

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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ALINORM 91/26

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

19th Session

Rome, FAO HQ, 1-10 July 1991

REPORT OF THE 17TH SESSION OF THE CODEX COMMITTEE ON
NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Bonn-Bad Godesberg, Germany, 18-22 February 1991

N.B.: This document incorporates CL 1991/12-NFSDU.

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CX 5/20

CL 1991/12-NFSDU
April 1991

TO: - Codex Contact Points
- Participants at the 17th Session of the Codex Committee on
Nutrition and Foods for Special Dietary Uses
- Interested International Organizations

FROM: Chief, Joint FAO/WHO Food Standards Programme
FAO, Via delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: Distribution of the Report of the 17th Session of the Codex Committee on
Nutrition and Foods for Special Dietary Uses, Bonn-Bad Godesberg,
18-22 February 1991 (ALINORM 91/26)

MATTERS OF INTEREST FOR THE 19TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION (1-10 July 1991)

1. DRAFT STANDARDS AND GUIDELINES AT STEP 8 OF THE PROCEDURE
 - 1.1 Draft Standard for Formula Foods for Use in Weight Control Diets
(ALINORM 91/26, paras 38-70 and App. III)
 - 1.2 Draft Standard for the Labelling of and Claims for Foods for Special Medical
Purposes (ALINORM 91/26, paras 71-85 and App. IV)
 - 1.3 Draft Guidelines on Formulated Supplementary Foods for Older Infants and Young
Children (ALINORM 91/26, paras 18-37 and App. II)
2. DRAFT AMENDMENTS AT STEP 5/8 OF THE PROCEDURE

The following draft amendments have been advanced to Step 5 of the Procedure. In view of their extensive review through written comments and discussions at the session, the Committee agreed to recommend to the Commission to consider omitting Steps 6 and 7 and adopt them at Step 8.

- 2.1 The Amendments to the General Principles for the Addition of Essential
Nutrients to Food, Definition of "Fortification or Enrichment" and
"Standardization" (ALINORM 91/26, paras 93-96 and App. V (A, B))
- 2.2 The Amendment for the Maximum Level of Cocoa in Codex Standard for Processed
Cereal-Based Foods (CODEX STAN 74-1981) (ALINORM 91/26, paras 97-99 and
App. V (C))

Governments wishing to propose amendments and comments on the above documents should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 (see Procedural Manual of the Codex Alimentarius Commission, 7th Edition) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, 00100 Rome, Italy, before 30 May 1991.

3. OTHER MATTERS REQUIRING CONSIDERATION BY THE COMMISSION

3.1 Proposal for a Draft Standard for Formula Foods for Use in Very Low Energy Diets (ALINORM 91/26, paras 108-111 and App. VI)

The Committee considered a proposed draft prepared by the Delegation of the Netherlands and agreed to request the Commission's advice on whether to proceed with the elaboration of such a standard.

3.2 Amendments to the Advisory List of Vitamin Compounds and Mineral Salts (ALINORM 91/26, paras 112-122 and App. VII)

An Ad-hoc Working Group reviewed a number of Amendments during the session and proposed five new additions to the Advisory List (CAC/Vol. IX, Part IV). The Committee agreed to the Amendments.

3.3 Iodization of Salts (ALINORM 91/26, paras 123-125)

The Committee considered a working paper outlining the status of salt iodization and the prevention of iodine deficiency disorders, and agreed to seek advice from the Commission in order to avoid duplicating the activities of other Organizations.

3.4 Vitamin and Mineral Supplements (ALINORM 91/26, paras 126-128)

Several delegations at the session expressed support for the development of guidelines for those vitamin and mineral supplements which could be identified as foods. It was noted that there was increasing trade in such products and that there was a wide divergence of national legislation on how to control their presentation and composition.

The Committee agreed to advise the Commission that work in this area would be appropriate, and welcomed the offer of the Delegation of Germany to prepare a working paper on Vitamin and Mineral Supplements for consideration at the Committee's next Session.

SUMMARY OF CONCLUSIONS AND RECOMMENDATIONS

The 17th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (Bonn-Bad Godesberg, 18-22 February 1991, ALINORM 91/26) reached the following conclusions and recommendations:

- Advanced to Step 8 of the Procedure for Adoption by the Commission:
 - The Draft Standard for Formula Foods for Use in Weight Control Diets (paras 38-70, Appendix III).
 - The Draft Standard for the Labelling of and Claims for Foods for Special Medical Purposes (paras 71-85, Appendix IV).
 - The Draft Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (paras 18-37, Appendix II).
- Forwarded to Step 5 the following texts and in view of their advanced and extensive discussion, recommended to the Commission to consider omitting Steps 6 and 7 and adopt them at Step 8:
 - The Amendments to the General Principles for the Addition of Essential Nutrients to Food, Definition of "Fortification or Enrichment" and "Standardization" (paras 93-96, Appendix V - A, B).
 - The Amendment for the Maximum Level of Cocoa in Codex Standard for Processed Cereal-Based Foods (CODEX STAN 74-1981) (paras 97-99, Appendix V - C).
- Agreed that the Proposed Draft Standard for the Labelling of and Claims for "Low-Energy" and "Reduced-Energy" Foods should be withdrawn and that further developments should be in the context of the Proposed Draft Guidelines by CCFL (para. 92).
- Agreed to recommend to the CCFL that the reference RDAs in the Guidelines on Nutrition Labelling should be replaced by the nutrient reference values suggested by the Helsinki Consultation (September 1988) (para. 102).
- Considered a proposal for a Draft Standard for Formula Foods for Use in Very Low Energy Diets and decided to request the Commission's advice on whether to proceed with the elaboration of such a standard (para. 110, Appendix VI).
- Agreed to the Amendments to the Advisory List of Vitamin Compounds and Mineral Salts as proposed by the Ad-Hoc Working Group (paras 112-122, Appendix VII).
- Welcomed the proposal that consideration should be given to the recruitment of a Consultant who would examine all current nutrition recommendations and guidelines and Codex standards and prepare specific proposals for the Committee's future action (para. 107).
- Considered the issue of salt iodization and decided to seek guidance from the Commission in order to avoid duplication of the activities of other organizations (para. 125).
- Agreed to advise the Commission that work on vitamin and mineral supplements would be appropriate and to consider a special working paper on the subject at its 18th Session (paras 126-128).

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INTRODUCTION

1. The Codex Committee on Nutrition and Foods for Special Dietary Uses held its Seventeenth Session from 18 to 22 February 1991 at the Wissenschaftszentrum in Bonn-Bad Godesberg by courtesy of the Government of the Federal Republic of Germany. The Session was chaired by Prof. Dr. G. Pahlke, Director and Professor, Federal Health Office of the Federal Republic of Germany.

2. The Session was opened by Prof. Dr. Dieter Eckert, Ministerialdirektor of the Federal Ministry of Health, who welcomed the delegates on behalf of the Minister of Health. Prof. Eckert pointed out that despite the difficult international situation, many delegations had come to the Session, including delegates from developing countries and, for the first time, an observer from Albania. The speaker noted that this reflected the increasing importance and priority given to the work of the Codex Alimentarius Commission which over the past 30 years has established itself as the basis for world food legislation, and has made decisive contributions to protecting the health of the consumer and promoting fair practices in international trade. Prof. Eckert underlined the particular benefits that the developing countries have been deriving from the work of Codex in strengthening their national food legislation, and improving their international food trade. He also outlined some future directions of the work of Codex Alimentarius Commission as a unique organization for the worldwide exchange of new knowledge and experience particularly with the developing countries, the East-West exchange, the close collaboration with, and the continuation of, the Uruguay Round of GATT Talks. In this respect, Prof. Eckert particularly noted the extensive scope and the importance of the forthcoming Joint FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade, 18-27 March 1991, Rome.

3. Prof. Eckert pointed out the specific role played by the CC/NFSDU in the areas of health hazards, fraud and fair trade practices related to special and dietary foods, and in providing nutritional guidance in the work of the Commission. The speaker wished the participants success in their work.

4. The delegates were also welcomed by the Chairman of the Committee, Prof. Dr. Pahlke, who noted the increased participation of the member countries in the work of the CC/NFSDU and acknowledged the efforts of the people involved in the preparation for the Session.

5. Dr. Alan W. Randell, Senior Officer of the Codex Secretariat in Rome, read an address to Prof. Eckert on the occasion of his retirement on behalf of Mr. John R. Lupien, Director, Food Policy and Nutrition Division, FAO, Mr. R.J. Dawson, Chief, Joint FAO/WHO Food Standards Programme and himself. Prof. Eckert was praised for his contributions to the work of CAC over more than 22 years as a Chairman of the Commission, Chairman of the CC/NFSDU and Chairman of the German National Codex Committee.

6. The Session was attended by 90 delegates from the following countries:

Albania, Argentina, Australia, Austria, Belgium, Canada, Congo, Denmark, Finland, France, Germany, Iran, Italy, Japan, Netherlands, Norway, Spain, Sweden, Switzerland, United Kingdom and United States.

7. Observers were present from the following international organizations:

European Economic Community (EEC); International Dairy Federation; International Union of Nutritional Sciences (IUNS); International Special Dietary Foods Industries (ISDI); Comité Européen des Fabricants de Sucre; Association of Sorbitol Producers within the EEC (ASPEC).

A list of participants, including the FAO Secretariat, the WHO representative and the Technical Secretariat is annexed as Appendix I.

ADOPTION OF THE AGENDA (Agenda Item 2)

8. The Chairman recalled that at the last meeting, the Committee agreed that the Working Group on the Advisory Lists for Vitamin Compounds and Mineral Salts should meet during the 17th Session to continue its work on the lists. The Committee requested the Chairman of the Group, Dr. Chopra (USA), to reconvene the Group and prepare a report for discussion under Item 14 of the Agenda.

9. The Committee adopted the agenda as proposed in CX/NFSDU 91/1.

APPOINTMENT OF RAPORTEURS (Agenda Item 3)

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

MATTERS OF INTEREST ARISING FROM THE WORK OF THE 18TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 4)

11. The Secretariat highlighted the most relevant matters contained in the document CX/NFSDU 91/2 - Conference Room Document No.2. Attention was drawn to the endorsement and adoption by the Commission of a number of items which were included in the agenda of the session for further elaboration.

12. The Committee noted that the Codex Committee on Processed Meat and Poultry Products (15th Session, ALINORM 91/16, paras 39-56) had moved to Step 8 the Draft Guidelines for the Use of Standardized Non-Meat Protein Products in Processed Meat and Poultry Products.

13. The Committee noted that the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation (Bethesda, USA, December 1989) had concluded that the protein digestibility-corrected amino acid score was considered the most suitable method for evaluating protein quality of foods and also noted that this methodology was being used and recommended in the documents involving protein evaluation elaborated by the Committee.

14. The Committee noted that a Joint FAO/WHO/IAEA Expert Consultation on Trace Elements in Human Nutrition was convened in June, 1990 to update the evaluation of these elements last carried out in 1973. The recommendations of the Consultation are presented in the form of safe ranges of intake for populations and will be published. The essential elements iron and cobalt (in Vitamin B12) were not included since they had been dealt with in the publication on the requirements of Vitamin A, Iron, Folate and Vitamin B12 (FAO, 1988). The document will contain chapters on Iodine, Fluorine, Zinc, Selenium, Copper, Molybdenum, Chromium, Arsenic, Lithium, Aluminium, Strontium, Silicon, Cadmium, Lead and Mercury have also been treated briefly because of potential overexposure.

15. The Secretariat informed the Committee about the decision of the Directors-General of FAO and WHO to convene an International Conference on Nutrition in December 1992 in Rome. The Conference will be a major world event in the area of nutrition and its main objectives will be:

- (a) to identify the problems of malnutrition and related disease factors, their magnitude and geographical distribution, their causes and impact on the population and measures to overcome them;
- (b) to develop and adopt a strategy and proposals for action to reach agreed nutrition and dietary goals;
- (c) to mobilize additional financial resources for concentrated efforts by governments, non-governmental organizations and international organizations to implement the strategy;

- (d) to increase awareness of the magnitude, causes and consequences of malnutrition and of the benefit of sound nutritional status in order to create momentum behind actions for a human nutrition focus within the Fourth Development Decade; and
- (e) to establish a global system of collecting and disseminating information on year-to-year changes in nutrition status of the populations with particular reference to the vulnerable groups.

16. The Committee noted with great interest the preparations for the Conference which involve all United Nations bodies dealing with nutrition as well as governments, non-governmental organizations and international institutions.

17. The representative of WHO described some activities of the Organization of interest to the Committee. One of these was the WHO Study Group on Diet, Nutrition and the Prevention of Chronic Diseases. The report of the Study Group containing the recommendations has been published in the WHO Technical Report Series, 1990 (TRS 797). Reference was also made to the document on Infant and Young Child Nutrition - progress and evaluation report and status of the implementation of the International Code of Marketing of Breast-Milk Substitutes. This document contains also a section on recent progress on the prevention of iodine deficiency disorders. The Committee was also informed about the First European Conference on Food and Nutrition Policy held in Budapest in October 1990 with the objective of defining broad coordinated policy programmes involving all member countries of the European Region.

DRAFT GUIDELINES ON FORMULATED SUPPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN AT STEP 7 (Agenda Item 5)

18. The Committee recalled that the Draft Guidelines had been considered by the 18th Session of the Commission (July 1989) at Step 8 of the Procedure, and that the Commission had decided to return the Guidelines to Step 6 of the Procedure for another round of government comments (ALINORM 89/40, paras 351-353). Comments were subsequently sought by means of Circular Letter 1990/6-NFSDU. The Committee had before it the Draft Guidelines as contained in Appendix III of ALINORM 89/26 and the comments of Cuba, Denmark, Egypt, France, Germany, Thailand and the United States contained in CX/NFSDU 91/3. Additional comments from Canada, France and Italy were provided in document CX/NFSDU 91/3-Add. 1 (CRD No. 5).

19. The Committee also recalled the background to the present Draft Guidelines, and the wish expressed by developing countries through FAO and WHO for guidance in preparing foods for infants and children from locally-available raw materials. It noted the comment of the Delegation of the Netherlands that both the title and the definition of the foods were ambiguous, covering not only the foods intended to be covered by the Guidelines, but also other similar foods. It also noted the statement of the Delegation of Argentina that as yet no provision had been made for such foods in their national food code, but the Draft Guidelines provided a good basis for such a provision.

Definitions

20. The Committee agreed to define the term "older infants" in place of the definition for "infants" (Section 3.2). "Older Infants" was defined as "a person from the 6th month and not more than 12 months of age".

Basic Ingredients

21. The Committee noted the comments of Canada and the USA in regard to complex carbohydrates and sugars (Section 4.2.2). The term "complex carbohydrate" was replaced by "digestible carbohydrate" so as to exclude any possible misunderstanding as to the nature of the permitted additions.

Technologies for and Effects of Processing

22. On the proposal of the Delegation of Germany, an additional paragraph referring to the effects of extrusion cooking was included under Section 5.5.1.

Formulation

23. The Committee noted that in certain countries or localities nutritional supplements may be provided through maternal and child health centres or other agencies. In such cases supplementation of foods with the same vitamins or minerals provided through these centres would not always be necessary. It agreed to reword Section 6.1.6 to reflect this.

24. The Delegation of Denmark proposed that the amino-acid score of the protein, corrected for digestibility, should be not less than 70 per cent of that of casein (Section 6.3.2). Reference to the amino-acid profile proposed by FAO/WHO/UNO (1985) for children of pre-school age (2-5 years) was deleted accordingly.

25. The Committee decided to include a maximum level of energy which should be derived from fat (Section 6.4.1), and included a level of 40 per cent as the maximum.

26. Noting the comments of several delegations concerning the problem of excessive fibre in foods intended for older infants and young children, especially in products derived from many different cereal sources, the Committee agreed to recommend that the level of dietary fibre should not exceed 5 g per 100 g (Section 6.5.2).

Labelling

27. The Delegation of the Netherlands drew attention to potential confusion in the use of the Name of the Food (Section 9.2.1.1) as "Formulated Supplementary Foods for Older Infants and Young Children". The Delegation noted that foods covered by the Guidelines were not necessarily formulated or supplemented, and that they could include foods covered by other Codex Standards. It was also noted that local names might be used in accordance with national legislation. The Delegation of Switzerland supported this opinion and stated that the further development of the Guidelines would lead to confusion between products prepared in accordance with existing standards, mainly that on Cereal-Based Products for Infants and Children, and those prepared under the Guidelines.

28. The Delegation of Argentina expressed the view that the Country of Origin and the Use of an Expiry Date should be explicitly stated in the Guidelines.

29. The Committee agreed on the following text for Section 9.2.1.1:

"9.2.1.1 The name of the food to be declared on the label shall indicate that the food is a formulated supplementary food, as appropriate, for older infants and younger children. The appropriate description should be in accordance with national legislation. "

30. The Committee also amended Section 9.2.1.2 (b) to bring it into conformity with the new definition for "older infants".

31. The Committee agreed to the expression of energy in both kilocalories and kiloJoules in accordance with the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses, and similarly argued to retain reference to the use of metric units in relation to the expression of vitamin content.

32. The Delegation of the United Kingdom drew attention to the burden imposed by the mandatory declaration of the content of vitamins and minerals, especially in relation to the analytical facilities required and the problem of consumers' understanding. The observer from the International Union of Nutritional Sciences stated that the nutrient declarations should refer to the totals in the finished food as consumed. It was inappropriate not to include nutrients derived from the raw materials, e.g., niacin and protein derived from a rice-based supplementary food. Relative to deriving the nutrient quantities declared on the product label, the observer stated that in the "worst-possible-case" situation without analytical capabilities, one could safely resort to published nutrient values for raw material

ingredients, plus accurately added amounts of nutrients. In many technologically advanced countries, very sophisticated compliance procedures had been introduced to ensure label accuracy within narrow specified limits. But, when there were minimal analytical capabilities, as may exist in some developing countries, this should not impede manufacture and use of locally produced supplementary foods consistent with the Guidelines.

33. The Committee agreed to replace Section 9.2.3 (c) with Section 9.3 (b) of the Standard for Cereal-Based Foods for Infants and Children (CODEX STAN 74-1981) which required the quantitative declaration of added nutrients only.

Model Nutrient Profile

34. The Committee established a small ad-hoc Working Group to review the content of the Model Nutrient Profile. The meeting was attended by representatives from Canada, France, Italy, the United Kingdom and the United States. The Working Group proposed amendments to the table of nutrients which deleted specific reference to levels of energy, fat and fibre as these were adequately covered in the main text of the Draft Guidelines. A new section of the Guidelines (6.3.5) was proposed concerning protein content. The Committee accepted the proposals of the Working Group and a proposal of the Delegation of Japan that reference to the need to take into account all conditions prevailing in different countries be maintained (see Section 6.1.1).

35. The Delegation of Argentina, referring to the Model Nutrient Profile, informed the Committee that the Ministry of Health and Social Action had provided for the incorporation of vitamins and minerals in other dietary supplements.

Status of the Guidelines

36. The revised Draft Guidelines, as contained in Appendix II to this report, were advanced to Step 8 of the Procedure for consideration by the Commission. The Delegation of Switzerland, supported by that of the Netherlands, reserved their positions on the Committee's decision, stating that their previously stated concerns about overlapping of the Guidelines with the existing Codex Standard had not been resolved. Therefore, the Delegation of Switzerland requested that in order to avoid confusion the Codex Standard for Cereal-Based Foods for Infants and Children should be revised in the light of the Draft Guidelines and that the two texts should be combined. The Delegation of France supported the proposal to revise the Standard for Cereal-Based Foods for Infants and Children.

37. The Committee noted the concerns about the overlapping of the Draft Guidelines with existing standards, mainly the Standard for Cereal-Based Foods, and requested the guidance of the Commission in this regard.

CONSIDERATION OF A DRAFT STANDARD FOR FORMULA FOODS FOR USE IN WEIGHT CONTROL DIETS (Agenda Item 6)

38. For the discussion of this item, the Committee had before it the Appendix V to ALINORM 89/26, and the papers CX/NFSDU 91/4 and CX/NFSDU 91/4-Add.1, CRD 6, containing the comments of Cuba, Denmark, Egypt, Finland, Federal Republic of Germany, the United States of America, France, Italy and Canada. These comments were taken into account during the discussion of the agenda. In replying to an inquiry by France, the Chairman recalled the decision of the Committee (ALINORM 89/26, para. 113) that the words "nutritionally complete" should be deleted from the title.

2. DEFINITION

39. Several delegations expressed concern that the definition did not make a clear distinction between foods for use as replacements of one or more daily meals and those which could replace the whole diet. The representative of the EEC and the UK Delegation pointed out that two different products may be involved. The Delegation of Canada pointed out that on the Canadian and possibly some other markets the same product could be proposed for one or more meals as well as for replacement of the total diet.

40. The French Delegation proposed that very low calorie diets be specifically excluded from the definition. This proposal was not accepted by the Committee.

41. The Delegation of Argentina stated that there were no rules in his country concerning formula foods for weight control diets and that they were not defined in the way proposed by this standard. The Committee agreed with the following definition:

"Formula foods for use in weight control diets are foods which, when presented as "ready-to-serve" or prepared in conformity with directions for use, are presented as a replacement for all or part of the total daily diet."

3.1 Energy Content

42. Several delegations pointed out that the composition and energy content would depend on what type of replacement was involved. The Delegation of the United Kingdom noted that control of energy content and composition should be much stricter in the case of total daily diet replacement than in single meal replacement.

43. The Delegation of the Federal Republic of Germany argued that the important consideration should be for the consumer to meet the essential nutritional requirements regardless of the type of product. The French and the Canadian Delegations proposed that the problem could be addressed by proper labelling and instructions for use. The Committee was unanimous that one single standard with one set of nutritional requirements should be elaborated.

44. The Delegations of Switzerland, The Netherlands and France supported the following "Provisions for Energy Content":

3.1.1 A formula food presented as a replacement for all meals of the daily diet shall provide not less than 800 kcal (3350 kJ) and not more than 1200 kcal (5020 kJ). The individual portions or servings contained in these products shall provide approximately one third or one fourth of the total energy of the product depending on whether the recommended number of portions or servings per day is 3 or 4 respectively.

3.1.2 A formula food presented as a replacement for one or more meals of the daily diet shall provide not less than 200 kcal (835 kJ) and not more than 400 kcal (1670 kJ) per meal. When such products are presented as a replacement for the major part of the diet, the total energy intake shall not exceed 1200 kcal (5020 kJ).

45. The Committee agreed with these provisions.

3.2 Nutrient Content

46. The Delegation of the United States of America proposed that a single compositional standard be adopted, based on 100% and 25% of FAO/WHO recommended daily allowances for the total replacement for all meals and a single meal respectively.

47. The Delegations of the Netherlands, France and Canada could not agree with such a provision and noted that specific compositional figures should be included in the standard with an appropriate footnote stating that they should be kept under review and updated as necessary.

3.2.1 Protein

48. The Delegation of Canada recalled its written proposal for rewording this section as presented in CX/NFSDU 91/4-Add.1, CRD 6. The Delegations of France supported the Canadian proposal on principle but argued strongly in favour of a fixed maximum value of 120 g of protein content.

49. The Committee agreed to delete Section 3.2.1.2 and to include the following text for 3.2.1.1 as proposed by Canada and modified to include an upper limit for protein:

"3.2.1.1 A minimum of 25% and a maximum of 50% of energy available from the food when "ready-to-serve" shall be derived from its protein content. The total amount of protein shall not exceed 125 g in the daily intake. "

3.2.3 Carbohydrates

50. The Delegation of the United States questioned the need for upper limits on sugars but supported the limits for sugar alcohols (polyols). Canada agreed that no upper limits for sugars are needed. The representative of EEC stated that the Scientific Committee for Food of the EC, in its report on the subject, had proposed no limits for sugars while for polyols it had recommended that a statement as to the laxative effects should appear on the label when polyol intake exceeds 20 g per day.

51. The Delegation of the Federal Republic of Germany pointed out that in view of the insulin-secretory effect and the undesirable sense of hunger produced by carbohydrates, a restriction on the content of sugars would be useful. A total of 70-90 grammes of available carbohydrates, preferably complex ones, should be ingested with the recommended daily intake of the product in order to avoid the detrimental ketogenic effects of a reducing diet which is rich in fats. Sugar alcohols should not be used. The Delegation of The Netherlands supported this statement in so far as it concerns a minimum level of carbohydrates.

52. The Secretariat informed the Committee that an upper limit on polyols would be in contradiction to the provisions for food additives under Section 4 of the Standard. The Joint FAO/WHO Expert Committee on Food Additives had evaluated polyols on a "no ADI specified" basis. The observer of the EEC proposed that a statement concerning the possible laxative effect of polyols be included on the label. The Committee accepted this proposal and agreed to delete the Section on Carbohydrates.

3.2.4 Vitamins and Minerals

53. The Delegation of the United Kingdom proposed that the list of vitamins and minerals be checked and accurately referenced. Several delegations (UK, France, the Netherlands) were of the opinion that the highest values, whether for the adult male or, as for example in the case of iron, the female, should be included in the list. They also recommended that a note be included to the effect that these values would be subject to automatic revision in accordance with FAO/WHO work on various nutrients.

54. The representative of the EEC expressed concern that the proposal for an automatic revision of these values would introduce an element of uncertainty and fluidity which may affect the usefulness of the standard in international trade.

55. The Secretariat informed the Committee that the selected list of minerals and vitamins should be based on the best available knowledge. The Secretariat proposed that a single set of values be included and that any changes should be introduced by decision of the Committee in accordance with an accepted procedure in the Codex Committee on Food Additives and Contaminants. A continuing item could be included in the agenda of the Committee devoted to considering any appropriate changes in the values. The values in the draft standard were revised in accordance with the latest values of FAO and WHO.

56. The Delegation of Denmark proposed that minimum and maximum levels be included in the list.

57. The Delegation of Norway supported this proposal and also suggested that upper limits for iodine be included in accordance with the evaluation by JECFA. The Secretariat brought to the attention of the Committee written proposals by the Delegation of Thailand for inclusion of biotin, vitamin K and pantothenic acid. The Chairman noted that all these proposals could be included for consideration by the Committee in its future sessions.

58. The Committee agreed to the revised list of vitamins and minerals, and also agreed to include in the agenda of its future sessions a continuing item on the consideration of changes in the scientific advice provided by FAO/WHO on nutrient intakes.

9. LABELLING

9.1 The Name of the Food

59. The Committee agreed with the proposal of the Delegation of the Netherlands that the name of the food should be "Meal Replacement for Weight Control" and that there was no need to require the addition of a common name.

9.3 Declaration of Nutritive Value

60. The Committee agreed that this section should be amended so that its wording conformed with the relevant section of the Codex Guidelines on Nutrition Labelling.

61. The Delegation of Argentina asked that a subsection should be added stating that the country of origin be made mandatory. But the Secretariat pointed out that this has not yet been agreed by the Codex Committee on Food Labelling.

9.10 Information for Utilization ^{1/}

62. The Delegation of France proposed that Section 9.10.2 (b) and 9.10.2 (c) be deleted and that 9.10.2 (a) should be extended with the inclusion of indications of the need to obtain sufficient dietary fibre. The Delegation of Italy and the Netherlands supported this. However, the Delegation of Canada supported by the Delegation of the Federal Republic of Germany proposed deleting the whole of Section 9.10 as it did not provide any essential information.

63. The Committee agreed to delete Section 9.10 and to record that this was not supported by the Delegations of France and Italy.

9.11 Additional Provisions

64. The Delegations of France and the United States of America agreed to the proposal from Canada that Sections 9.11.4 and 9.11.5 be deleted. The Delegation of France proposed an alternative wording in place of 9.11.5 stating clearly that when the formula food is used to replace the total daily diet for more than 3 weeks, this should be done under medical supervision.

65. The Delegation of Canada recalled its written proposition concerning the revision of 9.11 presented in CX/NFSDU 91/4-Add.1, CRD 6. The Delegation of the United States of America supported the proposed text. The Delegation of the Netherlands also supported the Canadian wording for 9.11 and also expressed strong opposition to Section 9.11.3 which envisages the inclusion in the label of scientific references and sources of nutritional counselling. Support for the Canadian proposal was also stated by the Delegations of Sweden and the United Kingdom.

66. The Delegation of France agreed with the Canadian revision of 9.11, but strongly insisted on the inclusion of a provision of a fixed time period of 3 weeks of use of the food after which medical counselling should be sought.

67. The position of France was supported by the Delegations of Denmark, Italy, Spain, Finland and Norway. The Delegations of the Netherlands and Switzerland agreed in principle with the French view, but proposed as a compromise that the time period

^{1/} The numbers of the Sections referred to in paras 60-68 are those appearing in Appendix V of ALINORM 89/26.

should be fixed at 6 weeks. The Delegations of Sweden and the United Kingdom were, however, of the opinion that the products as formulated were safe to use and that no such warning statement was needed.

68. The Delegations of Germany and USA and the observers from the IUNS and ISDI were of the opinion that provisions for medical guidance would only be necessary if accompanying disease conditions such as heart or kidney disorders were already present.

69. Although the UK expressed its reservation to the proposed Section 9.11.5, the Committee agreed to include the following text for Section 9.11:

"9.11 Additional Provisions

9.11.1 The label and labelling shall not make any reference to the rate or amount of weight loss which may result from the use of the food or to a reduction in the sense of hunger or 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 formulae foods for weight control are used.

9.11.3 If the food provides a daily intake of sugar alcohols in excess of 20 g per day, there shall be a statement on the label to the effect that the food may have a laxative effect.

9.11.4 The label and labelling shall carry a statement to the effect that the food may be useful in weight control only as part of an energy-controlled diet.

9.11.5 For those products presented as replacements of the total diet for a period of more than 6 weeks, the label should contain a statement recommending that medical advice be sought. "

70. The Committee agreed to advance the revised standard to Step 8 of the Procedure and to recommend its adoption by the Commission. The revised version is attached as Appendix III.

CONSIDERATION OF THE DRAFT STANDARD FOR THE LABELLING OF AND CLAIMS FOR FOODS FOR SPECIAL MEDICAL PURPOSES AT STEP 7 (Agenda Item 7)

71. The Committee had before it the Draft Standard as adopted by the Commission at Step 5 (ALINORM 89/26, Appendix IV) and comments received in response to Codex Circular Letter 1990/6-NFSDU as follows: CX/NFSDU 91/5, comments from Cuba, Denmark, Egypt, France, Germany, Thailand, United States and the EEC; CX/NFSDU 91/5-Add. 1, CRD No. 8, comments from ISDI; CX/NFSDU 91/5-Add. 2, comments from Canada, France and Italy; and CX/NFSDU 91/5-Add. 3, CRD No. 7, comments from IUNS.

Scope

72. The Committee agreed to delete the square brackets around the words "and presented as such".

73. The Delegation of Argentina noted that foods with drugs or non-nutrient substances, or food which because of their special composition and therapeutic value were considered as medical products in the Argentinian Food Code.

Definition

74. The observer from IUNS reported on the outcome of a workshop held in Taxco, Mexico, in January 1989, by the IUNS Committee on Nutritional Aspects of Food Standards, at which the proposed draft standard had been discussed. He noted that the definition needed further expansion to describe more completely the nature of the products encompassed by the standard. This position was supported by the

representative of ISDI who referred to three identifiable groups of products for which specific labelling provisions were required.

75. After considerable discussion the Committee agreed to retain the existing definition, but with modification to indicate that foods were foods for special medical purposes only if they were presented as such, and to improve the paragraph editorially. The representative of ISDI pointed out that the definition could exclude a number of foods presented for special medical purposes which may have other uses as well. The Delegation of France pointed out that the definition was both precise and flexible and covered the range of products appropriately.

General Principles

76. The Committee concurred with the Delegation of France that the opening sentence of the section could be deleted as it duplicated principles already expressed in the Commission's general standards on labelling. It also agreed with the proposal of the Delegation of Canada that the formulation of these foods should be based on recognized nutritional and medical principles, and that their use should be demonstrated to be safe and beneficial.

77. The Delegation of France proposed the inclusion of a statement prohibiting the advertising of foods for special medical purposes to the general public. The Committee noted that this was indeed a characteristic of the marketing of these foods in many countries and agreed to the inclusion of this provision. However, the Secretariat pointed out that the question of advertising as part of the mandate of the Codex Alimentarius Commission had been the subject of considerable debate, and the advice of FAO and WHO Legal Counsels had been that the Commission's mandate did not extend to the preparation of standards on advertising. The Committee was of the opinion that its inclusion may be appropriate in this particular standard, and agreed to bring it to the attention of Legal Counsel for advice.

Nutrition Labelling

78. The Committee agreed to amend Section 4.2.2 of the standard to require the labelling of energy content in both kilocalories and kiloJoules, as in other texts. It did not accept a proposal of the Delegation of Switzerland to delete the requirement to indicate, when appropriate, the acid-base balance (Section 4.2.5) as this was felt to be important in certain cases. This section was amended to indicate that osmolarity, osmolality and/or acid-base balance would be declared. The Delegation of Italy noted that the declaration of viscosity was also required in that country to facilitate tube-feeding.

79. Following a proposal by the Delegation of Italy in regard to the declaration of nutrients in the case of foods for pediatric uses, the Committee agreed to amend Section 4.2.6 to read:

"In addition, where it is appropriate, the quantity of nutrients may be expressed in terms of the percentages of the relevant internationally recognized recommended daily allowances. "

80. Although several delegations recommended determining reference to the amino acid, fatty acid or carbohydrate profile, the Committee agreed that Section 4.2.9 should be amended to indicate the nature of any specific modification and to allow the inclusion of information on the amino acid, fatty acid or carbohydrate profile where necessary. The square brackets surrounding this section were removed.

Date Marking

81. The Committee agreed with the Representative of the European Community that the Date of Minimum Durability was appropriate for these products, and amended this section accordingly. The square brackets were removed.

Additional Requirements

82. The Committee decided to separate the information which should be presented on the label of the food from the information which could be contained in accompanying documents. The latter documents include leaflets directed primarily at qualified health care personnel, and these could be provided separately from the package. In this regard the Committee used the written comments of Canada as a basis for its discussions. The Delegations of Australia, Canada and Denmark noted that national legislation in these countries prohibited claims on labels related to the treatment of specific disorders or medical conditions in foods sold directly to the public without prescription.

83. Upon the proposal of the Delegation of Germany, supported by the observer from ISDI, the Committee deleted the provision requiring a specific warning concerning adverse effects on reproductive functions, the developing foetus and breast-milk quality or quantity. It was noted that this information would be included if necessary among the known contraindications already required to be stated in the labelling. The Committee did not accept the proposal of the Delegation of the United States to delete this latter provision, or to amend it by deleting reference to drug-product interactions, as these were known to occur with certain formulations.

84. The Committee agreed to include a new provision specifying that there should be a prominent statement in the labelling indicating if the product was intended for use by a specific age group.

Status of the Standard

85. The Committee agreed to advance the Draft Standard for the Labelling of and Claims for Foods for Special Medical Purposes, as contained in Appendix IV to this report, to Step 8 of the Codex Procedure.

CONSIDERATION OF THE PROPOSED DRAFT STANDARD FOR THE LABELLING OF AND CLAIMS FOR "LOW-ENERGY" AND "REDUCED-ENERGY" FOODS AT STEP 4 (Agenda Item 8)

86. The Committee had before it the Proposed Draft Standard as contained in ALINORM 89/26, Appendix VI, and comments obtained in response to Circular Letters 1988/56-NFSDU and 1990/6-NFSDU, as follows: CX/NFSDU 91/6 - Cuba, Denmark, Finland, Germany, Italy, Spain, Thailand, United States; CX/NFSDU 91/6-Add. 1 (CRD No. 9) - Canada, France and Italy.

87. In introducing the documents, the Secretariat noted that the Commission at its Eighteenth Session had endorsed the decision of the Executive Committee (Thirty-sixth Session, ALINORM 89/4, paras 37 and 38) that the Codex Committee on Food Labelling held the primary responsibility for consideration of nutritional claims. It also stated that the CCNFSDU should retain the responsibility of advising the CCFL on what levels for reduction or increase of a nutritional component should qualify for the use of an appropriate nutrient descriptor (ALINORM 89/40, para. 269).

88. The Committee recalled that the words "for Special Dietary Uses" had been deleted from the Title of the Proposed Draft Standard at the Committee's previous session.

89. In considering the definition of "low-energy food" the Committee noted in particular the reservations of Finland, France and Italy it was not necessary to establish a standard or definition for these foods.

90. The Committee agreed to specify a maximum level of energy for such foods of 40 kilocalories (170 kiloJoules) for specified serving and that the energy density of solid foods should not exceed 40 kilocalories (170 kiloJoules) per 100 g. The Delegations of Germany and Switzerland expressed a preference for an energy density of 50 kilocalories per 100 g and the Delegation of France proposed 100 kilocalories per 100 g. In regard to liquid foods, the Delegations of Austria, France and the United Kingdom proposed a maximum energy density of 10 kilocalories per 100 ml in place of 20 kilocalories per 100 ml, but the Committee did not decide on a suitable figure. The

Delegation of the Netherlands expressed doubt as to the feasibility of manufacturing solid foods complying with the requirement of 40 Kcal/100 g.

91. The Delegation of Australia noted the importance of linking the maximum level of energy with specific serving sizes (or reference quantities) which would vary depending on the nature of the product.

Status of the Standard

92. The Committee noted that the Twenty-First Session of the CCFL would have before it proposed Draft Guidelines for Use of Health and Nutrition Claims in Food Labelling (CX/FL 91/9) which covered the question of "low-energy" and "reduced-energy" foods, but which was far more comprehensive. In order to avoid duplication of work, and along the lines recommended by the Commission (see above) the Committee agreed that the proposed draft standard should be withdrawn, and that further development should be in the context of the Proposed Draft Guidelines by CCFL. The Committee looked forward to the opportunity to provide the appropriate nutrition-related advice on the Guidelines.

CONSIDERATION OF PROPOSED AMENDMENTS TO THE GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (Agenda Item 9 (a))

93. The Committee recalled that following the adoption by the Commission of the General Principles (ALINORM 87/26, App. V) the CCNFSU had proposed at its 16th Session the inclusion of definitions for "nutrient density", "Fortification or Enrichment" and "Standardization". The Commission (18th Session) adopted the definition for "nutrient density" and recommended that the other two definitions as presented in ALINORM 89/26, App. VIII be circulated for further review.

Definition for "Fortification and Enrichment"

94. The Committee considered the comments on the proposed definitions submitted by Cuba, Denmark, Egypt, Finland, Federal Republic of Germany, Italy, Spain, Thailand, United States, as presented in CX/NFSU 91/7 and the comments of Canada presented in CX/NFSU 91/7-Add.1, CRD 10. The Delegations of Switzerland and France expressed support for the second definition of fortification or enrichment. The Committee noted that this was the one favoured by most government comments. It decided to advance it to Step 5 with the recommendation that the Commission adopt it at Step 8 with the omission of Steps 6 and 7. The definition is attached in Appendix V, A.

Definition for "Standardization"

95. The Committee noted that the written comments were generally supportive of the definition of "standardization" as presented in Appendix VIII of ALINORM 89/26, apart from those of the United States, Denmark and Finland.

96. The Delegation of the United States stated that in its opinion the definition of standardization was covered by the definition for restoration, but it would not oppose its inclusion in the General Principles. The Delegations of Denmark and the Netherlands still found the definition unnecessary but stated that it would accept it for inclusion in the Principles, and the delegation of Finland also expressed support for the definition. The Committee agreed to adopt the definition as originally proposed by Switzerland in Appendix VIII of ALINORM 89/26 and to advance it to Step 5 with the recommendation that Steps 6 and 7 be omitted and that the Commission adopt it at Step 8. The definition is attached in Appendix V, B.

CONSIDERATION OF MAXIMUM LEVELS FOR COCOA IN THE CODEX STANDARDS FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND CHILDREN (CODEX STAN 74-1981) (Agenda Item 9 (b))

97. The Committee recalled that at its last session the Delegation of Switzerland had proposed that the existing maximum level of 5% cocoa on a dry basis in the standard be changed into maximum level 1.5% in the ready-to-eat product. Comments on this proposal are contained in Appendix VIII of ALINORM 89/26 had been requested, and the written replies of Cuba, Denmark, Egypt, Finland, Federal Republic of Germany,

Italy, Spain, Thailand and the United States were presented in document CX/NFSDU 91/7. The Committee noted that all comments supported the proposal, except those of Spain and Finland who preferred the existing levels.

98. The Delegation of Finland stated that it still preferred the existing values, but would support the amendment since it was satisfied that the new provision for cocoa would not lead to increased exposure to toxic substances as shown by the written comments of the United States. The Delegation of Spain did not find the proposed changes entirely justified, but stated that it would not oppose the amendment.

99. The Committee agreed to endorse the amendment and to move it to Step 5. Considering the wide support for the proposal, the Committee decided to recommend to the Commission to omit Steps 6 and 7 and to adopt the amendment at Step 8. The amendment is attached as Appendix V - C.

CONSIDERATION OF THE REPORT OF THE JOINT FAO/WHO EXPERT CONSULTATION ON RECOMMENDED ALLOWANCES FOR NUTRIENTS FOR FOOD LABELLING PURPOSES (Agenda Item 10)

100. The Committee recalled that it had received an advance copy of the report of the Consultation which had been held in Helsinki in September 1988, at its last session (ALINORM 89/26, paras 41-47), and governments had been invited to comment on the report. Comments in response to Circular Letters 1989/19-FL, 1989/43-FL and 1990/6-NFSDU had been received from Denmark, Finland, Germany, Thailand, United States and EEC (CX/NFSDU 91/8), Spain (CX/NFSDU 91/10), Italy and IUNS (CX/NFSDU 91/8; Add.1 - CRD No. 15).

101. The observer from the EEC expressed the Community's thanks to FAO and WHO for the report of the Consultation and informed the Committee that the newly adopted Directive on Nutrition Labelling for Foodstuffs (90/496/EEC) contained identical values to those recommended for use as Nutrient Reference Values by the Consultation. He also noted that the values were under review by the EEC Scientific Committee for Food.

102. The Committee agreed with the proposal from the EEC to recommend to the CCFL that the Reference RDAs in the Guidelines on Nutrition Labelling should be replaced by the Nutrient Reference Values from the Helsinki Consultation. It also agreed with the proposal from the EEC that the following amendment be made to the appropriate paragraph of Section 3.3.4 of the Guidelines on Nutrition Labelling:

"In order to take into account future scientific developments, future FAO/WHO and other expert recommendations and other relevant information, the list of nutrients and the nutrient reference values should be kept under review. "

CONSIDERATION OF THE NUTRITIONAL ASPECTS OF THE USE OF TROPICAL OIL IN FOODS AND IMPLICATIONS FOR LABELLING (Agenda Item 11)

103. In introducing this item the Secretariat noted that the question had originally been raised by the Codex Coordinating Committee for Asia. The Committee was informed that FAO and WHO had agreed to convene a Joint Expert Consultation on Fats and Oils in Human Nutrition in 1992/93. This Consultation was planned as a major in-depth review of developments in all aspects of fats and oils. The preparation for the Consultation was likely to involve a number of preliminary specialized task groups similar to the procedure adopted by the FAO/WHO Expert Consultation for Vitamin A, Folate, Iron and Vitamin B12, and the recent FAO/WHO/IAEA Expert Consultation on Trace Metals in Human Nutrition.

104. The Committee noted that the exhaustive nature of the planned expert consultation would certainly have important implications for fats and oils standards and labelling. The Committee therefore agreed that it would be premature for it to undertake any action before the findings and the recommendations of this consultation became available.

NUTRITION GUIDELINES ON INTAKES OF FAT, SUGARS, SODIUM AND FIBRE AND THEIR IMPLICATION ON FOOD STANDARDS (Agenda Item 12)

105. The Committee recalled that, at its last session the Working Group on Nutritional Aspects of Codex Standards had suggested that the Committee should consider how it should go about developing new compositional standards or nutrition guidelines to address the concern over excessive intakes of fat, sugars and sodium and inadequate intake of fibre which is particularly acute in developed countries. It also drew attention to the need to consider whether some standards, by having 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 1988/56-NFSDU. Comments were received from: Cuba, Denmark, Finland, Germany, Italy, Spain, Thailand, USA (CX/NFSDU 91/10).

106. The Committee noted that the comments strongly supported work by the Committee in this area but did not provide clear guidance on how such work was to be carried out. It did however, note that the FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade (March 1991) would be considering how the development of general standards in all areas of the Codex Commission's work could be achieved. The WHO representative reported that a recent report of a WHO Study Group on Diet, Nutrition and Prevention of Chronic Disease also contained recommendations that the Codex Alimentarius Commission should undertake work in this area.

107. In view of the need for clear recommendations on a programme of work, the Secretariat proposed that consideration should be given to the recruitment of a consultant who would examine all current nutrition recommendations and guidelines and Codex standards and prepare specific proposals for the Committee's future action. The Committee welcomed this proposal.

CONSIDERATION OF A PROPOSAL FOR A DRAFT STANDARD FOR FORMULA FOODS FOR USE IN VERY LOW ENERGY DIETS (Agenda Item 13)

108. The Committee recalled that during its discussions on the Proposed Draft Standard for Formula Foods for Use in Weight Control Diets at the 16th Session of the CC/NFSDU, the Delegation of the Netherlands was of the opinion that very low-energy formula foods should also be covered by this standard, as such foods were hazardous if used improperly and therefore should be adequately controlled. The Committee noted that opinion that such foods would be foods for special medical purposes, and invited the Delegation of the Netherlands to prepare a paper on very low energy nutritionally complete formula foods for the present session (ALINORM 89/26, para. 115). The paper was available to the Committee as CX/NFSDU 91/11 (CRD No. 4).

109. In response to a suggestion that this should be a regional standard, the Delegation of Congo, supported by those of the Netherlands and the United Kingdom, stated that the problem of obesity was world-wide and as prevalent in the urban areas of most developing countries as it is in industrialized ones.

110. The Committee agreed to request the Commission to advise on whether to proceed with the elaboration of such a standard. It also agreed that government comments should be sought by Circular Letter on this matter, and on the Proposed Draft Standard itself, should the Commission agree to its further elaboration. The delegation of Switzerland suggested that such products should provide 400-800 Kcal per day rather than 450-600 Kcal.

111. The Proposed Draft Standard is contained in Appendix VI to the present report.

REPORT OF AN AD-HOC WORKING GROUP ON ADVISORY LISTS FOR VITAMIN COMPOUNDS AND MINERAL SALTS (Agenda Item 14)

112. The report of the Working Group was presented by its Chairman Dr. J. Chopra of the United States of America (CX/NFSDU 91/12, CRD No. 16).

113. The Working Group met during the 17th Session of the CCNFSU. The meeting was attended by representatives from Canada, Germany, France, The Netherlands, Norway, Sweden, Switzerland, United Kingdom and the United States of America. The following documents formed the basis of the discussion: ALINORM 89/26, paras 191-199; CL 1988/56-NFSU; CL 1990/6-NFSU.

114. Dr. Chopra reported to the plenary session that the Working Group considered the proposal of the Delegation of Switzerland for the amendment of the Codex Standard for Foods for Special Dietary Uses including Foods for Infants and Children (CAC/Vol. IX-Ed. 1, Part IV (Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children)).

115. The Delegation of Switzerland specifically requested the Working Group to consider the addition of the following compounds to the advisory list:

- Hydrochloric acid as a source of chloride.
- Phosphoric acid as a source of phosphorus.
- Silicon dioxide as an anticaking agent.
(A maximum level in ready-to-use foods of 10 mg/kg).
- Gum Arabic (gum acacia) as a stabilizer for vitamins.
(A maximum level in ready-to-use foods of 100 mg/kg).

116. On the basis of available information the Working Group concluded that hydrochloric acid, phosphoric acid and silicon dioxide were safe, biologically available (hydrochloric and phosphoric acid) and met the purity criteria (ALINORM 89/26, para. 192). The Working Group therefore recommended to the plenary session, that the aforementioned compounds should be added to the advisory list.

117. The Working Group also considered the proposal of the Delegation of Switzerland to add to the advisory list gum arabic (gum acacia), it is needed as a stabilizer for vitamins. Gum arabic is used extensively by the baby food industry as an emulsifier, flavouring agent, formulation aid, stabilizer and thickener. It is safe and meets the purity criteria. The Working Group recommended to the plenary session that gum arabic should be added to the advisory list.

118. The proposal by the Delegation of Switzerland to increase the maximum level of dextrans and modified starches from 100 mg/kg to 500 mg/kg in ready-to-use products (para. 198, ALINORM 89/26) was withdrawn on 26 February 1990. The maximum level of 100 mg/kg established earlier remains unaltered (CAC/Vol. IX-Ed. 1, Suppl. 1, page 11).

119. At its 16th Session, the CCNFSU requested the Secretariat to obtain from CCFAC endorsement for the proposal from the Delegation of Switzerland concerning the addition to the advisory list of gum arabic (gum acacia) as a stabilizer for vitamins and silicon dioxide as a anticaking agent. The plenary session was informed by the Secretariat that at the 22nd session the CCFAC endorsed the use of gum arabic and silicon dioxide in baby foods for the purposes stated above.

120. The Working Group reconsidered the proposal of the Delegation of the Netherlands to add potassium iodate as a source of iodine to the advisory list of mineral salts. On the basis of available information the Working Group concluded that potassium iodate is safe and suitable as a nutrient source. It is an approved food additive, is biologically available, and meets the purity criteria. The Working Group therefore recommended to the plenary session that potassium iodate should be added to the advisory list of mineral salts with specific limitations (i.e. use is not to exceed FAO/WHO ADI).

121. The Committee endorsed the Report of the Working Group and agreed to the amendments to the advisory list as proposed in Appendix VII to this report.

122. The Committee expressed its appreciation of the work of the Working Group and its Chairman Dr. J. Chopra. The Committee agreed to include the review of the advisory list in the agenda of its next session and to ask Dr. Chopra to continue to chair the Working Group.

CONSIDERATION OF THE IODIZATION OF SALT (Agenda Item 15)

123. In introducing the document for this agenda item CX/NFSDU 91/13, the Secretariat recalled that at its last session the CCNFSDU had agreed to consider providing advice on salt iodization to the Member Countries. The paper provided background information on the extent of iodine deficiency disorders, recommended daily allowances and tolerated levels of iodine, iodization programmes and international activities in the prevention of iodine deficiency.

124. The Delegation of Germany pointed out that the iodine intake from all foods should be taken into account, and that the Committee may decide to review all standards containing provisions related to iodine. The Delegation of Switzerland suggested that the possibility should be considered of elaborating guidelines covering the whole dietary iodine supply including the contribution from processed foods. The Delegation of Canada was of the opinion that if a consultant were engaged as proposed (see para. 107), this topic could be addressed by the consultant.

125. The Committee did not wish to duplicate the activities of other organizations and therefore agreed to seek further advice from the Commission.

CONSIDERATION OF VITAMIN AND MINERAL SUPPLEMENTS (Agenda Item 16)

126. The Committee recalled that during the discussion of the Report of the Ad-Hoc Working Group on Nutritional Aspects of Codex Standards at its previous session, several delegations referred to the need to consider food supplements, which were of concern in regard to consumer protection. However, since 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, it had been decided to seek the Commission's approval before undertaking any work in this area. The Commission had agreed that a Circular Letter should be sent to Governments seeking their views on whether or not work on vitamin and mineral supplements should be undertaken within the Codex System. Comments (CX/NFSDU 91/14) were received from: Canada, Denmark, Finland, Germany, Thailand, USA. Most comments stressed the need to clearly distinguish between foods and drugs, and there was general support for the development of guidelines, although questions remained as to whether these products fell within the Commission's Terms of Reference.

127. Several delegations expressed firm support for the development of guidelines for those vitamin and mineral supplements which could be identified as foods. It was noted that there was increasing trade in such products and that there was a wide divergence of national legislation on how to control their presentation and composition. It was also pointed out that dietary supplements were not limited to minerals and vitamins, but included supplements of amino acids, essential fatty acids and other substances.

128. The Committee agreed to advise the Commission that work in this area would be appropriate, and welcomed the offer of the Delegation of Germany to prepare a working paper on Vitamin and Mineral Supplements for consideration at the Committee's next session.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 17)

OTHER BUSINESS

129. The Committee noted that at the 6th Session of the Codex Coordinating Committee for Asia the Government of Thailand had undertaken to prepare a Code of Practice for the Use of "Low Energy" or "Reduced Energy" Foods for presentation to the next session of CC/Asia (ALINORM 91/15, paras 193-194). The purpose of this Code would be:

- (a) assure maximum benefits and proper prices for consumers of such foods;
- (b) development of local production;
- (c) support to research to evaluate the impact of the short term and long term consumption of low energy and reduced energy foods on consumers' health in order to avoid any hazards which may occur. (ALINORM 91/15, para. 193).

130. The Executive Committee at its 37th Session, July 1990, held the view that the undertaking of Thailand as above contained some elements on which action was required if the preparation of such a Code would not exceed the Commission's, and therefore CC/Asia's Terms of Reference. Firstly, the question of pricing of food products was outside the terms of reference of the Commission, as was the matter of support to research. Both functions may be carried out by governments, but not by the CAC. Secondly, the development of standards for these products, and for Codes or Guidelines concerning their preparation, was the responsibility of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), which took into account the production practices, and potential production practices in all member countries (ALINORM 91/3, paras 62-63).

131. The Committee stated that the Draft Standards on Formula Foods for Use in Weight Control Diets provided advice on products which could be used safely in the medium and, with medical advice, in the long term. The Proposed Draft Guidelines for the Use of Health and Nutrition Claims in Food Product Labelling (CX/FL 91/9) were also being prepared by CCFL with input from CCNFSDU and these would also be of use.

FUTURE WORK

132. The Committee noted that several of its standards contained provisions for specific levels for nutrients which were as far as possible based on the most recent FAO/WHO recommendations at the time of preparation of the standards. It agreed that such provisions should continue to reflect the latest FAO/WHO recommendations. It requested the Secretariat to keep it informed of changes made to FAO/WHO recommendations and to indicate where and how standards would be affected. A procedure similar to that used for the constant review of food additive and contaminant provisions was recommended. The Committee agreed that the first review should take place at its next session to ensure that the recommendations of the FAO/WHO Expert Consultation on Vitamin A, Folate, Iron and Vitamin B12 and the Joint FAO/WHO/IAEA Expert Consultation on Trace Elements would be taken into account.

133. In addition, the Committee agreed that its future work would include:

- Levels for Nutrient Descriptors contained in the Guidelines on Nutrition and Health Claims for Food Labelling;
- Proposed Draft Standard for Formula Foods for Very Low Caloric Diets;
- Guidelines on Dietary Supplements (a working paper on Vitamins and Minerals Supplements to be prepared by Germany);
- Revision of the Standard for Cereal-Based Foods for Infants and Children (CODEX STAN 74-1981) based on a draft to be prepared by Switzerland;
- Gluten-free Foods;
- Low-sodium Foods;
- Recommendations for the incorporation of nutritional guidance into Codex Standards, where applicable.

134. The Committee did not support the proposal of the Delegation of the Netherlands to the issue of the nutritional use of sweeteners in foods. Nor did it accept a proposal to review the Standard for Infant Formula without specific proposals for amendment.

DATE AND PLACE OF NEXT SESSION (Agenda Item 18)

135. The Committee was informed that its next session would be held in September 1992, most probably in Bonn-Bad Godesberg.

136. On behalf of all delegations, Dr. J. Chopra of the United States addressed Prof. Dr. H. Pahlke on occasion of his retirement from the Chairmanship of the Committee. The speaker praised Prof. Pahlke's high professional standing, tactfulness and dedication which enabled him to ably guide the Committee through the variety and complexities of its work. Dr. Chopra paid tribute to the personal contribution Prof. Pahlke had made to the successful elaboration of many of the documents prepared by the Committee.

137. The Delegation of Argentina expressed its acknowledgement to the Government of the Federal Republic of Germany for hosting the Committee but regretted the lack of interpretation into the Spanish language. The delegation recalled that according to the statement that had been made by the Delegation of Spain (ALINORM 89/26, para. 209) on the objection expressed by the Host Country on the scarce presence of Spanish-speaking countries, this was due to economic difficulties prevailing in these countries in spite of their wish to participate in Codex Alimentarius Sessions.

SUMMARY STATUS OF WORK

<u>Subject Matter</u>	<u>Step</u>	<u>Action to be taken by</u>	<u>Document Reference</u>
- Draft Standard for Formula Foods for Use in Weight Control Diets	8	CAC, 19th	ALINORM 91/26, Paras 38-70, Appendix III
- Draft Standard for the Labelling of and Claims for Foods for Special Medical Purposes	8	CAC, 19th	ALINORM 91/26, Paras 71-85, Appendix IV
- Draft Guidelines on Formulated Supplementary Foods for Older Infants and Young Children	8	CAC, 19th	ALINORM 91/26, Paras 18-37, Appendix II
- The Amendments to the General Principles for the Addition of Essential Nutrients to Food, Definition of "Fortification or Enrichment" and "Standardization"	5/8	CAC, 19th	ALINORM 91/26, Paras 93-96, App. V - A, B
- The Amendment for the Maximum Level of Cocoa in Codex Standard for Processed Cereal-Based Foods (CODEX STAN 74-1981)	5/8	CAC, 19th	ALINORM 91/26, Paras 97-99, App. V - C
- Proposal for a Draft Standard for Formula Foods for Use in Very Low Energy Diets (request the Commission's advice on whether to proceed with the elaboration of such a standard)	--	CAC, 19th (Governments) CCFNSDU, 18th	ALINORM 91/26, Para. 110, Appendix VI
- Amendments to the Advisory List of Vitamin Compounds and Mineral Salts	--	CAC, 19th CCFNSDU, 18th	ALINORM 91/26, Paras 112-122, Appendix VII
- Current Nutrition Recommendations and Guidelines and Codex Standards (consideration to be given to the recruitment of a Consultant who would prepare specific proposals for the Committee's future action)	--	CAC, 19th Codex Secretariat	ALINORM 91/26, Para. 107
- Salt Iodization (seek guidance from the Commission in order to avoid duplication of the activities of other Organizations)	--	CAC, 19th	ALINORM 91/26, Para. 125
- Vitamin and Mineral Supplements (advise the Commission that work on the subject would be appropriate and consider a special working paper at its 18th Session)	--	CAC, 19th Germany, CCFNSDU, 18th	ALINORM 91/26, Para. 128

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REVISED 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 "older infants" means persons from the 6th month and not more than 12 months of age.

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/:

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.

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.

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 Digestible carbohydrates including sugars. Energy density should preferably be increased by the addition of fat and/or digestible carbohydrates. If nutritive sweeteners are used, they should be used in moderation.

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

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

5. TECHNOLOGIES FOR AND EFFECTS OF PROCESSING

5.1 Preliminary Treatment of Raw Materials

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

^{1/} The following Guidelines were elaborated by the FAO/WHO/UNICEF Protein and Energy Advisory Group:

PAG Guideline No. 9: Fish protein concentrates for human consumption.

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 α -amylase which, during the slow heating to boiling, predigest partially the starch and reduce the amount of water needed for the preparation of the feed.

5.3 Toasting

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

available lysine, sulphur-containing amino acids, arginine and tryptophan. The process should therefore be carefully controlled.

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. The following sections might not be applicable under all conditions prevailing in different countries and appropriate modifications might have to be made for adapting them to specific conditions.

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 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 6.1.2 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.

6.1.4 In cases where older infants and young children are given specific vitamins and/or minerals through maternal and child health centres or other health agencies, the addition of these vitamins and/or minerals to supplementary foods may be unnecessary, provided that distribution of the supplementary foods is carefully limited to those receiving the vitamins and/or minerals.

6.2 Energy

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

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

- (a) the addition of fats and oils, and/or digestible carbohydrates including, 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 1/ (previously called the chemical score) corrected in accordance with the true digestibility of the crude proteins, should not be less than 70 per cent of that of casein. Higher values should be required if calculation of the score was based not, as is usually the case, on the most limiting amino acid 2/, but on two or more key amino acids such as lysine, methionine cystine, threonine and tryptophan.

6.3.3 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 digestibility.

6.3.4 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).

6.3.5 Taking into account the preceding considerations, the protein content should be in the order of 15 g per 100 g of the food on a dry matter basis. 3/

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 between 20% and 40% of energy derived from fat would be desirable. This corresponds to between about 10 g and 25 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.

1/ 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: $100 \times (\text{mg of the limiting amino acid in 1 g of the protein tested}) / (\text{mg of the same amino acid in 1 g of the protein with the reference amino acid profile})$.

2/ 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.

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

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 efficiency of absorption of various nutrients of significance in diets with a marginal nutrient content, so the dietary fibre content of the food should be reduced to a level not exceeding 5 g per 100 g.

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).

6.6.4 Table 1 in the Annex to these Guidelines contains the reference daily requirements for the vitamins and minerals that are most frequently deficient in the diets of older infants and young children. It is important to keep in mind that Table 1 is simply a guideline to emphasize the nutrients to be considered in the development of a supplementary food.

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.

^{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 the Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985). ^{1/}

9.2 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 indicate that the food is a formulated supplementary food, as appropriate, for older infants and young children. The appropriate description should be 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 the 6th month 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 per specified quantity of the food as suggested for consumption:

- (a) the amount of energy, expressed in kilocalories and kiloJoules;
- (b) the amounts of protein, carbohydrates and fat, expressed in grammes;
- (c) in addition to any other nutritional information required by national legislation, the total quantity in the final product of each vitamin and mineral added in accordance with Section 6.6 expressed in metric units.

9.2.4 Net Content

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

^{1/} Hereafter referred to as "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, sugars or other digestible carbohydrates 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.

TABLE

The vitamins and minerals listed in the Table include those for which deficiency is most frequently found in older infants and young children and should be considered in the formulation of a supplementary food. Local conditions including the nutrient contribution to the diet from the staple foods of the area and the nutritional status of the target population as well as national legislation should be taken into account in determining the nutrients to be added. When a food is supplemented with one or more of these nutrients, the total amount of the added vitamin(s) and/or mineral(s) contained in 100 g of the food on a dry matter basis should be at least 2/3 of the reference daily requirements.

<u>Nutrient</u>	<u>Reference Daily Requirements</u>
Vitamin A	400 µg retinol equivalents
Vitamin D <u>1/</u>	10 µg
Vitamin E	5 mg
Vitamin C	20 mg
Thiamine	0.5 mg
Riboflavin	0.8 mg
Niacin	9 mg
Vitamin B6	0.9 mg
Folate	50 µg
Vitamin B12	1 µg
Calcium	800 mg
Iron <u>2/</u>	12 mg
Iodine <u>3/</u>	---
Zinc	10 mg

1/ Vitamin D should be added if there is inadequate exposure to sunlight.

2/ Requirement with low bioavailability diet (5%).

3/ No FAO/WHO reference values are available. Recommended intakes are about 50-70 µg per day.

* * * * *

References:

- FAO/WHO Handbook on Human Nutritional Requirements, FAO, Rome, 1974.
- Requirements of Vitamin A, Iron, Folate and Vitamin B12, Report of Joint FAO/WHO Expert Consultation, Rome, 1988.

DRAFT STANDARD FOR FORMULA FOODS FOR USE IN WEIGHT CONTROL DIETS
(At Step 8 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

Formula foods for use in weight control diets are foods which, when presented as "ready-to-serve" or when prepared in conformity with the directions for use, are presented as a replacement for all or part of the total daily diet.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Energy Content

3.1.1 A formula food presented as a replacement for all meals of the daily diet shall provide not less than 800 kcal (3350 kJ) and not more than 1200 kcal (5020 kJ). The individual portions or servings contained in these products shall provide approximately one third or one fourth of the total energy of the product depending on whether the recommended number of portions or servings per day is 3 or 4 respectively.

3.1.2 A formula food presented as a replacement for one or more meals of the daily diet shall provide not less than 200 kcal (835 kJ) and not more than 400 kcal (1670 kJ) per meal. When such products are presented as a replacement for the major part of the diet the total energy intake shall not exceed 1200 kcal (5020 kJ).

3.2 Nutrient Content

3.2.1 Protein

3.2.1.1 A minimum of 25% and a maximum of 50% of the energy available from the food, when ready-to-serve, shall be derived from its protein content. The total amount of protein shall not exceed 125 g per day.

3.2.1.2 The protein shall be:

- (i) of a nutritional quality equivalent to egg or milk protein (the reference protein);
- (ii) where the protein quality is less than the reference protein, the minimum levels should be increased to compensate for the lower protein quality. 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.

3.2.1.3 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 Vitamins and Minerals

3.2.3.1 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.

Vitamin A	600 µg retinol equivalents
Vitamin D	2.5 µg
Vitamin E	10 mg
Vitamin C	30 mg
Thiamine	0.8 mg
Riboflavin	1.2 mg
Niacin	11 mg
Vitamin B6	2 mg
Vitamin B12	1 µg
Folate	200 µg
Calcium	500 mg
Phosphorus	500 mg
Iron	16 mg
Iodine	140 µg
Magnesium	350 mg
Copper	1.5 mg
Zinc	6 mg
Potassium	1.6 g
Sodium	1.0 g

3.2.3.2 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 3.2.3.1 to provide a minimum of 33% or 25% of these amounts, depending on whether the recommended number of servings per day is 3 or 4 respectively.

3.3 Ingredients

Formula foods for weight control shall be prepared from protein constituents of animals and/or plants 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.

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".

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, per 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 3.2.3 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 shall be done in accordance with the Codex Guidelines on Nutrition Labelling.

9.3.3 In addition, the quantities of vitamins and minerals may be expressed as a percentage of the Reference RDA in accordance with the Codex Guidelines on Nutrition Labelling.

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 per serving only as quantified on the label or per portion provided that the number of servings or portions 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.

9.4 Date Marking

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

9.5 Storage Instructions

9.5.1 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.

9.5.2 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.

9.6 Additional Provisions

9.6.1 The label and labelling shall not make any reference to the rate or amount of weight loss which may result from the use of the food or to a reduction in the sense of hunger or an increase in the sense of satiety.

9.6.2 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.

9.6.3 If the food provides a daily intake of sugar alcohols in excess of 20 g per day, there shall be a statement on the label to the effect that the food may have a laxative effect.

9.6.4 The label and labelling shall carry a statement to the effect that the food may be useful in weight control only as part of an energy-controlled diet.

9.6.5 For those products presented as replacements of the total daily diet, the label shall contain a prominent statement recommending that, if the food is used for more than six weeks, medical advice should be sought.

DRAFT STANDARD FOR THE LABELLING OF AND CLAIMS FOR
FOODS FOR SPECIAL MEDICAL PURPOSES
(At Step 8)

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 and presented 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 who have other special medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two.

3. GENERAL PRINCIPLES

The formulation of foods for special medical purposes should be based on sound medical and nutritional principles. Their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended. The labels, accompanying leaflets and/or other labelling and advertising of all types ^{1/} 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 advertising of these products to the general public should be prohibited. 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) ^{2/} except that:

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

4.2 Nutrition Labelling

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

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

4.2.2 Information on energy value shall be expressed in kJ and Kcal per 100 g or per 100 ml as sold as well as per specified quantity of the food as suggested for consumption.

^{1/} Legal advice is being sought on this Section.
^{2/} Hereafter referred to as "General Standard".

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 In addition, where it is appropriate the quantity of nutrients may be expressed in terms of percentages of the relevant internationally recognized recommended daily allowances.

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

4.2.7 In countries where serving sizes are normally used, the information described in Sections 4.2.2 to 4.2.4 may be given only per serving as quantified on the label or per portion provided that the number of servings or portions 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 specific modification of the content or the nature of the proteins, fats or carbohydrates shall bear a description of this modification and information on the amino acid, fatty acid or carbohydrate profile, when necessary.

4.3 Date Marking

The date of minimum durability as provided for in Section 4.7 of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1981) shall be declared.

4.4 Additional Information

4.4.1 A prominent statement "USE UNDER MEDICAL SUPERVISION" shall appear on the label in bold letters in an area separated from other written, printed, or graphic information.

4.4.2 Adequate directions for the preparation including the requirement to add other ingredients, for the use of the food and for its storage and keeping after the container has been opened, shall be included on the label.

4.4.3 An additional prominent warning statement consisting of an explanatory statement shall appear on the label in bold letters in an area separated from other written, printed or graphic information if the food for special medical purpose poses a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended.

4.4.4 A statement that the product is not to be used for parenteral administration shall appear on the label.

4.4.5 A prominent statement indicating whether the product is or is not intended as the sole source of nutrition shall appear on the label.

4.5 Information to be Included in the Labelling 1/

4.5.1 The statement "For the dietary management of" 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 has been shown to be effective.

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

4.5.3 A statement of the rationale for the use of the product and a description of the properties or characteristics that make it useful.

4.5.4 If the product has been formulated for a specific age group, it should carry a prominent statement to this effect.

4.5.5 A statement specifying the nutrient(s) which have been reduced, deleted, increased or otherwise modified, relative to normal requirements, and the rationale for the reduction, deletion, increase or other modification.

4.5.6 Feeding instructions, including the method of administration and serving size, if applicable.

1/ This information may be provided separately from the package.

PROPOSED AMENDMENTS TO CODEX STANDARDS AND GENERAL PRINCIPLES
AT STEPS 5/8

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)

The following new definitions have been proposed for inclusion in the General Principles:

- A. 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.
(Ref.: ALINORM 91/26, para. 94).
- B. 3.9 Standardization means the addition of nutrients to a food in order to compensate for natural variations in nutrient level.
(Ref.: ALINORM 91/26, para. 96).

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)

- C. 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."
(Ref.: ALINORM 91/26, paras 97-99).

PROPOSED DRAFT STANDARD FOR USE IN VERY LOW CALORIE DIETS
FOR WEIGHT CONTROL

1. SCOPE

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

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

2. DEFINITION

A formula food for use in very low calorie diet is a food specially prepared to supply a minimum amount of carbohydrates and the daily requirements of the essential nutrients in 450-600 calories which represents the sole source of energy intake.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Energy Content

A formula food for very low calorie diets shall provide a daily energy intake of 450-600 calories as the only source of energy.

3.2 Nutrients Content

3.2.1 Protein

- Not less than 50 g protein with a nutritional quality equivalent to egg or milk proteins shall be present in the recommended daily intake of energy.
- 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 Fats

Very low calorie diets shall provide not less than 3 g linoleic acid in the recommended daily intake of energy.

3.2.3 Carbohydrates

Very low calorie diets shall provide not less than 50 g of carbohydrates in the recommended daily intake of energy.

3.2.4 Vitamins and Minerals

Very low calorie diets shall provide the vitamins and minerals in the recommended daily intake of energy as given below. 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>

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/</u> <u>3/</u>
Potassium	1.5	g	<u>4/</u>
Sodium	1.5	g	<u>1/</u>

3.3 Ingredients

Very low calorie diets 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 Consultation 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 no residues of pesticides, which may be required in the production, storage or processing of the raw materials or the finished food ingredient, remain in the product, or, if technically unavoidable, are reduced to the maximum extent possible.

5.2 Other Contaminants

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

- 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 1990.
- 3/ Adjusted slightly to be equal to iron.
- 4/ Minimum amounts deemed to be safe and adequate.

6. HYGIENE

6.1 To the extent possible in good manufacturing practices, 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 foods. 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 the 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 of 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 shall be "Nutritionally Complete Formula Food for Very Low Calorie Regimes".

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.

9.4 Date Marking

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

9.5 Storage Instructions

9.5.1 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. 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.

9.6 Information for Utilization

The directions of use of the foods shall provide for:

- The statement "for the dietary management of obesity" shall be declared on the label, in close proximity to the name of the food.
- A statement that the product may not be recommended for use for purposes other than the dietary management of obesity.
- A prominent statement in bold letters in an area separated from other written, printed or graphic presentations "do not use longer than 6 weeks without medical supervision".
- The statement "drastic loss of weight over periods exceeding 6 weeks may involve health hazard".
- Reference to the importance of maintaining adequate daily fluid intakes.
- A statement to the effect that the prescribed quantity of the product must be completely consumed.
- A statement that the product may not be used by pregnant, nursing and lactating women or by infants, children and adolescents.
- A statement that patients on medications or those suffering from heart, kidney or liver diseases, infections gout, psychotic depression, malignancy, porphyria and cara, should consult their physician before use of the product.
- A statement that the foods may not be used again within 3 months after discontinuation of the feeding.

9.7 Additional Provisions

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.

The statements with respect to the name of the food and the indications for use as given in Sections 9.1 and 9.6, shall appear on the label of the package and/or sachet for use by the consumer. Other statements indications or contraindications as required under Section 9.6, may appear on an accompanying leaflet in which case reference shall be made to this fact on the label of the package and/or sachet.

PART IV OF VOLUME IX

Amendments to Advisory Lists of Mineral Salts

a. Vitamin Compounds for Use in Foods for Infants and Children

<u>Salts</u>	<u>Purity Requirements</u>	<u>Use in Foods for Infants and Children</u>
2. <u>Source of Phosphorus (P)</u>		
2.9 Phosphoric acid	FCC, FAO/WHO	All infant and follow-up formulae; cereal-based foods for infants and children
3. <u>Source of Chloride (Cl)</u>		
3.8 Hydrochloric acid	FCC, FAO/WHO	All infant and follow-up formulae; cereal-based foods for infants and children
9. <u>Source of Iodine</u>		
9.3 Potassium iodate	FCC, FAO/WHO	
<u>Special Vitamin Forms (Page 56)</u>		<u>Maximum Level in ready-to-use food</u>
gum arabic (gum acacia)		100 mg/kg
Silicon dioxide		10 mg/kg