codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME: Tel. 57971 Telex: 610181 FAO I. Cables Foodagri

ALINORM 87/26

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Seventeenth Session

Rome, 29 June - 10 July 1987

REPORT OF THE FIFTEENTH SESSION OF THE

CODEX COMMITTEE ON FOODS FOR SPECIAL DIETARY USES

Bon-Bad Godesberg, 12-16 January 1987

W/Z1696

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APPENDICES

INTRODUCTION (Item 1)

1. The Codex Committee on Foods for Special Dietary Uses held its Fifteenth Session from 12 to 16 January 1987 at the Wissenschaftszentrum in Bonn-Bad Godesberg by courtesy of the Government of the Federal Republic of Germany. The Session was chaired by Dr. G. Pahlke, Director and Professor, Federal Health Office of the Federal Republic of Germany.

2. The Session was opened by Under Secretary of State W. Chory of the Federal Ministry for Youth, Family Affairs, Women and Health, who welcomed delegates and outlined briefly the work undertaken by the Committee. Mr. Chory emphasized that the work of the Codex Alimentarius Commission had profoundly influenced food legislation world-wide and expressed the hope that formal acceptances of Codex Standards would progress. The full statement made by Mr. Chory is attached to this report as Appendix II.

3. The Session was attended by delegations from the following countries:

Argentina	Italy
Australia	Japan
Belgium	Korea, People's Dem. Rep. of
Brazil	Madagascar
Canada	Netherlands
Côte d'Ivoire	Norway
Cuba	Spain
Czechoslovakia	Sweden
Denmark	Switzerland
Finland	Thailand
France	United Kingdom
Germany, Fed. Rep. of	United States of America
Hungary	

Observers were present from the following countries and International Organizations:

- German Democratic Republic;
- Association of Official Analytical Chemists (AOAC);
- European Economic Community (EEC);
- International Association for Cereal Science and Technology (ICC);
- International Dairy Federation (IDF);
- International Federation of Margarine Associations (IFMA);
- International Society of Dietetic Including All Infant and Children Food Industries (ISDI).

A List of Participants, including officers from FAO and WHO, is included in Appendix I to this report.

4. The Session was preceded by meetings of the following Ad-Hoc Working Groups which took place from 7 to 10 October 1986:

WG I - on : Draft Standard for the Labelling of and Claims for Low Energy and Energy-Reduced Foods and on Draft Guidelines for Meal Replacements.

WG II - on : Draft Guidelines on [Medical Foods].

WG III - on : Matters Related to Nutrition.

WG IV - on : Supplementary Foods and Certain Aspects of the Draft Standard for Follow-up Foods for Older Infants and Young Children.

The reports of the above Working Groups are contained in CX/FSDU 87/6 and were considered under the relevant agenda items.

5. The following Ad-Hoc Working Groups met on 12 January, prior to the Plenary Session:

- Working Group on Methods of Analysis and Sampling.
- Working Group on the Advisory Lists for Vitamin Compounds and Mineral Salts.

The reports of these two Working Groups were considered under Items 13 and 14 respectively.

ADOPTION OF THE AGENDA (Item 2)

6. The Committee noted that the report of the Working Group on Methods of Analysis and Sampling would be presented in connection with the items dealing with foods for infants and children and that the report of the Working Group on the Advisory Lists would be considered in connection with Item 7 (Amendments to Codex Standards for Foods for Infants and Children). The Committee also agreed to consider Item 12 on Medical Foods after Item 9. The Committee was informed that the working paper containing the technological justification of the food additives in follow-up foods was available as a Conference Room Document (CRD) only and agreed that a small WG be established to examine the document. It was agreed that the Group would work under the Chairmanship of the United States and consist of members of the Delegations of France, Federal Republic of Germany, Netherlands, Sweden, Switzerland, United Kingdom and United States. The Committee unanimously adopted the provisional agenda for the session (CX/FSDU 87/1).

APPOINTMENT OF RAPPORTEURS (Item 3)

7. The Delegations of Canada and the United Kingdom, and of Switzerland and France were appointed to serve as Rapporteurs for the session.

MATTERS ARISING FROM THE SIXTEENTH SESSION OF THE COMMISSION AND OTHER CODEX COMMITTEES (Item 4(a))

8. The Committee had before it working paper CX/FSDU 87/2-Part I which contained matters of interest arising from the 16th Session of the Commission and from other Codex Committees, and a summary of notifications on government positions related to the standards elaborated by this Committee. It was noted, that additional matters had already been brought to the attention of the Meeting of the Intergovernmental Working Groups in October 1986, and that these matters would be further considered under Item 4 (c).

CODEX ALIMENTARIUS COMMISSION, 16TH SESSION - ALINORM 85/47

Amendment of Code of Ethics for International Trade in Food (CAC/RCP 20-1979) (Paras 167-172)

9. The Committee was informed that the Commission had amended the above Code to include cross reference to the WHO International Code for the Marketing of Breastmilk Substitutes by making the following changes:

(i) Add new paragraph (g) in the Preamble as follows:

" (g) The International Code of Marketing of Breastmil Substitutes sets forth principles for the protection and promotion of breastmilk feeding, which is an important aspect of primary health care".

(ii) Paragraph 5.9 to read as follows:

"5.9 Food for infants, children and other vulnerable groups should be in accordance with standards elaborated by the Codex Alimentarius Commission".

(iii) Paragraph 5.10(b) to read as follows:

"(b) Information concerning the nutritional value of food should not mislead the public".

Amendments to Codex Standards for Foods for Infants and Children set forth in Paras 127(a) and (b) of ALINORM 85/26 (Paras 467-469)

10. The Committee noted that the Commission had adopted at Step 8 the amendment to the Codex Standard for Infant Formula which reads as follows (para. 127(a) of ALINORM 85/26):

> "In this case, the provisions of Article 9 of the International Code of Marketing of Breast-milk Substitutes of the World Health Organization should be duly taken into account".

The Committee also noted that the Commission had considered the proposed amendment contained in para. 127(b) of ALINORM 85/26 at Step 5 of the Procedure and had advised that the amendment be further considered by this Committee. It was decided, to refer this matter to Item 7.

Draft Amendments to Codex Standards for Foods for Infants and Children (Appendix IX to ALINORM 85/26) (Paras 452-455)

11. The Committee was informed that the Commission had adopted at Step 8 only the amendment in Section B of Appendix IX. The other amendments had been adopted at Step 5. The Committee noted that on the latter comments at Step 6 had been obtained and agreed to consider these amendments under Item 7. It was also noted that the WG on Advisory Lists had considered the amendments and that a Report would be presented together with Item 7.

Proposal of the International Atomic Energy Agency (IAEA) to Amend Certain Codex Standards (Paras 474-479)

12. The Commission had been informed of the brief discussion at the 14th Session of the Committee of the request of IAEA to reconsider the prohibition of the use of irradiation treatment presently contained in the Codex Standards for Foods for Infants and Children. At the 16th Session of the Commission, the Observer of IAEA had pointed out "that the present Codex General Standard for Irradiated Foods recognized that the process of food irradiation had been established as safe for general application to food up to an absorbed dose level of 10 kGy. In his opinion, it was not the intention of the Codex General Standard to imply a need for clearance of the process on a food by food basis, or to restrict authorization of the process in any other way. A number of Codex standards (e.g., fruit juices and foods for infants and children) prohibited the application of irradiation either to the finished product, or to components used in the preparation of the food. Although the use of the irradiation process might not be relevant for the treatment of food products such as fruit juices or canned foods for children, it was possible that components might have been treated by irradiation (e.g., cereals for insect disinfestation purposes and the elimination of pathogens in spices or dried ingredients)".

13. During the discussion in the Commission, the following views had been expressed (para. 478): "The Delegations of the Federal Republic of Germany and Spain were of the opinion that nothing would be gained by referring the matter to the Codex Committee on Foods for Special Dietary Uses, since the general clearance referred to the average adult and that there was no technological need for the irradiation of foods for infants and children. Other delegations supported the proposal of the IAEA that the matter be further discussed by the appropriate Codex Committees. The Delegation of the United Kingdom was of the opinion that, as the issue raised by IAEA was a general one, it should be considered by the Codex Committee on Food Additives".

14. The Commission had therefore agreed that this matter should be further considered by the Committees concerned. The full text of the IAEA statement and the text of the General Standard for Irradiated Foods were attached to CX/FSDU 87/2-Part I.

15. The Secretariat further explained the meaning of the General Standard for Irradiated Foods which dealt with suitable conditions for the irradiation of all foods but did not list the foods as such.

16. The Committee agreed that it was important to examine carefully the provisions currently included in the Codex Standards for Infants and Children in the light of the Codex General Standard and decided that a Circular Letter should be issued to request written comments on this matter for further consideration at the next session. The statement of IAEA to the 16th Session of the Commission is attached as Appendix XV to this report.

Adoption of Codex General Labelling Standards and the Need to Revise the Labelling Provisions in Codex Standards for Foods for Special Dietary Uses

17. The Committee was informed that the Commission had adopted both the general labelling standard for all foods as well as the one for foods for special dietary uses. The Commission had also requested all Codex Committees to review and revise, as necessary, the labelling sections in their standards. The Committee agreed that, in view of the complexity of the matter, a paper containing proposals for such a revision, should be prepared by the Secretariat for the next session of the Committee.

CODEX COMMITTEE ON FOOD ADDITIVES, 18TH SESSION (ALINORM 87/12)

Intake of Glutamates (Paras 47-50)

18. The Committee was informed that concern had been expressed in CCFA about a possible high intake of Monosodium Glutamate (MSG) especially in countries where the use of MSG as carrier for Vitamin A was studied. CCFA had suggested that a survey on dietary intake be carried out for glutamates and other food additives of interest to Asia. The Committee wished to be kept informed of such a survey.

Intolerance to Food Additives (Paras 52-59)

19. The Committee noted that CCFA had considered a paper prepared by Sweden on this subject. The importance of full label declarations had been stressed. This did, however, not cover the amounts of food additives having allergenic properties which were present in a food as a matter of carry-over. CCFA had proposed that these substances be considered on a case by case basis, e.g., a minimum analytical level could be specified for individual problem additives, above which a label declaration would be mandatory. The Chairman expressed the view that many of the reactions to food additives should be classified as intolerances as opposed to true allergic reactions.

Definition of "Food Additive" (Para. 250)

20. The 16th Session of the Commission amended the above definition by deleting the word "the" thus referring to food additives as a substance which is not normally used as a "typical ingredient of food" in general.

21. The Committee noted that a proposal had been made by delegations to CCFA to add to the General Principles for the Use of Food Additives (see the Procedural Manual, 6th Ed.), the following clause:

> "The above principles also apply to vitamins, mineral salts and amino acids added to foods in order to fortify or to improve the nutritive qualities of the food".

22. The Committee noted that this would be of concern to its work on mineral salts and vitamin compounds. The Committee also noted that the WG on Advisory Lists of this Committee had discussed this matter and agreed that it should be further considered under Item 13.

COORDINATING COMMITTEE FOR ASIA, 5TH SESSION (ALINORM 87/15)

23. The Committee noted that a Report on the "Current Situation and Capabilities of Selected Countries in the Asian Region for the Manufacture of Infant Formula and Weaning Foods" prepared by a consultant had been considered by the above Committee at its 5th Session (CX/Asia 86/9). The Secretariat recalled that this Committee had discussed at tis 13th and 14th Sessions difficulties encountered by Thailand and other countries in the Asian Region in accepting the Codex Standard for infant Formula (CODEX STAN 72-1981).

24. The Committee noted the views expressed by members of the Region of Asia (paras 177-183 of ALINORM 87/15) and the conclusion of the Coordinating Committee for Asia that it could not endorse the above report. No further comments from the countries of the Asian Region had yet been received on this matter.

COORDINATING COMMITTEE FOR AFRICA, 7TH SESSION (ALINORM 85/28)

25. The Committee noted with appreciation the interest of the above Committee in the work on nutritional aspects carried out by this Committee. The Committee noted with particular interest the remarks by the delegation of Senegal on formulated foods which read as follows:

> "(119.) The Delegation of Senegal pointed out that the UN Agencies had, over the last 35 years, experienced difficulty in developing suitable food formulations. The difficulties arose from the fact that food formulations did not take into account sufficiently socio-economic and cultural factors. The Representative of FAO pointed out that, indeed, the development of suitable food products was a national matter. The Delegation of Kenya also drew attention to problems of shelf-life and packaging. "

26. The Committee agreed to take the above views into account in the consideration of standards and guidelines for the various formulated foods.

Progress Report on Acceptances

27. The Committee was informed of all notifications concerning the acceptance of standards which it had elaborated (Part E of CX/FSDU 87/2-Part I). The Secretariat underlined the importance of formal notifications from member countries on their positions regarding the acceptance of the Codex standards concerned. The Secretariat invited delegations to take this matter up with their national authorities.

28. The Delegation of Argentina informed the Committee that some of the papers considered under the above item, as well as for Item 4(b), were not received in time to analyze them thoroughly and to submit the views of the Argentinian Authorities on the matters concerned.

ACTIVITIES OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA) OF INTEREST TO THE COMMITTEE (Item 4(b))

Intake of Lead and Cadmium by Infants and Children

29. The Committee had before it working paper CX/FSDU 87/2-Part II containing information on the discussions which took place in CCFA on the data on the dietary intake of environmental contaminants such as aflatoxins, cadmium and lead collected by the Joint FAO/WHO Food Contamination Monitoring Programme and GEMS/Food (CX/FA 85/5A). The above data had shown that the dietary intakes for cadmium as well as lead collected by the above Programme were very high for infants and children.

30. The CCFA had endorsed the views of the WG on Food Additive Intakes of CCFA:

(a) To indicate to JECFA the risk of the above high intakes.
(b) To ask governments to continue monitoring these data.

The Chairman of the WG on Food Additive Intakes of CCFA had also recommended that maximum levels for contaminants in foods for infants and children should be established by this Committee.

31. The Committee was informed that JECFA had, at its 30th Session (July 1986), evaluated the health risks of lead to infants and children and had established a Provisional Tolerable Weekly Intake of 25 ug/kg body weight. The Committee noted that the full Report of the 30th Session of JECFA would be available in the near future.

32. The Committee was informed that CCFA differentiated between environmental contaminants and those which appeared in the food for technological reasons. The former

had been the subject of discussion in CCFA which had endeavoured to set limits generally applicable to food.

33. It was noted that provisions on numerical values for contaminants present due to technological reasons had been included in the Codex Standards of several Codex Committees after endorsement by CCFA.

34. It was also noted that such substances as lead were derived from both sources, technological as well as environmental. The Delegation of France pointed out that lead intoxication posed a major public health problem but food intake did not seem to play a major role. However, the Delegations of Canada and the United States reported that new developments in canning technology had considerably reduced the amounts of lead found in foods generally and especially in infant foods, particularly since industry was switching to forms of canning which did not use lead-solders.

35. The Delegation of Switzerland informed the Committee of average values for lead, cadmium, zinc and selenium which had been found in monitoring surveys in his country.

36. The Committee was informed by other delegations that a comprehensive specific survey, as undertaken by other Committees would be very costly and possibly duplicate the efforts of the Joint FAO/WHO Food Contamination Monitoring Programme.

37. The Committee decided, therefore, that a Circular Letter should be issued by the Secretariat requesting governments to supply information on the limits for all contaminants in foods for infants and children in force in their countries. Based on this information the Committee would further consider at its next session the feasibility of setting numerical values for contaminants in the Codex Standards for Foods for Infants and Children which, in due course, could replace the present sections on contaminants contained in these standards.

SELECTED MATTERS OF INTEREST ARISING FROM THE MEETING OF THE WORKING GROUPS OF THE 15TH SESSION OF THIS COMMITTEE (Agenda Item 4(c))

38. The Committee had before it working paper CX/FSDU 87/6 - the Report of the above Meeting. The Committee was informed that matters arising from the Commission and other Committees pertinent to the Items considered by the Working Groups which had met in October 1986 had been referred to these groups. The Committee agreed to consider, where possible, the views of the Meeting of the Intergovernmental Working Groups on the matters of interest referred to them, in connection with the relevant agenda items.

The Name of the Committee

39. The Committee noted that the Chairman had, at the Meeting of the Working Groups, drawn attention to the fact that the new responsibilities of the Committee concerning the nutritional aspects of Codex work had not yet been reflected in the name of the Committee.

40. The 14th Session of this Committee had considered it premature to amend its name to "Codex Committee on Nutrition and Foods for Special Dietary Uses".

41. The Working Group Meeting had recommended to the Plenary to amend the name of the Committee as indicated in para. 40 above (paras 33 to 38 of CX/FSDU 87/6).

42. The Committee also noted that the 16th Session of the Commission had accepted the kind offer of the Delegation of the United Kingdom to prepare a paper dealing with increasing nutritional considerations the work of the Commission which was submitted to the 8th Session of the Committee on General Principles.

43. The paper, CX/GP 86/11 also contained a recommendation to change the name of this Committee as indicated in para. 40 above. This paper had been endorsed by CCGP (see also paras 47-55).

44. The Committee decided to request the 17th Session of the Commission to amend its name to read "Codex Committee for Nutrition and Foods for Special Dietary Uses" in order

to reflect fully its terms of reference as amended by the 15th Session of the Commission. The delegation of Belgium suggested that the name of the Committee should be "Codex Committee on Nutrition".

Radionuclides (Paras 39-43 of CX/FSDU 87/6)

45. The Committee was informed that in response to an enquiry during the Meeting of the Working Group, the Secretariat had provided the following information:

> "Due of the concern expressed by Member Governments, the Director-General of FAO had felt that the time had come to think about extending the activities of the Commission to give attention to contamination of food by radioactive fall-out. As a first measure an Expert Consultation had been convened for December this year to consider the possibility of setting internationally acceptable levels and to advise the Codex Alimentarius Commission on all pertinent aspects of the problem."

46. The Expert Consultation prepared a report entitled "Recommended Limits for Radionuclide Contamination of Foods" which would be issued during the next weeks and would receive a wide distribution, including to Codex Contact Points.

MATTERS ARISING FROM THE REPORT OF THE EIGTH SESSION OF THE CODEX COMMITTEE ON GENERAL PRINCIPLES (Agenda Item 4(d))

47. The Committee had before it a paper prepared by the United Kingdom for the Eighth Session of the CCGP (November 1986) on Nutritional Considerations for the Future Work of the Codex Alimentarius Commission (CX/GP 86/11). The Committee noted that the CCGP had endorsed the UK paper and had recommended that the paper be further discussed both by the CC/FSDU and the CCFL. The Secretariat introduced the paper highlighting the more significant recommendations contained therein.

48. In its paper, the United Kingdom suggested that Codex standards should be drawn up bearing in mind the requirements of developing countries, i.e., not to include provisions which would make the food too expensive for the consumer. Codex standards should also reflect, as far as possible, current scientific dietary advice to consumers in developed countries. As regards "recommended daily allowances" (RDA) required for the inclusion of nutritional information on food labels, the paper suggested that it would be useful to have an international opinion on the subject, through an expert group. Other nutritional considerations such as problems arising from excessive intake of fat, sugar, sodium, etc., as well as the question of dietary fibre should also be discussed. The consideration of these questions would fall within the terms of reference of the CC/FSDU and of the CCFL. The United Kingdom had proposed that the name of the CC/FSDU should reflect this additional responsibility.

49. The Committee noted that the UK paper had been distributed only very recently and that the French and Spanish versions of the paper had been made available only during the session. It, therefore, agreed that, given the importance of the subject, a more detailed discussion of the paper should take place at the next session. However, it was agreed to discuss at the present time the proposal to change the name of the Committee and to advise the Commission on the need to arrange for expert advice on certain questions of interest to the Committee. As regards the name of the Committee, see paras 39-44.

50. The Committee discussed the recommendation that expert advice be obtained and be made available to the Committee on matters relating to nutrition, including the question of "recommended daily allowances" suitable for nutrition labelling. In this respect the Committee noted that various expert bodies existed within the UN System which could be requested to address certain problems of interest to the Committee. It also noted that Joint FAO/WHO Expert Committees had recently published reports which up-dated energy and protein requirements and also requirements for Vitamin A, Iron, Folate and Vitamin B_{12}. The Committee was informed that it had not been possible to obtain advice in the past from FAO/WHO Expert Committees on the question of RDAs for labelling purposes because of the particular expertise of the previous Joint FAO/WHO Expert Committees.

51. There was general agreement that a number of issues would require consideration by a committee of experts rather than by the inter-governmental mechanism. A number of delegations were of the opinion that there was an urgent need for advice from independent experts on generally applicable RDAs for labelling purposes. As regards the particular form of expert committee which would deal with such issues, the Committee noted that there were several options possible, including an ad hoc Consultation to which experts in specific fields could be invited.

52. A number of delegations were of the opinion that consideration of such problems as the intake of fats, sugars, sodium and dietary fibre and various other points included in the UK paper represented a major task for the Committee. It was, therefore, essential for the CC/FSDU to identify the issues it wished to consider and on which it wished to receive expert advice. The Delegation of Belgium was of the opinion that more frequent sessions of the Committee would be necessary to deal with these questions.

53. The Committee agreed that the Working Group on Matters Related to Nutrition (WG III) should continue to deal with nutritional questions. It should identify issues which required early attention by the Committee and on which expert advice was needed. A number of delegations were of the opinion that it would be desirable for the WG to meet before the next session of the Committee.

54. The Committee agreed that the establishment of RDAs for labelling purposes by an international group of experts represented an urgent need by the Committee and recommended that a Joint FAO/WHO Expert Consultation should be held at the earliest date (preferably before the next session of this Committee) to consider this question. Further such consultations would be needed in the future to consider questions identified by the Committee through its Working Group on Matters Related to Nutrition.

55. The Committee also agreed that Working Group III should meet prior to the 16th Session of the Committee.

56. As regards the paper prepared by the United Kingdom, the Committee agreed to seek government comments on it, so that it could be discussed in greater detail at the next session. (See Appendix XIV).

CONSIDERATION OF DRAFT STANDARD FOR FOLLOW-UP FOODS FOR OLDER INFANTS AND YOUNG CHILDREN (Item 5)

57. The Committee had before it the above draft standard contained in Appendix IV, ALINORM 85/26 and government comments in document CX/FSDU 87/5. In addition, a document prepared by WHO (CX/FSDU 87/5-Add.1) was available to the Committee as well as a document (CX/FSDU 87/5-Add.2) containing technological justification for food additives.

58. The Chairman drew the attention of the Committee to the fact that the above standard, which the Commission had adopted at Step 5 after extensive discussion in 1985, had been under consideration since 1974. It was imperative, therefore, that a decision be taken immediately whether or not to proceed with the standard. Should the Committee agree that it go forward, every effort should be made to bring work on it to a rapid and satisfactory close.

59. The Chairman reminded the Committee that the Thirty-ninth World Health Assembly in May 1986 had adopted a resolution (WHA 39.28) in which it had requested the Director-General of WHO inter alia to draw attention to the fact that "the practice ... of providing infants with specially formulated milks (so-called 'follow-up milks') is not necessary". In the light of this resolution, and following the participation of a WHO Representative at the Meeting of the Intergovernmental Working Groups in October 1986, the Chairman requested that WHO prepare a paper (document CX/FSDU 87/5-Add.1) outlining the Organization's views concerning the proposed draft standard.

60. The Representative of WHO introduced the WHO document and summarized its main points. He noted that while industrially prepared complementary foods, including those covered by the draft standard, may be a convenience under certain circumstances, a balanced diet for the vast majority of the world's infants could and should be ensured by using a variety of locally available foods in addition to breast-milk. Simply because a

product was judged "not necessary" on nutritional grounds, however, did not mean a priori that it should not be the subject of a Codex standard to ensure the appropriateness of its essential composition and quality factors. Therefore, as long as the products covered by the Proposed Draft Standard were intended and correctly labelled as part of the infant weaning diet, the continued development of the draft standard would not, strintly speaking, be in conflict with resolutions adopted by the World Health Assembly on infant and young child feeding and nutrition.

61. There were a number of points, however, which the Committee might wish to take into consideration during its deliberations. The term "follow-up food" could be misleading since it did not refer to an unlimited class of products, but to a single group of products within this category. It was advisable that the standard mention the importance of proper hygiene in preparation. There was also a need to ensure that the products covered by the draft standard were not introduced before complementary feeding was necessary. Finally, since healt hand allied personnel had an essential role to ply in guiding infant feeding practices, this role could perhaps be highlighted in the standard's labelling provisions.

62. Following the introduction of the WHO document, a number of delegations stated that they continued to consider follow-up milks to be breast-milk substitutes. They voiced their concern that these products could be too easily confused with infant formulas, which were intended to meet all of the nutritional requirements of infants up to the age of 4-6 months. Special care, therefore, needed to be taken in marketing these products in order to avoid any misunderstanding as to their intended use. These delegations wished to know whether or not the products covered by the draft standard came within the scope of the International Code of Marketing of Breast-milk Substitutes.

63. The Representative of WHO explained that according to Article 2 of the International Code, only those food products which were "marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast-milk" fell within its scope. As presently worded, the Draft Standard for Follow-up Foods appeared to cover only products that were intended as part of the infant's weaning diet. As long as there was no equivocation on this point, they would not fall within the scope of the International Code.

64. A number of other delegations spoke out strongly in favour of continuing discussion on and finalizing the standard. The Delegation of Switzerland pointed out that 65.000 tonnes of the products covered by it are being sold per year. It was both unrealistic and illogical that follow-up foods were covered by the scope of the International Code when other weaning foods were not.

65. The Representative of ISDI pointed out that follow-up foods were not intended by their manufacturers to compete with breast-milk or infant formula. Rather, they were being marketed in order to provide a sound alternative to whole cow's milk, which was often given to infants at an unsuitable age as part of the weaning diet.

66. Following lengthy discussion, the Chairman concluded that, despite some reservations expressed about the need for a standard and the implications of the International Code for the products covered by it, the majority of the delegations considered that work on it should continue. The Committee agreed with this conclusion.

Food Additives

67. The Committee decided to set up a small Working Group to discuss the technological justification for the use of food additives. Dr. R. Weik (USA) agreed to act as Chairman of the Working Group. The Delegations of France, Federal Republic of Germany, Netherlands, Sweden, Switzerland, United Kingdom and United States agreed to participate. The Committee then proceeded to a detailed discussion on the draft standard.

Title of the Standard

68. Following discussion it was agreed that the title of the standard and the name of the product should be "follow-up formula".

Section 1 - Scope

69. The Committee had detailed discussion on the age of the infant for the introduction of follow-up formula as part of the weaning diet. Opinion was divided on this issue. Some delegations expressed the view that this type of product was not suitable for some infants below 6 months of age, while other delegations thought that an earlier age would be acceptable. It was noted that follow-up formula could be used at an earlier age than 6 months under professional supervision, depending on the maturity of the infant. On the other hand, it was pointed out that such supervision was not always available or sought. It was, therefore, important to agree on a suitable age at which the product could be used so that appropriate information could be included on the label. It was also noted that the present wording "4-6 months" could lend itself to varying interpretation.

70. The Committee accepted the proposal of the Delegations of Sweden and France to amend Sections 1.1 and 2.1.1 in such a way as to make it clear that the product was intended for infants from the 6th month of age onwards. It was noted that the new wording gave a certain flexibility. The Committee requested the Secretariat to make the necessary consequential changes in the standard.

Section 2.1.3

71. The new definition of "young child" adopted by the Commission editorially amended (see Appendix IX, ALINORM 85/26) was included in the Section.

Sections 2.2 and 2.3

72. The Committee accepted an editorial re-wording of these sections and noted that in Section 2.3, the Spanish version needed to be aligned with the English version. The delegation of Argentina expressed the view that Section 2.2 was not necessary since the ingredients were listed in Section 3.2.

Section 2.4

73. The Delegation of Argentina was of the opinion that the last sentence of this section which required that the product should be nutritionally adequate should be part of the definition of the product. The Committee decided to leave the section unchanged.

Section 3.2.6

Potassium and Chloride

74. The Delegation of Switzerland proposed that the maximum levels for these minerals shuold be "not specified" and that the square brackets be deleted. The Committee accepted the proposal of Switzerland.

Calcium and Phosphorus

75. The Delegation of Switzerland supported by the Federal Republic of Germany proposed the adoption of the following minima for these minerals: calcium, 90 mg; phosphorus, 45 mg. The Delegation of the United States made a counter proposal of calcium, 50 mg; phosphorus, 25 mg.

76. Opinion was divided on the minimum values to be adopted for these minerals. It was noted that there was scientific support for the figures included in the standard in square brackets. It was recognized that infants, for whom follow-up formula was appropriate, would also normally consume other foods containing calcium and phosphorus. The point was made, however, that follow-up formula was a convenience food and that under certain circumstances it could represent a significant portion of the diet of the infant. Therefore, follow-up formula should supply adequate quantities of calcium and phosphorus.

77. The Committee decided to confirm the figures included in the draft standard and to delete the square brackets. The Delegation of the United States wished to reserve its position in this decision.

Choline and Copper

78. The Delegation of the United States proposed to include a provision for choline (7 mg) in non-milk-based formulas and copper (60 ug). The Delegation of Canada supported this proposal. The Delegation of the Federal Republic of Germany was of the opinion that there was no need to include a provision for copper, since follow-up formula would only be a part of the diet of the infant and since copper would be available from other foods. No evidence of copper deficiency had been observed. The delegation also expressed the opinion that choline was not essential in foods for infants beyond the age of 12 months. The Committee decided against the inclusion of provisions for copper and choline as proposed by the United States. The Delegations of Canada and the United States reserved their positions.

Section 3.3.2 - Optional Ingredients

79. The Delegation of Switzerland supported by the Delegations of Belgium, France and the United Kingdom proposed the addition of a further section which would provide for the use of other food ingredients of nutritional interest and which had been scientifically established as being suitable for follow-up formula. This was thought to be desirable in order to improve the acceptability of the product. A number of delegations were opposed to the addition of ingredients other than those already provided for in the standard and preferred to have a more restricted composition for follow-up formula. It was decided not to proceed further with this proposal.

Section 4 - Food Additives

80. The Committee received the report of the WG on Food Additives (CRD No. 4) (see para. 67). In introducing the report, the Chairman of the WG, Dr. R. Weik (USA) indicated that the use of the various groups of food additives included in the draft standard was technologically justified, with the exception of colours. He also suggested that the document CX/FSDU 87/5-Add. 2, should be revised on the basis of the conclusions of the WG and of the Committee before submission to the CCFA. The Committee concurred with this suggestion.

Thickening Agents

81. The Delegations of Sweden and Denmark were of the opinion that the use of thickening agents, other than native starch, was not technologically justified. The Delegation of the Federal Republic of Germany pointed out that there was no need and no technological justification for such a long list of thickening agents and expressed reservation against most of the listed thickening agents. The Delegation of Switzerland, supported by the Delegations of Norway and Belgium, informed the Committee that the use of alginates was technologically not necessary. It was recalled that the Observer of Marinalg had indicated at the meeting of the WGs that alginates were not used for this purpose. The Delegation of France was not in favour of using hydrolyzed protein and mixtures of amino acid in the manufacture of these products. The Delegation of the United States noted that all the thickeners included in the draft standard had been cleared toxicologically and could be regarded as technologically justified. Any deletion of individual thickeners, therefore, would not be for reasons of safety, but be a response to a request by delegations. The Committee agreed to delete alginates and concurred with the view expressed by the Delegation of the United States.

pH-Adjusting Agents

82. There was general agreement on this section. Reference to potassium in Section 3.2.6 was deleted, since that section no longer provided for a maximum limit for this mineral.

Antioxidants

83. The Delegation of Denmark was of the opinion that only α-tocopherol and L-ascorbic acid should be permitted in these products. The Committee decided not to make any changes to this section.

Flavours

84. The Delegations of Denmark, Federal Republic of Germany, Italy, Sweden and Switzerland were in favour of deleting the section on flavours. In response to a query, the Secretariat informed the Committee that natural fruit extracts were considered to be food additives within Codex, since these were preparations involving physical extraction from edible products and may contain carriers. The Delegation of France was in agreement with the conclusion of the WG on food additives that flavours should be allowed to be used in follow-up formula if they improved the acceptability of the product. The Committee agreed to leave the section unchanged.

Colours

85. The Committee noted the recommendations of the WG on food additives and agreed to delete this section.

Section 5 - Contaminants

86. The question was raised whether it would be desirable to include a provision for anti-nutritional factors in this section. Following discussion, it was agreed that Section 3.3.1.1 adequately covered this point, since it required that ingredients used in the preparation of this product shall be suitable for infants.

87. In response to a query from the Delegation of Argentina as to whether the section on pesticide residues could be made more specific by including maximum residue limits, the Chairman explained that Codex maximum residue limits applied to raw materials and that they were elaborated in accordance with specific procedures. Codex lists of pesticide residue limits changed continually making the suggestion made above unpractical.

Sections 6, 7, 8

88. There were no comments on these sections.

Section 9 - Labelling

89. The Committee noted that the 16th Session of the Commission had adopted the General Standard for the Labelling of Foods for Special Dietary Uses, but that the preamble to Section 9 made reference only to the General Standard for the Labelling of Prepackaged Foods. It agreed that the revision of the labelling section in respect of these two labelling standards should be carried out at a future session as part of the revision of Codex standards in respect of labelling.

Section 9.1 - The Name of the Food

90. The Committee accepted the proposal of the Delegation of the United States to delete the square brackets in Section 9.1.2 and confirmed that 90% was the appropriate figure for labelling a follow-up formula as being based on milk.

91. For the sake of clarity, the Committee decided to amend Section 9.1.3 as follows: "All sources of protein shall be clearly shown on the label in close proximity to the name of the food in descending order of proportion by weight".

Section 9.3 - Declaration of Nutritive Value

92. In response to a proposal from the Canadian Delegation, the Committee decided to bring this section in ine with the corresponding section in the Standard on Infant Formula. It was agreed that it should also be optional to declare nutrition information per 100 calories (or per 100 kilojoules). The Committee requested the Secretariat to prepare the revised text.

Section 9.6 - Country of Origin

93. The Delegation of Argentina was of the opinion that the declaration of the country of origin should always be obligatory. The Observer from the German Democratic Republic

pointed out that the corresponding section in the Standard on Infant Formula differed from the text of Section 9.6. The Committee noted that the labelling sections of all Codex standards were being revised and would be brought in line with the General Standard on Labelling.

Section 9.8 - Date Marking and Storage Instructions

94. The Delegations of Argentina and France indicated that they preferred a definite expiry limit for follow-up formula which was a perishable product, rather than the date of minimum durability. The Committee noted that these matters would be discussed during the general revision of the labelling section.

Section 9.9 - Information for Utilization

95. The Committee agreed to change Section 9.9.2 to be in line with Section 2.1.1 as follows: "The labelling of a Follow-up Formula shall include a statement that Follow-up Formula shall not be introduced before the 6th month of life".

Section 10 - Methods of Analysis and Sampling

96. The Committee noted that the methods of analysis for Infant Formula were also proposed for Follow-up Formula and would be referred for endorsement to the CCMAS as decided in connection with the report of the WG on Methods of Analysis and Sampling.

Status of the Standard

97. The Committee decided to advance the Draft Standard for Follow-up Formula to Step 8 of the Codex Procedure for the elaboration of standards. The revised text of the above standard is contained in Appendix III to this report.

AD HOC WORKING GROUP ON METHODS OF ANALYSIS AND SAMPLING

98. The Committee had before it a report of the ad hoc Working Group on Methods of Analysis and Sampling for Foods for Infants and Children (CRD No. 2). The Chairman expressed the appreciation of the Committee to the Chairman and the members of the WG for the excellent work. The Chairman of the WG, Prof. Dr. W. Krönert introduced the report of the WG. He also informed the Committee of two issues which required discussion by the Committee:

(a) The determination of crude fibre for the purposes of determining available calories in foods for infants and children and the analytical definition of dietary fibre from a nutritional point of view; and

(b) consideration of gliadin, for which a method of analysis had been recently developed, in relation to the possible amendment of the Codex Standard for Gluten-free Foods.

99. The Committee concurred with the recommendation of the WG that the question of sampling should be considered in relation to the various standards elaborated by the Committee and expressed its appreciation to Dr. Meech of the Delegation of the United Kingdom for accepting the task of preparing a paper for the next session on the basis of available documents and government comments (see para. 1 of Appendix XI).

100. The Committee noted that the WG had reviewed all methods of analysis included in or required for the standards so far elaborated by the Committee. It also noted that a number of methods, e.g., those for a determination of various minerals in salt substitutes and low-sodium foods, as well as for choline, linoleate, vitamin K_1, biotin (vitamin H) and iodine, still required to be elaborated. It concurred with the recommendations of the WG as indicated in Appendix XI concerning the withdrawal or up-dating of methods of analysis.

Crude Fibre and Dietary Fibre

101. The Secretariat pointed out that the Standards of Foods for Infants and Children elaborated by the Committee required the determination of available calories for the verification of the provisions for vitamins and minerals. The provisions in these standards for the declaration of nutritive value also required methods for the determination of carbohydrate. The determination of crude fibre was required so that available carbohydrate and available calories hence could be calculated from the results for protein, fat, ash and crude protein. In addition, it appeared that an analytical definition of dietary fibre was required from the nutritional point of view.

102. The Delegation of the Netherlands was of the opinion that dietary fibre as a general nutritional and analytical question should be considered by WG III of the Committee. The Delegation of Australia informed the Committee that there were methods of measure available carbohydrates directly. The Delegation agreed that the question of dietary fibre should be discussed since there was no consensus amongst scientists on the methodology to be used. It was pointed out by the Delegation of the Federal Republic of Germany that matters relating to dietary fibre had also been considered by an expert meeting jointly organized by FAO/WHO (see FAO Food and Nutrition Paper No. 15: Carbohydrates in Human Nutrition, Rome 1980). The Delegation of Sweden agreed to prepare a working paper on these questions for the next session of the Committee in the light of the discussion of these issues in the CCFL in connection with the Guidelines on Nutrition Labelling. WG III was requested to consider the Swedish paper at its next session.

Gliadin

103. The Delegation of the Netherlands informed the Committee that a WG consisting of scientists of a number of European countries had collaboratively tested an immuno-assay procedure for the determination of gliadin. In the opinion of the delegation it would be preferable to use gliadin as an indicator of the acceptability of gluten-free foods, setting maximum limits for this toxic principle in the final product. The present Codex standard contains a limit in terms of protein content which was not deemed to be sufficiently specific. Control of the suitability of gluten-free foods could only be carried out during the manufacturing process. There was an increased tendency to use gluten as food additive, a practice which may pose a risk for gluten intolerant persons, and furthermore several foods contained this toxic factor naturally.

104. The Committee noted that there were two issues involved:

(a) the possible amendment of the Codex standard; and
(b) consideration of the presence of gluten in food as a labelling issue relating to intolerance.

It requested the Secretariat and the Delegation of the Netherlands to develop proposals for the amendments of the Codex Standard for Gluten-free Foods and to submit them to governments for comments. The Secretariat was also requested to bring the matter of gluten intolerance to the attention of the CCFL in the light of the information to be provided by the Netherlands.

CONSIDERATION OF PROPOSED DRAFT GUIDELINES FOR THE DEVELOPMENT OF SUPPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN AT STEP 4 (Item 6)

105. The Committee noted that WG IV had given consideration to the above guidelines (Appendix XII to ALINORM 85/26) at the October Meeting and had recommended to amend the title to read "Proposed Draft Guidelines on Formulated Supplementary Foods for Older Infants and Young Children". The Committee further noted that the WG had also made recommendations for other provisions in the guidelines and that the report of the WG was contained in Appendix V to CX/FSDU 87/6. The WG had instructed the Secretariat to prepare a revised text of the guidelines. This text is contained in CX/FSDU 87/10.

106. The Committee expressed its appreciation to the members of the WG and agreed to consider the guidelines, section by section, on the basis of the revised text in CX/FSDU 87/10.

107. The Chairman recalled that the WG had given special attention to Sections 1, 2 and 3 of the above guidelines and expressed the hope that the Committee could accept the relevant recommendations made by the WG.

Title

108. The Committee agreed with the amended title and the consequential amendments in the text of the guidelines.

Section 1 - Purpose

109. The Committee agreed with the above section.

Section 2 - Scope

110. Several delegations were of the opinion that Section 2.2 should not appear under the scope but should be part of a preamble which could generally clarify the meaning of these guidelines. It was agreed that the following preamble be introduced in a box directly under the title of the guidelines:

> The guidelines on formulated supplementary foods for older infants and young children are intended to be used by member governments of FAO and WHO for the purpose indicated in Section 1 below. They are not subject to formal acceptance by member governments.
>
> Attention is drawn to the Codex Standards for Foods for Infants and Children, adopted by the Codex Alimentarius Commission that have been sent to governments with a view to acceptance and which have been published in Volume IX of the Codex Alimentarius.

Section 3 - Definition

111. The Committee recalled the extensive discussions on the age limits of 4-6 months in conjunction with the definitions of "follow-up formula" under Item 5. The Committee agreed that the foods covered by these guidelines were intended to supplement other foods used during weaning, and decided to amend the second sentence of Section 3.1 to read as follows:

> "They are not suitable for use for infants before the beginning of the weaning period. "

The Committee also agreed that the third sentence should be retained unchanged and did not adopt a proposal of the Delegation of the Netherlands to include a statement that the foods should provide 100% of the RDAs except for energy.

Section 3.3 was amended as in the standard for follow-up formula. (See para. 71).

Section 4 - Suitable Raw Materials and Ingredients

112. The Committee noted that the recommendations of the WG and the proposals of the Representative of WHO had been incorporated in this section. The Committee accepted the kind offer of the Delegation of the United Kingdom to provide the Secretariat with editorial amendments to this section which would be incorporated in the revised version of the guidelines, as contained in Appendix VI to this report. The Delegation of Argentina proposed to replace the term "protein products" by "protein concentrates and isolates". No action was taken by the Committee.

Section 4.1.5 - Fats and Oils

113. The delegation of Australia, referring to paras 23 and 24 of Appendix V of CX/FSDU 87/6, expressed concern at the present wording of Section 4.1.5.2 which recommended that no fats and oils containing arge proportions of saturated fatty acids should be used. She pointed out that this provision might create difficulties in countries of the Western Pacific Region, where plam oil was used extensively. The Delegation of France agreed that this provision cuold indeed lead to misunderstandings and proposed to replace it by the following wording:

"The minimum requirements for essential fatty acids should be met".

The Committee agreed with the French proposal.

114. The Committee decided to concentrate its further considerations on Sections 6 to 9 of the guidelines since these sections were of great importance from the nutritional point of view and had not been examined by the WG. The Committee agreed with the view expressed by the Chairman that every effort shuld be made to finalize the guidelines as soon as possible in view of the urgent need to provide expert advice on relatively economical supplementary foods.

Section 6.1 - Nutritional Aspects

115. The Committee noted that the presentwording of Section 6.1.2 was based on a proposal made by the United States to the WG Meeting. The Delegation of France, supported by the Delegations of the Federal Republic of Germany and Norway, proposed to delete Section 6.1.2 as well as Section 6.1.3 which contained concepts which were not clear and/or to which these countries could not agree. The Committee was informed of the intent of Section 6.1.2, i.e., to provide reference data for the use of Table 1. The Delegation of the United States stated, however, that these specific reference data might be too limiting and that further explanation of the meaning of the model in Table 1 might be more appropriate. The Committee decided to delete Section 6.1.2.

116. Several delegations, however, expressed the opinion that it was of utmost importance to emphasize clearly in the guidelines that Table 1 was a model only and that local circumstances required appropriate modifications of compositional as well as nutritional parameters. Attention was drawn to Sections 6.8.1 and 6.8.2.

117. Concerning Section 6.1.3 the Delegation of the Netherlands expressed the view that the last sentence of this provision should be amended to make reference to the most important vitamins and minerals. It was agreed to insert the term "appropriate". After extensive discussion concerning the percentage requirement ([100%] or [75%]) of the recommended intakes of protein, vitamins and minerals it was agreed to place the whole provision in square brackets to obtain further comments. The Secretariat recalled that Section 6.1.1 stated clearly that the product was intended to supply energy and nutrients over and above those already in the staple foods used for the feeding of older infants and young children, i.e. that they were intended to constitute only a part of the weaning diet. The Committee agreed that this should be kept in mind by governments when preparing their comments.

Section 6.3 - Protein

118. The Delegation of France was of the opinion that this section was not satisfactory and contained a number of errors. It was also not compatible with some of the ther sections of the guidelines. The Delegation of Canada informed the Committee that the Codex Committee on Vegetable Proteins would discuss provisions for the assessment of protein quality related to vegetable proteins at its forthcoming session. Furthermore, it was noted that the Representative of WHO had provided to the WG more appropriate data. The Committee decided to place the whole section in square brackets and to accept the kind offer of the Delegation of France to prepare a revised text which would take into account the work of CCVP.

Section 6.4 - Fat

119. The Delegation of Australia felt that the recommendation in Section 6.4.2 to add fat and sugar at the household level might not be appropriate for economic reasons. The Secretariat pointed out that this provision covered the possibility to produce foods with a low fat content which needed less expensive packaging.

Section 6.5 - Carbohydrates

120. The Delegation of Argentina expressed the opinion that it might not be suitable to recommend the addition of sugars to increase energy density because of nutritional considerations of infant feeding. The Delegation of Cuba drew attention to the

importance of sugars as a source of energy. The Delegation of the Netherlands expressed the view that the phrase relating to starch was not appropriate and discriminated unnecessarily against starch. Several delegations felt that all sub-sections should be further considered especially with regard to their nutritional implications. For example, Section 6.5.2 seemed inappropriate and it was noted that Section 6.5.3 made reference to crude fibre. The Committee agreed to place the whole Section 6.5 in square brackets.

Section 9 - Labelling

121. Concerning Section 9.2.1 - The Name of the Food, the Committee considered two alternative proposals for amending as follows:

> "A statement that the food should be used as a supplementary food when weaning has started".
>
> Or
>
> "For use when other foods are added to the diet of the infant".

It was agreed that further comments were needed on the above two proposals.

Section 9.2.3 - Declaration of Nutritive Value

122. The Committee agreed to delete from (c) the following words: "listed in table 1".

Section 9.2. - Date Marking

123. The Delegation of Argentina stated that in its country the declaration of an expiry date was mandatory for these products.

Table 1 - Model Nutrient Profile

124. The Committee noted that this table contained several mistakes which had to be corrected, namely Vitamin E: values to read: 5 mg/1.25 mg/0.3 mg; ascorbic acid: values to read: 20 mg/5.2 mg/1.2 mg. It was also agreed to use the IUNS nomenclature. The Committee decided that the amount of nutrients listed in the table should be reviewed and revised as appropriate in the light of the most recent recommendations of FAO/WHO on nutrient intakes, and accepted the kind offer of the Representative of WHO to carry out such revision.

Status of the Guidelines

125. The Committee agreed to advance the above guidelines as contained in Appendix VI to Step 5 of the Procedure. It was noted that a Circular Letter would be issued to request technical comments on the guidelines and, in particular, on the sections in square brackets after the 17th Session of the Commission had considered the above guidelines at Step 5. The Secretariat was instructed to include in the Circular Letter the revised Table 1 as well as an additional version of Section 6.3 which was offered by the Delegation of France.

CONSIDERATION OF DRAFT GUIDELINES FOR THE USE OF CODEX COMMITTEES ON THE INCLUSION OF PROVISIONS ON NUTRITIONAL QUALITY IN FOOD STANDARDS AND OTHER CODEX TEXTS AT STEP 8 (Item 8)

126. The Committee was informed that the 16th Session of the Commission had advanced the above guidelines to Step 6 of the Procedure and that WG III of the October Meeting had given consideration to the guidelines as contained in Annex 2 to Appendix V to ALINORM 85/26 in the light of government comments. The Committee noted that the report of WG III on the guidelines was contained in paras 2 to 28 of Appendix IV to CX/FSDU 87/6 and that a redraft of the guidelines, taking into account the amendments recommended by the WG, was contained in Annex 2 to the same Appendix.

127. The Committee decided to adopt the recommendations of the WG and to consider only those sections which had been identified by the WG as requiring further work.

128. The Delegation of Argentina pointed out that in his country there was a considerable difference in the definitions for "fortification" and "enrichment" and that, therefore, these terms should not be used as alternative terms in Section 3.5.

Preamble

129. The Committee considered the Swedish proposal for a revised preamble which was contained in Annex 3 to Appendix IV to CX/FSDU 87/6 and agreed that the proposed wording was an improvement on the present text. The Committee decided to amend the preamble accordingly.

Section 3.3 - Definition for "Nutritional Equivalence"

130. The Committee noted that the WG had been of the opinion that it was impossible, in practical terms, to comply with the present definition and had, therefore, placed Section 3.3 in square brackets. The Delegation of the United States proposed to add the following additional sentence to this provision:

> "For this purpose, NE means that all essential nutrients provided by the food being replaced, present at a level of [5%] or more of the recommended intake (or when there is no recommended intake, [5%] or more of the average daily intake) should be present in the substitute or partially substituted food (extender) in comparable amounts".

131. The Delegation of France, supported by several other delegations, expressed the view that the intake figures would have to be related to specified amounts of the food, such as 100 kcal or portions or servings, in order to make the provision meaningful. The Committee agreed to amend the provision accordingly.

132. The Committee had a lengthy discussion of the figure of 5%, which was finally accepted. The Delegations of Switzerland and Australia stated their reservation, Australia supporting a figure of 10% and Switzerland a higher figure.

133. It was further pointed out by the Delegation of the United Kingdom that it was not possible to comply with the requirement for equal nutritive value in the first sentence of Section 3.3. This could mean the addition of a multitude of nutrients which might have no particular value for the population in many countries and would also create an unnecessary burden. The Committee agreed to replace the term "equal" by the term "similar".

134. The agreed text of Section 3.3 reads as follows:

> "3.3 Nutritional Equivalence means of similar nutritive value in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients. For this purpose, nutritional equivalence means that essential nutrients provided by the food being substituted, that are present in a serving or portion or 100 kcal of the food at a level of 5% or more of the recommended intake of the nutrient(s), are present in the substitute or partially substituted food (extender) in comparable amounts. "

135. The Delegation of Australia expressed the view that, in this situation, it is not nutritionally sound to use the criteria relating the essential nutrient content to energy density, i.e. to 100 kcal. This can result in excessive fortification of low energy dense foods and inadequate fortification of high energy dense foods, regardless of their role in the diet.

136. The Committee noted that the definition for nutritional equivalence was also included in the General Principles for the Addition of Essential Nutrients to Foods which would be discussed under Item 9. (See para. 144).

137. The Committee agreed with a proposal of the Delegation of the United Kingdom to amend Section 4.2 by restructuring the order of the items according to their importance. The revised Section 4.2 reads as follows:

> "4.2 Provisions and advisory information on nutritional aspects of foods should be included in food standards and other Codex texts in the following circumstances, where:
>
> (a) the food is a major source of energy and nutrients in the diets of populations or specific population groups; or
>
> (b) the food is destined for use as a substitute for, or the principal ingredient in a substitute for, a common food.
>
> This is particularly important where:
>
> (a) the food may sustain significant losses of essential nutrients during processing, storage or handling; or
>
> (b) the food's nutritional quality is dependent upon the amount and/or characteristics of the principal ingredient present in the food; or
>
> (c) a variety of methods of processing with varying degrees of impact on nutritional quality is available. "

138. It was noted that the WG had deleted the square brackets from Section 4.3.5.

139. The Secretariat was requested to correct the French version by replacing the term "restitution" by the term "restoration" wherever it appeared in the text of the guidelines as well as in the General Principles (Item 9).

Status of the Guidelines

140. The Chairman stated that it was important to finalize the guidelines as soon as possible to provide advice to the other Codex Committees on the inclusion of nutritional aspects in Codex standards which these Committees were elaborating. The Committee decided to advance the Draft Guidelines for the Use of Codex Committees on the Inclusion of Provisions on Nutritional Quality in Food Standards and Other Codex Texts as contained in Appendix IV to this Report, to Step 8 of the Procedure.

CONSIDERATION OF THE GENERAL PRINCIPLES FOR THE ADDITION OF NUTRIENTS (Item 9)

141. The Committee was informed that the 16th Session of the Commission had agreed with the recommendation of this Committee to develop the General Principles outside the Step-Procedure.

142. The WG III of the October Meeting had examined the General Principles contained in Appendix VII to ALINORM 85/26 in the light of government comments, and had made recommendations for a revised version (see paras 29 to 44 of Appendix IV to CX/FSDU 87/6 and Annex 2 thereto).

143. The Committee agreed with the amendments made by the WG to the text in Annex 2, including the change of the title which referred now to essential nutrients only. It was noted, however, that several sections still contained square brackets which required further discussion. Furthermore, the report of the Working Group contained a proposal made by Switzerland concerning the introduction of two new definitions.

144. The Committee recalled that it had agreed under the previous item on a definition of "nutritional equivalence" and decided to introduce the same revised text in Section 3.3 of the General Principles.

Section 3.8 - Nutrient Density

145. The Committee noted that the proposal for a new definition for nutrient density had not been agreed to by WG III (paras 42 and 43 of Appendix IV to CX/FSDU 87/6). The

Delegation of the United States explained the rationale for introducing the nutrient density concept which was of particular importance for foods used as meal replacements. The delegation also proposed the introduction of a new provision in Section 4 for the same purpose. The proposed new Section 4.1.5 reads as follows:

> "providing a balanced nutrient composition by use of the nutrient density concept for formulated foods".

It was agreed to include in the definition reference to essential nutrients only.

146. Several delegations expressed the view that governments should have an opportunity to examine carefully the above proposals. The Committee agreed to request written comments. The Committee, however, was also aware that it was important to finalize the General Principles as soon as possible to make them available to the Codex Committees together with the Guidelines on Nutritional Aspects.

147. Since the amendments proposed by the United States were of interest mainly to this Committee, it was agreed that they could be added to the General Principles at a later date.

New Definitions for "Standardization" and "Supplementation" (Para. 41 of Appendix IV to CX/FSDU 87/6)

148. The Committee noted the two proposals for new definitions submitted by Switzerland, namely:

> "3.8 Standardization: is the addition of nutrients to a food in order to compensate the natural variations".
>
> "3.9 Supplementation: is the addition of nutrients to a food, which are not contained in that food or only in small quantities".

149. The Committee agreed to defer discussion on these proposals.

Section 5 - Nutrient Addition for Purposes of Restoration

150. The Committee noted that in Section 5.2 the numerical values of 10% which qualified a food as being a significant source of an essential nutrient were still in square brackets. While several delegations expressed the views that the value should be reduced to 5%, analoguous to the definition of "nutritional equivalence", other delegations pointed out that the concept was not applicable for the purpose of restoration. The latter delegations opted for maintaining 10%.

151. Since it was not possible to reach agreement on this point, it was decided to retain the figure of 10%, to delete the square brackets and to add a footnote to Section 5.2 explaining that it was under review. This will enable the General Principles to be submitted to the Commission for adoption without further delay.

Section 6 - Nutrient Addition for Purposes of Nutritional Equivalence

152. The Committee agreed to introduce into Section 6.2 numerical values of 5% and the reference to portions or servings or 100 kcal as a consequence of including the same provisions in the definition or nutritional equivalence (Section 3.3).

Amendment of the General Principles

153. It was noted that the General Principles could be amended without going through the Step Procedure. It was agreed that proposals to amend the Principles should include supporting information on the need for such amendments and a proposed draft text.

Status of the General Principles

154. The Committee decided to submit to the Commission for adoption the revised text of the General Principles for the Addition of Essential Nutrients to Foods as contained in

Appendix V to this Report and to continue its work on the amendments related to the nutrient density concept at its next session.

PROPOSED DRAFT STANDARD FOR THE LABELLING OF AND CLAIMS FOR FOODS FOR SPECIAL MEDICAL PURPOSES (Item 12)

155. The Committee had before it the report of the Meeting of Intergovernmental Working Groups (CX/FSDU 87/6) and a revised version of the previous guidelines prepared by the Secretariat on the basis of the conclusions of Working Group II and of government comments (Appendix III, CX/FSDU 87/6). The Committee noted that the Working Group had made progress in improving the previous text and that it had suggested that a standard instead of guidelines be developed. Although further comments had been requested on the draft, no comments had been received due the timing of the sessions.

156. The Chairman, speaking as a medical expert, drew attention to the fact that the products covered by the standard were used in hospitals and under medical supervision for a variety of reasons in the management of patients with specific diseases, disorders or medical conditions. Such products were essential and it was important to regulate their labelling and the claims made for them. The Delegation of Denmark was of the opinion that there was no need for the standard as any labelling and claims could be covered in the General Standard for the Labelling of and Claims for Foods for Special Dietary Uses. The delegation believed that special provisions for the labelling of and claims for foods for medical purposes might lead to misuse by consumers who try to treat themselves without proper advice from a physician.

157. The Committee agreed to proceed with the consideration of the revised standard contained in Annex 1 to Appendix III, CX/FSDU 87/6.

Section 1 - Scope

158. The Committee discussed whether nutritionally complete formulae should be included in the standard. The Delegation of the Federal Republic of Germany, supported by a number of delegations, was of the opinion that such formulae should be covered in the standard (i.e. suggested that the words in square brackets in Section 1 be deleted). The Delegation of the United States indicated that in the United States approximately 95% of the use of products falling under the standard was comprised of nutritionally complete formulae with a variety of modifications serving various medical purposes. The Delegation of Canada also quoted a number of specific diseases where the use of such formulae has been indicated. The Delegation of the United States also pointed out that deleting these formulae from the standard would mean that the standard would cover only a few special products intended for inborn metabolic diseases.

159. The Delegation of Switzerland was in favour of excluding nutritionally complete formulae from the standard (i.e. deletion of the square brackets only in Section 1). This view was also supported by a number of delegations. It was pointed out that these formulae were not necessarily foods for medical purposes but were available freely in retail trade. Furthermore, their composition had not been defined. The Delegation of France informed the Committee that nutritionally complete formulae intended for retail trade could be distinguished from formulae intended for use in hospitals or under medical supervision through different labelling requirements.

160. The Delegations of Argentina and Cuba expressed interest in the standard and indicated that their countries were in the process of developing regulations for foods for medical purposes. Guidance from Codex would be welcome. The Delegation of the Netherlands was doubtful about the standard and expressed the opinion that it would not be practical to list the various diseases and medical conditions on the label for which the various products were indicated. The products might be adequately described in terms of their compositional features. The delegation was of the opinion that it was necessary to prepare a list of the foods covered by the standard to assess better whether there is a real need to mention diseases on the label.

161. The Committee noted that the nutritionally complete formulae were directed both to the consumer through retail outlets and to medical and other professional users in hospitals or through outlets used for drugs. It was also noted that information

appropriate for the consumer could be included on the label, while associated information could be provided to the medical user where necessary. There were hundreds of formulae with various modifications which made them suitable for particular circumstances. It would be an enormous and unnecessary task to list all such products in the standard.

162. The Chairman was of the opinion that the approach followed by France in distinguishing through labelling between products intended for the retail trade and for medical use seemed worth pursuing. The delegation of France suggested that only formulae intended for the retail trade, i.e. not intended for specific uses in the hospital and medical environments might be excluded from the standard.

163. The Delegation of Sweden suggested that compositional standard should be developed for nutritionally complete foods. The Delegation of Switzerland, supported by some delegations, proposed that such a standard be developed in which labelling and claims provisions could be included.

164. As no agreement could be reached on whether nutritionally complete formulae should be included or excluded, the Committee agreed to leave the scope section unchanged. Governments were requested to send detailed comments on the issues in hand and to provide lists of foods intended for specific diseases and for medical conditions. The Secretariat was requested to identify the issues in the Circular Letter on which comemnts were needed.

Status of the Standard

165. The Committee adopted the Proposed Draft Standard and decided to place it at Step 3 of the Codex Procedure for the Elaboration of Codex Standard and to request comments on the text of the standard which is contained in Appendix X to this report.

CONSIDERATION OF DRAFT AMENDMENTS TO CODEX STANDARDS FOR FOODS FOR INFANTS AND CHILDREN AT STEP 7 (Item 7)

I.	Leavening agents	(Section A in Appendix IX to ALINORM 85/26)
	Guar Gum	(Section C in Appendix IX to ALINORM 85/26)
	Vitamin D	(Section D in Appendix IX to ALINORM 85/26)

166. The Committee recalled that the above three amendments had been submitted to the 16th Session of the Commission at Step 5 with a recommendation to adopt them at Steps 5 and 8 and to omit Steps 6 and 7 in view of the uncontroversial nature of these amendments.

167. The Committeed noted that the abbreviated procedure was only applicable if the amendments were adopted unanimously by the Commission. This had not been the case. (Paras 452-455 of ALINORM 85/47). Comments at Step 6 had been requested by CL 1985/44 and a paper containing the responses to the CL (CX/FSDU 87/7) had been considered by the Working Group on the Advisory Lists as decided by this Committee at its 14th Session (para. 140 of ALINORM 85/26). (See also Appendix XII).

168. The Chairman of the WG indicated that the above Working Group had examined the comments received on the above draft amendments and recommended to the Committee to advance the amendments to Step 8 of the Procedure. The Committee agreed with the recommendation.

169. The Delegation of Spain requested that in the Spanish version of the amendment concerning leavening agents in the title as well as in Section 5.6 the term "levaduras" be replaced by the term "gasificantes".

170. With regard to the proposal to increase the maximum amount of Vitamin D per 100 available calories from 80 to 100 I.U., the WG had noted that the Delegations of the Netherlands, Canada and the United Kingdom had been in favour of a further increase to 120 I.U.. The Delegation of the Netherlands had offered to prepare a paper on the justification of such an increase. The WG agreed that it would consider the paper at its next session.

171. The Committee confirmed that the WG should continue its consideration of the maximum level of Vitamin D in the Codex Standard for Infant Formula.

II. Amendment to the Codex Standards for Foods for Infants and Children (Except Infant Formula) on Labelling (Para. 127(b) of ALINORM 85/26)

172. The Committee noted that the 16th Session of the Commission had considered the following amendment applicable to Section 9 of the Codex Standards for Canned Baby Foods (CODEX STAN 73-1981) and Processed Cereal-based Foods for Infants and Children (CODEX STAN 74-1981):

> "If the food falls within the Scope of the International Code of Marketing of Breast-Milk Substitutes of the World Health Organization, the label should be designed in a manner duly taking into account the provisions of Article 9 of such code. "

No specific comments at Step 6 had been received on the above amendment.

173. The question was raised whether it was also necessary to include such a provision in the Labelling Section of the Draft Standard for Follow-up Formula (see Appendix III). The Delegation of France pointed out that the interpretation notes to Article 2 of the WHO International Code for the Marketing of Breast-milk Substitutes indicated clearly that any foods intended for infants after the age of 4-6 months were not covered by the scope of the code, independent of their presentation. The Delegation of France was therefore of the opinion that it was not appropriate to include the above provision in the Draft Standard for Follow-up Formula; this view was shared by the Delegation of Switzerland. The above expressed was not shared by the Delegation of Norway.

174. The Delegation of Australia pointed out that the definition of "follow-up formula" referred now to infants from the 6th month on, thus being included in the period of 4-6 months of the WHO Code.

175. The Committee agreed with the Delegation of France that reference to the presentation of the follow-up formula would clarify the meaning of the amendment and to amend the text as follows: replace "If the foods falls" by the following wording: "If the presentation of the food makes it fall".

176. The Committee agreed that the above amendment applied to the Codex Standards for Canned Baby Foods and Processed Cereal-Based Foods for Infants and Children and the Draft Standard for Follow-up Formula but that it was necessary to request further comments on the amended text and decided to return the above amendment to Step 6 of the Procedure.

177. The three draft amendments at Step 8 and the draft amendment at Step 6 are contained in Appendix VII to this Report.

REPORT OF THE AD-HOC WORKING GROUP ON THE ADVISORY LISTS FOR VITAMIN COMPOUNDS AND MINERAL SALTS FOR FOODS FOR INFANTS AND CHILDREN (Item 13)

178. The Committee had before it the report of the above WG which had met immediately prior to the Plenary (CRD No. 7). In introducing the report, the Chairman of the WG, Dr. R.W. Weik of the United States, stated that the WG was willing to continue its work and had emphasized that it was not necessary for CCFA to endorse provisions for vitamin compounds and mineral salts added to foods for infants and children for nutritional purposes, since they were not considered to be food additives.

179. He also indicated that the WG had considered details of working procedures and work assignments for its next session which was expected to be held in connection with the 16th Session of the Committee.

180. The Chairman thanked the WG and its Chairman for the excellent work. The Committee adopted the report of the WG and requested that CCFA be informed of the views of this Committee concerning the endorsement of vitamin compounds and mineral salts.

181. The full text of the report is contained in Appendix XII to this Report.

PROPOSED DRAFT STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED "LOW ENERGY" OR "REDUCED ENERGY" FOODS [FOR SPECIAL DIETARY USES] (Item 10)

182. The Committee had before it the above standard as revised by WG I which met in October 1986. The Chairman of the Committee pointed out that no further comments had been received on the revised text. The Committee agreed to consider the revised text prepared by the WG (Annex 1, Appendix II, CX/FSDU 87/6).

Title of the Standard

183. The Committee discussed whether the title of the standard should refer to "Foods for Special Dietary Uses". The Delegations of France and Italy were of the opinion that the standard should deal only with foods presented as special dietary foods. Others were of the opinion that all foods manufactured to be low in energy or reduced in energy should be covered in the standard.

184. It was noted that the title of other standards elaborated by this Committee did not contain reference to the product being intended for special dietary uses, e.g. "gluten-free" food.

185. An important issue to resolve was whether the Codex General Standards for Labelling of and Claims for Prepackaged Foods for Special Dietary Uses could be applied to low energy and reduced energy foods which were not foods for special dietary uses. It was agreed that legal advice should be sought.

186. The Committee decided to leave the title unchanged.

Section 1 - Scope

187. The Committee decided to delete the sentence in square brackets in order to make it clear that the standard did not apply to foods naturally low in energy.

Section 2 - Definitions

188. Low Energy Food (2.1) - Following discussion on the values for the maximum energy content, the Committee agreed that they should be as follows: 40 kcal per specified serving, 40 kcal per 100 g for solid foods and 20 kcal per 100 ml for liquid foods. Appropriate amendments were made to Section 2.1. The Delegation of Switzerland expressed its preference for a maximum of 50 kcal per 100 g for solid foods.

189. Reduced Energy Food (2.2) - The Delegation of the United States strongly supported a maximum energy content of 66 2/3% in respect of the energy content of the corresponding normal food. This value had been found to be accepatable in weight reducing diets and to the industry. The Delegation of France was of the opinion that the label should indicate the food which was being replaced. In the case of high caloric foods (300 kcal/100 g and above) a 50% reduction would be more appropriate. The Delegation of the Federal Republic of Germany was of the opinion that the maximum energy content of reduced energy foods should be 60% of the energy content of the corresponding normal food.

190. The Committee discussed whether a reduced energy food should be nutritionally equivalent to the food which it replaces. The Delegation of the United States was of the opinion that consumers should expect nutritional equivalence of these products except, of course, for energy content. This view was supported by the Delegation of the Netherlands, but opposed by the Delegation of the Federal Republic of Germany.

191. The Committee decided to leave the figures for energy reduction and the second sentence in Section 2.2 in square brackets.

192. Nutritional Equivalence (2.3) - As regards Section 2.3 which described nutritional equivalence, the Committee agreed to rediscuss this matter bearing in mind that this term had been also discussed in connection with Items 5 and 6. (See paras 130-136).

Section 3 - Labelling

193. In discussing this section, the Committee recalled its deliberations concerning the title and scope of the standard (see paras 183-187). The Secretariat pointed out that the Codex General Standard or the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses had been recently adopted and was intended to cover the labelling of all foods for special dietary uses. Exemptions on certain provisions are permitted for foods for special dietary uses covered by individual Codex standards.

194. The Delegation of Canada was of the opinion that the Codex Committee on Food Labelling should be informed that this Committee was developing a standard for low energy and reduced energy foods which would cover claims for the energy content of foods. The Committee concurred with the views expressed by the Secretariat and the Delegation of Canada.

Status of the Standard

195. The Committee agreed that the Proposed Draft Standard for the Labelling of and Claims of Low Energy and Reduced Energy Foods [for Special Dietary Uses] as contained in Appendix VIII, should be returned to Step 3 of the Codex Procedure for further comments.

PROPOSED DRAFT STANDARD FOR NUTRITIONALLY COMPLETE FORMULA FOODS FOR USE IN WEIGHT CONTROL DIETS (Item 11)

196. The Committee had before it the above standard revised by the WG which had met in October 1986 (Annex 2, Appendix II, CX/FSDU 87/6). The Chairman indicated that the standard contained a number of unresolved issues including the provisions for vitamins and minerals. For example, Section 3.2.4 listed the values proposed by the United States and the Federal Republic of Germany. The WG had not been able to develop recommendations on these and general other sections.

197. The Delegation of the United States was of the opinion that the Committee should consider the requirements for protein content in the light of the recommendations of the FAO/WHO (WHO Technical Report Series, 724; Energy and Protein Requirements) and attempt to align the standard with those recommendations.

198. The Delegation of the Netherlands was of the opinion that nutrient specifications should be given for a one-day regimen as well as a one-meal regimen.

199. The Committee concurred with the suggestion of the Delegation of the United States that the Codex Committee on Food Labelling should be informed of this work and also agreed that the points raised by the Delegations of the United States and the Netherlands (see paras 194-195) should be brought to the attention of governments in a circular letter.

Status of the Standard

200. It was agreed that it would not be useful to discuss the standard further in detail at the present session. The Committee accepted the suggestion of the Delegation of Switzerland that the Proposed Draft Standard for Nutritionally Complete Formula Foods for Use in Weight Control Diets, should be returned to Step 3 of the Codex Procedure for further government comments. The text of the above standard is contained in Appendix IX to this Report.

NATIONAL LABELLING REQUIREMENTS CONCERNING SPECIFIC INFORMATION FOR DIABETICS (Item 15)

201. The Committee considered a report on "nutritional labelling requirements concerning specific information for diabetics" (CX/FSDU 87/8). The report contained repliesf rom a number of countries in response to Circular Letter 1985/37. In introducing the document, the Chairman expressed the view that the extensive differences in the approach to dealing with the subject illustrated that agreement had not yet been reached at the scientific level on the question of nutritional and other information for diabetics. For this reason, it would be preferable to await further developments before considering this question again in the Committee.

202. The Delegation of France was of the opinion that the Committee should abandon consideration of this topic. The Committee agreed with the suggestion of the Federal Republic of Germany that the question of a standard should be adjourned, but not necessarily dropped altogether.

FOOD PRODUCTS SWEETENED WITH SUGAR SUBSTITUTES (Item 16)

203. The Committee had before it a paper on this topic prepared by the Netherlands (CX/FSDU 87/9).

204. The Delegation of Argentina reserved its position on the paper since it had not been received in Argentina prior to the session. The Delegation of the United States questioned the need for a standard for foods sweetened with sugar substitutes. The Observer from ISDI was of the opinion that the question of sugar substitutes related closely to the problem of foods for diabetics. As products suitable for use by diabetics could not move in trade in view of the wide differences in regulations governing these products, ISDI was of the opinion that there was a need to discuss this question within Codex in the interest of facilitating international trade in these products.

205. The Delegation of the Netherlands suggested that a start could be made with a standard for table-top sweeteners and offered to prepare a paper on this for the next session of the Committee. The Committee accepted the offer of the Delegation of the Netherlands, and requested that the paper should also set out an assessment of the priority for such a standard, as required in the Procedural Manual of the Commission.

FUTURE WORK PROGRAMME (Item 17)

206. The Committee reiterated its decision that the Ad-Hoc Working Groups on Nutritional Aspects, Methods of Analysis and Sampling and the Advisory Lists of Vitamin Compounds and Mineral Salts should be reinstalled to continue their work at the next session of the Committee.

207. The Committee strongly recommended that the meetings of the above WGs should be held in conjunction with its next session. (See also para. 53).

208. The Committee agreed that, in addition to the continuation of already existing work assignments, the WGs should deal with the following items:

WG on Nutritional Aspects:

(a) Specific RDAs for Labelling Purposes, taking into account expert advice (see paras 47 - 56).

(b) Further Work on Nutrition Considerations, based on comments on CX/GP 86/11 (see paras 47 - 56).

(c) Information Paper on Dietary Fibre (prepared by Sweden).

WG on Methods of Analysis and Sampling:

(a) Paper on Sampling (prepared by the United Kingdom).
(b) Review and Revision of Methods of Analysis.

WG on Advisory Lists for Vitamin Compounds and Mineral Salts:

(a) Criteria for Amendment of the Lists.
(b) New Proposals for Additions to the Lists.

209. The Committee agreed that the agenda for the 16th Session would include the following items:

(a) Draft Guidelines on Formulated Supplementary Foods for Infants and Young Children at Step 7.

(b) Proposed Draft Standard for the Labelling of and Claims for Low Energy and Energy-reduced Foods [for Special Dietary Uses] at Step 4.

(c) Proposed Draft Standard for Nutritionally Complete Formula Foods for Use in Weight Control Diets at Step 4.

(d) Proposed Draft Standard for Foods for Medical Purposes at Step 4.

(e) First Draft of a Standard for Table-Top Sweeteners and Paper on Work Priority Criteria (prepared by the Netherlands).

(f) Amendments to Standards elaborated by the Committee.

(g) Paper on the Revision of Labelling Provisions in Standards elaborated or under consideration by the Committee.

(h) Compilation of National Regulations on Levels of Contaminants in Foods for Infants and Children.

(i) Amendments to Codex Standard for "Gluten-Free" Foods (prepared by the Netherlands).

(j) Review of the Provisions on Irradiated Foods in Codex Standards for Infants and Children (IAEA paper - see Appendix XV).

(k) Proposals for Possible Amendments to General Principles for the Addition of Nutrients to Foods.

OTHER BUSINESS (Item 18)

Spanish Language

210. The Delegation of Cuba, speaking on behalf of the Coordinator of the Codex Region for Latin America and the Caribbean, Minister R. Darias Rodes, expressed the gratitude of the Countries of that Region to the Authorities of the Federal Republic of Germany for providing Spanish interpretation for the session.

211. The Delegations of Argentina and Spain associated themselves with the Delegation of Cuba and stated their appreciation for the availability of most of the working papers in the Spanish language which facilitated participation of Spanish speaking delegations.

212. The Delegation of Argentina expressed the view that the introduction of the Spanish would increase participation at future sessions at expert level.

Proposal to Increase the Limits for Vanillin in the Codex Standard for Processed Cereal-Based Foods for Infants and Children (CODEX STAN 74-1981)

213. The Delegation of the Netherlands proposed to increase the maximum level for vanillin in the Codex Standard for Processed Cereal-Based Foods for Infants and Children from presently 7 mg/100 g to 55 mg/100 g ready-to-eat food (Section 5.4.3 of CODEX STAN 74-1981).

214. The Delegation of the Netherlands provided the following information to support its proposal:

"This increase is required in order to improve the flavour and the acceptability of the foods, particularly those with high dry matter content. The Acceptable Daily Intake of vanillin as specified by the Codex Committee on Food Additives (10 mg/kg body weight) permits the proposed increase; the projected total intake of vanillin by children from all food sources will not exceed the ADI.

Calculation of projected intake of vanillin:

- Follow-up food will maximally supply 52.5 mg vanillin per child per day; based on a maximum intake of 750 ml food.

- Canned baby food will supply maximally 14 mg vanillin per child per day; based on a maximum intake of 200 g food.

- Processed cereal-based will maximally supply 13.5 mg vanillin per child per day; based on a maximum intake of 25 g food.

Total intake of vanillin from all sources is:

52.5 + 14 + 13.5 = 80 mg

Acceptable Daily Intake for a child of 6 months of age:

Body weight 8 kg = 10 x 8 = 80 mg. "

215. The Committee decided to request comments on the need to amend the provision for vanillin as proposed by the Delegation of the Netherlands and to consider this matter further at its next session.

DATE AND PLACE OF NEXT SESSION (Item 19)

216. The Secretariat of the Federal Republic of Germany informed the Committee that it hoped to hold the 16th Session of the Committee together with the Meeting of the Ad-Hoc Working Groups (see para. 204) in late September - early October 1988 in Bonn-Bad Godesberg. The exact date would be communicated in due course after consultation with the Codex Secretariat.

217. The German Secretariat indicated that it would like to retain Spanish as the fourth working language of the Committee including the Working Groups. However, in order to justify the additional costs, it would be appreciated if the number of Spanish-speaking delegations would increase. The Delegation of Argentina expressed its appreciation to the Federal Republic of Germany for its willingness to continue with the Spanish language and indicated that it would inform the Argentinian Authorities accordingly.

VALEDICTION

218. The Committee wished to place on record its appreciation for the excellent work of the previous Chairman of the Committee, Dr. H. Drews, who had recently retired, and conveyed its best wishes for the future to Dr. Drews.

SUMMARY STATUS OF WORK

Standard/Code/Document	Status Step	To be dealt with by	ALINORM/App. Document Reference
Standard for Foods with Low Sodium Content (Including Salt Substitutes)	9	Governments	CODEX STAN 53-1981, Vol. IX of the Codex Alimentarius (1st Ed.)
Amendments	9	Governments	Suppl. 1 to Vol. IX
Standard for Infant Formula	9	Governments	CODEX STAN 72-1981 Vol. IX of the Codex Alimentarius (1st Ed.)
Amendments	9	Governments	Suppl. 1 and 2 to Vol.IX
Standard for Canned Baby Foods	9	Governments	CODEX STAN 73-1981 Vol. IX of the Codex Alimentarius (1st Ed.)
Amendments	9	Governments	Suppl. 1 and 2 to Vol.IX
Standard for Processed Cereal-Based Foods for Infants and Children	9	Governments	CODEX STAN 74-1981 Vol. IX of the Codex Alimentarius (1st Ed.)
Amendments	9	Governments	Suppl. 1 and 2 to Vol.IX
Standard for "Gluten-Free" Foods	9	Governments	CODEX STAN 118-1981 Vol. IX of the Codex Alimentarius (1st Ed.)
Amendments	9	Governments	Suppl. 1 to Vol. IX
General Standard for the Labelling of and Claims for Foods for Special Dietary Uses	9	Governments	CODEX STAN 146-1985 Suppl. 2 to Vol. IX of the CAC (1st Ed.)
Code of Hygienic Practice for Foods for Infants and Children	9	Governments	CAC/RCP 21-1979 Vol. IX of the CAC, Corrigendum in Suppl. 1 to Vol. IX
Draft Standard for Follow-up Formula	8	17th CAC	ALINORM 87/26, App.III
Draft Guidelines for Use by Codex Committees on the Inclusion of Provisions on Nutritional Quality in Food Standards and Other Codex Texts	8	17th CAC	ALINORM 87/26, App.IV
General Principles for the Addition of Essential Nutrients to Foods		17th CAC	ALINORM 87/26, App. V
Proposed Draft Guidelines on Formulated Supplementary Foods for Older Infants and Young Children	5	17th CAC	ALINORM 87/26, App. VI
Draft Amendments to Codex Standards for Foods for Infants and Children	6/8	17th CAC (Step 8) 16th CC/FSDU (Step 6)	ALINORM 87/26, App. VII
Proposed Draft Standard for the Labelling of and Claims for Prepackaged "Low Energy" and "Reduced Energy" Foods /For Special Dietary Uses_7	3	16th CC/FSDU	ALINORM 87/26, App.VIII

SUMMARY STATUS OF WORK (Cont.)

Standard/Code/Document	Status Step	To be dealt with by	ALINORM/App. Document Reference
Proposed Draft Standard for Nutritionally Complete Formula Foods for Use in Weight Reduction Diets	3	16th CC/FSDU	ALINORM 87/26, App. IX
Proposed Draft Standard for the Labelling of and Claims for Foods for Special Dietary Uses	3	16th CC/FSDU	ALINORM 87/26, App. X
WG on Advisory Lists for Mineral Salts and Vitamin Compounds	-	16th CC/FSDU	ALINORM 87/26, Paras 178-181 and App. XII
WG on Methods of Analysis and Sampling	-	16th CC/FSDU	ALINORM 87/26, Paras 98-104 and App. XI
WG on Matters Related to Nutrition	-	16th CC/FSDU	ALINORM 87/26, Paras 47-56, 101-102 and Appendix XIV
First Draft of a Standard for Table-Top Sweeteners	-	16th CC/FSDU	CX/FSDU 88/... (To be prepared by the Netherlands)
Proposed Draft Standard for the Labelling of and Claims for Prepackaged Foods Claimed to be suitable for Incorporation in a Prescribed Dietary Regimen for Diabetics	3	Work Suspended See para.33 of ALINORM 85/26 and para.202 of ALINORM 87/26	ALINORM 83/26, App. V
Review Paper on Labelling Provisions	-	16th CC/FSDU	CX/FSDU 88/... (To be prepared by the Codex Secretariat)
Levels of Contaminants in Foods for Infants and Children (Survey of National Regulations)	-	16th CC/FSDU	CX/FSDU 88/...
Review of Provisions in Irradiated Foods in Codex Standards for Infants and Children	-	16th CC/FSDU	CX/FSDU 88/...
Proposals for Amendment of Codex Standard for "Gluten-Free" Foods (Paras 103-104 of ALINORM 87/26)	-	16th CC/FSDU	CX/FSDU 88/... (To be prepared by the Netherlands and the Secretariat)
Proposed Amendment of Codex Standards for Foods for Infants and Children	-	16th CC/FSDU	ALINORM 87/26, Paras 170 and 213-215
Proposed Amendments to the General Principles for the Addition of Essential Nutrients to Foods (Paras 145-154 of ALINORM 87/26)	-	16th CC/FSDU	CX/FSDU 88/...

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Opening Address

15th Session of the Codex Committee on "Foods for Special Dietary Uses"

Bonn - Bad Godesberg, 12 - 16 January 1987

Ladies and Gentlemen,

on behalf of the government of the Federal Republic of Germany I would like to welcome you most sincerely to the 15th Session of the Codex Committee on "Foods for Special Dietary Uses", traditionally held here in Bonn - Bad Godesberg. I am glad to convey to you the greetings of the Federal Minister for Youth, Health, Women and Family Affairs, Mrs. Süssmuth, who has also asked me to convey to you her best wishes for a positive and successful session.

I am very happy to see that you have followed our invitation so numerously. In my opinion, this illustrates the growing interest of the member states of the Codex Alimentarius Commission in the activities of the Committee.

Apart from the representatives of the member states, I particularly welcome Mrs. Dix and Dr. Ladomery of the Codex Secretariat in Rome, to whom I would like to thank most sincerely for their excellent cooperation in preparing the session. I especially appreciate the participation of the WHO representatives, Dr. Gurney and Mr. Akré.

Ladies and Gentlemen,

the Codex Alimentarius Commission is the only International Organization for the promotion of global harmonization of food regulations on such a large scale. The results of its activities over almost 25 years are most impressive. The "Codex Alimentarius", comprising up to now 15 volumes, contains almost 200 international food standards, more than 40 Codes of Practice, over 2000 individual maximum limits for pesticide residues and a large number of guidelines, thus regulating the majority of foods nowadays available on the international market. The work of the Codex Alimentarius Commission has significantly contributed to the safety of food products, to the protection of consumers against deception, as well as in guaranteeing good manufacturing practices and, finally, to encouraging international food trade.

Last but not least, the Third World countries, representing nearly three quarters of the member states of the Commission, have profited from the activities of the Codex Alimentarius Commission. In many cases, the Codex Standards and Codes of Practice have provided the basis for developing and improving their own legislation, thus enabling them to distribute their products more easily on the international market than before.

Certainly, the success of the Codex cannot only be evaluated on the basis of official acceptance declarations. Experience has shown that the Codex Standards, regardless of their formally binding character, have practically gained considerable importance. Not only have they served as a model for regional measures of harmonization; increasingly, they also have constituted a basis for private contracts and other agreements in international trade and will do so in future.

Above all, the significance of the Codex Alimentarius Commission as a forum not confined by national frontiers and systems and favourable to the exchange of ideas and experiences must be highly appreciated.

Regarding the Codex Committee on Foods for Special Dietary Uses, it has always been confronted with difficult and often controversial matters. In contrast to all the other regulatory areas, provisions for the protection against health risks and consumer deception concerning dietary foods require, with regard to special dietetic problems, a far more differentiated consideration. This applies to the composition of products as well as to the specifications for labelling and advertising claims. There are also additional aspects like the delimination of foods for general consumption and for special dietary purposes. Apart from the frequently debated questions of dietetics, it is this multitude of parameters which makes it particularly difficult to reach an agreement.

Within the framework of the Codex Alimentarius Commission, the Codex Committee of Foods for Special Dietary Uses plays a special role as a result of the extension of its terms of reference, as it is now responsible for the evaluation of the nutritional aspects of all commodity standards. It is evident from available studies that the risks for human health are primarily caused by improper and insufficient nutrition. For this reason, your Committee is charged with a special responsibility. The results achieved so far in this field justify an optimistic outlook.

Nutrition-related aspects will form the centre of interest in your work over the next few days. Besides, the deliberations will focus on the following subjects:

- Follow-up and supplementary foods for older infants and small children;
- Low energy and reduced energy foods for weight control;
- Medical foods (balanced diets).

The relevant Draft-Standards and Draft-Guidelines have already been discussed by two Working Groups at the meeting in Bonn from October 7th to 10th. These Working Groups have provided valuable preparatory work for the present session. Their deliberations concentrated on efforts to reach conclusions in those complicated matters on which the opinions of the Member States differ considerably. These conclusions should allow basic agreement between all participants, although the difficulties of the topics would suggest that not all questions can be resolved.

Ladies and Gentlemen,

In the next few days the detailed agenda will impose strenuous efforts on you. I hope that besides your work you will find time to talk with old and new friends and to enjoy the particular attractions of Bad Godesberg and the Rhine.

Thank you very much for your attention.

DRAFT STANDARD FOR FOLLOW-UP FORMULA
(At Step 8)

1. SCOPE

This standard applies to the composition and labelling of follow-up formula.

It does not apply to foods covered by the Codex Standard for Infant Formula (CODEX STAN 72-1981).

2. DESCRIPTION

2.1 Definitions

2.1.1 "Follow-up Formula" means a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children.

2.1.2 The term "infant" means a person of not more than 12 months of age.

2.1.3 The term "young children" means persons from the age of more than 12 months up to the age of three years (36 months).

2.1.4 The term "Calorie" means a kilocalorie (1 kilojoule (kJ) is equivalent to 0.239 Calories (kcal)).

2.2 "Follow-up Formula" is a food prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin, which have been proved to be suitable for infants from the 6th month on and for young children.

2.3 "Follow-up Formula" is a food processed by physical means only so as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution.

2.4 "Follow-up Formula", when in liquid form, is suitable for use either directly or diluted with water before feeding, as appropriate. In powdered form it requires water for preparation. The product shall be nutritionally adequate to contribute to normal growth and development when used in accordance with its directions for use.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Energy Content

When prepared in accordance with the instructions for use, 100 ml of the ready-for-consumption product shall provide not less than 60 kcal (or 250 kJ) and not more than 85 kcal (or 355 kJ).

3.2 Nutrient Content

"Follow-up Formula" shall contain the following nutrients at minimum and maximum levels indicated below:

3.2.1 Protein per 100 Available Calories (or kilojoules)

3.2.1.1 Not less than 3.0 g per 100 available Calories (or 0.7 g per 100 available kilojoules) of protein of nutritional quality equivalent to that of casein or a greater quantity of other protein in inverse proportion to its nutritional quality. The quality 1/ of the protein shall not be less than 85% of that of casein. The total quantity of protein shall not be more than 5.5 g per 100 available Calories (or 1.3 g per 100 available kilojoules).

3.2.1.2 Essential amino acids may be added to Follow-up Food only to improve its nutritional value. Essential amino acids may be added to improve protein quality, only

1/ Protein quality shall be determined provisionally using the PER method as laid down in the section dealing with methods of analysis.

in amounts necessary for that purpose. Only L forms of amino acids shall be used.

3.2.2 Fat per 100 Available Calories (or kilojoules)

3.2.2.1 Not less than 3 g and not more than 6 g per 100 Calories (0.7 and 1.4 g per 100 available kilojoules).

3.2.2.2 The level of linoleic acid (in the form of a glyceride) shall not be less than 300 mg per 100 Calories (or 71.7 mg per 100 available kilojoules).

3.2.3 Carbohydrates

The product shall contain nutritionally available carbohydrates suitable for the feeding of the older infant and the young child in such quantities as to adjust the product to the energy density in accordance with the requirements set out in Section 3.1.

3.2.4 Vitamins other than Vitamin E

	Amounts per 100 available Calories		Amounts per 100 available kilojoules	
	Minimum	Maximum	Minimum	Maximum
Vitamin A	250 I.U. or 75 µg expressed as retinol	750 I.U. or 225 µg expressed as retinol	60 I.U. or 18 µg expressed as retinol	180 I.U. or 54 µg expressed as retinol
Vitamin D	40 I.U. or 1 µg	120 I.U. or 3 µg	10 I.U. or 0.25 µg	30 I.U. or 0.75 µg
Ascorbic acid (Vitamin C)	8 mg	N.S. 1/	1.9 mg	N.S. 1/
Thiamine (Vitamin B_1)	40 µg	N.S. 1/	10 µg	N.S. 1/
Riboflavin (Vitamin B_2)	60 µg	N.S. 1/	14 µg	N.S. 1/
Nicotinamide	250 µg	N.S. 1/	60 µg	N.S. 1/
Vitamin B_6 2/	45 µg	N.S. 1/	11 µg	N.S. 1/
Folic acid	4 µg	N.S. 1/	1 µg	N.S. 1/
Pantothenic acid	300 µg	N.S. 1/	70 µg	N.S. 1/
Vitamin B_{12}	0.15 µg	N.S. 1/	0.04 µg	N.S. 1/
Vitamin K_1	4 µg	N.S. 1/	1 µg	N.S. 1/
Biotin (Vitamin H)	1.5 µg	N.S. 1/	0.4 µg	N.S. 1/
3.2.5 Vitamin E (α-tocopherol compounds)	0.7 I.U./ g linoleic acid 3/ but in no case less than 0.7 I.U./100 available Calories	N.S. 1/	0.15 I.U./g linoleic acid 3/ but in no case less than 0.15 I.U./100 available kilojoules	N.S. 1/

1/ N.S. = Not specified.

2/ Formulas should contain a minimum of 15 µg Vitamin B_6 per gramme of protein. See Section 3.2.1.1.

3/ Or per g polyunsaturated fatty acids, expressed as linoleic acid.

3.2.6 Minerals

	Amounts per 100 available Calories		Amounts per 100 available kilojoules	
	Minimum	Maximum	Minimum	Maximum
Sodium (Na)	20 mg	85 mg	5 mg	21 mg
Potassium (K)	80 mg	N.S. 2/	20 mg	N.S. 2/
Chloride (Cl)	55 mg	N.S. 2/	14 mg	N.S. 2/
Calcium (Ca) 1/	90 mg	N.S. 2/	22 mg	N.S. 2/
Phosphorus (P) 1/	60 mg	N.S. 2/	14 mg	N.S. 2/
Magnesium (Mg)	6 mg	N.S. 2/	1.4 mg	N.S. 2/
Iron (Fe)	1 mg	2 mg	0.25 mg	0.50 mg
Iodine (I)	5 µg	N.S. 2/	1.2 µg	N.S. 2/
Zinc (Zn)	0.5 mg	N.S. 2/	0.12 mg	N.S. 2/

3.3 Ingredients

3.3.1 Essential Ingredients

3.3.1.1 Follow-up Formula shall be prepared from the milk of cows or of other animals and/or other protein products of animal and/or plant origin which have been proved suitable for infants from the 6th month on and for young children and from other suitable ingredients necessary to achieve the essential composition of the product as set out in Sections 3.1 and 3.2 above.

3.3.1.2 Follow-up Formula based on milk shall be prepared from ingredients as set out in Section 3.3.1.1 above except that a minimum of 3 g per 100 available Calories (or 0.7 g per 100 kilojoules) of protein shall be derived from whole or skimmed milk as such, or with minor modification that does not substantially impair the vitamin or mineral content of the milk and which represents a minimum of 90% of the total protein.

3.3.2 Optional Ingredients

3.3.2.1 In addition to the vitamins and minerals listed under 3.2.4 to 3.2.6, other nutrients may be added when required in order to ensure that the product is suitable to form part of a mixed feeding scheme intended for use from the 6th month on.

3.3.2.2 The usefulness of these nutrients shall be scientifically shown.

3.3.2.3 When any of these nutrients is added, the food shall contain significant amounts of these nutrients, based on the requirements of infants from the 6th month on and young children.

3.4 Purity Requirements

3.4.1 General

All ingredients shall be clean, of good quality, safe and suitable for ingestion by infants from the 6th month on and young children. They shall conform with their normal quality requirements, such as colour, flavour and odour.

3.4.2 Vitamin Compounds and Mineral Salts

3.4.2.1 Vitamin compounds and mineral salts used in accordance with Sections 3.3.1 and 3.3.2 should be selected from the Advisory Lists for Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children approved by the Codex Alimentarius Commission.

1/ The Ca:P ratio shall be not less than 1.0 and not more than 2.0.
2/ N.S. = Not specified.

3.4.2.2 The amounts of sodium and potassium derived from vitamin and mineral ingredients shall be within the limit for sodium in Section 3.2.6.

3.5 Consistency and Particle Size

When prepared according to the directions for use, the product shall be free of lumps and of large, coarse particles.

3.6 Specific Prohibition

The product and its components shall not have been treated by ionizing radiation.

4. FOOD ADDITIVES

The following additives are permitted:

	Maximum Level in 100 ml of Product Ready-for-Consumption
4.1 Thickening Agents	
4.1.1 Guar gum 4.1.2 Locust bean gum	0.1 g
4.1.3 Distarch phosphate 4.1.4 Acetylated distarch phosphate 4.1.5 Phosphated distarch phosphate	0.5 g singly or in combination in soy-based products only
4.1.6 Acetylated distarch adipate	2.5 g singly or in combination in hydrolyzed protein and/or amino acid-based products only
4.1.7 Carrageenan	0.03 g singly or in combination in milk and soy-based products only 0.1 g singly or in combination in hydrolyzed protein and/or amino acid-based liquid products only
4.1.8 Pectins (amidated and non-amidated)	1 g
4.2 Emulsifiers	
4.2.1 Lecithin	0.5 g
4.2.2 Mono- and Diglycerides	0.4 g
4.3 pH-Adjusting Agents	
4.3.1 Sodium hydrogen carbonate 4.3.2 Sodium carbonate 4.3.3 Sodium citrate 4.3.4 Potassium hydrogen carbonate 4.3.5 Potassium carbonate 4.3.6 Potassium citrate 4.3.7 Sodium hydroxide 4.3.8 Potassium hydroxide 4.3.9 Calcium hydroxide 4.3.10 L (+) Lactic acid 4.3.11 L (+) Lactic acid producing cultures 4.3.12 Citric acid	Limited by Good Manufacturing Practices within the limits for Na in Section 3.2.6

4.4 Antioxidants

	Maximum Level in 100 ml of Product Ready-for-Consumption
4.4.1 Mixed tocopherols concentrate 4.4.2 α-Tocopherol	3 mg singly or in combination
4.4.3 L-Ascorbyl palmitate 4.4.4 L-Ascorbic acid and its Na, Ca salts	5 mg singly or in combination, expressed as ascorbic acid (See Section 3.2.6)

4.5 Flavours

4.5.1 Natural Fruit Extracts	GMP
4.5.2 Vanilla extract	GMP
4.5.3 Ethyl vanillin	5 mg
4.5.4 Vanillin	5 mg

4.6 Carry-Over Principle

Section 3 of the "Principle relating to the Carry-over of Additives into Foods" as set forth in Vol. I of the Codex Alimentarius shall apply.

5. CONTAMINANTS

5.1 Pesticide Residues

The product shall be prepared with special care under good manufacturing practices, so that residues of those pesticides which may be required in the production, storage or processing of the raw materials or the finished food ingredient do not remain, or, if technically unavoidable, are reduced to the maximum extent possible.

5.2 Other Contaminants

The product shall be free from residues of hormones and antibiotics, as determined by means of agreed methods of analysis, and practically free from other contaminants, especially pharmacologically active substances.

6. HYGIENE

6.1 To the extent possible in good manufacturing practice, the product shall be free from objectionable matter.

6.2 When tested by appropriate methods of sampling and examination, the product:

(a) shall be free from pathogenic microorganisms;

(b) shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health; and

(c) shall not contain any other poisonous or deleterious substances in amounts which may represent a hazard to health.

6.3 The product shall be prepared, packed and held under sanitary conditions and should comply with the relevant provisions of the Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979).

7. PACKAGING

7.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as packing media.

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

8. FILL OF CONTAINERS

In the case of products in ready-to-eat form, the fill of container shall be:

(i) not less than 80% v/v for products weighing less than 150 g (5 1/2 oz.);
(ii) not less than 85% v/v for products in the weight range 150-250 g (5 1/2 - 9 oz.); and
(iii) not less than 90% v/v for products weighing more than 250 g (9 oz) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20° C which the sealed container will hold when completely filled.

9. LABELLING

In addition to Sections 1, 2, 3, 4, 5.7 and 8 of the Codex General Standard for the Labelling of Prepackaged Foods 1/, the following specific provisions apply:

9.1 The Name of the Food

9.1.1 The name of the product shall be "Follow-up Formula". In addition thereto any appropriate designation may be used in accordance with national usage.

9.1.2 Those products which are prepared from whole or skimmed milk in accordance with Section 3.3.1.2 and where 90% or more of the protein is derived from whole or skimmed milk as such, or with minor modification that does not substantially impair the vitamin and mineral content of the milk, may be labelled "Follow-up Formula" based on Milk.

9.1.3 All sources of protein shall be clearly shown on the label in close proximity to the name of the food in descending order of proportion by weight.

9.1.4 A product which contains neither milk nor any milk derivative may be labelled "contains no milk or milk products" or an equivalent phrase.

9.2 List of Ingredients

The declaration of the list of ingredients shall be in accordance with Sections 4.2.1, 4.2.2 and 4.2.3 of the Codex General Standard for the Labelling of Prepackaged Foods except that in the case of added vitamins and added minerals, these ingredients shall be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

9.3 Declaration of Nutritive Value

The declaration of nutrition information shall contain the following information in the following order:

(a) The amount of energy, expressed in Calories (kcal) and/or kilojoules (kJ) per 100 g of the food as sold as well as per specified quantity of the food as suggested for consumption.
(b) The number of grammes of protein, carbohydrate and fat per 100 g of the food as sold as well as per specified quantity of the food as suggested for consumption. In addition, the declaration per 100 Calories (or per 100 kilojoules) is permitted.
(c) The total quantity of each vitamin, mineral and any optional ingredient, as listed in Section 3.3.2 of this standard per 100 g of the food as sold as well as per specified quantity of the food as suggested for consumption. In addition, the declaration per 100 Calories (or per 100 kilojoules) is permitted.

1/ Reference Number of revised text to be included, pending its adoption by the 16th Session of the Codex Alimentarius Commission.

9.4 Net Contents and Drained Weight

9.4.1 The declaration of net contents and drained weight shall be in accordance with Sections 4.3.1, 4.3.2 and 4.3.3 of the Codex General Standard for the Labelling of Prepackaged Foods. 1/

9.5 Name and Address

9.5.1 The declaration of the name and address shall be in accordance with Section 4.4 of the Codex General Standard for the Labelling of Prepackaged Foods. 1/

9.6 Country of Origin

9.6.1 The declaration of the country of origin shall be in accordance with Sections 4.5.1 and 4.5.2 of the Codex General Standard for the Labelling of Prepackaged Foods. 1/

9.7 Lot Identification

9.7.1 The declaration of the lot identification shall be in accordance with Section 4.6.1 of the Codex General Standard for the Labelling of Prepackaged Foods. 1/

9.8 Daté Marking and Storage Instructions

In addition to the declaration of date marking and storage instructions in accordance with Sections 4.7.1 and 4.7.2 of the Codex General Standard for the Labelling of Prepackaged Foods 1/, the following provisions apply:

9.8.1 Storage of Opened Food

Storage instructions of opened packages of a food for special dietary uses shall be included on the label if necessary to ensure that the opened product maintains its wholesomeness and nutritive value. A warning should be included on the label if the food is not capable of being stored after opening or is not capable of being stored in the container after opening.

9.9 Information for Utilization

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

9.9.2 The labelling of a Follow-up Formula shall include a statement that Follow-up Formula shall not be introduced before the 6th month of life.

9.9.3 Information that infants and children fed follow-up formula shall receive other foods in addition to the food shall appear on the label.

10. METHODS OF ANALYSIS AND SAMPLING

The Methods of Analysis and Sampling in Volume IX of the Codex Alimentarius - Codex Standards for Foods for Infants and Children - Part III apply as appropriate.

1/ Reference Number of revised text to be included, pending its adoption by the 16th Session of the Codex Alimentarius Commission.

DRAFT GUIDELINES FOR THE USE OF CODEX COMMITTEES ON THE INCLUSION OF PROVISIONS ON NUTRITIONAL QUALITY IN FOOD STANDARDS AND OTHER CODEX TEXTS
(At Step 8)

Nutritional quality as applied to food is related to the presence of essential nutrients and energy-yielding substances (in satisfying quantity and quality) and to other aspects of food traditionally considered as part of the science of nutrition.

These aspects include the nutritional effects of non-essential amino-acids, specific types of fatty acids and carbohydrates, dietary fibre, cholesterol, lipotropic substances, other components of specific foods (e.g. of human milk), nutrient bioavailability and nutrient interactions with other nutrients with food additives and with natural toxicants. They also include nutrient excesses and the effects (both positive and negative) of food processing on the nutrients and on the organoleptic properties of the food.

All these aspects of nutritional quality must be evaluated based on modern nutritional principles, standards and guidelines aimed at meeting human nutritional needs. The bases of evaluation include: recommended nutrient intakes, the role of the food in the diet of the population and the role of diet and nutrition in disease prevention and health promotion.

1. PURPOSE

1.1 To ensure that nutritional quality aspects are included in food standards and other Codex texts when appropriate.

1.2 To provide guidance to Codex Committees in their consideration of the need for provisions on nutritional quality in food standards and other Codex texts.

1.3 To assist Codex Committees in developing appropriate provisions on nutritional quality.

2. SCOPE

These guidelines are intended to be used by all Codex Committees in the development of food standards and other texts.

3. DEFINITIONS

For the purpose of these guidelines:

3.1 Nutrient means any substance normally consumed as a constituent of food:

(a) Which provides energy; or

(b) which is needed for the growth and development and maintenance of healthy life; or

(c) a deficit of which will cause characteristic biochemical or physiological changes to occur.

3.2 Essential nutrient means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life and which cannot be synthesized in adequate amounts in the body.

3.3 Nutritional equivalence means of similar nutritive value in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailábility of essential nutrients. For this purpose, nutritional equivalence means that essential nutrients provided by the food being substituted, that are present on a serving or portion or 100 kcal of the food at a level of 5% or more of the recommended intake of the nutriet(s) are present in the substitute or partially substituted food (extender) in comparable amounts.

3.4 Substitute food is a food which resembles a common food in appearance, texture, flavour and odour and is intended to be used as a complete replacement or partial replacement (extender) for the food it resembles.

3.5 Fortification or enrichment means the addition of one or more essential nutrients to a food over and above the levels normally contained in the food or the levels after restoration, for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups.

3.6 Restoration means the addition to a food of essential nutrient(s) which are lost during the course of good manufacturing practice or during normal storage and handling procedures, in amounts which will result in the presence in the food of the levels of the nutrient(s) present in the edible portion of the food before processing, storage or handling.

4. INSTRUCTIONS TO CODEX COMMITTEES

4.1 Committees should be aware of the broad range of factors which influence the nutritional quality of foods to ensure that their consideration of nutritional aspects takes into account all relevant matters including the importance of conserving nutrients as far as possible.

4.2 Provisions and advisory information on nutritional aspects of foods should be included in food standards and other Codex texts in the following circumstances; where:

(a) the food is a major source of energy and nutrients in the diets of populations or specific population groups; or

(b) the food is destined for use as a substitute for, or the principal ingredient in a substitute for a common food.

This is particularly important where:

(a) the food may sustain significant losses of essential nutrients during processing, storage and handling; or

(b) the food's nutritional quality is dependent upon the amount and/or characteristics of the principal ingredient present in the food; or

(c) a variety of methods of processing with varying degrees of impact on nutritional quality is available.

4.3 Addition of Essential Nutrients to Foods

4.3.1 Provision for the addition of essential nutrients to foods should be made, where appropriate, in conformity with the General Principles for the Addition of Essential Nutrients to Foods (Appendix V to ALINORM 87/26).

4.3.2 When provision is made for the addition of essential nutrients for the purpose of fortification, advisory information for the guidance of national Governments should be included. It should identify essential nutrients which have been or may be added to the food and suggest that countries where deficiencies of these nutrients exist and are of public health significance should consider the feasibility and effectiveness of fortifying the food with one or more of these nutrients. As a general rule, the advisory information should not identify quantities of essential nutrients to be added as these will depend upon the conditions of the country concerned.

4.3.3 Provisions in food standards and other Codex texts relating to the addition of essential nutrients to foods for the purposes of fortification should be of an advisory nature and subject to national legislation.

4.3.4 When provision is made in food standards and other Codex texts, for the addition of essential nutrients for the purposes of restoration and/or nutritional equivalence, advisory information for the guidance of national Governments should be included. It should identify the essential nutrients to be considered for restoration or nutritional equivalence and the levels at which they should be present in the food to achieve restoration or nutritional equivalence.

4.3.5 Where general agreement exists regarding the need for restoration or nutritional equivalence and particularly where risks to health may be involved, a mandatory provision should be included requiring that the food contains the essential nutrient(s) in specific amounts.

4.3.6 Where general agreement exists on the specific essential nutrients and amounts required, an optional provision should be included providing for the addition of these nutrients and specifying the amounts to be contained in the food.

4.3.7 Where general agreement does not exist, an advisory provision should be included permitting the addition of essential nutrients to the food in accordance with national legislation. Advisory information identifying the essential nutrients and the levels needed for restoration or nutritional equivalence should be included in an annex to the standard and should not be subject to acceptance.

4.3.8 Advisory lists of vitamin compounds and mineral salts for particular foods or classes of foods should be drawn up for the guidance of Governments, taking into account the Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (Codex Alimentarius, Volume IX, Part IV).

4.4 Quality criteria which influence nutritional quality such as minimum quantities of either principal or characterizing ingredients or nutrients from these ingredients should be included in the body of the standards whenever appropriate.

4.5 Advisory information on choice of processing methods to minimize adverse effects on established and recognized nutritional quality should be included where appropriate.

4.6 Should Codex Committees decide to include provisions pertaining to the nutritional aspects of foods in standards and other texts, they should submit these provisions to the Codex Committee on Foods for Special Dietary Uses for endorsement. Should they decide not to submit their provisions for endorsement, full justification for not doing so should be submitted to the Commission.

ALINORM 87/26
APPENDIX V

GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS

1. PURPOSE

1.1 To provide guidance to those responsible for developing guidelines and legal texts pertaining to the addition of essential nutrients to foods.

1.2 To establish a uniform set of principles for the rational addition of essential nutrients to foods.

1.3 To maintain or improve the overall nutritional quality of foods.

1.4 To prevent the indiscriminate addition of essential nutrients to foods thereby decreasing the risk of health hazard due to essential nutrient excesses, deficits or imbalances. This will also help to prevent practices which may mislead or deceive the consumer.

1.5 To facilitate acceptance in international trade of foods which contain added essential nutrients.

2. SCOPE

These principles are intended to apply to all foods to which essential nutrients are added.

3. DEFINITIONS

For the purpose of these guidelines:

3.1 Nutrient means any substance normally consumed as a constituent of food:

(a) which provides energy; or

(b) which is needed for growth and development and maintenance of healthy life; or

(c) a deficit of which will cause characteristic bio-chemical or physiological changes to occur.

3.2 Essential nutrient means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life and which cannot be synthesized in adequate amounts by the body.

3.3 Nutritional equivalence means being of similar nutritive value in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients. For this purpose, nutritional equivalence means that essential nutrients provided by the food being substituted, that are present in a serving or portion or 100 kcal of the food at a level of 5% or more of the recommended intake of the nutrient(s) are present in the substitute or partially substituted food (extender) in comparable amounts.

3.4 Substitute food is a food which is designed to resemble a common food in appearance, texture, flavour and odour, and is intended to be used as a complete or partial replacement for the food it resembles.

3.5 Fortification or enrichment means the addition of one or more essential nutrients to a food over and above the levels normally contained in the food or the levels after restoration for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups.

3.6 Restoration means the addition to a food of essential nutrient(s) which are lost during the course of good manufacturing practice, or during normal storage and handling procedures, in amounts which will result in the presence in the food of the levels of the nutrient(s) present in the edible portion of the food before processing, storage or handling.

3.7 Special purpose foods are foods that have been designed to perform a specific function, such as to replace a meal which necessitates a content of essential nutrients which cannot be achieved except by addition of one or more of these nutrients. These foods include but are not limited to foods for special dietary use.

4. BASIC PRINCIPLES

4.1 Essential nutrients may be added to foods for the purpose of:

4.1.1 restoration;

4.1.2 nutritional equivalence of substitute foods;

4.1.3 fortification;

4.1.4 ensuring the appropriate nutrient composition of a special purpose food.

4.2 The essential nutrient should be present at a level which will not result in either an excessive or an insignificant intake of the added essential nutrient considering amounts from other sources in the diet.

4.3 The addition of an essential nutrient to a food should not result in an adverse effect on the metabolism of any other nutrient.

4.4 The essential nutrient should be sufficiently stable in the food under customary conditions of packaging, storage, distribution and use.

4.5 The essential nutrient should be biologically available from the food.

4.6 The essential nutrient should not impart undesirable characteristics to the food (e.g. colour, taste, flavour, texture, cooking properties) and should not unduly shorten shelf-life.

4.7 Technology and processing facilities should be available to permit the addition of the essential nutrient in a satisfactory manner.

4.8 Addition of essential nutrients to foods should not be used to mislead or deceive the consumer as to the nutritional merit of the food.

4.9 The additional cost should be reasonable for the intended consumer.

4.10 Methods of measuring, controlling and/or enforcing the levels of added essential nutrients in foods should be available.

4.11 When provision is made in food standards, regulations or guidelines for the addition of essential nutrients to foods, specific provisions should be included identifying the essential nutrients to be considered or to be required and the levels at which they should be present in the food to achieve their intended purpose.

5. NUTRIENT ADDITION FOR PURPOSES OF RESTORATION

5.1 Where the food has been identified as a significant source of energy and/or essential nutrients in the food supply, and particularly where there is demonstrated evidence of public health need, restoration of the essential nutrients of concern lost during processing, storage or handling should be strongly recommended.

5.2 A food should be considered a significant source of an essential nutrient if the edible portion of the food prior to processing, storage or handling contains the essential nutrient in amounts equal to or greater than 10% of the recommended nutrient intake in a reasonable daily intake (or in the case of an essential nutrient for which there is no recommended intake, 10% of the average daily intake). 1/

6. NUTRIENT ADDITION FOR PURPOSES OF NUTRITIONAL EQUIVALENCE

6.1 Where a substitute food is intended to replace a food which has been identified as a significant source of energy and/or essential nutrients in the food supply, and particularly where there is demonstrated evidence of public health need, nutritional equivalence in terms of the essential nutrients of concern should be strongly recommended.

1/ This section remains under review.

6.2 A food being substituted or partially substituted should be considered a significant source of an essential nutrient if a serving or portion or 100 kcal of the food contains the essential nutrient in amounts equal to or greater than 5% of the recommended nutrient intake.

6.3 Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.

7. NUTRIENT ADDITION FOR PURPOSES OF FORTIFICATION

7.1 Fortification should be the responsibility of national authorities since the kinds and amounts of essential nutrients to be added and foods to be fortified will depend upon the particular nutritional problems to be corrected, the characteristics of the target populations, and the food consumption patterns of the area.

7.2 The following conditions should be fulfilled for any fortification programme:

7.2.1 There should be a demonstrated need for increasing the intake of an essential nutrient in one or more population groups. This may be in the form of actual clinical or subclinical evidence of deficiency, estimates indicating low levels of intake of nutrients or possible deficiencies likely to develop because of changes taking place in food habits.

7.2.2 The food selected as a vehicle for the essential nutrient(s) should be consumed by the population at risk.

7.2.3 The intake of the food selected as a vehicle should be stable and uniform and the lower and upper levels of intake should be known.

7.2.4 The amount of the essential nutrient added to the food should be sufficient to correct or prevent the deficiency when the food is consumed in normal amounts by the population at risk.

7.2.5 The amount of the essential nutrient added should not result in excessive intakes by individuals with a high intake of a fortified food.

8. NUTRIENT ADDITION TO SPECIAL PURPOSE FOODS

8.1 Nutrients may be added to special purpose foods including foods for special dietary uses to ensure an appropriate and adequate nutrient content.

PROPOSED DRAFT GUIDELINES ON FORMULATED SUPPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN (At Step 5).

The Guidelines on Formulated Supplementary Foods for Older Infants and Young Children are intended to be used by Member Governments of FAO and WHO for the purpose indicated in Section 1 below. They are not subject to formal acceptance by Member Governments.

Attention is drawn to the Codex Standards for Foods for Infants and Children, adopted by the Codex Alimentarius Commission that have been sent to Governments with a view to acceptance and which have been published in Volume IX of the Codex Alimentarius.

1. PURPOSE

To provide guidance on nutritional and technical aspects of the production of Formulated Supplementary Foods for Older Infants and Young Children as defined in Section 3.1, including:

- Formulation of such foods, based on the nutritional requirements of older infants and young children,
- Processing techniques,
- Hygienic requirements,
- Provisions for packaging,
- Provisions for labelling and instructions for use.

2. SCOPE

2.1 The provisions of these guidelines apply to Formulated Supplementary Foods for Older Infants and Young Children as defined in Section 3.1 below.

3. DEFINITIONS

3.1 Formulated Supplementary Foods for Older Infants and Young Children means foods suitable for use during the infant's weaning period and for feeding young children as a supplement to breastmilk or breastmilk substitutes or other food available in the country where the product is sold. They are not suitable for use for infants before the beginning of the weaning period. These foods provide such nutrients which are lacking in the basic staple foods.

3.2 The term "infant" means a person up to 12 months.

3.3 The term "young children" means persons from the age of 12 months up to the age of three years (36 months).

4. SUITABLE RAW MATERIALS AND INGREDIENTS

4.1 Basic Ingredients

The following raw materials are suitable ingredients for the production of Formulated Supplementary Foods for Older Infants and Young Children under the specified conditions given below:

4.1.1 Cereals

4.1.1.1 All milled cereals suitable for human consumption may be used provided that they are processed in such a way as to reduce the fibre content and to eliminate tannins or other phenolic materials which can lower the protein digestibility.

4.1.1.2 Besides carbohydrates (mainly consisting of starch) cereals contain a significant quantity of protein (8-12%). Whereas rice presents a satisfactory essential amino-acid composition, other cereals are as a rule limiting in lysine.

4.1.2 Pulses

4.1.2.1 Pulses, including chick peas, lentils, peas, cow peas, green gram, mungo beans, kidney beans, provided they have been appropriately processed to eliminate, as far as possible, the anti-nutritional factors present in pulses such as lectins (haemaglutinins) and trypsin and chymotrypsin inhibitors.

It should be noted that:

- Lectins can be destroyed by heat treatment.

- Trypsin inhibitor activity may be reduced to acceptable levels by heating to high temperatures or prolonged boiling.

4.1.2.2 Field beans (Vicia faba L.) while having a very good nutritional quality and being a high yield crop, should not be used in the formulation of supplementary foods because of the danger of favism. Heat treatment does not inactivate the toxic principles vicin and co-vicin.

4.1.2.3 Pulses are a good source of protein (20-24%) with a high content of lysine. They are, however, deficient in methionine. Depending on the nature of the other ingredients in the formulation, the addition of L-methionine might be desirable in order to improve the protein quality of the product.

4.1.3 Oil Seed Flours and Protein Products

4.1.3.1 Flours, protein concentrates and protein isolates of the following oil seeds, if manufactured to appropriate specifications 1/:

Soya beans: flour (full fat and defatted) concentrate, isolate;
Groundnuts: defatted flour, isolate;
Sesame seed: whole ground and defatted flour;
Cottonseed: defatted flour;
Sunflower seed: defatted flour.

4.1.3.2 Oil seed flours and protein products are a rich source of protein (50-95%). They could provide the main source of proteins in the Formulated Supplementary Foods for Older Infants and Young Children.

4.1.4 Fish Meals and Fish Protein Concentrates

4.1.4.1 Food quality meals from edible fish species and edible fish protein concentrates, produced under appropriate conditions. 1/

4.1.4.2 Fish protein concentrates have a protein content of 70-80%. The protein is of high quality and high in lysine content.

4.1.5 Fats and Oils

4.1.5.1 Fats and oils for the purpose of increasing the energy density of the food and for meeting physiological requirements of older infants and young children.

1/ The following Guidelines were elaborated by the FAO/WHO/UNICEF Protein and Energy Advisory Group:
"PAG Guideline No. 2: Preparation of food quality groundnut flour; PAG Guideline No. 4: Preparation of edible cotton seed protein concentrates; PAG Guideline No. 5: Guideline for heat processed soy grits and flours; PAG Guideline No. 14: Preparation of defatted edible sesame flour; PAG Guideline No. 9: Fish protein concentrates for human consumption.

4.1.5.2 The minimum requirements for essential fatty acids should be met.

4.2 Other Ingredients

The following ingredients may be used to improve the nutritional quality and/or acceptability of the food provided that they are readily available:

4.2.1 Milk and/or Milk Products.

4.2.2 Nutritive Sweeteners except sugar alcohols.

4.2.3 Flavours: vanilla and/or traditional flavours provided they have been evaluated for their safety-in-use.

4.2.4 Other ingredients of food quality, provided they have been proven to be suitable for their intended purpose.

5. TECHNOLOGIES FOR AND EFFECTS OF PROCESSING

5.1 Preliminary Treatment of Raw Materials

Cereals, pulses and oilseeds should first be treated to obtain wholesome and clean raw materials of good quality. Such treatments include:

5.1.1 Cleaning or washing: to eliminate dirt, damaged grains, foreign grains and noxious seeds, insects and insect excreta and any adhering material. 1/

5.1.2 Dehulling: pulses, oilseeds and certain cereals such as oats, barley, sorghum, millet and teff should be dehulled as completely as is feasible to reduce the crude fibre content to acceptable levels and to eliminate tannins and other phenolic materials which can lower the protein digestibility.

5.2 Milled Products

5.2.1 Milling or grinding of suitable raw materials should be carried out in such a way as to minimize the loss of nutritional value and to avoid undesirable changes in the technological properties of the ingredients.

5.2.2 Dry raw materials may be milled together, if technologically feasible, or mixed after milling or grinding.

5.2.3 Formulations containing milled cereals, pulses and/or oilseeds without further processing require prolonged boiling during the preparation of the feed to gelatinize the starch portions and/or eliminate anti-nutritional factors present in pulses. Boiling improves the digestibility and absorption of nutrients and sterilizes the feed.

5.2.4 The bulkiness of feeds from food formulations containing dry ingredients obtained by milling of the raw materials, can be reduced by adding, during the formulation, adequate amounts of α-amylase which, during the slow heating to boiling, predigest partially the starch and reduce the amount of water needed for the preparation of the feed.

5.3 Toasting

5.3.1 Toasting (dry heating) enhances the flavour and the taste of the food through dextrinization of starch. It also improves digestibility and contributes to reducing the bulkiness of the formulated food.

1/ Note: It is recommended to consider a provision for drying. Such a provision should also require that the process should not result in losses of nutritional value.

5.3.2 Pulses as well as oilseeds such as soya beans, groundnuts and sesame seeds can be toasted as whole grains directly or after soaking. Soaking results in puffed grains with a light texture.

5.3.3 Toasted raw materials are milled or ground for use as ingredients.

5.4 Sprouting and Malting

5.4.1 Cereals and pulses can be induced to germinate by soaking or humidifying. The action of natural amylases contained in the grains results in the predigestion of the starchy portion of the grain (dextrinization) thus reducing the bulk of the food when prepared for feeding and, ultimately, increasing the nutrient density of the food.

5.4.2 During the process, the seedcoat of the grain splits and can be removed by washing. The malted raw material is milled or ground after drying.

5.5 Advanced Processing Technologies

5.5.1 Extrusion Cooking

5.5.1.1 The mix of milled or ground basic ingredients (cereals, pulses, oilseed flours) may be further processed by extrusion-cooking.

The extruded product, after drying if necessary, is milled or ground to the desired particle size.

5.5.1.2 The effects of this technology are:

- gelatinization of the starchy portion of the mixture with minimal quantities of water;
- inactivation of lectins and simultaneous reduction of trypsin inhibitor activity;
- a reduction in the quantities of water needed for preparation of the feed.

5.5.2 Enzymatic Predigestion

5.5.2.1 Under this process the milled or ground basic ingredients (cereals, pulses, oilseed flours) are slowly heated under continuous stirring with 1-2 volumes of water and α-amylase (in amounts of 0.05 - 0.1% of the weight of the dry mixture) to a temperature of 60 ° - 70 ° C until the mixture acquires the desired fluidity. Starch molecules are split into dextrins and reducing sugars. After raising the temperature to 85° - 90° C to inactivate the enzyme, the slurry is dried and comminuted to flour or to small flakes.

5.5.2.2 The predigested product has improved organoleptic characteristics, higher digestibility, good solubility and requires less water for the preparation of the feed.

6. FORMULATION

6.1 Nutritional Aspects (General)

6.1.1 In accordance with the purpose of these guidelines and the definition of "Formulated Supplementary Foods for Older Infants and Young Children", the product is intended to supply additional energy and nutrients to the staple foods used for the feeding of older infants and young children.

[6.1.2 One hundred grammes of the product, when prepared according to the instructions, is considered a reasonable quantity which an older infant or young child can ingest easily in two or more feedings. This quantity of the product, if produced in accordance with the compositional model in Table 1, will provide approximately one third of the energy requirements and [100%] of the recommended intake of protein and appropriate vitamins and minerals.]

6.2 Energy

6.2.1 The energy density of a mixture of milled cereals and pulses and defatted oilseed meals and flours is relatively low.

6.2.2 The energy density of the food can be increased by:

(a) the addition of fats and oils, and/or nutritive sweeteners and/or,
(b) processing the basic ingredients as indicated in Section 5.

6.2.3 One hundred grammes of the food should provide at least 400 kcal.

6.3 Protein

6.3.1 The amino acid score of mixtures of cereals, legumes and/or oilseed flours should be adjusted to at least 65 and correspondingly to PER values not less than 2.1 and preferably above 2.3 (casein: 2.5).

6.3.2 The protein quality can be improved by the addition at adequate but safe levels of methionine or lysine in their L-form.

6.3.3 In order to cover [75%] of the protein recommended intake through the supplementary food, its protein content should be adjusted at 16 x 0.75 = 12. With an amino acid score of 65 its protein content should be 12.65 x 100 = 18.5 g or 20g/100g.

6.4 Fat

6.4.1 Incorporation of adequate quantities of fats and/or oils, as technologically feasible, is recommended in order to increase the energy density of the product. A level of 25% of energy deriving from fat would be desirable. This corresponds to 11 g of fats and/or oils in 100 g of the food.

6.4.2 Where it is economically not feasible to include fats and/or oils in the formulation of the food, the instructions for use on the label should recommend the addition of a specified quantity of fats and oils during the preparation of the feed.

6.4.3 The level of linoleic acid (in the form of a glyceride) should not be less than 300 mg per 100 kcal or 1.4 g per 100 g of product.

6.5 Carbohydrates

6.5.1 Carbohydrates in the form of nutritive sweeteners can increase the energy density, are more easy digested and absorbed than starch, and enhance acceptability.

6.5.2 Where it is economically not feasible to include nutritive sweeteners in the formulation of the food, the instructions for use on the label should recommend the addition of a specified quantity of sugars, syrups or similar sweeteners during the preparation of the feed.

6.5.3 Dietary fibres (a) are slowly absorbed and fermented by the intestinal flora, having a laxative effect, and (b) may affect the efficiency of absorption of various nutrients of significance in diets with a marginal nutrient content. The crude fibre content of the food should therefore not exceed 5 grammes per 100 grammes of the food. Higher levels may be acceptable, although it would require clinical testing of the formulated food.

6.6 Vitamins and Minerals

6.6.1 The addition of vitamins and minerals should take into account local nutrition and health conditions as well as the requirements stipulated by national legislation.

6.6.2 When establishing the specifications for the premix of vitamin compounds and mineral salts, the vitamin and mineral content of the other ingredients used in the formulation of the food should be taken into account.

6.7 Technological and Economic Aspects

6.7.1 The selection of ingredients for the formulation of Formulated Supplementary Foods for Older Infants and Young Children should be made, having regard to the provisions in Sections 4 to 6.6 above and taking into account the following aspects:

- nutrient content of staple food;
- dietary habits;
- other socio-economic aspects as determined by the national authorities dealing with nutrition;
- availability and costs of raw materials and other ingredients.

6.7.2 In cases where older infants and young children are given vitamins and minerals through MCH centres or other health agencies, their addition to supplementary foods may be unecessary.

6.8 Proposed Nutrient Profile

6.8.1 Table 1 in the Annex to these Guidelines contains a proposed nutrient profile for Formulated Supplementary Foods for Older Infants and Young Children which is intended to serve as a model for the nutrient content of these foods.

6.8.2 The model might not be applicable under all conditions prevailing in different countries and appropriate modifications have to be made for adapting it to specific conditions.

7. HYGIENE

It is recommended that Formulated Supplementary Foods for Older Infants and Young Children comply with the following mandatory hygiene requirements:

7.1 To the extent possible in good manufacturing practice, food products shall be free from objectionable matter.

7.2 When tested by appropriate methods of sampling and examination, the product:

(a) shall be free from pathogenic microorganisms;
(b) shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health; and
(c) shall not contain any other poisonous or deleterious substances in amounts which may represent a hazard to health.

7.3 The product /should/ be prepared, packed and held under sanitary conditions.

8. PACKAGING

8.1 It is recommended that Formulated Supplementary Foods for Older Infants and Young Children be packed in containers which will safeguard the hygienic and other qualities of food.

8.2 The containers, including packaging material, shall be made only of materials which are safe and suitable for their intended uses.

9. LABELLING

9.1 It is recommended that the labelling of Formulated Supplementary Foods for Older Infants and Young Children be in accordance with Sections 2, 3, 5, 7 and 8 of the Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985). 1/

9.2 In addition, the following mandatory provisions should apply:

1/ Hereafter referred to as "General Standard".

9.2.1 The Name of the Food

9.2.1.1 The name of the food to be declared on the label shall be "Formulated Supplementary Foods for Older Infants and Young Children". In addition thereto any appropriate designation may be used in accordance with national legislation.

9.2.1.2 The following information shall appear in close proximity to the name of the food:

(a) the major sources of protein;

(b) [a statement that the food should be used as a supplementary food when weaning has started,]

Or

[the following statement: "For use when other foods are added to the diet of the infant".]

9.2.2 List of Ingredients

9.2.2.1 The list of ingredients shall be declared in accordance with Section 4.2 of the General Standard.

9.2.3 Declaration of Nutritive Value

9.2.3.1 The declaration of energy and nutrients on the label or in labelling shall contain the following information:

(a) the amount of energy, expressed in Kilocalories and/or Kilojoules, per 100 grammes of the food as sold;

(b) the amounts of protein, carbohydrates and fat, expressed in grammes, per 100 grammes of the food as sold;

(c) the total quantity of each of the vitamins and minerals and of any other nutrient as required by the legislation of the country in which the food is sold, expressed in metric units, per 100 grammes of the food as sold.

9.2.4 Net Content

9.2.4.1 The net content shall be declared in weight in accordance with Section 4.4 of the General Standard.

9.2.5 Name and Address

9.2.5.1 The name and address shall be declared in accordance with Section 4.5 of the General Standard.

9.2.6 Country of Origin

9.2.6.1 The country of origin shall be declared in accordance with Section 4.6 of the General Standard.

9.2.7 Lot Identification

9.2.7.1 The declaration of lot identification shall be declared in accordance with Section 4.7 of the General Standard.

9.2.8 Date Marking and Storage Instructions

9.2.8.1 Date marking and storage instructions shall be declared in accordance with Section 4.8 of the General Standard.

9.2.9 Information for Utilization

9.2.9.1 Directions as to the preparation and use of the food shall be given; preferably accompanied by pictorial presentations.

9.2.9.2 The directions for the preparation shall include a precise statement that:

(a) in the case of foods containing non-heat-processed basic ingredients, the food must be adequately boiled in a prescribed amount of water;

(b) in the case of foods containing heat-processed basic ingredients: (i) the food requires boiling or (ii) can be mixed with cold or warm boiled water, as appropriate.

9.2.9.3 Foods which have been formulated with the intent that fats and/or nutritive sweeteners are added during preparation of the feed shall contain an indication of the amounts which are required to achieve the desired nutrient density of the feed.

9.3 Exemptions

(To be elaborated).

TABLE 1

MODEL NUTRIENT PROFILE

Nutrient	Amounts per 100 g	Amounts per 100 kcal	Amounts per 100 kj
Protein	20 g.	5.2 g.	1.21 g.
Fat	10 g.	2.6 g.	0.6 g.
Crude fibre	5 g.	1.3 g.	0.3 g.
Acid-insoluble ash	0.05 g.	-	-
Vitamins 1/			
Vitamin A, as retinol	400 µg	100 µg	24 µg
Vitamin D, (cholecalciferol)	10 µg	2.5 µg	0.6 µg
Vitamin E, (α-tocopherol)	5 mg	1.25 mg	0.3 mg
Ascorbic acid	20 mg	5.2 mg	1.2 mg
Thiamine	500 µg	125 µg	32 µg
Riboflavin	800 µg	200 µg	48 µg
Niacin	9 mg	2.20 mg	0.57 mg
Vitamin B_6	900 µg	220 µg	57 µg
Folic acid	100 µg	27 µg	6 µg
Vitamin B_{12}	2 µg	0.52 µg	0.12 µg
Minerals			
Calcium	800 mg	200 mg	48 mg
Phosphorus	800 mg	200 mg	48 mg
Iron	10 mg	2.7 mg	0.6 mg
Iodine	70 µg	18 µg	4.5 µg

1/ The amounts for vitamins and minerals are minimum levels, except in the case of Vitamin D, where no further increase is desirable. Additional amounts of vitamins added should not exceed those needed to maintain label requirements over the expected shelf-life of the product.

DRAFT AMENDMENTS TO CERTAIN PROVISIONS OF THE CODEX STANDARD FOR FOODS FOR INFANTS AND CHILDREN

I. Draft Amendments at Step 8 of the Procedure

A. LEAVENING AGENTS

Standard concerned: Codex Standard for Processed Cereal-based Foods for Infants and Children (CODEX STAN 74-1981). It is proposed to include the following provisions in Section 5:

"5.6 Leavening Agents

5.6.1	Ammonium carbonate	) Limited by Good Manufacturing
5.6.2	Ammonium hydrogen carbonate	) Practice "

B. GUAR GUM

Standard concerned: Codex Standard for Canned Baby Foods (CODEX STAN 73-1981). It is proposed to include the following provision into Section 4:

"4.1.2	Maximum level in 100 g of ready-to-eat product	
Guar Gum	0.2 g	"

C. MAXIMUM LEVELS FOR VITAMIN D CONTENT

Standard concerned: Codex Standard for Infant Formula (CODEX STAN 72-1981). It is proposed to amend Section 4.1.2 (a) as follows:

	"Amount per 100 available Calories		Amount per 100 available Kilojoules		
	Minimum	Maximum	Minimum	Maximum	
Vitamin D	40 I.U.	100 I.U.	10 I.U.	25 I.U.	"

II. Draft Amendments at Lower Steps of the Procedure

A. AMENDMENT TO THE CODEX STANDARDS FOR FOODS FOR INFANTS AND CHILDREN (EXCEPT INFANT FORMULA) ON LABELLING AT STEP 6

See paras 172-177 of ALINORM 87/26.

PROPOSED DRAFT STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED "LOW ENERGY" OR "REDUCED ENERGY" FOODS [FOR SPECIAL DIETARY USES]

(At Step 3 of the Procedure)

1. SCOPE

This standard applies to the labelling of and claims for foods manufactured to be low in energy or reduced in energy as defined in Section 2 below, and which are intended for controlling or reducing energy intake.

2. DEFINITIONS

2.1 Low energy food means: A manufactured food which provides a maximum of 40 kilocalories or 170 kilojoules per specified serving. Solid foods must also have an energy density of no more than 40 kilocalories or 170 kilojoules per 100 g and liquid foods must have an energy density of no more than 20 kilocalories or 80 kilojoules per 100 ml of the finished product as served.

2.2 Reduced energy food means a food which provides not more than [60/75/66 2/3%] of the energy that would be normally provided in the same weight of that food if it were not energy reduced. [A "reduced energy food" should be nutritionally equivalent, except with respect to energy content, to the food for which it substitutes].

2.3 Nutritionally equivalent means of equal nutritive value in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients. 1/

3. LABELLING

3.1 "Low energy" or "Reduced energy" foods for special dietary uses as defined in Sections 2.1 and 2.2 shall be labelled in conformity with the Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN ...-1985) 2/ except that the following specific provisions apply:

3.2 Section 4.1.2 of the General Standard - The Name of the Food - The following additional provisions apply:

3.2.1 The term "low energy" or "a low energy food" may be declared on the label only if the food complies with the definition in Section 2.1, and in such a case it shall be in close proximity to the name of the food.

3.2.2 The term "reduced energy" or "a reduced energy food" may be declared on the label only if the food complies with the definition in Section 2.2, and in such a case it shall be in close proximity to the name of the food.

3.2.3 The label of a "reduced energy" food [shall] bear a statement comparing the energy content of a [specified serving] of the food and an [equivalent serving] of the food if it were not energy reduced or the food for which it substitutes having at least [1.5] times as many Kcal.

1/ See para. 192 of this Report.

2/ Thereafter referred to as "General Standard".

3.2.4 The term "Calorie" or "Joule" shall be permitted as an alternative for the term "Energy".

GENERAL CONSIDERATIONS

It may not be technologically feasible to manufacture a "reduced energy" food under the criteria set forth in Section 2.2 for all foods that are significant dietary sources of energy and for which it would be useful to those on energy-restricted diets to have a reduced energy substitute. Accordingly, the Committee on Foods for Special Dietary Uses, may establish (by issuance of a Codex Standard) acceptable alternative criteria for a "reduced energy" food if:

(a) It is demonstrated that it is not feasible to attain a greater energy reduction than that for which approval is sought; and

(b) it is demonstrated that the use of the food with the energy reduction attained, will result in a significant reduction in energy in the diet, and be useful to those on energy reduced or weight controlled programmes.

ALINORM 87/26
Appendix IX

PROPOSED DRAFT STANDARD FOR NUTRITIONALLY COMPLETE FORMULA FOODS FOR USE IN WEIGHT CONTROL DIETS
(At Step 3 of the Procedure)

1. SCOPE

This standard applies to nutritionally complete formula foods for use in weight control diets, as defined in Section 2.

It does not apply to prepackaged meals controlled in energy and made from conventional foods.

2. DEFINITIONS

2.1 A nutritionally complete formula food for use in weight control diets is a food which, when presented as "ready-to-serve" or when diluted with water, milk or a combination thereof, as directed, is represented as a replacement for one or more meals of the total diet.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Energy Content

3.1.1 When ready-to-serve, a specified serving of the food constituting a meal shall contain between 200 and 400 Kcal or between 835 and 1670 KJ.

3.1.2 A food presented as a replacement for all meals in a diet shall be accompanied by directions for use which assure a daily energy intake of between 800 and 1200 Kcal or between 3350 and 5020 KJ.

3.2 Nutrient Content

3.2.1 Protein 1/ 2/

3.2.1.1 Not less than 20% and not more than 50% of the energy available from the food, as ready-to-serve, shall be derived from its protein content.

3.2.1.2 The protein present shall be:

(i) of a nutritional quality equivalent to casein; or

(ii) where a protein has a Protein Efficacy Ratio (PER) of less than that for casein, the minimum levels should be increased to compensate for the lower PER. No protein with a PER of less than 85% of that of casein should be used in a meal replacement for weight control or weight reduction.

3.2.1.3 Essential amino acids may be added to improve protein quality only in amounts necessary for that purpose. Only L-forms of amino acids shall be used.

3.2.2 Fat and Linoleate 3/

3.2.2.1 Not more than 30% of the energy available from the food shall be derived from fat including not less than 3% of the energy available derived from linoleic acid (in the form of a glyceride).

3.2.3 Carbohydrates 4/

3.2.3.1 Except in the case of a meal replacement for weight control or weight reduction presented for consumption as a liquid, not more than 30% of the available carbohydrates shall be in the form of sugars (mono-, di- and/or oligosaccharides up to four units) and/or sugar alcohols.

1/ The Federal Republic of Germany proposes that the protein content shall not be less than 25 grammes per meal, with daily portions of 50 grammes, consisting mainly of animal protein of high value or protein which is biologically equivalent.

2/ The United States propose that the minimum content of protein be 45 grammes per 1000 kcal if the PER is equal to or greater than casein and 65 grammes per 1000 kcal if the PER is lower than that of casein.

3/ The Federal Republic of Germany proposes that the content of essential fatty acids shall not be less than 3 grammes per meal, with daily portions of 7 grammes, calculated as linoleic acid.

4/ The Federal Republic of Germany proposes that the content of available carbohydrates shall not be less than 20 grammes per meal, with daily portions of 90 grammes and a maximum limit of 50% of the above levels in the case of lactose.

3.2.4 Vitamins and Minerals 1/

Meal replacements for weight control or weight reduction shall contain the following minimum amounts per 1000 kcal of the following vitamins and minerals:

Vitamins	2/	3/
Vitamin A (IU)	2497	5000
Vitamin D (IU)	80	400 (optional)
Vitamin E (IU)	20	30
Vitamin C (mg)	62	60
Thiamine (mg)	1.3	1.5
Riboflavin (mg)	1.7	1.7
Niacin (mg)	-	20.0
Vitamin B-6 (mg)	1.5	2.0
Vitamin B-12 (ug)	-	6.0
Folic acid (mg)	-	0.4
Biotin	-	0.3
d-panthothenic acid (mg)	-	10.0
Minerals		
Calcium (gm)	-	1.0
Phosphorus (gm)	0.8	1.0
Iron (mg)	15.0	18.0
Iodine (ug)	-	150
Magnesium (mg)	-	400
Copper (mg)	-	2.0
Zinc (mg)	-	15.0
Potassium (gm)	-	1.2
Manganese (mg)	-	2.0
Sodium (g)	-	1.0

1/ The Federal Republic of Germany proposes to express the requirements per 400 kcal (equivalent to one meal) and per 1200 kcal (equivalent to the daily portion) as follows:

Vitamins	(per 400 kcal)	(per 1200 kcal)
Vitamin A (IU)	1000	2997
Vitamin D (IU)	30	100
Vitamin E (IU)	6	18
Vitamin C (mg)	25	75
Thiamine (mg)	0.5	1.6
Riboflavin (mg)	0.7	2.0
Niacin (mg)	-	-
Vitamin B-6 (mg)	0.6	1.8
Vitamin B-12 (ug)	-	-
Folic acid (mg)	-	-
Biotin	-	-
d-panthothenic acid (mg)	-	-
Minerals		
Calcium (gm)	0.3	0.8
Phosphorus (gm)	0.0	0.9
Iron (mg)	6.0	18.0
Iodine (ug)	-	-
Magnesium (mg)	-	-
Copper (mg)	-	-
Zinc (mg)	-	-
Potassium (gm)	-	-
Manganese (mg)	-	-
Sodium (g)	-	-

2/ Values proposed by the Federal Republic of Germany.
3/ Values proposed by the United States.

3.3 Ingredients

3.3.1 Essential Ingredients

3.3.1.1 Meal replacements for weight control or weight reduction shall be prepared from protein constituents of animal and/or plant which have been proved suitable for human consumption and from other suitable ingredients necessary to achieve the essential composition of the product as set out in Sections 3.1 and 3.2 above.

3.3.2 Optional Ingredients

(To be elaborated).

[3.3.2.1 Meal replacements for weight control or weight reduction may contain non-nutritive ingredients such as, dietary fiber.

3.3.2.2 Meal replacements for weight control or weight reduction may contain intense and/or non-nutritive sweetener(s).

3.3.2.3 Meal replacements for weight control or weight reduction may contain a combination of nutritive, intense and/or non-nutritive sweetener(s).] 1/

4. FOOD ADDITIVES

(To be elaborated).

5. CONTAMINANTS

(To be elaborated).

6. HYGIENE

6.1 To the extent possible in good manufacturing practice, the product shall be free from objectionable matter.

6.2 When tested by appropriate methods of sampling and examination, the product:

(a) shall be free from pathogenic microorganisms;

(b) shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health; and

(c) shall not contain any other poisonous or deleterious substances in amounts which may represent a hazard to health.

7. PACKAGING

7.1 The product shall be packed in containers which will safeguard hygienic and other qualities of the food. When in liquid form, the product shall be thermally processed and packed in hermetically sealed containers to ensure sterility; nitrogen and carbon dioxide may be used as packing media.

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

8. FILL OF CONTAINER

In the case of products in ready-to-eat form, the fill of container shall be:

1/ Proposal by the Chairman of the WG.

(a) Not less than 80% v/v for products weighing less than 150 g (5 oz);

(b) not less than 85% v/v for products in the weight range 150-250 g (5-8 oz); and

(c) not less than 90% v/v for products weighing more than 250 g (8 oz) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20° C which the sealed container will hold when completely filled.

9. LABELLING

In addition to the appropriate Sections of the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses, the following specific provisions apply:

9.1 The Name of the Food

9.1.1 The name of the food shall be "Meal Replacement of Weight Control or Weight Reduction" and shall be accompanied by a common or usual name as applicable or an appropriate descriptive term.

[9.1.2 A meal replacement for weight control or weight reduction which uses a non-nutritive ingredient must declare on its label the presence of non-nutritive ingredients and its percentage by weight, e.g., dietary fiber.

9.1.3 A meal replacement for weight control or weight reduction which uses intense and/or non-nutritive sweetener(s) must bear a statement on its label that it contains intense and/or non-nutritive sweetener(s) but need not state the percentage by weight of the intense and/or non-nutritive sweetener(s).

9.1.4 If a nutritive sweetener(s) as well as an intense and/or non-nutritive sweetener(s) is added to the meal replacement for weight control or weight reduction the label statement shall indicate the presence of all types of sweetener(s) for example sweetened with nutritive sweetener(s), intense and/or non-nutritive sweetener(s).] 1/

9.2 List of Ingredients

A Complete list of ingredients shall be declared in accordance with Section 4.2 of the General Standard.

9.3 Declaration of Nutritive Value

9.3.1 The nutritive value shall be declared on the label per 100 grammes or 100 ml of the food as sold and, where appropriate, for a specified quantity of the food as suggested for consumption (per serving):

(a) the amount of energy expressed in kilocalories (kcal) and kilojoules (kJ);

(b) the amounts of protein, available carbohydrates and fat expressed in grammes;

(c) the amounts of vitamins and minerals expressed in units in conformity with Section 3.3;

(d) in addition thereto the amounts of cholesterol and sodium may also be declared.

9.3.2 If the fatty acid composition is declared on the label it should be done in accordance with the Codex Guidelines on Nutrition Labelling.

1/ Proposal by the Chairman of the WG.

9.3.3 If the directions for use indicate that the food should be combined with other ingredient(s), the nutritive value of the final combination may be provided on the label in addition to the declaration required in Section 9.3.1.

9.4 Net Contents

9.4.1 The declaration of net contents should be in accordance with Sections 4.3.1 and 4.3.2 of the Codex General Standard for the Labelling of Prepackaged Foods.

9.5 Name and Address

9.5.1 The declaration of the name and address shall be in accordance with Section 4.4 of the Codex General Standard for the Labelling of Prepackaged Foods.

9.6 Country of Origin

9.6.1 The declaration of the country of origin shall be in accordance with Sections 4.5.1 and 4.5.2 of the Codex General Standard for the Labelling of Prepackaged Foods.

9.7 Lot Identification

9.7.1 The declaration of the lot identification shall be in accordance with Section 4.6.1 of the Codex General Standard for the Labelling of Prepackaged Foods.

9.8 Date Marking

9.8.1 The use-by-date shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer. In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

9.9 Storage Instructions

9.9.1 Un-opened Food

Any special conditions for the storage of the food shall be declared on the label if the validity of the date depends thereon.

9.9.2 Opened Food

Storage instructions of opened packages of the food shall be included on the label to ensure that the opened food maintains its wholesomeness and nutritive value. A warning should be included on the label if the food is not capable of being stored after opening or is not capable of being stored in the container after opening.

9.10 Information for Utilization

9.10.1 Directions as to the preparation and use of the food shall appear on the label.

9.11 Additional Provisions

9.11.1 Claims

(To be elaborated).

9.11.2 Reference Material

The label may contain information on scientific references, sources of information for diet counseling and information on obtaining supplies of the food.

PROPOSED DRAFT STANDARD FOR THE LABELLING OF AND CLAIMS FOR FOODS FOR SPECIAL MEDICAL PURPOSES

(At Step 3)

1. SCOPE

This standard applies to the labelling of and claims for Foods for Special Medical Purposes as defined in Section 3 below. It does not apply to the labelling of and claims for:

- conventional foods
- foods covered by other Codex standards
- [- nutritionally complete formulae.]

2. DEFINITIONS

"Foods for Special Medical Purposes" means a category of foods for special dietary uses which are specially processed or formulated for the dietary management of patents with (a) specific disease(s), disorder(s) or medical condition(s) (including malnutrition) and which are presented as such. Foods for Special Medical Purposes are distinguished from other foods for special dietary purposes by the requirement that they shall be used under medical supervision.

3. GENERAL PRINCIPLES

Foods for Special Medical Purposes should not be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding their character in any respect. The labels, accompanying leaflets and other labels and advertising of all types of Foods for Special Medical Purposes should provide sufficient information on the nature and purpose of the food as well as detailed instructions and precautions for their use. The format of the information given should be appropriate for the person for whom it is intended.

4. LABELLING

4.1 Foods for Special Medical Purposes shall be labelled in accordance with the Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN ... -1985) 1/ except that:

(a) Sections 4.3, 5.1, 5.2.2, 5.2.3 and 6 of the General Standard do not apply to the Labelling of Foods for Special Medical Purposes; and

(b) the following specific provisions apply:

4.2 Nutrition Labelling

Foods for Special Medical Purposes shall be labelled with complete nutrition labelling as follows:

4.2.1 The declaration of nutrient content shall be numerical. However the use of additional means of presentation should not be excluded.

4.2.2 Information on energy value shall be expressed in KJ or Kcal per 100 g or per 100 ml or per package if the package contains only a single portion.

4.2.3 Information on the amounts of protein, carbohydrate and fat in the food shall be expressed in g per 100 g or per 100 ml or per package if the package contains only a single portion. Information on the amounts of essential and non-essential amino acids and/or essential fatty acids may be expressed similarly in metric units as appropriate.

1/ Thereafter referred to as "General Standard".

4.2.4 Information on the amounts of vitamins and essential minerals shall be expressed in metric units or international units as applicable per 100 g or per 100 ml or per package if the package contains only a single portion.

4.2.5 Information on osmolality or osmolarity and on acid-base balance shall be given when appropriate.

4.2.6 In addition, the quantity of nutrients may be expressed in terms of percentages of internationally acceptable recommended daily nutrient standards.

4.2.7 In countries where serving sizes are normally used, the information described in Sections 4.3.2 to 4.3.4 may be given only per serving as quantities on the label or per portion provided that the number of servings or portion contained in the package is stated.

4.3 The Labelling of Foods for Special Medical Purposes shall include the following:

[4.3.1 The claim "For the dietary management ....." either in close proximity to the name with the blank to be filled in with the specific disease(s), disorder(s) or medical condition(s) for which the product is intended, and for which it is known to be effective or in the labelling accompanying the product.]

4.3.2 A prominent statement "USE ONLY UNDER MEDICAL SUPERVISION", in bold letters in an area separated from other written, printed, or graphic matter.

4.3.3 An additional prominent warning statement consisting of an explanatory statement printed in bold letters in an area separated from other written, printed, or graphic matter if:

(a) The Food(s) for Special Medical Purposes pose(s) a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the product is intended; or

(b) the Food(s) for Special Medical Purposes may adversely affect reproductive functions, the developing fetus, or breast-milk quality or quantity.

[4.3.4 A complete statement concerning adequate precautions, known side effects, contraindications, and product-drug interactions, as applicable.]

[4.3.5 A statement of the rationale for the product's use and a description of the properties or characteristics that make it useful.]

[4.3.6 A statement specifying the nutrient(s) reduced, deleted, or increased content of certain substances relative to a normal diet and the reason why the nutrient is reduced, deleted, or increased.]

[4.3.7 A statement indicating whether the product is or is not intended for use as the sole source of nutrition.]

[4.3.8 Adequate directions for preparation, including the necessity of adding other ingredients, if appropriate, and adequate directions for use.]

[4.3.9 Feeding instructions, including administration and serving size, if applicable.]

REPORT OF THE MEETING OF THE AD-HOC WORKING GROUP ON METHODS OF ANALYSIS AND SAMPLING FOR FOODS FOR INFANTS AND CHILDREN

The above Working Group met on 12 January 1987 in Bonn-Bad Godesberg in conjunction with the 15th Session of the CC/FSDU, under the Chairmanship of Prof. Dr. W. Kronert (Federal Republic of Germany). A list of participants is given in Annex I to this Appendix.

SAMPLING

1. The Working Group was informed by the FAO Secretariat of the request of CC/MAS to Codex Commodity Committees to propose sampling plans taking into account the instructions on sampling procedures in documents CX/MAS 86/3 and 86/8. The Working Group thanked the UK delegate, Dr. Meech, for agreeing to consider information and comments from Governments and to prepare a paper on sampling for the next session of the Working Group. All delegations of the CC/FSDU were requested to send relevant informations on sampling to Dr. Meech.

REVIEW OF METHODS OF ANALYSIS

2. The Working Group had before it ALINORM 85/26, Annex II to Appendix XI; CX/FSDU 87/3 and CX/FSDU 87/3-Add. 1 and the letter of the Working Group Chairman dated July 1986. The Working Group was also informed about document CX/MAS 87/10-Part I, setting out the current status of endorsement of methods of analysis included in the Codex standards.

3. The Working Group decided to ask the Committee to withdraw the endorsement of the following methods of analysis. The review has shown that these methods had been only collaboratively studied for food items other than those listed in the Codex standards. It was thought essential that Codex methods be studied in relation to the products for which they were intended.

Item in Annex II to Appendix XI, ALINORM 85/26	Provision	Standard
1.1	Silica content	CODEX STAN 53-1981
1.2	Iodine content	"
3.3	Calcium content	"
3.4	Magnesium content	"
3.5	Ammonium content	"
3.6	Phosphorus content	"
3.13	Copper, Manganese, Zinc, Magnesium	CODEX STAN 72/74-1981
3.14	Iron	"
2.2	Calcium	"
2.3	Sodium, Potassium	"

For the determination of calcium, sodium and potassium (Items 2.2 and 2.3), the present methods should be replaced by the proposed IDF 119/1984 method and classified as Type II method. As regards the other standards for foods for infants and children (CODEX STAN 73 and 74-1981) appropriate methods would have to be selected.

4. For the determination of the criteria listed under 3.13 and 3.14 (copper, manganese, zinc, magnesium, iron in infant foods) the Working Group proposed the AOAC method, AOAC, XIV, 1984, 43.292-43.296 as Type III method for infant formula only. The reason why this method was not proposed as a reference (Type II) method was that this higher sophisticated method is not everywhere available. There is no other method which could be proposed as a Type II method. Governments were requested to propose simpler suitable methods for consideration as reference method.

5. The Working Group confirmed the need to classify the conversion factors from nitrogen to protein in line with the different sources as Type I method, but to remain the present Kjeldahl-method as Type II method. The US Delegation proposed to take the

factors given by the Joint FAO/WHO Expert Committee on nutrition. The Working Group noted that the question of whether the determination of protein should be a Type I method or a combination of Type I and II method, would be discussed by the CC/MAS. It wished to be informed of developments.

6. The Working Group took note that the FDA and IFC were studying a method for the determination of choline in infant formula. Governments and International Organisations were requested to provide suitable methods for the determination of choline in infant formula and salt substitute.

7. The Group noted that there were suitable methods for the determination of linoleate. The Representataive of AOAC was asked to check whether the method of AOAC is identical to the method of IUPAC and to report to the Chairman of the Working Group.

8. The Working Group again considered the need for methods of analysis for the determination of crude fibre in connection with the calculation of energy in infant foods. It was of the opinion that advice from nutritionists was needed to clarify what exactly had to be measured in relation to "available carbohydrate" and also in relation to "dietary fibre".

9. Methods for the determination of vitamin K_1, biotin and iodine in infant formula and baby foods were being developed in USA. The delegations expressed the need to be informed if there is the possibility to take part in collaborative studies. The Representative of AOAC stated that it was difficult to obtain information about nationally planned collaborative studies. Governments and International Organisations were invited to inform the Secretariat of such studies so that the announcement could be included in the "Referee" (AOAC) or the Swedish "Food Laboratory News Letter". The Representataive of AOAC also informed the Group that the results of collaborative tests could be published free of charge in the Journal of AOAC.

10. The Working Group noted that the methods for the determination of sodium and potassium in salt substitutes and low sodium foods required further consideration on the basis of information to be supplied by the USA and AOAC. The previous temporary endorsement was converted to non-endorsement.

11. The delegation of the Netherlands informed the Working Group that a method of the determination of gliadin had been tested collaboratively and was available. The Working Group noted that this method could be used to generate information on the basis of which a provision could be drawn up for inclusion in the Codex Standard for Gluten-Free Foods.

12. The Working Group agreed that the method included in the Netherlands paper be circulated during the session and that the results of collaborative testing might usefully be published in the AOAC. The CC/FSDU was invited to consider these developments.

13. The Secretariat was requested to ensure that the references to adopted methods be changed to the most recent ones, where the methods were identical to those originally included in the standards.

14. The Working Group also agreed on the classification of the methods adopted by the CC/FSDU (i.e. as Type I, II, III, etc.). The revised listing of methods of analysis is given in Annex II to the Report of the Working Group.

Appendix XI
Annex

MEETING OF THE AD HOC WORKING GROUP ON METHODS OF ANALYSIS AND SAMPLING FOR FOODS FOR SPECIAL DIETARY USES

LIST OF PARTICIPANTS

Name	Country
Joginder G. Chopra M.D.	USA
Rudolph M. Tomarelli	USA
J.A. Boerma	Netherlands
M.V. Meech	UK
Pierre Rossier	Switzerland
Kim Myong Guk	D.P.R. of Korea
Kim Duk Hi	D.P.R. of Korea
Cho Du Hyong	D.P.R. of Korea
Ruth English	Australia
A.M.M. Abdellatif	Netherlands
E. Rabe	ICC
Margreet Lauwaars	AOAC

(Conference Room Document No. 7)

REPORT OF THE WORKING GROUP ON ADVISORY LISTS FOR MINERAL SALTS AND VITAMIN COMPOUNDS IN FOODS FOR INFANTS AND CHILDREN

The Working Group met on 12 January 1987 in Bonn-Bad Godesberg in conjunction with the 15th Session of the CC/FSDU, under Chairmanship of Dr. R.W. Weik (USA). Appendix X of ALINORM 85/26 formed the basis for the discussion.

Terms of Reference of the Working Group

Concerning the terms of reference stated in para. 140 of ALINORM 85/26, the Working Group would like to limit their terms of reference to "Advisory Lists for Mineral Salts and Vitamin Compounds". In this way a clear distinction is made between on the one hand nutrients and on the other hand additives.

Further the Working Group was of the opinion that insofar as its work is limited to "Advisory Lists for Mineral Salts and Vitamin Compounds" it can work autonomously, i.e., without endorsement of CC/FA.

The Working Group would like to know if the Plenary Session can endorse these proposals.

Proposed Procedure

The Working Group proposes to the Plenary Session the following informal procedure for including mineral salts and vitamin compounds on the advisory lists:

Step 1 - Governments and Interested International Organizations can ask the Working Group to put without any further justification mineral salts and/or vitamin compounds on the list of Proposed Mineral Salts and/or the Proposed List of Vitamin Compounds.

Step 2 - Full justification must be given by the proposer, considering in the case of Mineral Salts, the Criteria listed in ALINORM 85/26, Section B (i) (a) to (d) and in the case of Vitamin Compounds, the Criteria listed in Section D (i) (a) to (d).

Step 3 - Justifications must be sent to the Chairman of the Working Group, who will distribute them to the Members of the Working Group for consideration.

Step 4 - Approval by the Working Group.

Step 5 - Approval by the Plenary Session.

Step 6 - Approval by the Codex Commission.

Step 7 - Inclusion of the proposed Mineral Salt(s) and/or Vitamin Compound(s) in the Advisory List(s).

Proposed Changes to the Criteria for Amendments of the Advisory Lists for Mineral Salts and Vitamin Compounds (ALINORM 85/26, Appendix X, Section B(i) (a) and Section D (i) (a))

The Working Group considered in detail Section B (i)(a) and D (i)(a), noting that the use of the phrase "technological and/or" was subject to misinterpretation, because the basic purpose of the Criteria is to require that the Mineral Salts and Vitamin Compounds be sources of essential nutrients. The Working Group also noted that there was a need to include the concept of safety in the Criteria, and recognized the desirability of indicating that the compounds be technologically suitable for the purposes for which they are intended. Hence, the Working Group proposes that:

Subsections (i)(a) of Sections B and D be replaced by the following:

(i) (Mineral Salts), (Vitamin Compounds) may be added to the Advisory Lists only if:

(a) They are known to be safe and suitable as nutrient sources.

The Secretariat was requested to look into the possibility of merging the two sections and to append the revised text to the final version of this report.

Justifications for Some Mineral Salts Provided by the Netherlands

In a letter of August 1985 the Delegation of the Netherlands has sent full justification for the following mineral salts:

Magnesium gluconate
Manganese gluconate
Zinc gluconate
Potassium iodate

Dr. Weik will, according to the above procedure, distribute these justifications to the Members of the Working Group.

Proposal for Another Way of Listing the Permitted Mineral Salts in the Advisory List

The Delegation of the Netherlands proposed to list the permitted mineral salts in a block-diagramme with on one side the anions and on the other side the cations. The Working Group felt that such a block-diagramme could not replace the advisory list, since this list contains more information. However, such a block-diagramme could be useful as additional information.

The Delegation of the Netherlands was asked to work out such block-diagrammes for the Infant Formula Standard, the Canned Baby Foods Standard, the Processed Cereal-based Foods for Infants and Children Standard and for the Draft Follow-up Formula Standard.

Proposed Amendments to Certain Provisions of the Codex Standard for Foods for Infants and Children (At Step 5) (ALINORM 85/26, Appendix IX)

The Working Group has been asked by the 14th Session of CC/FSDU (para. 140 of ALINORM 85/26) to consider the above proposed amendments. The Working Group would like to advise the following to the Plenary Session:

A. Leavening Agents

To accept inclusion of ammonium carbonate and ammoniumhydrogen carbonate limited by G.M.P. as leavening agents in the Codex Standard for Processed Cereal-based Foods for Infants and Children.

B. Definition of Children

Amendment has already been accepted by the Codex Commission at Step 8.

C. Guar gum

To accept inclusion of guar gum at a maximum level of 0.2 g/100 g of ready-to-eat product as thickening agent in the Codex Standard for Canned Baby Foods.

D. Maximum Levels for Vitamin D Content

To accept to increase the maximum allowed level of Vitamin D in Infant Formulas to 100 IU/100 kcal or 25 IU/100 kJ.

The following remarks were submitted to the Plenary Session:

All delegations in the Working Group agreed to increase the maximum allowed level of Vitamin D in Infant Formulas to 100 IU/100 kcal. However, the Delegations of the Netherlands, Canada and the United States were in favour of increasing the Vitamin D upper limit even further to 120 IU/100 kcal. The Delegation of the Netherlands offered to prepare a justification for this further increase, which will be discussed at the next Working Group Session.

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LIST OF PARTICIPANTS

Ms. M.C. Cheney	Canada
Ms. B. Dix	Codex Secretariat
Mr. A.L. Forbes	USA
Mr. J.G. Franklin	UK
Mr. R. Grossklaus	Fed. Rep. of Germany
Mr. R.A. Hendey	UK
Mr. K. Morita	Japan
Mr. N. Hosoya	Japan
Mr. H. Takeuchi	Japan
Mr. G. Huschke	Switzerland
Mr. H.P. Joos	Switzerland
Mr. P. Lackenby	UK
Mr. J. Rey	France
Mr. N. Snow	Australia
Mr. B.F. van Woelderen	Netherlands

ADVISORY LISTS FOR MINERAL SALTS AND VITAMIN COMPOUNDS FOR USE IN FOODS FOR INFANTS AND CHILDREN

1. The Advisory Lists for Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children approved by the Codex Alimentarius Commission are included in Volume IX of the Codex Alimentarius.

Proposals for Amendment of the Advisory Lists

2. The 15th Session of CC/FSDU agreed to the following informal procedure for the amendment of the above Advisory Lists:

Step 1 - Governments and Interested International Organizations request the Ad-Hoc Working Group of CC/FSDU on the Advisory Lists to place their proposed amendments on the List or as appropriate. No supporting information is required at this point.

Step 2 - In order to enable the Ad-Hoc Working Group of CC/FSDU on the Advisory Lists to consider the proposed amendments, however, full supporting material in accordance with the Criteria set out below must be provided to the chairman of the Working Group.

Step 3 - The Chairman of the Ad-Hoc Working Group of CC/FSDU on the Advisory Lists distributes the material to the Members of the Working Group which is being convened as the need arises.

Step 4 - Consideration of and recommendation to the Plenary concerning proposed amendments by the Ad-Hoc Working Group of CC/FSDU on the Advisory Lists.

Step 5 - Consideration, approval and submission to the Codex Alimentarius Commission of proposed amendments by CC/FSDU.

Step 6 - Consideration and approval of proposed amendments by the Codex Alimentarius Commission.

Step 7 - Publication of approved amendments in the Advisory Lists (Volume IX of the Codex Alimentarius).

Criteria for the Amendment of the Advisory Lists of Mineral Salts and Vitamin Compounds of Use in Foods for Infants and Children

(i) Mineral Salts and Vitamin Compounds may be added to the above Lists only if:

(a) they are known to be safe and suitable as nutrient sources.

(b) the anion (or acids from which the anion is derived) is an approved additive and its use does not exceed the ADI;

(c) it is demonstrated by appropriate studies in animals and/or infants that the vitamin element is biologically available from the compound;

(d) the purity requirements for the vitamin compound are established in an internationally recognized specification.

(ii) Mineral Salts and Vitamin Compounds shall be deleted from the list if they are found no longer to meet the above criteria or if there is no evidence of their continued commercial application.

MINERAL SALTS PROPOSED FOR INCLUSION IN THE ADVISORY LIST OF MINERAL SALTS FOR USE IN FOODS FOR INFANTS AND CHILDREN

The following substances have been proposed for inclusion in the Advisory List of Mineral Salts for Use in Foods for Infants and Children. They have not been included due to lack of data required by the criteria set out above:

Source of	Salts	Use in Foods for Infants and Children
Calcium (Ca)	Calcium glucuronate Calcium malate Calcium tartrate	
Magnesium (Mg)	Magnesium acetate Magnesium gluconate	Infant formula, processed cereal-based foods
Iron (Fe)	Ferrous ascorbate Ferrous glucuronate Ferrous glycerophosphate 1/ Ferrous phosphate Ferrous saccharate Ferric lactate 2/ Ferric tartrate	
Copper (Cu)	Cupric acetate Lysine/copper complex	Baked products, protein supplement formulae
Iodine (I)	Calcium iodostearate Sodium iodine 1/	Milk-based, milk substitute protein hydrolysate formulae
Zinc (Zn)	Potassium iodate Zinc lactate Zinc gluconate	
Manganese (Mn)	Manganese lactate Manganese gluconate	
Sodium (Na)	Sodium glucuronate Sodium glycerophosphate Sodium malate	
Potassium (K)	Potassium ascorbate Potassium glucuronate Potassium malate	
Chloride (Cl)	Zinc chloride 1/	

1/ Animal feeding studies have been carried out.

2/ Not for use in powdered formulae, cereals or baby foods.

VITAMIN COMPOUNDS PROPOSED FOR INCLUSION IN THE ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR INFANTS AND CHILDREN

The following substances have been proposed for inclusion in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children. They have not been included due to lack of data required by the criteria set out above:

Vitamin	Vitamin Compound	Purity Requirements
Provitamin A	Beta-apo-8'-carotenal	FAO/WHO
Vitamin A	Vitamin A Alcohol	USP, FCC
Vitamin B_2	Riboflavin tetrabutyrate	JSFA
Vitamin B_6	Pyridoxal 5'-phosphate Pyridoxine di-palmitate	
Pantothenic Acid	Sodium pantothenate	
Vitamin C	Potassium ascorbate Ascorbyl stearate	JSFA
Choline	Choline hydrogen citrate	

[CX/FSDU 87/5-Add. 2
Revised]

TECHNOLOGICAL JUSTIFICATION FOR FOOD ADDITIVE PROVISIONS IN THE DRAFT STANDARD FOR FOLLOW-UP FORMULA (At Step 8)

INTRODUCTION

The 14th Session of the Codex Committee on Foods for Special Dietary Uses (CCFSDU), January 24-February 1, 1985, revised the list of food additives permitted for use in the Draft Standard for Follow-up Foods. In compliance with the guidelines of the Codex Committee on Food Additives (CCFA) the CCFSDU agreed to prepare a paper for the CCFA justifying the use of the food additives in Follow-up Foods. The Task of receiving information from the member governments of CCFSDU and preparing the Technological Justification paper was assigned to the United States (US) delegation. The US delegation prepared such a Technological Justification paper, document CX/FA 85/10-Part I, Annex II, presented at the 18th CCFA questioned the status of this document in view of the fact that the CCFSDU had not met since preparation of the paper and could not have endorsed this paper. The CCFSDU presents this Technological Justification for the Food Additive provisions in the draft standard for Follow-up Formula 1/ (at Step 8) for consideration at the 19th CCFA.

SCOPE OF THE DRAFT STANDARD FOR FOLLOW-UP FORMULA

Follow-up Formula is comminuted regular food intended to be used for weaning infants from formula to regular foods. Follow-up Formula is prepared from protein-rich foods, such as milks or vegetable proteins, comminuted to a consistency for feeding to older infants at an age from the 6th month on. Depending on cultural traditions in different nations the weaning period may be at ages later than 4-6 months and for this reason the standard also applies to young children up to 2 years of age. Furthermore, not all nations have weaning foods such as described in the draft standard because their cultural tradition includes a short weaning period going from breast milk or infant formula to regular foods without the use of commercial weaning foods.

1/ Please note that the title of the Draft Standard has been amended by the 15th Session of CCFSDU to read: "Draft Standard for Follow-up Formula".

The CCFSDU has elaborated standards for two other weaning foods: Canned Baby Foods and Processed Cereal-based Foods for Infants and Children, both of which are Codex Standards (at Step 9). The draft standard for Follow-up Formula is meant to complement feeding with other weaning foods, such as those included within Codex Standards and those included in the CCFSDU's Proposed Draft Guidelines on the Development of Formulated Supplementary Foods for Older Infants and Young Children. Although Follow-up Formula has the appearance of an "infant formula for older infants", Follow-up Formula is not intended to be a total dietary supplement as are infant formulas, which are the sole source of nutrients for infants. Rather, Follow-up Formula is intended for use as a liquid part of the weaning diet and they are primarily regular foods, such as ingested by adults, comminuted to a consistency for older infants to ingest.

FOOD ADDITIVES PROVISIONS IN THE DRAFT STANDARD

Because Follow-up Formula is regular foods comminuted to a consistency for older infants to ingest, many of the food additives provided in the standard are necessary for the same functional effect as required in regular foods. Because Follow-up Formula is intended for use in weaning the food additives may be used to attain the consistency necessary for infant feeding or to obtain the flavours or to obtain storage stability necessary for regular foods.

Most of the food additives requested for Foolow-up Formula are currently permitted in another Codex Standard for infants or children, and all of the food additives are permitted in at least one Codex Standard. Those food additives requested for Follow-up Formula which are permitted in another Codex Standard for infants or children have already been subjected to a rigorous evaluation by the Codex Committee on food Additives at its 10th Session. Immediately prior to the 10th Session of the CCFA, an ad hoc Working Group on Food Additives of the CCFSDU met to consider the technical justifications submitted by member governments for food additives in three draft standards for infant foods: Infant Formula, Canned Baby Food and Cereal-based foods. This Working Group included participants not only from the CCFSDU but also from the CCFA and the scope of the Working Group included consideration of not only the technological need for each additive but also the estimated intake of each additive by body weight of infants in relation to the JECFA evaluation. Furthermore, the Working Group determined technological need in light of the recommendation of the 15th JECFA, which concluded via adoption of a report of an ad hoc Joint FAO/WHO Meeting on Additives in baby Foods (June 14-16, 1971), that "...Baby foods should be prepared without food additives whenever possible. Where the use of a food additive becomes necessary in baby foods, great caution should be exercised regarding both the choice of additive and its level of use". Therefore, the 10th CCFA explicitly evaluated all technological and health considerations for each additive listed in the current Codex Standards for Infant Formula, Canned Baby Food and Cereal-based baby food. Hence our technological justification will describe the general need for each class of additives and will compare the use in Follow-up Formula with other Codex authorized uses for each additive in infant foods.

THICKENING AGENTS

Thickening agents are necessary for obtaining an appropriate texture for infant feeding. Addition of thickening agents give liquid Follow-up Formulae more homogeneity through their shelf life, help to maintain proper viscosity, to retard sedimentation and allow the liquid to flow freely through a nipple when fed to infants. Omission of thickening agent(s) from a Follow-up Formula formulation can result in either a product which is too thick and gels or which is too thin - resulting in sedimentation and fat separation. In either situation, the liquid food without thickening agent(s) would not be satisfactory for use in feeding infants.

The list of thickening agents represents the alternative food additives which may be used. In any specific brand of Foolow-up Formula only one thickening agent will be used, or if a combination of thickening agents were to be used their levels of addition would be such that the total level of thickener would not exceed a practical self-limiting level reflected by the respective Codex Maximum Levels for each thickening agent.

The two seed gums, Guar and Locust bean gum, are permitted for use in Infant Formula up to the same Codex Maximum Levels as requested for Follow-up Formula.

Of the four modified starches, all four are permitted in Canned Baby Food up to a Codex Maximum Level of 6 grams per 100 g (compared to 2.5 g/100 mls for Follow-up Formula) and three of the four are permitted in Infant Formula at the same Codex Maximum Levels requested for Follow-up Formula.

Carrageenan is permitted for use in Infant Formula up to the same Codex Maximum Level as requested for Follow-up Formula.

Pectins are permitted in Canned Baby Food at the same Codex Maximum Level as requested for Follow-up Formula.

EMULSIFIERS

Emulsifiers are necessary for effective comminution of foods containing lipid matter and stabilization of the comminuted mixture with respect to separation into insoluble layers. Emulsifiers assist thickening agents to prepare homogeneous foods suitable for feeding through a nipple and proper homogenization is also necessary so that uniform heating can be achieved during sterilization. Both Lecithin and Mono- and Diglycerides are permitted in the Codex Standards for Infant Formula, Canned Baby Food and Cereal-based Foods at Maximum Levels the same as or greater than those requested for Follow-up Formula.

pH ADJUSTING AGENTS

Some of the protein sources used to produce Follow-up Foods are derived by isolation from food or may be the result of protein hydrolysis. Thereby the pH of protein material may have to be adjusted for ingestion by infants. Use of an improper pH-adjusting agent could cause loss of nutrients or coagulation of protein. The list of alternative pH-adjusting agents has been carefully selected to minimize nutrient loss and optimize digestibility of the protein. All of the pH-adjusting agents requested for Follow-up Formula are currently permitted in the Codex Standard for Infant Formula.

ANTIOXIDANTS

Because some Follow-up Formulae are milk-based and contain the lipids normally present in milks, antioxidants are necessary for protection against oxidative changes. Such oxidative changes may result in reduction in nutritive value as well as fat rancidity. The tocopherols and ascorbate additives may be used in combination, at levels less than the Codex Maximum Levels, to obtain a synergistic antioxidant effect. Mixed tocopherols concentrate and L-Ascorbyl palmitate are permitted in the Codex Standards for Infant Formula, Canned Formula, Canned Baby Food and Cereal-based baby food at Maximum Levels equal to or greater than those requested for Follow-up Formula. Alpha-Tocopherol, L-Ascorbic acid and sodium L-ascorbate are permitted in Codex Standards for othere weaning foods: Canned baby Foods and Cereal-based baby food, at Maximum levels greater than requested for Follow-up Formula. Calcium ascorbate is not listed in any Codex Standard for infant foods, however, it is permitted in the Codex Standard for Bouillons and Consommés. Furthermore, there should be no significant health effect from substituting calcium ascorbate for another ascorbate additive at the low Codex Maximum level of 5 mg (as ascorbic acid) per 100 ml of Follow-up Formula.

FLAVOURS

In the endorsement of flavouring agents for infant foods by the 10th CCFA it was noted that certain canned baby foods and cereal-based baby foods after initial processing do not have acceptable organoleptic properties. The vanillin-based flavours were considered to be necessary to improve the acceptability of certain baby foods such that the general nutriture of older infants and young children would be enhanced through increased food intake. The current Codex standards for Canned Baby Food and Cereal-based foods permit Vanilla extract at GMP levels and permit Ethyl Vanillin and Vanillin at levels not to exceed 7 mg/ 100 g, in comparison to the proposed limit of 5 mg/100 ml in the draft standard for Follow-up Formula.

The provision for Natural Fruit Extracts has no analogy in current Codex Standards for infant foods. The 10th CCFA considered a provision for "Natural Flavourings" in the draft Standards for Canned Baby Food and Cereal-based foods, however, these provisions were not endorsed due to the fact that "Natural Flavourings" had an undefined scope at that time, 1975. Since that time numerous Codex Standards have been elaborated with provisions for use of Natural Flavours in regular foods. The CCFSDU observes that the draft standard for Follow-up Formula restricts natural flavours to Natural Fruit Extracts. The technological need for such fruit extracts is the same as the reason for use of vanillin flavourings, i.e., to improve the organoleptic quality of certain foods and, thereby to enhance nutriture of weaning infants. Because Follow-up Formula will be used in the weaning period, the older infant/young children will undoubtly ingest the same naturally-occurring substances present in Natural Fruit Extracts through ingestion of fresh fruits and fruit juices.

[CX/GP 86/11
Revised]

NUTRITIONAL CONSIDERATIONS FOR THE FUTURE WORK OF THE CODEX ALIMENTARIUS COMMISSION
Discussion paper prepared by the United Kingdom

Background

1. At the Sixteenth Session of the Codex Alimentarius Commission in 1985 there was a detailed discussion of its future programme of work (1). It was noted that nutritional considerations were becoming increasingly important in people's choice of diet both in developed and in developing countries, and that the Commission might therefore explore the extent to which its work could help to promote better nutrition. Accordingly the delegation of the United Kingdom was requested to prepare a document for the Codex Committee on General Principles to address ways in which the Commission might play a greater role as regards nutritional considerations in Codex work in the years to come.

Earlier nutritional considerations

2. A detailed review of nutrition and the work of the Codex Alimentarius Commission prior to 1981 was prepared by Professor R.J.L. Allen (2) and considered at the Fourteenth Session of the Commission. The conclusions of the paper were as follows:

- Nutritional considerations have not been neglected in the Codex programme. Nutritional and dietary aspects are central to the work on foods for special dietary uses and on nutritional labelling, and are playing a major part in the development of standards such as those for cereals and vegetable proteins. In the general work of the Commission and its subsidiary bodies many draft and existing standards either contain specific nutritional provisions or individually or collectively help to protect the nutritional quality of the food supply by controlling the composition and description of foods passing in trade. Work now in course and planned by the Commission will increase the commitment to nutrition in the Codex programme.

- No radical alteration is required in the scope of the Codex programme nor in the machinery for the elaboration of standards. Nevertheless, some changes and consolidation in specific parts of the work of the Commission and its subsidiary bodies are desirable especially in view of the new orientation of the Codex programme and with it the prospect of a closer and more detailed involvement with nutritional problems. For these reasons the following recommendations are made:

(1) The Codex Committee on Foods for Special Dietary Uses should become formally responsible for advising the Commission and its subsidiary bodies on the nutritional aspects of all food standards and for endorsing nutritional provisions in these standards.

(2) The terms of reference of the Committee and its name should be changed so as to take account of its wider responsibilities.

(3) Work on guidelines for food fortification should be continued and expanded as appropriate.

(4) Consideration should be given to the introduction into the Codex system of a general provision to supplement specific provisions in preventing false or misleading representations as to the nutritional or dietary quality of any food.

(5) The trend towards the formulation of codes of practice, guidelines and other advisory documents relating to nutritional matters in addition to quasi-mandatory standards should be continued.

(6) Cooperation with other units of FAO, WHO and the UN system in relation to the nutritional aspects of the Codex programme should be continued and wherever possible extended.

- Codex food standards are not suitable instruments for the implementation of nutritional policies intended to alleviate acute or chronic national nutritional problems. Their application is through the establishment of food legislation and food control systems agreed between some 120 governments. In this way they contribute to sound nutrition based on foods of controlled composition and quality. It is through the continued development of the food standards programme along present lines that the Commission can best pursue its objectives, especially in relation to the needs of developing countries.

3. The conclusions of the Commission after discussion of this document in 1981 were as follows (3):

(i) The Commission considered that nutrition considerations had not been neglected in the work of the Codex Alimentarius Commission; on the contrary the past and present work of the Commission had and was continuing to have a considerable nutritional impact. No radical change was necessary, therefore, in the Commission's programme of work.

(ii) The Commission agreed with the overall philosophy and recommendations in the consultant's report.

(iii) The Commission agreed with the Executive Committee that the idea of a "general standard" should not be pursued.

(iv) The Commission agreed in principle with the proposed new terms of reference for the Codex Committee on Foods for Special Dietary Uses, but wished to have the views of the Committee itself on these before finalization of them by the Commission at its 15th Session.

(v) The Codex Committee on Foods for Special Dietary Uses should report to the next session of the Commission on the extent to which it could undertake the wider reponsibilities proposed for it in the consultant's paper, and on what would be a feasible time-scale for dealing with the work arising from the proposed additional responsibilities.

(vi) The Codex Committee on Foods for Special Dietary Uses should report on methods of operating within the proposed new terms of reference.

(vii) The Commission endorsed the recommendations concerning continued support from the units concerned in FAO, WHO and the UN System in the nutrition field.

(viii) The Commission agreed with the views expressed in paragraphs 51 and 52 of the consultant's report concerning the value and limitation of food standards in relation to nutrition policy.

(ix) The Secretariat should consult with the Host Government (Federal Republic of Germany) concerning any organizational and administrative questions which might need to be discussed before the next session of the Committee.

(x) The Commission agreed that the Codex Committee on Foods for Special Dietary Uses would not be an endorsing Committee in the full sense. It was not the intention that the Committee should automatically scrutinize every standard or draft standard. It would be a matter for each Committee developing standards to decide for itself whether to refer any or all of its standards to the Codex Committee on Foods for Special Dietary Uses for endorsement on nutrition matters, aided, if necessary, by guidelines which might be developed by the Codex Committee on Foods for Special Dietary Uses.

4. These conclusions were discussed by the Codex Committee on Foods for Special Dietary Uses as requested, with the assistance of a document "Proposals for Approach by CCFSDU to Work on Nutritional Aspects in Codex Standards and Texts"(4), prepared by a consultant. The new terms of reference of the Committee as ratified by the Commission, have now become:

- To develop guidelines, general principles and standards for foods for special dietary uses, alone or in cooperation with other Committees, and to endorse provisions for special dietary purposes contained in commodity standards. The standards should be elaborated on a worldwide basis except where this is found not be be possible, in which case the standard could be elaborated on a regional or group of countries basis.

- To study specific nutritional problems assigned to it by the Commission and to draft provisions concerning the nutritional aspects of all foods.

- To advise the commodity and general subject Codex committees on the nutritional aspects of the standards for which they are responsible and to elaborate guidelines for this purpose.

The name of the Committee has, however, remained unchanged. 1/

5. In 1985 the Committee on Foods for Special Dietary Uses reviewed general principles for the addition of essential nutrients to foods (i.e., food fortification) (5), and proposed Draft Guidelines for the Use of Codex Committees on the Inclusion of Provisions of Nutritional Quality in Food Standards and Other Codex Texts (6). These are at Step 8 (see Appendix IV). The Committee also continues to develop standards or guidelines for low and reduced energy foods, meal replacements, foods for medical purposes and foods for older infants and young children. The Codex Committee on Food Labelling is also concerned with nutrition, and has now completed the main part of its Guidelines on Nutrition Labelling (7), which was adopted at Step 8 by the Commission in 1985 (8) with one reservation (see paragraph 8 below).

Future considerations

6. Why, then, is there any need for further nutritional work? First, the 1981 review (1) addressed only the nutritional advantages which accrue from setting minimum compositional standards for a range of foods. For producers in developing countries this helps to ensure acceptance of their products in international trade, but at the same time it may carry a disadvantage for consumers in these countries if higher quality levels result in higher price levels with little or no nutritional improvement.

1/ Note: See para. 44 of the Report.

Thus Codex standards which discourage the use of vegetable fats in chocolate (9) or which insist upon minimum levels of hydroxymethyl furfural in honey (10) will tend to increase the prices of these products and therefore discourage their consumption especially by the poor.

7. Second, there is increasing concern in developed countries about overconsumption of certain nutrients, particularly of sugars, fats and sodium. Nutritional disadvantages may therefore result from the prescription of minimum fat levels in Codex standards for a variety of dairy products (11), of minimum sugar levels for each class of syrup for canning fruit (12), and from the absence of maximum fat contents for meat products. It is therefore recommended that future Codex work should consider such additional nutritional parameters, including the development of standards for foods containing less fat, sugar or salt, or more dietary fibre than in present standards. Since these foods would be for general consumption and not for special dietary use, this may perhaps be done through the development by the Committee on Food Labelling of suitable controls over the nutritional claims which may be made for such foods, addressing for example, what should be meant by "low in fat", "low in salt" for "high in fibre", after obtaining advice from an independent expert committee (see below).

8. Third, there is an increasingly important need for the development of new FAO/WHO Recommended Daily Amounts of Nutrients (RDAs), particularly for Codex labelling purposes. The RDAs provisionally accepted by the Codex Committee on Food Labelling have not been thoroughly discussed, but are simply those for 23-50 year old American men. These are not only much higher than the amounts recommended previously by FAO/WHO but are also higher than those recommended in almost every other country in the world. The Committee on Food Labelling and the Committee on Foods for Special Dietary Uses have both recommended that the FAO/WHO should reconsider their own RDAs (13, 14). Furthermore, the Commission itself has recognised this need (8). The UK has already recorded its concern about the consequences in the report of the Eighteenth Session of the Codex Committee on Food Labelling (15), noting "that there had been no discussion of the values [chosen by the Committee] nor of the principles behind their selection. The UK believes that it is unrealistic to expect people (particularly women and children) in developing countries or even most people in developed countries to achieve such levels of nutrient intake. This could lead to a loss of confidence in the nutritional quality of the food supply and to the unnecessary use of vitamin and mineral supplements. It could also increase the difficulty of educating such populations to improve their diets through a better choice of unprocessed (unlabelled) as well as processed foods."

9. The need for Codex Committees to pay regard to additional nutritional parameters (paragraphs 6 and 7) and the need for a review of RDAs (paragraph 8) raises the question of to whom the Codex Committees should turn for an assessment and interpretation of the relevant scientific literature. In the Codex Alimentarius programme similar situations have arisen in relation to the safety data on food additives, contaminants, pesticides and irradiated foods. In these cases the appropriate Codex Committees (the Codex Committee on Food Additives and the Codex Committee on Pesticide Residues) have relied on recommendations of independent experts - namely the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the Joint FAO/WHO Expert Meeting on Pesticide Residues (JMPR), and the Joint FAO/IAEA/WHO Expert Committee on Food Irradiation (JECFI). A similar new expert body is also being set up to advise the Codex Committee on Residues of Veterinary Drugs in Foods. Each of these Joint Expert Committees comprises invited experts from all parts of the world acting in an independent capacity and not representing the views of Member Countries. The UK believes that some of the nutritional issues to be faced by Codex in the near future (particularly concerning sugars, fat and RDAs) are sufficiently contentious as to require the benefit of independent advice on a continuing basis from a newly constituted Joint FAO/WHO Expert Committee on Nutrients (JECN). Far from detracting from the work of existing Committees such as the Codex Committee on Foods for Special Dietary Uses, JECN would facilitate its work by lifting the scientific issues out of the more political forum of Government representatives in the same way that JECFA does not detract from the work of CCFA but is an essential source of advice without which CCFA would have great difficulty in fulfilling its terms of reference. JECN should be an expert nutritional reference point for Codex as a whole. It would of course be up to Governments at the appropriate Codex Committees to establish how best to implement the independent advice received. The establishment of such an expert Committee would not only facilitate the work of a number of Codex Committees but would also signal the increasing importance that Codex places on nutritional issues.

10. The Codex Committee on General Principles will wish to consider whether it agrees in principle that there is a need for a new independent Expert Advisory Committee on Nutrients. If so, FAO and WHO will wish to consider whether the resources are presently available to service this new Committee and, if not, what steps need to be taken to generate the necessary resources.

Summary

11. At its last three sessions, the Commission has:

(i) reviewed the nutritional implications of Codex work prior to 1981;

(ii) extended the terms of reference of the Committee on Foods for Special Dietary Uses to cover additional nutritional matters; and

(iii) adopted at Step 5 the Draft Guidelines for Use of Codex Committees on the Inclusion of Provisions of Nutritional Quality in Food Standards and other Codex Texts. 1/

The Codex Committee on General Principles may wish to endorse the view that many of the newer nutritional issues can be resolved within the presently existing Committee structure - for example:

(i) the need to consider whether some standards, by including unnecessarily restrictive non-nutritional quality criteria could reduce the availability, and hence raise the price, of nutritious food particularly in developing countries

(ii) the need to develop new compositional or labelling standards or guidelines to address the concern, particularly in developed countries, about excessive intakes of fat, sugars and sodium, and inadequate intakes of dietary fibre.

Other nutritional issues may be better resolved by an independent committee of invited experts, so that the work of the Codex Committees can proceed with the benefit of an up-to-date world-wide consensus of scientific expertise in the field. It would, however, be for Government representatives at the Codex Committees to implement the recommendations of this independent expert advisory committee. Examples of the nutritional issues which could best be resolved by a new Joint FAO/WHO Expert Committee on Nutrients are:

(i) the definition of the term Recommended Daily Amounts (RDA) of nutrients, and the numerical values for individual nutrients for food labelling and other purposes

(ii) the definition of 'excessive' in relation to the intake of fat, sugars and sodium.

The Codex Committee on General Principles is invited to consider these matters and make recommendations. 2/

1/ The 15th Session of CC/FSDU advanced the above guidelines to Step 8 of the Procedure.

2/ The 8th Session of CC/GP considered this document and referred it to CC/FL and to this Committee (see paras 66-70 of ALINORM 87/33).

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1. Codex Alimentarius Commission (1985). Report of the Sixteenth Session (ALINORM 85/47), paras 150-162. Rome: FAO/WHO.
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4. Committee on Foods for Special Dietary Uses (1982). Proposals for Approach by CCFSDU to Work on Nutritional Aspects in Codex Standards and Texts (CX/FSDU 83/3). Rome: FAO/WHO.
5. Codex Alimentarius Commission (1985). Report of the Fourteenth Session of the Codex Committee on Foods for Special Dietary Uses (ALINORM 85/26), Appendix VII. Rome: FAO/WHO.
6. Ibid, Appendix V, Annex 2.
7. Codex Committee on Food Labelling (1985). Report of the Eighteenth Session (ALINORM 85/22A), Appendix III. Rome: FAO/WHO.
8. Reference 1, paras 190-191.
9. Codex Alimentarius Commission (1981). Codex Standard for Chocolate. STAN 87 - 1981. Rome: FAO/WHO.
10. Codex Alimentarius Commission (1969). Recommended European Regional Standard for Honey. Rome: FAO/WHO.
11. Reference 2, para. 7.
12. Reference 2, para. 13.
13. Reference 7, para. 3.3.4.
14. Reference 5, paras 153-155.
15. Reference 7, para. 45.

[LIM 1
16th Session of CAC]

PROPOSAL FROM THE INTERNATIONAL ATOMIC ENERGY AGENCY (IAEA) FOR AMENDMENT OF THE CODEX STANDARDS FOR FOODS FOR INFANTS AND CHILDREN

BACKGROUND

At its 15th Session, held in July 1983, the Codex Alimentarius Commission adopted a Codex General Standard for Irradiated Foods (CAC/VOL XV-Ed.1; CODEX STAN 106-1983).

This standard recommends that the "overall average dose" absorbed by a food processed by irradiation should not exceed 10 kGy. In establishing the recommended "maximum overall average absorbed dose" in relation to health protection, consideration was given to the conclusions of a Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food*, held in 1980. This Committee reviewed a considerable data base including:

- toxicological studies carried out on a large number of individual foods (from almost every type of food commodity) which produced no evidence of adverse effects as a result of irradiation.

- radiation chemistry studies, which have shown that the radiolytic products of major food components are identical, regardless of the food from which they derive. Knowledge of the nature and concentration of these radiolytic products indicated that there was no evidence of a toxicological hazard.

- supporting evidence which demonstrated the absence of any adverse effects resulting from the feeding of irradiated diets to laboratory animals, the use of irradiated feeds in livestock production, and the practice of maintaining immunologically incompetent patients on irradiated diets.

The Committee therefore concluded that:

- the irradiation of any food commodity up to an overall average dose of 10 kGy presents no toxicological hazard.

- the irradiation of food up to the mentioned dose introduces no special nutritional or microbiological problems.

The Committee emphasized that attention should be given to the significance of any changes in relation to each particular food and to its role in the diet.

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* Report of a Joint FAO/AIEA/WHO Expert Committee on Wholesomeness of Irradiated Foods. Technical Report Series, 659, WHO, 1981.

FOOD IRRADIATION

The Codex General Standard for Irradiated Foods recognizes that the process of food irradiation has been established as safe for general application to an overall average level of absorbed dose of 10 kGy. This "maximum overall average abosrbed dose" of 10 kGy should not be interpreted that it is appropriate to irradiate all foods up to that level from a technological point of view. Such a practice would in most cases be technologically unaccpetable, because foods would suffer adverse organoleptic and quality changes, making them unacceptable to the consumer from a point of view of quality. Similar technological restrictions apply to the thermal processing of food which cannot be applied to every kind of food without affecting its quality.

It is not the intention of the Codex General Standard for Irradiated foods to imply a need for clearance of the process on a food by food basis, or to restrict the authorization of the process in another way.

Just as thermal processing is not applied indiscriminately to every food possible, but is used for specific technological needs, so food irradiation is applied where it offers technological advantages over other methods of processing.

Irradiation of food may be used to achieve a variety of desirable objectives including the following:

- removal of human pathogens
- control of insect infestation of cereals
- inactivation of parasites
- reduction of microbial load

DISCREPANCY ON CODEX STANDARDS

There appears to be a discrepancy between the Codex Standard for Irradiated Foods and other Codex Standards (Fruit Juices, Infant Formual, Canned Baby-Foods, Processed Cereal-Based Foods for Infants and Children, etc.). The latter Standards, adopted by the Codex Alimentarius Commission long before the one for Irradiated Foods, contain clauses which prohibit the use of ionizing radiation for treating the product and its components. Although the use of ionizing radiation may be irrelevant for treating food items such as fruit juices, infant formula and canned baby-foods, it is highly feasible and probably desirable for treating cereals for insect disinfestation purposes. Such treated cereals may be incorporated in any food including foods for infants and children. Such use of ionizing radiation would render the product insect and residue-free in compliance with the Codex General Standard for Irradiated Foods.

PROPOSAL

Considering the efficiency of the food irradiation process to ensure the safety of food and food components in accordance with the Codex General Standard for Irradiated Foods, the Commission is respectfully requested to endorse the use of irradiation wherever it serves a technological need regardless of the food items. Clauses prohibiting the use of ionizing radiation in certain Codex Standards should be deleted to be in conformity with the Codex General Standard for Irradiated Foods.