government Experts had decided to request this Committee to reconsider the provision for the use of nitrate in cheeses in the light of the evidence presented. Several delegations were not convinced of the technological need of nitrate during cheese-making. Other delegations were of the opinion that for the production of "brine-salted" cheese types the use of nitrate was a necessity.

76. The Committee agreed to endorse the use of nitrates in the manufacture of brine-salted cheeses only, provided the residues in the final product did not exceed 50 mg/kg. The delegation of Denmark expressed a reservation concerning the restriction in the use of nitrates to brine-salted cheeses only, as such a restricted provision would not meet the technological need for nitrates in hermetically canned mould cheese.

Pimaricin on cheese

77. The representative of WHO informed the Committee that pimaricin had been evaluated by JECFA at its 20th meeting and an ADI had been allocated to it. The Committee noted that pimaricin was now officially registered with WHO under the name natamycin. The Committee endorsed the use of natamycin on the cheese or in the plastic coating. The delegations of the Federal Republic of Germany, Japan and Poland expressed the view that, in principle, antibiotics used for therapeutic purposes should not also be used in food.

Standard for Hard Grating cheese

78. The delegation of Australia reserved its position as to the endorsement of sorbic acid, because of insufficient technological justification.

Standard for Quick Frozen Shrimps or Prawns (CAC/RS 91-1976)

79. The Committee postponed the endorsement of sodium thiosulphate because of lack of justification.

Standard for Canned Crab Meat (CAC/RS 90-1976)

80. The use of monosodium glutamate was not endorsed as no additional information had been forthcoming from the Commodity Committee (see para 75, ALINORM 76/12).

Standard for Pickled Cucumbers (ALINORM 78/20, Appendix IV)

Various Additives

81. The Committee postponed the endorsement of tragacanth gum, aluminium potassium sulphate, aluminium sulphate and aluminium sodium sulphate pending toxicological evaluation. It was noted that benzoic acid or its sodium and potassium salts and potassium sorbate should read singly or in combination.

Colours

82. The Committee postponed the endorsement of oleoresin of turmeric. Furthermore, the Commodity Committee was requested to indicate which caramel was meant. Caramel not treated with ammonia and ammonium sulphite caramel could be endorsed.

Thickening Agents

83. The Committee postponed the endorsement of modified starches asking the Commodity Committee for more details on the substances used. The Committee further wished to have information on the levels used of thickening agents having an ADI. The Commodity Committee was also requested to specify the pectins.

Acidifiers

84. The Committee postponed the endorsement of tartaric acid. The Commodity Committee was asked to reconsider the need for this additive.

Standard for Canned Carrots (ALINORM 78/20, Appendix V)

85. The Committee postponed the endorsement of the use of monosodium glutamate pending the decision of the Commodity Committee. The Committee also postponed the endorsement of starch sodium succinate and gum tragacanth as these substances had not yet been cleared toxicologically by JECFA.

Standard for Dried Apricots (ALINORM 78/20, Appendix II)

86. The Committee postponed the endorsement of glycerol pending the decision of the Commodity Committee.

ENDORSEMENT OF MAXIMUM LEVELS FOR CONTAMINANTS IN CODEX COMMODITY STANDARDS

87. The Committee had before it a working paper on provision for contaminants requiring endorsement, (CX/FA 77/IO-Part II). The decisions of the Committee regarding endorsement are summarized in Appendix IV to this report. The delegation of the Federal Republic of Germany expressed the view that there were insufficient data available to decide whether or not to endorse limits of contaminants in the foods under consideration, and recommended that the Commodity Committee should supply appropriate data. The Committee was informed by the representative of WHO that the Joint FAO/WHO/UNEP group on Food and Animal Feed Contamination Monitoring Programme would meet during 1977 to discuss questions of food contamination. The findings of the Joint Monitoring Programme would be made available to this Committee as well as to other interested bodies.

88. As a general consideration, the delegation of Poland, supported by the delegations of the Federal Republic of Germany and Czechoslovakia, expressed the opinion that maximum levels for contaminants in concentrated fruit juices should be established on the basis of appropriate data on concentrated fruit juices rather than using the figures for the single strength juices expressed on the reconstituted juice basis.

Arsenic

89. The delegation of Canada was of the opinion that the maximum level of arsenic in fructose, black currant juice and concentrated black currant juice was too high in view of findings in that country showing that a maximum level of 0.1 mg/kg was more appropriate.

Lead

90. The Committee postponed the endorsement of the maximum level for lead in soups and broths as well as in fructose, because the limits indicated were still under consideration in the Commodity Committees.

Tin

91. The Committee postponed the endorsement of the maximum level of tin in soups and broths, because the limit was still under consideration in the Commodity Committee.

92. The delegations of Czechoslovakia, the Federal Republic of Germany and Poland were of the opinion that the maximum levels of tin in general were too high.

Contaminants in Follow-up Milk for Infants

93. The Committee postponed the endorsement of contaminants in follow-up milk for infants and children pending further reconsideration of this standard by the Codex Committee on Foods for Special Dietary Uses.

Contaminants in Natural Mineral Water

94. The Committee noted that the purpose of the general provision for various contaminants such as nitrites, phenolic compounds, pesticides, and polynuclear aromatic hydrocarbons was to ensure that natural mineral waters would contain no detectable residues of these substances, in order to safeguard the purity of the water. In view of the fact that the methods of analysis had not yet been developed and that, therefore, it was not possible to know exactly what substances would be present and at what levels, the Committee decided to give this provision only a temporary endorsement.

CONSIDERATION OF HYDROLYZED PROTEIN

95. The Committee considered a paper prepared by the FAO Secretariat summarizing comments from governments concerning hydrolyzed protein (CX/FA 77/IO-Part III). It was noted that there were a number of different products covered under this heading. Some delegations were of the opinion that the hydrolyzed products of protein should be regarded as foods as well as food ingredients. Other delegations were of the opinion that the issue of whether some hydrolyzed proteins were foods or food additives was not of any great significance. The Committee was of the opinion that, in any event, food standards should be elaborated for these products.

96. The delegation of Switzerland suggested that there would be a possibility that the Codex Committee on Soups and Broths could examine the question of hydrolyzed proteins. The Committee was also informed that the Codex Committee on Processed Meat Products was considering to start work on meat extenders and texturized vegetable protein. The USA delegation informed the Committee that the Commission might consider the establishment of a new Codex Committee on special proteins (e.g. isolated proteins, TVP, etc.).

97. The Committee was of the opinion that there was little to be gained from requesting further government comments on this subject and agreed that:

- (a) hydrolyzed proteins appeared to require standardization;
- (b) they did not fit into the normal approach used for food additives; and
- (c) the question was rather complex requiring detailed attention. The Commission was requested to consider this matter from a point of view of assigning the task to a newly established Committee on Proteins, or, if this is not possible, to the Codex Committee on Soups and Broths.

LIST C OF FOOD ADDITIVES

98. The Committee had before it a paper prepared by the Netherlands Technical Secretariat (CX/FA 77/3) containing comments received on ALINORM 76/12, Appendix VII.

99. In discussing List C (1) of this document, the Committee decided to delete Sassafras officinale (C.B. No. 424 - Codex Veg. Steinmetz No. 1030) since this substance is covered by a maximum level set for safrole in various foods, based on the final product.

100. In discussing List C (2) of this document, the Committee noted that the substances mentioned in this List were residues from plant materials used as flavours in the preparation of certain foods. For this reason their incorporation in List C (2) was not appropriate as this list dealt with food additives the use of which, in the opinion of the Joint FAO/WHO Expert Committee, should be restricted to certain specific cases. It was also noted that cyclamates would be transferred to List A in view of the conclusions of the 1977 JECFA session.

101. The delegation of the USSR stated that the setting of maximum levels in List C (2) was premature. To illustrate its statement it drew the Committee's attention to the fact that there were no appropriate methods of analysis available to determine the residues in question. It also pointed out that the content of solanine in raw potatoes (15-20 mg/kg) exceeded the maximum figures given in List C (2). The view of the USSR was supported by several delegations.

102. The delegation of Switzerland suggested that it should be indicated on the list that the figures related to the product ready for consumption. The Committee agreed with this proposal. It also decided to await the results of further discussions on flavours within the Council of Europe (Partial Agreement) and to reconsider this matter at the next session.

ESTABLISHMENT OF REVISED CODEX LIST B OF FOOD ADDITIVES

103. The Committee had before it a paper prepared by the Netherlands Technical Secretariat containing a revised List B established on the basis of the previous List B and government comments (CX/FA 77/2). The Committee proceeded to discuss the revised List B in detail in order to ensure that the final List B would be representative of food chemicals of current interest to governments and to the food industry. In order to bring the revised List B up-to-date, the Committee requested the Secretariat to make such changes as necessary on the basis of the 20th and 21st reports of the joint Expert Committee on Food Additives.

Group 1, List B

104. The Committee noted that stannous chloride appeared both in List B and in List A (1) and requested the Secretariat to ensure that this inconsistency would be removed. The Committee considered that the whole question of tin salts and tin as a contaminant should be resolved by the Joint Expert Committee on Food Additives.

Group 3, List B

105. As regards castor oil, the Committee noted that this oil was used as a lubricant in the manufacture of sugar confectionary products as well as a solvent for special purposes. With respect to the triglycerides (item 3.18), the Committee was informed that this group of substances included synthetic triglycerides of both odd and even number fatty acids and that, therefore, they were appropriately listed as food additives. However, it amended item 3.18 to read "synthetic triglycerides". The delegation of the USA questioned the use of diethylene glycol as a food additive. The Committee deleted ethyl lactate and isopropyl alcohol as these had already been cleared by JECFA.

Group 4, List B

106. The Committee noted that the 21st session of the JECFA had evaluated a number of the colours listed in this section and requested the Secretariat to make the necessary changes.

Group 5, List B

107. The Committee deleted Carob bean gum as this additive had been given a temporary ADI by JECFA. The delegation of Czechoslovakia was of the opinion that oxidized hydroxypropyl distarch glycerol (i.e. a starch receiving a combined treatment of oxidation and addition of hydroxypropyl and glycerol groups) should be evaluated by JECFA. The representative of EFEMA stated that esters of glycerol and thermally oxidized soybean fatty acids intended for use as emulsifiers for margarine were currently the subject of long term toxicity tests and metabolic studies.

Group 6, List B

108. The Committee deleted avian pepsin as this enzyme had already been cleared by the JECFA and agreed, on the proposal of the delegation of the U.K., to add the enzyme carbohydrase (Aspergillus awamori).

Group 7, List B

109. On the proposal of the delegation of the U.K., the Committee agreed to specify the individual chlorinated-fluorinated hydrocarbons, e.g. 1,1,2-trichloro-trifluoro-ethane; 1,2-dichlorotetrafluoroethane and dichlorofluoromethane.

Group 8, List B

110. The delegation of Czechoslovakia was of the opinion that the pyrazine derivatives should be examined toxicologically by JECFA and questioned the need for the pharmacologically active substance paraldehyde as a flavour for use in food.

Group 9, List B

111. In view of the conclusions reached in para 95, the Committee decided to delete hydrolyzed protein from this list.

Group 10, List B

112. The Committee agreed to add, on the proposal of the delegation of the U.K., beeswax, carnauba wax, shellac, condensed tannis and wood flour. One delegation informed the Committee that wood flour was used to dust surfaces in the oven in bread baking to ensure free sliding of the baked product.

113. The Committee adopted List B with the above amendments and requested the Working Group on Priorities to consider it in establishing the Priority List of Food Additives to be submitted to the JECFA.

LISTS A AND C

114. The Committee discussed a proposal of the FAO Secretariat to reconsider the status of the present First Edition of "List of Food Additives Evaluated for their Safety-in-Use in Food" (CAC/FAL 1-1973 and Supplement 1). In the opinion of the FAO Secretariat the above information lists had, in fact, become advisory lists for use by Codex committees and governments. It seemed, therefore, appropriate to reflect this change in the title of the Second Edition to be published during 1977. The representative of WHO was of the opinion that there would be certain difficulties should the status of

Codex Advisory Lists be changed, since the annual meetings of the JECFA would necessitate amendments to the toxicological evaluation of the additives included in a Codex advisory list. The FAO Secretariat was of the opinion that such annual amendments would be possible.

115. The delegation of Brazil was of the opinion that the existence of an Advisory List of Food Additives could give rise to difficulties as individual governments might be using additives not on the Codex advisory list. On the suggestion of the delegation of the U.K. the Committee requested the Secretariat to prepare a paper for the next session of the Committee pointing out the issues in connection with Lists A and C.

ADVISORY LIST OF ADDITIVES IN SOFT DRINKS

116. The paper (CX/FA 77/8) prepared by Canada briefly reviewed the background rational for the development of an Advisory List of Additives in Soft Drinks. It noted that the Secretariat had received replies from six countries in response to requests for comment. A number of minor modifications had been proposed to the List (Appendix V of ALINORM 76/12).

117. As regards the question of how to proceed further with the elaboration of the Advisory List, the delegation of Canada recommended two options: (1) to include the present Advisory List in the next issue of Codex List A for the information of governments as an open ended advisory list; or (2) to refer the Advisory List to the Commission for guidance.

118. The Committee noted that the method used by Canada for estimating the possible intake of additives from soft drinks was different from that used by WHO. It was generally agreed that the purpose of the "List" was to enumerate the food additives (given an ADI by JECFA) used in soft drinks by manufacturers in various countries which had responded to the original Canadian questionnaires. The delegation of Brazil emphasized the importance of this study to countries with tropical climate and thus with likely high consumption figures and was of the opinion that the approach of estimating the intake of food additives from soft drinks and the setting of maximum levels for the various additives should be revised and the technological information obtained concerning the levels of additives actually used should also be considered.

119. After considerable discussion of the Advisory List, the Committee agreed that:

- (1) it was desirable to have a list of food additives known to be used in soft drinks and that have been evaluated by JECFA;
- (2) coconut oil, being a food, and Patent Blue V (not yet evaluated by JECFA) be deleted from the list;
- (3) cyclamates, azorubine and Ponceau 4R be added to the list as these were used in certain soft drinks and have been cleared or temporarily cleared by JECFA;
- (4) the document be forwarded to the ad hoc Working Group on Food Additives Intake to consider methods of determining intakes of food additives in soft drinks, particularly with respect to consumption by children (member countries were requested to send intake information on additives in soft drinks to the Chairman of the Working Group);
- (5) the Advisory List be up-dated by the Secretariat as to the important additives used in soft drinks which have been evaluated by JECFA; and that

- (6) when printing the Advisory List the proposed maximum limits should not be included but that the status of toxicological evaluation be shown.

CONSIDERATION OF PROCESSING AIDS

120. The Committee had before it a paper prepared by the Technical Secretariat (CX/FA 77/12). In introducing the paper, the Technical Secretariat pointed out that the purpose of the paper was to guide the Committee in its discussion on the need to consider processing aids as a special group of substances.

121. A number of delegations supported the view of defining and listing processing aids as a special group of substances forming part of the definition of "food additives", while other delegations wanted a complete separate listing of processing aids which, in their opinion, were not food additives but should be considered as "contaminants". The delegation of Australia pointed out that, in cases where the substances may be used as both a food additive and a processing aid in the same food, it should be treated as a food additive. The Committee considered the draft definition for processing aids, contained in CX/FA 77/12, page 2. The delegation of Italy put forward an alternative definition, taking into account occurrence of residues in the final product. The Committee requested an ad hoc Working Party consisting of the delegations of Belgium, Italy and the Federal Republic of Germany, to draft a new version of the definition to be put into the report (see para 123).

122. The representative of WHO indicated that the evaluation of pesticide residues might serve as a model for the evaluation of processing aids. The Committee suggested that JECFA might consider the procedure for the evaluation of processing aids bearing also in mind the residues in the final product, the nature of the process, details of analysis and other such relevant information.

123. The Committee decided to request governments, Commodity Committees and interested International Organizations to comment on the definition for processing aids and to send information concerning these substances. The Committee decided to request Codex Commodity Committees to elaborate provisions for processing aids in all commodity standards that are being or have been elaborated by them (e.g. listing all processing aids including maximum levels for their residues). The Technical Secretariat was requested to make a compilation of the processing aids, used for consideration by the Committee at its next session and to prepare a summary of comments received on the definition. The proposed definition of the ad hoc Working Party (see para 121) is as follows:

Definition of Processing Aids

"A processing aid is a substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product".

124. It was noted that, in drawing up this definition the ad hoc Working Party had made two observations:

- the Working Party held the view that the definition of Food Additives already included processing aids, but that a more precise definition of processing aids was needed;

- the Working Party had considered the necessity to incorporate a reference to hazards to health in the definition as suggested by the delegation of the Federal Republic of Germany, but had concluded that, as processing aids were food additives, it went without saying that an adequate toxicological evaluation had to be made.

CONSIDERATION OF THE REPORT OF THE WORKING GROUP ON SPECIFICATIONS

125. The Committee had before it the report of the above ad hoc Working Group (see para 9) (CX/FA 77/LIM 1). In introducing the report, the Chairman of the Working Group, Mr. D.F. Dodgen, USA, informed the Committee that the Group had considered all government comments contained in documents CX/FA 77/7-Parts I, II and IV and addenda. It had accepted the conclusions of the Secretariat not to consider certain specifications, e.g. (a) which were tentative; (b) which, subsequently, had been revised by JECFA; or (c) specifications for additives for which the ADI had been withdrawn. It was noted that governments had sent comments on such specifications but that those comments had been or would be submitted to JECFA for consideration. The Working Group was of the opinion that the procedure for the consideration of specifications could be improved and had requested the Secretariat to look into the matter.

126. The Committee discussed the need or otherwise to continue with work on specifications within the framework of Codex. The FAO Secretariat informed the Committee that, because of budgetary restrictions affecting printing allocations for the biennium 1978/1979, shift in emphasis in the priorities of FAO and the cost of the Codex programme on food additive specifications, the Executive Committee would examine the possible suspension of work on Codex food additive specifications.

127. The Chairman of the committee was of the opinion that it was desirable to elaborate food additive specifications which would have been adopted at the intergovernmental level. He pointed out that duplication in work on specifications related mainly to the printing of the specifications, and that it was possible to economize by, for example, submitting specifications to the Commission at Step 5 by reference to the monographs of the Expert Committees which contained such specifications rather than reprinted in extenso in ALINORM documents.

128. Several delegations stressed the importance of work on internationally adopted food additive specifications. The delegation of the USA was of the opinion that, if work on specifications had to be curtailed, then priority should be given to the need to continue the establishment of specifications at the Expert Committee level.

129. The Committee decided that:

- (a) work should be continued on the elaboration, of Codex food additives specifications and that budgetary difficulties should, as far as possible, not be allowed to overturn the work of several years;
- (b) the specifications listed in the report of the ad hoc Working Group (see Appendix X and summarized in Appendix XI) should be submitted to the Commission at Step 5; and
- (c) the comments of Working Group 4 on other specifications should be submitted to JECFA for consideration.

SPECIFICATIONS FOR FOOD GRADE SALT

130. The Committee considered several papers on specifications for salt prepared by the Netherlands (CX/FA 77/13), the European Committee on Salt Studies (CX/FA 77/13-Addendum 1) and Norway (CX/FA 77/13-Addendum 2). In the introduction of the Dutch paper, the delegation of the Netherlands stated that the proposals of the European Committee on Salt Studies (E.C.S.S.) had been used as the basis of its own proposals, except that a provision to restrict natural impurities had been included and a paragraph with suggested upper limits for natural contaminants had also been added. The list of permitted additives - largely similar to the one proposed by the E.C.S.S. - could be considered as an advisory list. The use of edible salt as a carrier for certain substances such as nitrite and iodide for specific purposes was not described further, it being understood that the salt used in such preparations would have to comply with the specifications.

131. The representative of the E.C.S.S. expressed his willingness to cooperate in the establishment of specifications for food grade salt. He drew the attention to differences in the various papers. In the Netherlands version of the definition he noted a lack of coherence, and was of the opinion that limits for moisture content and natural impurities did not serve any sanitary purpose. Strict limits for contaminants could also reduce the possibility of marketing certain types of salts. As regards additives for specific purposes, he was in favour of their introduction.

132. The delegation of Norway stated that its paper was largely similar to the one prepared by the Netherlands. However, at the request of the fishery industry, a special provision for curing salts had been made with further limits for certain contaminants, as these could give rise to discoloration of fish.

133. In the discussion that followed, the delegation of Spain declared to be opposed to the proposals of the Netherlands and Norway and indicated that the Spanish comments would be submitted in writing for further consideration. Several delegations, including Spain, supported the E.C.S.S. proposals. A question as to whether the strict limit for mercury was based on actual data, was answered in the affirmative.

134. Some delegations were in favour of having a standard for food grade salt instead of only specifications. One delegation suggested that the problem could be solved by elaborating only a definition and a list of permitted food additives to be included in the Codex Lists of Food Additives (CAC/FAL 1-1973 and Supplement I) and in addition, maximum limits for contaminants in salt could be elaborated.

135. The delegation of the Netherlands agreed to prepare a revised version of the specifications taking into account the foregoing discussion. The revised text would be circulated for government comments.

REVISED PROPOSED DRAFT GENERAL STANDARD FOR THE LABELLING OF FOOD ADDITIVES WHEN SOLD AS SUCH

136. The Committee considered the Revised General Standard for the Labelling of Food Additives when sold as such at Step 4 of the Codex Procedure (CX/FA 77/9).

137. The Committee noted that, at the 10th session of the Committee (June 1975), it had been decided that, because of the numerous comments on the Draft Standard and the complex issues involved in preparing a revised draft, an ad hoc Working Group should be formed. The terms of reference of the Working Group were to consider all comments and prepare an amended document for the next session of the Committee

(ALINORM 76/12, para 106). Australia, Canada, France, the Netherlands, Norway, the U.K. (Rapporteur) and the U.S.A. had participated in the group (see also para 8).

138. The rapporteur, Mr. D. Maskell (U.K.) introduced the revised document and pointed out that the major difference between the revised text and the paper previously considered was that separate provisions for the labelling of additives sold by retail and for those sold other than by retail had been included.

Definitions

139. Several delegations proposed additional terms to be defined, e.g. processing aids, carrier, solvent and bulk containers. It was agreed that these proposals would be considered at the next session and that any additional definitions would be identical to definitions of the same terms used elsewhere by the Codex Alimentarius Commission and its subsidiary bodies.

Mandatory Labelling of Prepackaged Food Additives Sold by Retail and Sold Other than by Retail

140. The delegation of Poland stated that, in its view, the label of a substance containing two or more food additives (sections 4.1(b) and 5.1(b)) should not only list the names of these substances but should also indicate the proportion or weight in which they were present. The Committee decided to make no change in the provision since the mixture would be bought and used as such.

141. The Committee agreed, however, to add to the provisions (4.1(b) and 5.1(b)) a clause stating that "if food ingredients are part of the preparation they shall be declared in the list of ingredients in descending order of proportion".

142. It was agreed that the amount of information provided on the label should not be related to the size of the container. The provisions (4.1(e) and 5.1(e)) exempting containers "with insufficient space for all the particulars ... to appear on the label" were deleted.

143. In line with a general decision of the Codex Committee on Food Labelling, a provision on "Lot Identification" was included as a mandatory requirement in both sections (new 4.6 and 5.6).

144. The Committee considered a proposal to broaden the scope of the preamble to the section on Mandatory Labelling of Prepackaged Food Additives sold Other than by Retail (Section 5) by allowing the mandatory labelling requirements for all food additives supplied to manufacturers for use in the production of prepackaged foods to be given on the documents relating to the sale. The proposal found no support in the Committee.

Additional or Different Requirements for Specific Food Additives

145. The question was raised whether there was a need for a special provision to be included in the standard on irradiated food additives. It was stated that iron oxide and cochineal (insects) might be irradiated and that the provision was applicable to substances thus treated. The delegation of Belgium was of the opinion that this section should be titled in the same way as the relevant section on labelling in the Proposed Draft General Standard for Irradiated Foods (see Section 5, Appendix VII).

Status of the Standard

146. The Committee agreed to advance the Proposed Draft General Standard for the Labelling of Food Additives when Sold as Such to Step 5 of the Codex Procedure for

submission to the Commission at its 12th session. The revised document is contained in Appendix VI to this report.

CONSIDERATION OF THE FOOD IRRADIATION PROCESS

147. The Committee had before it a report of an ad hoc Working Group established during the session (CX/FA 77/LIM 4) (see para 10), a redraft of the General Standard on Irradiated Foods (CX/FA 77/LIM 2) and the Code of Practice for the Operation of Radiation Facilities used for the Treatment of Foods (CX/FA 77/LIM 3).

General Standard on Irradiated Foods

148. In introducing the report, the chairman of the ad hoc Working Group informed the Committee that the Working Group had examined the above General Standard contained in document CX/FA 77/14 in detail and had made a number of changes to it. It had done so after a full review of all comments received on the standards (see CX/FA 77/14-Addendum I).

149. The Committee, on the suggestion of the Australian delegation, made a slight change to section 2.3 of the standard to make it clear that the absorbed dose had to be within the range specified for the appropriate irradiation treatment indicated for individual foods. The delegation of the UK indicated that, although food irradiation was not permitted in that country and that it was not aware of any demand for this process in the UK, it would be willing to participate in Codex work in this field. It also informed the Committee that the CX/FA 77/14 had been received by the UK only prior to the session. The delegation of Belgium was of the view that wheat, being an important component of human diet, should be carefully examined in order to remove any reservations concerning the acceptability of the irradiated product; on the other hand it was of the opinion that only those foods included in the category "unconditional acceptance" should form part of the standard.

150. The delegation of Thailand informed the Committee that all the Codex recommendations concerning food irradiation would be accepted by that country and that, in fact, the recommendations for the irradiation of onions had already been accepted.

151. The delegation of France was of the opinion that irradiation and treatment by chemicals should be mutually exclusive and that the General Standard should include a provision to this effect. The representative of OECD pointed out that consideration of good manufacturing practices and economic considerations would preclude such dual treatment. The Committee noted that the Working Group had considered this question in detail and had concluded that the inclusion of such a requirement was not necessary.

152. Noting (a) that the General Standard had been elaborated-by a Joint FAO/IAEA Technical Group on the basis of the recommendations of the Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Foods; (b) that government comments had been requested and received; and (c) that reports of the Joint Meeting on Pesticide Residues and the specifications established by the Joint FAO/WHO Expert Committee on Food Additives were normally sent to governments at Step 3 without being considered by the Codex committees at Step 2, agreed that the Proposed Draft Standard on Irradiated Foods (see Appendix VII) should be submitted to the Commission at its 12th session at Step 5 of the Codex Procedure for the Elaboration of Standards.

Code of Practice for the operation of Radiation Facilities used in the Treatment of Foods

153. The Committee then proceeded to consider the Proposed Draft Code of Practice for the Operation of Radiation Facilities used in the Treatment of Foods. It noted that the ad hoc Working Group had not found it necessary to make any but editorial changes to the Code. As the above code (see Appendix VIII) and the General Standard were closely linked, it was agreed that they should be advanced together to Step 5 of the Codex Procedure.

Instruments to deal with Standardization of Food Irradiation in the Codex

154. The Committee considered a proposal of the Working Group that future Joint FAO/IAEA/WHO Expert Committees on the wholesomeness of Irradiated Food should be designated as advisory bodies to the Codex Committee on Food Additives and that this should be reflected in the organizational chart of the Codex Alimentarius Commission. It was noted that WHO, IAEA and FAO were willing to make the above Joint Expert Body available to the Commission for that purpose and that, in turn, the Commission had already referred previous reports of Joint FAO/IAEA/WHO Expert Committees on food irradiation to the Codex Committee on Food Additives. The Committee adopted the proposal of the Working Group and referred the question to the Commission.

155. The question was raised as to whether the name of the Committee should not be changed to reflect this added responsibility, i.e. to "Codex Committee on Food Additives and Food Processing". The Committee was of the opinion that there was no need to change its name, but that the Secretariat should ensure that the terms of reference would adequately reflect the actual responsibilities of the Committee.

Dosimetry Services and Training in Food Irradiation Technology

156. The Committee noted that the services of the IAEA/WHO Secondary Standard Dosimetry Laboratories Network could be made available to member states wishing to have a check on dosimetry in their food irradiation facilities.

157. The Committee was informed of the fact that, as a result of the generous offer of the government of the Netherlands, IAEA was now considering the establishment of an International Facility for Food Irradiation Technology in Wageningen, the Netherlands. The Committee was of the opinion that such an international facility could be very useful and would serve a good purpose also in providing inplant training of personnel in the field of food irradiation, especially personnel from developing countries, in an attempt to ensure proper preparation of such facilities in conformity with the Draft General Standard on Irradiated Foods and with the Code of Practice for the Operation of Radiation Facilities used for the Treatment of Foods. The Committee was of the opinion that the establishment of such a facility was in the interest of proper application of, and control on, food irradiation.

The Use of X-Rays as a Source of Radiation

158. The Committee noted that the Working Group had discussed a proposal to include X-rays into the types of ionizing radiation mentioned by the Draft General Standard, i.e. gamma rays from ^{60}Co or ^{137}Cs and electron rays up to 10 MeV. Furthermore, it had also been suggested to use the general term "electromagnetic radiations" instead of, or in addition to, the specific types of radiations mentioned in the Draft General Standard. The Group had decided to recommend adherence for the time being to the original text of the Draft General Standard which was based on the report of

a Joint FAO/IAEA/WHO Expert Committee on the wholesomeness of Irradiated Food (31 August - 7 September 1976). The Group had further recommended that a future Joint Expert Committee be asked to examine the necessity and the possibility of revising the present text in order to widen the scope of radiations permitted and/or to specifically mention X-rays, or more generally, electromagnetic waves, of energy below 5 MeV. The Committee concurred with the views of the Working Group.

Re-irradiation

159. The Committee noted that the Group had discussed a proposal to amend section 4.2 of the Draft General Standard concerning the prohibition of re-irradiation, and to replace section 4.2 by the following text: "No food shall be irradiated to a dose greater than the maximum permissible dose specified in the regulation. The optimum dose may be applied in stages". The Group had recommended to refer to section 2 describing the administration of the dose and to leave otherwise the present text unchanged. If "irradiation in stages" should later be found to be of significance, the Group had recommended that the proposal for revision of 4.2 be referred to a future meeting of a Joint Expert Committee. The Committee concurred with the conclusions of the Working Group.

Dose Rate

160. The Committee noted that the Group had discussed the question raised about the effect of dose rate and had noted that the dose rate effect mentioned in the comment had been observed in dilute solutions, but that analysis of the radiolytic products from food exposed to very high (10^{10} rads/sec. in 100 krad pulses) and to low dose rates from isotope sources had failed to show qualitative or quantitative differences. The Group had further noted that the Joint FAO/IAEA/WHO Expert Committee on Wholesomeness of Irradiated Food had considered this matter and that the following statement had been included in the report of that Expert Committee (last paragraph of section 3.2, page 12, wholesomeness of Irradiated Food, Report of a Joint FAO/IAEA/WHO Expert Committee, WHO Techn. Rep. Ser. No. 6045 FAO Food and Nutrition Series No. 6): "On the other hand, radiation chemical data show that extrapolation within a wide range of irradiation conditions (with regard, for example, to water content and dose rate) is permissible; therefore, an evaluation of wholesomeness that is arrived at under one set of conditions will often be valid for practical application under a different set of conditions".

PRIORITY LIST FOR FOOD ADDITIVES

161. The Committee discussed the report of the ad hoc Working Group concerning Codex List B which was introduced by Dr. J. Drum (Canada) who had acted as Chairman of the Group. The representative of WHO informed the Committee that on the priority list presented by the Working Group there appeared certain substances which had been already evaluated by the JECFA and for which there were already monographs, but for which the available data had not been found sufficient to establish an ADI. It was pointed out that the fact that these substances appeared again on the priority list demonstrated that there was still interest in the evaluation of these substances.

162. The Chairman stressed that an evaluation could be done by JECFA only when toxicological and chemical data were available and, therefore, urged the delegations to collaborate in sending the relevant information (toxicological data, specifications and methods of analysis) to the JECFA before 1 November 1977 (toxicological data to the chief, Food Additives, WHO, Geneva; data on specifications to the Food Control Group,

ESN, FAO, Rome). The Committee adopted the Priority List of Food Additives given in Appendix IX for the guidance of the JECFA.

NOTE CONCERNING THE VARIOUS AD HOC WORKING GROUPS

163. The Committee expressed its appreciation for the work done by the various Working Groups and thanked all persons associated with the Groups for their contribution and expertise.

FUTURE WORK

164. The Committee decided not to undertake work on any new subjects in view of the existing workload.

OTHER BUSINESS

165. The delegation of Denmark expressed its satisfaction on the results achieved by the various Working Groups during this meeting and suggested to continue in the future in the same way. To allow delegates to take part fully in the work in the plenary session, it proposed that the various Working Groups convene one day before the beginning of the meeting of this Committee. The Chairman welcomed the proposal and undertook to investigate the possibility of carrying out the suggestion.

166. In order to expedite the consideration of the endorsement procedure, the delegation of the U.K. suggested the following amendments to the procedure:

- (1) Provisions for additives, processing aids and contaminants should preferably be considered in commodity standards at Step 5 or Step 7 of the Codex procedure;
- (2) the Secretariat should make a recommendation to the Committee for each item on the paper on endorsement based on the following guidelines:
 - (a) endorsed at GMP if the additive appeared in List A (1) (ADI not specified);
 - (b) endorsed with a limit in the final product if the additive appeared in List A (1) with a specified ADI;
 - (c) temporarily endorsed with a limit in the final product if the additive appeared in List A (2);
 - (d) endorsement postponed (i) if no ADI has been established by JECFA; (ii) if justification of technological need has not been adequately established by the Commodity Committees;
- (3) when endorsements are being considered, the Committee should be informed of all the provisions in the standard;
- (4) the Committee should have the possibility to get expert information through attendance at its session of representatives of Commodity Committees (see also para 50).

167. The Committee endorsed the above procedure for transmission to the Commission. The delegations of Denmark and the Federal Republic of Germany were of the opinion that this new procedure should be further considered by the committee at its next session.

TIME AND PLACE OF NEXT SESSION

168. The Chairman informed the Committee that the next session would probably take place in the second part of September 1978 in The Hague. The exact date would be determined in consultation between the government of the Netherlands and the Codex Secretariat.

CLOSURE OF THE SESSION

169. At the closure of the session the delegate of Brazil stated the importance of the work of the Committee in the field of food additives and contaminants. He pointed out that, in particular, developing countries requiring guidance could benefit substantially from the work of the Codex Committee on Food Additives as regards food technology questions and the protection of the health of the consumer.

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Figuran en primer lugar los Jefes de las delegaciones; los Suplentes, Asesores y Consultores aparecen por orden alfabético.

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REPORT OF THE AD HOC WORKING GROUP ON FLAVOURS¹

¹ See paras 7, 30-38 of this Report.

1. Introduction

At the 10th session of the Codex Committee on Food Additives (CCFA), June 1975, it was decided to establish an ad hoc Working Group on Flavours "to consider procedures for establishing positive lists and to examine the question on flavouring agents" (ALINORM 76/12, para 30).

Belgium, Denmark, France, Federal Republic of Germany, Italy, the Netherlands, Switzerland, U.K. and the U.S.A. participated in the Working Group. Representatives of the EEC, of the International Organization of the Flavour Industry (IOFI) and of the Fédération Internationale des Industries et du Commerce en Gros des Vins, Spiritueux, Eaux-de-Vie et Liqueurs (F.I.C.G.V.S.) provided technical assistance to the Group. The delegation of the Netherlands acted as Rapporteur.

The Working Group interpreted its instruction to propose to which extent CCFA and JECFA should be involved in matters of food flavouring. To obtain a survey of the present state of affairs, a summary is given below of relevant observations and conclusions, appearing in the report of the 10th session of the CCFA (ALINORM 76/12) and in the responses to circular CL 1974/51, summarized in document CX/FA 75/13.

- (a) On the definition: classification in 3 classes including one of "nature-identical" flavouring substances, was adopted at the 8th session and confirmed at the 10th session of the CCFA;
- (b) On the consideration of flavours as food additives: there is unanimity on this as regards the "artificial flavouring substances" (and, of course, the carriers). On the other hand, there are parts of plants (fruits, vegetables, spices) which are generally looked upon as being food;
- (c) On the toxicological approach: all participants agreed that there should be no difference in this respect between naturals, nature-identicals and artificials. It was pointed out, however, that natural and nature-identical substances may differ in their accompanying impurities and hence may differ in their toxicological evaluation;
- (d) On the listing of substances: all countries agreed on the elaboration of a positive and open list of approved artificials, subject to the toxicological assessment by JECFA, together with the establishment of an ADI and of chemical specifications.

2. Discussion

2.1 On the consideration as food or as food additive

The question of which flavouring substances have to be considered as food additives and which not was the subject of several discussions in the CCFA already. While a common opinion exists for artificial flavouring substances and parts of edible plants, views diverge for the classes in between: extracts of plant parts (natural flavours), single substances isolated from these extracts (natural flavouring substances and the synthetic equivalents of the latter (nature-identical flavouring substances). Those differences in opinion are caused not only by the existence of different legal systems in

the countries involved, but they are also due to the inadequacy of the definition itself of "food additive" in this borderline between "food" and "food additive", where food flavour generally is; e.g. what is considered to be "typical" or "normal" in some countries, need not necessarily be so in others. A majority in the Working Group is of the opinion that a repeated discussion on problems of definition is not very useful at present. The relevant question to be answered primarily is not: which kinds of flavours are food additives ? but rather: which kinds of flavours should be treated as food additives ? and: to which extent?

2.2 On possible groupings of flavouring agents

In order to get a clear outline of the problem that faces us, let us consider the various kinds of flavouring materials possible. It should be borne in mind, however, that commercial products are often a mixture of different kinds of material.

(a) Parts of edible plants are food by definition. Nevertheless, it may be useful to restrict the intake of known toxic components - in a way similar to the limitation of high erucic acid rapeseed oil in food, for example. Essentially, therefore, the consideration of parts of edible plants should be part of a programme for the safety evaluation of the basic diet.

(b) Extracts of parts of edible plants (including essential oils) can likewise be treated as food. Only the possible accompanying solvents (carrier solvents and residues of extraction solvents), added antioxidants and preservatives are food additives.

(c) Single substances isolated from these natural extracts can be treated in the same manner. Apart from some exceptions they are of no commercial interest.

(d) Single substances, obtained by chemical synthesis and identical to the natural isolates above (nature-identical substances) are of considerable commercial interest because they represent the bulk of the available flavouring materials. They also represent the main problem in the international dispute concerning flavours. It must be admitted, however, that this is largely a labelling problem, on which the CCFA does not decide upon. Chemically they are not distinguishable from the corresponding natural substances unless they contain "unnatural" impurities: e.g. starting materials and by-products of synthesis. Suitable specifications of purity could reduce the amount of toxicological work to be done on the nature-identical substances.

(e) Single substances, obtained by chemical synthesis and not yet found in natural food (artificial substances) are food additives by definition. They are mostly used in small proportions to improve the flavour of blends of natural extracts with nature-identical substances. As there is no doubt on their classification, artificial substances must be subject to specification and toxicological evaluation. It is to be noted that the distinctive criterion for classifying a given substance as artificial may be purely accidental in the sense that a substance classified today as artificial may be found tomorrow in a natural foodstuff. This distinction, while being administratively expedient, is of limited scientific relevance.

2.3 On criteria for evaluation

Whether artificial or not, and whether considered as food additive or not, flavouring substances represent a unique class of food ingredients by virtue of their large number on the one hand and of their often very small dosage on the other hand. For instance, a world-wide total annual, production of less than 100 kg is not uncommon for

individual artificial flavouring substances. It is clearly necessary to collect data on use levels and specific consumption patterns.

Prior to any safety evaluation, a comprehensive enquiry is needed regarding the criterion to be used for flavouring substances, regardless of whether they are natural, nature-identical or artificial flavouring materials. In their 17th report, JECFA already stated some principles as regards the toxicological evaluation of flavouring substances (WHO Techn. Rep. Ser. No. 539 or FAO Nutrition Meetings Rep. Ser. No. 53). It is recommended that these principles be expanded and emphasized as it is clearly necessary to adopt some alternative to those processes traditionally used by the Expert Committee to evaluate other types of food additives.

3. Recommendations

In view of the above considerations and taking into account the limited facilities available for laboratory research, and evaluation, noting the willingness of IOFI to cooperate and to supply useful and indispensable information, the ad hoc Working Group recommends to the CCFA that priority be given to:

- (1) the establishment of criteria to be used for the safety evaluation of flavouring substances irrespective of their nature;
- (2) (a) the preparation of specifications of chemical purity of artificial and nature-identical flavouring substances, and
(b) the toxicological evaluation of artificial flavouring substances establishing a positive and open list of those substances.

For an orderly progression in the problem of flavour evaluation some reasonable priority system is needed. An indispensable part of such a system is progress re-evaluation. So, any recommendation will be liable to modification as time elapses.

ENDORSEMENT OF MAXIMUM LEVELS OF FOOD ADDITIVES IN CODEX
COMMODITY STANDARDS

(See also Appendix II, ALINORM 76/12)

This Appendix summarizes all provisions as at end of May 1977 which were considered by the Codex Committee on Food Additives at its 11th session. For other decisions of the Codex Committee on Food Additives, ALINORM 71/12, 72/12 and 74/12 should be consulted.

Abbreviations Used

E	=	Endorsed
EP	=	Endorsement postponed for reasons given in the footnotes.
TE	=	Temporarily endorsed
Limited by GMP	=	Limited by Good Manufacturing Practice (see definitions and explanatory notes in the codex List of Food Additives CAC/FAL 1-1973)

Contents

Sugars	=	Item A
Fats and Oils	=	Item B
Foods for Infants and children	=	Item C
Quick Frozen Foods	=	Item D
Cocoa Products	=	Item E
Fruit Juices and Nectars	=	Item F
Fish and Fishery Products	=	Item G
Processed Fruits and Vegetables	=	Item H
Meat Products	=	Item I
Milk Products	=	Item J
Edible Ices	=	Item K
Soups and Broths	=	Item L

A. SUGARS

1. Fructose (see ALINORM 76/27)
(Standard at Step 6)

	<u>Maximum level</u>	<u>Paragraph</u>	<u>Status of Endorsement</u>
Sulphur dioxide	not more than [20] mg/kg	56	E

B. FATS AND OILS ¹

¹ See also Part II, Item 21.

1. Low Fat Spreads (see ALINORM 76/19, App. III)
(Standard at: Step 6)

The following substances may be added singly or in combination:

	<u>Maximum level</u>	<u>Paragraph</u>	<u>Status of Endorsement</u>
<u>Colours</u>			
Alpha-, Beta-, Gamma-carotenes Bixin, Norbixin, Annatto Turmeric Curcumin	Limited by GMP	57, 58	EP
<u>Flavours</u>			
Natural flavours as defined in the Codex Alimentarius and their identical synthetic equivalents Other synthetic flavours approved by the Codex Alimentarius Commission	Limited by GMP		TE
<u>Emulsifiers</u>			
Lecithins Mono- and diglycerides of fatty acids Polyglycerol esters of fatty acids Polyglycerol esters of inter-esterified ricinoleic acid	Limited by GMP	59	E E EP EP
Esters of fatty acids with poly-alcohols other than glycerol:			
Sorbitan monopalmitate Sorbitan monostearate Sorbitan tristearate Polyoxyethylene (20) sorbitan monolaurate Polyoxyethylene (20) sorbitan monopalmitate Polyoxyethylene (20) sorbitan monostearate Polyoxyethylene (20) sorbitan tristearate Polyoxyethylene (20) sorbitan monooleate	10 g/kg individually or in combination	59	E

Thickening agents

Pectins			TE
Agar			E
Carrageenan			E
Guar gum			E
Locust bean gum			TE
Tragacanth gum	10 g/kg	60	EP
Xanthan gum	individually		E
Gelatine	or in		Food
Methyl cellulose	combination		E
Carboxymethyl cellulose and its Na salt			E
Na, K, Ca and NH. alginates			E
Propylene glycol alginate		E	
Natural starches	Limited by GMP		Food

Preservatives

Sorbic acid and its Na, K and Ca salts	1000 mg/kg		E
Benzoic acid and its Na and K salts	individually		
	or in		E
	combination		

Antioxidants

Propyl, octyl and dodecyl gallates	100 mg/kg of the fat content		
Butylated hydroxytoluene (BHT)	individually		TE
Butylated hydroxyanisole (BHA)	or in combination		
Ascorbyl palmitate/stearate	500 mg/kg of the fat content		E
L-ascorbic acid	300 mg/kg of the fat content		E
Natural and synthetic tocopherols ¹	Limited by GMP		E

Antioxidant-synergist

Calcium disodium salt of EDTA	[75 mg/kg]	61	EP
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PH Correcting agents

Lactic acid			
Citric acid			
Sodium hydrogen carbonate			
Sodium carbonate	Limited by GMP		E
Sodium hydroxide			
Sodium monophosphates (ortho-phosphates)			

¹ Alpha-tocopherol and mixed tocopherols concentrate is in List A (1).

2. Edible Vegetable Oils (see ALINORM 76/19)
(Standards at Step 3)

Red Palm Oil and Edible Bleached Palm Oil Grapeseed Oil Coconut Oil Palm Kernel oil Babassu Oil	62	E ²
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² The endorsement follows that of additives in other standards for fats and oils.

The Codex Committee on Fats and Oils is proposing the same food additive provisions for these edible oils as have been already endorsed (or temporarily endorsed) for other edible oils except that oxystearin is included only in grapeseed oil.

3. Low-Erucic Acid Rapeseed Oil (see ALINORM 76/19, App. XIII)
(Standard At Step 6)

The Codex Committee on Fats and Oils is proposing the same food additive provisions as in the Recommended International Standard for Edible Rapeseed Oil (CAC/RS 24-1969) except for oxystearin, which is not required.	62	E ³
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³ The endorsement follows that of the standard for Edible Rapeseed Oil.

C. FOODS FOR INFANTS AND CHILDREN

1. Canned Baby Foods (see CAC/RS 73-1976 and paras 55-56, ALINORM 76/26A) (Standard at Step 9)

	<u>Maximum level in 100 g of the ready-to-eat product</u>	<u>Paragraph</u>	<u>Status of Endorsement</u>
<u>Thickening agents</u>			
Distarch glycerol Acetylated distarch glycerol	6 g, singly or in combination	63	E ¹
<u>pH Adjusting agents</u>			
L(+)-Tartaric acid (in the fruit-based product only) ²	1 g	64	EP
<u>Emulsifiers</u>			
Mono- and diglycerides	0.15 g (at present the provision reads 1 g/100 g fat)	64	E

¹ Already adopted by the Commission (para 352, ALINORM 76/44).

² Proposed amendment submitted to the Commission.

2. Follow-up Milk for Infants and Children (see App. IX, ALINORM 76/26A)
(Standard at Step 3)

Endorsement of the food additive provisions <u>in toto</u> is postponed.	65
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3. Infant Formula (see CAC/RS 72-1976)
(Amendment submitted to the Commission)

pH Adjusting agents

Calcium hydroxide Potassium hydroxide Sodium hydroxide	Limited by GMP and within the limits for Na, K and Ca in Section 4.1.2(c) in all types of Infant Formulae	E
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D. QUICK FROZEN FOODS

1. Quick Frozen Cauliflower (see App. II, ALINORM 76/25A)
(Standard at Step 6)

	<u>Maximum Level</u>	<u>Paragraph</u>	<u>Status of Endorsement</u>
Ascorbic acid (as processing aid for use in the blanching or cooling water)	Limited by GMP		E

2. Quick Frozen Carrots (see CX/QFF 77/2)
(Standard at Step 3)

Mint essence	Limited by GMP		E
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3. Quick Frozen Fried Potato Chips (see CX/QFF 77/5)
(Standard at Step 5)

Endorsement of the food additives provisions <u>in toto</u> is postponed.	67
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4. Quick Frozen Corn-on-the-Cob (see CX/QFF 77/3)
(Standard at Step 3)

	<u>Maximum level</u>	<u>paragraph</u>	<u>Status of Endorsement</u>
Citric acid as a processing aid used in the blanching and cooling water	Limited by GMP		E

5. Quick Frozen Green Beans (see CX/QFF 75/16)
(Standard at Step 3)

Natural flavours and their identical synthetic equivalents except those which are known to present a toxic hazard	Limited by GMP	66	TE
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6. Quick Frozen Cauliflower (see App. V, ALINORM 78/25)
(Standard at Step 6)

Malic acid as a processing aid for use in the blanching and cooling water	Limited by GMP		E
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E. COCOA PRODUCTS ¹

¹ See also Part II, Item 21.

1. Cocoa Powders and Dry Cocoa Sugar Mixtures (see App. III, ALINORM 78/10) (Standard at Step 8)

Sucrose esters of fatty acids	10 g/kg		TE
Sodium silico-aluminate	10 g/kg in cocoa-sugar mixtures for vending machines only		E
Colloidal silicon dioxide			
Tricalcium phosphate			

F. FRUIT JUICES AND NECTARS ²

² See also Part II, Item 3.

1. Black Currant juice and Concentrated Black Currant Juice (see App. II and III, ALINORM 78/14)

(Standards at step 5)

Processing aids

Clarifying and filtering agents as approved by the Codex Alimentarius Commission and used in accordance with good manufacturing practice			E
Vegetable carbon	Limited by GMP		E
Nitrogen			
Carbon dioxide			

2. Small Fruit Pulpy Nectars (see App. IV, ALINORM 78/14)
(Standard at Step 5)

L-ascorbic acid	Limited by GMP	68	E
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G. FISH AND FISHERY PRODUCTS ³

³ See also Part II, Items 5, 6, 7, 8, 13.

1. Canned Sardines and sardine-type Products (see para 5, ALINORM 78/18)
(Standard at Step 6)

	<u>Maximum level</u>	<u>Paragraph</u>	<u>Status of Endorsement</u>
<u>Thickening or jellifying agents</u> (for use in packing medium only)			
Sodium carboxymethyl cellulose (CMC)	2.5 g/kg		E
Modified starches			E
Agar	20 g/kg singly or in combination	69	E
Carrageenan			E
Guar gum			E
Carob bean gum			TE
Alginic acid and its Ca, K and Na salts			E
<u>Acidifying agents</u>			
Acetic acid			E
Citric acid			E
Lactic acid			E
Natural flavours, e.g. spice oils spice extracts	Limited by GMP	69	TE
Smoke flavours (natural smoke solutions and their extracts)			TE

2. Canned Mackerel and Jack Mackerel (see App. III, ALINORM 78/18)
(Standard at Step 3)

<u>Thickening or jellifying agents</u> (for use in packing medium only)			
Sodium carboxymethyl cellulose (CMC)	2.5 g/kg		E
Pectins	2.5 g/kg		TE
Modified starches			E
Agar	20 g/kg (total singly or in combination)	69	E
Carrageenan			E
Guar gum			E
Carob bean gum			TE
Alginic acid and its Ca, K and Na salts			E
<u>Acidifying agents</u>			
Acetic acid	Limited by GMP	69	E
Citric acid			E
Lactic acid			E

Natural flavours, e.g. spice oils spice extracts			TE
Smoke flavours (natural smoke solutions and their extracts)			TE
3. <u>Quick Frozen Lobsters</u> (see App. V, ALINORM 78/18) (Standard at Step 7)			
<u>Preservatives</u>			
Sulphite, bisulphite or meta- bisulphite, Na or K (for use in the raw product only) (singly or in combination)		100 mg/kg raw product expressed as SO ₂ 30 mg/kg cooked product expressed as SO ₂	E
Ascorbates, Na or K salts		1000 mg/kg, expressed as ascorbic acid	E

H. PROCESSED FRUITS AND VEGETABLES ¹

1. Jams (Fruit Preserves) and Jellies (see App. II, ALINORM 76/20A) (standard at Step 9)

Anti-foaming agent

Dimethylpolysiloxane	10 mg/kg		E
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Colouring matters

Erythrosine 45430			E
Amaranth 16185			TE
Fast Green FCF 42053			E
Ponceau 4R 16255			TE
Tartrazine 19140			E
Sunset Yellow FCF 15985			E
Brilliant Blue FCF 42090			E
Indigo Carmine (Indigotin) 73015			E
Caramel colours (made by the ammonium sulphite process)	200 mg/kg, singly or in combination	70, 71	TE
Caramel colours (<u>not</u> made by the ammonia process)			E
Chlorophylls 75810			E
Beta-apo-8'-carotenal 40820			E
Ethyl ester of beta-apo-8'- carotenoic acid 40825			E
Canthaxanthine			E
Any safe and suitable natural food colours	Limited by GMP		EP

Preservatives

Sodium benzoate	1000 mg/kg,	E
Sorbic acid or potassium salt	singly or in	
Methyl, ethyl and propyl esters	combination	
of parahydroxybenzoic acid		

Flavours

Vanilla (in chestnut preserves only)		E
Vanillin (in chestnut preserves only)	Limited by GMP	E

Firming agents (for use only on the fruit)

Calcium bisulphite	200 mg/kg, expressed as Ca ²	E
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Antioxidants

L-ascorbic acid		
(generally)	500 mg/kg	E
(in black currant jam]	750 mg/kg	

8. Citrus Marmalade (see App. III, ALINORM 76/20A)
(Standard at Step 9)

	<u>Maximum level</u>	<u>Paragraph</u>	<u>Status of Endorsement</u>
<u>Colouring matters</u>			
Caramel colour (made by ammonium sulphite process)	1500 mg/kg	70, 71	TE
Sunset Yellow FCF	200 mg/kg		E
Tartrazine	100 mg/kg,		E
Fast Green FCP	singly or in combination in lime marmalade only		E

9. Canned Mature Processed Peas (see App. IV, ALINORM 76/20A)
(Standard at Step 9)

<u>Softening agents</u>	<u>Maximum level in the end product</u>	
Sodium bicarbonate	150 mg/kg.	E
Sodium citrate	expressed as Na singly or in combination ¹	E

Colours

Fast Green FCF	200 mg/kg, singly or in combination	81	E
Tartrazine			E
Brilliant Blue FCF			E

¹ Note by the Secretariat: The addition of salt (NaCl) is permitted in the standard.

10. Canned Tropical Fruit Salad (see App. III, ALINORM 76/20) (Standard at Step 7)

Antioxidant

L-ascorbic acid	700 mg/kg		E
Natural flavours and nature- identical flavours as defined in the Codex Alimentarius	Limited by GMP		TE

11. Pickled Cucumbers (see App. IV, ALINORM 78/20) (Standard at Step 5)

Maximum level

Solubilizing and dispersing agents

Polysorbate 80 (polyoxyethylene/20 sorbitan monooleate)	500 mg/kg, singly or in combination	81	E
Xanthan gum			E
Gum Tragacanth			EP
Gum Arabic			E
Alginates			E
Carrageenan			E

Firming agents

Alum (aluminium potassium sulphate)		81	EP
Aluminium sulphate	250 mg/kg	81	EP
Aluminium sodium sulphate			EP
Calcium chloride			E

Preservatives

Sulphur dioxide (as a carry- over from raw product)	50 mg/kg		E
Benzoic acid or its Na and K salts	1000 mg/kg, singly or in combination	81	E
Potassium sorbate			E

Colouring matters

Fast Green FCF			E
Chlorophylls			E
Tartrazine 19140			E
Annatto			TE
Oleoresin of Turmeric			EP
Turmeric	300 mg/kg, singly or in combination	82	TE
Sunset Yellow FCF 15985			E
Beta-carotene			E
Paprika			Food
Oleoresin of paprika			E
Brilliant Blue FCF 42090			E
Caramel			EP

Thickening agents (in mustard type only)

Modified starches			EP
Xanthan gum			EP
Carrageenan			EP
Alginates			EP
Pectins	According to GMP	83	EP
Gum Tragacanth			EP
Guar gum			E
Gum Arabic			E
Carboxymethylcellulose			EP
Locust bean gum			TE

Acidifiers

Acetic acid			E
Lactic acid			E
Malic acid	According to GMP	84	E
Citric acid			E
Tartaric acid			EP

Flavours

Natural flavours and nature- identical flavours, as defined in the Codex Alimentarius	According to GMP		TE
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12. Canned Carrots (see App. V, ALINORM 78/20)
(Standard at Step 5)

Thickening agents (to be used only when butter or other animal or vegetable fats or oils are used as ingredients as in "sauce pack")

Starch sodium succinate	10 g/kg singly	EP
Gum tragacanth	or in combination [with other modified thickening agents already endorsed]	EP

13. Dried Apricots (see App. VI, ALINORM 78/20)
(Standard at Step 5)

	<u>Maximum level</u>	<u>Paragraph</u>	<u>Status of Endorsement</u>
[Glycerol	500 mg/kg]	86	EP
Sorbic acid and its Na and K salts	500 mg/kg singly or in combination expressed as sorbic acid		E
Sulphur dioxide	2000 mg/kg		E

I. MEAT PRODUCTS

1. Cooked Cured Chopped Meat (see App. IV, ALINORM 78/16)
(Standard at Step 8)

5'-Guanylate, disodium	500 mg/kg, expressed as guanylic acid	E
5'-Inosinate, disodium	500 mg/kg, expressed as inosinic acid	E
Monosodium glutamate	5000 mg/kg, expressed as glutamic acid	E
Glucono-delta-lactone	3000 mg/kg	E

J. MILK PRODUCTS ¹

¹ See also Part II, Items 1, 2, 9, 10, 11, 14-21.

1. Flavoured Yoghurt (See App. III, Report of the 18th session of the Committee of Government Experts on Milk and Milk Products)

(Submitted to government comments for acceptance)

Flavours

The terms below are defined in the "List of Additives Evaluated for their Safety-in-Use in Food", CAC/FAL 1-1973 and Supp. 1.

	<u>Maximum level</u>	<u>Paragraph</u>	<u>Status of Endorsement</u>
Natural flavours and flavouring substances	Limited by GMP	72	TE
Nature-identical flavouring substances			TE
Artificial flavouring substances appearing in the Codex List CAC/FAL 1-1973 and Supp. 1			TE
<u>Food colours</u> (which come exclusively from flavouring substances as a result of carry-over)			
Tartrazine	18 mg/kg	73	EP
Sunset Yellow FCF (Orange Yellow S)	12 mg/kg		
Cochineal or Carminic acid	20 mg/kg		
Azorubine (Carmoisine)	57 mg/kg		
Ponceau 4R (Cochineal Red A)	48 mg/kg		
Erythrosine	27 mg/kg		
Indigotine (Indigo Carmine)	6 mg/kg		
Green S (Acid Brilliant Green BS or Lissamine Green)	2 mg/kg		
Caramel colours	150 mg/kg		
Brilliant Black PN (Black PN)	12 mg/kg		
Beetroot Red (Betanin)	250 mg/kg		
Chocolate Brown FB	30 mg/kg		
Red 2G	30 mg/kg		
Brilliant Blue FCF	-		
Other colouring ingredients extracted from natural fruit and vegetable sources	-		
<u>Stabilizers</u>			
Starches and modified starches appearing in the Codex List CAC/FAL 1-1973 and Supp. 1	10 g/kg ¹		EP

¹ Pending specification of the individual modified starches.

2. Cream for Direct Consumption (see App. IV, Report of the 18th session of the Committee of Government Experts on Milk and Milk Products)

(Submitted to governments for acceptance)

Orthophosphates, Na, K, Ca Polyphosphates, Na, K, Ca	2 g/kg singly 3 g/kg in combination expressed as anhydrous substances	
Microcrystalline cellulose Preparations of rennin	5 g/kg singly or in combination in whipped pasteurized creams or in UHT cream and sterilized cream intended for whipping	E
Vanillin	Limited by GMP	
Ethyl vanillin		

3. Edible Acid Casein (see App. V, Report of the 18th session of the Committee of Government Experts on Milk and Milk Products)

Citric acid	Limited by GMP	E
Acetic acid		E

4. Edible Caseinates (See App. VI, Report of the 18th session of the Committee of Government Experts on Milk and Milk Products)

Optional neutralizing agent

Magnesium hydroxide	Limited by GMP	E
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Optional buffering agents

Sodium carbonate Sodium bicarbonate Citrate, Na, Ca, K Lactate, Na, Ca, K Acetate, Na, Ca, K	Limited by GMP	E
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- K. EDIBLE ICES (See ALINORM 78/11, paras 52-59, App. II and App. IV)
(Standard at Step 8)

Endorsement of the food additive provisions in toto is postponed (see paras 51-54).

- L. SOUPS AND BROTHS (See ALINORM 76/9, para 35, App. II)
(Standard at Step 3)

Endorsement of the food additive provisions in toto is postponed (see para 55).

PART II - Food Additive Provisions in Codex Standards the Endorsement of Which has been Postponed at Previous Sessions of the Codex Committee on Food Additives

<u>Additive</u>	<u>Food</u>	<u>Limit</u>	<u>Para</u>	<u>Status of Endorsement</u>
1. Phosphoric acid	Cheese (except as otherwise specified) CX 5/70, 16th session, App.IV-B	Not specified	74	EP
2. L-ascorbic acid	Quick Frozen Shrimps or Prawns CAC/RS 92/1976	Limited by GMP		E
3. L-ascorbic acid	Grape juice CAC/RS 82-1976	400 mg/kg		E
4. L-ascorbic acid	Concentrated grape juices, CAC/RS 83-1976	Limited by GMP		E
5. Sodium thiosulphate (Syn.: sodium hyposulphate)		100 mg/kg in the edible part of the raw product; 30 mg/kg in the edible part of the cooked product, expressed as SO ₂ singly or in combination	79	EP
6. Sodium bisulphite	Quick frozen Shrimps or Prawns CAC/RS 92-1976			E
7. Sodium sulphite				E
8. Sodium or potassium metabisulphite				E
9. Brilliant Blue FCF	Provolone cheese CAC/C1-C25 (1972)	Not specified	74	EP
10. Fast Green FCF				
11. Indigotine				
12. Monosodium glutamate	Canned carrots App. VII, ALINORM 76/20	[500 mg/kg]	85	EP
13. Monosodium glutamate	Canned crab meat App. IV, ALINORM 76/18	500 mg/kg	80	EP

14. Benzoyl peroxide or a mixture of benzoyl peroxide with K alum, Ca sulphate and Mg carbonate ¹	Extra hard grating cheese, CX 5/70, 16th session, App. VI	20 mg/kg of the milk, singly or in combination with alum, calcium sulphate and magnesium carbonate	74	EP
15. Hexamethylenetetramine	Cheese (except as otherwise specified) CX 5/70, 16th session App. IV-B	Not specified	74	EP
16. Hexamethylenetetramine	Provolone cheese CAC/C1-C25 (1972)	600 mg/kg of the liquid used to work the curd	74	EP
17. Nitrate, K, Na (in brine-salted cheeses only)	Cheese (except as otherwise specified) CX 5/70, 16th session, App. IV-B	200 mg/kg of the milk used singly or in combination, provided that		E
18. Nitrate, K, Na	Individual cheeses ²	there is no more than 50 mg/kg in the final product	75, 76	E
19. Natamycin (Syn.: Pimaricin)	Cheese (except as otherwise specified) CX 5/70, 16th session, App. IV-B	2 mg/kg in the rind without plastic coating 500 mg/kg in the plastic coating	77;	E
20. Propionic acid	Same as Item 19	Limited by GMP		E
21. Sorbic acid and Na and K salts	Extra hard grating cheese, CX 5/70, 18th session, App. III	1000 mg/kg singly or in combination, expressed as sorbic acid	78	E
22. 1,1,2-Trichloroethylene	Cocoa butter CAC/RS 86-1976	5 mg/kg ³		EP

¹ The weight of Ca sulphate and Mg carbonate not to exceed six times the weight of benzoyl peroxide.

² Danablu, Danbo, Edam, Gouda, Havarti, Samsøe, Tilsiter, Limburger, Saint-Paulin, Svevia, Herrgårdssost, Hushållsost, Norvegia, Maribo, Fynbo, Esrom, Amsterdam, Leidse, Friese.

³ Need to reconsider the use of this solvent. See also para 217 of the report of the 11th session of the Commission.

ENDORSEMENT OF PROVISIONS FOR CONTAMINANTS IN CODEX COMMODITY
STANDARDS

(See also ALINORM 76/12 and CAC/FAL 2-1973 and CAC/FAL 3-1976)

Abbreviations used in this Appendix

E	= Endorsed
EP	= Endorsement postponed for reasons given in the report
Maximum Level	= mg of contaminant, as defined, in 1 kg of finished product and including amounts of the contaminants naturally present in the food
TE	= Temporarily endorsed

<u>Contaminant Provision</u>	<u>Maximum level (mg/kg)</u>	<u>Ref. to ALINORM</u>	<u>Status of Endorsement</u>
1. <u>Arsenic (As)</u>			
1.1 Fructose	1	76/27, App. II	E ¹
1.2 Low-fat spreads	0.1	76/19, App. III	E
1.3 Edible coconut oil	0.1	76/19, App. VI	E
1.4 Edible red palm oil and bleached red palm oil	0.1	76/19, App. VII	E
1.5 Edible palm kernel oil	0.1	76/19, App. VIII	E
1.6 Edible grape seed oil	0.1	76/19, App. IX	E
1.7 Edible Babassu oil	0.1	76/19, App. X	E
1.8 Black currant juice	0.2	78/14, App. II	E ¹
1.9 Concentrated black currant juice	0.2 on a reconstituted basis	78/14, App. III	E ¹

¹ See para 39 of this Report.

<u>Contaminant Provision</u>	<u>Maximum level (mg/kg)</u>	<u>Ref. to ALINORM</u>	<u>Status of Endorsement</u>
2. <u>Copper (Cu)</u>			
2.1 Fructose	2	76/27, App. II	E
2.2 Low-fat spreads	0.1	76/19, App. III	E
2.3 Edible coconut oil		76/19, App. VI	E
virgin oil	0.4		
non-virgin oil	0.1		
2.4 Edible red palm oil and bleached red palm oil		76/19, App. VII	E
virgin oil	0.4		
non-virgin oil	0.1		
2.5 Edible palm kernel oil	0.1	76/19, App. VIII	E
2.6 Edible grape seed oil	0.1	76/19, App. IX	E
2.7 Edible Babassu oil	0.1	76/19, App. X	E
2.8 Black currant juice	5	78/14, App. II	E
2.9 Concentrated black currant juice	5 on a reconstituted basis	78/14, App. III	E

3.	<u>Iron (Fe)</u>			
3.1	Low-fat spreads	1.5	76/19, App. III	E
3.2	Edible coconut oil		76/19, App. VI	E
	virgin oil	5		
	non-virgin oil	1.5		
3.3	Edible red palm oil and bleached red palm oil		76/19, App. VII	E
	virgin oil	5		
	non-virgin oil	1.5		
3.4	Edible palm kernel oil	1.5	76/19, App. VIII	E
3.5	Edible grape seed oil	1.5	76/19, App. IX	E
3.6	Edible Babassu oil	1.5	76/19, App. X	
3.7	Black currant juice	15	78/14, App. II	E
3.8	Concentrated black currant juice	15 on a reconstituted basis	78/14, App. III	E
4.	<u>Lead (Pb)</u>			
4.1	Soups and broths	[0.3]	76/9, para 36, App. II	EP ¹
4.2	Fructose	[2]	76/27, App. II	EP ¹
4.3	Cocoa powders and cocoa sugar mixtures	2	78/10, App. II	TE
4.4	Low-fat spreads	0.1	76/19, App. III	TE
4.5	Edible coconut oil	0.1	76/19, App. VI	TE
4.6	Edible red palm oil and bleached red palm oil	0.1	76/19, App. VII	TE
4.7	Edible palm kernel oil	0.1	76/19, App. VIII	TE
4.8	Edible grape seed oil	0.1	76/19, App. IX	TE
4.9	Edible Babassu oil	0.1	76/19, App. X	TE
4.10	Black currant juice	0.3	78/14, App. II	TE
4.11	Concentrated black currant juice	0.3 on a reconstituted basis	78/14, App. III	TE
4.12	Edible caseinates	2	App. VI, CX 5/70 18th session	TE
4.13	Edible acid casein	2	App. V, CX 5/70 18th session	TE
5.	<u>Tin (sn)</u>			
5.1	Soups and broths	[250]	76/9, para 36, App. II	EP ²
5.2	Non-pulpy black currant nectar	150	76/12, para 87, App. I	TE
5.3	Black currant juice	150	78/14, App. II	TE
5.4	Concentrated black currant juice	150 on a reconstituted basis	78/14, App. III	TE
5.5	Pulpy small fruit nectar	150	78/14, App. IV	TE
5.6	Canned fruit cocktail	250	76/20, App. II, 78/20, para 18	TE
5.7	Canned tropical fruit salad	250	76/20, App. III	TE
5.8	Canned carrots	250	76/20, App. VII	TE

5.9	Canned mature processed peas	250	76/20A, App. IV	TE
5.10	Pickled cucumbers	250	76/20A, App. V	TE

¹ See para 90 of this Report.

² See paras 90 and 91 of this Report.

Contaminant Provision	Maximum level (mg/kg)	Ref. to ALINORM	Status of Endorsement	
6. <u>Zinc (Zn)</u>				
6.1	Black currant juice	5	78/14, App. II	E
6.2	Concentrated black currant juice	5 on a reconstituted basis	78/14, App. III	E
7. <u>Insoluble Impurities (II), Matter Volatile at 105 (VM) and Soap Content (SC)</u>				
7.1	Edible coconut oil	II: 500 VM: 2000 SC: 50	76/19, App. VI-App. X	E
7.2	Edible red palm oil and bleached red palm oil			
7.3	Edible palm kernel oil			
7.4	Edible grape seed oil			
7.5	Edible Babassu oil			
8. <u>Sulphur dioxide</u>				
8.1	Apricot, peach and pear nectars	10	78/14, para 28	E
8.2	Black currant juice	10	78/14, App. II	E
8.3	Concentrated black currant juice	10 on a reconstituted basis	78/14, App. III	E
8.4	Orange juice	10	CAC/RS 45-1971	E
8.5	Grapefruit juice	10	CAC/RS 46-1971	E
8.6	Lemon juice	10	CAC/RS 47-1971	E
8.7	Tomato juice	10	CAC/RS 49-1971	E
8.8	Concentrated orange juice	10 on a reconstituted basis	CAC/RS 64-1972	E
9. <u>Sum of Cu, Zn and Fe</u>				
9.1	Non-pulpy black currant nectar	20	78/14, App. I	E
9.2	Black currant juice	20	78/14, App. II	E
9.3	Concentrated black currant juice	20 on a reconstituted basis	78/14, App. III	E
9.4	Pulpy small fruit nectars	20	78/14, App. IV	E
9.5	Orange juice	20	CAC/RS 45-1971	E
9.6	Grapefruit juice	20	CAC/RS 46-1971	E
9.7	Lemon juice	20	CAC/RS 47-1971	E
9.8	Tomato juice	20	CAC/RS 49-1971	E
9.9	Apricot, peach and pear nectars	20	CAC/RS 44-1971	E
9.10	Apple juice	20	CAC/RS 48-1971	E
9.11	Concentrated apple juice	20 on a reconstituted basis	CAC/RS 63-1972	E

9.12	Concentrated orange juice	20 on a reconstituted basis	CAC/RS 64-1972	E
10.	<u>Mineral Impurities Insoluble in 10% HCl</u>			
10.1	Black currant juice	20	78/14, App. II	E
10.2	Concentrated black currant juice	20 on a reconstituted basis	78/14, App. III	E
11.	<u>General Provisions</u>			
11.1	Follow-up milk for Infants and Children		76/26A, App. IX	EP ¹
	<u>Contaminants</u>			
11.2	Natural Mineral Waters		CX/MIN 77/2	TE ²

¹ See para 93 of this Report.
² See para 94 of this Report.

Contaminants

- Nitrites
- Phenolic compounds
- Surface active agents
- Pesticides and PCBs
- Mineral Oil
- Polynuclear aromatic hydrocarbons

ADVISORY LIST OF FOOD ADDITIVES FOR USE IN SOFT DRINKS

Note by the Secretariat; This list of food additives used in soft drinks serves the purposes of the ad hoc Working Group on Food Additives Intake of the Codex Committee on Food Additives (see para 119, 4) of this report) and the Joint FAO/WHO Expert Committee on Food Additives. It will be printed without the maximum levels but showing the status of toxicological evaluation in future editions of Codex lists of food additives, for the information of governments.

Definition

For the purpose of this list, "soft drink" is a beverage other than fruit juice, fruit nectar, milk, milk-based beverages, alcoholic beverages, mineral waters, tea and tea substitutes, coffee, chicory, maté, cocoa and chocolate drink.

Food Additives1. ACIDULANTS

1.1	Acetic acid	Limited by GMP
1.2	Adipic acid	¹
1.3	Citric acid	Limited by GMP
1.4	Fumaric acid	¹
1.5	Hydrochloric acid	Limited by GMP
1.6	Lactic acid	Limited by GMP
1.7	Malic acid	Limited by GMP
1.8	Ortho-phosphoric acid	600 mg/kg
1.9	L(+)-Tartaric acid	600 mg/kg ¹

¹ Requires re-examination, particularly regarding levels of use.

2. BUFFERING AGENTS

2.1	Acetates, K and Na	Limited by GMP
2.2	Carbonates, Ca, Mg, K, Na and NH.	Limited by GMP
2.3	Citrates, Ca, K and Na	Limited by GMP
2.4	Lactates, K, Ca, Na and NH.	Limited by GMP
2.5	Tartrates, NaK, Na and K	²
2.6	Phosphates, Na, K and Ca	²

² Additional data required concerning levels of use; combined use of acid and salts of the acid should not exceed the established ADI.

4. EMULSIFIERS AND STABILIZERS

4.1	Acacia gum	Limited by GMP
4.2	Guar gum	Limited by GMP
4.3	Carob bean gum	Limited by GMP
4.4	Carrageenan	1000 mg/kg
4.5	Alginic acid and its Na, K and Ca salts	300 mg/kg
4.6	Propylene glycol alginate	500 mg/kg ³
4.7	Pectin (not amidated)	Limited by GMP
4.8	Sodium carboxymethyl cellulose ³	500 mg/kg, as sum of total cellulose derivatives

4.9	Hydroxypropyl methyl cellulose	500 mg/kg, as sum of total cellulose derivatives
4.10	Methyl cellulose	500 mg/kg, as sum of total cellulose derivatives
4.11	Lecithin	Limited by GMP
4.12	Mono- and diglycerides of fatty acids	Limited by GMP
4.13	Polyglycerol esters of fatty acids	³
4.14	Sucrose esters of fatty acids ⁴	50 mg/kg ³
4.15	Sorbitan monostearate	500 mg/kg
4.16	Polyoxyethylene (20) sorbitan monolaurate	500 mg/kg as sum of polyoxyethylene (20) sorbitan esters ³

³ Additional data required regarding use levels.

⁴ Does not include SAIB.

4.17	Polyoxyethylene (20) sorbitan monostearate	See 4.16
4.18	Polyoxyethylene (20) sorbitan monooleate	See 4.16
4.19	Polyoxyethylene (8) stearate	¹
4.20	Dextrins from starch	Limited by GMP
4.21	Sodium metaphosphate	²

¹ Data required concerning use levels.

² Additional data required regarding use levels; must be considered with phosphoric acid and other phosphate salts.

5. FLAVOURS ⁸

5.1	Natural flavours (including fruit extracts) and natural flavouring substances	Limited by GMP
5.2	Nature-identical flavouring substances	Limited by GMP
5.3	Artificial flavouring substances	³

6. FOAMING AGENTS

No compound considered to be suitable for the Advisory List.

7. ANTI-FOAMING AGENTS

7.1	Dimethyl polysiloxane	10 mg/kg
7.2	Mono- and diglycerides	Limited by GMP

8. COLOURS

8.1	Amaranth	15 mg/kg
8.2	Annatto	25 mg/kg ⁴
8.3	Azorubine	
8.4	Canthaxanthine	50 mg/kg
8.5	Caramel (by ammonium sulphite process)	2000 mg/kg ⁵
8.6	Caramel	Limited by GMP
8.7	Chlorophyll ⁶	Limited by GMP
8.8	Chlorophyllin copper complex	50 mg/kg
8.9	Beta-carotene	25 mg/kg, singly or in combination
8.10	Beta-apo-8'-carotenal	25 mg/kg, singly or in combination
8.11	Beta-apo-8'-carotenoic acid, methyl and ethyl esters	25 mg/kg, singly or in combination

8.12	Brilliant Blue FCF	75 mg/kg
8.13	Erythrosine ⁷	25 mg/kg
8.14	Fast Green FCF ⁷	50 mg/kg
8.15	Indigotine ⁷	50 mg/kg
8.16	Ponceau 4R	₉
8.17	Riboflavin	10 mg/kg
8.18	Sunset Yellow FCF	50 mg/kg
8.19	Tartrazine	75 mg/kg

9. NON-NUTRITIVE SWEETENERS

9.1	Saccharin and Ca and Na salts	350 mg/kg ¹⁰
9.2	Cyclamates, Ca and Na	₉

³ Level of Use and ADI depends on flavouring in question.

⁴ Need to specify the types of extracts used.

⁵ Further data required regarding use levels.

⁶ Need to specify the type of chlorophyll used.

⁷ Inclusion of this colour may not be technologically justified.

⁸ See definition in document CAC/FAL 1-1973.

⁹ Level to be specified.

¹⁰ Use level correlated to ADI of 15 mg/kg; this ADI is specific for saccharin in special dietary food applications. Therefore, if used at a level of 350 mg/kg. the beverage must be represented and sold for special dietary use.

10. ANTIOXIDANTS

10.1	L-Ascorbic acid	300 mg/kg
10.2	BHA	200 mg/kg singly or in combination, based on fat or oil content of food to be used only in essences and flavours
10.3	BHT	
10.4	Calcium disodium EDTA	25 mg/kg
10.5	Gallate, dodecyl	200 mg/kg, singly or in combination, based on fat or oil content of food to be used only in essences and flavours
10.6	Gallate, propyl	
10.7	Iso-ascorbic acid	80 mg/kg
10.8	Tocopherols	₁

11. PRESERVATIVES

11.1	Benzoic acid	₂
11.2	Formic acid	20 mg/kg
11.3	p-Hydroxybenzoates, methyl and propyl	₂
11.4	Sorbic acid	400 mg/kg
11.5	Sulphur dioxide (SO ₂)	₂
11.6	Glucose oxidase/catalase	Limited by GMP

¹ Additional data needed on the use levels in essences and flavours; need to specify the types of tocopherols used.

² Use-patterns and use-levels of this compound require re-examination.

PROPOSED DRAFT GENERAL STANDARD FOR THE LABELLING OF FOOD
ADDITIVES WHEN SOLD AS SUCH³

(Advanced to Step 5)

³ See paras 136-146 of this Report.

1. SCOPE

This standard applies to the labelling of food additives sold as such whether by retail or other than by retail, including sales to caterers and food manufacturers for the purpose of their businesses.

2. DEFINITIONS OF TERMS

For the purpose of this Standard:

- (a) food additive means any substance not normally consumed as a food in its own right and not normally used as a typical ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include contaminants, or substances added to food for maintaining or improving nutritional qualities, or sodium chloride;
- (b) contaminant means any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination;
- (c) label includes any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container;
- (d) labelling includes the label and any written, printed or graphic matter relating to and accompanying the food additives. The term does not include bills, invoices and similar material which may accompany the food additives;
- (e) container means any form of packaging of food additives for sale as a single item, whether by completely or partially enclosing the food additives, and includes wrappers;
- (f) ingredient means any substance, excluding a food additive, used in the manufacture or preparation of a food and present in the final product;
- (g) sale by retail means any sale to a person buying otherwise than for the purpose of resale but does not include a sale to caterers for the purposes of their catering business or a sale to manufacturers for the purposes of their manufacturing business;
- (h) bulk container¹

(i) processing aid¹

¹ see para 139 of this Report.

3. GENERAL PRINCIPLES

3.1 Food additives shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding their character in any respect.

3.2 Food additives shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive, either directly or indirectly, of any other product with which such food additives might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food additive is connected with or derived from such other product; provided that the term "x flavour" may be used to describe a flavour which is not derived from, but reproduces the flavour of x.

4. MANDATORY LABELLING OF PREPACKAGED FOOD ADDITIVES SOLD BY RETAIL

The labels of all food additives sold by retail shall bear the information required by sub-sections 4.1 to 4.5 of this section, as applicable to the food additive being labelled.

4.1 Details of the Food Additive

- (a) The name of each food additive present shall be given. The name shall be specific and not generic and shall indicate the true nature of the food additive. where a name has been established for a food additive in a Codex list of additives, that name shall be used. In other cases the common or usual names shall be listed or, where none exists, an appropriate descriptive name shall be used.
- (b) If two or more food additives are present, their names shall be given in the form of a list. The list shall be in the order of the proportion by weight which each food additive bears to the total contents of the container, the food additive present in the greatest proportion by weight being listed first. Where one or more of the food additives is subject to a quantitative limitation in a food covered by a Codex standard, the quantity or proportion of that additive may be stated. If food ingredients are part of the preparation, they shall be declared in the list of ingredients in descending order of proportion.
- (c) In the case of mixtures of flavourings, the name of each flavouring present in the mixture need not be given. The generic expression "flavour" or "flavouring" may be used, together with a true indication of the nature of the flavour. The expression "flavour" or "flavouring" may be qualified by the words "natural" or "artificial", or both, as appropriate. This provision does not apply to flavour modifiers, but does apply to "herbs" and "spices", which generic expressions may be used where appropriate.
- (d) The words "For Food Use" or a statement substantially similar thereto shall appear in a prominent position on the label.

4.2 Instructions on Keeping and Use

Adequate information shall be given about the manner in which the food additive is to be kept and is to be used in food.

4.3 Net Contents

The net contents shall be declared in either the metric (Système International units) or avoirdupois or both systems of measurement as required by the country in which the food additive is sold. This declaration shall be made in the following manner :

- (a) for liquid food additives, by volume or weight;
- (b) for solid food additives, other than those sold in tablet form, by weight;
- (c) for semi-solid or viscous food additives, either by weight or volume;
- (d) for food additives sold in tablet form, by weight together with the number of tablets in the package.

4.4 Name and Address

The name and address of the manufacturer, packer, distributor, importer, exporter or vendor of the food additive shall be declared.

4.5 Country of Origin

- (a) The country of origin of a food additive shall be declared if its omission is likely to mislead or deceive the consumer.
- (b) When a food additive undergoes processing in a second country which changes its chemical or physical nature, the country in which the processing is performed shall be considered to be the country of origin for the purposes of labelling.

4.6 Lot Identification

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

5. MANDATORY LABELLING OF PREPACKAGED FOOD ADDITIVES SOLD OTHER THAN BY RETAIL

The labels of all food additives sold other than by retail shall bear the information required by sub-sections 5.1 to 5.5 of this section, as applicable to the food additive being labelled; provided that, where the food additives are delivered in bulk by tankers, demountable containers, or similar means, the required information may be given on the documents relating to the sale.

5.1 Details of the Food Additive

- (a) The name of each food additive present shall be given. The name shall be specific and not generic and shall indicate the true nature of the food additive. where a name has been established for a food additive in a Codex list of additives, that name shall be used. In other cases, the common or usual name shall be listed or, where none exists, an appropriate descriptive name shall be used.
- (b) If two or more food additives are present, their names shall be given in the form of a list. The list shall be in the order of the proportion by weight which each food additive bears to the total contents of the container, the food additive present in the greatest proportion by weight being listed first. Where one or more of the food additives is subject to a quantitative limitation in a food covered by a Codex standard, the quantity or proportion of that additive shall be stated. If food ingredients are part of the preparation, they shall be declared in the list of ingredients in descending order of proportion.

- (c) In the case of mixtures of flavourings, the name of each flavouring present in the mixture need not be given. The generic expression "flavour" or "flavouring" may be used, together with a true indication of the nature of the flavour. The expression "flavour" or "flavouring" may be qualified by the words "natural" or "artificial", or both, as appropriate. This provision does not apply to flavour modifiers, but does apply to "herbs" and "spices" which generic expressions may be used where appropriate.
- (d) The words "For Food Use" or a statement substantially similar thereto shall appear in a prominent position on the label.

5.2 Instructions on Keeping and Use

Adequate information shall be given about the manner in which the food additive is to be kept and is to be used in food. This information may be given on the label or on the documents relating to the sale.

5.3 Net Contents

The net contents shall be declared in either (a) metric units or "Système International" units or (b) avoirdupois, unless both systems of measurement are specifically required by the country in which the food additive is sold. This declaration shall be made in the following manner:

- (i) for liquid food additives, by volume or weight;
- (ii) for solid food additives, by weight;
- (iii) for semi-solid or viscous food additives, either by weight or volume.

5.4 Name and Address

The name and address of the manufacturer, packer, distributor, importer, exporter or vendor of the food additive shall be declared.

5.5 Country of Origin

- (a) The country of origin of a food additive shall be declared if its omission is likely to mislead or deceive the consumer.
- (b) When a food additive undergoes processing in a second country which changes its chemical or physical nature, the country in which the processing is performed shall be considered to be the country of origin for the purposes of labelling.

5.6 Lot Identification

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

6. PRESENTATION OF MANDATORY INFORMATION

6.1 General

Statements required to appear on the label by virtue of this Standard or any other Codex standard shall be clear, prominent and readily legible by the consumer under normal conditions of purchase and use.- Such information shall not be obscured by designs or by other written, printed or graphic matter and shall be on contrasting ground to that of the background. The letters in the name of the food additive shall be in a size reasonably related to the most prominent printed matter on the label. Where the container is covered by a wrapper, the wrapper shall carry the necessary information, or

the label on the container shall be readily legible through the outer wrapper or not obscured by it. In general the name and net contents of the food additive shall appear on that portion of the label normally intended to be presented to the consumer at the time of sale.

6.2 Language

The language used for the declaration of the statements referred to in paragraph 6.1 shall be a language acceptable to the country in which the food additive is intended for sale. If the language on the original label is not acceptable, a supplementary label containing the mandatory information in an acceptable language may be used instead of relabelling.

7. ADDITIONAL OR DIFFERENT REQUIREMENTS FOR SPECIFIC FOOD ADDITIVES

7.1 Nothing in this Standard shall preclude the adoption of additional or different provisions in a Codex standard, in respect of labelling, where the circumstances of a particular food additive would justify their incorporation in that standard.

7.2 Irradiated Food Additives

Food additives which have been treated with ionizing radiation, shall be so designated.

8. OPTIONAL LABELLING

8.1 General

Any information or pictorial device may be displayed in labelling provided that it is not in conflict with the mandatory requirement nor would mislead or deceive the consumer in any way whatsoever in respect of the food additive.

DRAFT GENERAL STANDARD FOR IRRADIATED FOODS¹
(Advanced to Step 5)²

¹ See paras 147-152 of this Report.

² See para 152 of this Report.

1. SCOPE

This standard applies to foods which have been treated by means of ionizing radiation. It does not apply to foods exposed to doses of 50 rad (0.5 Gy)(*) or less. This standard refers only to the irradiation aspects of the processing and handling of foods.

(*) Doses are expressed in rad and in Gy (g ray), the newly introduced SI unit (1 Gy = 102 rad).

2. GENERAL REQUIREMENTS FOR THE PROCESS

2.1 Gamma rays from the isotope ⁶⁰Co or ¹³⁷Cs or electrons generated from machine sources operated at or below an energy level of 10 MeV shall be used.

2.2 No food shall be irradiated except as provided for in Annex I of this standard.

2.3 In order to meet the requirements of safety and efficacy of food processing, the dose absorbed (**) by the food shall be within the range (***) specified for each individual food irradiation treatment in Annex I of this standard.

(**) General definition in the "Manual of Food Irradiation Dosimetry" (IAEA, Vienna, 1977, Chapter III).

(***) In this context, "dose range" figures indicate that no part of the foods to be irradiated shall receive less than the minimum absorbed dose or more than the maximum absorbed dose stated (see: Wholesomeness of Irradiated Food; Report of a Joint FAO/IAEA/WHO Expert Committee; WHO Techn. Rep. Ser. 604, Geneva, 1977, p. 11).

2.4 Radiation treatment of foods shall be carried out in facilities licensed and registered for this purpose by the competent national authority. In this respect, the following is relevant:

2.4.1 Such facilities shall be designed to meet the requirements of safety and efficacy of food processing.

2.4.2 The facilities shall be staffed by adequately trained and competent personnel.

2.4.3 Control of the process within the facility shall include the keeping of adequate records including quantitative dosimetry.

2.4.4 Premises and records shall be open to inspection by appropriate authorities.

2.4.5 Control shall be carried out in accordance with the Recommended Code of Practice for the Operation of Radiation Facilities used for the Treatment of Foods.

3. SAFETY OF IRRADIATED FOODS

In order to protect the health of the consumer, irradiated foods shall have been thoroughly evaluated and found to be safe and wholesome by competent and appropriate authorities, not only from the toxicological but also from the nutritional and microbiological points of view.

In this respect, at the international level, only those irradiated foods which have been evaluated and found to be safe and wholesome by a Joint FAO/IAEA/WHO Expert Committee on the wholesomeness of Irradiated Food are acceptable. Two categories of acceptance have been used, unconditional and provisional, and are defined in Annex 2 of this Standard.

4. FOODS TO BE IRRADIATED AND THEIR PRE- AND POST-IRRADIATION HANDLING

4.1 Foods to be irradiated and their packaging materials shall be of suitable quality, acceptable hygienic condition and appropriate for this process 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.

4.2 Food irradiated in accordance with Section 2 (General Requirements of the Process) shall not be re-irradiated.

5. LABELLING

5.1 For the information of the consumers, labelling shall be in conformity with the provisions of the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969).

5.2 For the information of the trade and for the purposes of control, foods which have been treated with ionizing radiation shall be designated in an appropriate way in the accompanying documents and/or on the label. The accompanying documents and/or the label shall also identify the registered facility which has irradiated the food.

ANNEX I

PROVISIONS FOR THE IRRADIATION OF SOME INDIVIDUAL FOOD ITEMS

1. chicken (*) (Gallus domesticus)

1.1 Purpose of the Process

The purpose of irradiating chicken is:

(a) to prolong storage life of

and/or

(b) to eliminate pathogenic microorganisms from eviscerated chicken stored below 10°C.

1.2 Specific Requirements

In addition to meeting the general requirements of the standard, the following specific requirements shall be met:

1.2.1 Dose Range

(a) 200 - 700 krad (2-7 kGy)

(b) 500 - 700 krad (5-7 kGy)

1.2.2 Temperature Requirement

During irradiation and storage the product shall be kept at or below 10°C.

2. Papaya (*) (Carica papaya L.)

2.1 Purpose of the Process

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

2.2 Specific Requirements

In addition to meeting the general requirements of the standard, the following specific requirements shall be met:

2.2.1 Dosage range

50 - 100 krad (0.5 - 1.0 kGy)

2.2.2 Source of radiation

The source of radiation is limited to ⁶⁰Co or ¹³⁷Cs in order to provide adequate penetration.

3. Potatoes (*) (Solanum tuberosum L.)

3.1 Purpose of the Process

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

3.2 Specific Requirements

In addition to meeting the general requirements of the standard, the following specific requirement shall be met:

3.2.1 Dose range

3-15 krad (0.03 - 0.15 kGy)

4. Strawberry (*) (Fragaria species)

4.1 Purpose of the Process

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

4.2 Specific Requirements

In addition to meeting the general requirements of the standard, the following specific requirement shall be met:

4.2.1 Dose range

100 - 300 krad (1-3 kGy)

5. Wheat and Ground wheat Products (*) (Triticum species)

5.1 Purpose of the Process

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

5.2 Specific Requirements

In addition to meeting the general requirements of the standard, the following specific requirements shall be met:

5.2.1 Dose range

15 - 100 krad (0.15 - 1.00 kGy)

5.2.2 Prevention of Reinfestation

These products, whether prepackaged or handled in bulk, shall be stored under such conditions as will prevent reinfestation.

6. Cod and Red Fish (**) (Gadus morhua and Sebastes marinus)

6.1 Purpose of the Process

The purpose of irradiating cod and red fish is to:

(a) reduce microbial spoilage of the packaged or unpackaged fish refrigerated at or below 3 C, and

(b) reduce the number of pathogenic microorganisms in packaged or unpackaged fish refrigerated at or below 3 C.

6.2 Specific Requirements

In addition to meeting the general requirements of the standard, the following specific requirements shall be met:

6.2.1 Dose range

100 - 220 krad (1.0 - 2.2 kGy)

6.2.2 Temperature requirement

During irradiation and storage the product shall be kept at or below 3°C.

7. Onion (**) (*Allium cepa*)

7.1 Purpose of the Process

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

7.2 Specific Requirements

In addition to meeting the general requirements of the standard, the following specific requirement shall be met:

7.2.1 Dose range

2-15 krad (0.02 - 0.15 kGy)

8. Rice (**) (*Oryza* species)

8.1 Purpose of the Process

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

8.2 Specific Requirements

In addition to meeting the general requirements of the standard, the following specific requirements shall be met:

8.2.1 Dose range

10 - 100 krad (0.1 - 1.0 kGy)

8.2.2 Prevention of reinfestation

This product, whether prepackaged or handled in bulk, shall be stored under such conditions as will prevent reinfestation.

(*) Granted "Unconditional Acceptance" by the Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food; Geneva, 31 August - 7 September 1976.

(**) Granted "Provisional Acceptance" by the Joint FAO/IAEA/WHO Expert Committee on the wholesomeness of Irradiated Food; Geneva, 31 August - 7 September 1976.

ANNEX 2

DEFINITIONS OF CATEGORIES OF ACCEPTANCE OF IRRADIATED FOODS (*)

(*) (Report from the meeting of a Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food (Geneva, 31 August - 7 September 1976)).

"Unconditional Acceptance - Acceptance granted when adequate data are available for the unequivocal establishment of the wholesomeness of the irradiated product".

"Provisional Acceptance - Acceptance granted when additional testing is required to establish the wholesomeness of the irradiated product for life time use by humans but when there are sufficient existing data to indicate that no hazards to health would arise from consumption of the irradiated product in the diet over the period that would elapse before the additional testing was carried out and the findings were evaluated. It is recommended, therefore, that a provisional acceptance should remain in force until the new data are evaluated by a future FAO/IAEA/WHO joint Expert Committee".

DRAFT COPE OF PRACTICE FOR THE OPERATION OF RADIATION FACILITIES
USED FOR THE TREATMENT OF FOODS

(Advanced to Step 5) ¹

¹ See para 153 of this Report.

1. INTRODUCTION

This code refers to the operation of radiation facilities based on the use of either a radioisotope source (⁶⁰Co or ¹³⁷Cs) or an electron accelerator. The radioisotope source plant may be of two designs, either "continuous" or "batch". Control of all types of plants involve the monitoring of the physical parameters of the process and the use of accepted methods of dosimetry.

2. RADIOISOTOPE SOURCE PLANTS

2.1 Parameters

The doses absorbed by a product depend on the source strength and its photon energy, the dwell time or the conveyor speed and the bulk density of the material to be irradiated. In practice the conveyor system is at a fixed distance from the source when in its exposed position.

2.1.1 Source

The source strength as measured in curies (Ci) (*) is stated by the supplying organizations and records should be kept by the operator giving details of each consignment as well as of any isotope which is returned. The actual total source strength will be known at any time. This strength will take into account the natural decay rate of the source which is constant for each isotope.

(*) The SI unit now introduced is Bq (becquerel); 1 MCi = 37 PBq (peta Bq = 10¹⁵Bq).

2.1.2 Source Movement and Conveyor Speed

There should be a positive indication of the correct operational position of the source which should be interlocked with the conveyor drive. The speed of the conveyor intended to give the required dose is determined by dosimetry procedures referred to herebelow. The actual speed should be monitored continuously using a pen-recording chart situated outside the cell. Such chart should be kept for inspection. This chart should also show the position of the source, i.e. whether in the "exposed" or in the "safe" position.

In the case of a "batch" plant a timing device should be linked to the source movement mechanism which causes the source to descent automatically to the "safe" position when the pre-set time has expired.

Changes in the conveyor speed in the case of a "continuous" plant, or dwell times in the case of a "batch" plant, should be made in accord with the natural decay of the source. Such changes should be recorded in the plant record book.

2.2 Dosimetry

Various techniques for dosimetry pertinent to sources are available for measuring absorbed dose in a quantitative manner (**).

Special studies should be carried out at the commissioning of a plant and, similarly, if modifications are made to the source strength or type. Routine dosimetry measurement should be made during operation and recorded.

(**) Detailed in the "Manual of Food Irradiation Dosimetry", IAEA, Vienna, 1977.

2.2.1 Dosimetry on commissioning and after source changes

In order to establish the dose distribution throughout the product to be treated and also to derive the correct setting of the conveyor speed, dosimeters should be distributed in suitable numbers throughout the product. These dosimeters should be placed at such positions as will give the best indication of dose variability. When the dose distribution is known, the conveyor speed should be determined which ensures that at least the specified minimum dose is given and that the maximum dose allowed is not exceeded.

If the source size or its geometry is changed or the type of product to be processed is changed, the procedure described above should be repeated,

2.2.2 Routine dosimetry

Dosimeters should be included with the product itself so that at least two dosimeters are used at least every 24 hours of operation of a "continuous" plant. In case of a "batch" operation, 2 dosimeters should be used in every batch. Their locations and the results obtained should be recorded in the plant record book.

2.3 Product

2.3.1 The incoming product should be physically separated from the outgoing irradiated product.

2.3.2 where appropriate, a visual colour change radiation indicator should be affixed to each product pack for ready identification of irradiated and non-irradiated products.

2.3.3 Records should be kept in the plant record book which show the nature of the product being treated, its bulk density, the type of source, the dose given, and the date of treatment.

3. ELECTRON MACHINE PLANTS

3.1 Parameters

A conveyor carries the product through a beam of electrons generated by a suitable accelerator. Various machine parameters (energy, average current and width of scan) are adjusted to ensure a consistent beam; thus giving the correct irradiation to the product for a given conveyor speed. A scanner is incorporated into the machine to oscillate the beam to give an even distribution over the surface of the product packages.

3.2 Dosimetry

Various techniques for dose measurements pertinent to machines are available. A considerable programme of measurements is made when the machine is first installed. Following this, routine dosimetry should be performed and recorded.

3.2.1 Dosimetry after installation and following modification of operating parameters

The parameters of the beam should be measured when the installation is brought into use and following any interruption of the accelerator which might entail a modification of these parameters. The techniques for measuring the beam parameters should be those appropriate to the type of machines used.

To determine the speed of the conveyor for a given set of parameters of the beam, the distribution of the dose in a plant package should be established. Because of the highly variable absorption characteristics of high energy electrons, the plant packages to be treated successively should be of the same density and the contents should be evenly distributed within the packages. The dosimeters should be placed at such locations as will give the best indication of dose variability. A recognized system (*) of dosimetry should be used.

When the distribution of the dose has been determined for a given set of parameters of the beam, the conveyor speed should be adjusted to ensure that the specified dose is received at the point of minimum dose within the plant and that the maximum dose is not exceeded.

This investigation should be repeated each time there is a modification in any of the operating parameters of the installation or in the characteristics of the product to be irradiated.

(*) Detailed in the "Manual of Food Irradiation Dosimetry", IAEA, Vienna, 1977.

3.2.2 Routine dosimetry

When the characteristics of the installation have been determined and the conveyor speed adjusted to ensure that the plant package receives the correct dose throughout, routine controls can be limited to the following:

- (i) measurements of the stability of the operating parameters by continuously recording the characteristics of the beam and the conveyor speed;
- (ii) there should be an immediate and simultaneous automatic stop device for the accelerator and conveyor in the case of any operating irregularities either of the beam or of the conveyor;
- (iii) there should be a procedure for the regular measurement of the correct dose absorbed by the product. Where large numbers of similar packs have to be treated it is acceptable to place dosimeters on only a small fraction of the packs and at least during each 8 hours of operation. The dosimeters should be placed in pre-determined positions which give the best indication of the acceptable absorbed dose within the product pack. Their locations and the results obtained should be recorded in the plant record book.

3.3 Product

3.3.1 The incoming product should be physically separated from the outgoing irradiated products.

3.3.2 Where appropriate, a visual colour change radiation indicator should be affixed to each product pack for ready identification of irradiated and non-irradiated products.

3.3.3 Records should be kept in the plant record book which show the nature of the product being treated, its bulk density, the type of electron machine, the dose given, and the date of treatment.

CODEX PRIORITY LIST OF FOOD ADDITIVES¹

¹ See paras 161-169 of this Report.

Note; The following groups of additives are in order of priority as regards their evaluation or re-evaluation by JECFA.

Miscellaneous

Aspartame
Stannous chloride
Tin as a contaminant
Nitrous oxide
Xylitol
Asbestos
Glycerol esters of wood resin
Sucrose acetate isobutyrate

Emulsifiers

Ethyl cellulose
Sorbitan monolaurate
Sorbitan monooleate
Oxidized hydroxypropyl distarch glycerol
Gum ghatti
Karaya gum
Quillaia extract
Tragacanth gum.
Bleached lecithins
Hydroxylated lecithin
Esters of glycerol and thermally oxidized soybean fatty acids
Stearoyl monoglyceridyl citrate
Succinylated monoglycerides

Carrier Solvents

Benzyl alcohol
Butane-1, 3-diol
Castor oil
Diethyl tartrate
Glycerol mono-acetate²
Isopropyl myristate
Polyethylene glycol
1,2-Propylene glycol acetates
Triethyl citrate

² Di- and tri-acetates of glycerol have been evaluated by JECFA.

Extraction Solvents

Butan-1-ol
Butan-2-ol
Diethyl ether
Di-isopropyl ether
Methyl ethyl ketone

Iso-butanol
Isopropyl acetate
Liquid carbon dioxide
Light petroleum ¹
n-Propanol
Chloroform
1,1-Dichloroethane
1,1,1-Trichlorotrifluoroethane
1,2-Dichlorotetrafluoroethane
Dichlorofluoromethane
Methylene chloride
1,1,1-Trichloroethane
Tetrachloroethylene

¹ Hexane and heptane have already been evaluated by JECFA.

Enzymes

Microbial rennet (*Bacillus cereus*)
Microbial rennet (*Lipex lacteus*)
Ficin
Catalase (*Aspergillus niger* varieties)
Carbohydrase (*Aspergillus oryzae* varieties)
Protease (*Aspergillus oryzae* varieties)
Catalase (*Micrococcus lysodeikticus*)
Microbial glucose oxidase (*Penicillium amagasakiense*)
Microbial carbohydrase (*Arthrobacter*)
Carbohydrase (*Aspergillus awamori*)

REPORT OF THE AD HOC WORKING GROUP ON SPECIFICATIONS FOR FOOD
ADDITIVES²

² See paras 125-129 of this Report.

A. General Comments

1. The Working Group felt that there was room for improvement in many of the specifications for additives of natural origin. Since it is not always possible to chemically identify all the components present in additives of natural origin, recourse has to be made to specifying the method of manufacture. For example, in the case of natural extracts, it was felt that, at the very least, the specifications should include a list of those solvents that may be used in the extraction process. The need for microbiological criteria in the specifications for such additives should also be carefully considered. A constant approach to the establishment of such criteria should be made both for additives of plant and animal origin, where microbial contamination is considered likely, and for additives produced by fermentation.

2. Several specifications describe both a food additive as such, in addition to commercial preparations of the additive containing organic solvents, oils, fats, and other ingredients. However, it is often not specified that these ingredients shall also be "food grade". It is recommended that such a requirement be included in the specifications where these preparations are described.

3. All references to C.I. numbers should be up-dated to the latest edition of the Colour Index.

4. Many of the specifications have been developed at different times and they vary in format. Minor editorial amendments are needed to the specifications to ensure that all the specifications are presented in a standard format.

5. In connection with the use of processing aids, special problems are involved, because these additives are used in a special way, which can cause a concentration of the impurities and/or leaves residues in the food. It is, therefore, recommended that the specifications for processing aids are given a general consideration to find out if these additives shall be specified in the same way as for the other food additives, or if special requirements should be added.

6. In order to protect the health of analysts, many countries now restrict the availability of certain laboratory reagents, especially those such as o-toluidine and benzidine that are known carcinogens. In establishing methods of analysis, JECFA should pay due regard to the safety-in-use of the laboratory reagents specified.

7. JECFA should be encouraged to publish as soon as possible a book containing all general methods and test solutions which are referenced in the individual specifications.

B. Recommendations pertaining to Government Comments on Specifications for Food Additives established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

Specifications Established by the 14th Meeting of JECFA

1. It is recommended that the following specifications be submitted to the Commission for final adoption at Step 5 of the Procedure:

Additive

- 1.1 Cupric sulphate
- 1.2 Ethyl maltol
- 1.3 Stannous chloride

2. It is recommended that the following specifications not be proposed to the Commission for adoption at this time:

Additive

Objections/Comments

- | | |
|--------------------------|--|
| 2.1 Curcumin | (a) The specifications apply only to the pure crystalline material, which is not available commercially.
(b) Corrections needed for structural formula. |
| 2.2 Oleoresin of Paprika | An analytical method should be given for determination of colour content. |
| 2.3 Acetone | (a) JECFA should consider a Pb limit of 1 mg/kg.
(b) Increase residue on evaporation limit to 0.002%, for more reproducible determination. |
| 2.4 1,2-Dichloroethane | ... see 2.3(a)
(b) The o-toluidine reagent used in the test for free chlorine is a carcinogen; change to F.C.C. method. |
| 2.5 Dichloromethane | (a) ... see 2.3(a)
(b) ... see 2.4(b) |
| 2.6 Ethanol | (a) ... see 2.3(a)
(b) The statement in the Definition pertaining to denaturents should be clarified.
(c) Are these specifications adequate to define the purity of synthetic ethanol ?
(d) A numerical limit should be indicated in the purity test for alkalinity.
(e) The suitability of the refractive index as a measure of purity is questioned. |
| 2.7 Methanol | (a) ... see 2.3(a)
(b) ... see 2.6(d)
(c) ... see 2.6(e) |
| 2.8 Propan-2-ol | (a) ... see 2.4(a)
(b) ... see 2.6(e) |

Specifications Established by the 18th Meeting of JECFA

3. It is recommended that the following specifications be referred to the Commission for final adoption at step 5 of the Procedure:

Additive

- 3.1 Glutamates, Ca, NH₄, K
- 3.2 5'-Guanylates, Ca, Na
- 3.3 5'-Inosinates, Ca, Na
- 3.4 5'-Nucleotides, Ca, Na
- 3.5 L(+)-Glutamic acid
- 3.6 Calcium gluconate
- 3.7 Calcium lactate
- 3.8 Dioctyl sodium sulphosuccinate
- 3.9 Ferrous gluconate
- 3.10 Potassium acetate
- 3.11 Potassium lactate (solution)
- 3.12 Sodium acetate
- 3.13 Sodium lactate (solution)

4. The ad hoc Working Group decided not to review the following specifications at this meeting due to lack of information from the 21st meeting of JECFA:

Additive

- 4.1 Caramel colour (NH₃ process)
- 4.2 Calcium saccharin
- 4.3 Saccharin
- 4.4 Sodium saccharin

5. It is recommended that the following specifications not be proposed to the Commission for adoption at this time:

Additive

Objections/Comments

- | | |
|--|---|
| 5.1 Annatto extracts | (a) Corrections needed for definitions of the source, and for the structural formulae.
(b) Methods of assay should state determination of-carotenoid content (not pigment content).
(See General Comment 1) |
| 5.2 Beet Red | |
| 5.3 Beta-apo-8'-carotenal | (a) Chemical names, and structural formulae should be corrected.
(b) Description should indicate that these substances should be protected from exposure to oxygen and light (especially the crystalline forms).
(c) The assay methods should be clarified as to their applicability to the crystalline substance or stabilized commercial forms. |
| 5.4 Beta-apo-8'-carotenoic acid, methyl and ethyl esters | |
| 5.5 Beta carotene | |
| 5.6 Canthaxanthine | |

		(d) Additional revisions pertaining to chemical nomenclature are required in the French version of 54B for Beta-apo-8'-carotenal.
5.7	Erythrosine	The assay method should indicate the basis on which the % dye content is calculated; if erythrosine exists as the anhydride as well as monohydrate, this should be stated in the Definition.
5.8	Indigotine	The purity test for "Isatin sulfonic acid" should be changed to "Intermediates", the limit being kept at 1%.
5.9	Iron oxides, hydrated oxides	The analytical method specified for mercury is obsolete and should be replaced by a modern procedure (e.g. atomic absorption).
5.10	Turmeric	(a) A limit for arsenic should be added. (b) It is also noted that ISO is establishing specifications for turmeric as a spice.
5.11	Gluconodeltalactone	The specific rotation and pH tests are unreliable.
5.12	Monoglyceride citrate	The structural formula and the Definition should be clarified.

Specifications Established by the 15th Meeting of JECFA

6. It is recommended that the following specifications be referred to the Commission for final adoption at Step 5 of the Procedure:

Additive

- 6.1 Hexamethylenetetramine
- 6.2 The ad hoc Working Group did not review the specifications for caramel colour due to the lack of information from the 21st Meeting of JECFA.

7. It is recommended that the following specifications not be proposed to the Commission for adoption at this time:

Additive

Objections/Comments

- | | | |
|-----|---------------------------|---|
| 7.1 | All enzymes | (a) Microbiological criteria should be reviewed.
(b) The limit for aflatoxins should be reviewed.
(c) The nomenclature for the enzymes should refer to the IUB numbers. |
| 7.2 | Sodium Stearoyl lactylate | (a) The specifications for acid value, ester value, sodium content, and lactic acid content should be revised to describe current commercial products. |

(b) The chemical name should be corrected.

7.3 Calcium Stearoyl lactylate ... see 7.2(a)

SPECIFICATIONS OF IDENTITY AND PURITY OF FOOD ADDITIVES

(submitted to the Commission at Step 5 of the Codex
Procedure for the Elaboration of Specifications)¹

¹ See paras 125-129 of this Report.

	<u>Reference</u> ²
<u>Flavour Enhancers</u>	
L(+)-Glutamic acid	(3)
L(+)-Glutamate, ammonium	(3)
L(+)-Glutamate, calcium	(3)
L(+)-Glutamate, potassium	(3)
5'-Guanylate, calcium	(3)
5'-Guanylate, sodium	(3)
5'-Inosinate, calcium	(3)
5'-Inosinate, sodium	(3)
5'-Nucleotide, calcium	(3)
5'-Nucleotide, sodium	(3)
<u>Salts of Organic Acids</u>	
Calcium gluconate	(3)
Calcium lactate	(3)
Ferrous gluconate	(3)
Potassium acetate	(3)
Potassium lactate (solution)	(3)
Sodium acetate	(3)
Sodium lactate (solution)	(3)
<u>Salts of Inorganic Acids</u>	
Cupric sulphate	(1)
Stannous chloride	(1)
<u>Preservatives</u>	
Hexamethylenetetramine	(2)
<u>Artificial Flavouring Substances</u>	
Ethyl maltol	(1)
<u>Surface Active Agent</u>	
Diocetyl sodium sulphosuccinate	(3)

² Available from the FAO and WHO Distribution and Sales Services and distributed to Codex Contact Points.

Reference

- (1) Specifications for the Identity and Purity of Some Extraction Solvents and certain other Substances, FAO Nutrition Meetings Rep. Ser. No. 486 (or WHO/ Food Add./70.40).
- (2) Specifications for the Identity and Purity of some Enzymes and certain other Substances, FAO Nutrition Meetings Rep. ser. No. 50B (or WHO Food Additives Series, 1972, No. 2).
- (3) Specifications for the Identity and Purity of some Food Additives, FAO Nutrition Meetings Rep. Ser. No. 548 (or WHO/Food Add./7).