

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

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ALINORM 78/26

## CODEX ALIMENTARIUS COMMISSION

Twelfth Session, 1978

### REPORT OF THE CODEX COMMITTEE ON FOODS FOR SPECIAL DIETARY USES

Tenth Session

Bonn, 28 February - 4 March 1977

#### INTRODUCTION

1. The Codex Committee on Foods for Special Dietary Uses held its Tenth Session in Bonn from 28 February to 4 March 1977 by the courtesy of the Government of the Federal Republic of Germany. Dr. R. Franck, First Director and Professor of the Federal Health Office, Berlin, was in the chair. On the occasion of the 10th Session Ministerialdirigent Professor Dr. D. Eckert opened the session on behalf of the Federal Minister of Health. He briefly recalled progress in the work and the growth of interest amongst members of the Codex Alimentarius Commission in the activities of the Codex Committee on Foods for Special Dietary Uses. He congratulated those participants who had attended the Committee since its first session and welcomed representatives of six countries who were participating for the first time.

2. The session was attended by representatives from the following 29 countries:

Australia	Germany, Fed.Rep.of	Norway
Austria	Hungary	Poland
Canada	Ireland	Spain
Chile	Italy	Sweden
Costa Rica	Japan	Switzerland
Czechoslovakia	Korea, Rep.of	Thailand
Denmark	Liberia	United Kingdom
Finland	Libyan Arab Republic	United States of America
France	Netherlands	Zaire
Gabon	New Zealand	

Observers were present from the following international organizations:

- Association of Official Analytical Chemists (AOAC)
- International Association for Cereal Chemistry (ICC)
- International Federation of Margarine Associations (IFMA)
- International Secretariat for the Industries of Dietetic Food Products (ISDI)
- Marinalg International
- European Economic Community (EEC)
- Institut Européen des Industries de la Pectine (IEIP)
- International Union of Nutritional Sciences (IUNS)
- International Council of Infant Food Industries (ICIFI)

The List of Participants, including officers from FAO and WHO, is contained in Appendix I to this Report.

#### ADOPTION OF PROVISIONAL AGENDA

3. Following a brief discussion the Committee adopted the agenda with a slight change in the order of items to be discussed.

#### APPOINTMENT OF RAPORTEURS

4. Professor J. Rey (France) and Dr. S.J. Darke (United Kingdom) were appointed rapporteurs for the session.

#### MATTERS ARISING FROM THE ELEVENTH SESSION OF THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES

##### STANDARDS FOR FOODS FOR INFANTS AND CHILDREN AT STEP 9

5. The Committee was informed that the Commission had adopted the three Standards for Foods for Infants and Children (Infant Formula, Canned Baby Foods and Cereal-based Foods for Infants and Children). Although the standards were accepted, several delegations held the view that some provisions, especially in the Standard for Infant Formula, were not satisfactory.

6. The Commission had instructed the Secretariat to include in the introduction to the Standard for Infant Formula (i) a paragraph stating that the standard would be reviewed in the future as required to conform with advances in knowledge in the field of infant feeding and (ii) a statement outlining the policy of FAO/WHO on infant feeding and emphasizing the importance of, and preference for, breast feeding. The Secretariat had been furthermore instructed to include the section on Methods of Analysis which had been considered by the Codex Committee on Methods of Analysis. Further work required on methods of analysis for infant foods was discussed under agenda item 5(d) (see paragraph 48).

7. The Commission had agreed to add to the Food Additives List for Canned Baby Foods distarch glycerol and acetylated distarch glycerol, provided the Codex Committee on Food Additives would endorse these provisions.

8. The Representative of WHO had informed the Commission that the Joint Expert Committee on Food Additives would review the use of modified starches and other additives in infant foods.

##### Date Marking

9. The Committee noted that the Codex Committee on Food Labelling had amended the provision on date marking in the above standards to read "The date of minimum durability of the food shall be declared in clear". The Commission adopted the provision until such time as the date marking guideline could be adopted, and recommended generally that all Codex Commodity Committees should elaborate date marking provisions, if appropriate.

##### Food Additives and Contaminants

10. The Commission had endorsed the carry-over principle as contained in ALINORM 76/12, Appendix IV, as a guide to Codex Commodity Committees. The question of labelling of carried-over additives had been referred to the Labelling Committee.

11. The Commission had agreed that the amendment procedure would not have to be applied to amendments of food additive provisions in Step 9 Standards resulting from JECFA decisions.

12. It had been noted that sometimes provisions for contaminants in standards had not been elaborated. This was due to lack of data upon which maximum levels for contaminants could be proposed by Commodity Committees. WHO had informed the Commission that the data compiled by the Joint FAO/WHO Food Contamination Monitoring Programme would be made available to the Commission. Also national monitoring programmes could be used as a source of more information.

13. The Committee was informed that the Joint Expert Committee on Food Additives would discuss at its forthcoming session in April 1977 the problem of exposure of infants and children to contaminants in food (see also paragraph 28).

#### PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR FOODS FOR INFANTS AND CHILDREN AND MICROBIOLOGICAL SPECIFICATIONS

14. The Committee noted that the Commission had amended the terms of reference of the Codex Committee on Food Hygiene to cover endorsement of hygiene provisions in codes of practice including, where necessary, microbiological specifications and associated methodology.

15. At its 13th Session the Hygiene Committee had discussed the draft code (ALINORM 76/13A, Appendix V). The code, revised in accordance with the revised General Principles of Food Hygiene and government comments, would be discussed at Step 4 together with another round of comments at the 14th Session of the Codex Committee on Food Hygiene.

16. A special Working Group had been convened in November 1976 at the FAO/WHO Collaborative Centre for Research and Training in Food Hygiene in Berlin. The Working Group discussed the initial proposals for microbiological specifications as contained in Appendix A to the Code which would be submitted to the Second Joint FAO/WHO Expert Consultation on Microbiological Specifications for Foods (Geneva, 21 February - 2 March 1977) for review. Governments would have an opportunity to comment on microbiological specifications and related methodology prior to the next session of the Hygiene Committee to which the papers would be submitted at Step 4.

#### REPORT OF THE AD HOC WORKING GROUP ON FOOD ADDITIVES IN BABY FOODS

17. The Ad Hoc Working Group had met from 24-25 February 1977, prior to the Session of this Committee. The Group had discussed the following items:

- (i) applicability of the carry-over principle to foods for infants and children;
- (ii) the need for certain further additives;
- (iii) maximum levels for mono- and di-glycerides; and
- (iv) levels of nitrates, metal and metalloid contaminants in baby foods.

18. Dr. K. Murray, Chairman of the Working Group, introduced the Report of the meeting (Room Document No. 1), which will appear as an appendix to this Report (see Appendix III).

19. Dr. Murray expressed concern that few comments and data had been received from governments on certain agenda items and regretted the absence of several members of the Ad Hoc Working Group from the meeting of the Working Group.

20. On the use of BHA and BHT in foods for infants and children the Committee agreed with the decision of the Working Group not to recommend the use of the above antioxidants. However, the delegation of the United States of America was not opposed to the use of these compounds.

21. The Committee was informed that the use of Ammonium carbonate and -bicarbonate could be recommended by the Working Group in rusks and biscuits only, provided that the delegation of the United Kingdom submitted the relevant residue data to JECFA for consideration.

22. Furthermore the Committee was informed that the Working Group had postponed a decision on the use of Trypsin in cereal-based products for infants and children pending technological justification to be provided by the United Kingdom.

23. As regards the use of Tartaric Acid in certain canned baby foods, the Committee agreed with the Working Group to permit only the use of L (+) Tartaric Acid at a maximum level of 1% in fruit-based products.

24. The Committee confirmed the view of the Working Group that the use of pectin (non amidated) should be permitted only in fruit-based foods at the level of 1% as accepted in the Standard for Canned Baby Foods, and that the use of pectin should not be extended to other products.

25. It was decided to accept the proposal of the Working Group not to relate the use of mono- and di-glycerides in canned baby foods to the fat content of the products, but to permit the addition of the substance at a maximum level of 0.15% on a ready-to-eat basis (Section 4.2.2 of the Standard for Canned Baby Foods).

26. Considerable discussion took place as to whether to permit the use of sodium- , potassium- and calcium hydroxides to prevent protein precipitation in infant formula. The delegation of the United Kingdom was of the opinion that their use involved a smaller quantity of cation and would thus reduce the solute load. In some cases their use might be necessary to avoid too high a concentration of sodium and potassium which would result if the carbonate were used to adjust the pH. The Federal Republic of Germany recommended only the use of calcium hydroxide. The Representative of WHO reminded the Committee that JECFA had placed no restriction on the use of these bases provided that they would be acceptable within the limits of the dietary load. The Committee decided to recommend the use of the above substances taking into account the Committee's deliberations later during the session on the use of mineral salts.

### Levels of Nitrates in Baby Foods

27. The Committee took note that some countries had prescribed a maximum limit for nitrates in foods for infants and children. The delegation of the Federal Republic of Germany was of the opinion that in their view the establishment of maximum levels did in themselves lead to a reduction in nitrate level found in these products due to a more careful selection of raw materials. The delegation of the United States said that agricultural conditions did not allow production of vegetables which complied with these proposals because of varying conditions (temperature, soil type, seasons, etc.). Extreme variability had been observed which could not be evaluated nor controlled prior to processing of the food. Formulation in some member countries did not permit reduction of the total nitrate content by dilution with other ingredients. This opinion was not fully supported by the rest of the Committee. The delegation of France said that for health reasons, very low limits should be established for products intended for infants under the age of 4 months. The Committee agreed with the opinion of the majority of the Working Group as set out in paragraph 26 of the Report of the Group.

### Metal and Metalloid Contaminants

28. The Committee agreed with the view of the Working Group that additional information would be required from governments before any firm recommendation could be made for maximum levels for these contaminants in foods for infants and children. The Committee was informed that JECFA would consider the problem of exposure of infants and children to contaminants in food.

### Carry-over Principle

29. The Committee noted that the Working Group had proposed that governments, when accepting the three standards at Step 9, should be requested to indicate whether or not the carry-over principle was applied to the products in their countries. This proposal had been put forward because the Working Group had been unable to recommend whether or not the carry-over principle should apply. The Committee considered views expressed for and against the application of the carry-over principle and was of the opinion that if at all possible a decision should be taken in respect of each of the three Step 9 Standards. It was agreed that because of the nature and important rôle of infant formula as the sole food for young infants the carry-over principle should not apply. In the case of canned baby foods and cereal-based products, even though some delegations thought that there should be specific restrictions on the application of the carry-over principle (e.g. for artificial colours and flavours), the Committee decided to apply the carry-over principle. A few delegations, however, were of the opinion that the carry-over should not apply to canned baby foods and cereal-based products for infants and children. It would be open to governments when accepting the standards to indicate any restrictions by means of specified deviations. These recommendations would follow the established procedure and be brought to the attention of the Codex Committee on Food Additives and the Commission. The delegation of the United Kingdom informed the Committee that a review of carry-over additives was currently being made in their country.

### LIST OF MINERAL SALTS AND VITAMINS FOR FOODS FOR INFANTS AND CHILDREN

30. The Committee had before it CX/FSDU 77/2, List of Mineral Salts for Use in Foods for Infants and Children - prepared by the United States, and CX/FSDU 77/3, List of Vitamins - prepared by Switzerland. No written comments had been received on the above papers.

31. As regards specifications for mineral salts and vitamins, the Committee had already decided that reference to existing national and international specifications would be sufficient (ALINORM 76/26A, para 70).

32. In document CX/FSDU 77/2 criteria had been established for the use of mineral salts which were not contained in the present list.

### MINERAL SALTS

33. Several delegations informed the Committee that in their opinion certain mineral salts had been omitted from the present list and that there was adequate technological justification for the inclusion of these salts. Proposals were also made to delete certain salts from the list because they would interfere with the absorption of other

nutrients. The delegation of the United States expressed the view that the list should indicate the practical uses of the mineral salts according to the product in which they are used. The Committee concluded that it would be more appropriate for a small working group of experts to examine the suitability or otherwise of both mineral salts already on the list and those to be proposed for inclusion in the list in the light of the following criteria:

- (a) the salts can be shown to provide technological and nutritional improvements;
- (b) the anion of the salt (or the acid from which the anion is derived) is a food additive endorsed by the Codex Committee on Food Additives and its use would not exceed the ADI; and
- (c) it can be demonstrated that the mineral nutrient is biologically available from this salt.

34. The delegation of the United Kingdom proposed that all mineral salts must be used in accordance with the following rule: the total intake of each anion and each cation from all sources must be within the acceptable level of intake for that ion for infants.

35. The Committee fully discussed whether the list should be regarded as an open or closed list and concluded that a decision on that point should closely be linked to the status assigned to the list, i.e. whether it would be a permitted list or an advisory text. A number of delegations emphasized that a permitted list would have distinct advantages for those countries which at present have no legislation in this field. Other delegations took the view that a permitted list might be construed as not being consistent with the earlier decisions of the Committee and Commission to leave the use of mineral salts in canned baby foods and cereal-based products to national legislation. As to the status of the list it was agreed to postpone a decision on this matter pending further discussion of the list at the next session of the Committee.

36. The Working Group, as mentioned in paragraph 33, was established under the Chairmanship of the United States with the following members: France, Canada, United Kingdom, Federal Republic of Germany and Switzerland.

37. Governments were requested to supply technological and nutritional information as soon as possible on any mineral salt they might wish to include or have reinstated in the list contained in CX/FSDU 77/2.

#### Vitamins

38. The delegation of Switzerland introduced the paper and drew attention to some problems outlined in the document which would require a decision of the Committee. He stated that the names of vitamin compounds had been brought into conformity with the IUNS nomenclature. The Committee discussed whether the list should be an open or a closed list. Some delegations stated that if it were decided to have a closed list, other vitamin sources, which could be used either as additives for technological purposes or as vitamins, would need to be added to the list. The delegation of Australia raised the question of how to deal with certain substances used as carriers for the vitamins because these could be considered either as carry-over additives or as additional ingredients to the final product. The Committee has already decided that the carry-over principle should not apply to infant formula.

39. A majority of the Committee expressed themselves in favour of having an advisory list. Governments were requested to supply data on those vitamin compounds which they would like to have added to the list including specifications and possible requirements for them. The delegation of Switzerland at the request of the Committee undertook to revise the list in the light of the above information for the next session of this Committee.

40. As regards the use of thiamine mononitrate, the Committee agreed that the additional intake of nitrate resulting from this compound would be negligible and the compound could be included in the list.

41. The Committee concluded that the use of nicotinic acid would not cause undesirable side-effects at the level which may be used to reach the recommended daily intake of niacin proposed. One delegation stated that cholecalciferol-cholesterol was not used in their country and that specifications and technological requirements should be provided before a decision could be taken on the acceptance of the compound.

42. It was further proposed that substances such as choline and biotin should also be considered.

43. The delegation of Switzerland explained that IUNS had decided that pteroyl monoglutamic acid should be referred to as folic acid.

44. As to the status of the List the Committee decided to postpone a decision until the next session.

#### SAMPLING PLANS FOR FOODS FOR INFANTS AND CHILDREN

45. The Chairman of the Working Group on Methods of Analysis and Sampling for Foods for Infants and Children, Professor Krönert, informed the Committee that the group met on 25 February to discuss the very complex problem of devising a sampling plan.

46. The group had concluded that it was not possible to draw up one general sampling plan as there were two different basic categories of characteristics for which the plan would have to provide, namely, those which related to health and nutritional factors and those which related to such matters as fill of container. He mentioned that the Working Group on Microbiological Specifications had also considered a proposal for a sampling plan which they proposed could be used as a basis for the future work of the Working Group on Sampling of this Committee. Governments were requested to indicate which of the above criteria they would regard as most important in assessing the suitability of the sampling plan.

#### METHODS OF ANALYSIS FOR FOODS FOR INFANTS AND CHILDREN

47. The Committee had before it document CX/FSDU 77/5 which outlined the status of Methods of Analysis included in the three standards for foods for infants and children at Step 9. The Committee's attention was drawn by Professor Krönert to methods requiring further elaboration.

48. The Committee agreed that the action should be taken on the following points raised by the Chairman of the Working Group:

(a) Protein Efficiency Ratio

Although the AOAC method had been endorsed, it was noted that there was a possibility of lactose interference in the estimation of PER. Governments should supply evidence to the AOAC, Box 540, Benjamin Franklin Station, Washington, D.C. 20044, USA.

(b) Vitamin K<sub>1</sub>

An inter-laboratory study would be carried out on the proposed GLC method for the determination of vitamin K<sub>1</sub>. Any laboratory wishing to participate should inform the AOAC (see para (a) above).

(c) Crude Fibre and Linoleic Acid

The Chairman of the Working Group on Methods of Analysis agreed to follow up the developments for the above two methods and to obtain the AOAC/ISO joint text and the IUPAC Study respectively.

(d) Loss on Drying, Ash, Sodium and Potassium

The above methods are under discussion by the Codex Committee on Methods of Analysis. Governments were invited to send their comments to Dr. P.L. Schuller, National Institute of Public Health, Post Box 1, Bilthoven, Netherlands and to the Chairman of the Working Group.

(e) Iodine, Vitamin E and Vitamin D

The chairman of the Working Group agreed to serve as a coordinator in matters related to the above nutrients as far as this Committee is concerned.

CONSIDERATION OF THE PROPOSED DRAFT STANDARD FOR "FOLLOW-UP MILK" AT STEP 4

49. The Committee had before it the proposed Draft Standard as contained in ALINORM 76/26A, Appendix IX, and government comments in document CX/FSDU 77/6 prepared by the Secretariat of the Federal Republic of Germany. At its Ninth Session the Committee had briefly discussed the proposed draft and had decided to postpone the decision on whether such a standard should be developed until governments had had an opportunity to consider the above draft (see para 32, ALINORM 76/26A).

50. The Chairman therefore reminded the Committee that before discussing the details of the standard the Committee should decide whether there was a need to elaborate a standard for follow-up milk. The delegations of Canada, Norway and the United States expressed the view that at least in their own countries there appeared to be no need on nutritional grounds for such products. The delegation of Australia stated that there was no need for such a standard in its present form. However, there might be a need for such products provided they were not necessarily milk-based but included foods derived from plant and/or animal origin or based on suitably modified milks. The delegations of the Federal Republic of Germany, France and Sweden supported by other delegations were in favour of a standard on nutritional grounds and also because of the need to regulate products already on the market in ever increasing quantities. The delegations of the United Kingdom and Australia stated that the Committee should consider in particular the need to provide a cheap but nutritionally adequate weaning food, particularly for infants over the age of six months in families with low income, and that such a product should be fortified with certain nutrients e.g. vitamin A and iron, etc. Considerable discussion took place whether infants at the weaning age would need a primarily milk-based diet. It was pointed out that sources of protein other than milk could serve the same purpose and might be more readily available in certain countries. The delegation of Switzerland cited Swiss figures on production of different types of liquid infant foods containing milk used during the weaning period, and it was shown that only about 10% of the total volume were infant formula and 90% of the marketed products were actually products which would be covered by the proposed standard for a "follow-up formula". The Representative of WHO emphasized the keen interest of his Organization in the nutritional requirements of infants in developing countries as well as the need to regulate the composition of products on the market. The Representative of FAO pointed out that there were two major aspects of malnutrition to be borne in mind - a protein-calorie deficiency in developing countries, and nutritionally inadequate diets in affluent societies.

51. He quoted the recommendation of PAG:

"The importance of the weaning phase serves to emphasize the great need for inexpensive nutritious foods to be developed and marketed for young children. Such foods should as far as possible be prepared and blended locally in the countries, using commodities available in the area. These foods should play a major nutritional rôle, which milk plays in more affluent populations. Toward this end, it may be necessary to diversify the infant food industry and embark with government support to produce reasonably priced, easy to prepare and calorie-dense nutritious weaning foods."

(PAG REGIONAL SEMINAR: OVERCOMING PROBLEMS IN INFANT AND YOUNG CHILD FEEDING PRACTICES, Singapore, November 1974).

52. The delegation of France cited instances of improper nutritional feeding in affluent societies which could lead to illness in later life.

53. The delegation of Switzerland was requested to redraft the standard taking into consideration the deliberations of the Committee. The title of the standard was changed to read:

"Follow-up Foods for Older Infants and Children".

54. Governments were requested to submit their views on sources and minimum amount of protein on which nutrients were essential and those which were considered desirable but optional. The delegation of the United States proposed, and the Committee agreed, that the recommendations of PAG about nutrient concentration should be taken into account.

### Status of the Standard

55. The delegation of Switzerland agreed to revise the Proposed Draft Standard for Foods for Older Infants and Children which would be submitted to governments for comments at Step 3 prior to the next session of the Committee.

### CONSIDERATION OF DRAFT STANDARD FOR "GLUTEN-FREE" FOODS AT STEP 7

56. The Committee had before it document CX/FSDU 77/7 containing the Draft Standard for "Gluten-Free" Foods. This had been revised by the delegation of Finland in collaboration with the delegation of the Netherlands in the light of government comments received from the different governments.

57. The draft standard had already been discussed at Step 7 by this Committee at its Ninth Session, but as important questions concerning nutritional value of the products and labelling provisions could not be cleared, the draft had been returned to Step 6 (paras 66-67, ALINORM 76/26A).

58. The delegation of Finland stated, while introducing the paper, that in their opinion the main points for discussion would be the definition of "Gluten-Free" in section 2.2.2 and the lack of adequate methods of analysis for the determination of gliadin. He drew attention to the fact that some governments had suggested the inclusion of hygiene provisions in the standard. He was of the opinion that no special hygiene provisions were necessary. The Committee discussed whether the standard should also cover products partially free of gluten and foods naturally free from gluten. It was decided that the standard should apply only to products from which the gluten had been removed or substituted by other cereals and the Scope section was amended accordingly. It was furthermore decided to delete from the Scope any reference to a particular disease and to refer to gluten intolerance instead of to gluten enteropathy. A consequential amendment was made to section 2.2.1.

59. The delegation of the Federal Republic of Germany expressed the view that the products should be totally free of gluten, as even small amounts could present problems for persons having an intolerance to gluten. Several delegations doubted whether a clinical testing as proposed in 2.2.2 to determine the amount of gluten present would be practicable on a world-wide basis. The delegation of the Netherlands confirmed that a biochemical method was being elaborated but was not yet available. The Committee therefore decided to amend section 2.2.2 linking the term "gluten-free" to the protein content of the cereal used in the product and agreed to provide provisionally for a limit of 0.4% residual protein. Governments were requested to comment specifically on this figure.

60. In discussing section 3.2, the Committee considered what provisions might be appropriate concerning the use of vitamins and minerals. A number of countries held the view that products from which the gluten had been removed should contain the same amount of vitamins and minerals as the normal product. In some countries vitamins and minerals were added to restore those removed in manufacture i.e. to the original quantities, whilst in others larger amounts of vitamins and minerals were added, i.e. the foods were fortified. The Committee concluded therefore that the addition of vitamins and minerals should be in accordance with national legislation and the section was amended accordingly.

61. It was proposed that for the information of the consumer reference be made on the label to the type of illness. The Committee did not agree to this proposal.

62. The delegation of the United Kingdom pointed out that the provisions with regard to vitamins and minerals in section 4.3 - Declaration of Nutritive Value - were now in contradiction to the amended section 3.2.

63. The Committee therefore agreed to amend provision 4.3.1 and to replace section 4.3.2 with the relevant text contained in the Standard for Canned Baby Foods (Section 9.3(b)).

64. The Committee decided that the provision regarding claims (section 5) would have to be clarified in order to be explicit that claims relating to the term "gluten-free" could not be applied to food naturally free of gluten. Nevertheless it was considered of value that the consumer should be informed that certain foods which are naturally free of gluten would be suitable for use in a gluten-free diet.



65. The Committee agreed upon the following text:

"5.1 A food prepared according to 3.1 may be called a "gluten-free" food.

5.2 A food which naturally has no gluten may not be called "gluten-free"; however, a cereal or a food product containing a cereal which naturally has no gluten may be labelled to show that it is naturally free of gluten and is suitable for use in gluten-free diets."

66. The Committee noted that the Working Group on Methods of Analysis and Sampling would await the results of work at present being done in the Netherlands to develop a suitable method for the determination of gliadin.

#### Status of the Standard

67. The Committee decided to refer the standard to governments for a further round of comments at Step 6 and requested governments to pay special attention to the amount of residual protein in gluten-free foods as signified in section 2.2.2.

#### CONSIDERATION OF THE PROPOSED DRAFT STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES AT STEP 4

68. The Committee considered document CX/FSDU 77/8 containing government comments on the above proposed draft standard prepared by the United Kingdom.

69. When the Committee had discussed, at its Ninth Session, the proposed draft standard, it had been decided to request governments to comment on Sections 1 to 4 and not to elaborate further, at least at the present time, Section 5 (paras 63-65, ALINORM 76/26A).

70. The delegation of the United Kingdom emphasized the importance of a general labelling standard to cover all dietary foods because it was unlikely that individual standards would be elaborated for all products. This view was shared by most delegations, which expressed themselves in favour of a standard rather than guidelines. It was considered that such a general standard would serve a dual purpose. It would be a standard per se for acceptance by governments and would also provide the appropriate labelling provision for individual standards elaborated for certain dietary foods.

71. The Committee fully discussed Section 2.1 - Definition of "Foods for Special Dietary Uses". The Committee decided to delete any reference to dietary classes because such classes would not cover every type of product used for dietary purposes. However, it was thought to be of great importance that the definition of a food for special dietary use should state that the composition had been modified compared with normal food. Several delegations expressed the opinion that a judgement as to which foods were to be called "dietary" should be left to national authorities and that such products should be suitable for the purpose indicated. The Committee decided that these matters should be discussed further at the next session and amended the Section as follows:

"Foods for Special Dietary Uses (Special Dietary Foods) are those foods which are specially processed or formulated to satisfy a particular dietary requirement(s) which exist(s) because of a physical or physiological condition and/or specific diseases and disorders. The composition of these foodstuffs must differ significantly from the composition of normal foods of comparable nature, if such normal foods exist."

72. The Committee noted that Section 2.2 on claims, as drafted at present, was a definition of any claim in respect of food. The Committee therefore considered that it would be desirable to await examination by the Codex Committee on Food Labelling of the "General Guidelines for Claims". The point was made that the listing of ingredients as part of the declaration of ingredients or nutritional labelling should not be regarded as constituting a claim. The Committee decided that it would not be possible at present to agree on a wording for Section 2.2 and requested the delegation of the United Kingdom to redraft the standard without changing Section 2.1 as agreed upon above by the Committee.

73. The Committee requested delegations to confirm in writing their comments on the various sections of the standard made during the session and to submit any other comments they might wish to make on the standard as soon as possible to the Codex Secretariat, FAO, Rome. The delegation of the United Kingdom undertook to redraft the standard in the light of these comments and of the deliberations of the next session of the Codex Committee on Food Labelling concerning claims and nutritional labelling. The Codex Secretariat was requested to assist the United Kingdom in this task.

#### Status of the Standard

74. The Committee decided that the redrafted proposed draft standard should be sent to governments for comments at Step 3 prior to the next session.

#### CONSIDERATION OF THE PROPOSED DRAFT STANDARD FOR FOODS FOR USE IN A DIET FOR DIABETICS AT STEP 4

75. The Committee had before it document CX/FSDU 77/9 containing the above proposed draft standard revised by the German Secretariat. The Committee had discussed the standard at previous meetings and had decided at its Ninth Session that further consideration should be given to the elaboration of a standard for foods specially suited for diabetics set forth in Appendix VII to ALINORM 70/26.

76. The delegation of the Federal Republic of Germany, when introducing the standard, expressed the view that the continuation of the elaboration of the standard was justified by new scientific knowledge influencing the treatment of persons suffering from diabetes.

77. A large number of delegations outlined the way in which diabetes, in its different forms, was treated in their countries. There was almost general agreement that a balanced diet from normal foods with possibly a reduction in energy intake was the most important measure to help many diabetics and that no special products were needed to achieve this. Some delegations furthermore emphasized that not only carbohydrate was involved but also the lipid intake should be controlled. The Committee agreed that any diet for diabetics should be established and controlled by a physician. The vast majority of delegations expressed their opposition to the elaboration of a standard for foods intended for use by diabetics. The delegation of France proposed that in considering a standard for carbohydrate-reduced foods appropriate provisions should be made to cover the interests of diabetics. The delegation of Norway emphasized that the diabetic could eat normal foods, and any foods specially modified for diabetics could be controlled by labelling. It was recognized, however, that there were products intended for use in a diet for diabetics on the market in many countries. Such products provided a wider choice of foodstuffs for these patients. The importance and usefulness of label information as to the composition and purpose of such foods was stressed. The Committee discussed whether guidelines for such labelling should be developed. Several delegations stated that the introduction of nutritional labelling in their countries had proved to be one of the most practical aids for diabetics. The Committee recognized that diverging opinions existed among countries, and within the medical profession in individual countries, on how to treat persons suffering from diabetes in its various forms. The Committee considered that the control of foods sold for use in a diet for diabetics should be left to the national authorities of individual countries. Notwithstanding this view the Committee thought there would be merit in trying to secure international agreement on the form and information to be included in labelling which could help diabetics in following a medically prescribed dietary regime.

78. There was considerable discussion as to how the Committee should proceed. Some delegations thought international expert opinion should be obtained from both the International Diabetes Federation and WHO. Other delegations considered that their own authorities and national diabetes associations had sufficient expertise available for delegations to consider the subject within the Committee. The Committee concluded that the most practical procedure was the establishment of a working group composed of members of the Committee with the delegation of the Federal Republic of Germany as coordinator. The following countries volunteered to participate in the work of the above group: Sweden, United Kingdom, Switzerland, Italy, France, Netherlands, United States and the Federal Republic of Germany. The delegation of Austria stated that their country might also wish to participate. It was explained that further consideration of these matters would be held in abeyance until the recommendations of the Working Group were available.

CONSIDERATION OF THE PROPOSED DRAFT STANDARD FOR LOW CARBOHYDRATE (CARBOHYDRATE-REDUCED) FOODS AT STEP 4

79. The Committee considered the revised Draft Standard for Low-Carbohydrate (Carbohydrate-reduced) Foods as contained in CX/FSDU 77/10 prepared by the Secretariat.

80. The draft standard in Appendix IX to ALINORM 70/26 had been revised in the light of government comments (CX/FSDU 70/10 and Addenda I and II) and of decisions taken by the Committee on other standards.

81. In view of the fact that products covered by any standard for carbohydrate-reduced foods might also be of use to some diabetics, the Committee decided to refer the need for a standard for such products to the Working Group set up to discuss foods for diabetics. Some delegations also drew attention to the fact that products to be covered by this standard could be of use in other diets, e.g. for the control of obesity. Some delegations held the view that there was no need for a standard for carbohydrate-reduced foods and the establishment of a minimum reduction for carbohydrates could be made in the claims section.

FUTURE WORK

82. The Committee had before it the proposals made at its Ninth Session for future work (see para 73 of ALINORM 76/26A). The Committee accepted an offer of the delegation of the United States to prepare a paper which would provide guidelines for terminology of use in the elaboration of any standard for foods to control energy intake.

83. Concerning the possibility of elaborating a standard for low-cholesterol foods the Committee was informed that there was likely to be a Joint FAO/WHO Expert Consultation on the Rôle of Fats in the Human Diet. The delegation of Canada, which had originally proposed the elaboration of such a standard, recommended postponement until the report of this Expert Committee was available.

84. The delegation of Hungary requested that the Joint Expert Committee on Food Additives should evaluate certain new non-nutritive sweeteners. When information on toxicology and the relevant specifications were available, the substances would be referred to JECFA. It was mentioned that products containing medium chain triglycerides were of increasing importance in many countries.

85. The United Kingdom reminded the Committee that at the meeting of the Codex Commission in May 1976, a recommendation was made "to review the Standard for Infant Formula in the light of further knowledge". It was agreed to add this to the list of subjects for future work. The delegation of Japan supported the United Kingdom and wished the standard for infant formula to be revised as soon as possible.

86. After consideration of the foregoing matters the Committee concluded that it should concentrate on the completion of its current work programme.

DATE AND PLACE OF NEXT SESSION

87. The Committee was informed that its next session would be scheduled to take place between the 12th and the 13th sessions of the Commission. The Chairman indicated that this would be preferably in Autumn 1978 or at the latest in Spring 1979 depending on the progress made in the different Working Groups and on the availability of the redrafted documents. The exact venue and time of the session would be communicated at a later date.

Summary Status of Work

Standard/Code/Document	Status Step	to be dealt with by	ALINORM/App. Document
Standard for Foods with Low Sodium Content (including salt substitutes)	9	Governments	CAC/RS 53-1971
Standard for Infant Formula	9	Governments	CAC/RS 72-1976
Standard for Canned Baby Foods	9	Governments	CAC/RS 73-1976
Standard for Processed Cereal-based Foods for Infants and Children	9	Governments	CAC/RS 74-1976
Draft Standard for Gluten-Free Foods	6	11th FSDU	ALINORM 78/26, Appendix II
Proposed Draft Standard for Follow-up Foods for Older Infants and Children	3	11th FSDU	CX/FSDU 79/..1/
Proposed Draft General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses	3	11th FSDU	CX/FSDU 79/..1/
Proposed Draft Standard for Foods to be used in a Diet for Diabetics	4	11th FSDU & Working Group see para 78	CX/FSDU 77/9
Proposed Draft Standard for Carbohydrate-reduced Foods	4	11th FSDU & Working Group see para 81	CX/FSDU 77/10
Proposed Draft Standard for Consumer-Packaged Protein Food	4	see para 86	ALINORM 71/26 Appendix VII
Cholesterol-reduced Foods	-	postponed see para 83	ALINORM 76/26A para 73
Medium chain triglycerides	-	postponed see para 84	-
Low-calorie Foods	}	see para 86	ALINORM 76/26A para 73
Low-protein Foods			
List of Vitamin Compounds	-	11th FSDU	CX/FSDU 79/..1/
List of Mineral Salts	-	11th FSDU	CX/FSDU 79/..1/
Code of Hygienic Practice for Foods for Infants and Children	4	14th FH	CX/FH 78/... 1/
Microbiological Specifications for Foods for Infants and Children including Sampling Plan (see paras 14-16 and 46)	4	14th FH	CX/FH 78/... 1/
Guidelines for Terminology (see para 82)	2	11th FSDU	CX/FSDU 79/..1/
Revision of Standard for Infant Formula (CAC/RS 72-1976)	-	-	ALINORM 78/26 para 85
<hr/> <p>1/ To be distributed in due course.</p>			

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APPENDIX II

PROPOSED DRAFT STANDARD FOR "GLUTEN-FREE" FOODS  
(Returned to Step 6)

1. SCOPE

1.1 This standard applies to those processed foods which have been specially prepared to meet the dietary needs of persons intolerant to gluten.

1.2 The standard refers only to the specific provisions related to the special dietary purpose for which these foods are intended.

1.3 This standard does not apply to foods which in their normal form do not contain gluten.

2. DESCRIPTION

2.1 Definition

"Gluten-free food" is a food so described (a) consisting of or containing as ingredients such cereals as wheat, triticale, rye, barley, or oats or their constituents, which have been rendered "gluten-free", or (b) in which any ingredients normally present containing "gluten" have been substituted by other ingredients not containing "gluten".

2.2 Subsidiary Definitions

2.2.1 For the purpose of this standard, "gluten" is defined as those proteins, commonly found in wheat, triticale, rye, barley, or oats to which some persons are intolerant.

2.2.2 For the purpose of this standard, "gluten-free" means that the "gluten" expressed as the total protein content of the cereal grains used in the product does not exceed 0.4%.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 A "gluten-free" food shall be based on or shall contain:

- (a) gluten-containing cereals such as wheat, triticale, rye, barley, or oats or their constituents, which have been rendered "gluten-free" according to section 2.2.2; or
- (b) ingredients which do not contain gluten in substitution for the ingredients containing gluten which are normally used in a food of that kind; or
- (c) any mixture of two or more ingredients as in (a) and (b).

3.2 Gluten-free foods, substituting important basic foods like flour or bread, must supply approximately the same amount of vitamins and minerals as the original foods they replace in accordance with the national legislation of the country in which the food is sold.

4. LABELLING

In addition to Sections 1, 2, 4 and 6 of the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969) the following specific provisions apply (subject to endorsement by the Codex Committee on Food Labelling):

4.1 The term "gluten-free" shall be given in immediate proximity to the name of the product.

4.2 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and added minerals, these shall be arranged as separate groups of vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

4.3 Declaration of Nutritive Value

The label shall include the following nutritional information:

4.3.1 The amount of energy, expressed in Calories (Kcal) or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes of the food and where appropriate per specified quantity (e.g. one biscuit) of the food as suggested for consumption.

4.3.2 In addition to any other nutritional information required by national legislation, the total quantity in the final product of each vitamin and mineral added, according to Section 3.2, shall be declared per 100 g as well as according to the serving size of the food suggested for consumption.

5. CLAIMS

5.1 A food prepared according to Section 3.1 may be called a "gluten-free" food.

5.2 A food which naturally has no gluten may not be called "gluten-free"; however, a cereal or a food product containing a cereal which naturally has no gluten, may be labelled to show that it is naturally free of gluten and is suitable for use in gluten-free diet. <sup>1/</sup>

6. PACKAGING

6.1 The product shall be prepacked for safeguarding the hygienic and other qualities of the food.

6.2 The containers including packaging material shall be made only of substances which are safe and suitable for their intended use. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging material, that standard shall apply.

7. METHODS OF ANALYSIS AND SAMPLING

(to be developed).

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<sup>1/</sup> This provision is implicit in the Draft General Standard for the Labelling of and Claims for Foods for Special Dietary Uses (Section 4.2, CX/FSDU 75/10) and will be redundant when that standard is established.

REPORT OF AN INFORMAL AD HOC WORKING GROUP ON  
FOOD ADDITIVES IN FOODS FOR INFANTS AND CHILDREN  
Bonn (Fed. Rep. of Germany), 24-25 February 1977

INTRODUCTION

1. The Ninth Session of the Codex Committee on Foods for Special Dietary Uses, Bonn, 22-26 September 1975, directed that the Ad Hoc Working Group on Food Additives in Foods for Infants and Children should continue its work under the Chairmanship of Dr. K. Murray (Canada).
2. As a result, the Working Group met in Bonn, 24-25 February 1977. A list of participants is shown in Appendix I.
3. The meeting was opened by Dr. H. Drews, Ministerialrat, Federal Ministry of Youth, Family and Health. Dr. Drews emphasized the value of having a small group of specialists examine the use of food additives before the matters are taken to the Codex Committee on Foods for Special Dietary Uses.

ADOPTION OF THE AGENDA

4. The Working Group adopted the Provisional Agenda with a slight re-arrangement of the order in which the items were to be discussed.

BHA and BHT as Antioxidants

5. The Working Group agreed not to recommend the use of BHA and BHT in any baby foods. The USA delegate, supported by the United Kingdom delegate, indicated that it was not opposed to the use of these compounds.

Ammonium Carbonate and Bicarbonate

6. The Working Group had before it a suggestion that ammonium carbonate and ammonium bicarbonate be provided for as leavening agents in cereal-based infant foods. While some delegates had no objection to the use of these two additives, others expressed the view that the technological justification was not convincing particularly since other chemicals were available. The Working Group agreed to recommend that ammonium carbonate and bicarbonate be accepted for use in "crusks and biscuits" only and asked the United Kingdom delegate to provide residue data which could be put before the Joint FAO/WHO Expert Committee on Food Additives for its consideration as present in these baby foods.

Trypsin

7. The Working Group gave consideration to the request that trypsin be provided for in cereal foods for babies. In view of the lack of enthusiasm for this request based on concern about the technological justification, the Working Group agreed to defer a decision on it pending further information from the United Kingdom delegate on technological justification.

Tartaric Acid

8. The Working Group then gave consideration to the use of tartaric acid in certain canned baby foods. Some concern was expressed regarding the fact that the intake of tartaric acid, in general, may considerably exceed the acceptable daily intake. The Working Group agreed to recommend that only L (+) tartaric acid should be used, that it should be restricted to fruit-based products, and that the level should not exceed 1%.

Calcium, Potassium and Sodium Hydroxide

9. The Working Group had before it a request for the use of calcium, potassium and sodium hydroxide in infant formula to prevent protein precipitation and other changes during processing. After some discussion, including expressions of concern regarding the use of these hydroxides, the Working Group agreed to recommend the use of these additives in infant formula. It was pointed out to the Committee that this decision was consistent with an earlier decision which had been taken by the Codex Committee on Foods for Special Dietary Uses.

### Pectin

10. The Working Group then turned its attention to the question of the use of pectin in infant formula, canned baby food and cereal-based food. The Working Group had before it a number of replies from governments indicating in what baby foods pectin was used and at what levels. It was pointed out to the Working Group that carrageenan was already provided for in infant formula and that for consistency pectin should also be provided for. The Working Group's attention was also drawn to the fact that pectin was already provided for in fruit-based canned baby foods at a level of 1%.

11. After considerable discussion the Working Group agreed to make the following recommendations:

- (i) pectin should not be provided for in infant formula;
- (ii) pectin should not be provided for in cereal-based products;
- (iii) pectin should not be provided for in canned baby foods other than in fruit-based canned baby food which has already been accepted.

12. These decisions were primarily based upon the fact that considerably more pectin would be required in infant formula than for similar additives already approved. With respect to the cereal-based baby foods the Working Group saw no technological justification for a thickening agent.

### Mono- and di-glycerides

13. The Working Group had before it a request that the mono- and di-glycerides be permitted in canned baby foods at a level of 0.15% on a ready-to-eat basis and not related to fat content. It was further pointed out that at the present time, the mono- and di-glyceride content in canned baby foods was limited to 1.0% based on fat, whereas cereal foods may contain 1.5% on a dry basis.

14. The Working Group agreed to recommend that provision be made for the use of the mono- and di-glycerides in canned baby foods at a maximum level of 0.15% on a ready-to-eat basis.

### Carry-over Principle to Foods for Infants and Children

15. The Working Group then turned its attention to the applicability of the carry-over principle to foods for infants and children.

16. The Working Group had before it the "Principle Relating to the Carry-over of Additives into Foods" which had been prepared by the Codex Committee on Food Additives and endorsed by the Codex Alimentarius Commission as a guide to Codex Commodity Committees at the Eleventh Session of the Commission. The delegates present at the Working Group familiarized themselves with the details of this Principle.

17. It soon became apparent that the Working Group could not reach agreement as to whether or not to recommend that the carry-over principle be accepted as applying to baby foods. In view of this, the Working Group turned its attention to other possible recommendations which might be made.

18. In the ensuing discussion the following suggestions were made:

- (i) that governments, when accepting baby food standards, be asked to comment specifically on whether or not the carry-over principle applies;
- (ii) that there be established a list of food additives which are acceptable to be carried over into baby foods in general or in specific classes of baby foods (positive list);
- (iii) that there be established a list of food additives which should not be carried over into baby foods, in general, or in specific classes of baby foods (negative list).

19. The delegates, in attendance, cited examples of food additives which would fall into these categories and presented reasons, pro and con, regarding each of the suggestions.

20. The Working Group finally agreed to recommend to the Codex Committee on Foods for Special Dietary Uses that governments, in the Codex acceptance procedure, be specifically asked, when accepting baby food standards, to indicate whether or not the carry-over principle applies, and if affirmative, does it apply generally or only to specific baby foods and/or specific additives.

### Levels of Nitrates in Baby Foods

21. The Working Group next considered the question of establishing maximum nitrate levels in baby foods. Documentation on this matter from the Federal Republic of Germany and from Norway is available.

22. The delegate of the Federal Republic of Germany in speaking on this matter made reference to the fact that in his country the content of nitrate in foods for infants and children must not exceed 400 mg/kg. From 1 January 1979 the maximum level will be restricted to 250 mg/kg. This restriction appears to have had the effect of reducing the levels of nitrates in baby foods in that country.

23. Other delegates did not agree with the need to establish maximum levels for nitrates in these foods, but rather felt that the requirement to be found in Sections 9.9.1 and 9.9.2 of the Standard for Canned Baby Food to adequately cover the situation. These Sections read:

"9.9.1 Directions as to the preparation and use of the food and its storage and keeping before and after the container has been opened, shall appear on the label or on the accompanying leaflet."

"9.9.2 For canned beets (beetroot) and spinach, the following statement shall appear on the label: "Use after the age of 12 weeks"."

24. It was pointed out to the Working Group that the question of nitrates in baby foods was not a simple matter and that such factors as time of harvest, weather conditions, degree of blanching and washing, disposal of products which exceed the maximum, were examples of factors to be considered.

25. It was also pointed out by two delegates that no demonstrated health hazard because of nitrate content of commercial baby food had been reported.

26. A majority of the Working Group agreed that the present storage and labelling instructions as found in Sections 9.9.1 and 9.9.2 of the Standard for Baby Foods was satisfactory at present. A minority group, however, held the view that maximum levels for nitrates in baby foods should be established. In this and other discussions, the Working Group suffered from the small number of delegates attending the meeting.

### Metals and Metalloid Contaminants

27. The Working Group had before it a document prepared by the United Kingdom with the metal content of baby foods in that country. Some delegates pointed out that in their countries, data on this matter would be forthcoming.

28. Pending the receipt of this additional data, the Working Group did not feel that it could usefully discuss this matter.