**codex alimentarius commission**

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME: Tel. 5797 Cables Foodagri

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX ALIMENTARIUS COMMISSION
Thirteenth Session, December 1979

# REPORT OF THE TWELFTH SESSION OF THE CODEX COMMITTEE ON FOOD ADDITIVES

The Hague
10-16 October 1978

TABLE OF CONTENTS



APPENDICES

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## INTRODUCTION

1. The Codex Committee on Food Additives held its 12th session in The Hague, The Netherlands, from 10 to 16 October 1978, by courtesy of the government of The Netherlands. Dr. G.F. Wilmink (Netherlands) acted as Chairman. The session was attended by 137 participants, including government delegations from 29 countries, observers from 22 international organizations and the secretariat (see Appendix 1 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 informed the participants that, at its last session, when revieving its activities, the Commission had agreed that the work of the Committee was essential to the progress of the Food Standards Programme. He also pointed out how the Committee responded, to the need to protect consumers against possible health hazards in food.

## APPOINTMENT OF RAPPORTEURS

3. Mr. M. Fondu (Belgium), Mr. T. Avigdor (Switzerland) and Dr. A.V. Randell (Australia) were appointed as rapporteurs.

## ADOPTION OF THE AGENDA

4. The Committee adopted the provisional agenda (CX/FA 78/1) from which had been deleted item 4(c) "Report of the 22nd session of JECFA" (since the report had not yet been published) and item 7(d) "Up-dating of the Codex Advisory List of Food Additives for Use in Soft Drinks".

## APPOINTMENT OF WORKING GROUPS

5. In order to facilitate dealing With the agenda the existing ad hoc Working Groups were retained. Participation was the same as during the 11th session except that the chairman of the ad hoc Working Group on the Labelling of Food Additives was Mr. H.M. Goodall (U.K) and that the Federal Republic of Germany also participated in the ad hoc Working Group on Priority Lists for Food Additives.

## MATTERS OF INTEREST TO THE CODEX COMMITTEE ON FOOD ADDITIVES

6. The Committee had before it document CX/FA 78/4 which was presented by the Secretariat. It was agreed that the majority of the matters would be dealt with under the relevant agenda items, but the Committee noted the following points which had been considered by the Commission at its 12th session.

### Endorsement of Food Additive Specifications

7. The Committee and the Executive Committee had proposed changes in the procedure for the endorsement of food additive specifications (see ALINORM 78/3, paras 26-32). It was noted that the Commission had agreed to the Committee's

proposals which suggested that the Committee, when examining such specifications should forward those which it considered acceptable directly to the Codex Alimentarius Commission. Those, which, in the opinion of the Committee, required amendment, would be re-submitted to the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and subsequently returned for further consideration by the Committee.

Hydrolyzed Proteins

8. The Committee was informed that the Commission had noted the Committee's opinion that hydrolyzed proteins would be either considered as food ingredients or food additives according to their function in the final product. The Commission had agreed with the conclusions of the Committee that the use of hydrolyzed proteins from whatever source required detailed attention and had recommended that the matter would be best discussed by the Codex Committee on Soups and Broths.

Reports and Monographs from JECFA

9. The Representative of WHO explained that agreement had been reached between FAO and WHO for the publication of documents and that matters related to the distribution of the above documents were presently under discussion. It had been agreed that JECFA reports would be published and distributed only by WHO. The summary of toxicological data would also be produced and distributed only by WHO as a WHO Food Additive Series mimeographed document. Publications containing the specifications for identity and purity would be published and distributed only by FAO as a FAO Food and Nutrition Paper. Reports and monographs resulting from the Joint Meeting on Pesticide Residues would be published and distributed only by FAO. The Committee was assured that all documents, including the toxicological summaries, would be distributed to Codex Contact Points.

21st and 22nd Sessions of JECFA

10. The Committee noted that, at its 21st session, the JECFA had made an evaluation of some acids and salts, antioxidants, food colours, sweeteners, thickening agents and a miscellaneous group of additives. In addition, important aspects of the general principles for the evaluation of both natural and synthetic food colours had been reported.

11. At its 22nd session, the JECFA had discussed such general topics as criteria for microbiological provisions to be included in specifications for food additives, general considerations of enzymes used in food processing, principles for setting priorities for testing and evaluation of intentional and Unintentional food additives, the problem of such contaminants in food, requirements for toxicological testing and the impact of new scientific methods on the safety evaluation of chemical substances. The following additives had been evaluated: aluminium potassium sulphate, aluminium sodium sulphate, aluminium sulphate, amaranth, azorubine, beet red. Brilliant Black PN, chlorophyllin copper complex and its sodium and potassium salts, dioctyl sodium sulphosuccinate, iron oxides and hydrated iron oxide, maltoi, nitrous oxide, Ponceau 4R, Quinoline Yellow, sodium thiosulphate, sorbitol, stannous chloride, turmeric/curcumin and xylitol. The following food contaminants had also been examined: asbestos, lead, mercury (total), methyl-mercury and organic and inorganic tin salts.

12. The Committee also noted that, in considering specifications for enzymes at its 22nd session, the JECFA had requested manufacturers to supply details of their microbiological testing programmes so that soundly based microbiological criteria could be submitted for examination by the Codex Committee on Food Hygiene.

Principle relating to the Carry-over of Additives into Foods

13. The Committee noted that the last session of the Codex Committee on Foods for Special Dietary Uses had concluded that the Carry-over Principle did not apply to the Standard for Infant Formula, but that it did apply to the standards for canned baby food and cereal-based foods for children. The Codex Committee on Foods for Special Dietary Uses had also noted that there appeared to be no guidance as to how to express the provision for the Carry-over Principle in Codex standards. The Commission, at its 12th session, agreed that this was a problem of a general nature which would also affect other Codex standards. It requested the advice of the Codex Committee on Food Additives as to how to incorporate into Codex standards provisions concerning food additives present in food in accordance with sections 3 or 4 of the Carry-over Principle. The Committee also noted that the Codex Committee on Food Labelling had concluded that any additive present in the final product in accordance with the circumstances described in paragraph 4 of the Carry-over Principle must be declared on the label.

14. The Committee set up an ad hoc Drafting Group to look into the above questions. The Drafting Group consisted of delegates from Australia, France, The Netherlands, USA and representatives from the EEC and FAO. The Committee considered a report by the Drafting Group and the following paragraphs indicate the conclusions of the Committee.

15. The Committee noted that section 2 of the Carry-over Principle (ALINORM 76/12, App. IV) stated that the Principle applied to all Codex standards unless otherwise specified in individual Codex standards. This raised a question not, only of the status of the Carry-Over Principle, but also a question of how the Principle should be implemented in Codex standards.

16. One possible legal interpretation of Section 2 was that the Carry-over Principle was meant to be adopted by governments as a general provision governing the presence of additives in foods resulting from their presence in ingredients or raw materials (i.e. if "Codex Standards" in Section 2 were to be interpreted as commodity standards in national legislation). Another possible interpretation was that the Carry-over Principle was intended only as an advisory approach to regulating carried over additives.

17. The Committee recommended that, as a practical approach and in view of the decision of the 11th session of the Commission (ALINORM 76/44, para 121), the Carry-Over Principle should be regarded as being applicable only to Codex standards and should be examined on a standard by standard basis. This involved the publication of the Carry-over Principle in such Codex publications as the Procedural Manual of the Codex Alimentarius commission and/or the Codex List of Food Additives and the insertion of a statement in the food additives sections of individual Codex standards concerning the applicability or otherwise of the Carry-over Principle. However, the Committee noted that this approach would also mean that, at the national level, governments would decide whether or not to apply the Carry-over Principle to foods not covered by Codex standards.

18. The Committee was of the opinion that, for practical reasons, and in view of section 2 of the Carry-over Principle, it would be more appropriate to state in Codex standards that the Carry-over Principle either applied or that it did not apply, as appropriate. As stated in Section 5 of the Principle, this decision rested with Codex commodity committees in conjunction with the Codex Committee *on* Food Additives. It was recognized that it would be necessary to reconsider Codex standards so far issued

to governments for acceptance in respect of the Carry-over Principle. The secretariat was requested to look into this matter.

19. As regards the exact wording to be used in applying the Carry-over Principle, the Commission suggested the following:

(a) "Section 3 of the "Principle relating to the Carry-over of Additives into Foods" (ALINORM 76/12, App, III) shall apply" or

(b) "No food additives shall be present as a result of carry-over from raw materials or other ingredients".

20. As regards food additives present in the food in accordance with section 4 of-the Carry-Over Principle, the Committee agreed that these should be actually listed in the food additives section of individual Codex standards and be subject to maximum levels as appropriate. Therefore, the attraction of section 4 of the Carry-over Principle by reference served no useful purpose.

21. The Committee also discussed the conclusion of the Codex Committee on Food Labelling that food additives carried over into food in accordance with section 4 of the Carry-Over principle should be declared on the label. The Committee agreed with this conclusion and also recommended that additives not present in significant amounts nor in an amount sufficient to perform a technological function (i.e. in accordance with section 3) need not be declared on the label.

22. In respect of the declaration of carried over additives on the label as discussed in para 21 above, the Committee was of the opinion that this matter could be dealt with by including an appropriate paragraph in the Carry-Over Principle.

23. The Committee agreed that the questions outlined in the preceding paragraphs in connection with the Carry-over Principle should be brought to the attention of the / Codex Alimentarius Commission and possibly also to the attention of the Codex Committee on General Principles.

24. It was pointed out that additives were occasionally present in food both as a result of carry-over from ingredients or raw materials and as a result of intentional and permitted uses. The Committee agreed that such additives should only be listed once, i.e. as permitted food additives. It was noted that maximum levels expressed on the whole product basis would include the amount of any additives carried over into the food. The question was raised as to whether additives carried over in accordance with section 4 of the Principle should be indicated in the standard as having been carried over from ingredients or raw materials. The purpose of such indication would serve to make it clear that the direct use of such additives was not permitted in the preparation of the product concerned. After some discussion, the Committee concluded that it did not seem to be necessary to draw a distinction in the section of food additives between substances intentionally used in the preparation of the food and substances carried over in accordance with section 4.

25. The delegations of New Zealand and France pointed out that, unless Codex commodity committees were in full knowledge of the various food additives and the amounts of such additives present in the ingredients or raw materials which would result in a functional level in the food, they would not be in a position to judge whether or not the additives carried over were present in accordance with section 3 or section 4. The Committee noted that modern food manufacturing methods involved thorough quality control of ingredients and raw materials used and that commodity committees were in a

position to judge whether or not an additive would be functional at a given level. Therefore, there was every reason to believe that commodity committees would be aware, at the time of preparing the standards, of any food additives which would have to be listed in accordance with section 4 of the Carry-over Principle.

26. It was pointed out to the Committee that the additives contained in raw materials and ingredients were not always the same and that industry would find it difficult to comply in practice with the mandatory declaration of additives carried over in conformity with section 4. This requirement would necessitate the preparation of a variety of labels. In this respect it was noted that the number of additives carried over in conformity with section 4 would not be expected to be large.

27. Concerning the criteria for accepting the presence of additives in accordance with sections 3 and 4 of the Carry-over Principle, the delegation of the Federal Republic of Germany drew attention to their remarks contained in para 124 of ALINORM 78/12 on processing aids. In the opinion of the delegation, the same criteria applied to food additives, which were carried over, and to processing aids, i.e. that carried over substances should not only be non-functional but also harmless and free from flavour or taste. The delegation of the Federal Republic of Germany also pointed out that, in accordance with the Carry-over Principle, the presence of substances which had not been evaluated by the JECFA would be permitted. The chairman of the Committee pointed out that, as regards the question of the safety of carried over additives, general requirements in food laws that food shall be wholesome and of an acceptable quality would be a safeguard as regards the health of the consumer.

Activities of the Council of Europe

28. The Representative of the Council of Europe informed the Committee on recent work undertaken by the Council. The objectives which the Committee of Public Health (Partial Agreement) had laid down for its activities on food standards concerned a study directed towards the modernization of national food legislation, especially with regard to the protection of public health, without taking into account economic or other factors if these factors were contradictory to the protection of health. This point of view had already been accepted by the industries concerned.

29. Recent activities of the Committee of Public Health in the field of food additives emphasized the criteria of selection which had been adopted in order to determine categories of substances with a view to elaborating standards for foods.

30. Parallel to the establishment of new methods of production and distribution, food additives had increased and diversified to such a point that the question of their possible toxicity had become one of the principle problems in the field of food safety.

31. More specifically, the work of the Committee of Public Health in the field of additives had concentrated on natural and artificial flavours. Studies undertaken by an ad hoc Working Group of the Committee of Experts for the Health Control of Foods had resulted in the publication which is known under the title "Natural flavours, their sources, and artificial flavouring substances" - the "Blue Book". as indicated at the 11th session of this committee, the Council of Europe hoped to be in a position to present the third edition of this publication in 1979 under the title "Flavouring substances and sources of natural flavouring substances".

32. The Committee was also informed that a publication would soon be issued on substances used in plastic materials intended to come into contact with foods. The study had been carried out by the Expert Committee on the Health Control of Foods, the aim

of which was to establish a list of substances harmless to public health for use in plastic materials which come into contact with foods, but with the exception of adhesive materials, lacquers, varnishes, rubber and cellulose films. This list will be revised on a yearly basis in the light of toxicological and technological development.

33. In addition, the competent bodies of the Partial Agreement of the council of Europe have elaborated two resolutions concerning the use of antibiotics in animal husbandry. The first, already adopted by the Committee of Ministers under reference AP (77) 2, is entitled "Antibiotics which can be used in animal feeds to stimulate growth and antibiotics which may only be used *for* therapeutic purposes". A second resolution at present under examination by the Committee of Ministers deals with the use of antibiotics and other antimicrobial agents in animal husbandry.

34. In conclusion, the observer of the Council of Europe referred to another resolution prepared in this area which concerned the health control of all persons who, in exercising their profession, come into direct contact with foodstuffs during the production, preparation, packaging or distribution stages, including producers of raw milk for direct consumption, but excluding other agricultural workers. This resolution, which will be examined by the Committee of Ministers in the near future, lays down priorities for health control, examines the precautions to be taken to assure the protection of the public against risk of food borne infections, identifies dangerous microorganisms and gives precise instructions in the field of food control, medical examination and education in food hygiene.

REPORT OF THE AD HOC WORKING GROUP ON FOOD ADDITIVE INTAKE

35. The Committee had before it the report of the ad hoc Working Group on Food Additive Intake. This report was based on a discussion of documents CX/FA 78/5 -Parts I and II which had been discussed by the ad hoc Working Group during its meeting held on October 9, 1978 in The Hague. In introducing the report of this meeting (CX/FA 78/LIM.l) the Chairman of the Working Group (Mr. M. Fondu, Belgium) reviewed the information given in the earlier documents. He mentioned that additional information had been provided during the meeting by the delegations of Brazil, Canada, Ireland and Switzerland. This additional information underlined the point that food "additive intake depended on food habits, national food laws, etc. Brazil had stated that it would be difficult to apply general values to situations in developing countries. He stressed that, in his country, estimation of the intake of food contaminants and pesticides should be given more attention than estimation of the intake of food additives, as most food was grown locally and there was little importation *o£* processed foods, on the other hand, some developing countries imported food and the estimation of the intake of additives might be more important in. those countries. The delegation of Canada had reported that, in a study of one food colour, the potential daily intake (PDI) did *not* exceed the ADI for the additive studied. In the younger age groups, however, the PDI did exceed the ADI. This delegation, therefore, suggested that one should pay special attention to these groups. The delegation of Ireland had reported that, in their country, a study had been carried out on food additive intake based on annual production and sales and on information from the industry on the levels used. Switzerland had reported on a theoretical study on the intake of benzoic acid. The intake of this additive calculated in this way corresponded well with the range obtained in other studies. The USA had reported that a study of theoretical food additive intake was under way in that country and results should be available at the next meeting.

36. In reviewing the work of the ad hoc Working Group, its chairman reported that the Working Group had discussed in particular the intake of benzoic acid, sulphur dioxide and phosphoric acid. He indicated that on certain occasions such as in cases of authorization of high levels of additives in soft drinks, in particular in younger age groups, the daily intake of benzoic acid was considered to be too high. A comparable situation existed with respect to the intake of sulphur dioxide in wine. Regarding the intake of phosphorus-containing additives, no conclusions could be drawn because no information on the phosphorus content of foodstuffs was available and since the total amount of phosphorus which could be accepted in food depended on total Ca intake.

37. The Chairman of the ad hoc Working Group proposed that the work should be continued for the additives already in examination. He also proposed that, in the case of colours, and as a first approach to the problem, only those colours having an ADI lower than 2 mg/kg body-weight should be included in the intake studies. Furthermore, he suggested that, for the purpose of the study on food additive intake carried out by the Committee, 60 kg should be used as an average human body-weight; this weight would be used to calculate the daily intake of the various additives for comparison with the acceptable daily intake. The representative of the Federal Republic of Germany pointed out that calculations on food additive intake were valid only when the intake of the additive from all sources had been taken into account.

38. Recalling the terms of reference of the ad hoc Working Group, the chairman of the Working Group stressed the fact that the working Group's task was to assemble data on the average ingestion of food in order to determine the probable intake of additives authorized or proposed by commodity committees.

39. The Chairman of the Committee drew attention to the responsibility of commodity committees to state the technological need for the various food additives and to provide this Committee with an estimate of the proportion which each food formed of the total average diet. In this way the Committee would be better able to judge the acceptability of each proposed use of food additives. The Chairman also reminded the Committee of the fact that the ADI was established on the basis of a lifetime consumption of food additives, and that estimates of the PDI were usually made on the population as a whole. Therefore, it was possible for the ratio of PDl/ADI to approach unity for the general population, thus indicating no problems. However, an examination of special groups with individually different food habits might reveal a different situation. Special studies of these groups may be necessary and he drew attention to the proposals made in document CX/FA 75/5-1, p. 27, on estimates of food additive intake. The chairman noted that the 21st meeting of the JECFA had paid special attention to the problems of the exposure of infants and children to contaminants and additives in food.

40. Dr. Kouthon (FAO) informed the Committee that a paper was in preparation in cooperation with UNEP on the intake of contaminants present in food. In presenting Part II of document C*X/FA* 78/5, the chairman of the ad hoc Working Group proposed that, for the purposes of the Committee and as a first approximation, an intake of 600 ml should be accepted as representing the average intake of soft drinks by those who consume these products. This proposal was accepted by the Committee.

41. The Committee agreed that the work of the ad hoc Working Group should be continued. The delegations of Denmark, Finland and Japan indicated that they wished to be included in the ad hoc Working Group. The chairman agreed that the Working Group should pay attention to the intake of food colours and the preparation of guidelines for methods of determination of intake of food additives. Mr. F. Fondu agreed to continue as

chairman of the Working Group. The Committee requested Mr. Fondu to prepare a study on the PDI of the additives authorized in the soft drinks for the next session, based on the Canadian document presented at the 10th session of the Committee and using a daily intake of 600 ml soft drinks per day.

42. The following countries form part of the new ad hoc Working Group, on Food Additive Intake, established at the session: Belgium (Chairman), Canada, Denmark, Finland, France, Germany, Fed. Rep. of, Ireland, Israel, Italy, Japan, the Netherlands, Spain, United Kingdom and the United States of America.

ENDORSEMENT OF FOOD ADDITIVES PROVISIONS IN CODEX STANDARDS

43. The Committee had before it document CX/FA 78/lO-Part I containing provisions in Codex standards requiring endorsement by the Committee. The secretariat pointed out that it had attempted to comply with the new arrangements for the endorsement of food additive provisions adopted at the last session of the Committee and also adopted by the Commission. The working paper, therefore, contained only those food additives the use of which had been technologically fully justified by the Commodity committees concerned. The paper also contained information concerning the toxicological evaluation of the various additives by the JECFA. The Committee noted that the new procedure for the endorsement of food additive provisions had been referred to the Codex Committee on General Principles by the Commission.

44. The Committee had detailed discussions on various additives included in the Codex standards before it. A summary of the conclusions of the Committee and other observations made by delegations is given in the succeeding paragraphs. The decisions of the Committee concerning the endorsement, temporary endorsement or postponement of the endorsement of food additive provisions is indicated in Part I of Appendix II to this report.

General Remark

45. The delegation of the Federal Republic of Germany drew attention to paras 47 and 48 of ALINORM 78/12 in which it had expressed concern about the endorsement procedure. Although the efforts made in order to improve the procedure of endorsement were appreciated, the delegation reiterated its remarks made at the previous meeting and reserved its position generally concerning the endorsement of additives.

A. Bouillons and Consommés (Appendices II and III of ALINORM 78/9) [1/]

[1/] See also para 75.

Acids, Bases and Salts

46. The Committee agreed with the conclusion of the Commission (12th session) that the maximum level for phosphates should be related to total rather than added phosphates, in the ready-to-eat product.

Ascorbate, calcium

47. The Committee noted that the calcium salt of ascorbic acid had not been included in the evaluation of ascorbic acid and its sodium and potassium salts by the JECFA and no specifications had been drawn up by the Expert Committee for the calcium salt of ascorbic acid. The Committee was informed that appropriate specifications of identity and purity for this salt of ascorbic acid was included in the publication "Food chemicals Codex" and that the EEC had also drawn up specifications

for this substance. The Committee endorsed the use of calcium ascorbate but referred it to the Expert Committee for consideration.

Caramel Colour (made by the ammonia process)

48. Noting that the ADI for this colour had been withdrawn by the JECFA but that caramel colour made by the ammonium sulphite process had been temporarily cleared by the Expert Committee, the Committee decided to substitute this latter caramel colour for the one included in the standard.

Chlorophyll

49. The Committee noted that the specifications for natural chlorophyll had been withdrawn by the JECFA in view of uncertainties concerning the availability and identity of this food colour. However, it noted that chlorophyll copper complex had an ADI as well as specifications for identity and purity. As it was not clear which chlorophyll colour had been intended by the commodity committee, and as chlorophyll copper complex would require the establishment of a maximum level in the standard, the Committee was not in a position to either endorse the provision for chlorophyll or endorse a provision for chlorophyll copper complex.

50. Noting that the commodity committee had adjourned sine die, the Committee requested the secretariat of the Codex Committee on Soups and broths and the Codex secretariat to make arrangements for the clarification of this matter and for the proposal of a maximum level for the appropriate chlorophyll colour to be used. It was agreed to consider this question at the next session.

51. It was noted that the next session of the Codex Alimentarius Commission or the Executive Committee could be requested to decide on the inclusion of an appropriate chlorophyll colour and maximum level for that colour on the basis of the arrangements described in para 75.

Furcellaran

52. It was noted that furcellaran was a specific type of carrageenan and that both had been included in one and the same specification by the JECFA. The Committee decided to combine these two stabilizers as "carrageenan (including furcellaran)".

Pectins

53. The Committee noted that, when referring to these stabilizers in the plural in Codex standards, both the natural pectin and the amidated pectin were meant. As no maximum level had been proposed by the commodity committee for "Pectins", the Committee decided that the provision should be amended in such a way that only the natural pectin would be provided for in the standard. It was agreed that the endorsement of the use of amidated pectin could be considered at the next session in the light of a proposed maximum level for that substance. The Committee agreed that the same procedure should be followed as in the case of chlorophyll (see para 75).

Xanthan gum

54. The Committee noted that xanthan gum was not a "vegetable" gum and decided to make appropriate editorial amendments to the section on Vegetable Gums to take this into consideration.

Flavours

55. In discussing the endorsement of the use of the various types of flavours, the Committee noted that there was a lack of consistency in the way reference was made in Codex standards to the use of "natural", "nature-identical" and "artificial" flavours. The Committee recognized that, when providing for natural flavours and natural flavouring substances as well as nature-identical flavouring substances in Codex standards, it did so only in general terms and that it was necessary to refer to the Codex definitions for these substances. This was a practical approach in view of the fact that the Codex had not yet elaborated workable lists of permissible natural and nature-identical flavours. It was hoped that such lists would eventually be developed on the basis of the work of the Council of Europe and of the JECFA. In the meantime, decisions concerning the safety of natural and nature-identical flavours rested with governments.

56. As regards "artificial" flavouring substances, the Committee reiterated its , previous position that it could endorse only those substances which were included in Codex List A and which have been evaluated toxicologically by the JECFA. The Committee adopted a standard phraseology to cover all the various flavouring substances as shown in Appendix II to this report.

Cysteine

57. The Committee was aware that this amino-acid had not been considered by the JECFA as a food additive. In the absence of an opinion of the JECFA concerning the safety of this free amino-acid when used as an additive and in the absence of specifications of identity and purity, the Committee decided to postpone endorsement and to refer the matter to the JECFA for consideration.

Glutamate, magnesium

58. The Committee decided to postpone endorsement of this salt of glutamic acid pending evaluation by the JECFA and the establishment of specifications. The JECFA was requested to consider the inclusion of magnesium glutamate in the evaluation of glutamic acid and its salts. The delegation of Finland was of the opinion that the maximum level of 10 g/kg was too high and that it should be reduced to 2 g/kg. It was also of the opinion that the use of glutamates could mislead the consumer concerning the true nature of the product and considered that the use of appropriate food ingredients was preferable to the use of flavour enhancers.

59. The Committee noted that the ADI for glutamic acid and its salts did not apply to infants under 12 weeks of age. A proposal was made to include an appropriate footnote in the standard to draw attention to the need to exercise caution in feeding very young infants with products containing glutamates. The Committee considered that the question of the consumption of foods containing additives by very young infants represented a general problem since it was the policy of the Committee that very young infants should not consume food additives other than those found technologically indispensable and safe. It was further considered that the inclusion of a footnote was not an effective way of ensuring that foods containing glutamates or other additives would not be consumed by very young infants. Rather it was considered that it was through appropriate labelling that this could be achieved. The Committee decided not to insert a footnote in the standard as proposed.

Carry-over

60. In view of the conclusions reached concerning the Carry-over Principle (see paragraphs 13-27), the Committee endorsed the Carry-over Principle as applicable to the products covered by the standard. It was agreed that the new phraseology adopted by the Committee (see para 19) should be substituted in the section dealing with Carry-over. As regards the maximum level of 20 mg/litre sulphur dioxide, it was pointed out that this maximum level referred to the reedy-to-eat product rather than the ready-to-use product as stated in the standard. The Committee decided to make this editorial change.

B. Edible ices and Ice Mixes (Appendix II, ALINORM 78/11)

61. The Committee, at its last session, had concluded that the individual food additives included in the Standard for Edible Ices and ice Mixes required technological justification. It was noted that the additives included in that standard had been considered by a working group on the basis of government comments. The resulting revised list of food additives included in document CX/FA 78/lO-Part I represented those substances the use of which was considered technologically justified. It was also noted that the list of food additives included in the original draft standard had been significantly reduced. The Committee discussed the various additives in detail and the following paragraphs represent the conclusions of the Committee and remarks made by delegations:

Chlorophyll

62. For reasons stated in paragraphs 49 and 50 the Committee decided to postpone endorsement of this food colour.

General consideration of colours

63. Several delegations were of the opinion that the overall limit of 100 mg/kg singly or 300 mg/kg in combination proposed by the commodity committee would lead to difficulties concerning the intake which could result from the use of some of the colours. This was particularly so in the case of colours with an ADI less than 1 mg/kg body-weight, it was noted that the standard covered a variety of products and that the various colours had different tinctorial powers. Given these circumstances the commodity committee had been faced with the alternatives of laying down an overall maximum level covering all colours in the standard or laying down differing individual maximum levels for the various colours taking into consideration more closely the actual levels used (see also para 68).

64. Noting that edible ices and ice mixes were consumed by young children and considering that the consumption of these foods was subject to seasonal variation resulting in high consumption during certain parts of the year, the Committee decided to postpone the endorsement of those colours included in the standard which had an ADI lower than 1 mg/kg body-weight. It was also decided that the question of the intake of these colours should be referred to the Working Group on food Additive Intake.

65. The Committee also noted that animal experiments designed to establish safety of food additives involved the consumption of standard daily amounts of food containing the additive, whereas, in the case of certain additives, a modulated intake by humans was observed. The Committee decided to refer this matter to the JECFA in order to see whether this question should be taken into consideration in the design of animal testing.

Caramel (made by the ammonia process)

66. For reasons stated in paragraph 48 the Committee decided to substitute caramel (made by the ammonium sulphite process) for the caramel colour included in the standard.

Alpha-carotene and Gamma-carotene

67. Doubt was expressed concerning the commercial availability of alpha- and gamma-carotenes. Furthermore, it was noted that these colours had not been evaluated by the JECFA. The Committee, therefore, decided to postpone endorsement of these colours.

Emulsifiers, stabilizers and thickening agents

68. The delegations of the U.K. and the U.S.A. pointed out that the relationship between the maximum level proposed by the commodity committee for these additives and the ADI established for some of the additives included in the standard under this section bore a similarity to that noted in connection with certain of the food colours (see para 63). These delegations were of the opinion that a mathematical approach such as adopted in the case of food colours was not consistent with the endorsement of the various emulsifiers, stabilizers and thickening agents included in the standard and further questioned whether the approach adopted in the endorsement of food colours was justified.

Modified starches

69. The Committee agreed that the modified starches (both chemically and physically modified) should be listed individually in the standard.

Flavours

70. The Committee decided to proceed in the same manner as indicated in paragraph 55.

L-ascorbic acid

71. The Committee noted that L-ascorbic acid, which was usually used as an antioxidant, had been included under acids, bases and salts in the standard. As no maximum level had been proposed for this additive (which had an ADI) the Committee decided to postpone endorsement.

L-lactic and L-malic acids

72. The Committee noted that these two acids were components of foods and that their presence in a diet of very young infants had not been restricted by the JECFA. The Committee also noted that the JECFA had only evaluated di-lactic and di-malic acids and that specifications did not appear to be available and had not been established by the JECFA for the l-isomers. For these reasons the Committee decided to postpone the endorsement of l-lactic and l-malic acids pending consideration by the JECFA.

L(+)tartaric acid and its salts

73. The Committee postponed endorsement of these substances in view of the fact that no maximum level had been proposed by the commodity committee for additives which had been assigned an ADI by the JECFA.

Saccharin and its salts

74. The delegation of Iran was against the use of saccharin in edible ices and ice mixes. It was also questioned whether edible ices and ice mixes prepared with artificial sweeteners should not be considered special dietary products. In view of the fact that no maximum level had been established for saccharin and its salts the Committee decided to postpone their endorsement.

Procedure to be adopted in dealing with postponed endorsements

75. Noting that the Codex Committee on Edible Ices and the Codex Committee on Soups and Broths had adjourned sine die, the Committee agreed that the following procedure should be adopted to deal with the additives the endorsement of which was postponed. The Secretariat was requested to issue a circular letter requesting governments to provide information to the Secretariats of the Codex committee on Edible Ices and the Codex Committee on Soups and Broths on the food additives the endorsement of which was postponed during this session, on the basis of information received the Secretariats of the Codex Committee on Edible Ices and the Codex Committee on Soups and Broths, in cooperation with the Codex secretariat, would make arrangements for the establishment of maximum levels and the clarification of questions indicated by the Committee.

76. It was agreed that, at the next session of the Committee, the question of the postponed endorsements would be reconsidered and the Commission would then be requested to decide whether the approach adopted by the Committee would be acceptable.

C. Revised General Standard for Edible Fats and Oils (Appendix II, ALINORM 78/17)

77. The Committee endorsed the three additional antioxidants proposed by the commodity committee. As regards ascorbyl stéarate, the committee noted that this ester of ascorbic acid was not widely used.

D. Reduced Fat Margarine (Appendix III, ALINORM 78/17)

Bixin. Norbixin and Annatto Extracts

78. In discussing the endorsement of these colours, the Committee noted that bixin and norbixin were active principles of annatto extracts, but that they had not been evaluated by the JECIA, nor did they appear on Codex List B. This either indicated that bixin and norbixin were of little or no interest for use in food, or that the substances were commercially not available. The Committee decided to endorse only annatto extracts and to delete bixin and norbixin from the list of colours.

Tragacanth gum

79. Nothing that this thickening agent had not been toxicologically evaluated by the JECFA, the Committee postponed endorsement of this vegetable gum. In this respect the committee agreed that governments and interested international organizations should make all efforts to ensure that the JECFA will receive appropriate information on the basis of which substances such as tragacanth which have been in use as food additives for many years, can be evaluated.

Ethylene diamine tetra-acetic acid (EDTA)

80 The delegation of New Zealand objected to the use of EDTA as an antioxidant synergist, indicating that the other antioxidants provided for in the standard were sufficient. The Committee decided to endorse the use of this additive.

E. Edible Low Erucic Acid Rapeseed Oil (Appendix IV, ALINORM 78/17)

81. The Committee endorsed, without comments, the additional food additives proposed by the commodity committee.

F. Canned Mackerel and Jack Mackerel (Appendix III, ALINORM 78/18A)

82. The Committee endorsed the additional food additives proposed by the commodity committee without amendment, but noted that the Codex Committee on Fish and Fishery Products would draw up a list of specified modified starches for use in the packing media of the products.

G. Canned Sardines and Sardine-type Products (Appendix IV, ALINORM 78/18A)

83. For reasons given in paragraph 53, the Committee agreed to amend the provision for pectin's in such a way as to indicate that both the natural pectin and the amidated pectin would be provided for in the standard.

H. General Standard for Cheese (Appendix II, CX 5/70-19th session)

84. The Committee endorsed the general provisions of Sections 3.1 and 3.2 of the above general standard and noted that the food additive section had been amended in the new revised standard.

85. In view of the fact that the report of the 19th session of the Joint FAO/WHO Committee of Government Experts on the Code of Principles concerning Milk and Milk Products had not yet been published and was not available to the Committee, it was decided to postpone consideration of the food additive provisions included in standards A-8(a), A-8(b) and A-8(c) until the next session.

ENDORSEMENT OF PROVISIONS FOR CONTAMINANTS IN CODEX STANDARDS

86. The Committee had before it CX/FA 78/lO-Part II containing provisions for contaminants in Codex standards requiring endorsement by the Committee. The decisions of the Committee are tabulated in Part II of Appendix II to this report.

87. During the discussion related to maximum levels for contaminants in foods submitted for endorsement to the Committee, the WHO representative brought to the attention of the Committee the opinion expressed in the 22nd report of the JECFA with regard to irreducible levels of contaminants in foodstuffs. The Expert Committee had defined an "irreducible level" as that concentration of a substance which could not be eliminated from a food without involving the discarding of that food altogether, thus severely compromising the ultimate availability of major food supplies.

A. Bouillons and Consommés

88. The representative of the European Secretariat of Manufacturers of Light Metal Packages (SEFEL) informed the Committee that the food industry could meet the maximum levels for contaminants included in the standard for bouillons and consommés, although he pointed out that levels of contaminants found in foods depended on storage conditions, storage time and other factors. It might have been better if a system of setting maximum levels on a product by product basis had been

followed, in view of the fact that the standard for bouillons and consommés covered a vide variety of products. The representative of SEFEL also drew the Committee's attention to paragraphs 22-25 of ALINORM 78/9 in which the question of sampling plans in relation to the determination of maximum levels of contaminants in food was discussed.

89. The delegation of the U.K. was of the opinion that, given the particular distribution curve, which the results of analysis of a large number of samples of food followed (i.e. the "long tail" situation), the Codex should develop appropriate sampling procedures for the determination of contaminants in food. The Secretariat further pointed out that the Codex should concern itself with the definition of the meaning of maximum levels of contaminants in food with respect to large consignments moving in international trade. It was this lack of definition of the meaning of maximum levels which may have led in the past to the establishment of high legal limits in an attempt to prevent the rejection of food.

90. The Committee agreed that the question of sampling plans for the determination of contaminants in food as well as the definition of the meaning of maximum levels in relation to consignments of food moving in international trade should be considered by the Codex Committee on Methods of Analysis and Sampling as well as by this Committee at a future session.

91. The contaminant provisions in bouillons and consommés were temporarily endorsed. B. Natural Mineral waters (App. II, ALINORM 78/19)

Total beta-activity

92. There was a feeling that the endorsement of provisions relating to the presence of trace radio nuclides Was beyond the scope of the Committee and that such matters were normally dealt with by the expert bodies of WHO and IAEA. The Committee was informed that the level of 1 pCi/1 (37 m Bq) seemed very reasonable in the light of the recommendations of WHO concerning drinking water (see the latest edition of the "WHO International Standards for Drinking Water"). The provision for total beta-activity was endorsed.

Cyanide and Nitrite ions

93. These provisions were endorsed. The delegation of France was of the opinion that the level of nitrite could be too high for young children who might consume mineral waters if they were used as a base for the preparation of infant formulae.

C. Fructose

Lead

94. The delegation of Canada, supported by the delegations of the Federal Republic of Germany and Sweden, considered that the level of 2 mg/kg for lead was toxicologically unacceptable, as a weekly intake of 1 kg fructose Would yield two-thirds of the provisional tolerable Weekly intake of lead, it was noted that this maximum level was the same as that given for other sugars. It was also claimed that the analysis of sugars in trade shoved levels of less than 1 mg/kg. The Committee did not endorse the provision and referred the matter of levels of contamination by lead to the Committee on sugars.

CONSIDERATION OF THE STATUS OF CODEX LISTS "A" AND "C"

95. The Committee had before it a paper prepared by the Codex Secretariat (CX/FA 78/15), that described the history of the discussions in earlier sessions on the need to list food additives and the status of Lists A and C. In introducing the paper the Codex Secretariat reminded the Committee that harmonization of legislation of food additives on an international basis was one of the aims of the Codex Commission. The Committee was informed that in 1972 the Executive Committee had judged that the Work by the Codex Committee on Food Additives on lists of food additives was not sufficiently advanced and had, therefore, recommended that lists of food additives should be of an advisory nature for the information of governments. Accordingly, the Secretariat had prepared Lists A, B and C on food additives. Lists A and C were published as a document for information of governments; List B was issued as a discussion paper for the Codex Committee on food Additives.

96. The Secretariat drew the attention of the Committee to the fact that the publication containing Lists A and C (CAC/FAL 1-1973 and its Supplement 1) gave additional information on food additives and that this information may or may not have the same status in the Codex procedures as the various lists of food additives, e.g. definitions for the purpose of Codex; toxicological evaluations; and food additive provisions in Codex standards. The information presented in these publications was used by Codex commodity committees as well as by governments as advisory information on food additives. In their use the publications could be considered as containing information on food additives comparable to information in other documents adopted by the Codex Commission without, however, the status accorded to Codex Alimentarius publications which have passed through the full stepwise procedure. Many of the additives in List A were already included in Codex standards, but there were some which had not been taken up in individual commodity standards. Part 2 of the publication showed the status of those additives which had been included in codex standards at Step 9 of the Procedure.

97. The Secretariat concluded that there might be arguments in favour of recognizing Lists A and C in a more formal way and proposed that the Committee consider whether Lists A and C should be given the status of having been officially approved by this Committee. The Secretariat informed the Committee that a second edition of the Lists A and C was in preparation.

98. The chairman pointed out that much work needed to be done before the Lists were complete; the number of flavours which still needed evaluation was a typical example. Nevertheless it seemed possible to propose to the Commission that Lists A and C should be accorded a more formal status and it also appeared necessary to put forward to the Commission by means of List B those additives whose evaluation by the JECFA was considered necessary.

99. A number of delegations supported the view of the delegation of Canada that the publication of the Lists A and c was valuable for use not only by Codex commodity committees but also by governments. They were an important source of information on food additives. Therefore, it was important for them to be updated regularly, other Lists, such as the advisory list of additives for use in soft drinks, could usefully be incorporated in the publication as could the committee's decisions on such subjects as the Carry-over Principle.

100. The Chairman pointed out that no data were given in the publication containing the Lists A and C on the technological usefulness of the additives named. This could cause difficulties for governments wishing to make specific use of the lists.

101. Several delegations pointed out that an acceptable procedure for such a complex document would be very cumbersome. The Chairman concluded from the discussion that the present status of Lists A and c was satisfactory. It was noted that the status or title of the publication (CAC/FAL) detracted little from its value.

102. The Secretariat of the JECFA informed the committee that the JECFA would prepare a list of the toxicological evaluations made by the JECFA. It was suggested by that Secretariat that a document which reviewed all the different information included in the publication of Codex Lists A and e could serve as a basis to discuss the status of these Lists. The delegation of the Netherlands was of the opinion that clarification and updating of the introduction to the Lists would be useful to their users.

103. The Chairman concluded that the forthcoming second edition of Lists A and e would give the Committee the opportunity to express its opinion at the next meeting., A separate working paper would not be necessary.

PROPOSED ADDITION TO CODEX LIST C ON FOOD ADDITIVES

104. The Committee had before it a paper prepared by the Codex Secretariat (CX/FA 78/3). This listed 13 plant sources of natural flavours and flavouring substances which, it was suggested, might be added to Codex List C. It also listed some natural and nature-identical flavouring substances or their components with proposals as to their maximum level which should be allowed in food. Questions were also posed by the Secretariat as to whether the latter list should be included in Codex List C and how both lists should be handled in terms of status, publishing and further elaboration.

105. In the absence of the Council of Europe observer, the EEC observer informed the Committee that the Council of Europe would shortly be issuing a revision of these lists in the third edition of their list of flavours and flavouring substances used in food (Blue Book). Several delegations pointed out that in their view it was premature to incorporate these lists in List C since significant revisions of these lists were expected. The Canadian delegation pointed out that for a proper evaluation of the second list (i.e. the list of substances which should be limited in food) information on both the technological and toxicological aspects was needed, including JECFA's authority, since most countries had no input into the Council of Europe's deliberations. The delegations of Australia and the USA concurred with this opinion.

106. It was agreed to ask the JECFA for a toxicological view on the maximum levels proposed in the second list. It was thought more appropriate to consider the approach of limiting certain flavouring substances or their components in food after the results of the Council of Europe's deliberations were known.

107. The Committee concluded that the first of these lists dealing with botanicals which should not be used as a source of natural flavours or flavouring substances, should be included as a separate list in the next publication - updating CAC/FAL 1-1973. This list should have a separate heading to show that these substances were not normally regarded as food additives. The delegation of the U.K. recommended that Item 1.12, Slippery Elm, be deleted from the list in the light of possible reconsideration by the Council of Europe and this was agreed to by the Committee. The USA delegation stated that it would like to propose some additions to the list before it was finally published.

## CODEX LIST B OF FOOD ADDITIVES

108. The Committee had before it documents CX/FA 78/2 and CX/FA 78/2-Corr.l, the latter representing a revised Codex List B of additives, which the Secretariat had updated on the basis of the evaluations of the JECFA at its 21st and 22nd meetings, and at the same time incorporating certain corrections. The Committee noted that nitrous oxide had been evaluated by the JECFA and was thus now to be incorporated in List A(l).

109. The representative of OECD informed the Committee that item 7.20, 2-nitropropane, had recently been found to be carcinogenic to humans and questioned its place on the list. The Secretariat of the JECFA informed the Committee that this substance was already on the agenda for the next meeting of the JECFA. The Chairman pointed out that information on suspected toxicity is one of the arguments (apart from other considerations such as commercial importance of a substance) to propose a substance for the priority list of food additives to be evaluated by the JECFA.

110. He also reminded the Committee that putting a substance on the priority list was a way of requesting available information on the substance for the JECFA. Without such information the JECFA would not be able to evaluate the substance under consideration. In connection with the statement of the representative of OECD, the U.K. delegation pointed out that it would be dangerous for the Committee to delete from List B a substance believed to be carcinogenic since its presence on the list would lead to evaluation by the JECFA. Should it be evaluated as being a carcinogen, this represented useful information as a result of, which the additive might be placed on List C.

111. The Committee agreed to the deletion of these flavouring substances listed in para 1 of document CX/FA 78/2-Corr. 1 whose existence in food had been established. This action was thought to conform with the policies of the JECFA to evaluate artificial flavouring substances as a matter of first priority. The representative of FIVS and the delegate of Iran questioned the listing of saffron (item 4.27) as a colour. They considered this substance to be principally a natural flavouring substance. Further information was required to determine if saffron per se is used as a colour. The delegation of the Federal Republic of Germany propose to put isomaititol (a disaccharide of sorbitol) on List 8 since it had certain beneficial technological properties. Information on the substance was available. The delegation of the UK proposed to add modified polydextrose and hydrogenated glucose syrup to Group 10 (Miscellaneous). (An updated version of List B of food additives is attached as Appendix VIII to this report).

## CONSIDERATION OF PROCESSING AIDS

112. The Committee had before it papers prepared by the Netherlands Technical Secretariat (CX/FA 78/12, Add. 1 and 2) containing the comments of various governments on the definition of processing aids and a draft list of processing aids, in introducing these papers, the Technical Secretariat drew the attention of the Committee to the comments of Australia (CX/FA 78/12, Add. 1) on a possible procedure for the evaluation of processing aids. The Technical Secretariat concluded from the comments received that the governments that had commented agreed with the proposed definition for processing aids.

113. The Netherlands delegation felt that adopting the definition on processing aids automatically made them food additives and thus their presence would need to be stated on the label. The delegation of Netherlands held the view that this would be impractical.

114. The chairman reminded the Committee that in the discussions at the last session it was already considered that, as regards labelling, processing aids were substances that needed to be dealt with like contaminants. Consequently, processing aids should not be recorded on the label, in this respect, the Committee decided that the Codex Committee on Food Labelling should be advised that, although processing aids were a particular type of food additives, they should not appear on the label. The Committee decided to accept the definition for processing aids and to propose to the Commission to adopt this definition for the purpose of the Codex Alimentarius.

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 fulfill 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".

115. The Committee discussed the different categories of food additives listed by the Technical secretariat as processing aids. The Committee concluded that carrier solvents and flour-treatment agents cannot be considered as processing aids because they were deliberately added to the food or had a function in the end product. The other categories listed, i.e. clarifying agents, enzyme preparations, extraction solvents and filtration aids were considered to be processing aids. The delegation of France was of the opinion that enzymes could be both processing aids and food additives. When listing those used as processing aids, this should be mentioned for the guidance of the users of the list. It was noted that governments, in making suggestions for the inclusion of any substance in the list, should provide examples of how a particular material functioned as a processing aid.

116. The Committee discussed other categories not listed by the Technical Secretariat, in view of the complexity of the subject, the Committee decided to set up an ad hoc Working Group under the chairmanship of the USA to consider which categories of Food additives could be considered as processing aids. The delegations of Australia, Austria, Belgium, France, Italy, the U.K. and the USA agreed to participate in this Working Group.

117. In introducing the report of the Working Group, it was explained that a list of food additive categories used in the USA had been used as a basis for discussion. From this list those categories were chosen that were considered to encompass processing aids. The Working Group's proposed list of processing aid categories was adopted by the Committee with slight modifications. This modified list, together with the working Group's introduction explaining the principles followed, is contained in Appendix IV of this report.

118. The Committee agreed that the proposed list of processing aid categories should be sent to governments and interested international organizations for comment together with a request to provide the names of substances that should be listed under the different categories. The Netherlands Technical secretariat was requested to prepare a proposed list of processing aids based on the replies. In this list the status of individual substances as to their evaluation by the JECFA should be shown.

PRIORITY LIST OF ARTIFICIAL FLAVOURING SUBSTANCES

119. The ad hoc Working Group set up during the last session (in continuation from the 10th session) tabled its report (Room Document 78/6-Revised) which contained a proposed priority list. The rapporteur of the Working Group, Mr. J.P. Goddijn (The

Netherlands) indicated that the priority list was based on comments received from Hungary, Finland and IOFI. He pointed out that the subject was also receiving attention in the Council of Europe and that care was, therefore, needed to avoid duplication of efforts. Selection had mainly been based on the availability of data. The Committee accepted the list without amendment (see Appendix V of this report) and requested the JECFA to evaluate the substances on the list.

120. Dr. F. Grundschober of IOFI introduced his informal document on a proposed priority ranking scheme which was before the Committee. The chairman thanked him on behalf of the Committee which agreed that JECFA' s opinion should be sought on the IOFI proposal.

121. The Chairman thanked the Working Group for their work which had now been concluded. He asked that any information on the substances in the priority list (especially those few shown in Appendix V of this report on which there was no data available). be forwarded to the Joint Secretaries of the Expert Committee on Food Additives (toxicological data to Dr. G. Vettorazzi of WHO in Geneva and specification data to Dr. G.D. Kouthon of FAO in Rome).[1/]

[1/] Governments and interested international organizations are requested, by means of Circular Letter (CL 1978/44, November) to send information on the additives to be evaluated by the 1979 meeting of the JECFA.

## CONSIDERATION OF THE REPORT OF THE WORKING GROUP ON SPECIFICATIONS

122. The Committee had before it the report of the ad hoc Working Group on Specifications (CX/FA 78/LIM.2). 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 78/7-Parts I, II and III, their addenda and the comments of the members of the Working Group. The working Group recommended that 38 specifications be proposed to the commission for acceptance and that 10 others not be proposed. A total of 49 were not reviewed because these specifications were designated as tentative or the additives concerned appeared on Codex List A(2), in spite of the fact that governments had submitted substantial comments on such specifications. The Working Group requested clarification from the Committee on some procedural matters.

123. The Codex Secretariat informed the Committee of the new procedure for adoption of specifications, it was explained that amendments to specifications could be recommended by the Committee to the Secretariat of the JECFA which, after evaluation or re-evaluation, could re-issue the specifications. Revisions adopted by the JECFA would eventually be submitted to the Committee for final adoption.

124. The committee discussed the proposal of the Working Group with regard to the specifications which were designated as tentative. The U.K. member of this Group suggested that specifications indicated as tentative because of lack of toxicological data, de referred to the Codex Committee on Food Additives after having been included in List a(2) or temporarily in List B. Other delegations recommended that the Committee should examine only those specifications for substances which had been allocated an ADI.

125. The Committee decided that Codex specifications should, be established for substances which had been allocated an ADI.

126. The observer from the BBC drew the attention of the Committee to the EEC specifications and expressed the need for a procedure to guarantee their consideration in drawing up Codex specifications. The Chairman of the Working Group explained that

the Group included 5 member states of the EEC, who had been pointing out the relevant differences between codex and EEC specifications. It was emphasized that Codex specifications were advisory for governments, while EEC specifications had a mandatory nature.

127. The delegation of the Federal Republic of Germany stated that their delegation was about to submit some amendments to the proposed Codex specifications. It was agreed that these be referred to the JECFA.

128. The Committee decided that:

(a) work should continue on the elaboration of Codex specifications for food additives; and

(b) those specifications listed in the report of the ad hoc working Group (see Appendix VII of this report) should be submitted to the Commission at Step 5 for final adoption.

129. The Committee agreed that the ad hoc Working Group should continue its work under the chairmanship of the USA. The following countries agreed to participate: Brazil, France, Greece, Ireland, Japan, the Netherlands, Switzerland and the U.K.

SPECIFICATIONS FOR FOOD GRADE SALT

130. The Committee had before it several papers on specifications for salt prepared by the Netherlands (CX/FA 78/13 and CX/FA 78/13A), Spain (CX/FA 78/13-Add.l), and Sweden (CX/FA 78/14-Add.l). In introducing these papers, the delegation of the Netherlands drew the attention of the Committee to Appendix I to CX/FA 78/13A, containing a second revision of the specifications. In this revised version, the written comments received, as summarized in CX/FA 78/13A, had been taken into account.

131. It was stated by many delegations that they could accept the proposals as made in the second revision, with the note that the limits for contaminants should be provisional pending the establishment of appropriate methods of analysis and information on actual levels.

132. The delegation of the Federal Republic of Germany proposed a maximum level of 2 mg/kg for cadmium to be added to the section on contaminants. This view was supported by the delegations of France and Spain. Following a proposal from the delegation of Japan, the word "springs" was deleted from the description.

133. With regard to the question as to whether specifications or a standard be elaborated for food grade salt, the majority of the opinions expressed was in favour of specifications only. The delegations of New Zealand and Australia, however, spoke in favour of a standard. A labelling section, and a section on methods of analysis and sampling would then have to be added, in accordance with the Codex format for commodity standards.

134. The representative of the European Committee on Salt Studies (ECSS) offered to contribute in the establishment of methods of analysis for the contaminants "listed. This offer was accepted by the Committee.

135. The specifications were amended in accordance with the foregoing discussion (see Appendix III of this report). Government comments were requested, particularly on the question as to whether a specification or a standard is preferred.

## PRIORITY LIST FOR FOOD ADDITIVES

136. The Committee discussed the report of the ad hoc Working Group concerning Codex List B (CX/FA 78/11) which was introduced by Dr. J. Drum, Canada, who had acted as Chairman of the Group. He pointed out that the Working Group had decided that the List would remain current for three sessions, after which any substance for which no data had been submitted or were likely to be forthcoming on the basis of which the JECFA could make an evaluation, would be automatically dropped from the list.

137. Certain editorial changes were made to the priority list by the chairman of the Group whilst others were proposed during the discussion. The addition of riboflavin 5'-phosphate was agreed by the Committee. The Codex Priority List of Food Additives, as amended, is given in Appendix VI to this report;

138. The representative of AMFEP stated that some sources "of microbial enzyme preparations were not known sources to his Organization. In view of this uncertainty, it was suggested by the UK delegation that all known names should be placed on the list; those which were incorrect would be deleted automatically. The delegation of the USA proposed a number of microbial glucose isomerase preparations to be included in the priority list. Toxicological data and specifications were said to be available. The representative of AMFEP proposed the inclusion of a glucose isomerase produced by Streptomyces albus. The Committee decided to place these preparations on the list (see also paras 119-121).

## DRAFT GENERAL STANDARD FOR IRRADIATED FOODS AND DRAFT CODE OF PRACTICE FOR THE OPERATION OF RADIATÌON FACILITIES USED FOR THE TREATMENT OF FOODS

139. The Committee had before it the report of an ad hoc Working Group which had met prior to the session under the chairmanship of Dr. A. Brynjolfsson (USA) assisted by Dr. K. was (IAEA) as Secretary. The following countries had participated in the work: Belgium, Canada, Federal Republic of Germany, Italy, the Netherlands, Switzerland and the USA. Of the international organizations,. EFLA, FAO, IAEA and OECD were represented on the Working Group.

140. In introducing the report of the Working Group, Dr. Brynjolfsson informed the Committee that the Group had reviewed all comments received from member states (Argentina, Australia, Belgium, Hungary, the Netherlands, Sweden, the U.K.) and IAEA an the Draft General Standard and on the Draft Code of Practice. Those Government comments received in time had been analyzed by the Secretariat in document CX/FA 78/14; others arriving later had been scrutinized at the Working Group session.

141. The Committee discussed the Draft General Standard and the Code of Practice in the light of recommendations of the ad hoc Working Group.

### A. Draft General Standard for Irradiated Foods

### Section 3. Safety of Irradiated Foods

142. The Committee agreed to delete the second paragraph of this section, which stated that for the purposes of the standard only those irradiated foods which had been evaluated by the Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Foods would be acceptable. It was considered that this paragraph described a working procedure of the Codex Committee on Food Additives and was not intended to be part of a standard sent to governments for acceptance.

Section 5. Labelling

143. The Committee made a-slight editorial amendment to this section in order to make it clear that the declaration of the registered facility which had irradiated the food should be declared on the label of prepackaged foods unless labelling was not feasible as in the case of irradiated foods shipped in bulk. In such a case the information would be included in the accompanying documents.

144. The committee noted the conclusion of the ad hoc Working Group that further consideration should be given to the question of the labelling of irradiated foods subjected to further processing or used as ingredients. In the opinion of the delegation of Austria, the label of processed foods prepared from irradiated raw materials or of composite foods containing irradiated ingredients should bear an appropriate declaration indicating that the raw material or the ingredient had been irradiated. The Committee decided that there was no need to make any changes to this effect as the General standard was only intended for irradiated foods sold as such.

Dose Limits

145. The Committee concurred with the conclusion of the ad hoc Working Group that the dose ranges included in the original text should be replaced by limits showing the maximum permissible dose of irradiation. The reason for this change was that dose ranges and minimum dose limits would be covered by good manufacturing practice. It was also noted in this respect that the standard covered only the irradiation aspects of the processing and handling of foods and that these foods would be subject to all relevant standards and regulations governing foods generally.

Annex I

Section 1, Chicken; and Section 6, Cod and Red Fish

146. The Committee made changes to the sub-section dealing with the purpose of the process by referring to the, reduction of certain pathogenic microorganisms rather than to their elimination. This change was thought necessary in view of the fact that the total elimination of pathogenic microorganisms, especially spores of such microorganisms, was not feasible. The delegation of Brazil stressed that the absence of pathogenic microorganisms in foods should be determined on a standard sample size and that this matter should be brought to the attention of the Codex Committee on Food Hygiene.

147. As regards the requirement for temperature of storage of irradiated chicken, the Committee decided to reduce the temperature requirement to 4 C in order to be consistent with the recommendations included in the Code of Hygienic Practice for Poultry Processing.

General Remarks

148. The delegation of Italy was of the opinion that the recommendations contained in Annex I required further consideration. The Italian delegation had reservations concerning the irradiation of animal products such as chicken and fish with radiation doses such as indicated in the standard. The delegation of Brazil was also of the opinion that further consideration should be given to the recommendations in Annex I. That delegation, however, pointed out that the process of irradiation would represent an important method of treatment of foods in that country and indicated that it looked forward to the establishment of a Codex standard for irradiated foods. The delegation of the UK also felt that the standard required further consideration by governments, especially in view of additional on-going work on the acceptability of the irradiation

process. The delegation of the Netherlands was of the opinion that food irradiation was a useful process which could solve problems such as contamination of food by Salmonellae.

149. The Committee was informed that the standard represented the views of experts who had considered evidence concerning the wholesomeness of irradiated foods not only from the point of view of toxicology but also of the microbiological and nutritional acceptability of irradiated foods. The limits included in Annex I, represented radiation doses which need not be exceeded from a technological point of view and which were acceptable from a point of view of safety.

150. The question was raised as to whether the standard should be sent to the Codex Committee on Food Hygiene for endorsement. Some delegations were of the opinion that this was essential» especially as the standard did not provide for a minimum absorbed dose in the case of chicken and fish, on the other hand, it was noted that the working Group had considered that, as the standard did not contain provisions for hygiene or microbiological standards, endorsement by the Codex Committee on food Hygiene might not be necessary. It was understood that, like non-irradiated foods» irradiated foods were subject to the same Codex provisions and Codes of Hygienic Practice governing the food items concerned. The Committee decided that the standard should be sent to the Codex Committee on Food Hygiene for consideration and noted that it would be possible to consider the views of that Committee, as well as the views of the Codex Committee on Food Labelling, at the next session of this Committee.

151. It was noted that the 12th session of the Commission had requested governments to supply information concerning the volume of international trade in irradiated foods. The Committee noted that no such information had been communicated to the Secretariat. It also noted the views of the Working Group that this should not be construed to mean that international trade in irradiated foods did not exist. The Working Group had recognized that international trade in irradiated foods, and information about such trade, could only develop as a result of internationally accepted clearances, and thus it was premature to expect substantial trade while no such world-wide clearance and international standard existed.

B. Draft Code of Practice

152. The Committee noted that the Working Group had made only editorial amendments to the Draft Code and also noted that, on the basis of government comments, the Draft Code appeared to be generally acceptable.

Status of the Draft General Standard and Draft Code

153. The Committee decided that the Draft General Standard for Irradiated Foods and that the Draft Code of Practice for the Operation of Radiation Facilities used for the Treatment of Foods, as amended, should be advanced to Step 8 of the codex Procedure (see Appendices X and XI of this report). The delegation of the UK reserved its position on the decision to advance the standard to Step 8. it considered that more time should be allowed for government comments and that the views of the Codex Committees on Food Labelling and Food Hygiene on the provisions in the standard should be available to the Committee for consideration before a final decision could be taken to advance the standard to Step 8. The delegation of Austria also reserved its position concerning the advancement of the standard and the code, in this connection, the delegation of the Federal Republic of Germany pointed out that the advancement of the standard and code to Step 8 of the Procedure did not in any way bind governments regarding the

ultimate acceptance of the recommendations of the Commission concerning food irradiation.

DRAFT GENERAL STANDARD ON LABELLING OF FOOD ADDITIVES WHEN SOLD AS SUCH

154. The Committee considered the report of the ad hoc Working Group which had met under the chairmanship of Mr. H.M. Goodall (UK) with the participants from the following countries: Australia, the Netherlands, Canada and FAO.

155. The Committee noted that the Draft General standard (ALINORM 78/12, App. VI) had been advanced at the 12th session of the Codex Alimentarius Commission to step 6 of the Procedure but that there were still some outstanding questions to consider. Written comments on the Draft General Standard had been received from the governments of Austria, the Netherlands and from the Organization of Manufacturers of cellulose Products for Foodstuffs in the EEC (OFCA). these were summarized in a working document prepared by the UK for consideration by the Working Group. In presenting the report, the Chairman of the Working Group noted the following points:

Processing Aids

156. The working Group had proposed to include in the standard under section 2(i) the definition of Processing Aids adopted by the Committee (see para 114) and had proposed to amend the scope section of the standard to make it clear that processing aids were covered by the standard.

Bulk Containers

157. The Working Group had noted that different options for the labelling and definition of bulk containers were still a matter for discussion at the Codex Committee on Food Labelling where General Guidelines for the Labelling of Bulk Containers were being developed.

158. It had also noted that, in the case of food additives sold other than by retail, it was inappropriate to refer under 5.6 "Lot Identification" to the permanent marking of the container, since it was possible that such containers would be used on more than one occasion. The Working Group proposed that sub-section 5.6 be amended accordingly.

Mandatory Labelling of Prepackaged Food Additives, sold other than by Retail

159. It was noted that the Working Group had proposed an amendment to cover the situation where a small food manufacturer would be unable to make adequate use of the percentage declaration of ingredients. It had agreed that alternative information could be given so as to ensure that, when used according to instructions, there would be no possibility of exceeding the maximum limits of Use of the additives.

160. In view of the previous discussion, the working Group had proposed to amend sub-section 5.1 "Details of Food Additives", to make clear the necessity for adequate limitation of a food additive in a food. This information or instruction should be supplied not only where such a limitation was included in a Codex standard, but in all cases where limitations were imposed in the country in which the additive was to be sold.

161. The Working Group considered whether special mixtures of food additives, in particular stabilizers and thickeners, should be exempt from the ingredient listing provisions of, the standard, as was the case for flavours. It was of the opinion, however, that the considerations concerning the listing of all ingredients in flavour mixtures did not apply with equal force in the cases of stabilizers and thickeners. The working, Group

had, therefore, proposed not to extend the exemption for food additives other than flavours.

Instructions for Keeping and Use

162. The Working Group had noted that the guidelines to Codex committees prepared by the Codex Committee on Food Labelling required that Codex committees should consider whether date marking was required in Codex standards. If they considered that a provision was not necessary, they should give reasons for their decision.

163. The working Group: had also noted that there were some food additives which were sufficiently liable to deterioration so as to justify date marking. It, therefore, proposed to include in paragraphs 4.2, and 5.2. a requirement for the date of minimum durability, using an expression suggested by- the Codex Committee on Food Labelling, i.e. "will keep at least until....". It was suggested that these requirements should apply only to food additives with a shelf life not exceeding 18 months.

Conclusions of the Committee

164. The Committee agreed to the amendments proposed by the Working Group as indicated in paragraphs 156, 158, 159, 160, 161 and 163.

165. As regards the question of bulk labelling, the Committee recognized that this question was yet to be considered by the codex committee on Food Labelling and noted that there would be a further opportunity for the Committee to discuss the conclusions of the Codex Committee on Food Labelling before the next session of the Codex Alimentarius Commission, which would be held in December 1979.

166. As regards instructions for keeping and use, the observer of AMFEP (Association of Microbial Food Enzyme Producers) was of the opinion that in certain cases, the user of food additives would be better served by data sheets instructing him/her in the usual labelling information and suggested that the Industry prepare a paper on this matter for consideration by the codex committee on Food Additives at its next session. The Committee noted that the labelling provisions in the standard in no way prevented the issuing of such data sheets and that, m particular for bulk containers, both labelling provisions and instructions for use could be given in documents accompanying the products.

Status of the Standard

167. The committe decided to advance the Draft General Standard for the Labellinq of Food Additives when sold as such to step 8 of the codex Procedure. The amended Draft Standard is attached as Appendix IX.

FUTURE WORK

168. The noted that the Commission, at its 12th session (ALINORM 78/41. para 201), had concurred with the view that the whole question of provisions for contaminants in Codex standards required more attention. This also applied to environmental contaminants which entered the food chain. The Committee noted that there was not yet sufficient information from the FAO/WHO/UNEP Monitoring Programme to enable the Committee to work on environmental contaminants but that public concern made this an important area for future work, in addition, the Committee could expect that its present work-load with regard to screening and endorsement of food additives would be maintained.

## OTHER BUSINESS

169. The delegation of Norway stressed that the Codex Committee on Food Additives should give more attention to policy matters regarding the use of food additives It was particularly concerned with the excessive use of food additives and felt that the Committee might address itself more to questioning the technological need for additives than it did at present. If it was not considered appropriate that technological questions be discussed at sessions of the Codex Committee on Food Additives, the Norwegian delegation questioned where in the Codex system such aspects might be expected to be considered.

170. The Chairman pointed out that such considerations were the duty of Codex commodity committees in the first instance and subsequently of this committee on the basis of scientifically assessed toxicology, including considerations of intake.

171. The representative of WHO recalled the principles established by the first session of the JECFA for the use of additives and suggested that they might usefullv be revised and brought up-to-date. The Committee considered that the Principles which had been based on the conclusions of the first session of the JECFA, were still valid and, moreover, were adequately covered by the General Principles for the Use of Food Additives set out in the Procedural Manual of the Commission (4th Edition).

## DATE AND PLACE OF THE NEXT SESSION

172. The Chairman announced that the next session would be held in The Hague, from 11 to 17 September 1979. Working Groups would meet on the day before the session.

# APPENDIX I

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

* The Heads of Delegations are listed first; Alternates, Advisers and Consultants are listed in alphabetical order.

Les chefs de délégations figurent en tête et les suppléants, conseillers et consultants sont enumeres par ordre alphabétique.

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

Chairman of the Session
Président de la Session
Presidente de la Réunion

Dr. G.F. Wilmink
Ministry of Agriculture and Fisheries
Bezuidenhoutseweg. 73
POB 20401, 2500 EK The Hague
The Netherlands

Delegates
Délégués
Delegados

AUSTRALIA
AUSTRALIE

Dr. R.H.C. Fleming
Department of Health
P.O. Box 100
Woden, A.C.T. 2606

H. Govers
Council of Australian Food Technology Assoc.
44 Miller Street
North Sydney, N.S.V. 2060

Dr. A.W. Randell
Dept. of Primary Industry
Edmund Barton Building
Broughton Street
Barton, A.C.T. 2600

M.V. Tracey
C.S.I.R.O.
Division of Food Research
P.O. Box 52
N. Ryde, N.S.W. 2113

AUSTRIA
AUTRICHE

Dr. V. Koechlin
Bundesanstalt fur Lebensmitteluntersuchung und forschung
Kinderspitalgasse 15
A-1090 Vienna

Dr. St. Gergely
Fachreferent im Fachverband der Nahrungs und Genuszmittelindustrie Dsterreichs
Zaunergasse 1-3
1030 Vienna

BELGIUM
BELGIQUE
BELGICA

Ir. Ch. Crémer
Inspecteur des Denrées Alimentaires
Ministère de la Santé Publique
Cité Administrative de l'Etat
Quartier Vésale
1010 Bruxelles

M. Demanet
F.I.A.
72A, Avenue de Bruxelles
B 1820 Grimbergen

M, Fondu
Université Libre de Bruxelles
institut d'Etudes Européennes
Avenue F.D. Roosevelt, 39
1050 Bruxelles'

Dr. M. Vander Stichelen Rogier
Institut d'Hygiène et
d'Epidemiologie
Rue J. Wytsman; 14
1050 Bruxelles ;

BRAZIL
BRESIL
BRASIL

Dr. Ialmo de Moraes
Chef de la Section Technique
de Nourritures du Ministère
de la Santé
Rua Prudente de Moraes 663
Ap. 201;
20.000 Rio de Janeiro

Dr. Roberto Resende
Cámara Tecnica de Alimentos
Avenida Brasil 4036 - Sala 903
Rio de Janeiro

CANADA

R.O. Read
Chief'Additives and Pesticides Div.
Bureau of Chemical Safety
Food Directorate
Health Protection Branch
Health and Welfare Canada
Ottawa

J. Drum
Grocery Products
Manufacturers of Canada
c/o Coca-Cola Ltd.
42 Overlea Boulevard
Toronto, Ontario M4H 1B8

CZECHOSLOVAKIA
TCHECOSLOVAQUIE
CHECOSLOVAQUIA

Dr. A. Wolf
Head of Food Hygiene
Research Centre
Srobárova 48
Praha: 10 Vinohrady

DENMARK
DANEMARK
DINAMARCA

M. Bjørn, Chem. Eng.
Food Technologist
National Food Institute
Mørkhøj Bygade 19
DK 2860 soborg

Mog. Kondrup
Food Technologist
Federation of Danish Industries
Aldersrogade 20
DK 2200 Copenhagen N

Peter Th. Madsen, Chem. Eng.
Food Technologist
Chr. Hansen's Laboratories A/S
Sankt: Annae Plads 3
DK 1250 Copenhagen K

B. Moeller Christensen
The Danish Embassy
Koninginnegracht 30
Den Haag.(The Netherlands)

FINLAND
FINLANDE
FINLANDIA

Dr. K. Salminen
Head of Food Bureau
National Board of Trade and
Consumer Interests
Box 9
00531 Helsinki 53

K. Dufholm
Head, of Div. of Consumer Affairs
National Board of Trade and
Consumer Interests
Box 9
0053l Helsinki 53

T. Neuvoneh M.Sc.
Chief Inspector
National Board of Trade and
Consumer Interests
Box 9
00531 Helsinki 53

E. Niemi
chemist
Customs Laboratory
Box 168
00161 Helsinki 16

E. Pajunen, M.Sc. (Techn.)
Assistant Manager
Food Industries Federation
Unioninkatu 14
00130 Helsinki 13

Dr. P. Pakkala
Senior Supervisor
The National Board of Health
Siltasaarenkatu 18
00530 Helsinki 53

J. Rájama
Research Officer
Technical Research Centre of Finland
02150 Espoo 15

FRANCE
FRANCIA

S. Roehize
Inspecteur Divisionnaire
Service de la Répression des Fraudes et du Contrôle de la Qualité
44 Boulevard de Grenelle
F. 75015 Paris

J. Théyenot
Inspecteur Divisionnaire
Service de la Répression des Fraudes et du Contrôle de la Qualité
44 Boulevard de Grenelle
F. 75015 Paris

M. Zimmerman
Syndicat National des Producteurs d'Additifs Alimentaires (SYNPA)
41 bis, Boulevard de Latour Maubourg
75007 Paris

GERMANY, FED. REP. OF
ALLEMAGNE, REF. FED. D'
ALEMANIA, REP. FED. DE

H.P. Mollenhauer
Ministerialrat
Bundesministerium fur Jugen, Familie
und Gesundheit
Deutschhherrenstrasse 87
D-5300 Bonn 2

K. Jones
Verband der Deutschen Essenzenindustrie
Neusser Strasse 104
5000 Köln 1

Dr. W. Lucas
Wissenschaftlicher oberrat
im Bundesgesundheitsamt
Postfach 330013
D-1000 Berlin 33

Dr. E. Luck
Bund fur Lebensmittelrecht und Lebensmittelkttnde e.v.
5300- Bonn 1

GREECE
GRECE
GRECIA

C. Constantopoulos
Director of the chemical Applications Department
General Chemical State Laboratory
16, An. Tsoha Street
Athens

GUYANA
GUYANE

Dr. Rex B. Voo-Ming
Government Analyst/Commissioner of Food and Drugs
Analyst/Food and Drug Dept.
Georgetown

HUNGARY
HONGRIE
HUNGRÍA

Dr. Judit Sohâr
Head of Dept. on Food Additives
Institute of Nutrition
Gyáli út 3/a
Budapest IX

IRAN

Dr. S.E. Hashemy-Tonkabony
Legal Expert on Food Analysis and Toxicology
Medico-Legal Laboratory
Ministry of Justice
Tehran

IRELAND
IRLANDE
IRLANDA

M. Lyons
Assistant Principal Officer
Department of Health
Food, Drugs and Public Health Div.
Hawkins House,
Dublin 2

Dr. T.D. Feeley
Galway Region Public Analyst
Public Analyst's Laboratory
Regional Hospital
Galway

ITALY
ITALIE
ITALIA

Prof. A. Stacchini
Ricercatore
Istituto Superiore di Sanità
Viale Regina Elena 299
00161 Roma

Dr. D. Baraldi
Ricercatore Chimico
Divisione Applicazioni Radiazioni
C.S.N. Casaccia
S. Maria di Galería
Roma

Dr. T. Garlanda
Chimico
L. Donegani, l
Milano

A. Perinélli
Monopoli di Stato
Roma

Dr. G. Porcelli
Chimico Superiore I
Ministero della Sanità
Roma

Prof. E. Quattrucci
Ricercatore
Istituto Nazionale della Nutrizione
Viale Lancisi 29
00185 Roma

JAPAN
JAPON

M. Fujii
Food Chemistry Specialist
Food Chemistry Division
Ministry of Health and welfare
2-2, 1-chome, Kasumigaseki
Chiyoda-ku
Tokyo 100

T. Akiyama
Technical Adviser
Federation of Food Additives Association in Japan
Shokhin Eisei Center
Jingu-mae 2-6-1
Shibuya Ku
Tokyo 150

F. Fukutomi
Technical Adviser
Federation of Food Additives Association in Japan
Shokhin Eisei Center
Jingu-mae 2-6-1
Shibuya Eu
Tokyo 150

H. Sasaki
Technical Adviser
Federation of Food Additives Association in Japan
Shokhin Eisei Center
Jingu-mae 2-6-1
Shibuya Ku
Tokyo 150

NETHERLANDS
PAYS-BAS
PAÍSES BAJOS

J.P. Goddijn
Ministry of Public Health and Environmental Hygiene
P.O. Box 439
2260 At Leidschendam

Dr. H. van den Dool
Commission for the Dutch Food and Agricultural Industry
International Flavours and Fragrances Nederland B.V.
Liebergerweg 72-98
1221 JT Hilversum

A. Febervee
Ministry of Agriculture and Fisheries
P.O. Box 20401.
2500 EK The Hague

E.G. de Jeu
General Commodity Board for Arable Products
P.O. Box 29739
2502 LS The Hague

J.G. van.Kooij
Head, Food Preservation Section
Joint FAO/IAEA Division, IAEA
Kärtner Ring 11
A-1011 Vienna
Austria

Dr. C. Nieman
Commission for the Dutch Food and Agricultural Industry
Netherlands Federation of Christian Employers
P.O. Box 5100
2508 AC Tlje Hague

C.A.H. Verhulsdonk
Dutch Consumers Association
P.O. Box 28101
2502 KC The Hague

NEW ZEALAND
NOUVELLE-ZELANDE
NUEVA ZELANDIA

M. Thomas
Food Technologist
Department of Health
P.O. Box 5013
Wellington

NORWAY
NORVEGE
NORUEGA

Dr. S. Aasen
Director
Div. of Hygiene and Epidemiology
Directorate of Health
P.O. Box 8128 Dep.
Oslo 1

Dr. B. Bøe
Head of Section
Directorate of Fisheries
P.O. Box 185/7
5001 Bergen

A. Bragstad
Norwegian Soft Drink Association
P.O. Box 8 - Alnabru
Smalvollveien 65
Oslo 6

Dr. S. Nossen
Government Quality Control
(Processed Fruits and Vegetables)
Gladengveien 3 B
Oslo 6

PORTUGAL

Dr. E.C.C. Amarai
Food Department
National Institute of Health
Av. Padre Cruz
Lisbon 5

SPAIN
ESPAGNE
ESPANA

Dr. J.M. Ponz Marín
Jefe Control Bromatológico
Ministerio de Sanidad
Plaza de España 17
Madrid 13

Dr. J.M. Rafols
Research Manager
Unión Salinera de España S.A.
Ramula Estudios 109-1
Barcelona 2

Dr. I. Vila Valero
servicio Control Bromatolcfgico
Ministerio de Sanidad
Plaza de España 17
Madrid 13

SWEDEN
SUEDE
SUECIA

A. Karlsson
Assistant
Food Standards Division
National Food Administration
Box 622
S-751 26 Uppsala

Dr. Techn. A. Edhborg
Manager of Food Research
duality Control
Findus AB
Box 85
S-267 00 Bjuv

B. Eriksson
Cooperative Union and
Wholesale Society
Fack
S-104 65 Stockholm

M. Olausson
Assistant
Codex Secretariat
National Food Administration
Box 622
S-751 26 Uppsala

SWITZERLAND
SUISSE
SUIZA

E. Tremp
Food Control Division
Swiss Federal Office of
Public Health
Haslerstrasse 16
CH-3008 Berne

Dr. J. Hofstetter
Hoffman-La Roche & Co. AG
CH-4000 Basel

G. Huschke
Hoffman-La Roche & Co. AG
CH-4000 Basel

Dr. E. Nittner
Meyhall Chemical AG
Postfach 862
CH-8280 Kreuzlingen

Dr. R. Riklin
Société Suisse des Industries
Chimiques
Postfach
CH-8035 Zurich

H.J. Zehnder.
Eidg. Forschungsanstalt fur Obst,
wein und Gartenbau
CH-8820 wadenswill

THAILAND
THAILANDE
TAILANDIA

T. Satasuk
Director
Food Control Division
Ministry of Health
Bangkok 2

V. Trangkhasombat
Technical Services Manager
The Coca-Cola Export Corporation
P.O. Box 523
28/1 Surasak
Bangkok

UNITED KINGDOM
ROYAUME-UNI
REINO UNIDO

H.M. Goodall
Assistant. Secretary
Head of Food Additives and Contaminants Division
Ministry of Agriculture, Fisheries and Food
Room 545
Great Westminster House
Horseferry Road
London SW1P 2AE

A.E. Billington
Food and Drink industries Council
25 Victoria Street
London

T. Avigdor
Nestec
Case Postale 88
CH-1814 La Tour de Peilz

Dr. F.M. Carpanini
Principal Scientific Officer
Medical Aspects of Chemical Contamination of the Environment
Food and Smoking Division
Department of Health and Social Security
Friars House
Blackfriars Road
London SEI

J.N. Counsell
Chairman
Food Additives Group :
Chemical Industries Association
Alembic House ,
93 Albert Embankment
London SEl 7TU

M.T. Damer
Head
Food Additives Section
Chemical Industries Association
Alembic House
93 Albert Embankment
London SEl 7TU

Dr. W.H.B Dertner
Principal Scientific Officer
Food Science Division
Ministry of Agriculture, Fisheries and Food.
Room 444
Great Westminster House
Horseferry Road
London SW1P 2AE

M.J. Griffiths
Principal
Head of Food Additives Branch
Ministry of Agriculture, Fisheries and Food
Room 554
Great Westminster House
Horseferry Road
London SW1P 2AE

Dr. A. Tolan
Principal Scientific Officer
Food Science Division
Ministry of Agriculture, Fisheries and Food
Great Westminster House
Horseferry Road
London SW1P 2AE

UNITED STATES OF AMERICA
ETATS-UNIS D'AMERIQUE
ESTADOS UNIDOS DE AMERICA

R.J. Ronk
Director
Division of Food and Colour Additives
Bureau of Foods
Food and Drug Administration, DHEW
Washington, D.C. 20204

Dr. H. Blumenthal
Director
Division of Toxicology
Bureau of Foods
Food and Drug Administration, DHtiW
Washington, D.C. 20204

E. Bouchard
Director
Safety and Regulatory Affairs
Chemical Products R + D
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Dr. A. Brynjolfsson
Chief
Radiation Preservation of Food Div.
Food Engineering Laboratory
Natick, MA 01760

D.F. Dodgen
Director
Food Chemicals Codex
National Research Council
National Academy of Sciences
2101 Constitution Avenue, N.w.
Washington, D.C. 20418

Dr. O.D. Easterday
Vice President
Chief Toxicologist
International Flavours
Fragrances, Inc.
521 west 57th Street
New York, NY 10019

Dr. A. Ebert
Vice President
Scientific and Technical Affairs
Wm. Underwood Company
One Red Devil Lane
Westwood, MA 02090

Ch. Feldberg
Director
Health and Safety
CPC International
International Plaza
Englewood, NJ 07632

K.R. Fulton
Director
Food Additive Surveys
National Research Council
National Academy of Sciences
Washington, D.C. 20418

Dr. J.C. Kirschman
Manager
Regulatory Sciences
General Foods Corporation
250 North Street
White Plains, NY 10625

L. Sebranek
Assistant Agricultural Attaché
U.S. Mission to the
European Community
40 Blvd. du Régent
Brussels (BELGIUM)

U.S.S.R.
U.R.S.S.

Dr. A. Zaitsev
Head of Laboratory on Hygienic
Examination of Food Additives
Institute of Nutrition USSR's AMS
Ustinsky projezd 2/14
Moscow G-240

YUGOSLAVIA
YOUGOSLAVIE

Mrs. Lj. Bastic
Yugoslav Institute for
Meat Technology
Additives Department
Kacanskog Street 13
11000 Beograd

Dr. B. Briski
Food and Food Additives Unit
Central Institute of Hygiene
of Croatia
Rockefeller Street 7
41000 Zagreb

<u>INTERNATIONAL ORGANIZATIONS
ORGANISATIONS INTERNATIONALES
ORGANIZACIONES
INTERNACIONÀTIS</u>

ASSOCIATION OF MICROBIAL FOOD
ENZYME PRODUCERS (AMFEP)

Drs. P.F. Noordervliet
Chairman AMFEP
Gist-Brocades N.V.
P.O. Box 1
Delft (The Netherlands)

J.L. Mahler
Secretary AMFEP
NOVO Industri A/S
DK-2880 Bagsvaerd (Denmark)

BUREAU DE LIAISON DES SYNDICATS EUROPEENS (CEE) DES PRODUITS AROMATIQUES

Dr. A. Maltese
Via Fatebenefratelli 10
20121 Milano (Italy)

CONFEDERATION OF EUROPEAN SOFT DRINKS ASSOCIATION (CESDA)

Drs. C.J. Kievit
Vice-President of CESDA
General Secretary of CESDA
Heemraadssingel 167
3022 CG Rotterdam (The Netherlands)

COUNCIL OF EUROPE (CE)
CONSEIL DE L'EUROPE (CE)

Dr. O. Messer
Deputy Director of Economic and Social Affairs
Council of Europe
67006 Strasbourg Cedex (France)

EUROPEAN COMMITTEE FOR THE STUDY OF SALT (ECSS)
COMITE EUROPEEN D'ETUDE DU SEL (CEES)

J. Mignon
Président de la Commission des Sels Alimentaires du Comité Européen d'Etude du Sel
11 bis, Avenue Victor Hugo
75116 Paris (France)

M. Viard
Directeur des Services Technico-commerçiaux de la Compagnie des Salines du Midi et des Salines de l'Est
51, Rue d'Anjou
75008 Paris (France)

EUROPEAN ECONOMIC COMMUNITY (EEC)
COMMUNAUTE ECONOMIQUE EUROPEENNE (CEE)

R. Haigh
Principal Administrator
Commission of the European Communities
Rue de la Loi 200
1049 Brussels (Belgium)

EUROPEAN FOOD EMULSIFIER MANUFACTURERS' ASSOCIATION (EFEMA)
ASSOCIATION DES FABRICANTS EUROPEENS D'EMULSIFIANTS ALIMENTAIRES (EFEMA)

J.J. Jenkins
Food Industries Ltd.
Bromborough Port
Merseyside L 62 4SU (U.K.)

C. Vrang
A/S Grindstedvaerket
Edwin Rahrs Vej, 38
DK-8220 Brabrand (Denmark)

EUROPEAN FOOD LAW ASSOCIATION (EFLA)
ASSOCIATION EUROPEENNE POUR LE DROIT DE L'ALIMENTATION (AEDA)

Prof. A. Gerard
Secrétaire Général
3-Boulevard de la Cambre
B-1050 Brussels (Belgium)

J.H. Byrne
General Foods Europe
Astro Tower
Avenue de l'Astronomie
Brussels (Belgium)

EUROPEAN SECRETARIAT OF MANUFACTURERS OF LIGHT METAL PACKAGES (SEFEL)
SECRETARIAT EUROPEEN DES FABRICANTS D'EMBALLAGES METALLIQUES LEGERS (SEFEL)

Dr. C.J.H. Wevers
Thomassen en Drijver - Verblifa
Deventer (The Netherlands)

FEDERATION INTERNATIONALE DES INDUSTRIES ET DU COMMERCE EN GROS DES VINS, SPIRITUEUX, EAUX-DE-VIE ET LIQUEURS (F.I.V.S.)

Dr. S. Valvassori
F.I.V.S.
Via San Secondo 67
10128 Torino (Italy)

INSTITUT EUROPEEN DES INDUSTRIES DE LA GOMME DE CAROUBE (INEC)

Dr. E. Nittner
Meyhall Chemical AG
Sonnenwiesenstrasse 18
CH-8280 Kreuzlingen (Switzerland)

INTERNATIONAL ASSOCIATION FOR CEREAL CHEMISTRY (ICC)
ASSOCIATION INTERNATIONALE DE CHIMIE CEREALIERE (ICC)

Dr. D.F. Anderson
Technical Director
Quality Control
General Miils
Minneapolis (U.S.A.)

INTERNATIONAL ATOMIC ENERGY AGENCY (IAEA)
AGENCE INTERNATIONALE DE L'ENERGIE ATOMIQUE (AIEA)

Dr. K. Vas
Director
Central Food Research Institute
Herman Otto út IS
H-1525 Budapest (Hungary)

INTERNATIONAL FEDERATION OF GLUCOSE INDUSTRIES (IFG)
FEDERATION INTERNATIONALE DES INDUSTRIES DE GLUCOSE (FIG)

E.G. Rapp
Avenue Ernest Claes 4
B-1980 Tervueren (Belgium)

INTERNATIONAL GLUTAMATE TECHNICAL COMMITTEE (IGTC)

Dr. A.G. Ebert
IGTC
P.O. Box 744
Westwood, Ma 02090 (U.S.A.)

INTERNATIONAL ORGANIZATION OF THE FLAVOUR INDUSTRY (IOFl)
ORGANISATION INTERNATIONALE DE L'INDUSTRIE DES PRODUITS AROMATIQUES (IOFl)

Dr. F. Grundschooer
Scientific Advisor of IOFl
8 Rue Charles-Humpert
CH-1205 Geneva (Switzerland)

Dr. J. Stofberg
PFV, Inc.
Chairman of the Committee of Experts of IOFl
33 Sprague Avenue
Middletown, NY 10940 (U.S.A.)

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)
ORGANISATION INTERNATIONALE DE NORMALISATION (ISO)

W.G. de Ruig
Government Dairy Station
Vreewijkstraat 12 B
Leiden (The Netherlands)

INTERNATIONAL PECTIN PRODUCERS ASSOCIATION (IPPA)
UNION INTERNATIONALE DES PRODUCTEURS DE PECTINE (UIPP)

A. Overeem
Director General
Institut Européen des Industries de la Pectine
P.O. Box 61138
2555 HA The Hague (The Netherlands)

Prof. Dr. W. Pilnik
Chairman of the IPPA
c/o Agricultural University
Dept. of Food Science
De Dreijen 12
6703 BC Wageningen The Netherlands)

INTERNATIONAL TECHNICAL CARAMEL ASSOCIATION (ITCA)

Dr. A.W. Noites
195 Khightsbridge (2nd Floor)
London SW7 IRQ (U.K.)

ASSOCIATION MONDIALE DES INDUSTRIES DE TRAITEMENT DES ALGUES MARINES (MARINALG INTERNATIONAL)

J. Dugoujon
President Marinalg International
World Assoc, of Seaweed Processors
46, Rue Jacques Dulud
92202 Neuilly sur Seine (France)

ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD)
ORGANISATION DE COOPERATION ET DE DEVELOPPEMENT ECONOMIQUES (OCDE)

Dr. P.S. Elias
Project Director
International Project in the
Field of Food Irradiation
c/o. Institut für Strahlentechnologie
Postfach 3540
7500 Karlsruhe (Fed. Rep. of Germany)

ORGANIZATION OF MANUFACTURERS OF CELLULOSE PRODUCTS FOR FOODSTUFFS IN THE EEC (OFCA)
ORGANISATION DES FABRICANTS DE PRODUITS CELLULOSIQUES ALIMENTAIRES DE LA CEE (OFCA)

Ir. G.J.J. Nijhoff
Secretary
Organization of Manufacturers of
Cellulose Products for Foodstuffs
in the EEC (OFCA)
12, winselingseweg
P.O. Box 31
6500 AA Nijmegen (The Netherlands)

<u>JOINT SECRETARIAT</u>
<u>SECRETARIAT MIXTE</u>
<u>SECRETARIA CONJUNTA</u>

FAO

Dr. L.G, Ladomery
Food Standards officer
Joint FAO/WHO Food Standards Programme
FAO, 00100 Rome,(Italy)

J.M. Hutchinson
Food Standards Officer
Joint FAO/WHO Food Standards Programme
FAO, 00100 Rome (Italy)

Dr. G.D. Kouthon
Nutrition Officer
Food Control and Consumer Protection Group
Food Standards & Food Science Service
Food Policy and Nutrition Division
FAO, 00100 Rome (Italy)

WHO
OMS

Dr. G. Vettorazzi
Scientist
Environmental Health criteria
and Standards (Food Safety)
WHO, 1211 Geneva (Switzerland)

TECHNICAL SECRETARIAT
SECRETARIAT TECHNIQUE
SECRETARIA TECNICA

Dr. W. Rozenboom
Secretary Toxicological Committee
Health Council of the Netherlands
P.O. Box 4 Rijswijk (The Netherlands)

Drs. K. de Jong
Unilever Research Laboratorium
Olivier van Noortlaan 120
Vlaardingen (The Netherlands)

Dr. R.W. Stephens
Shell International Petroleum Co. Ltd.
Toxicology Division TOX/41
Shell Centre
London SEI 7NA (U.K.)

Dr. A. Ruiter
Lecturer in Food Chemistry
Faculty of Veterinary Medicine
University of Utrecht
Institute for Foods of Animal Origin
Biltstraat 172
3572 BP Utrecht (The Netherlands)

Ir. R. Top
Ministry of Agriculture and Fisheries
P.O. Box 20401
2500 EK The Hague (The Netherlands)

APPENDIX II - PART I

## ENDORSEMENT OF MAXIMUM LEVELS OF FOOD ADDITIVES IN CODEX COMMODITY STANDARDS

This Appendix summarizes all provisions which were considered by the Codex Committee on Food Additives at its 12th session.

Abbreviations Used

| | | |
|---|---|---|
| E | = | Endorsed |
| EP | = | Endorsement postponed for reasons given in the footnotes |
| TE | = | Temporarily endorsed |
| Limited by GMP | = | Limited by Good Manufacturing Practice |

Contents



A. Bouillons and Consommes (see ALINORM 78/9, App. II and III, paras 17-20)

| | Maximum Level (on ready-to-eat basis) | Paragraph | Status of Endorsement |
|---|---|---|---|
| 1. Acids, Bases and Salts | | | |
| Acetic acid and its potassium and sodium salts | Limited by GMP | | |
| Citric acid and its potassium and sodium salts | | | |
| dl-Lactic acid and its potassium and sodium salts | | | |
| L(+) artaric acid and its potassium and sodium salts | 250 mg/kg | | |
| Monophosphate, potassium and sodium | 1000 mg/kg (sum of phosphates, expressed as $P_2O_5$) | 46 | E |
| Diphosphate, potassium and sodium | | | |

| | | | | |
|---|---|---|---|---|
| | Triphosphate, potassium and sodium | | | |
| | Polyphosphates, potassium and sodium | | | |
| 2. | Anti-caking Agents (in dehydrated products only) | | | |
| | Silicon dioxide, amorphous<br>Stearate, aluminium, calcium and magnesium<br>Calcium phosphate | 15 g/kg on dry matter, singly or in combination | | E |
| 3. | Anti-foaming Agents | | | |
| | Dimethylpolysiloxane | 10 mg/kg | | E |
| 4. | Antioxidants and Antioxidant Synergists | | | |
| | L-Ascorbic acid | | | E |
| | L-Ascorbate, calcium | 1000 mg/kg, singly or in combination | 47 | E [2] |
| | L-Ascorbate, sodium | | | E |
| | L-Ascorbate, potassium | | | E |
| | alpha-Tocopherol<br>Tocopherols mixed concentrate | 50 mg/kg, singly or in combination | | E |
| 5. | Colours | | | |
| | Annatto extracts (CI Natural Orange 4) | 150 mg/kg | | TE |
| | Canthaxanthine (xanthophyll) | 30 mg/kg | | E |
| | Caramel colour (made *ay* ammonium sulphite process) | 3000 mg/kg | | TE |
| | Caramel colour (not made by ammonia process) | Limited by GMP | | E |
| | beta-apo-8'-Carotenal | 200 mg/kg, singly or in combination | 47, 48, 49 | E |
| | beta-apo-8'-Carotenoic acid, methyl and ethyl esters | | | E |
| | beta-Carotene | | | E |
| | Chlorophyll | Limited by GMP | | EP [1] |
| | Curcumin | 50 mg/kg | | TE |
| | Riboflavine | 200 mg/kg | | E |
| 6. | Emulsifiers, Stabilizers, Thickening agents | | | |
| | Agar | Limited by GMP | | E |
| | Alginates, potassium and sodium | 3000 mg/kg | | E |
| | Cellulose, sodium carboxymethyl (Syn.: cellulose gum) | 4000 mg/kg | | E |
| | Carrageenan (including Furcellaran) | 5000 mg/kg | 52 | E |
| | Lecithin | Limited by GMP | | E |
| | Mono- and diglycerides of fatty acids | Limited by GMP | | E |
| | Modified starches: | Limited by GMP | | E |

| | | | |
|---|---|---|---|
| Monostarch phosphate<br>Distarch phosphate<br>Phosphated distarch phosphate<br>Acetylated distarch phosphate<br>Acetylated distarch adipate<br>Starch acetate<br>Hydroxypropyl starch<br>White or Yellow Dextrins, Roasted starches<br>Acid-treated starches<br>Bleached starches<br>Enzyme-treated starches<br>Oxidized starches | | | |
| Pectin (not amidated) | | 53 | E [3] |
| Carob bean gum | | | TE |
| Guar gum | | | E |
| Xan than gum | 3000 mg/kg | 54 | E |

[1/] Pending clarification of the type of chlorophyll used.
[2/] Referred to the JECFA for consideration.
[3/] Amidated pectin was not endorsed, pending proposal for a maximum level.

Maximum Level

| | Maximum Level (on ready-to-eat basis) | Paragraph | Status of Endorsement |
|---|---|---|---|
| 7. Flavour Enhancers | | | |
| L-Glutamic acid and calcium, potassium and sodium salts | 10 g/kg, singly or in combination | | E |
| L-Glutamate, magnesium | | | EP [1] |
| Inosinic acid and sodium and potassium salts | Limited by GMP | 59 | E |
| Guanylic acid and sodium and potassium salts | | | E |
| 8. Flavours | | 55, 56 | |
| Natural flavours and flavouring substances and nature-identical flavouring substances as defined for the purpose of the Codex Alimentarius (see Codex Guide to the Safe Use of Food Additives, (CAC/FAL 5-1979) | | | TE |
| Artificial flavouring substances as defined for the purpose of the Codex Alimentarius and included in List A (see Codex Guide to the Safe Use of Food Additives, (CAC/FAL 5-1979) | | | |
| Cysteine | 100 mg/kg | | EP [2] |
| 9. Preservatives | | 60 | |

| | | | |
|---|---|---|---|
| In products containing ingredients which have been treated with sulphur dioxide or other sulphurizing substances the residual amount in the ready-to-eat product shall not exceed 20 mg/litre | | | E |
| Carry-over | | 60 | |
| Section 3 of the "Principle Relating to the Carry-over of Additives into Foods" (see Guide to the Safe Use of Food Additives, CAC/FAL 5-1979) shall apply | | | E |

[1] Pending evaluation by the JECFA (see para 58).
[2] Pending consideration by the JECFA (see para 57).

B. Edible Ices and Ice Mixes (see ALINORM 78/11, Appendix II, CL 1977/23 and CL 1977/38) (Standard at Step 8 - retained)

| | Colour Index No. | Maximum Level in the final product | Paragraph | Status of Endorsement |
|---|---|---|---|---|
| 1. Colours [3] | | | | |
| Black | | | | |
| Brilliant Black PN | 28440 | 100 mg/kg, singly or 300 mg/kg in combination | | E |
| Blue | | | | |
| Brilliant Blue FCF | 42090 | | | E |
| Indigotine | 73015 | | | E |
| Green | | | | |
| Chlorophyll | 75810 | | | EP [1] |
| Chlorophyll copper complex | 75810 | | 62 | E |
| Chlorophyllin copper complex | 75810 | | | E |
| Fast Green FCF | 42053 | | | E |
| Red | | | | |
| Amaranth | 16185 | | | EP [2] |
| Azorubine (Carmoisine) | 14720 | | | TE |
| Beet Red | | | | TE |
| Brythrosine | 45430 | | | E |
| Ponceau 4R | 16255 | | | EP [2] |
| Yellow, orange | | | 67 | |
| Annatto extracts | 75120 | | | TE |
| alpha-Carotene | | | | EP [1] |
| beta-Carotene | | | | E |
| gamma-Carotene | | | | EP [1] |
| beta-apo-8'-Carotenal | | | | E |

| | | | | |
|---|---|---|---|---|
| beta-apo-8'-Carotenoic acid, ethyl ester of | | | | |
| Canthaxanthine | | | | E |
| Curcumin | | | | EP [2] |
| Riboflavin (Lactoflavin) | | | | EP [2] |
| Quinoline Yellow | 47005 | | | EP [2] |
| Sunset Yellow FCF | 15985 | | | E |
| Tartrazine | 19140 | | | E |
| Brown | | | | |
| Caramel colour (not made by the ammonia process) | | Limited by GMP | | E |
| Caramel colour (made by the ammonium sulphite process) | | 3 g/kg | 66 | TE |

[1] Pending the establishment of specifications of identity and purity and/or evaluation by the JECFA.
[2] Maximum level, singly or in combination, requires reconsideration by the commodity committee (see para 63).
[3] See paras 63-65.

2. Emulsifiers, Stabilizers and Thickening agents

| | | | |
|---|---|---|---|
| Agar | 10 g/kg, singly or in combination | | E |
| Alginic acid and its sodium, potassium and calcium salts | | | E |
| Alginate, propylene glycol | | | E |
| Alginate, ammonium | | | E |
| Cellulose, hydroxypropylmethyl | | | E |
| Cellulose, methyl | | 68 | E |
| Cellulose, methylethyl | | | E |
| Cellulose, microcrystalline | | | E |
| Carboxymethylcellulose and its sodium and potassium salts | | | E |
| Glycerol mono- and di-esters of fatty acids derived from edible fats | | | E |
| Mono- and di-glycerides: | | 68 | E |
| a acetic acid esters of | | | E |
| b) citric acid esters of | | | E |
| c) lactic acid esters of | | | E |
| d) L-tartaric acid esters of | | | |
| e) diacetyl-tartaric acid esters of | | | |
| Carrageenan (incl. Furcellaran) | | | E |
| Gum arabic | | | |
| Gum carobah (locust bean Gum) | | | TE |
| Gum guar | | | E |
| Gum xanthan | | | E |
| Pectin (amidated) | | | E |
| Pectin (not amidated) | | | E |
| Polyglycerol esters of fatty acids | | | E |

| | | | |
|---|---|---|---|
| Polyoxyethylene (20) orbitan monostearate | | | E |
| Polyoxyethylene (20) orbitan mono-oleate | | | *E* |
| Polyoxyethylene (20) orbitan tristearate | | | E |
| Sucrose esters of fatty acids and sucroglycerides | | | TE |
| 3. <u>Modified Starches</u><br>a) acid-treated starches<br>b) alkali-treated starches<br>c) bleached starches<br>d) dextrins, white and yellow<br>e) distarch adipate, acetylated<br>f) distarch glycerol<br>g) distarch glycerol, acetylated<br>h) distarch glycerol, hydroxypropyl<br>i) distarch phosphate<br>j) distarch phosphate, hydroxypropyl<br>k) distarch phosphate, phosphated<br>l) distarch phosphate, acetylated<br>m) enzyme-treated starches<br>n) monostarch phosphate<br>o) oxidized starch<br>p) starch acetate<br>q) starch, hydroxypropyl | 30 g/kg, singly or in combination | 69 | E |
| 4. <u>Flavours</u> | | 55, 70 | |
| Natural flavours and flavouring substances and nature-identical flavouring substances as defined for the purpose of the Codex Alimentarius (see Codex Guide to the Safe Use of Food Additives, (CAC/FAL 5-1979) | | | TE |
| Artificial flavouring substances as defined for the purpose of the Codex Alimentarius and included in List A (see Codex Guide to the Safe Use of Food Additives, (CAC/FAL 5-1979) | | | |

| | Maximum Level in the final product | Paragraph | Status of Endorsement |
|---|---|---|---|
| 5. Acids, Bases and Salts | | | |
| Acetic acid | | 71 | E |
| L-Ascorbic acid | | | EP 1 |
| Citric acid and its sodium, potassium and calcium salts | | | E |
| dl-Lactic acid and its sodium, potassium and calcium salts | Limited by GMP | | E |
| L-Lactic acid | | 72 | EP [2] |
| dl-Malic acid | | | E |
| L-Malic acid | | 72 | EP [2] |
| Sodium, potassium and calcium orthophosphates | 2 g/kg, singly or in combination, expressed as $P_2O_5$ | | E |
| Sodium and potassium poly-phosphates | | | E |
| Sodium hydrogen carbonate | Limited by GMP | | E |
| L(+) artaric acid and its sodium and potassium salts | Limited by GMP | 73 | EP [3] |
| 6. Miscellaneous | | | |
| Glycerol | 50 g/kg, singly or in combination | | E |
| Sorbitol | | | TE |
| Saccharin and its sodium and calcium salts | Limited by GMP | 74 | EP [3] |

C. Revised General Standard for Edible Pats and oils not Covered by Individual Codex Standards (Step 6)

(ALINORM 78/17, Appendix II (CAC/RS 19-1969), paras 34-38)

| Antioxidants | Maximum Level | Paragraph | Status of Endorsement |
|---|---|---|---|
| tert-butylhydroquinone (TBHQ) | 200 mg/kg, singly or in combination with BHT and/or BHA | 77 | E |
| Ascorbyl palmitate<br>Ascorbyl stearate | 500 mg/kg, singly or in combination | | |

D. Reduced Fat Margarine (Step 6)
(ALINORM 78/17, App. III, para 60)

| | | | |
|---|---|---|---|
| 1. Colours (See ALINORM 78/12, paras 57-58) | | | |
| beta-Carotene | 25 mg/kg | 78 | E |
| Annatto extracts | 20 mg/kg, singly or in combination, calculated as total bixin or norbixin | | E |
| Bixin and norbixin | | | EP [4] |

| | | | |
|---|---|---|---|
| Turmeric or curcumin (CI 75300) | 5 mg/kg, singly or in combination, calculated as total curcumin | | TE |

1/ Pending clarfication of use and the establishment of a maximum level by the Commodity committee.
2/ Peding the establishment of specifications of identity and purity by the JECFA.
3/ Peding the establishment of maximum level by the commidity committee.
4/ Peding evaluation by the JECFA.

2. Emulsifiers

| | Maximum Level | Paragraph | Status of Endorsement |
|---|---|---|---|
| 2. Emulsifiers (see ALINORM 78/12, para 59) | | | |
| Polyglycerol esters of fatty-acids<br>Polyglycerol esters of inter-esterified ricinoleic acid | 10 g/kg, singly or in combination with esters of fatty acids with polyalcohols other than glycerol | | E |
| 3. Thickening Agents (see ALINORM 78/12, para 60) | | | |
| Tragacanth gum | 10 g/kg, singly or in combination with other thickening agents | 79 | EP [1] |
| 4. Antioxidant Synergist (see ALINORM 78/12, para 61) | | | |
| Calcium disodium salt of EDTA | 100 mg/kg | 80 | E |
| E. Edible Low Erucic Acid Rapeseed Oil (Step 6) (see ALINORM 78/17, Appendix IV, paras 68, 34) | | | |
| Antioxidants | | | |
| tert-butylhydroguinone (TBHQ) | 200 mg/kg, singly or in combination with BHT and/or BHA | 81 | E |
| Crystallization inhibitor | | | |
| Oxystearin | 1250 mg/kg | | |
| F. Canned Mackerel and Jack Mackerel (Step 6) (see ALINORM 78/18A, Appendix III, paras 43-44) | | | |
| Xanthan gum | 10 g/kg (20 g/kg total thickening or jellifying agents in the packing medium) | 82 | E |

At its 13th session (May 1979)

| | | | |
|---|---|---|---|
| the Codex Committee on Fish and Fishery Products will draw up a list of specified modified starches for use in the packing medium of the product. | | | |
| G. Canned Sardines and Sardine-type Products (Step 9) (see ALINORM 78/18A, Appendix IV) | | | |
| Pectin (amidated and not amidated) | 2.5 g/kg singly or 10 g/kg in combination (20 g/kg total thickening or jellifying agents in the packing medium) | | E [2] |
| Xanthan gum | | 83 | E |

[1/] Pending toxicological evaluation by the JECFA.
[2/] Amidated Dectin TE.

| | Status of Endorsement |
|---|---|
| H. Quick Frozen French Fried Potatoes (Step 6) [1] (See ALINORM 78/25, Appendix VIII, paras 100-101) | |
| I. General Standard for Cheese - Revised (Step 7) (see CX 5/70-19th Session, Appendix II, paras 18-20) | |
| 3.1 Flavouring substances (para 82) For cheese for which there is an international individual or group standard only those additions permitted in the individual or group standard may be used. Natural flavouring substances not derived from milk such as spices, may be added in such quantity that they can be considered only as flavouring substances, provided that such substances are not intended to take the place of any milk constituent and provided that the cheese remains the major constituent. | E |
| 3.2 Other additions (para 82) For cheese for which there is no international individual or group standard only those additions may be used which are technologically necessary and which are permitted in an international individual or group standard for a similar type of cheese according to the characteristics classified in the Annex or, in the absence of a similar type of cheese, for the type of cheese nearest in character. | E |
| J. Extra Hard Grating cheese (Step 7)[1/] (see CX 5/70-19th Session, Appendix IV, paras 43-45) | |
| K. General Standard for Named Variety Process(ed) Cheese and spreadable Process(ed) Cheese - A-8(a) (step 7) (see CX 5/70-19th Session, Appendix III(A), paras 55-56) [1/] | |

L. General Standard for Process(ed) cheese and Spreadable Process(ed) Cheese - A-8(b) (Step 7) [1/]
(see CX 5/70-19th Session, Appendix III(B), -paras 55-56, 69, 72-73)

M. General Standard for Process(ed) cheese Preparation [1/]
(Process(ed) Cheese Food and Process(ed) Cheese Spread) - A-8(c)
(Step 7)
(see CX 5/70-19th Session, Appendix III(c), paras 55-56, 74)

APPENDIX II
PART II

## ENDORSEMENT OF MAXIMUM LEVELS FOR CONTAMINANTS IN CODEX COMMODITY STANDARDS

Contents



A. Bouillons and Consommes (retained at Step 8)
(see ALINORM 78/9, Appendix II, paras 21-25)

| Contaminants | Maximum Level | Paragraph | Status of Endorsement |
|---|---|---|---|
| Lead (Pb) in dry products as sold | 1 mg/kg | | |
| Lead (Pb) in canned products | 0.5 mg/kg | 88, 89, 90 | TE |
| Tin (Sn) | 150 mg/kg | | |

[1/] Consideration postponed to the next session, awaiting the publication of the official report of the Committee (see para 85 of this Report).

B. Revised General Standard for Edible Fats and Oils not Covered uy Individual Codex Standards (Step 6)
(see ALINORM 78/17, Appendix II (CAC/RS 19-1969) (paras 39-40)

The same contaminant provisions for the Revised standard as have already been endorsed (or temporarily endorsed) for the original standard. (see also CL 1978/23, Part a).

C. Natural Mineral Waters (Step 9)
(see ALINORM 78/19, Appendix II, paras 27, 31-33) »

Note: Pending the establishment of methods of analysis, the provisions for contaminants will remain provisional.

| | Maximum Level | Paragraph | Status of Endorsement |
|---|---|---|---|
| Total beta-activity (except $K^{40}$ and $H^3$) | not more than 1 p Ci/l [1] | 92 | E |
| Cyanide | not more than 0.01 mg/l (as CN) | 93 | E |
| Nitrite | not more than 0.005 mg/l (calculated as | 93 | E |

$NO_2$)

D. Fructose (Step 9)
(see ALINORM 78/27, Appendix II)

| | | |
|---|---|---|
| Lead (Pb) | not more than 2 mg/kg | EP [2] |

1/ 1 p Ci = 37 m Bg.
2/ The maximum level to be reconsidered by the Commodity committee (see para 94 of this report).

APPENDIX III

## DRAFT SPECIFICATIONS [STANDARD] FOR FOOD GRADE SALT [1/]

1/ See paras 130-135 of this report.

### 1. Description

Food grade salt is a product consisting predominantly of sodium chloride. It is obtained from the sea, from underground rock salt deposits or from natural brine. Salt from other origins - and notably the salt which is a by-product of chemical industries - is excluded.

### 2. Composition

2.1 The content of NaCl shall not be less than 97.0% on a dry matter basis, additives excluded.

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

### 3. Contaminants

3.1 Food grade salt may not contain contaminants in amounts and in such a form that may be harmful to the health of the consumer. [In particular the following maximum limits, expressed on a dry matter basis, shall not be exceeded]. [1/]

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

| | | |
|---|---|---|
| 3.2.1 | Arsenic | not more than *[*2 *]* mg/kg, expressed as As |
| 3.2.2 | Copper | not more than *[*2*]* mg/kg expressed as Cu |
| 3.2.3 | Lead | not more than *[*2*]* mg/kg expressed as Pb |
| 3.2.4 | Cadmium | not more than *[*2*]* mg/kg, expressed as Cd |
| 3.2.5 | Mercury | not more than *[*0.2*]* mg/kg, expressed as Hg |

### 4. Transport, packaging and Storage

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

### 5. Food Additives

5.1 All additives used shall be of food grade quality. Codex specifications of identity and purity apply whenever available. [Additives appearing on this list indicated by means of an asterisk have not yet been evaluated by the Joint FAO/WHO Expert Committee on Food Additives].

| | | | Maximum Level |
|---|---|---|---|
| 5.2 | Anticaking Agents | | |
| 5.2.1 | Dehydrated silica gel | $CaSiO_3$) | |
| 5.2.2 | Calcium carbonate | ($CaO_3$) | |
| 5.2.3 | Magnesium carbonate | ($MgCO_3$) | |
| 5.2.4 | Magnesium oxide | ($MgO.xH_2O$) | |
| 5.2.5 | Tricalcium orthophosphate | ($Ca_3$ ($PO_4$)2) | |
| 5.2.6 | Calcium silicate | ($MgSiO_3$) | 20 g/kg, singly or in combination |
| 5.2.7 | Magnesium silicate | | |
| 5.2.8 | Sodium silico-aluminate | | |
| 5.2.9 | Potassium silico-aluminate * | | |
| 5.2.10 | Aluminium stearate | (Al($C^{17}H_{35}$coo)3) | |
| 5.2.11 | Calcium stearate | (Ca($C^{17}H_{35}$coo)2) | |
| 5.2.12 | Magnesium stearate | (Mg($C^{17}H_{35}$coo)2) | |
| 5.3 | Crystallization Aids | | |
| 5.3.1 | Sodium hexacyanoferrate-II | ($Na_4Fe(CN)_6.1H_2O$) | 20 mg/kg, singly or in combination, expressed as $Fe(CN)_6$ |
| 5.3.2 | Potassium hexacyanoferrate-II | ($K_4Fe(CN_6.3H_2O$) | |
| 5.3.3 | Calcium hexacyanoferrate-II | (Ca2Fe($CN_6$ $H_2O$) | |
| 5.3.4 | Manganese hexacyanoferrate-II * | (Mn3[$Fe(CN)_6$]2 | |
| 5.3.5 | Magnesium hexacyanoferrate-II * | ($Mg_2Fe(CN)_6$ $H_2O$) | |
| 5.3.6 | Ferro-II-hexacyanomanganate-II* | ($Fe_3$[$Mn(CN)_6$]$^2$ | |

6. Other Requirements

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

7. Labelling

To be elaborated, if it is decided that a "standard" rather than "specifications" will be drawn up.

8. Methods of Analysis and Sampling To be elaborated.

APPENDIX IV

# PROPOSED LIST OF PROCESSING AID CATEGORIES

## Report of an ad hoc Working Group (see paras 116-118)

### Introduction

There are certain compounds used during food processing which are removed during a later step and, therefore, do not become part of the finished product. The Working Group requested the advice of the Codex Committee on food Additives as to whether these should be listed as processing aids. Examples include EDTA, oxalic acid and citric; acid used as sequestrants in crude oil, which are removed during subsequent processing of the oil. The Working Group felt that this situation was clearly not covered by the definition of "processing aids".

Another problem area was the category of boiler water additives, where the additive itself only becomes part of the food by accident and should, therefore, be considered a "contaminant".

There are also problems with processing aids and other additives in drinking water which should be considered by the appropriate Committee. In the opinion of the Working Group these were not under the purvue of this Committee. It was noted that there were a number of substances which had a dual function, i.e. both as processing aids and/direct food additives (e.g. pH modifiers). The Working Group recommended that this fact be noted in the list as a guidance for the users of the list.

### List

A. Clarifying agents
B. Enzyme preparations (including immooilized enzymes)
C. Extraction solvents
D. Filtration agents (including gel-filtration media)
E. Catalysts
F. Flocculating agents
G. Propellants and packaging gases
H. Washing and peeling aids; vegetable cleaning agents
I. Contact freezing and cooling agents
J. Ion-exchange resins and membranes; molecular sieve resins
K. Desiccating agents
L. Lubricants; release agents; anti-stick agents; moulding aids.

APPENDIX V

## PRIORITY LIST OF ARTIFICIAL FLAVOURING SUBSTANCES [1/]

[1/] The numbering follows that in List B (Appendix VIII). NB. See also Appendix VI.

| | | |
|---|---|---|
| * | 8.11 | Allyl cyclohexylpropionate |
| * | 8.15 | Allyl hexanoate |
| * | 8.17 | Allyl alpha-ionone |
| | 8.20 | Allyl tiglate |
| * | 8.23 | alpha-Amylcinnamaldehyde dimethyl acetal |
| * | 8.24 | alpha-Amylcinnamaldehyde |
| * | 8.26 | alpha-Amylcinnamyl alcohol |
| * | 8.30 | Anisylacetone |
| * | 8.35 | Benzyl butyl ether |
| * | 8.38 | Benzyl isobutyl carbinol |
| * | 8.40 | Benzyl isoeugenol |
| * | 8.46 | Butyl butyryllactate |
| * | 8.65 | Dibenzyl ether |
| * | 8.68 | Dibutyl sebacate |
| * | 8.80 | 2,6-Dimethyl-5-heptenal |
| * | 8.91 | 7-Ethoxy-4-methyl-coumarine |
| * | 8.111 | Ethyl phenylglycidate |
| * | 8.126 | Geranyl acetoacetate |
| * | 8.131 | alpha-Hexylcinnamaldehyde |
| * | 8.133 | Hydroxycitronellal |
| * | 8.135 | Hydroxycitronellal dimethyl acetal |
| * | 8.136 | Hydroxycitronellol |
| * | 8.151 | Iso-alpha-methylionone |
| * | 8.155 | Isoquinoline |
| | 8.167 | Methoxypyrazine |
| * | 8.171 | alpha-Methylcinnamaldehyde |
| * | 8.172 | 6-Methylcoumarin |
| | 8.177 | 2-Methyl-3,5 or 6-furfuryl-thiopyrazine |
| | 8.187 | Methyl-beta-ionone |
| | 8.193 | 2-Methyl-3,5 or 6-methylthio-pyrazine |
| * | 8.194 | 2-Methyloctanal |
| * | 8.195 | Methyl octine carbonate |
| * | 8.201 | *2*-(2-Methylpropyl) yridine |
| | 8.202 | 3-(2-Methylpropyl) yridine |
| * | 8.218 | beta-Naphthyl ethylether |
| | 8.219 | beta-Naphthyl methyl ketone |
| * | 8.231 | Phenoxyethyl isobutyrate |
| * | 8.240 | 2-Phenyl-l-propanol |
| * | 8.241 | 2-Phenylpropanal dimethyl acetal |
| * | 8.249 | Piperonyl acetate |
| * | 8.252 | Propenylguaethol |
| * | 8.253 | p-Propyl anisole |
| * | 8.260 | Pyrazine ethanethiol |
| | 8.261 | Pyrazine methanethiol |
| | 8.262 | Pyrazinyl methyl sulphide |
| * | 8.264 | Resorcinol dimethyl ether |

* 8.268 Tetrahydrolinaloöl
* 8.278 10-Undecenal
8.279 Vanillin acetate

* Data sheets are available containing specification data; some also contain toxicological data.

APPENDIX VI

## CODEX PRIORITY LIST OF FOOD ADDITIVES

(See paras 136-138)

### Current

* Magnesium glutamate
* Calcium ascorbate
* Chlorophyll (natural Mg complex) 1,2-Dichloroethane
Isomaltitol
Modified polydextrose
Hydrogenated glucose syrup

### Emulsifiers

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

### Enzyme Preparations

Microbial rennet (Bacillus cereus)
Microbial rennet (Irpex lacteus)
Ficin
Microbial catalase (Micrococcus lysodeilcticus)
Microbial glucose oxidase (Pénicillium amagasakiense)
Microbial glucose isomerase (Actinoplanes missouriensis)
Microbial glucose isomerase (Arthrobacter globiformis)
Microbial glucose isomerase (Streptomyces olivochromogenes)
Microbial glucose isomerase (Streptomyces ruoiginosus)
Microbial glucose isomerase (Streptomyces albus)

### Colour

Riboflavine 5'-phosphate

* Evaluation is required since these additives are included in Codex commodity standards adopted by the Commission and sent to governments for acceptance.

APPENDIX VII

# SPECIFICATIONS OF IDENTITY AND PURITY OF FOOD ADDITIVES

(Submitted to the Commission at Step 5 of the Codex Procedure for the Elaboration of Specificatins) [1/]

| | | Reference [2] |
|---|---|---|
| 1. | **Acids** | |
| 1.1 | Acetic acid, glacial | (1) |
| 1.2 | Adipic acid | (1) |
| 1.3 | dl-Malic acid | (1) |
| 1.4 | L (+) artaric acid | (3) |
| 2. | **Antioxidants** | |
| 2.1 | tert-Butylhydroquinone | (3) |
| 2.2 | Mixed tocopherols concentrate | (3) |
| 3. | **Bases** | |
| 3.1 | calcium hydroxide | (1) |
| 3.2 | Calcium oxide | (1) |
| 3.3 | Magnesium hydroxide | (1) |
| 3.4 | Potassium carbonate | (1) |
| 3.5 | Potassium hydroxide | (1) |
| 3.6 | Sodium carbonate | (1) |
| 3.7 | Sodium hydroxide | (1) |
| 4. | **Buffers, Leavening Agents, Sequestrants** | |
| 4.1 | Ammonium carbonate | (1) |
| 4.2 | Calcium citrate | (1) |
| 4.3 | Dipotassium hydrogen phosphate | (1) |
| 4.4 | Disodium hydrogen phosphate | (1) |
| 4.5 | Potassium dihydrogen phosphate | (1) |
| 4.6 | Potassium hydrogen carbonate | (1) |
| 4.7 | Potassium phosphate | (1) |
| 4.8 | Sodium hydrogen carbonate | (1) |
| 4.9 | Sodium phosphate | (1) |
| 4.10 | Tripotassium citrate | (1) |
| 4.11 | Trisodium citrate | (1) |
| 5. | **Firming and Texturizing Agents** | |
| 5.1 | Calcium chloride | (1) |
| 5.2 | Powdered cellulose | (2) |
| 6. | **Flour and Dough Conditioning Agents** | |
| 6.1 | Azodicarbonamide | (1) |
| 6.2 | Benzoyl peroxide | (1) |
| 6.3 | Calcium hydrogen phosphate | (1) |
| 6.4 | Calcium sulphate | (1) |
| 6.5 | Potassium bromate | (1) |
| 7. | **Food Colours** | |
| 7.1 | Aluminium powder | |
| 7.2 | Titanium dioxide | (3) |

8. Preservatives

| | | |
|---|---|---|
| 8.1 | Calcium hydrogen sulphite | (2) |
| 8.2 | Pimaricin | (2) |
| 8.3 | Sorbic acid | (2 |

9. Solvents

| | | |
|---|---|---|
| 9.1 | Glycerol | |
| 9.2 | Glycerol diacetate | (2) |

[1/] See paras 122-129 of this report.

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

References


(1) Specifications for the Identity and Purity of Some Acids, Bases, Buffers, Flour and Dough Conditioning Agents and Certain other Additives, FAO Nutrition Meetings Report Series No. 55B (or WHO/Food Add. 9).

(2) Specifications for the Identity and Purity of Some Food Additives, FAO Food and Nutrition Series No. IB (or WHO Food Add. 11),

(3) Specifications for the Identity and Purity of Some Antioxidants, Food Colours, Thickeners and Certain other Food Additives, FAO Nutrition Meetings Report Series No. 57.


APPENDIX VIII

## UP-DATED CODEX LIST B OF FOOD ADDITIVES

Introduction

Codex List B of Food Additives contains those substances, the evaluation of which by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), is pending or the temporary acceptable daily intake of which has been withdrawn by the JECFA.

During the 12th session of the Codex Committee on Food Additives the revised list published in December 1977 (document CX/FA 78/2) was up-dated, taking into account the evaluations of food additives made at the 21st and 22nd meetings of the JECFA, new information on flavouring substances that had been proved to be "nature-identical" and additions proposed during the meeting.

In List B the JECFA references are given in those cases where either the JECFA has evaluated analogous substances or where the JECFA has considered the substances without reaching conclusions concerning the acceptability of the additive.

The conclusions of the Committee in connection with List B are given in paras 108-lli of this report.

| | | JECFA Ref. |
|---|---|---|
| 1. | ACIDS, BASES, SALTS | |
| 1.1 | Acetate, ammonium | |
| 1.2 | Acetate, magnesium | (10), (41) |
| 1.3 | Adipate, calcium | |
| 1.4 | Adipate, magnesium | |
| 1.5 | Calcium hydrogen carbonate | (10) |
| 1.6 | chloride, ammonium | |
| 1.7 | chloride, magnesium | |
| 1.8 | Chloride, potassium | |
| 1.9 | Citrate, triammonium | |
| 1.10 | Citrate, magnesium | (10) |
| 1.11 | Citrate, sodium dihydrogen | |
| 1.12 | citrate, potassium dihydrogen | |
| 1.13 | Fumarate, calcium | |
| 1.14 | Fumarate, potassium | (33) |
| 1.15 | Fumarate, sodium | |
| 1.16 | Gluconate, magnesium | |
| 1.17 | Gluconate, potassium | (33) |
| 1.18 | Gluconate, sodium | |
| 1.19 | 1,4-Heptanolactone, calcium and sodium salts | |
| 1.20 | Lactate, magnesium | (30) |
| 1.21 | Magnesium hydrogen carbonate | (10) |
| 1.22 | dl-malate, calcium | |
| 1.23 | dl-malate, potassium | (16) |
| 1.24 | dl-malate, sodium , | |
| 1.25 | dl-malate, sodium hydrogen | |
| 1.26 | dihydrogen orthophosphate, ammonium (ammonium phosphate, (monobasic) | |
| 1.27 | hydrogen orthophosphate, diammonium (ammonium phosphate, dibasic) | (30) |
| 1.28 | hydrogen orthophosphate, magnesium (magnesium phosphate, dibasic) | |
| 1.29 | diphosphate, dicalcium (calcium pyrophosphate) | |
| 1.30 | diphosphate, tetrapotassium (potassium pyrophosphate) | |
| 1.31 | Phosphate, bone | |
| 1.32 | Sodium aluminium phosphate, acidic | |
| 1.33 | Sodium aluminium phosphate, basic | |
| 1.34 | Triphosphate, pentapotassium | |
| 1.35 | Polyphosphate, ammonium | (30) |
| 1.36 | Polyphosphate, calcium | |
| 1.37 | Polyphosphate, potassium | |
| 1.38 | Phytate, calcium | |

| | | |
|---|---|---|
| 1.39 | Succinic acid | |
| 1.40 | Succinate, ammonium | |
| 1.41 | Succinate, calcium | |
| 1.42 | Succinate, magnesium | |
| 1.43 | Succinate, potassium | |
| 1.44 | Sulphate, aluminium | (32) |
| 1.45 | Sulphate, aluminium-ammonium | |
| 1.46 | Sulphate, aluminium-potassium | (32) |
| 1.47 | Sulphate, ammonium, potassium and sodium | |
| 1.48 | Sulphate, hydrogen, potassium and sodium | |
| 1.49 | Sulphuric acid | |
| 1.50 | L(+) Tartrate, ammonium | (35) |
| 1.51 | L(+) Tartrate, calcium | |
| 1.52 | L(+) Tartrate, magnesium | |
| 1.53 | Sesquicarbonate, sodium ($Na_2$-$CO^3$.$NaHCO_3$.$2H_2O$) | |
| 1.54 | dl-Tartaric acid and its salts | (41) |
| 2. | ANTIOXIDANTS | |
| 2.1 | 4-Hydroxymethyl-2,6-di-tert-butylphenol | |
| 2.2 | Calcium ascorbate | (29) |
| 3. | CARRIER SOLVENTS | |
| 3.1 | Benzyl alcohol | |
| 3.2 | Butane-1,3-diol | |
| 3.3 | Castor oil | (38) |
| 3.4 | Diethylene glycol | |
| 3.5 | Diethylene glycol monoethyl ether | |
| 3.6 | Diethylene glycol monopropyl ether | |
| 3.7 | Diethyl tartrate | |
| 3.8 | Dipropylene glycol | |
| 3.9 | Glycerol monoacetate | (35), (38) |
| 3.10 | Hexylene glycol | |
| 3.11 | Isopropyl myristate | |
| 3.12 | Paraffins (not defined) | |
| 3.13 | Polyethylene glycol | |
| 3.14 | 1,2-Propylene glycol acetates | |
| 3.15 | Triethyl citrate | |
| 3.16 | synthetic triglycerides | [1] |
| 4. | COLOURS | |
| 4.1 | Alkanet | 41 [2] |
| 4.2 | Alkanin | 41 [2] |
| 4.3 | Allura Red | 32, (41) |
| 4.4 | Anthocyanins (incl. anthocyanine) | 41 |
| 4.5 | Black 7984 | 41 |
| 4.6 | Brown FK | 41 |
| 4.7 | Capsanthine | 41 [2] |
| 4.8 | Capsorubine | 41 [2] |
| 4.9 | Carotene (natural) | 32 |
| 4.10 | Carthamus (yellow and red) | (41) |
| 4.11 | Caramel colour (ammonia process) | 41 |

| | | |
|---|---|---|
| 4.12 | Chrysoine | 41 |
| 4.13 | Cochineal, carminic acid and carmine | 32, (41) |
| 4.14 | Past Red E | 41 |
| 4.15 | Fast Yellow AB | 41 |
| 4.16 | Green S | 32 |
| 4.17 | Indanthrene Blue | 32 |
| 4.18 | Lithol Rubine BE | 41 |
| 4.19 | Lycopene | 32, (41) |
| 4.20 | | |
| 4.21 | Orange RN | (32), (38), (41) |
| 4.22 | Orange G | 32 |
| 4.23 | Orange GGN | 32, (41) |
| 4.24 | Patent Blue V | 32 |
| 4.25 | Ponceau 6R | 32, (41) |
| 4.26 | Quercetin and quercitron | 41 |
| 4.27 | Saffron | 41 |
| 4.28 | Scarlet GN | (41) |
| 4.29 | Silver | 41 |
| 4.30 | Ultramarines | 41 |
| 4.31 | Xanthophylls | 41 |

[1/] See para 105, SEINORM 78/12.
[2/] JECFA has expressed doubts concerning the availability and use of these substances as food additives.

| | | JECFA Ref. |
|---|---|---|
| 5. | EMULSIFIERS AND STABILIZERS | |
| 5.1 | Ethyl cellulose | 30 |
| 5.2 | Sorbitan monolaurate | 30 |
| 5.3 | Sorbitan monoöleate | 30 |
| 5.4 | Starch aluminium octenyl succinate | |
| 5.5 | Starch sodium octenyl succinate | |
| 5.6 | Starch sodium succinate | |
| 5.7 | Oxidized hydroxypropyl distarch glycerol | (38) |
| 5.8 | Benzoin gum | (41) |
| 5.9 | Gum ghatti | |
| 5.10 | Karaya gum | (41) |
| 5.11 | Oat gum | (41) |
| 5.12 | Ouillaia extract | |
| 5.13 | Tragacanth gum | 41 |
| 5.14 | Bleached lecithins | 30 |
| 5.15 | Hydroxylated lecithin | 41 |
| 5.16 | Esters of glycerol and thermally oxidized soybean fatty acids | 38 |
| 5.17 | Stearoyl propylene glycol hydrogen succinate | |
| 5.18 | Stearoyl monoglyceridyl citrate | |
| 5.19 | Succinylated monoglycerides | (30) |
| 5.20 | Sodiunt carboxymethyl distarch glycerol | |
| 5.21 | Dioctyl sodium sulphosuccinate | (45) |
| 6. | ENZYMES | |
| 6.1 | Ficin | |
| 6.2 | Catalase (Aspergillus niger varieties) | |
| 6.3 | Carbohydrase (Aspergillus oryzae varieties) | |

6.4 Protease (Aspergillus oryzae varieties)
6.5 Microbial rennet (Bacillus cereus)
6.6 catalase (Micrococcus lysodeikticus)
6.7 Microbial rennet (Irpex lacteus)
6.8 Microbial glucose oxidase (Penicillium amagasakiense)
6.9 Microbial carbohydrase *(*Arthrobacter)
6.10 Microbial carbohydrase (Aspergillus awamori) [1]

7. EXTRACTION SOLVENTS

7.1 Benzene
7.2 Butane
7.3 Butan-1-ol
7.4 Butan-2-ol
7.5 cyclohexane
7.6 Chloroform
7.7 1,1,2-trichloro-trifluoroethane
7.8 1,2-dichlorotetrafluoroethane
7.9 Dichlorofluoromethane
7.10 1,1-Dichloroethane
7.11 Furfural
7.12 Diethyl ether
7.13 Di-isopropyl ether
7.14 Methyl ethyl ketone
7.15 Iso-butanol
7.16 Isopropyl acetate
7.17 Liquid carbon dioxide
7.18 Methylene chloride
7.19 Methylated spirit (industrial)
7.20 2-Nitropropane
7.21 Naphtha
7.22 Petroleum ether
7.23 Propane
7.24 n-Propanol
7.25 Toluene
7.26 1,1,1-Trichloroethane
7.27 Trichloroethylene (38)

1/ See para 108, ALINORM 78/12.

| 8. | FLAVOURS [1] | Council of Europe No. | FEM No. | JECFA Reference |
|---|---|---|---|---|
| 8.1 | Acetaldehyde benzyl methoxyethyl acetal | 523 | 2148 | |
| 8.2 | 3-Acetyl-2,5-dimethylfuran | - | 3391 | |
| 8.3 | Acetyl nonanoyl | 155 | 3090 | |
| 8.4 | Acetyl isovaleryl | | 3190 | |
| 8.5 | Allyl acetic acid | 2004 | 2843 | |
| 8.6 | * Allyl cinnamate | 334 | 2022 | |
| 8.7 | | 2222 | - | |
| 8.8 | Allyl cyclohexylacetate | 2070 | 2023 | |
| 8.9 | Allyl cyclohexylbutyrate | 283 | 2024 | |
| 8.10 | Allyl cyclohexylhexanoate | 2180 | 2025 | |
| 8.11 | Allyl cyclohexylpropionate | 2223 | 2026 | |
| 8.12 | Allyl cyclohexylvalerate | 474 | 2027 | |
| 8.13 | Allyl 2-ethylbutyrate | 281 | 2029 | |
| 8.14 | * Allyl furoate | 360 | 2030 | |
| 8.15 | * Allyl hexanoate | 2181 | 2032 | |
| 8.16 | * Allyl hexenoate | 610 | - | |
| 8.17 | Allyl-a-ionone | 2040 | 2033 | |
| 8.18 | * Allyl sorbate | 2182 | 2041 | |
| 8.19 | Allyl thiopropionate | - | 3329 | |
| 8.20 | * Allyl tiglate | 2183 | 2043 | |
| 8.21 | * Allyl phenoxyacetate | 228 | 2038 | |
| 8.22 | * Allyl undecen-10-oate | 441 | 2044 | |
| 8.23 | a-Amylcinnamaldehyde dimethyl acetal | 47 | 2062 | |
| 8.24 | a-Amylcinnamaldehyde | 128 | 2061 | |
| 8.25 | a-Amylcinnamyl acetate | 216 | 2064 | |
| 8.26 | a-Amylcinnamyl alcohol | 79 | 2065 | |
| 8.27 | a-Amylcinnamyl formate | 357 | 2066 | |
| 8.28 | a-Amylcinnamyl isovalerate | 463 | 2067 | |
| 8.29 | 2-Amyl-5 or 6-keto-l,4-dioxane | 2205 | 2076 | |
| 8.30 | Anisylacetone | 163 | 2672 | |
| 8.31 | Benzaldehyde propylene glycol acetal | 2226 | 2130 | |
| 8.32 | Benzilidene methyl acetone | 161 | 2734 | |
| 8.33 | 2-Benzofurancarboxaldehyde | 2247 | 3128 | |
| 8.34 | Benzoin | 162 | 2132 | |
| 8.35 | Benzyl butyl ether | 520 | 2139 | |
| 8.36 | Benzyl-2,3-dimethyl crotonate | 2187 | 2143 | |
| 8.37 | Benzyl-4-heptanone | 2140 | 2146 | |
| 8.38 | Benzyl isobutyl carbinol | 2031 | 2208 | |
| 8.39 | Benzyl isobutyl ketone | 159 | 2740 | |
| 8.40 | Benzyl isoeugenol | 522 | - | |
| 8.41 | Benzyl propyl carbinol | 83 | 2953 | |
| 8.42 | Butan-3-one-2-yl butanoate | - | 3332 | |
| 8.43 | 2-Butyl-2-butenal | - | 3392 | |
| 8.44 | 2,3-Butanedithiol | - | 3477 | |
| 8.45 | Butyl butyrylglycollate | 2188 | - | |
| 8.46 | Butyl butyryllactate | 2107 | 2190 | |
| 8.47 | 2-sec-Butylcyclohexanone | - | 3261 | |
| 8.48 | 2-Butyl-5 or 6-keto-l,4-dioxane | 2206 | 2204 | |

| | | | |
|---|---|---|---|
| 8.49 | a-Butylcinnamaldehyde | 127 | 2191 |
| 8.50 | Carvacryl ethylether | 2057 | 2246 |
| 8.51 | Cinnamaldehyde ethyleneglycol acetal | 46 | 2287 |
| 8.52 | * Cinnamyl anthranilate | 255 | 2295 |
| 8.53 | * cinnamyl phenylacetate | 235 | 2300 |
| 8.54 | Citral propylene glycol acetal | 4064 | - |
| 8.55 | Citronellyl oxyacetaldehyde | 2012 | 2310 |
| 8.56 | Cyclohexylacetic acid | 34 | 2347 |
| 8.57 | * Cyclohexyl anthranilate | 257 | 2350 |
| 8.58 | * Cyclohexyl cinnamate | 337 | 2352 |
| 8.59 | Cyclohexylethyl acetate | 218 | 2348 |
| 8.60 | Cyclohexyl mercaptan | 529 | - |
| 8.61 | cyclopentanethiol | | 3262 |
| e.62 | Dehydrodihydroionol | - | 3446 |
| 8.63 | Dibenzyl disulfide | 4077 | - |
| 8.64 | Dibenzyl ketone | 2054 | 2397 |
| 8.65 | Dibenzyl ether | 2150 | 2371 |
| 8.66 | Di-(butan-3-one-l-yl) sulfide | | 3335 |
| 8.67 | 4,4-Dibutyl-y-butyrolactone | 2231 | 2372 |
| 8.66 | * Dibutyl sebacate | 622 | 2373 |
| 8.69 | Dicyclohexyl disulfide | | 3448 |
| 8.70 | 5,7-Dihydro-2-methylthiano(3,4-D) pyrimidine | - | 3338 |
| 8 71 | | | |
| 8.72 | 2,4-Dimethyl-5-acetylthiazole | - | 3267 |
| 8.73 | 2,4-Dimethylbenzaldehyde | - | 3427 |
| 8.74 | 2,5-Dimethyl-2,5-dihydroxy-l,4-dithiane | - | 3450 |
| 8.75 | 2,5-Dimethyl-3-furanthiol | - | 3451 |
| 8.76 | Dis-(2,5-Dimethyl-3-furyl) disulfide | - | 3476 |
| 8.77 | 2,5-Dimethyl-3-thiofuroylfuran | - | 3481 |
| 8.78 | 2,5-Dimethyl-3-thioisovalerylfuran | - | 3482 |
| 8.79 | 2,6-Dimethyl-4-heptanol | 4030 | 3140 |
| 8.80 | 2,6-Dimethyl-5-heptenal | 2006 | 2389 |
| 8.81 | 2,6-Dimethyloctanal | 112 | 2390 |
| 8.82 | 2,4-Dimethyl-2-pentenoic acid | 4081 | 3143 |
| 8.83 | * Dimethyl phenyl carbinyl isobutyrate | 4240 | 2388 |
| 8.84 | Dimethyl phenylethyl carbinyl acetate | 219 | 2735 |
| 8.85 | Diphenyl disulfide | 4085 | 3225 |
| 8.86 | spiro-(2,4-Dithia-l-methyl-8-oxabicyclo(3.3.0) octane-3,3'-(1'-oxa-2'-methyl) cyclopentane) and spiro (2,4-dithia-6-methyl-7-oxabicyclo(3.3.0) octane-3,3'-(1'-oxa-2'-methyl) cyclopentane) | | 3270 |
| 8.87 | 2,2-Dithiodithiophene | - | 3323 |
| 8.88 | Dodeca-3,6-dional | 2121 | - |
| 8.90 | p-Ethoxybenzaldehyde | 626 | 2413 |
| 8.91 | 7-Ethoxy-4-methyl-coumarine | 2193 | - |
| 8.92 | 0-(Bthoxymethyl) phehol | - | 3485 |
| 8.93 | 2-Ethoxythiazole | - | 3340 |
| 8.94 | Ethyl 2-acetyl-3~phenylpropionate | 2241 | 2416 |
| 8.95 | Ethyl benzoylacetate | 627 | 2423 |
| 8.96 | * Ethyl butyryllactate | 2242 | - |

| | | | | |
|---|---|---|---|---|
| 8.97 | Ethyl cresoxyacetate | 2243 | 3157 | |
| 8.98 | Ethyl cyclohexylpropionate | 2095 | 2431 | |
| 8.99 | Ethyl 2,4-dioxohexanoate | - | 3278 | |
| 8.100 | Ethyl N-ethylanthranilate | 629 | - | |
| 8.101 | Ethyl 2-ethyl-3-phenylpropanoate | - | 3341 | |
| 8.102 | Ethyl furfuracrylate | 545 | - | |
| 8.103 | Ethyl furylpropionate | 2091 | 2435 | |
| 8.104 | 2-Ethyl-2-heptenal | 120 | 2438 | |
| 8.105 | Ethyl-iso-eugenol | 190 | 2472 | |
| 8.106 | Ethyl 2-mercaptopropionate | - | 3279 | |
| 8.107 | Ethyl nitrite | 2190 | 2446 | |
| 8.108 | Ethyl octine carbonate | 480 | 2448 | |
| 8.109 | Ethyl 4-phenylbutyrate | 307 | 2453 | |
| 8.110 | * Ethyl phenyl carbinyl butyrate | 628 | 2424 | |
| 8.111 | Ethyl 3-phenyl glycidate | 2097 | 2454 | |
| 8.112 | Ethyl thioacetate | - | 3282 | |
| 8.113 | 2-Ethylthiophenol | - | 3345 | |
| 8.114 | * Ethyl 10-undecenoate | 2102 | 2461 | |
| 8.115 | Ethylene tridecanedioate | 4094 | - | |
| 8.116 | 3-Ethyl-2-hydroxy-4-methyl-cyclopent-2-en-l-one | - | 3453 | |
| 8.117 | 5-Ethyl-2-hydroxy-3-methyl-cyclopent-2-en-1-one | - | 3454 | |
| 8.118 | N-Ethyl-2-isopropyl-5-methyl-cyclohexanecarboxa-mide | - | 3455 | |
| 8.119 | Ethyl-2-methyl-3-pentenoate | - | 3456 | |
| 8.120 | 2-Ethyl-l,3,3-trimethyl-2-norbornanol | - | 3491 | |
| 8.121 | Ethyl methyl phenylglycidate | - | | (32) |
| 8.122 | 2-Furanmethanethiol formate | 4112 | 3158 | |
| 8.123 | 2-Furfurylidene butanal | 2251 | 2492 | |
| 8.124 | Furfuryl isopropyl sulphide | 2248 | 3161 | |
| 8.125 | Furfuryl thiopropionate | - | 3347 | |
| 8.126 | Geranyl acetoacetate | 243 | 2510 | |
| 8.127 | Guaiyl acetate | 552 | | |
| 8.128 | 3-Hep tyl-5-methyl-2(3H) furanone | | 3350 | |
| 8.129 | * trans-3-Heptenyl-2-methylpropanoate | - | 3494 | |
| 8.130 | | | | |
| 8.131 | a-Hexylcinnamaldehyde | 129 | 2569 | |
| 8.132 | 2-Hexylidene cyclopenthanone | 167 | 2573 | |
| 8.133 | Hydroxycitronellal | 100 | 2583 | |
| 8.134 | Hydroxycitronellal diethyl acetal | 44 | 2584 | |
| 8.135 | Hydroxycitronellal dimethyl acetal | 45 | 2585 | |
| 8.136 | Hydroxycitronellal | 559 | ?586 | |
| 8.137 | 2-Hydroxy-2-cyclohexen-l-one | | 3458 | |
| 8.138 | 2-Hydroxy-3,5,5-trimethyl-2-cyclohexenone | - | 3459 | |
| 8.139 | 6-Hydroxy-3,7-dimethylocatnoic acid lactone | - | 3355 | |
| 8.140 | 3-(Hydroxymethyl)-2-octanone | - | 3292 | |
| 8.141 | γ-Ionone | 4139 | 3175 | |
| 8.142 | Isoamyl furylbutyrate | 2080 | 2070 | |
| 8.143 | isoamyl furylpropionate | 2092 | 2071 | |
| 8.144 | * Isobornyl formiate | 565 | 2162 | |

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|---|---|---|---|
| 8.145 | * Isobornyl isovalerate | 452 | 2166 |
| 8.146 | * Isobornyl propionate | 412 | 2163 |
| 8.147 | Isobutyl furylpropionate | 2093 | 2198 |
| 8.148 | Isoeugenyl butylether | 2151 | - |
| 8.149 | *Isoeugenyl formate | 356 | 2474 |
| 8.150 | *Isoeugenyl phenylacetate | 237 | 2477 |
| 8.151 | Iso-a-methylionone | 169 | 2714 |
| 8.152 | | | |
| 8.153 | p-Isopropyl phenyl acelaldehyde | 132 | 2954 |
| 8.154 | 3-(p-Isopropyl)-phenyl propanal | 2261 | 2957 |
| 8.155 | Isoquinoline | 4871 | 2978 |
| 8.156 | 2-Keto-4-butanethiol | - | 3357 |
| 8.157 | | | |
| 8.158 | 2-Mercapto-3-butanol | - | 3502 |
| 8.159 | 3-Mercapto-2-butanone | - | 3298 |
| 8.160 | 3-Mercapto-2-pentanone | - | 3300 |
| 8.161 | 2,3 or 10-Mercaptopinane | - | 3503 |
| 8.162 | 2-Mercaptopropionic acid | 4156 | 3180 |
| 8.163 | | | |
| 8.164 | | | |
| 8.165 | | | |
| 8.166 | l-(p-Methoxyphenyl)-1-penten-3-one | 164 | 2673 |
| 8.167 | Methoxypyrazine | - | 3302 |
| 8.168 | p-Methylbenzyl acetone | 160 | 3074 |
| 8.169 | Methylbenzyl disulphide | - | 3504 |
| 8.170 | Methyl p-tert-butylphenylacetate | 577 | 2690 |
| 8.171 | d-Methylcinnamaldehyde | 578 | 2697 |
| 8.172 | 6-Methylcoumarin | 579 | 2699 |
| 8.173 | Methyl decine carbonate | 2111 | 2751 |
| 8.174 | | | |
| 8.175 | 2-Methyl-3-furanthiol | 4172 | 3188 |
| 8.176 | Methyl furfuracrylate | 2267 | - |
| 8.177 | 2-Methyl-3,5 or 6-furfuryl-thiopyrazine | (2287) | 3189 |
| 8.178 | | | |
| 8.179 | 3-(5-Methyl-2-furyl) utanal | - | 3307 |
| 8.180 | bis (2-Methyl-3-furyl) isulfide | | 3259 |
| 8.181 | bis (2-Methyl-3-furyl) etrasulfide | | 3260 |
| 8.182 | Methyl heptine carbonate | 481 | 2729 |
| 8.183 | 5-Methyl-5-hexen-2-one | - | 3365 |
| 8.184 | a-Methyl-beta-hydroxypropyl-(a-methyl-beta-mercaptopropyl) sulphide | | 3509 |
| 8.185 | Methyl-iso-butylcarbinyl acetate | 2073 | - |
| 8.186 | | | |
| 8.187 | Methyl-beta-ionone | 144 | 2712 |
| 8.188 | Methyl-delta-ionone | 2145 | 2713 |
| 8.189 | a-Methyl-p-methoxy-cinnamaldehyde | 584 | 3182 |
| 8.190 | 2-Methyl-5-methoxythiazoie | 4034 | 3192 |
| 8.191 | Methyl 4-(methyithio) utyrate | | 3412 |
| 8.192 | 2-Methyl-4-(methylthio) uran | - | 3366 |
| 8.193 | 2-Methyl-3, 5 or 6-methylthio-pyrazine | (2290) | 3208 |
| 8.194 | 2-Methyloctanal | 113 | 2727 |

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|---|---|---|---|
| 8.195 | Methyl octine carbonate | 479 | 2726 |
| 8.196 | 2-Methyl-4-pentenoic acid | - | 3511 |
| 8.197 | 2-Methyl-4-phenylbutanal | 134 | 2737 |
| 8.198 | 3-Methyl-2-phenylbutanal | 135 | 2738 |
| 8.199 | Methyl 4-phenylbutyrate | 308 | 2739 |
| 8.200 | 3-Methyl-5-propyl-2-cyclohexen-l-one | 4178 | 3577 |
| 8.201 | 2-(2-Methylpropyl) yridine | - | 3370 |
| 8.202 | 3-(2-Methylpropyl) yridine | | 3371 |
| 8.203 | 2-(l-Methylpropyl) hiazole | - | 3372 |
| 8.204 | | | |
| 8.205 | Methyl styryl carbinol | 2032 | 2880 |
| 8.206 | 3-Methylthiobutanal | - | 3374 |
| 8.207 | 4-Methylthiobutanal | - | 3414 |
| 8.208 | 4-Methylthio-2-butanone | - | 3375 |
| 8.209 | Methyl thiofuroate | - | 3311 |
| 8.210 | 3-Methylthio-1-hexanol | - | 3438 |
| 8.211 | 4-Methylthio-4-methyl-2-pentanone | - | 3376 |
| 8.212 | 2-Methyl-3-tolyl-propanal | 587 | 2748 |
| 8.213 | Musk ambrette | 495 | 2758 |
| 8.214 | Musk ketone | 2147 | - |
| 8.215 | Musk xylol | 2218 | - |
| 8.216 | 2-Naphthalenthiol | - | 3314 |
| 8.217 | beta-Naphtyl anthranilate | 2170 | 2767 |
| 8.218 | beta-Naphtyl ethylether | 2058 | 2768 |
| 8.219 | beta-Naphtyl methyl ketone | 147 | 2723 |
| 8.220 | beta-Naphtyl isobutyl ether | 2273 | - |
| 8.221 | 1,9-Nonanedithiol | - | 3513 |
| 8.222 | Nonanoyl 4-hydroxy-3-methoxybenzylamide | 590 | 2787 |
| 8.223 | 1,3-Nonanediol acetate | 2075 | 2783 |
| 8.224 | 3-Nonanon-l-yl acetate | 2076 | 2786 |
| 8.225 | Octanon-l-ol | 592 | 2804 |
| 8.226 | 2-trans-6-trans-Octadienal | - | 3466 |
| 8.227 | 1,8-Octanedithiol | - | 3514 |
| 8.228 | 6-Octenal | 664 | - |
| 8.229 | Paraldehyde | 594 | [1] |
| 8.230 | Pentyl 2-furyl ketone | - | 3418 |
| 8.231 | Phenoxyethyl isobutyrate | 2089 | 2873 |
| 8.232 | 4-Phenyl-2-butyl acetate | 671 | 2882 |
| 8.233 | 2-Phenyl-3-carbethoxy-furan | - | 3468 |
| 8.234 | | | |
| 8.235 | Phenylethyl methyl carbinol | 85 | 2879 |
| 8.236 | Phenylethyl methyl ethyl carbinol | 86 | 2883 |
| 8.237 | 5-Phenylpentanol | 674 | - |
| 8.238 | 3-Phenyl-4-pentenal | - | 3318 |
| 8.239 | 2-Phenyl-4-pentenal | - | 351? |
| 8.240 | 2-Phenyl-l-propanol | 2257 | 2732 |
| 8.241 | 2-Phenylpropanal dimethyl acetal | 2017 | 2888 |
| 8.242 | 1,2-Propanedithiol | - | 3520 |
| 8.243 | 2-Phenylpropionaldehyde | 126 | 2886 |
| 8.244 | l-Phenyl-2-propyl butyrate | 2276 | 3197 |
| 8.245 | 2-Phenylpropyl butyrate | 285 | 2891 |

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|---|---|---|---|
| 8.246 | 3-Phenylpropyl cinnamate | 597 | - |
| 8.247 | 2-Phenylpropyl isobutyrate | 2087 | 2892 |
| 8.248 | 2-(3-Phenylpropyl) tetrahydrofurane | 489 | 2898 |
| 8.249 | Piperpnyl acetate | 2068. | 2912 |
| 8.250 | Piperohyl acetone | 165 | 2701 |
| 8.251 | Piperonyl isobutyrate | 305 | 2913 |
| 8.252 | Propenylguaethol | 170 | 2922 |
| 8.253 | p-Propyl anisole | 2026 | 2930 |
| 8.254 | Propylene glycol dibenzoate | - | 3419 |
| 8.255 | Propyl furylacrylate | 2090 | 2945 |
| 8.256 | 3-Propylidenephtalide | 494 | 2952 |
| 8.257 | o-Propylphenol | | 3522 |
| 8.258 | Propyl thioacetate | - | 3385 |
| 8.259 | Pseudocyclocitral | 2133 | - |
| 8.260 | Pyrazine ethanethiol | (2285) | 3230 [1] |
| 8.261 | Pyrazine methanethiol | - | 3299 [1] |
| 8.262 | Pyrazinyl methyl sulfide | (2288) | 3231 [1] |
| 8.263 | 2-Pyridine methanethiol | 2279 | 3232 |
| 8.264 | Resorcinol dimethyl ether | 189 | 2385 |
| 8.265 | Tetrahydrofurfuryl butyrate | 2081 | 3057 |
| 8.266 | Tetrahydrofurfuryl cinnamate | 4224 | 3320 |
| 8.267 | Tetrahydrofurfuryl propionate | 2096 | 3058 |
| 8.268 | Tetrahydrolinaloöl | 77 | 3060 |
| 8.269 | Tetrahydro-pseudo-ionone | 2053 | 3059 |
| 8.270 | Tetramethyl ethylcyclohexenone | 168 | 3061 |
| 8.271 | Thiogeraniol | - | 3472 |
| 8.272 | Thioguaiacol | 2219 | - |
| 8.273 | 2-(p-Tolyl)-propanal | 131 | 3078 |
| 8.274 | 2,6,6-Trimethyl-l-cyclohexen-l-acetaldehyde | - | 3474 |
| 8.275 | 3,5,5-Trimethylhexanal | - | 3524 |
| 8.276 | 3,5,5-Trimethyl-l-hexanol | - | 3324 |
| 8.277 | 9-Undecenal | 123 | 3094 |
| 8.278 | 10-Undecenal | 122 | 3095 |
| 8.279 | * Vanillin acetate | 225 | 3108 |
| 8.280 | Vanillidene acetone | 691 | - |
| 8.281 | | | |
| 8.282 | * Allyl anthranilate | 254 | 2020 |
| 8.283 | * Allyl heptanoate | 369 | 2031 |
| 8.284 | * Allyl isovalerate | 2098 | 2045 |
| 8.285 | Amylheptin carbonate | 2172 | - |
| 8.286 | Benzyl ethyl carbinol | 2137 | - |
| 8.287 | * Cinnamyl formate | 352 | 2299 |
| 8.288 | * Cinnamyl propionate | 414 | 2301 |
| 8.289 | * Cyclohexyl butyrate | 2082 | 2351 |
| 8.290 | * Cyclohexyl formate | 498 | 2353 |
| 8.291 | * Cyclohexyl hexanoate | 528 | - |
| 8.292 | * Cyclohexyl isovalerate | 459 | 2355 |
| 8.293 | * Cyclohexyl propionate | 421 | 2354 |
| 8.294 | Dehydrodihydroionone | - | 3447 |
| 8.295 | * Diethyl sebacate | 623 | 2376 |
| 8.296 | Dihydroanethole | 2026 | 2930 |

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|---|---|---|---|---|
| 8.297 | * Dimethylbenzylcarbinyl acetate | 2077 | 2392 | |
| 8.298 | * Dimethylbenzylcarbinyl isobutyrate | 2084 | 2394 | |
| 8.299 | 3,7-Dimethyl-2,6-octadienyl 2-ethylbutyrate | - | 3339 | |
| 8.300 | 4-Heptanol | 555 | - | |
| 8.301 | Isoamyleugenol | 563 | - | |
| 8.302 | Isoamyl heptin carbonate | 2173 | - | |
| 8.303 | * Isobornyl butyrate | 564 | - | |
| 8.304 | Isobutyl benzyl carbinol | 2031 | 2208 | |
| 8.305 | * Isobutyl N-methylanthranilate | 649 | - | |
| 8.306 | beta-Isomethyl ionone | 650 | - | |
| 8.307 | * Isopropyl cinnamate | 325 | 2939 | |
| 8.308 | 3-Mercapto-2-butanol | - | 3502 | |
| 8.309 | 2-Mercapto thiophene | 478 | - | |
| 8.310 | 4-Methyl-5-(beta-acetoxy ethyl) thiazole-3-methyl-5-ethylphenol | 580 | | |
| 8.311 | Methyl thiazol acetate | - | 3205 | |
| 8.312 | Phenylethyldimethylcarbinyl isobutyrate | 2086 | 2736 | |
| 8.313 | * Phenylpropyl propionate | 419 | 2897 | |
| 8.314 | l-Phenyl-3(5)-propylpyrazole | 2277 | - | |
| 8.315 | Piperonyl formate | 2154 | - | |
| 8.316 | * Sucroseoctaacetate | 4219 | FDA/GRAS | |
| 8.317 | l,5,5,9-tetramethyl-13-oxatri-cyclo (8,3,0,0 $^{4,9}$) tridecane | - | 3471 | |
| 8.318 | p-Tolylacetaldehyde | 130 | 3071 | |
| 8.319 | Trideca-4,7-dienal | 684 | - | |
| 8.320 | Licorice | | | |

[1/] See para 110, ALINORM 78/12.

9. FLAVOUR ENHANCERS

| | | |
|---|---|---|
| 9.1 | Aspartate, monosodium | |
| 9.2 | Glutamate, magnesium | |
| 9.3 | Glutamate, L-Arginine | (29),(30) |
| 9.4 | Glutamate, L-Lysine | |

| | | JECFA Reference |
|---|---|---|
| 10. | MISCELLANEOUS | |
| 10.1 | Acetone peroxide | |
| 10.2 | Chlorine | |
| 10.3 | Nitrogen | |
| 10.4 | Carbon dioxide | |
| 10.5 | Thermally oxidized soyabean oil | |
| 10.6 | Glycerol esters of wood resin | (32), (38) |
| 10.7 | Polyvinyl pyrrolidone | |
| 10.8 | | |
| 10.9 | Saccharate of lime | |
| 10.10 | Aspartame | (35), (38), (41) |
| 10.11 | Sucrose acetate isobutyrate | (35), (41) |
| 10.12 | Sorboyl palmitate | (32), (38) |
| 10.13 | Licorice | (41) |
| 10.14 | Xylitoi | (41), (45) |
| 10.15 | Beeswax | [1] |
| 10.16 | Carnauba wax | [1] |
| 10.17 | Shellac | [1] |
| 10.18 | Condensed tannins | [1] |
| 10.19 | Wood flour | [1] |
| 10.20 | Modified polydextrose | |
| 10.21 | Hydrogenated glucose syrup | |
| 10.22 | Isomaltitol (a glucopyranoside of sorbitol) | |
| 11. | PROCESSING AIDS | |
| 11.1 | Bentonite | (38) |
| 11.2 | Asbestos | |
| 11.3 | Diatomaceous earth | (41) |
| 11.4 | Perlite | |
| 12. | PRESERVATIVES | |
| 12.1 | Parahydroxybenzoate, butyl | (30) |

[1/] See para 112, ALINORM 78/12.

## REFERENCES


(10) (Toxicoiogical Monographs Resulting from the 9th and 10th Reports of the Joint FAO/WHO Expert Committee on Food Additives) Toxicoiogical Evaluation of Some Antimicrobials, Antioxidants, Emuisifiers, Stabilizers, Flour-Treatment Agents, Acids and Bases; WHO/Food Add./67.29; FAO Nutrition Meetings Report Series No. 40 A, B, C.

(16) 13th Report of the Joint FAO/WHO Expert Committee on Food Additives; Specifications for the Identity and Purity of Food Additives and their Toxicoiogical Evaluation; Some Food Colours, Emulsifiers. stabilizers, Anti-Caking Agents and Certain Other Substances; WHO Techn. Rep. Series No. 445; FAO Nutrition Meetings Report Series No. 46.

(30) (Toxicoiogical Monographs Resulting from the 17th Report of the Joint FAO/WHO Expert Committee on Food Additives); FAO Nutrition Meetings Report Series No. 53 A; WHO Food Additives Series No. 5.

(32) 18th Report of the Joint FAO/WHO Expert Committee on Food Additives; FAO Nutrition Meetings Report Series No. 54; WHO Techn. Rep. Series No. 557.

(33) (Toxicological Monographs Resulting from the 18th Report of the Joint FAO/WHO Expert Committee on Food Additives); FAO Nutrition Meetings Report Series No. 54 A; WHO Food Additives Series No. 6.

(35) 19th Report of the Joint FAO/WHO Expert Committee on Food Additives; FAO Nutrition Meetings Report Series No. 55; WHO Techn. Rep. Series No. 576.

(38) 20th Report of the Joint FAO/WHO Expert Committee on Food Additives; FAO Food and Nutrition Series No. 1; WHO Techn. Rep. Series No. 559.

(41) 21st Report of the Joint FAO/WHO Expert Committee on Food Additives; WHO Techn. Rep. Series No. 617 (published only by WHO).

(45) 22nd Report of the Joint FAO/WHO Expert Committee on Food Additives (published by WHO).

APPENDIX IX

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

(Advanced to Step 8)

### 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. This standard also applies to food "processing aids"; any reference to food additives includes food processing aids.

### 2. DEFINITION 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 hot include contaminants, or substances added to food for maintaining or improving nutritional qualities, or sodium chloride;

(b) processing aid means 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 other ingredients to fulfill 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:

(c) 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;

(d) label includes any tag, brand, mark, pictorial or other descriptive matter, written, painted, stencilled, marked, embossed or impressed on, or attached to, a container;

(e) 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;

(f) 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;

(g) ingredient means any substance, excluding a food additive, used in the manufacture or preparation of a food and present in the final product;

(h) 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; :

## 3. GENERAL PRINCIPLES

3.1 Food additives [1/] 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 [1/] 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".

[1/] The term includes "processing aids" as defined (see Scope section).

## 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 1/ 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 hot 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) Food additives with a shelf-life not exceeding 18 months shall carry the date of minimum durability using words such as "will keep at least until

(e) 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 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 name 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 food additives is subject to a: quantitative limitation in a food in the country in which the food additive is to be sold or used, the quantity or proportion of that additive and/or; adequate instruction to enable the compliance with the limitation shall be given, 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) Food additives with a shelf-life not exceeding 18 months shall carry the date of minimum durability using words such as "will keep at least until

(e) 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 in 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 pr deceive the user.

(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 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 oh 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.

APPEND X

# DRAFT GENERAL STANDARD FOR IRRADIATED FOODS

(Advanced to Step 8)

## 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 (gray), the newly introduced SI unit (1 Gy – $10^2$ rad).

## 2. GENERAL REQUIREMENTS FOR THE PROCESS

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

2.2 In order to meet the requirements of safety and efficacy of food processing, the dose absorbed (**) by any part of the food shall not exceed the dose limit specified for each individual food irradiation treatment in ANNEX 1 of this standard.

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

2.3 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:

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

2.3.2 The facilities shall be staffed by adequate trained and competent personnel.

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

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

2.3.5 Control should be carried out in accordance with the Recommended Code of Practice for the Operation of Radiation Facilities used for the Treatment of Foods (see APPENDIX XI).

## 3. SAFETY OF IRRADIATED FOODS

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

## 4. FOODS WHICH MAY BE IRRADIATED AND THEIR PRE- AMD POST-IRRADIATION HANDLING

4.1 Foods which may be irradiated are listed in ANNEX 1.

4.2 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. The packaging material to be used in the irradiation of pre-packaged food should be defined in the national authorization for the specific food item.

4.3 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 consumer, the trade and for the purposes of control, foods which have been treated with ionizing radiation shall be designated in an appropriate way on the label and, where labelling is not feasible in the accompanying documents. The accompanying documents and the label shall also give appropriate information to identify the registered facility which has irradiated the food.

## ANNEX 1

## PROVISIONS FOR THE IRRADIATION OF SOME INDIVIDUAL FOOD ITEMS

1. Chicken (*) (Gallus domesticus)

(*) Granted "Unconditional Acceptance" by the Joint FAO/IAEA/WHO Expert Committee on the wholesomeness of Irradiated Food; Geneva, 31 August - 7 September 1976 (ANNEX 2).

1.1 Purpose of the Process

The purpose of irradiating chicken is:

(a) to prolong storage life of

and/or

(b) to reduce the number of certain pathogenic microorganisms, such as Salmonella, from eviscerated chicken.

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 Limit

700 Krad (7 k Gy)

1.2.2 Temperature Requirement

During irradiation and storage the product shall be kept at or below 4°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 Dose Limit

100 Krad (1 k Gy)

2.2.2 Source of Radiation

The source of radiation is limited to Co or Cs 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 Limit

15 Krad (0.15 k Gy)

(*) Granted "Unconditional Acceptance" by the Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food; Geneva, 31 August -7 September 1976 (ANNEX 2).

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 Limit

300 Krad (3 k Gy)

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 Limit

100 Krad (1 k Gy)

5.2.2 Prevention of Reinfestation

These products, whether prepackaged or handled in bulk, shall be stored, as far as possible, 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 (ANNEX 2).

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:

(a) to reduce microbial spoilage of the packaged or unpackaged fish, and

(b) to reduce the number of certain pathogenic microorganisms, such as Salmonella, in packaged or unpackaged fish

(**) Granted "Provisional Acceptance" by the Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food; Geneva, 31 August - 7 September 19 76 (ANNEX 2).

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 Limit

220 Krad (2.2 k Gy)

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 Limit

15 Krad (0.15 k Gy)

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 Limit

100 Krad (1 k Gy)

8.2.2 Prevention of Reinfestation

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

(*) (Report from the meeting of a 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).

## ANNEX 2

## DEFINITIONS OF CATEGORIES OF ACCEPTANCE OF IRRADIATED FOODS (*)

"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."

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

APPENDIX XI

## DRAFT CODE OF PRACTICE FOR THE OPERATION OF RADIATION FACILITIES USED FOR THE TREATMENT OF FOODS

(Advanced to Step 8)

### 1. INTRODUCTION

This code refers to the operation of radiation facilities baaed 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 is measured in curies (Ci) (*) and should be stated by the supplying organizations. Records should be kept by the operator giving details of each consignment, as well as of any isotope which is returned. The actual total strength of the source installed should be recorded. This strength should take into account the natural decay rate of the source.

(*) 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 and recorded continuously. Such

records should be kept for inspection and should 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 descend 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 accordance 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 (**).

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

Special studies should be carried out on commissioning of a plant and, similarly, when modifications are made to the source strength or type. Routine dosimetry measurement should be made during operation and records kept of such measurements.

### 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 through the product. These dosimeters should be placed at such positions as will give the best indication of dose variability. A recognized system (**) of dosimetry should be used. When the dose distribution is known, the conveyor speed should be determined which ensures that at least the Intended 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

Dose meters 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, at least 2 dose meters 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) should be adjusted to ensure a consistent beam thus giving the correct irradiation to the product for a given conveyor speed. A scanner should be incorporated into the machine to oscillate or spread 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 should be 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 dose meters should be placed at such locations as will give the best indication of dose variability. A recognized system (*) of dosimetry should be used.

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

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 intended 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.

#### 3.2.2 Routine Dosimet

When the characteristics of the installation have been determined and the conveyor speed adjusted to ensure that the plant package receives the intended 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 dose absorbed by the product. Where large numbers of similar packs have to be treated it is acceptable to place dose meters 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 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.