

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

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ALINORM 89/26

JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX ALIMENTARIUS COMMISSION  
Eighteenth Session  
Geneva, 3 - 14 July 1989

REPORT OF THE SIXTEENTH SESSION OF THE  
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES  
Bonn-Bad Godesberg, Federal Republic of Germany, 29 September - 7 October

NOTE: Circular Letter CL 1988/56-NFSDU will be issued separately

### Summary and Conclusions

The Sixteenth Session of the Codex Committee on Nutrition and Foods for special Dietary Uses reached the following conclusions during its deliberations:

- (1) Advanced standards/guidelines to the CAC at Steps 8 and 5 of the Procedure as follows:
  - Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (para. 93)
  - Nutritionally Complete Formula Foods for Use in Weight Control Diets (paras. 112-125)
  - Labelling and Claims for Foods for Special Medical Purposes (paras. 126-151)
- (2) Referred to Governments standards/guidelines and other questions for consideration as follows:
  - Labelling of and Claims for Prepackaged Low-Energy or Reduced-Energy Foods (Step 3) (para. 100-111)
  - Nutrition standards or guidelines on excessive intake of fat, sugars, sodium and inadequate intake of fibre (para. 39)
  - Table Top Sweeteners (paras. 174-176)
  - Vitamin and Mineral Supplements (para. 37)
- (3) Referred to Governments and CAC proposals for review/amendment as follows:
  - Review of labelling of foods for special dietary uses and foods for infants and children (paras. 98-99 and 152-156)
  - Review of methods of analysis (paras. 178-184)
  - Review of sampling (paras. 188-190)
  - Review of Codex Lists of Mineral Salts and Vitamin Compounds (paras. 194-199)
  - Amendment of the General Principles for the Addition of Essential Nutrients to Foods (paras. 162-169)
  - Amendment of the Codex Standard for Processed Cereal-based Foods for Infants and Children (paras. 200-201) (max. level for cocoa)
  - Possible amendment of the Codex standard for Gluten-free Foods (paras. 157-158)
- (4) Reached conclusions on specific topics as follows:
  - Very low-energy foods (para. 115)
  - Dietary fibre (paras. 24-29, 185-187)
  - Criteria for Amendment of Advisory List of Mineral Salts and Vitamin Compounds (para. 193)

Summary and Conclusions (Cont.)

- Iodization of Salt (paras. 202-203)
- Nutrition and labelling aspects related to tropical oils (paras. 13, 206)
- (5) Had preliminary discussions of the Joint FAO/WHO Expert Consultation on Recommended Allowances for Nutrients for Labelling Purposes (Helsinki, 1988)
- (6) Discussed the relationship of foods for infants and children with the International Code for the Marketing of Breast-Milk Substitute (paras. 9, 152-156)
- (7) Called upon participating governments to increase their technical support of the work of the Committee (para. 40)
- (8) Discussed the application of the Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses to foods which are not "special dietary", and related matters (paras. 94-97)
- (9) Decided not to consider further amendment of the maximum level for Vit. D in infant formula (para. 159) and of the maximum level for vanillin in processed cereal-based products for infants and children (paras. 160-161)
- (10) Decided that it was not in a position to recommend maximum levels for contaminants in foods for infants and children (paras. 170-171)
- (11) Agreed not to amend the Codex standards for infants and children to permit irradiation of foods and their components (paras. 172-173)
- (12) Agreed not to proceed with a study of the impact of the standards of the CCNFSDU or any particular population group (para. 204)

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## INTRODUCTION (Agenda Item 1)

1. The Codex Committee on Nutrition and Foods for Special Dietary Uses held its Sixteenth Session from 3-8 October 1988 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 the Under Secretary of State, Mr. W. Chory of the Federal Ministry of Youth, Family Affairs, Women and Health, who welcomed delegates and outlined briefly the work undertaken by the Committee. Mr. Chory pointed out that increased participation was an indication of the importance to governments of the work of the Committee. The recommendations of the Committee on Nutrition and Foods for Special Dietary Uses will be useful to all countries, whether developed or developing. He stressed the importance of having an international forum on these subjects where a free exchange of opinions and technical information was possible. Increasing international trade in food called for efforts by the Codex directed towards consumer protection. The Committee which was meeting under its new title for the first time, had an important task ahead in contributing to resolving nutritional problems whether due to over-nutrition or under-nutrition. Mr. Chory wished the Committee every success in its deliberations.

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

Argentina	Kenya
Australia	Korea (Dem. People's Rep. of)
Austria	Netherlands
Belgium	Norway
Canada	Spain
China (People's Rep. of)	Sweden
Denmark	Switzerland
Finland	Thailand
France	Turkey
Germany (Fed. Rep. of)	United Kingdom
Hungary	United States of America
Italy	Zimbabwe
Japan	

Observers were present from the following countries and International Organizations:

- Democratic Republic of Germany
- European Economic Community (EEC)
- International Society of Dietetic Including All Infant and Young Children Food Industries (ISDI)
- EEC Wheat Starch Manufacturers Association (EWSA)
- International Dairy Federation (IDF)
- Association of Sorbitol Producers within the EEC (ASPEC)
- International Life Science Institute (ILSI)

A list of participants, including officers from FAO and WHO and the Technical Secretariat, 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 29-30 September 1988:

- Working Group on Nutritional Aspects of Codex Standards and Related Matters.
- Working Group on Methods of Analysis and Sampling.
- Working Group on Advisory Lists of Vitamin Compounds and Mineral Salts for Foods for Infants and Children

The reports of the above Working Groups were considered under the relevant Agenda Items and are incorporated into the Report of the Committee.

#### IN MEMORIAM

5. The Committee was deeply saddened to hear of the deaths of Dr. E. Forschbach and Dr. R. Franck, its first and second Chairmen respectively; and of Dr. R. Weik, leader of the US delegation for many years. The Committee stood in a minute's silence as a tribute to their contribution to the Committee's work and in memory of their friendship.

#### ADOPTION OF THE AGENDA (Agenda Item 2)

6. In order to enable delegations to study the reports of the Working Groups and on the request of the delegations of Belgium, France and the United Kingdom, the Committee agreed to rearrange the order of the items in the Agenda.

#### APPOINTMENT OF RAPPORTEURS (Agenda Item 3)

7. The delegations of Canada, United Kingdom, France and Switzerland were appointed to serve as rapporteurs for the Session.

#### MATTERS OF INTEREST TO THE COMMITTEE (Agenda Item 4)

##### Matters arising from the Report of the Seventeenth Session of the Codex Alimentarius Commission and from other Codex Committees (Agenda Item 4(a))

8. The Committee had before it document CX/NFSDU 88/2, Parts I and II containing summaries of information arising from other Codex sessions. Part I of the paper, which dealt exclusively with matters on nutritional aspects had been discussed in detail by the Working Group on Nutrition; and this discussion is reported below in the context of the Working Group's report (see paras. 30-40).

9. The Committee noted that the Standard for Follow-up Formula (CODEX STAN 156-1987) had been adopted by the Commission at Step 8. The Commission had been informed that products covered by this standard did not fall within the scope of the International Code for the Marketing of Breast-Milk Substitutes. The standard was being distributed as part of Supplement 3 to Volume IX of the Codex Alimentarius. The Commission had also adopted amendments to the standards for foods for infants and children (CODEX STANDARDS 73, 74 and 75), as proposed by the Committee; the Guidelines for the Use of Codex Committees on the Inclusion of Provisions on Nutritional Quality in Food Standards and Other Codex Texts and the General Principles for the Addition of Essential Nutrients to Foods. The Proposed Draft Guidelines on the Development of Formulated Supplementary Foods for Older Infants and Young Children were adopted as draft guidelines at Step 5.

10. In view of the increased importance of the nutritional implications of the Commission's work, the Commission had agreed to change the name of the Committee to the Codex Committee on Nutrition and Foods for Special Dietary Uses.

#### Radionuclides

11. The Commission, noting the report of the FAO Expert Consultation on Recommended Levels for Radionuclide Contamination of Foods and the on-going work of WHO to develop Guideline Procedures for Derived Intervention Levels for Radionuclides in Foods, had called for joint proposals to be presented to the 35th Session of the Executive Committee, for establishing levels for foods moving in international trade. The Secretariat reported that a joint proposal had been circulated to governments for comment and would be discussed by the forthcoming 21st Session of the Codex Committee on Food Additives and Contaminants.

12. The delegation of Argentina expressed that country's appreciation for the FAO report on radionuclide contamination. It also drew attention to the forthcoming FAO/WHO/IAEA/ITC (UNCTAD-GATT) Conference on Irradiated Foods, and stated that Argentina had taken steps to consider its acceptance of the Codex Standard and Code of Practice relating to food irradiation.

Executive Committee/Codex Coordinating Committee for Asia

13. The Committee took note of the request of the Executive Committee to consider the nutritional implications of the labelling of foods containing certain vegetable oils such as palm oil, palm kernel oil and coconut oil. It agreed to take this matter up under Future Work, in view of the heavy agenda of the present session (see para. 206 below).

14. The Chairman drew attention to work being undertaken in the Regional Coordinating Committees, which had nutritional implications for the Commission's programme of work. The Committee requested to be kept informed of all such work in order that it might contribute positively to work being carried out.

PROGRESS REPORT ON ACCEPTANCES OF CODEX STANDARDS FOR FOODS FOR SPECIAL DIETARY USES (Agenda Item 4(b))

15. The Committee noted the summary report given in document CX/NFSU 88/2 - Part III which indicated that three more countries (Cuba, Finland, Switzerland) had made positive statements with respect to the acceptance of one or more of the standards elaborated by the Committee.

ACTIVITIES OF FAO AND WHO OF INTEREST TO THE COMMITTEE (Agenda Item 4(c))

16. The Representative of WHO introduced document CX/NFSU 88/2, Part IV and summarized its main points. He informed the Committee that a report on minor and trace elements in breast milk, which was the result of a WHO/IAEA collaborative study, was expected by the end of 1988. A document on "Infant Feeding: the Physiological Basis" was under preparation by WHO. It included chapters on the perinatal and immediate postpartum period; health factors which may interfere with breast-feeding; physiological development of the infant and its implications for complementary feeding; the low-birth weight infant; and the infant and young child during periods of acute infection.

17. A progress and evaluation report on infant and young child feeding that had been discussed by the Eighty-first Session of the WHO Executive Board and the Forty-first World Health Assembly, in January and May 1988 respectively, had been the subject of an Assembly resolution (WHA 41.11). Through it, the Assembly had urged Member States to develop or enhance national programmes to improve the health and nutritional status of their populations, especially infants and young children, and to ensure practices and procedures that were consistent with the aims and principles of the International Code of Marketing of Breast-milk Substitutes.

18. Preparatory work was going ahead, together with FAO, for the holding of a Joint WHO/FAO/IAEA Expert Committee on Requirements for Trace Elements in 1990. Meanwhile, WHO was organizing a study group on diet, nutrition and prevention of non-communicable diseases in March 1989 to review current scientific knowledge on the association between nutrition and non-communicable diseases.

19. The WHO Representative drew the Committee's attention to three additional points of interest. Firstly, the World Health Organization's Global Advisory Committee on Health Research was currently meeting in Geneva to consider, among other items, the development of a formal nutrition research strategy that was to take WHO through the remainder of this century and on into the next. In this connection, he noted that the development of such a strategy coincided with the decision that the subject of the technical discussions taking place at the Forty-third World Health Assembly in May 1990 was to be the role of health research in the strategy of health for all by the year 2000.

20. Secondly, WHO and UNICEF were preparing another joint statement concerning the special role of maternity services in protecting, promoting and supporting breast-feeding. The Committee would be kept informed about the development of WHO's nutrition research strategy and the publication and wide dissemination of the joint WHO/UNICEF statement.



21. Finally, WHO had published in May 1988 a 40th anniversary issue of its World Health magazine in the form of a health and nutrition atlas, which was available on request in the English, French, Spanish, German, Portuguese and Russian languages. The atlas presented 11 maps that were based, not on the number of square kilometres that each nation occupies, but on a variety of other data, which emphasized the socio-economic inequalities between countries. The computer-generated images of the results of the unequal distribution of the world's resources and overall health situation covered diet and growth and infection and growth; wasting and stunting; birth weight and child survival; education and women; food availability; and specific nutritional deficiencies.

REPORT OF AN AD-HOC WORKING GROUP ON NUTRITIONAL ASPECTS OF CODEX STANDARDS AND RELATED MATTERS (Agenda Item 5)

22. A Working Group on Nutritional Aspects of Codex Standards and Related Matters met under the Chairmanship of Dr. U. Barth (Fed. Rep. of Germany) from 29-30 September 1988. Delegates and observers from Australia, Canada, Federal Republic of Germany, Finland, France, German Democratic Republic, Japan, Netherlands, Norway, Sweden, Switzerland, Thailand, Turkey, United Kingdom, United States of America, Zimbabwe, the International Association for Cereal Science and Technology (ICC); and the International Society of Dietetics Including All Infants and Young Children Food Industries (ISDI), participated in the meeting. The agenda of the meeting was given in document CX/NFSDU 88/1 and the Working Group decided to consider Items (a) and (d) of its agenda together, following the distribution of the Report of the Joint FAO/WHO Expert Consultation on Recommended Allowances of Nutrients for Food Labelling Purposes.

Amendments to the General Principles for the Addition of Essential Nutrients

23. The Committee decided to consider the Working Group's recommendations when discussing Item 11(e) of its agenda (see paras. 162-169 below).

Nutritional and Dietary Aspects of Dietary Fibre

24. It was recalled that the 15th Session of the Commission had considered the need to establish appropriate methodology for the determination of dietary fibre for use in standards for foods for infants and children and to arrive at an analytical definition of dietary fibre for nutritional purposes. The Working Group had considered the definition of dietary fibre from a nutritional and analytical point of view on the basis of a paper prepared by Sweden (CX/NFSDU 88/5). It was noted that, an analytical definition was needed for the calculation of available carbohydrate and energy for the Codex Guidelines on Nutrition Labelling. In this regard the definition of dietary fibre in the paper prepared by Sweden was intended to be the same as that in the Codex Guidelines on Nutrition Labelling.

25. During the discussion it was pointed out that there was more than one type of dietary fibre and that one value might not prove to be sufficient for labelling purposes. It was noted that the various effects claimed for dietary fibre had not all been substantiated scientifically and that, therefore, the description of physiological effects given in CX/NFSDU 88/5 may not be valid. It was further noted that the AOAC method tabled for discussion by the Working Group on Analysis and Sampling gave results which included resistant starches, Maillard reaction products and certain proteins which remained following the removal of proteins and starches. Such a determination might nevertheless be adequate for correction in determining available carbohydrate and energy value in infant formulae.

26. The Committee was informed that collaborative studies were in progress or completed for measuring dietary fibre and that these methods should be considered since the present AOAC method did not meet with the approval of all concerned. However, it was noted that it would take some time before any new official AOAC or other methods would be available, but consumers expected the labelling of dietary fibre content now. The selection of an existing method on an interim basis would, therefore, be desirable. The delegation of Zimbabwe requested that the costs of the method of analysis be considered in its selection as a Codex method.

27. The Committee noted that its ad hoc Working Group on Methods of Analysis and Sampling had recommended that the AOAC method was adequate for the purpose of calculating carbohydrates and energy in accordance with the Standards for Foods for Infants and Children and agreed to refer this method to the Codex Committee for Methods of Analysis and Sampling for endorsement (see also paras. 177-187 below).

28. The Committee also noted that the Codex Committee on Food Labelling (CCFL) would be examining methods of analysis for verification of nutrition labelling. The Committee agreed that CCFL should be advised of the present discussions. Furthermore, as regards the calculation of energy, it was pointed out that some dietary fibres were digested, especially by microbial enzyme activity, following a period of adaptation. Therefore, the energy contribution from the dietary fibre should be included in the calculation of energy values.

29. The delegation of the Netherlands proposed that the Commission should seek expert advice on dietary fibre in the light of new findings made since the previous FAO/WHO report on carbohydrates in human nutrition (FAO Food and Nutrition Paper No. 15, 1980). The Committee, however, noting that current scientific opinion was far from being in agreement, agreed that such a step would be premature and should await further research developments.

#### Matters of Interest to the Committee

30. The Chairman of the Working Group reported that two draft Codex texts had been studied by the Working Group, and that comments had been made on the nutritional aspects of these texts. They were:

- Draft Guidelines for the Utilization of Vegetable Protein Products (ALINORM 87/30, Appendix IV), and
- Proposed Draft Revision of the Codex General Guidelines on Claims (ALINORM 87/22, Appendix II, Annex I)

31. The comments and points raised during the Working Group's discussions are contained in Appendices IX and X respectively. The Committee agreed to transmit these comments to the responsible Committees.

#### Nutritional Considerations of the Future Work of the Codex Alimentarius Commission

32. The Working Group had studied Appendix XIV of ALINORM 87/26 (the Report of the Committee's Fifteenth Session) and government comments received from Cuba, Denmark, Finland, France, Federal Republic of Germany, Sweden, Spain, Switzerland, Thailand and the United States of America contained in CX/NFSDU 88/3. Dr. Barth noted that the proposals contained in Appendix XIV of ALINORM 87/26 had originally been presented to the Committee on General Principles by the delegation of the United Kingdom and had been further discussed at the Seventeenth Session of the Commission (ALINORM 87/39, paras. 115-118 and 455-457). The paper had proposed the establishment of a Joint FAO/WHO Expert Committee on Nutrients and had outlined a programme of work which could be undertaken by such a Committee. Among the principal recommendations for work was the re-evaluation of reference Recommended Daily Allowances (RDA's) used for labelling purposes.

33. The Committee was informed that, subsequent to the Commission's Seventeenth Session, an ad hoc Joint FAO/WHO Expert Consultation on Recommended Allowances of Nutrients for Food Labelling Purposes had been held in Helsinki, 12-16 September 1988 (see paras. 42-43). Also FAO and WHO had convened expert meetings on Protein and Energy Requirements (with UNU, 1980) and on Requirements for Vitamin A, Folate, Iron and Vitamin B12 (1985). In addition, a further consultation was being planned together with IAEA, on requirements for trace elements (1990).

34. The Committee expressed its appreciation to FAO and WHO for their initiative in convening such expert meetings which were considered essential in providing the basic scientific evaluations upon which the work of the Committee could be based. It agreed,

therefore, to recommend to the Committee that the establishment of a new Joint Expert Committee on a standing basis was not appropriate. It stressed that specific items or areas of the Committee's work which would require expert opinion would continue to be identified by the Committee, and the convening of ad hoc expert meetings provided the flexibility by which such needs would be met.

35. In regard to the future work of the Codex Committee on Nutrition and Foods for Special Dietary Uses, attention was drawn to the "Future Considerations" contained in the report of the Helsinki Expert Consultation, and it was noted that they contained many fundamental implications for the Committee's future work. It, therefore, recommended that governments should be requested, by means of a Circular Letter, to comment on this part of the Helsinki report with a view to establishing future priorities for the work of the Committee.

36. The Working Group had drawn attention to the proposal contained in the UK paper in regard to the use of certain modifying adjectives used in nutritional claims ("low", "high", "rich", "reduced", etc.). It recommended that the Committee should develop definitions of these terms, as they were principally a matter arising from nutritional science, and that these definitions could then be uniformly used and applied by other bodies, such as the Codex Committee on Food Labelling.

37. Several delegations referred to the need to consider food supplements, which were of concern in regard to consumer protection. The Secretariat, however, stated that consideration of these products, which fall within the category of pharmaceutical products in some countries, might exceed the Codex Alimentarius Commission's terms of reference and that it would be appropriate to seek the Commission's approval before undertaking any work in this area.

38. The delegation of the United States of America stated that experience in their country indicated that the Committee may need to give consideration to disease-specific health claims in the near future, as a way to assist in the reduction of degenerative diseases.

39. The Committee noted that the Working Group had requested the Committee to consider how it should go about developing new compositional standards or nutrition guidelines to address the concern (particularly in developed countries) over excessive intakes of fat, sugars and sodium and inadequate intake of fibre. It also drew attention to the need to consider whether some standards, by unnecessarily restrictive non-nutritional quality criteria, could reduce the availability or raise the price of nutritive food, particularly in developing countries. It was agreed to seek the opinion of governments by means of a Circular Letter.

40. The Committee also called upon all participating governments to increase their technical support for the work of the Committee, especially by ensuring the participation of nutrition experts as members of their delegations as a means of providing essential support in this area.

#### Survey of Provisions for Recommended Daily/Dietary Allowances in Codex Member Countries

41. The Commission, at its Seventeenth Session, instructed the Secretariat to obtain information, by means of a Circular Letter, on current recommended daily allowances (RDAs) used for labelling purposes in order to explore the possibility of revising the RDAs currently used in the Guidelines on Nutrition Labelling, possibly through the convening of an expert group. Replies to this Circular Letter (CL 1987/44-NFSDU) were summarized in document CX/NFSDU 88/6.

42. Subsequent to the Commission's discussion, FAO and WHO, with the generous assistance of the Government of Finland, convened a Joint Expert Consultation on Recommended Allowances for Nutrients for Food Labelling Purposes, which was held in Helsinki, 12-16 September 1988. A limited number of pre-publication copies of the report of this meeting were made available to the Committee (CRD No. 1). The report was

introduced by the Secretariat and by Dr. M. Astier-Dumas, Chairman of the Expert Consultation. It was noted that the responses to CL 1987/44-NFSDU had been fully tabulated in this report.

43. Dr. Astier-Dumas drew attention to the problems faced by the Consultation in arriving at recommendations which would be applicable world-wide. The Consultation, therefore, had decided to adopt an approach which would be specific for food labelling purposes. To avoid misuse or misunderstanding of these recommendations it had adopted the term Nutrient Reference Values (NRVs) for this specific purpose. These values were based, wherever possible, on average requirements and on recent FAO/WHO recommendations where available. They were, in general, lower than the RDAs now in the nutrition Labelling Guidelines.

44. The delegation of the United Kingdom welcomed the report, but would have liked more detail of the rationale behind the choice of the values. It was concerned that many of the values recommended by the Consultation were higher than in many people's diets and that there was still the possibility of misunderstanding in regard to their use. The delegation suggested that, if the population could not achieve these values in a normal diet, then the way was open to purveyors of vitamin and mineral supplements to use the NRVs as means of influencing consumers to resort to the use of supplements.

45. Other delegations did not share this view, and expressed their warm approval of the report, especially the adoption of the concept of NRVs. The delegation of the United States of America stated that many fundamental policy issues had been addressed in the report and that there would be important implications for the future work of the Committee and for governments which should be invited to comment on the future considerations identified by the Expert Consultation.

46. The Committee noted that it was too early to endorse the report formally as it had not yet been published or distributed to governments. Nevertheless, it recognized that the report marked an important step forward which would enable the Codex Committee on Food Labelling to revise the Guidelines on Nutrition Labelling on the basis of the new approach recommended by the Consultation.

47. The Committee expressed its appreciation to FAO, WHO and the Government of Finland for the timeliness of the report and for their response to the need of the Committee for expert advice in this matter.

48. Finally, the Committee expressed its warm appreciation to Dr. Barth for the progress achieved by the Working Group and for the thoroughness of his report.

**DRAFT GUIDELINES ON FORMULATED SUPPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN**  
**(AT STEP 7) (Agenda Item 6)**

49. The Committee had before it the above draft standard (App. VI, ALINORM 87/26), a re-draft of Section 6.3 included in Circular Letter CL 1988/4-NFSDU prepared by France and of the values in Table I by the representative of WHO, document CX/NFSDU 88/10 containing comments from governments and comments from Sweden and Australia distributed during the Session. The Committee discussed the Guidelines section by section.

**Section 1 - Purpose**

50. The delegations of the Netherlands and Zimbabwe suggested that reference be made to raw materials available in developing countries. The Committee agreed to keep this in mind when discussing Section 4 on suitable raw materials and ingredients.

**Section 2 - Scope**

51. The Committee adopted the text without change.

### Section 3 - Definitions

52. The delegation of Australia proposed to add the words "or present in insufficient quantities" in the last sentence after the word "lacking". The Committee agreed with this proposal.

#### Section 4.1

53. At the suggestion of the delegation of Sweden, the Committee agreed to add the words "most of which are locally available" in relation to raw materials in order to stress that the Guidelines were intended to cover the formulation of supplementary foods from locally available ingredients.

##### Section 4.1.1 - Cereals

54. At the suggestion of the delegation of the Netherlands, the Committee agreed to clarify that in Section 4.1.1.1 the reduction of fibre content was only required "when necessary".

##### Section 4.1.2 - Pulses

55. On the suggestion of the delegation of France, supported by the delegation of the Fed. Rep. of Germany, the Committee agreed to use the text included in the written comments of France in document CX/NFSDU 88/10.

##### Section 4.1.3

56. The Committee agreed to amend the title editorially to read "Oil Seed Flour and Oil Seed Protein Products".

###### Section 4.1.3.2

57. The delegation of the Netherlands suggested that, as a preference, a mixture of protein sources should be used to achieve a product with the appropriate protein quality. Where this was not possible, amino acids could be added for this purpose. It was agreed to take up this point under section 6.3.1 of the Guidelines. The delegation of Argentina proposed that instead of the term "protein products", the term "concentrates and isolated proteins" should be used.

##### Section 4.1.5 - Fats and Oils

###### Section 4.1.5.1

58. The Committee agreed to use the text of the written comments of France in document CX/NFSDU 88/10 which indicates that, wherever possible, the addition of fats and oils should be made for the purpose of increasing the energy density of the food.

###### Section 5.1.2 - Dehulling

59. The Committee agreed to add the words "when necessary" in order to indicate that dehulling was not always required.

###### Section 5.2.4 and Section 5.5.2

60. The Committee agreed to make changes to these texts to indicate that  $\alpha$ -amylase was not the only enzyme that could be used (Section 5.2.4). It was also agreed to delete certain technical details involving treatment with  $\alpha$ -amylase (Section 5.5.2.1).

##### Section 5.3 - Toasting

61. The Committee agreed that reference should be made to other advantages and disadvantages of dry heating such as the destruction of insects, improvement of keeping

quality, reduction of microorganisms and the reduction of protein quality due to the formation of Maillard reaction products.

#### Section 5.4

62. The Netherlands proposed that reference should be made in Section 5.4.1 to a possible disadvantage of sprouting and malting by inserting the phrase "It is necessary, however, to ensure that growth of toxin-producing organisms does not occur."

#### Section 6.1 - Nutritional Aspects (general)

63. The Committee had extensive discussions on Section 6.1.2 (in square brackets). The delegation of the United States of America suggested that the product need only provide 75% of the recommended intake of vitamins and minerals, whereas the delegations of the Netherlands and Spain proposed that two thirds of this requirement was sufficient. Other delegations supported a provision of 100% of such nutrients. The Committee noted that the purpose of this section was to provide a reasonable example of a product which would supply energy and nutrients to older infants and young children to supplement their diet. It was recognized that the addition of vitamins and minerals to these products would depend on requirements for nutrients in particular situations prevailing in the various countries. In this light the Committee agreed to a re-wording of Section 6.1.2 drafted by the delegations of Sweden, the United States of America and France.

#### Section 6.2 - Energy

64. The Committee noted that Section 6.2.2 may be in contradiction with Sections 6.4 and 6.5 and agreed to make the necessary amendments to remove the contradictions. Regarding reference to "nutritive sweeteners", it was agreed to replace this term with "sugars".

#### Section 6.3 - Protein

65. The Committee agreed to discuss the text included in Circular Letter CL 1988/4-NFSDU proposed by France to re-word Section 6.3.

#### Section 6.3.2

66. It was agreed that the expression "crude digestibility" should be replaced by "true digestibility". Several delegations suggested that there should be a higher protein score for foods intended for older infants than for the young child. The delegation of the United Kingdom also proposed that because amino acid composition was difficult to measure, the values should include a tolerance. The Committee decided that the original value of 65 should remain. The delegation of the Netherlands suggested that a calculation of the amino acid score based on two or more limiting amino acids was automatically higher than one based on a single limiting amino acid. The Committee decided to leave the text unchanged.

#### Section 6.3.3

67. The Committee agreed to delete the section.

#### Section 6.3.4

68. The Committee agreed to amend this section in such a way as to ensure that the appropriate reference made to the FAO/WHO recommendations for children concerning amino acid profile be consistent with the scope of the Guidelines. The delegations of Sweden and France undertook to provide a redraft of the section.

#### Section 6.3.5

69. The delegation of the United States of America indicated that a collaborative test to study the measurement of protein quality was nearing completion and would be submitted to the Codex Committee on Vegetable Proteins. For this reason the text proposed by France had to be redrafted. The Committee agreed to such a re-drafting by the delegation of the United States of America.

#### Section 6.3.6

70. Following discussion, the Committee agreed to delete this section.

#### Section 6.3.7

71. In order to be consistent with the Guidelines for the Utilization of Vegetable Protein Products (VPP) in Foods (App. IV, ALINORM 87/30) the Committee agreed to the rewording of this section as proposed by the delegation of the United States of America.

#### Table 1 - Model Nutrient Profile

72. It was agreed that there was a need to examine carefully the recommendations contained in Table 1. The delegation of Canada suggested the inclusion of zinc to the Table.

The Committee agreed to set up an ad hoc Working Group consisting of the delegations of Canada, France, Norway, the United States of America, Zimbabwe and the representatives from WHO and FAO to finalize the nutrient profile included in Table 1 of Circular Letter CL 1987/4-NFSDU.

73. The Committee received a report from the Working Group (CRD No. 12). The Committee noted that the nutrient profile did not represent an optimum but rather a practical example for a product which could be prepared using locally available ingredients to provide a nutritionally adequate supplement to the diet. The Committee made a number of corrections to the model nutrient profile.

74. In reply to a question from the delegation of Turkey, the Committee was informed that phosphorus was not included in Table 1 as this element would be present in adequate amounts in the raw materials used. Regarding the calcium to phosphorus ratio, the presence of phosphorus as phytate could make this calculation misleading. Regarding the ratio of iron to zinc, the Working Group had considered a 1 : 1 ratio by weight to be appropriate. The Committee noted that the nutrient profile took into account the protein and energy requirements of the age group covered by the Guidelines.

75. The delegation of Austria was of the opinion that the nutrient profile suggested by the Working Group would result in products too rich in carbohydrates and that this was contrary to the intent of the Guidelines. The Committee noted that the Guidelines would permit the preparation of products with higher protein and fat content. To make this clear it was decided that the introduction to Table 1 be amended to indicate that formulated supplementary foods should provide at least 400 kcal/100 g (see also Section 6.2.3).

#### Section 6.4 - Fat

76. The proposal was made by the delegation of the Netherlands that Section 6.4.2 should be deleted, since the product could not have a minimum content of 400 kcal/100 g without the addition of fats and oils. The Committee agreed to delete reference to economic feasibility concerning the addition of fats and oils and to refer to situations where not all of the desired fats and oils could be used in the formulation.

## Section 6.5 - Carbohydrates

77. The Committee discussed the use of nutritive sweeteners (i.e. sugars) to increase the energy density of the product and agreed that the use of sugars was not to be encouraged for this purpose. However, it was recognized that sugars would also have the effect of making the products more palatable to children. The delegation of the United Kingdom proposed that a new section be included concerning the need for starches to be in a digestible form.

78. It was agreed that Section 6.5.2 which referred to the economic feasibility of using sugars in the formulation of the food should be deleted. Regarding Section 6.5.3 on dietary fibres, the Committee discussed a proposal to reduce the maximum level of 5 g/100 g to 3-4 g/100 g. The Committee agreed to replace "crude" fibre with "dietary" fibre in the second sentence and that this would have the effect of reducing the maximum level of fibre included in the section.

79. Following consideration of various suggestions concerning the re-drafting of Section 6.5, the Committee agreed that the question of the use of carbohydrates including complex carbohydrates as sources of energy would be better dealt with in Section 6.2 on energy. Section 6.2.2(a) was amended accordingly and Sections 6.5.1 and 6.5.2 were deleted. It was further agreed that Section 6.5 should contain the proposal of the United Kingdom concerning the use of starches in a utilizable form and revised Section 6.5.3 on dietary fibre proposed by the Federal Republic of Germany in its written comments, as amended editorially by the Committee.

## Section 6.6 - Vitamins and Minerals

80. The Committee noted the conclusions of the Working Group (see paras 73-75) concerning the model nutrient profile and concluded that this section contained general recommendations which were not in any way in contradiction with the provisions on nutritional aspects.

81. It was agreed to add a new section parallel in wording to Section 4.2.2.1 of the Codex Standard for Processed Cereal-based Foods for Infants and Children to indicate that the vitamins and minerals should be selected from the Advisory Lists.

## Section 7 - Hygiene

82. The Committee noted that the contents of this section were being recommended to governments for use as mandatory hygiene requirements. It was, therefore, agreed to change the word "should" to "shall" and to delete the square brackets. It was also agreed to make reference in Section 7.3 to the standards proposed in the PAG Guideline No. 11.

## Section 9 - Labelling

### Section 9.2.1 - The Name of the Food

83. The Committee discussed the two alternative texts given in Section 9.2.1.2 (b). The delegation of France suggested a text indicating that the food may be administered during the weaning period. Other delegations proposed to make reference to the use of these products when normal foods were not sufficient. Other delegations were of the opinion that the label should indicate the age group of children for whom the product was intended, since these products were not appropriate for consumption by very young children. It was agreed to include the text from the written comments of France, amended to require that the label indicate that the product is intended for use as a supplement during the weaning period and when nutritional requirements were no longer covered by locally available foods.



Section 9.2.3 - Declaration of Nutritive Value

84. On the suggestion of the delegation of the United States of America, the Committee agreed to add in subsections 9.2.3.1 (a), (b) and (c) the following phrase: "as well as per specified quantity of food as suggested for consumption".

Section 9.2.5 - Name and Address

85. The delegation of Zimbabwe suggested that the physical address of the manufacturer be specified rather than a postal address. It was noted that this section referred to a text applicable to pre-packaged foods generally. The Committee decided to leave the text unchanged.

Section 9.2.6 - Country of Origin; 9.2.7 - Lot Identification

86. The delegation of Argentina suggested that the country of origin should always be declared and that lot identification and expiry date should always be a mandatory requirement for labelling.

Section 9.2.9.2

87. The delegation of the Netherlands was of the opinion that, to ensure the safety of the preparation from a hygienic point of view, there was a need to boil the product whether or not the basic ingredients were heat-processed and that sub-section (b) should be deleted. It was also noted that this Section did not provide for foods that did not require the addition of water.

88. During the discussion it was noted that sub-sections (a) and (b) dealt with the question of rendering the food digestible rather than with hygienic considerations. It was, therefore, agreed to include the phrase "In the case that addition of water is needed" in the preamble to Section 9.2.9.2.

89. The delegation of the United States of America, supported by Zimbabwe, drew attention to the need for instructions regarding the avoidance of contamination of the food once prepared. The Committee agreed to include an additional section 9.2.9.4 requiring that the label indicate the need to prepare an amount of the food sufficient for one meal only.

Section 9.2.9.3

90. The Committee agreed to amend the section editorially.

Section 9.3 - Exemptions

91. Following discussion the Committee agreed that there was no need to specify any exemptions from the General Standard for the Labelling of and Claims for Foods for Special Dietary Uses.

Statement by the Delegation of China

92. The delegation of China considered that the Guidelines under discussion represented a very important, although complex, matter. The delegation informed the Committee of a nutritional study of around 100,000 children below the age of 6 months in twenty provinces in China. This study revealed that there was a positive correlation between the incidence of disease and the feeding of mother's milk substitutes. The lowest incidence of disease (3.4%) was seen in the group of infants fed mother's milk (48.8% of children studied). The highest incidence of disease (52%) was seen in the group of infants fed artificially (15% of children studied). From the study it also appeared that the protein intake by infants was higher than necessary. The delegation of China welcomed work on the nutrient profile and expressed the opinion that the Guidelines should enable appropriate foods to be prepared using indigenous raw materials available in developing countries.

## Status of the Guidelines

93. Following discussion, the Committee agreed to advance the Guidelines to Step 8 of the Codex Procedure (see Appendix III). The delegations of Switzerland and Belgium opposed this decision indicating that too many changes had been made during the meeting and feared that the guidelines were a duplication of existing standards.

## MATTERS RELATED TO LABELLING PROVISIONS IN CODEX STANDARDS FOR SPECIAL DIETARY USES (Agenda Item 7)

### Establishment of Specific Labelling Provisions for Low and Reduced-Energy Foods (Agenda Item 7(a))

94. The Committee recalled that, at its 15th Session, it had discussed whether the title of the proposed Draft Standard for the Labelling of and Claims for Prepackaged "Low Energy" or "Reduced Energy" Foods, which is not intended to apply to foods naturally low in energy, should contain reference to such foods being "special dietary foods". The Committee noted that the title of other standards elaborated by the Committee did not contain reference to the product being intended for special dietary uses (paras. 183-187, ALINORM 87/26). The Committee had also discussed the issue of whether the Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) could be applied to low- and reduced-energy foods which were not foods for special dietary uses. The Committee had agreed to seek legal advice on the matter (see para. 185, ALINORM 87/26).

95. The opinion of FAO Legal Council was contained in document CX/NFSU 88/11-Part I (Conference Room Document). As regards the question whether the title of the standard should contain reference to low- and reduced-energy foods being "special dietary foods", the FAO Legal Council was of the opinion that, if it were determined by the Committee that such products were "special dietary foods", it would be logical to include the term as part of the standard. However, this would not appear to be an absolute requirement to the extent that it was made absolutely clear at the outset of the standard that the food was for that use.

96. As regards the question of whether the Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses could be applied to low- and reduced-energy foods which were not foods for special dietary uses, the FAO Legal Council was of the opinion that this question was scientific in nature, rather than legal. It turned on whether the types of food to which reference was made were, in fact, "for special dietary uses". In other words, did the special characteristics of these foods meet the specific criteria set out in paragraph 2.1 on the definition of terms.

97. The Committee, on this basis, agreed that the standard for Low- and Reduced-Energy Foods would be considered in the wider context, and that the expression "for special dietary purposes" could be deleted from the title (see paragraph 101 below). The labelling provisions for inclusion in the standard would be considered in this light (see paras. 100-111).

### Review of Labelling Provisions in Standards for Foods for Special Dietary Uses (Agenda Item 7(b))

98. The Committee had for its consideration, document CX/NFSU 88/11-Part II (Conference Room Document). The document set out certain issues which had to be considered within the context of the revision of labelling provisions throughout all Codex Standards subsequent to the adoption of the Revised Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985).

99. Taking into account recent recommendations by the Executive Committee in regard to labelling provisions in standards, and the fact that the document had not been distributed to governments sufficiently in advance of the meeting, the Committee agreed to request government comments on the conclusions of paper CX/NFSU 88/11-Part II. It noted that further advice from the Codex Committee on Food Labelling would be made

available in response to the Executive Committee's recommendations and proposed to the Secretariat that the Circular Letter should be distributed only when such advice was known.

PROPOSED DRAFT STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED "LOW-ENERGY" OR "REDUCED-ENERGY" FOODS /FOR SPECIAL DIETARY USES/ (Agenda Item 8)

100. The Committee had before it the above draft standard at Step 3 included in Appendix VIII, ALINORM 87/26 and government comments included in document CX/NFSDU 88/12. The Committee discussed the draft standard in detail on the basis of the comments received.

Title of the Standard

101. The Committee agreed to delete the words "for special dietary uses" from the title since it considered that not all products presented as "low-energy" or "reduced-energy" could be considered to be "foods for special dietary uses".

Section 1 - Scope

102. On the suggestion of the delegation of the Netherlands the Committee agreed to indicate in this section that the standard applied to products presented as "low-energy" or "reduced energy" foods. It was, therefore, agreed to delete the words "intended for controlling or reducing energy intake" and substitute "presented as such".

Section 2 - Definitions

103. The Committee had detailed discussions on the definition of "low-energy foods" (Section 2.1). Various proposals were made for changing the values for energy density and for maximum energy content per serving. The Committee noted that, in order to define a low energy food, it was necessary to specify not only the energy density of the product which should not be exceeded, but also to specify a maximum energy value for each serving. This was necessary in order to prevent the sale of high energy products on the basis of a small serving.

104. As regards liquid products claimed to be low-energy foods some delegations were of the opinion that a maximum of 20 kcal would be excessive.

105. As no agreement could be reached on specifications for energy values, the Committee agreed to leave Section 2.1 unchanged and to place it into square brackets.

106. Considerable discussion took place on the extent to which the energy value of a food should be reduced before it could be labelled as "reduced energy food" (Section 2.2).

107. It was pointed out that there were basically two approaches to regulating reduced energy foods. One approach was to specify a large reduction in energy which could be achieved for very few foods. The other approach was to specify a smaller but still significant reduction which would result in the availability of a wider range of products. The degree of reduction of energy content suggested by delegations ranged between approximately 25% and 33%. The opinion was expressed that a reduction of around 30% was not always feasible, especially with products containing a small amount of fat. Some delegations indicated that another approach being followed in national legislation was to specify different values for energy reduction according to the type of food products.

108. A proposal was made to indicate a range for energy reduction to 65-75% and to include a statement in the standard that reduction within this range would depend upon national dietary practices. The Committee agreed to the suggestion of the delegation of Canada that government comments should be sought on an approach to defining reduced energy foods by specifying a maximum of 75% energy content in relation to a reference food used for comparison and a requirement that the amount of the energy reduction as compared to such a reference food be a mandatory labelling requirement. The text of Section 2.2 is given in Appendix VI to this Report in square brackets.

109. The delegation of the United States of America informed the Committee that, in that country, a new practice of shelf labelling applying to both pre-packaged and fresh products had been found to be successful. It had led consumers to be more selective in their purchases. The Committee noted the information provided by the delegation of the United States with interest.

110. Some delegations suggested that the sentence in square brackets in Section 2.2 and Section 2.3 concerning nutritional equivalence be deleted. Others were in favour of its retention. The suggestion was made that reduction of energy should always be accompanied by a reduction in fat and sugar content. The delegation of the United Kingdom was of the opinion that it would not be realistic to require complete nutritional equivalence and suggested that the definition be the same as in the Guidelines for the Use of Codex Committees on the Inclusion of Provisions of Nutritional Quality in Food Standards and other Codex Texts. The Committee decided not to proceed with further discussions of the draft Standard pending definitions of low-energy and reduced-energy foods and a clarification of the term "nutritionally equivalent" in the light of what was required for these types of products.

#### Status of the Standard

111. It was decided to return the proposed draft standard to Step 3 of the Procedure (see App. VI). Comments were requested from governments, particularly on the definitions, and, on the suggestion of the delegation of the United Kingdom, concerning nutritional equivalence.

#### PROPOSED DRAFT STANDARD FOR NUTRITIONALLY COMPLETE FORMULA FOODS FOR USE IN WEIGHT CONTROL DIETS (Agenda Item 9)

112. The Committee had before it the above Draft Standard (App. IX, ALINORM 87/26) and Government Comments at Step 3 (Document CX/NFSDU 88/13).

113. The delegation of the United Kingdom pointed out that the inclusion of the words "nutritionally complete" in the Title of the Standard and in the Scope and Definition had the effect that any formula food which was not nutritionally complete would fall outside the scope of this Standard. The Committee wished to ensure that all formula foods for use in weight control diets met all the provisions of the Standard, including the essential composition and quality factors, and therefore decided to amend the Title, Scope and Definitions by deleting the words "nutritionally complete".

#### Scope - Section 1

114. It was agreed to indicate that the Standard applied to formula foods for use in weight control diets which were presented as such. The delegation of Australia, supported by the delegations of the Netherlands and Switzerland, suggested that it should be further specified that prepackaged meals controlled in energy and presented in the form of conventional foods were excluded from the Standard. This was accepted by the Committee.

#### Section 3.1 - Energy Content

115. The delegation of the Netherlands was strongly of the opinion that very low-energy formula foods should also be included in the Standard, as such foods were hazardous if used improperly and should be adequately controlled. The Committee noted that such foods would be Foods for Special Medical Uses and should not be covered in the Standard. The delegation of the Netherlands was invited to prepare a paper for the next session on very low energy nutritionally complete formula foods.

#### Section 3.2 - Nutrient Content

116. Following a discussion, it was agreed that the Standard was for too detailed. On the suggestion of the delegation of the United States of America, the Committee agreed to re-write Section 3.2 making reference to existing FAO/WHO recommended nutrient intake and where these were not available to other nutrient intake recommendations.

117. The key points concerning the nutrient content of formula foods agreed to by the Committee in its discussions were as follows:

- (a) For replacements of the total diet, 100% of an appropriate recommended intake would be specified for protein, vitamins and minerals per day;
- (b) For replacements of meals, between 25-33 1/3% per meal (depending on the recommendation for use) would be specified for the same nutrients;
- (c) A minimum protein of 50 g/per day adjusted upwards for quality with reference to egg or milk protein, and a maximum of 100 g protein/per day;
- (d) Protein quality equivalent to at least 80% egg or milk protein. No change was needed concerning the addition of amino acids, except that DL-methionine could be used;
- (e) Sections 3.2.2 and 3.2.3 dealing with fat, linoleate and carbohydrates would not be changed; and
- (f) A revised table for vitamins and minerals based primarily on FAO/WHO recommendations for the young adult male would be developed by a small drafting group consisting of the delegations of the United States of America, France, Canada, Fed. Rep. of Germany, Switzerland and the Netherlands.

#### Section 3.3 - Ingredients

118. The Committee did not consider that it was necessary to elaborate a section on optional ingredients and agreed to delete Section 3.3.3.2.

#### Section 4 - Food Additives

119. In view of the wide range of products covered by the Standard the Committee agreed that it would be difficult to draw up a section on food additives. It was, therefore, agreed to include the text contained in the written comments of the United States of America and to seek the endorsement of the Codex Committee on Food Additives and Contaminants which was also invited to advise the Committee on how to proceed in this matter. A number of delegations were not in favour of such a broad provision. The Committee invited the interested parties to provide a list of food additives for consideration at a future session.

#### Section 5 - Contaminants

120. As it was not considered feasible to include specific provisions for contaminants in a General Standard covering many types of foods, it was agreed to use the wording in the Codex Standard for Infant Formula.

#### Section 9 - Labelling

121. As regards Section 9.1 concerning the name of the food, the Committee agreed that Sections 9.1.2 - 9.1.4 should be deleted. The delegations of France and Spain suggested that these should be included in Section 9.2 concerning the list of ingredients. The delegation of the Netherlands was of the opinion that thickening agents and other similar additives should be declared quantitatively on the label. The Committee noted that "dietary fibre" per se would not be an ingredient, although it may be present in the ingredients.

#### Section 9.8 - Date Marking

122. The delegations of France and Italy were of the opinion that a date of expiry should be given on the label, since it was essential that the nutritional quality of the product be adequate at the time of consumption. The Committee considered that this would be achieved on the basis of an indication of minimum durability. No change was made to the section.

#### Section 9.10 - Information for Utilization

123. The delegation of Spain pointed out that it was necessary to drink a minimum of 2 litres of water per day during the period of dietary management in weight control and proposed that the label should so indicate. The Committee agreed to make reference to the need for an adequate fluid intake.

The delegation of Canada proposed that the directions for use for foods which are not intended as a replacement for the total diet include information on obtaining adequate amounts of nutrients from the remainder of the diet.

#### Section 9.11.1 - Claims

124. On the proposal of the delegations of Italy and France, the Committee agreed to include in square brackets a requirement that the label indicate that it is inappropriate to make claims relating to the rate of weight loss which may result from the use of the product or that the product will cause a reduction of the sense of hunger or increase the sense of satiety. The delegation of Italy proposed to add on the label of products presented as meal replacements the following warning: "The use of the product is suitable when it forms part of a diet which is controlled in its entirety"

#### Status of the Standard

125. The Committee decided to advance the Draft Standard to Step 5 of the Codex Procedure (see Appendix V).

#### CONSIDERATION OF THE PROPOSED DRAFT STANDARD FOR THE LABELLING OF AND CLAIMS FOR FOODS FOR SPECIAL MEDICAL PURPOSES, AT STEP 4 (Agenda Item 10)

126. The Committee had for its consideration, the proposed draft standard as contained in Appendix X of ALINORM 87/26, and comments from Cuba, Denmark, Egypt, Federal Republic of Germany, Finland, France, Sweden, Switzerland, Spain, Thailand, United States of America, the European Economic Community and the International Society of Dietetic Including All Infant and Young Children Food Industries, as contained in CX/NFSDU 88/14.

127. In introducing this item, the Chairman noted that the products covered by the proposed draft standard were considered in some countries to be pharmaceutical products and were, therefore, regulated in conformity with procedures for the registration of such products. Other countries, however, regulated these products as a special class of special dietary foods. In either case, because of their world-wide use and their importance in the care of patients, it was appropriate that Codex should provide for the facilitation of trade in these products through the establishment of a standard which would harmonize the labelling requirements of and claims made for such foods.

#### Section 1 - Scope

128. The Committee was concerned that the scope of the standard should not be extended to cover nutritionally complete formulae which were not foods for special medical purposes, as defined, or not presented as such. In particular, the observer from the International Society of Dietetic Including All Infant and Young Children Food Industries (ISDI) expressed the opinion that nutritionally complete formulae used by sailors, mountain climbers or other persons without facilities to prepare and cook meals, should be excluded from the standard. On the other hand, the Committee was concerned that the distribution of foods for special medical purposes through normal commercial channels could lead to the abuse of these products. This could be the case with nutritionally complete formulae which were labelled as such. The delegation of France drew attention to the need to exclude from the scope nutritionally complete formulae which were not intended for special medical purposes. The Delegation of Spain stated that, in view of the proposal put forward by various delegations, among them that of the EEC, which it considered adequate, the Delegation had reconsidered its previously declared position as stated in CX/NFSDU 88/14, and supported the proposal that nutritionally complete formulae should be included in the Standard.

129. The Committee considered the following alternative statements in regard to the exclusion of nutritionally complete formulae from the scope of the Standard:

- (a) deletion of the square brackets from "nutritionally complete formulae";
- (b) use of the expression "nutritionally complete formulae not bearing medical claims";
- (c) use of the expression "complete food preparations which are not intended for special medical purposes"; and
- (d) use of the expression "nutritionally complete formulae for which no claims concerning dietary management of patients with (a) specific disease(s), disorder(s) or medical condition(s) (including malnutrition) are made".

130. It agreed, however, to consider the scope in relation to the definition of foods for special medical purposes, on the understanding that an improved definition was needed in order to differentiate between the various types of products available commercially (see also para 134 below).

### Section 2 - Definition

131. The Committee agreed to discuss a proposed definition contained in the written comments of the European Economic Community (EEC), as contained in CX/NFSU 88/14, in addition to the proposed draft definition in Appendix X of ALINORM 87/26. It was agreed that the essential element of foods for special medical purposes was that they should be used under medical supervision, and that they were a special category of foods for special dietary uses for which specific claims were made.

132. The delegation of the United States of America expressed the opinion that the proposed EEC definition would be acceptable if widened to cover foods for use in certain other medical conditions; eg. hypermetabolic states where the capacity to take or absorb nutrients was not limited or impaired. Other delegations were concerned that the definition should not be so wide as to allow the abuse of these products by consumers.

133. The Committee agreed to the following definition:

"Foods for special medical purposes are a category of foods for special dietary uses which are specially processed or formulated for the dietary management of patients and may only be used under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolise ordinary foodstuffs or certain nutrients contained therein or have other special medically determined nutrient requirements, the dietary management of whom cannot be achieved by the modification of the normal diet alone, by other foods for special dietary uses, or by a combination of the two."

134. The delegation of Switzerland stated that this definition seemed too broad, and reserved its position in regard to the definition. It proposed to keep the original definition (ALINORM 87/26, Annex X, Section 2) but to modify the second sentence as follows: "Foods for Special Medical Purposes shall be used under medical supervision".

135. The Committee, on the proposal of the Secretariat and in view of the above definition, adopted the following Scope:

"This standard applies to the labelling of and claims for Foods for Special Medical Purposes as defined in Section 2 below and presented as such7.

### Section 3 - General Principles

136. No changes were made to this section.

#### Section 4 - Labelling

137. The Committee did not accept the proposal of the International Society of Dietetic Including All Infant and Young Children Food Industries (ISDI) that labelling should be in accordance with national practice, preferring instead to provide a text on which international harmonization of labelling practices could be achieved.

#### Section 4.2 - Nutrition Labelling

138. The Committee agreed, in Sections 4.2.2, 4.2.3 and 4.2.4 to provide for the mandatory declaration of nutrient contents per 100 g and per specified quantity of the food as suggested for consumption.

139. It was agreed to provide for the declaration of energy content in both kilojoules and kilocalories (Section 4.2.2) and to delete all reference to "international units" in favour of "metric units" when referring to vitamins (Section 4.2.4).

140. On the proposal of the delegation of the Federal Republic of Germany, the Committee agreed to include a new section (4.2.8), as follows:

"In addition, information on the nature of the animal or plant proteins or protein hydrolysates should be provided."

141. The Committee also agreed to include a new Section (4.2.9), as proposed by the delegation of the Netherlands; but placed the text in square brackets for government comments as follows:

"Foods for special medical purposes in which the essential characteristic involves a modification of the content or the nature of proteins, fats or carbohydrates shall bear a complete quantitative declaration of the amino acid, fatty acid or carbohydrate profile, as applicable."

142. The Committee agreed with the delegation of France, that the inclusion of the expiry date on the label was necessary for products covered by the Standard, and proposed a new Section (4.2.10), in square brackets, for this purpose.

#### Other Labelling (Section 4.3)

143. In discussing the present section, the Committee took into account that the definition of "labelling" included statements which were contained in accompanying information, or which were displayed near the food at its point of sale, as well as the information included in the label on the food container.

144. The Committee agreed to retain the statement given in Section 4.3.1, and deleted the square brackets accordingly.

145. The Committee deleted in Section 4.4.2 the word "only" in the statement to be included on the label that the product should be used under medical supervision, so as to avoid the possibility of indicating wrongly, that direct medical supervision was required.

146. The Committee affirmed that a statement related to known side-effects or other contraindications was required, and deleted the square brackets surrounding Section 4.3.4. The Committee also decided to replace "as applicable" with "if applicable."

147. Taking into account the definition of the expression "labelling", which extended to accompanying literature, the Committee agreed to retain Sections 4.3.5 and 4.3.6. However, Section 4.3.6 was modified to read:

"A statement specifying the nutrient(s) reduced, deleted, increased or otherwise modified, relative to normal nutrient requirements and the reason why the nutrient(s) is (are) reduced, deleted, increased or otherwise modified."



The delegation of Switzerland expressed the opinion that Sections 4.3.4, 4.3.5 and 4.3.6 should be deleted.

148. The Committee agreed to retain Section 4.3.7 and to delete the square brackets.

149. The Committee agreed to modify Section 4.3.8 to delete reference to the directions for use. At the same time, Section 4.3.9, which covered directions for use, was expanded to include a reference to the "route of administration". The square brackets were deleted from both sections.

150. The Committee adopted the proposal of International Society of Dietetic Including All Infant and Young Children Food Industries (ISDI) that the products covered by the standard should bear a statement "Not to be used for parenteral administration." (new Section 4.3.10).

#### Status of the Standard

151. The Committee agreed to advance the proposed draft standard to Step 5 for adoption by the Commission as a draft standard. The revised draft standard is contained in Appendix IV to the present report.

#### AMENDMENT TO LABELLING SECTION IN CODEX STANDARDS FOR FOODS FOR INFANTS AND CHILDREN (EXCEPT INFANT FORMULA), AT STEP 7 (Agenda Item 11(a))

152. In opening the discussion, the Chairman suggested that it might be useful to introduce a statement in the standards in question, as well as in the Draft Guidelines on Formulated Supplementary Foods for Older Infants and Young Children, to the effect that the products covered should not be marketed in a way that could create the impression that they could serve as breast-milk substitutes.

153. The delegation of Switzerland supported the Chairman's proposal and suggested the following wording:

"The products covered by this Standard are not breast-milk substitutes and shall not be presented as such."

The delegation of the Netherlands preferred to retain the wording contained in paragraph 172 of ALINORM 87/26, as amended by the delegation of France in paragraph 175 of the same document. The delegation of Japan, however, pointed out that this proposal would lead to confusion between infant formulae and foods for weaning purposes.

154. The delegation of Canada reiterated the proposal of the delegation of Switzerland, which was further supported by the delegations of Australia, Austria, Belgium, Japan and Norway. The delegation of France could agree if the amendment indicated "shall not be presented or marketed as such".

155. The Representative of WHO drew attention to the principles and aim of the International Code of Marketing of Breast-milk Substitutes and, in particular, to its scope (Article 2). Any of the products in question would fall within the scope of the code if they were "marketed or otherwise represented to be suitable ... for use as a partial or total replacement of breast milk". The Code stood on its own and its intent was clear. Any wording that the Committee wished to adopt to convey this intent would be quite suitable.

#### Status of the Amendment

156. The Committee agreed on the text proposed by the delegation of Switzerland and decided to recommend its adoption at Step 8, by the Codex Alimentarius Commission, as an amendment to the Codex Standards for Foods for Infants and Children (except Infant Formula). A consequential amendment was made to the Draft Guidelines for Formulated Supplementary Foods for Older Infants and Young Children (see Appendix VIII).

PROPOSAL FOR AMENDMENTS TO THE CODEX STANDARD FOR "GLUTEN-FREE FOODS" (Agenda Item 11(b))

157. The Committee had before it document CX/NFSDU 88/15 - Part II which contained proposals for a revised text of the Standard for Gluten-Free Foods (CODEX STAN 118-1981), prepared by the Netherlands. The proposed amendments principally concerned methods of analysis for gliadins. Comments from Cuba, Egypt, Federal Republic of Germany, Finland, Ireland, the Netherlands, Spain, Sweden and the United States of America were contained in CX/NFSDU 88/15 - Part II, Add. 1.

158. The Committee recalled that no collaboratively tested method was available for gliadins (see para 182 below), and therefore agreed not to proceed with the amendment of the Standard at the present time. It agreed that the matter should be taken up again once an appropriate method was available.

AMENDMENT TO THE CODEX STANDARD FOR INFANT FORMULA (CODEX STAN 72-1981) - MAXIMUM LEVEL OF VITAMIN D CONTENT (Agenda Item 11(c))

159. The delegation of the Netherlands proposed that the minimum level of Vitamin D in infant formula should be increased from 40 to 60 IU/100 kcal and the maximum level increased from 100 to 120 IU/kcal (1.0 to 1.5 µg/kcal and 2.5 to 3.0 µg/kcal, respectively). Upon the advice of its ad hoc Working Group on Advisory Lists of Vitamin Compounds and Mineral Salts for Use in Foods for Infants and Children, the Committee agreed that it was unnecessary to increase the level of Vitamin D in infant formula. The Committee also noted the opinion of the Helsinki Expert Consultation with respect to the availability of the vitamin formed by exposure to ultraviolet light.

AMENDMENT TO THE CODEX STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND CHILDREN (CODEX STAN 74-1981) (Agenda Item 11(d))

160. The Committee recalled that the delegation of the Netherlands, at the Committee's Fifteenth Session, had proposed an amendment to the above standard to allow for an increase in the level of addition of the flavouring "vanillin" (ALINORM 87/26, paras. 213-215). Comments on this proposal, received from Argentina, Denmark, Egypt, Federal Republic of Germany, Sweden, Switzerland, Spain, Thailand and the United States of America were contained in document CX/NFSDU 88/15-Part III.

161. In view of the general negative opinion of the proposal contained in these comments, and the further statements made by the delegations of Canada and Italy, the Committee decided not to proceed with the proposed amendment of the standard.

AMENDMENTS TO THE GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (Agenda Item 11(e))

162. The Committee noted that the Commission had adopted the General Principles at its Seventeenth Session, and had noted that the question of nutrient density required further consideration (ALINORM 87/39, paras. 444 and 447). The Committee considered this question in the light of government comments contained in document CX/NFSDU 88/4 (Argentina, Denmark, Federal Republic of Germany, Ireland, Spain, Sweden and Switzerland) and on the advice of its ad hoc Working Group on Nutritional Aspects of Codex Standards.

Nutrient Density

163. During the discussion the opinion was expressed by a number of delegations that there was no need for the inclusion of provisions dealing with nutrient density, except perhaps for meal replacement products. It was noted that the proposed reference to nutrient density in the General Principles was not meant for labelling purposes, but as advice for controlling the levels of nutrients to be added to the product, where appropriate. Following detailed discussions, the Committee agreed to include reference to nutrient density in Section 8.1 and to adopt the definition of nutrient density as proposed by the delegation of Sweden, as follows:

"3.8 Nutrient density means the amount of nutrients (in metric units) per stated unit of energy (MJ or kcal).

8.1 Nutrients may be added to special purpose foods, including foods for special dietary uses, to ensure an appropriate and adequate nutrient content. Where appropriate, such addition should be made with due regard to the nutrient density of such foods."

164. The opinion was expressed that it would be more appropriate to refer to "special dietary foods" rather than to "special purpose foods", but the Committee agreed that the text of Section 8.1 be left unchanged.

#### Status of the Proposed Amendment

165. The Committee agreed to recommend to the Commission the adoption of the above amendments outside the Step Procedure, as the Commission had previously been informed of the intention to amend the Guidelines in this manner.

#### Supplementation and Standardization

166. The delegation of Switzerland proposed the inclusion of a definition of "Supplementation" because, in their view, the definition of fortification did not allow the addition of a nutrient to a food that did not contain that nutrient.

167. It was the view of the delegation of the United States of America that the term "Supplementation" was not appropriate since in the American context, it referred to vitamin and mineral supplements.

The following alternative revised definitions of fortification were offered for consideration:

"3.5 Fortification or enrichment means the addition of one or more essential nutrients to a food for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population of specific population groups.

OR

3.5 Fortification or enrichment means the addition of one or more essential nutrients to a food whether or not it is normally contained in the food for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups."

168. As regards the addition of a definition of "Standardization" to Section 3 and the inclusion of a further provision of Section 4 to permit the addition of nutrients to standardize nutrient content, the delegation of Switzerland proposed the following text:

"3.9 Standardization means the addition of nutrients to a food in order to compensate for natural variations in nutrient level.

4.1.5 Standardization of nutrient content."

#### Status of the Proposed Amendment

169. The Committee did not reach agreement on the inclusion of these sections. It decided, therefore, to propose to the Commission that the amendment procedure should be initiated, and in the meantime requested comments on the above proposals at Step 3 in accordance with the Codex Procedure.

**SURVEY OF NATIONAL REGULATIONS ON LEVELS OF CONTAMINANTS IN FOODS FOR INFANTS AND CHILDREN (Agenda Item 12)**

170. The Committee recalled that, at its previous session, it had considered the necessity of amending the Standards for Foods for Infants and Children in the light of recent findings on the intakes of lead and cadmium by infants and children by the Joint FAO/WHO Food Contamination Monitoring Programme and the Joint FAO/WHO Expert Committee on Food Additives (paras. 29-31, ALINORM 87/26). The Committee had agreed to request 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 consider 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. Information had been received from Denmark, Egypt, Federal Republic of Germany, Finland, Sweden, Switzerland, Spain, Thailand, and the United States of America and was available to the Committee in document CX/NFSDU 88/16.

171. The Committee noting the diversity of opinion reflected in the national regulations decided to retain the general statements contained in its present standards.

**REVIEW OF PROVISIONS ON IRRADIATED FOODS IN CODEX STANDARDS FOR FOODS FOR INFANTS AND CHILDREN (Agenda Item 13)**

172. The Committee had before it a proposal of the International Atomic Energy Agency (IAEA) to amend the Codex Standards for Foods for Infants and Children (ALINORM 87/26, App. XV) and comments on this proposal, as contained in document CX/NFSDU 88/16 from Cuba, Denmark, Egypt, Federal Republic of Germany, Finland, Sweden, Switzerland, Spain, Thailand and the United States of America.

173. The Committee, noting that no country had given unequivocal support to the IAEA proposal and that most countries which had replied were opposed to it, decided not to proceed with the amendment of the standards that had been requested by IAEA.

**CONSIDERATION OF A FIRST DRAFT OF A STANDARD FOR TABLE-TOP SWEETENERS IN RELATION TO THE CODEX WORK PRIORITY CRITERIA (Agenda Item 14)**

174. The Committee had before it document CX/NFSDU 88/18 (Conference Room Document No. 9) prepared by the delegation of the Netherlands following discussion of a proposal made at the Committee's Fifteenth Session (ALINORM 87/26, paras. 203-205). In introducing the paper, the delegation of the Netherlands stated that there was an increasing use of such products and that it appeared that there was a significant trade between countries. The proposed draft was intended to cover intense sweeteners (acesulfame K, aspartame, cyclamate and saccharine) in liquid, tablet or powder form, with or without a carrier substance, intended for direct use by the consumer.

175. The delegations of France, Switzerland and the United States of America questioned whether the Committee's terms of reference extended to the consideration of such products, or whether they would fall within the mandate of the Codex Committee on Food Additives and Contaminants. They suggested that the Committee on Nutrition and Foods for Special Dietary Uses might possibly have a role to play in the preparation of guidelines for the use of such substances, should this be considered necessary. The delegation of Spain supported the elaboration of a standard as proposed by the Netherlands.

176. The Committee agreed to request the advice of the Commission on whether this subject fell within its terms of reference. It also agreed to request governments, by means of a Circular Letter, to indicate to the Commission whether such a standard should be elaborated.

**REPORT OF THE WORKING GROUP ON ANALYSIS AND SAMPLING (Agenda Item 15)**

177. The Committee discussed the report (Conference Room Document No. 10) of a Working Group which had met under the Chairmanship of Prof. Dr. Krönert (Fed. Rep. of Germany) on

30 September 1988 to discuss certain specific analytical and sampling problems and to complete the review of methods of analysis included in Standards developed or being developed by the CCNFSDU.

#### Methods of Analysis

178. The Committee noted that the Working Group had considered paper CX/NFSDU 88/8, and comments received from the United States of America, Switzerland and the AOAC. In reviewing methods of analysis the Working Group had paid particular attention to (a) the matrix effect (i.e. to the nature of the food products in which the method had been collaboratively tested), (b) the availability of the method in official publications, (c) problems facing laboratories in developing countries, and (d) the decision of the Commission that Codex methods of analysis (Type II) would be subject to acceptance by governments for use in situations of dispute. The Committee discussed the report of the Working Group.

179. The Committee agreed that, where a method had been published by several organizations in official publications, references to these should be included in Codex Standards.

180. The Committee noted that updating references to Codex methods of analysis caused practical problems. For instance, particular care had to be taken to ensure that the new reference did not represent a method which had been significantly amended. It was noted that laboratories had to acquire the latest editions of publications even though the new references represented identical methods published previously. The suggestion was made that a list of equivalent references to Codex methods might be useful for laboratories in applying the Codex standards in food control. The Committee noted that Codex Type I methods, which are inseparable from the provision in Codex standards which they measured, were not always included in extenso in Codex standards. The opinion was expressed that such an inclusion would be desirable especially for methods which were not readily available.

181. As regards Type II Codex methods, which were subject to acceptance by governments and used for settling disputes, it was necessary to ensure that the methods were relevant to the Codex standard and had performance characteristics appropriate for the purpose. This called for an adequate input of time and resources during sessions of Codex Committees. The Committee noted that in reviewing Codex methods of analysis, several methods had to be reclassified as Type IV methods because they had to be studied with reference to the matrix. For the determination of Vitamin C, the AOAC microfluorimetric method (AOAC XIV, 1984, 43.069) was classified as a Type II method. In spite of being the simpler and more widespread method, the dichloroindophenol method had to be classified as Type III, because of the restricted field of application.

182. A method was discussed for the determination of gliadins in gluten-free foods, proposed in a paper prepared by the delegation of the Netherlands. This delegation indicated that the method in question was not a radioimmunoassay as mentioned in document CX/NFSDU 88/8. It informed the Committee that a collaborative study with this method was being planned for the near future. Interested countries should contact the delegation of the Netherlands. A method for the rapid determination of gliadins, developed in Australia, and available as a kit, was distributed by the delegation of the United Kingdom during the meeting of the Working Group. It was noted that, for the moment, the selection of a Codex method for gliadins was not possible (see paras. 157-158).

183. The Committee decided to recommend the withdrawal of the Codex method for the determination of biotin (Growth Response *Lactobacillus plantarum* ATTC, 8014). The view was expressed that chemical methods were preferable to microbiological methods for the determination of compositional criteria.

184. The AOAC representative was asked to update the AOAC references in the list, in the light of the discussion in paras. 180-181.

### Dietary Fibre

185. The Committee considered the question of dietary fibre from an analytical point of view (a) for the purpose of declaring dietary fibre on the label and (b) for the purpose of correcting for dietary fibre (referred to "crude fibre" in the Codex Standards for foods for infants and children) in the determination of available carbohydrate and the calculation of available energy.

186. The Committee agreed that the AOAC method given in Appendix VII would be adequate for the latter purpose and that any errors introduced by the use of this method would be insignificant.

187. It was noted that the Codex Committee on Food Labelling would be considering the question of analytical definition of dietary fibre for the purposes of label declaration and that the methodology would have to be discussed further in the light of developments (see paras. 24-29).

### Sampling

188. The Committee noted that the Working Group had discussed document CX/NFSDU 88/7 distributed to its members. The working paper, prepared by the United Kingdom, reflected the Instructions in Codex Sampling Procedures (CX/MAS 1-1987) and identified those provisions in the various standards elaborated by the CCNFSDU which required analytical determination and, therefore, sampling. The types of characteristics requiring analysis were compositional (eg. provisions for nutrients, contaminants, food additives, food ingredients) for which a "variable" type of sampling plan rather than "attribute" type of sampling plan would be appropriate. Suggestions for including reference to such plans were given in the paper.

189. The Committee noted that sampling for net contents and for specific health-related properties (eg. mycotoxins, microbiological specifications) would be dealt with by other Codex Committees. It was agreed that:

- (a) Guidance to governments on certain aspects of sampling was desirable, especially for cases of disputes;
- (b) The Committee should consider the various compositional criteria included in its standards and identify those which require attention with regard to sampling;
- (c) Before the Committee could proceed to develop sampling procedures, guidance was required on the purpose of Codex sampling methods and the extent to which international recommendations in this field were required;
- (d) Should the Committee be required to work in the field of sampling, there will be a need to convene a small group of persons with the appropriate expertise in, for example, food control and inspection.

190. The Committee noted that the work on review of methods had been essentially completed. However, any specific analytical problems and the question of sampling which would have to be considered at the next session, might well require the setting up of an ad hoc Working Group. The Committee thanked the Working Group and its chairman for their valuable assistance (see also para. 210). The results of the review of methods of analysis are given in Appendix VII.

### REPORT OF AN AD HOC WORKING GROUP ON ADVISORY LISTS FOR VITAMIN COMPOUNDS AND MINERAL SALTS (Agenda Item 16)

191. The Working Group met during the 16th Session of the Committee. The meeting was attended by representatives from the Federal Republic of Germany, the Netherlands, Sweden, Switzerland, United Kingdom and the United States of America. Dr. J. Chopra from the United States of America acted as Chairman.

192. The following documents formed the basis of the discussion.

CX/NFSDU 88/9-Part I (CRD 4), CX/NFSDU 88/9-Part II (CRD 5), CX/NFSDU 88/9-Part III (CRD 6), and CX/NFSDU 88/9-Part IV (CRD 7)

Review of the Criteria for the Amendment of Advisory Lists of Mineral Salts and Vitamin Compounds (ALINORM 87/26, App. XII, Annex I; CX/NFSDU 88/9-Part I and CRD 4)

193. Dr. Chopra reported that the Working Group had reviewed the Criteria and made the necessary editorial amendments. The Committee adopted the revised Criteria which now read as follows:

- (i) Mineral salts and vitamin compounds may be added to the above lists only if:
  - (a) they are shown 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 mineral salts and vitamin compounds are biologically available;
  - (d) the purity requirements for the mineral salts and vitamin compounds 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.

Consideration of Proposed Additions to the Advisory Lists (CX/NFSDU 88/9, Parts II, III and IV, and Conference Room Documents 5, 6 and 7)

194. Dr. Chopra reported that the Working Group had considered and agreed to a proposal from the Netherlands to list mineral salts in the format of a block diagramme, and that it should form an annex to the Advisory List of Mineral Salts. The delegation of the Netherlands had also proposed the addition of magnesium gluconate, manganese gluconate and zinc gluconate to the Advisory List. On the basis of information provided by the Netherlands, the Working Group had concluded that the aforementioned mineral salts were safe, biologically available and met the purity criteria. It, therefore, recommended that these salts be added to the Advisory List of Mineral Salts.

195. The Working Group had considered a proposal of the delegation of the Netherlands to add potassium iodate to the Advisory List of Mineral Salts. It was agreed that the Netherlands should submit to the Secretariat the necessary data to demonstrate that all criteria for the amendment of the Advisory List had been met. The data will be distributed and reconsidered at the next session of the Committee.

196. The delegation of Switzerland proposed the addition to the Advisory List of gum arabic (Gum acacia) as a carrier for vitamin compounds, and silicon dioxide as an anticaking agent. After review of the information the Secretariat was requested to submit this proposal to the CCFAC for endorsement.

197. The delegation of Switzerland also proposed the addition of hydrochloric acid as a source of chloride and the addition of phosphoric acid as a source of phosphorus in foods for infants and children. This proposal was accepted at Step 2 and Switzerland was requested to submit the necessary data to demonstrate that all criteria for amendment of the Advisory List have been met. These data will be distributed and reconsidered at the next meeting.

198. The delegation of Switzerland stated that current use of dextrans and modified starches in vitamin and mineral pre-mixes would require that the maximum levels for these substances given in the section on "Special Vitamin Forms" (see Supplement 1 of Volume IX of the Codex Alimentarius, page 11) should be raised from 100 mg/kg to 500 mg/kg in the ready-to-use food. The Committee agreed with the recommendation of the Working Group to adopt this proposal at Step 2 of the Procedure for the Amendment of the Advisory List.

199. The Committee expressed its appreciation to Dr. Chopra and to the members of the Working Group for the work undertaken in this specialized area, and agreed that the Working Group should meet in conjunction with the next session of the Committee to continue its work on the Advisory List.

**OTHER BUSINESS (Agenda Item 17)**

200. The delegation of Switzerland proposed the following amendment to the Codex Standard for Processed Cereal-Based Foods for Infants and Children (CODEX STAN 74-1981), which would change the maximum level of use of cocoa in such products to be consumed after nine months of age:

Present limit: maximum level of 5% on a dry basis  
Proposed new limit: maximum level of 1.5% in the ready-to-eat product.

The delegation explained that the reconstitution procedures for cereals to be prepared with milk or with water may be substantially different. For that reason, it suggested that the maximum level for cocoa be expressed on a ready-to-eat basis, as was done for other constituents such as sodium or vanillin. Whereas the present limit of 5% on dry basis was generally sufficient for cereal preparations already containing milk, it was quite low for products which need milk for reconstitution. The following examples illustrate this difference:

- (a) Product to be reconstituted with water (eg. 50 g + 150 ml) - 1.5% cocoa in the pap corresponds to 6% in the powder
- (b) Product to be reconstituted with milk (eg. 25 g + 160 ml) - 1.5% cocoa in the pap corresponds to 11.5% in the powder

201. The Committee agreed to request the approval of the Commission to initiate the amendment procedure, and to forward the proposed draft amendment to governments for comment at Step 3 of the Procedure.

**FUTURE WORK (Agenda Item 18)**

202. The Committee considered two proposals for future work transmitted to it by the Commission:

- standardization of iodine content in iodized salt; and
- impact of standards for infant formula and nutritional standards for infant feeding.

203. The Committee agreed that it would be possible to prepare advice on the iodization of salt, but noted that the usefulness of such advice could be limited to those countries which had a policy of iodization with salt as the vector for supplementation. It requested the Secretariat to arrange for a discussion paper to be prepared for its next session. The delegation of Zimbabwe strongly supported this decision.

204. The Committee felt that a study of the impact of its standards on any particular population group would be outside its terms of reference, and, in any case, would require such resources that its major programme of work would be severely impeded.

205. The delegation of the United States of America noted that the Committee's future work might include dietary fibre; new foods for special medical purposes; non-absorbable substitutes for food constituents; and the regulation of disease-specific health claims, and that these areas could occupy much of the time available to the Committee over several years. The delegation of the United Kingdom suggested that many aspects of this programme of work would first require expert advice from within the United Nations system.



206. The Committee agreed that the following topics would be discussed at its next session:

- Draft Standard for the Labelling of and Claims for Foods for Special Medical Purposes, at Step 7
- Draft Standard for Formula Foods for Use in Weight Control Diets, at Step 7
- Proposed Draft Standard for the Labelling of and Claims for Prepackaged Low Energy and Reduced Energy Foods, at Step 4
- Amendments to Codex Standards and Guidelines for:
  - Gluten-Free Foods (if the required information becomes available)
  - Cereal-based Food for Infants and Children (if authorized by the Commission)
  - General Principles for the Addition of Essential Nutrients to Foods (if authorized by the Commission)
- Standards or guidelines for the use of table-top sweeteners (if authorized by the Commission)
- Standard for vitamin and mineral supplements (if authorized by the Commission)
- Standardization of the iodine content of iodized salt
- Review of labelling provisions in Standards for Foods for Special Dietary Uses
- Review of the nutritional aspects of the use of tropical oils in foods and implications for the labelling of these foods
- Consideration of other nutritional aspects in Codex standards
- Review of the Advisory List of Vitamin Compounds and Mineral Salts for Use in Foods for Infants and Children.

**DATE AND PLACE OF THE NEXT SESSION (Agenda Item 19)**

207. The Committee was informed that its next session was scheduled to be held in Bonn-Bad Godesburg in early October 1990.

208. The representative of the national Secretariat of the Federal Republic of Germany stated that their government, while being pleased to host the Committee and to provide all translation and interpretation services, regretted that very few Spanish-speaking countries had attended recent sessions of the Committee. He stated that the host government would be required to re-evaluate its decision to provide Spanish language facilities, unless improved attendance by these countries could be assured. The host government was contacting the Codex Coordinator for Latin America and the Caribbean to see what improvements could be made.

209. The delegation of Spain expressed its appreciation to the Government of the Federal Republic of Germany for providing services in Spanish, but pointed to the economic difficulties of the countries of the region of Latin America and the Caribbean which prevented them from attending Codex sessions.

**VALEDICTION**

210. The Committee expressed its deep appreciation to Prof. Dr. W. Krönert for his valuable contribution to the work of the Committee, especially in the field of methods of analysis, and wished him and his family all the best in his retirement.

SUMMARY STATUS OF WORK (Cont.)

<u>Standard/Code/etc</u>	<u>Step</u>	<u>Action to be taken by:</u>	<u>Document Reference</u>
- Nutrition standards/guidelines on excessive intakes of fat, sugars and sodium, and inadequate intake of fibre	--	Governments CCNFSDU	Para. 39, ALINORM 89/26
- Gluten-free Foods - consideration of information on gliadins	--	CCNFSDU	Paras. 157-158 ALINORM 89/26
- Very Low-Energy Foods - a study of the problem	--	The Netherlands CCNFSDU	Para. 115, ALINORM 89/26
- Table Top Sweeteners - consideration of problem in relation to terms of reference of CCNFSDU	--	Governments CAC CCNFSDU	Paras. 174-176, ALINORM 89/26
- Review of Labelling Provisions in Standards for Foods for Special Dietary Uses	--	CCFL Governments CCNFSDU	Paras. 98-99, ALINORM 89/26
- Review of methods of analysis	--	CCMAS CAC	Paras. 178-184 and App. VII of ALINORM 89/26
- Dietary Fibre (labelling, analytical and nutritional considerations)	--	CCFL CCNFSDU CCMAS	Paras. 185-187 ALINORM 89/26
- Consideration of Sampling	--	CCMAS CAC CCNFSDU	Paras. 188-190 ALINORM 89/26
- Additional Criteria for Amendment of Advisory Lists of Mineral Salts and Vitamin Compounds	--	CAC	Para. 193 of ALINORM 89/26
- Review of Lists of Mineral Salts and Vitamin Compounds	--	The Netherlands Switzerland Governments CCNFSDU	Paras. 194-199, ALINORM 89/26
- Discussion paper on the iodization of salt	--	Secretariat	Para. 203, ALINORM 89/26
- Possible elaboration of standard for vitamin and mineral supplements	--	CAC CCNFSDU	Para. 37 of ALINORM 89/26
- Consideration of nutritional aspects of the use of tropical oils in foods and implications for labelling	--	CCNFSDU	Paras. 13, 206, ALINORM 89/26

SUMMARY STATUS OF WORK

<u>Standard/Code/etc</u>	<u>Step</u>	<u>Action to be taken by:</u>	<u>Document Reference</u>
- Draft Guidelines on Formulated Supplementary Foods for Older Infants and Young Children	8	CAC	Para. 93 and Appendix III, ALINORM 89/26
- Proposed Draft Standard for Nutritionally Complete Formula Foods for Use in Weight Control Diets	5	CAC Governments CCNFSDU	Paras. 112-125 and App. V of ALINORM 89/26
- Proposed Draft Standard for the Labelling of and Claims for Foods for Special Medical Purposes	5	CAC Governments CCNFSDU	Paras. 128-151 Appendix IV of ALINORM 89/26
- Proposed Draft Standard for the Labelling of and Claims for Prepackaged "Low-Energy" or "Reduced-Energy" Foods (approach to defining reduced-energy foods, and nutritional equivalence)	3	Governments CCNFSDU	Paras. 100-111 and App. VI of ALINORM 89/26
- Proposed Amendments, at Step 8, to Codex Standards and Guidelines:			
(a) Labelling Section of Codex Standards for Canned Baby Foods and Processed Cereal-based Foods for Infants and Children	8	CAC	Paras. 152-156 App. VIII of ALINORM 89/26
(b) Draft Amendment to the General Principles for the Addition of Essential Nutrients to Foods	--	CAC	Paras. 162-164 and App. VIII ALINORM 89/26
- Other Proposed Amendments			
(a) General Principles for the Addition of Essential Nutrients to Foods	--	CAC Governments CCNFSDU	Paras. 166-169 and App. VIII, ALINORM 89/26
(b) Maximum level for cocoa in Codex Standard for Processed Cereal-based Foods	1 - 3	CAC Governments CCNFSDU	Paras. 200-201, and App. VIII ALINORM 89/26
- Report of the Joint FAO/WHO Expert Consultation on Recommended Allowances for Nutrients for Food Labelling Purposes, 1988 (Future considerations)	-	Governments CCNFSDU	Para. 35, ALINORM 89/26

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Opening Address

by the

Under-Secretary of State

Mr. Werner Chory

Mr. Chairman,

Ladies and Gentlemen,

on behalf of the Government of the Federal Republic of Germany I would like to welcome you most sincerely to the 16th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses here in Bonn-Bad Godesberg. I am pleased to convey to you the greetings of Mrs. Süßmuth, Federal Minister for Youth, Health, Women and Family Affairs. She has asked me to express to you her best wishes for a positive and successful session.

I am very happy to see that, once again, there has been a great response to our invitation. The increasing number of participants at every session reflects the importance of the activities of this Committee. Today, I have the pleasure to welcome representatives from more than 30 nations as well as from 10 international organizations. For the first time, representatives of the People's Republic of China, Equatorial Guinea, Zimbabwe, Senegal and the Central African Republic will attend as participants - I would like to welcome them especially.

I also particularly welcome Dr. Randell and Dr. Ladomery of the Codex Secretariat in Rome, as well as the WHO representative, Dr. Akéré.

The Codex Alimentarius Commission has existed now for over 25 years. The successful work of the Commission and its committees enjoys a high, worldwide reputation. The considerable achievements are reflected in the numerous codex standards, codes of practice and guidelines that have been elaborated in often difficult and tough negotiations. Meanwhile, almost 200 standards and about 50 codes of practice have been adopted. Moreover, a great number of methods of analysis, as well as of individual maximum limits for pesticide residues, are available.

We are aware of the importance of this standardization for international trade and should like to point out its importance for developing countries. The standards, codes of practice and guidelines can provide a basis for their own legislation.

It would be an incomplete evaluation of the activities of the Codex Alimentarius Commission if reference were made only to the standards, codes of practice and guidelines. In my opinion, the Commission, as well as the committees, as international fora for the exchange of information and experience, have gained increasing importance over the past years. In an age

of diminishing distances in the world due to technological developments and the global trade in foods gaining considerable dimensions, international cooperation cannot be appreciated highly enough. After all, there are now 134 member states of the Codex Alimentarius Commission.

Globally we may state that the activities of the Codex Alimentarius Commission not only mark an important contribution to the improvement of consumer protection against deception and health risks due to foods, but also ensure good manufacturing and trading practices.

Today, the Committee for the first time meets under its new title "Codex Committee on Nutrition and Foods for Special Dietary Uses". The inclusion of nutrition into the name of the committee underlines the importance of the new tasks in this area. In particular, nutritional matters have moved into the focus of interest over the last few years. They are important on a global scale, though evaluated differently.

While there is still a struggle against hunger and deficient nutrition in many parts of the world, most developed countries concentrate on the problems of over-feeding and malnutrition. Over the last years, science has demonstrated the relationship between nutrition and a number of diseases. Concerning the fact that proper and balanced nutrition represent an essential basis for human health, I would like to point out the importance of the novel tasks of this Committee.

Reviewing the agenda of the session shows that the issue of nutrition will be the focus of your activities during this week. In addition, many other issues will have to be discussed, particularly the draft guidelines and standards, respectively, in the areas of:

- food supplements for older infants and children;
- low-energy and energy-reduced foods for special dietary uses;
- formula foods for use in weight control diets; and
- foods for special medical purposes (the so-called balanced diets).

It would be desirable if considerable progress could be made in these drafts despite their problematic nature.

The discussions in the next few days, however, will also cover issues such as gluten-free foods, contaminants in foods for infants and children, and table-top sweeteners - just to mention a few.

There lies a busy working week ahead of you. I hope that, besides your expert deliberations, you will find time to make the acquaintance of new colleagues or to cultivate existing, long-standing relationships. Perhaps you will find time to enjoy the charming environs of autumnal Bonn, which is celebrating its 2000th anniversary next year. I hope you will enjoy your time here and I wish you a successful and harmonious session.

Thank you very much for your attention.

**DRAFT GUIDELINES ON FORMULATED SUPPLEMENTARY FOODS**  
**FOR OLDER INFANTS AND YOUNG CHILDREN**  
**(Advanced to Step 8)**

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 those nutrients which either are lacking or are present in insufficient quantities 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, most of which are locally available, 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, when necessary, 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 has 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, mungo beans, green gram and kidney beans are a source of appropriate proteins (20-24%).

4.1.2.2 On the whole, pulses have 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 methionine might be desirable in order to improve the nutritional value of the product.

4.1.2.3 Pulses have to be appropriately processed to eliminate, as far as possible, the anti-nutritional factors normally present such as lectins (haemagglutinins) and trypsin and chymotrypsin inhibitors;

- Lectins can be destroyed by heat treatment.
- Trypsin inhibitor activity may be reduced to acceptable levels by heating to high temperatures or by prolonged boiling.

4.1.2.4 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 food because of the danger of favism. Heat treatment does not inactivate the toxic principles vicin and co-vicin.

##### 4.1.3 Oil Seed Flours and Oil Seed Protein Products

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

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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".



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 are acceptable if 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 should be added to the preparation if possible for the purpose of increasing the energy density of the product.

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 Complex carbohydrates and/or sugars.

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.

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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".

## 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.

5.1.2 Dehulling: when necessary, 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 enzymes such as  $\alpha$ -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. Moreover, it destroys micro-organisms and insects and reduces enzyme activity, thus improving keeping qualities.

5.3.2 Protein damage due to the Maillard reaction may occur in the presence of reducing carbohydrates. The toasting process should therefore be carefully controlled.

5.3.3 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.

5.3.4 Toasted raw materials can be 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. It is necessary, however, to ensure that growth of mycotoxin producing microorganisms does not occur. 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 until the mixture acquires the desired fluidity. Starch molecules are split into dextrans and reducing sugars. After raising the temperature 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.

6.1.3 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.

6.1.4 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.

6.1.5 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 6.1.4 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.

6.1.6 In cases where older infants and young children are given vitamins and minerals through maternal and child health centres or other health agencies, their addition to supplementary foods may be unnecessary.

## 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 complex carbohydrates and/or, in moderation, sugars 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 Proteins

6.3.1 Cereals, legumes and/or oilseed flours, alone or preferably mixed, can constitute an appropriate source of proteins, provided they are prepared in such a way that in the finished product the proteins in the mixture satisfy the criteria below.

6.3.2 The amino-acid score <sup>1/</sup> (previously called the chemical score) corrected in accordance with the true digestibility of the crude proteins, should not be less than 65. Higher values should be required if calculation of

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<sup>1/</sup> The amino acid score is the ratio between the quantity of limiting amino acid in the protein tested and the quantity of the same amino acid in the reference protein:  $100 \times (\text{mg of the limiting amino acid in 1 g of the protein tested}) / (\text{mg of the same amino acid in 1 g of the protein with the reference amino acid profile})$ .

the score was based not, as is usually the case, on the most limiting amino acid 1/, but on two or more key amino acids such as lysine, methionine cystine, threonine and tryptophan.

6.3.3 The amino acid profile proposed by the FAO/WHO/UNU (1985) for children of pre-school age(2-5 years) is the most suitable one available for older infants and young children. It closely agrees with that of the NRC (1980) and should be used as a reference in calculating the amino acid score. 2/

6.3.4 If, for technical reasons, the amino acid score and the digestibility of a protein cannot be determined, the protein quality should be measured by biological assays. Alternatively, the protein quality may be computed from published data on essential amino acid patterns of dietary proteins and their availability in terms of digestibility.

6.3.5 The addition of methionine, lysine, tryptophan or other limiting amino acids, solely in the L-form (except for DL-methionine, which may be used in foods for children over 12 months of age) should be contemplated only when, for economic and technological reasons, no mixture of vegetable and/or animal proteins makes it possible to obtain an adequate protein quality (see 6.3.2).

#### 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 at least 20% of energy deriving from fat would be desirable. This corresponds to about 10 g of fats and/or oils in 100 g of the food.

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

6.4.3 Where it is not feasible to include all of the desired 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.

#### 6.5 Carbohydrates

6.5.1 Starch is likely to be a major constituent of many supplementary foods for older infants and young children. To ensure that its energy value is realized, this starch should be provided in a readily digestible form. Guidance on increasing the digestibility of starches is given in Section 5.

6.5.2 Dietary fibres and other non-absorbable carbohydrates are partially fermented by the intestinal flora to produce short-chain fatty acids, lactate and ethanol which may subsequently be absorbed and metabolized. Increasing the intake of dietary fibres enhances stool bulk. They also may affect the

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1/ The limiting amino acid is the essential amino acid present in the lowest proportion as compared with the quantity of this amino acid in the reference protein.

2/ Joint FAO/WHO/UNU Expert Group (1985), Energy Requirements and Protein Requirements, World Health Organization, Tech. Rep. Ser. No. 724.

efficiency of absorption of various nutrients of significance in diets with a marginal nutrient content, so the fibre content of the food should be reduced to a physiologically justifiable level.

#### 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.

6.6.3 Vitamins and/or minerals should be selected from the Advisory Lists of Vitamin Compounds and Mineral Salts for Use in Foods for Infants and Children (Codex Alimentarius Vol.IX-Ed.1, Part IV).

#### 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 shall be prepared, packed and held under sanitary conditions 1/.

#### 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.

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1/ Standards proposed by the Protein Advisory Group of the United Nations System are outlined in PAG Guideline No. 11.

**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:

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, 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 may be administered as a food supplement during the weaning period but not before 6 months of age and when nutritional requirements are not covered by locally available foods.

9.2.2     List of Ingredients

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

9.2.3     Declaration of Nutritive Value

The declaration of energy and nutrients on the label or in labelling shall contain the following information expressed per 100 grammes of the food as sold as well as specified of food as suggested for consumption:

- (a) the amount of energy, expressed in Kilocalories and/or Kilojoules;
- (b) the amounts of protein, carbohydrates and fat, expressed in grammes;
- (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.

9.2.4     Net Content

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

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1/        Hereafter referred to as "General Standard"

9.2.5 Name and Address

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

9.2.6 Country of Origin

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

9.2.7 Lot Identification

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

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 In the case that addition of water is needed, the directions for the preparation shall include a precise statement that:

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

(b) where the food contains 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, complex carbohydrates and/or sugars are added during preparation, shall bear an indication of the amounts which are required to achieve the desired nutrient density of the food.

9.2.9.4 Directions for use shall include a statement that only the amount of food sufficient for one meal should be prepared at one time.



**MODEL NUTRIENT PROFILE**

The following model nutrient profile is based on a formulated supplementary food which will provide at least 400 kcal energy per 100 g, and not less than 2/3 of the average daily requirements of other nutrients. Not more than 2 x the amount of any of the nutrients listed below should be present in 100 g of the formulated supplementary food.

Nutrient	Reference Daily Requirements	Approximate amount per 100 g dry weight
Protein <u>1/</u>	13.5 - 15.5 g	15 g
Fat	--	10 g
Dietary fibre (maximum)	--	5 g
Vitamin A	200 - 400 µg	200 µg
Vitamin D	10 µg	7 µg
Vitamin E	5 µg	4 mg <u>2/</u>
Vitamin C	20 mg	13 mg
Thiamine	500 µg	500 µg <u>3/</u>
Riboflavin	800 µg	600 µg
Niacin	9 mg	6 mg
Vitamin B <sub>6</sub>	900 µg	600 µg
Folic Acid <u>4/</u>	40 µg	27 µg
Vitamin B <sub>12</sub>	1 µg	0.7 µg
Calcium	800 mg	600 mg
Iron	10 mg	10 mg <u>5/</u>
Iodine	--	50 µg
Zinc	10 mg	10 mg

Footnotes

- 1/ The Reference Daily Requirement of protein is based on egg or milk protein equivalence; the approximate amount/100 g is based on a protein equivalent to an amino acid score of 65 corrected for true digestibility of the crude protein.
- 2/ See also Section 6.4.3
- 3/ The recommended value is higher than 2/3 of the Reference Daily Requirements to compensate for high levels of carbohydrate in formulated supplementary foods.
- 4/ Expressed as the monoglutamate form of folacin.
- 5/ The recommended value is higher than 2/3 of the Reference Daily Requirements to compensate for reduced bioavailability.

References (\*)

1. Joint FAO/WHO/UNU Expert Group (1973), Energy Requirements and Protein Requirements, WHO Tech. Rep. Series No. 522.
2. Joint FAO/WHO/UNU Expert Group (1985), Energy Requirements and Protein Requirements, WHO Tech. Rep. Series No. 724
3. Report of a Joint FAO/WHO Expert Consultation on Recommended Allowances of Nutrients for Food Labelling Purposes, 1988.

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(\* Other references will be added prior to publication of the Guidelines.

**DRAFT STANDARD FOR THE LABELLING OF AND CLAIMS FOR**  
**FOODS FOR SPECIAL MEDICAL PURPOSES**  
**(At Step 5)**

**1. SCOPE**

This standard applies to the labelling of and claims for Foods for Special Medical Purposes as defined in Section 2 below, [and presented as such].

**2. DEFINITIONS**

Foods for special medical purposes are a category of foods for special dietary uses which are specially processed or formulated for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foodstuffs or certain nutrients contained therein, or have other special medically-determined nutrient requirements, the dietary management of whom cannot be achieved by modification of the normal diet alone, by other foods for special dietary uses, or by a combination of the two.

**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/or other labelling 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 146-1985) 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:

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1/ Hereafter referred to as "General Standard"

## 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 as sold as well as per specified quantity of the food as suggested for consumption.

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 as sold, as well as per specified quantity of the food suggested for consumption. 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.

4.2.4 Information on the amounts of vitamins and essential minerals shall be expressed in metric units per 100 g or per 100 ml as sold as well as per specified quantity of the foods as suggested for consumption.

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.

4.2.8 In addition, information on the nature of the animal or plant proteins or protein hydrolysates should be provided.

[4.2.9 Foods for special medical purposes in which the essential characteristic involves a modification of the content or the nature of the proteins, fats or carbohydrates shall bear a complete quantitative declaration of the amino acid, fatty acid or carbohydrate profile, as applicable.]

### Date Marking

[4.2.10 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.]

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 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 foetus, or breast-milk quality or quantity.

4.3.4 A complete statement concerning adequate precautions, known side effects, contra-indications, and product-drug interactions, if 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, increased or otherwise modified, relative to normal nutrient requirements and the reason why the nutrient(s) is (are) reduced, deleted, increased or otherwise modified.

4.3.7 A statement indicating whether the product is 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.

4.3.9 Feeding instructions, including the route of administration and serving size, if applicable.

4.3.10 A statement that the product is not to be used for parenteral administration.

**DRAFT STANDARD FOR FORMULA FOODS FOR USE IN WEIGHT CONTROL DIETS**  
**(At Step 5 of the Procedure)**

**1. SCOPE**

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

It does not apply to prepackaged meals controlled in energy and presented in the form of conventional foods.

**2. DEFINITIONS**

A 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 per day 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**

3.2.1.1 For a formula food represented as a replacement for all meals per day, not less than 50 grammes and not more than 100 grammes of portion shall be present in the amount of the product recommended for use per day.

3.2.1.2 For a formula food represented as a replacement for a single meal, the amount of protein shall be reduced below the amounts specified in 3.2.1.1 to 33 1/3 % or 25 % of these amounts depending on whether the recommended number of servings per day is 3 or 4 respectively.

3.2.1.3 The portion shall be:

- (i) of a nutritional quality equivalent to egg or milk protein (the reference protein); or

(ii) where the protein quality is less than the reference protein, the minimum levels should be increased to compensate for the lower protein quality, but the total amount of protein shall not exceed 100 grammes in the daily intake. No protein with a quality of less than 80% of that of the reference protein shall be used in a formula food for use in a weight control diet.

3.2.1.4 Essential amino acids may be added to improve protein quality only in amounts necessary for this purpose. Only L-forms of amino acids shall be used, except that DL-methionine may be used.

### 3.2.2 Fat and Linoleate

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

3.2.3.1 Except in the case of a formula food 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.

### 3.2.4 Vitamins and Minerals

3.2.4.1 For a formula food represented as a replacement for all meals per day at least 100 % of the amounts of vitamins and minerals specified below shall be present in the daily intake. Other essential nutrients not specified below may also be included.

#### Vitamins

Vitamin A	800 µg	<u>1/</u>
Vitamin D	2.5 µg	<u>1/</u>
Vitamin E	10 mg	<u>2/</u>
Vitamin C	50 mg	<u>1/</u>
Thiamine	1.4 mg	<u>1/</u>
Riboflavin	2.0 mg	<u>1/</u>
Niacin	24 mg	<u>1/</u>
Vitamin B-6	2 mg	<u>2/</u>
Vitamin B-12	1 µg	<u>1/</u>
Folic acid (as monoglutamate)	100 µg	<u>1/</u>

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1/ Derived from current FAO/WHO recommended dietary intakes (in most cases, derived from requirements for the adult male).

2/ Derived from the most frequently used values internationally, as presented in Recommended Nutrient Reference Values for Food Labelling Purposes, Report of a Joint FAO/WHO Expert Consultation on Recommended Allowances of Nutrients for Food Labelling Purposes, Helsinki, Finland, 12-16 September 1988.

Minerals

Calcium	800 mg	<u>1/</u>
Phosphorus	800 mg	<u>2/</u>
Iron	14 mg	<u>1/</u>
Iodine	140 µg	<u>1/</u>
Magnesium	300 mg	<u>1/</u>
Copper	2 mg	<u>1/</u>
Zinc	14 mg	<u>2/ 3/</u>
Potassium	1.5 g	<u>4/</u>
Sodium	1.5 g	<u>1/</u>

3.2.4.2 For a formula food represented as a replacement for a single meal, the amounts of vitamins and minerals shall be reduced below the amounts specified in 3.2.4.1 to provide a minimum of 33 1/3% or 25% of these amounts, depending on whether the recommended number of servings per day is 3 or 4 respectively. Other essential nutrients not specified below may also be included.

3.3 Ingredients

Meal replacements for weight control 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.

4. FOOD ADDITIVES

Food additives cleared by the Joint FAO/WHO Expert Committee on Food Additives shall be permitted at levels not exceeding the equivalent of their Acceptable Daily Intake.

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.

- 
- 1/ Derived from current FAO/WHO recommended dietary intakes (in most cases, derived from requirements for the adult male).
- 2/ Derived from the most frequently used values internationally, as presented in Recommended Nutrient Reference Values for Food Labelling Purposes, Report of a Joint FAO/WHO Expert Consultation on Recommended Allowances of Nutrients for Food Labelling Purposes, Helsinki, Finland, 12-16 September 1988.
- 3/ Adjusted slightly to be equal to idem.
- 4/ Minimum amounts deemed to be safe and adequate.



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.

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:

- (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

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

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:

- (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 in Section 3.2.4 expressed in metric units;
- (d) the amounts of other nutrients 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.

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

9.3.4 In countries where serving sizes are normally used, the information described in Sections 9.3.1 to 9.3.3 may be given only per serving as quantified on the label or per portion provided that the number of servings or portion contained in the package is stated.

9.3.5 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.

9.8 Date Marking

The date of minimum durability shall be declared in accordance with section 4.7.1 of the General Standard.

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.

9.10.2 The label of a formula food for weight control that is not represented as a replacement for all meals in a diet shall include, in the directions for use, a sample menu-plan in which the food is used and that meets the following requirements:

- (a) each day's menu should include a variety of foods;
- (b) not more than 35% of the daily energy intake should be derived from fat;
- (c) the mean daily nutrient levels set out in Section 3.2 should be obtained.

### 9.11 Additional Provisions

9.11.1 Reference shall not be made on the label or in labelling to rate and/or amount of weight loss or to a reduction in the sense of hunger or an increase in the sense of satiety.

9.11.2 The label or labelling should make reference to the importance of maintaining an adequate daily fluid intake when formula foods for weight control are used.

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

[9.11.4 The label shall not make claims relating to the rate of weight loss which may result from the use of the product or to a reduction of the sense of hunger or to an increase in the sense of satiety.] 1/

[9.11.5 The label shall include a warning that the use of the product presented as meal replacement is suitable when it forms part of a diet which is controlled in its entirety.] 1/

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1/ See para. 124 of the report.

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 presented as such.

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; or

Reduced energy food is a food which provides not more than 75% of the energy, that would normally be provided in the same weight of that food if it were not energy-reduced (hereafter termed the reference food). The label of a reduced energy food shall bear a statement comparing the energy value of the food with that of the reference food.]

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.

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 146-1985) 1/ except that the following specific provisions apply:

3.2 The following additional provisions to those in Section 4.1.2 of the General Standard, The Name of the Food, shall apply:

---

1/ Hereafter referred to as the "General Standard".

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.

METHOD/TITLE	STANDARD REFERENCE	PRESENT METHOD (References updated)	PROPOSED METHOD	CLASSIFICATION
1.9 Thiamine (Vitamin B <sub>1</sub> )	CODEX STAN 72-1981 ALINORM 87/26, Appendix III	AOAC XIV, 1984, 39.024-39.030 (Fluorometric method)	Unchanged	II
1.10 Riboflavin (Vitamin B <sub>2</sub> )	CODEX STAN 72-1981 ALINORM 87/26, Appendix III	AOAC XIV, 1984, 43.039-43.042 (Fluorometric method)	Unchanged	II
1.11 (a) Nicotinamide for milk-based foods	CODEX STAN 72-1981, ALINORM 87/26, Appendix III	AOAC XIV, 1984, 43.191-43.199 (Titrimetric/Turbidimetric methods)	Unchanged	II
1.12 (b) Nicotinamide for foods not based on milk	- " -	AOAC XIV, 1984, 43.048-43.050	Unchanged	II
1.13 Vitamin B <sub>6</sub>	- " -	AOAC XIV, 1984, 43.229-43.234	Unchanged	II
1.14 Folic acid	- " -	AOAC XIV, 1984, 43.183-43.190 (Pteroyl glutamic method)	Unchanged	II
1.15 Pantothenic acid	- " -	AOAC XIV, 1984, 43.220-43.208 (Titrimetric and turbidimetric method)	Unchanged	II
1.16 Vitamin B <sub>12</sub>	- " -	AOAC XIV, 1984, 43.175-43.182 (Titrimetric and turbidimetric method)	Unchanged	II
1.17 Chloride	- " -	Codex General Method App.IV of ALINORM 76/23 (5)	Unchanged	II
1.18 Water Capacity of Containers	All standards	CAC/RM 46-1972. CA, Vol. II	Unchanged	I

SECOND REVIEW OF METHODS OF ANALYSIS IN CODEX STANDARDS ELABORATED BY CC/NFSDU

1. Methods given in the standard and endorsed and classified by the Working Group:

METHOD/TITLE	STANDARD REFERENCE	PRESENT METHOD (Reference updated)	PROPOSED METHOD	CLASSIFICATION
1.1 Silica	CODEX STAN 53-1981	AOAC XIV, 1984, 35.049*		IV(8)
1.2 Iodine	- " -		Not needed (2)	
1.3 (a) Fat in Foods containing starch, meat or vegetable products	CODEX STAN 72-74, 53, 118-1981	CAC/RM 55-1976 (Vol. IX) n-Hexane extraction	Unchanged	I
1.4 (b) Fat in Infant Foods not containing starch, meat or vegetable products	CODEX STAN 72-1981, ALINORM 87/26 Appendix III	Method B-2 of Code of Principles for Milk and Milk Products, CAC/RM 1-1973, Volume XVI of the Codex Alimentarius	Unchanged	I
1.5 Ash	CODEX STAN 53, 72-74, 118-1981, ALINORM 87/26 Appendix III	AOAC XIV 1984, 7.009	Unchanged	I
1.6 Crude protein	- " -	Kjedahl method for total nitrogen, text in Vol. IX of the Codex Alimentarius		II (3)
1.7 Loss on Drying	- " -	AOAC XIV, 1984, 7.003 Moisture Drying in Vacuo 95-100°C	Unchanged	I
1.8 Vitamin C (L-Ascorbic Acid)	CODEX STAN 72-1981 ALINORM 87/26, Appendix III	AOAC XIV, 1984, 43.069 (micro-fluorometric), or 43.064 (dichloroindophenol)	AOAC (microfluorometric) AOAC (dichloroindophenol)	II III (9)

2. Methods given in the standards but to be replaced by new methods as proposed:

METHOD/TITLE	STANDARD REFERENCE	PRESENT METHOD (References updated)	PROPOSED METHOD	CLASSIFICATION
2.1 Nitrogen (6)	CODEX STAN 118-1981	--		
2.2 Calcium	CODEX STAN 72-1981, ALINORM 87/26, Appendix III	AOAC XI, 1970, 14.014*	IDF 119/1984; ISO DIS 80740 (7) AOAC XIV, 1984, 43.292-43.296	II
2.3 Sodium and Potassium	- " -	US Flame photometric method (CX/FSDU 71/17) (Temporarily endorsed)	IDF 119/1984; ISO DIS 80740 (7) AOAC XIV, 1984, 43.292-43.296	II



3. Methods given in the standards but to be amended or replaced by new methods to be elaborated:

METHOD/TITLE	STANDARD REFERENCE	PRESENT METHOD (References updated)	PROPOSED METHOD	CLASSIFICATION
3.1 Sodium Content	CODEX STAN 53-1981	US Flame photometric method (see 2.3)	AOAC XIV, 1984, 43.292-43.296	
3.2 Potassium Content	- " -			
3.3 Calcium Content	- " -	AOAC XIII, 1980, 2.109-2.113* (Atomic absorption spectrophotometry)	To be elaborated	
3.4 Magnesium Content	- " -		To be elaborated	
3.5 Ammonium Content	- " -	AOAC XIV, 1984, 2.065* (Ammoniacal nitrogen)	To be elaborated	
3.6 Phosphorus Content	- " -	AOAC XIV, 1984, 43.292-43.296*	To be elaborated	
3.7 Protein Efficiency Ratio (PER)	CODEX STAN 72-1981, ALINORM 87/26, Appendix III	AOAC XIV, 1984, 43.253-43.257 (bioassay)	AOAC XIV, 1984, 43.253-43.257 (bioassay); AOAC XIV, 1984, 43.255-43.267 (method by calculatiob)	I
3.8 Vitamin A	- " -	AOAC XIV, 1984, 43.001-43.007, 43.008-43.013, 43.014-43.017		IV (8)
3.9 Vitamin D	- " -	AOAC XIV, 1984, 43.236-43.249		
3.10 Pantothenic acid for non-enriched foods	- " -	USDA Handbook 97 or "The Analyst" For non-enriched foods: 89, 1, 1964		

METHOD/TITLE	STANDARD REFERENCE	PRESENT METHOD (References updated)	PROPOSED METHOD	CLASSIFICATION
3.11 Vitamin E	CODEX STAN 72-1981, ALINORM 87/26, Appendix III	AOAC XIV, 1984, 43.128-43.137		) IV (8) ) ) ) )
3.12 Phosphorus	- " -	AOAC XIV, 1984, 22.040-22.042 (Gravimetric quinoline molybdate method)		) ) )
3.13 Copper, Manganese, Zinc, Magnesium	- " -	AOAC XIV, 1984, 43.292-43.296* ) (Atomic absorption ) Spectrophotometry) ) )		)
3.14 Iron	- " -	AOAC XIV, 1984, 43.292-43.296* )		)

4. Methods proposed but more information needed:

METHOD/TITLE	STANDARD REFERENCE	PRESENT METHOD	PROPOSED METHOD	CLASSIFICATION
4.1 Choline	CODEX STAN 53-1981		To be elaborated	--
4.2 Choline	CODEX STAN 72-1981 ALINORM 87/26, Appendix III		Under elaboration by FDA/IFC	--
4.3 Linoleate (See para. 90 of ALINORM 76/23)	CODEX STAN 72-1981, ALINORM 87/26, Appendix III		IUPAC Standard Methods for the Analysis of Fats and Oils (7); and AOAC XIV, 1984, 14.019 then 28.056-28.068 14.019 then 28.082-.085	--
4.4 Crude Fibre (4) (See para. 102 of ALINORM 78/23)	CODEX STAN 53, 72- 74, 118-1981, ALINORM 87/26 Appendix III		AOAC Enzymatic - gravimetric method modified version**	I

5. Method to be elaborated:

METHOD/TITLE	STANDARD REFERENCE	PRESENT METHOD	PROPOSED METHOD	CLASSIFICATION
5.1 Vitamin K-1	CODEX STAN 72-1981, ALINORM 87/26 Appendix III		To be elaborated	--
5.2 Biotin (Vitamin H)	- " -	Growth Response, Lactobacillus plantarum ATCC, 8014 (Skeggs Analytical Microbiology, F. Kavanaugh Ed., Academic Press, 1963, p.461)(1)	To be elaborated	--
5.3 Iodine	- " -		To be elaborated	--

Footnotes

- (1) To be withdrawn.
- (2) Optional additive to conform with national legislation.
- (3) The calculation factors are classified: Type I
- (4) Needed for estimating "carbohydrate by difference"
- (5) The FAO Secretariat is asked to publish the method.
- (6) Standard being amended to include provision for gliadins or prolamin
- (7) To be published.
- (8) To be studied collaboratively with reference to the matrix.
- (9) Restricted to the field of application mentioned in the method.

\* Endorsement withdrawn.

\*\* Reference to be provided

PROPOSED AMENDMENTS TO CODEX STANDARDS AND GENERAL PRINCIPLES

A. DRAFT AMENDMENTS AT STEP 8 OF THE PROCEDURE

Labelling Sections of the Codex Standards for Canned Baby Foods (CODEX STAN 73-1981), Cereal-based Foods for Infants and Children (CODEX STAN 74-1981) and Follow-up Formula (CODEX STAN 156-1987)

Add the following new section:

"Additional Requirements

The products covered by this Standard are not breast-milk substitutes and shall not be presented as such."

(Ref. paras. 172-176, ALINORM 87/26; paras. 152-155, ALINORM 89/26)

B. PROPOSED AMENDMENTS OUTSIDE THE CODEX PROCEDURE

Reference to "nutrient density" in the General Principles for the Addition of Essential Nutrients to Foods (adopted by the 17th Session of the Commission, Appendix V, ALINORM 87/26)

Include the following new sections in the above General Principles:

"3.8 Nutrient density means the amount of nutrients (in metric units) per stated unit of energy (MJ or kcal).

8.1 Nutrients may be added to special purpose foods, including foods for special dietary uses, to ensure an appropriate and adequate nutrient content. Where appropriate, such additional should be made with due regard to the nutrient density of such foods."

(Ref. paras. 162-165, ALINORM 89/26)

C. PROPOSAL TO INITIATE THE CODEX AMENDMENT PROCEDURE

(1) New definitions to be included in the General Principles for the Addition of Essential Nutrients to Foods (adopted by the 17th Session of the Commission, Appendix V, ALINORM 87/26)

(a) The following revised/new definitions have been proposed for inclusion in the General Principles:

"3.5 Fortification or enrichment means the addition of one or more essential nutrients to a food for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population of specific population groups.

OR

3.5 Fortification or enrichment means the addition of one or more essential nutrients to a food whether or not it is normally contained in the food for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups.

3.9 Standardization means the addition of nutrients to a food in order to compensate for natural variations in nutrient level."

(Ref. paras. 148-149, ALINORM 87/26; para. 446, ALINORM 87/39; paras. 166-168, ALINORM 89/26)

- (b) The following additional criterion for adding essential nutrients to foods is proposed to be included in Section 4 of the General Principles:

"4.1.5 Standardization of nutrient content."

(Ref. para. 168, ALINORM 89/26).

- (2) Amendment of the Maximum Level of Use of Cocoa in the Codex Standard for Processed Cereal-Based Foods for Infants and Children (CODEX STAN 74-1981)

The following change to the maximum level for cocoa in Section 4.2.1 of the above standard is proposed: " ..... 1.5% m/m in the ready-to-eat product."

(NB: The present limit is "5% m/m on a dry basis")

(Ref. paras. 200-201, ALINORM 89/26)

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COMMENTS ON THE DRAFT GUIDELINE FOR THE UTILIZATION OF  
VEGETABLE PROTEIN PRODUCTS

An ad hoc Working Group of the Committee on Nutrition and Foods for Special Dietary Uses studied the Draft Guidelines contained in ALINORM 87/30, Appendix IV. The Committee agreed to transmit these comments to the Codex Committee on Vegetable Proteins for its consideration (see also para. 30, ALINORM 89/26).

Definition of Vegetable Protein Product (VPP)

The Working Group drew the CCVP's attention to an inconsistency between the definition of VPP in Section 3 and the definition of VPP in the general standard for VPP (App. V, ALINORM 87/30).

Protein Quality

The point was made by the delegation of the Netherlands that protein quality should be determined on the basis of physiological effects rather than chemical score.

Supplementation

The point was made by the delegation of the United States of America that the term "supplementation" was not appropriate since, in the American context, it referred to vitamin and protein supplements. It was suggested that the term be deleted and the text in that section be transferred under "complementation".

Utilizable Protein

The delegations of the United Kingdom and Zimbabwe suggested that specific conversion factors be applied to specific proteins. The Working Group was informed that this matter had been discussed by the CCVP and that the CCVP had decided against the use of specific factors.

Section 5.1

The delegation of the United Kingdom was of the opinion that it would not be practical to expect that the use of VPP for functional purposes would not result in some of the principal protein being replaced. The section should be deleted. The delegation of Canada did not agree as this section set out the principle that there should be no replacement or diminution of the original protein in the food.

Section 5.2

In the opinion of the delegation of the United Kingdom this section should be made clearer.

Section 6.2

Same remarks as for "Supplementation".

Section 6.3

The delegation of the United States of America proposed that tryptophan (at 1.1%) be included.

#### Section 6.4

The delegation of the United States of America informed the Working Group that the racemic form (DL) of methionine was permitted in the USA (except for infant foods) and suggested that Section 6.4 should do likewise.

#### Section 6.6

Following discussion the Working Group expressed a preference for the second option (ie. 6.6.1 and 6.6.2).

It was noted that "nutritional equivalence" was defined in the Codex General Principles for the Addition of Essential Nutrients to Food.

#### Section 6.7

The delegation of the United Kingdom pointed to an apparent inconsistency between Sections 6.7 and 4.3 concerning the indication of the VPP on the label.

#### Section 7.5

The delegation of Norway, supported by several delegations proposed the deletion of the words "unless properly qualified" in Section 7.5 (III), since this would confuse the consumer. Some other delegations were in favour of retaining them.

The delegation of the United States of America indicated that the term "nutritional adequacy" was frequently used in the Guidelines, whereas in fact "nutritional equivalence" was meant.

#### Proposed Guidelines for Testing Safety and Nutritional Quality of VPP Sections 1.2 and 2.3

##### General remarks

The delegation of the United Kingdom queried whether there was a need for such a detailed protocol for the testing of all the various types of VPP, as it was the final food product which would have to be considered from a point of view of safety. It was pointed out that novel foods required testing for safety and nutritional quality and that the preamble explained that the full protocol would not be required for all VPP. The Secretariat was strongly of the opinion that the development of the testing guidelines was outside the responsibility of Codex. The delegations of the United States of America and Norway were not in agreement and noted that macronutrients had never been considered by JECFA. It was appropriate for Codex to take the initiative in the interest of making progress.

It was noted that collaborative tests were in progress for the determination of protein quality, involving a comparison of amino acid score and biological methods.

#### Section 2.4 - Toxicological evaluation

The suggestion was made that chronic studies should also be contemplated. In this respect the difficulties which would be encountered in devising a test method involving food which provided more than 10% of the diet.



**COMMENTS ON THE PROPOSED DRAFT REVISION OF THE CODEX GENERAL  
GUIDELINES ON CLAIMS**

The ad hoc Working Group of the Codex Committee on Nutrition and Foods for Special Dietary Uses studied the Proposed Draft Revision of the Codex General Guidelines on Claims as contained in ALINORM 87/22, Appendix II, Annex 1. The Committee agreed to transmit the comments made during this discussion, to the Codex Committee on Food Labelling for its consideration (see also paras. 30-31).

Section 1.1

The delegation of the United States of America proposed that the phrase "in its labelling" be inserted in Section 1.1 after the word "food" to make it clear that the Guidelines did not apply to advertising.

Section 3.2

It was suggested that Section 3.2 concerned misleading claims and should be moved to Section 4, since there were occasions where a diet of ordinary foods cannot meet the nutrient needs of some populations.

Section 3.4(a)

It was pointed out that the name of the Codex Committee on Nutrition and Foods for Special Dietary Uses should be corrected in Section 3.4(a).

Section 4.1

It was agreed that the word "incomplete" should be inserted before "comparatives and superlatives" in Section 4.1.

Section 4.3

It was proposed that Section 4.3 be moved to Section 5, since criteria were being developed in some countries for the use of the word "organic".

The delegation of France stated that products could not be "biological". In fact, it was only agriculture which could be biological. Therefore, it proposed the following phrase:

"product derived from raw materials obtained from "biological"  
agricultural practices."

In this situation, the word "biological" should be used only when agricultural practices were controlled.

New Section 4.4

The recommendation of the Expert Consultation in Helsinki (CRD No. 1, page 26) that the CCNFSDU consider claims for food substances which were not essential nutrients, was brought to the attention of the Committee. The delegation of the United Kingdom, supported by France, pointed out that it would be possible to develop a positive list of essential nutrients for which claims could be made. The delegation of the United States of America proposed the addition of a new Section as follows:

"4.4 Claims for substances which are alleged to be essential nutrients but which are not."

Section 5.1

It was proposed that the end of the first sentence of Sub-Section 5.1(1) be changed to: "... has been made in accordance with the Codex General Principles for the Addition of Nutrients to Foods". The last sentence of the Sub-Section should then be deleted.

It was pointed out that the meaning of 5.1(iv)(c) was not clear. The word "ingredient" should be inserted after the word "another" and the use of the word "qualité" was inappropriate in the French version. It was agreed that the Codex Committee on Food Labelling should be asked to clarify the subsection.

It was pointed out that a claim for the absence of an ingredient when that ingredient was not permitted by law in the food was misleading even when accompanied by a disclaimer. It was, therefore, agreed to recommend that subsection 5.1(iv)(d) be replaced as follows: "is permitted for use in the food".

The observer from ISDI pointed out the difficulty of ensuring the complete absence of a substance. The delegation of Canada suggested that there was a need to develop criteria for claims for the absence of a nutrient.