

codex alimentarius commission

FOOD AND AGRICULTURE
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WORLD HEALTH
ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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CODEX COMMITTEE ON FOODS FOR SPECIAL DIETARY USES

Bonn-Bad Godesberg, FRG

24 January - 1 February 1985

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INTRODUCTION

1. The Codex Committee on Foods for Special Dietary Uses held its 14th Session from 28 January to 1 February 1985 in Bonn-Bad Godesberg by courtesy of the Government of the Federal Republic of Germany. The meeting was chaired by Dr. H. Drews, Ministerialrat in the Federal Ministry of Youth, Health and Family Affairs.

2. Under-Secretary of State, W. Chory, opened the Session and welcomed the delegates. Mr. Chory recalled the continuing interest of the Federal Republic of Germany in the work of this Committee which had, in the eighteen years of its existence, developed expertise not only in the field of foods for special dietary uses but also on nutritional aspects of all foods, thus providing guidance for health protection of consumers. The full text of Mr. Chory's address is contained in Appendix II to this Report.

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

Argentina	Finland	Spain
Australia	France	Sweden
Austria	Germany, Fed. Rep. of	Switzerland
Bahrain	Iran	Thailand
Brazil	Italy	United Kingdom
Cameroon	Japan	United States of America
Canada	Kuwait	
Cuba	Madagascar	
Czechoslovakia	Mexico	
Denmark	Netherlands	
Dominican Republic	Norway	

Observers were present from the following countries and International Organizations:

- Germany, Democratic Republic of
- South Africa
- Association of Official Analytical Chemists (AOAC)
- European Economic Community (EEC)
- International Association for Cereal Science and Technology (ICC)
- International Dairy Federation (IDF)
- International Federation of Glucose Industries (IFG)
- International Society of Dietetic including all Infant and Children Food Industries (ISDI)
- MARINALG International

A list of participants, including officers from FAO and WHO, is included in Appendix I to this Report.

4. The Session was preceded by meetings of the following ad-hoc Working Groups:

24-25 January 1985:

- Working Group I on Nutritional Aspects in Codex Standards and Related Matters. For details see paras 94-110 and Appendix V.

28 January 1985:

- Working Group II on Certain Standards and Guidelines (Standards for Low-Energy and Energy-Reduced Foods, Meal Replacers, Guidelines on Medical Foods). (See paras 111-124 and Appendix VII).

- Working Group III on Methods of Analysis and Sampling.
(See paras 143-147 and Appendix XIV).
- Working Group IV on Advisory Lists for Mineral Salts and Vitamin Compounds in Foods for Infants and Children.
(See paras 137-142 and Appendix XII).

ADOPTION OF THE AGENDA (Item 2)

5. The Committee unanimously adopted the Provisional Agenda (CX/FSDU 85/1) without change.

APPOINTMENT OF RAPORTEURS (Item 3)

6. Messrs. A. Duran and J.L. Allain of the delegation of France and Drs. R.W. Weik and D. Benton of the delegation of the United States were appointed to serve as rapporteurs for the session.

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

7. The Committee had before it a working paper (CX/FSDU 85/2) which outlined matters arising from the 15th Session of the Commission and other Codex Committees and Addendum 1 to CX/FSDU 85/2 - a Summary of Notifications of Acceptances related to the standards elaborated by this Committee (up-date from 1st February 1983 onwards).

Length and Content of Codex Reports (Paras 13-14 of ALINORM 83/43)

8. The Committee was informed that the 29th Session of the Executive Committee had considered the need for improving the format of reports of Codex Committees. The 15th Session of the Commission had agreed that keywords should be underlined and that Codex Committees should be requested to examine which type of report best suited their individual needs.

9. The Committee expressed its satisfaction with the present format of the reports of its sessions and agreed that a table of contents would be an improvement.

Matters Related to Methods of Analysis and Sampling

10. The Committee noted that the Commission had adopted General Principles for the Establishment of Selection of Codex Sampling Procedures and agreed on the meaning of acceptance of certain types of Codex Methods (paras 205, 207-209 of ALINORM 83/43). The Committee also noted that the 13th Session of CCMAS had endorsed several methods for foods for infants and children and that the Secretariat would report to WG III on the 13th and 14th Sessions of CCMAS. The Committee agreed to refer these matters to WG III. The request of CCFA (paras 189-198 of ALINORM 85/12) to consider sampling plans for contaminants was also referred to WG III. For details see paras 143-147 and Appendix XIV.

Nutritional Aspects of Codex Work and Extended Terms of Reference of the Committee (Paras 353-359 of ALINORM 83/43)

11. The Committee was informed that the Commission had agreed with the Committee's conclusions on the revised terms of reference and its mode of working as outlined in para. 23(a-g) of ALINORM 83/26. The Committee had only slightly modified the last clause of the terms of reference requiring specific referral of provisions on nutritional aspects.

Action Taken on Proposed Amendments to Codex Standards as Contained in Appendix XIII to ALINORM 83/26

12. The Committee noted that the following amendments had been adopted by the 15th Session of the Commission and subsequently included in Supplement 1 to Volume IX of the Codex Alimentarius.
- Section 5.5 of the Codex Standard for Infant Formula concerning carry-over of food additives and carrier substances for vitamin compounds.
 - "Special Vitamin Forms" in the Advisory List for Vitamin Compounds.
 - Date Marking for Foods with Low-Sodium (including Salt Substitutes) (consequential amendment).
 - Date Marking for Foods for Infants and Children (editorial amendment).
13. The Committee was informed that the Commission had also approved that the amendments contained in Section I of Appendix XIII be elaborated in accordance with the appropriate procedure. The Committee agreed to discuss these amendments (at Step 4) under Item 13 (see paras 134-136 and Appendix XII).

Definition of Food Additives (Paras 36-40 of ALINORM 85/12)

14. The 17th Session of CCFA had considered the need to amend the definition of "food additives" with a view to including certain nutrients such as vitamins and minerals. The Committee noted that CCFA had decided that the Federal Republic of Germany, the originator of the proposal, should prepare a paper setting out the issue and the reasons for the amendment proposal for the next Session of CCFA. The Committee agreed that it would be more appropriate to await a more detailed paper from CCFA before commenting on this matter.

Report on Acceptances and other Notifications concerning Codex Standards for Foods for Special Dietary Uses (Addendum 1 to CX/FSDU 85/2)

15. The Committee was informed that the Secretariat received since February 1983 a considerable number of notifications from governments stating their positions on Codex Standards elaborated by the Committee. These notifications were either full or target acceptances, acceptances with specified deviations as well as responses concerning the free circulation of products complying with Codex Standards. The Committee noted that these notifications were included in the up-dated version of the Codex Summary of Acceptances (in print).

16. The Committee expressed its appreciation to the countries which had accepted the standards and expressed the hope that more countries would follow soon.

Further Action on the Paper by Thailand Outlining Problems of Developing Countries in Asia in Connection with Accepting the Codex Standard for Infant Formula (Paras 127-132 of ALINORM 83/26)

17. The Committee recalled that Thailand had submitted to the 13th Session a document outlining three major difficulties which had been encountered with the Codex Standard for Infant Formula (CODEX STAN 72-1981), concerning: (a) the minimum nutritional requirements; (b) use of appropriate technology and locally available raw materials; and (c) need for economic cooperation to develop nutritionally adequate foods at a reasonable price. The Committee had confirmed at its 13th Session that the nutritional requirements were scientifically sound and should not be lowered. In fact all countries should aim at complying with these requirements, whenever possible. The Committee had also noted the cooperation between the Australian Dairy Corporation and Thailand and had recommended that governments should submit more information concerning the problems introduced by Thailand.

18. The 4th Session of the Coordinating Committee for Asia had been informed of Thailand's view that the levels for protein and iron in infant formula were rather high. However, the Committee had expressed the opinion that the nutritional requirements in the standard for infant formula were satisfactory. The Committee had also held the view that the problems indicated by Thailand were mainly of a techno-economic nature. The Committee had suggested the employment of a consultant to survey the current situation and the capabilities of Asian countries for the manufacture of infant foods (infant formula and weaning foods). Based on the Consultant's report, concrete projects for technical cooperation could be developed (paras 156-162 of ALINORM 85/15). The Committee noted with satisfaction the technological assistance of the Australian Dairy Corporation in Malaysia.

19. The Committee received a summary report from Mrs. M. Astier-Dumas of France who had carried out the above consultancy. Her detailed report was being submitted as a working paper to the 5th Session of the Coordinating Committee for Asia. 1/ Mrs. Astier-Dumas reported as follows:

"Five countries: India, Indonesia, Malaysia, Philippines and Thailand, were visited. Of these, only India used considerable quantities of milk (cow and buffalo) for the production of infant formula. The others used imported raw materials. Between 4 to 6 months complementary foods were introduced. All countries have developed weaning foods; however purchases were limited due to lack of appropriate educational measures. These foods mainly complied with the Codex Standard for Cereal-Based Processed Foods (protein-enriched). Difficulties had been encountered with the addition of vitamins and minerals since they increased the price considerably. Recommendations were being submitted by the Consultant to the 5th Session of the Coordinating Committee for Asia on the production of infant formula, follow-up foods and cereal-based foods, and supplements for pregnant and lactating women, with an emphasis on the need for appropriate nutritional education to ensure an optimal use of these products. "

20. The delegation of Thailand expressed its appreciation to the Committee and to the consultant. Reporting on the conclusions of the Thai National Codex Committee, the delegation of Thailand indicated that in Thailand standards had been promulgated for three different types of products: (a) a modified milk for infants up to 12 months; (b) an infant formula based also on other protein sources (up to 12 months); and (c) a supplementary food for 3 months to 3 years. Consultations were being held with Thai medical experts to consider closer agreement of the Thai Standards with Codex Standards.

21. The delegation of France expressed the view that the Committee should closely follow the difficulties with the Codex Standards which were encountered by Governments and attempt to adjust the standards, as appropriate, to the conditions which prevailed in the member countries concerned.

CONDITIONS OF STORAGE AND DISTRIBUTION, AND THEIR IMPACT ON THE NUTRITIONAL VALUE AND SAFETY OF PRODUCTS ESPECIALLY INTENDED FOR INFANT AND YOUNG CHILD FEEDING (Item 4(b))

22. A report on conditions of storage and distribution encountered in India, the Philippines and Trinidad and Tobago which had been prepared by a consultant to WHO (document WHO/NUT/83.4) was presented by the representative of WHO to the Committee. The report had been prepared in pursuance of the World Health Assembly resolution on this item (ALINORM 83/26, para. 138). Finished products and raw materials were found to be

1/ Copies will be available from the Codex Secretariat.

exposed intermittently and for various periods of time to maximum temperatures of 50° C and more. However, in no case had tests for possible deterioration of nutritive value been carried out in routine studies of commercial products. Contamination of raw material, especially milk, with pesticide residues and enterotoxigenic bacteria was suggested in some localities and identified as a potential problem of product safety. The report made recommendations regarding the systematic study of the effects of high temperature on the nutritional value of the products in question, as well as for monitoring of raw materials for different kinds of contamination.

23. In the discussion that followed the possible importance of storage-related deterioration in nutritional quality for the work of the Committee was pointed out.

RECONSIDERATION OF DRAFT GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES AT STEP 8 (Item 5)

24. The Committee had before it CX/FSDU 85/10 which contained a redraft of the above standard and the reasons for the revision of the document. The Committee recalled that it had, at its 13th Session, finalized the above standard and submitted it for adoption to the 15th Session of the Commission (Appendix III to ALINORM 83/26). The Commission had decided not to adopt the standard but to recommend to this Committee that it align the text with the revised version of the General Standard for the Labelling of Prepackaged Foods, being finalized by CCFL (paras 361-363 of ALINORM 83/43).

25. The 17th Session of CCFL had decided that the Scope of the General Standard for the Labelling of Prepackaged Foods should cover all foods and that this Committee should only consider the following sections which were specific for foods for special dietary uses: 2.1, 2.4, 3.2, 4.1.2, 4.1.3 and Section 6.

26. Based on the advice of the Commission and CCFL and with the assistance of the Chairman of this Committee, the standard was revised as contained in CX/FSDU 85/10.

27. The Committee noted that Section 3.2 had erroneously been included in the standard and agreed to delete this section. The delegation of Argentina indicated its national requirements for certain aspects of labelling such as date marking, lot identification and language requirements on labels and its disagreement with Section 5.2.3.

Status of the Standard

28. The Committee decided that the redraft of the above standard be resubmitted to the Commission at Step 8 of the Procedure. The standard is contained in Appendix III to this report.

CONSIDERATION OF THE PROPOSED DRAFT STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS CLAIMED TO BE SUITABLE FOR INCORPORATION INTO A PRESCRIBED DIETARY REGIMEN FOR DIABETICS AT STEP 4 (Item 6)

29. The Committee had before it the above standard as contained in Appendix V to ALINORM 83/26 and comments received thereon in CX/FSDU 85/11 (Denmark, Egypt, Federal Republic of Germany, Finland, Hungary, New Zealand, Spain, Thailand, Switzerland, United States and ISDI).

30. Several countries expressed their opposition to the elaboration of the standards at the present time and in its present format. The proposal was made to include appropriate labelling provisions into the General Standard for the Labelling of and Claims for Foods for Special Dietary Uses. In recent years numerous scientific findings had shown that it was not possible to predict from the sugar content the effect a certain food would have on the blood glucose level of diabetics. It was, however, recognized by

many delegations that the declaration of the nutrient content on the label of normal foods or foods for special dietary uses might provide valuable information to the diabetic patient.

31. The observer of the German Democratic Republic and the delegation of Kuwait outlined the extent of the problem of diabetics in their respective countries. While the former was in favour of specific foods for diabetics to ensure a greater variety of foods, the delegation of Kuwait was opposed to carbohydrate modified foods which were, however, not reduced in their energy content and therefore not suitable for diabetics.

32. The Committee noted with interest that in several countries specific labelling provisions for information for diabetics were in the course of being elaborated.

33. The Committee concluded that in view of the new scientific developments in diabetes research in recent years it was appropriate to suspend work on the draft for some time. It was also agreed that the Secretariat should issue a circular letter, requesting information on national labelling requirements for the information for diabetics; for the next session a synopsis of the comments should be prepared by the Secretariat and submitted together with the detailed comments. The Committee agreed that the paper should also provide information on nutrition labelling provisions in the relevant Codex standards and guidelines.

34. The delegation of France proposed that a Working Group should, in the near future, evaluate the more recent scientific findings and make recommendations and proposals for appropriate labelling and compositional provisions. The Committee noted that two Working Groups on this matter had met in 1978 as well in 1980 and decided not to convene a new Working Group at this time. No further action was taken.

CONSIDERATION OF PROPOSED DRAFT STANDARD FOR FOLLOW-UP (FOODS) FOR OLDER INFANTS AND YOUNG CHILDREN AT STEP 4 (Item 7)

35. The Committee had before it the above standard as contained in Appendix IX to ALINORM 83/26 and comments thereon in working paper CX/FSDU 85/12 (Canada, Egypt, Federal Republic of Germany, Hungary, New Zealand, Poland, Switzerland, Spain, Thailand, United States, EEC and ISDI).

36. The Chairman introduced the item and noted that the written comments of countries not present repeated the position of those countries as, in some cases, already presented to earlier sessions of the Committee; in particular the view that several countries did not support the elaboration of this standard. The Committee agreed to discuss the standard section by section, having regard also to the written detailed comments.

Section 1 - Scope

37. The Committee noted the comment from the delegation of the United States that the Scope in Section 1.1 was not meaningful and could be clarified by substituting it with the following wording:

"This standard applies to the composition and labelling of follow-up foods for infants from 4-6 months on and young children."

This was agreed.

The Committee did not agree with the deletion of Section 1.2 since the provision was useful in distinguishing the products covered by this standard from infant formula.

Section 2.1 - Definitions

Follow-up Foods

38. The Committee recalled that specific comments had been requested on 6 months as the lower age limit for foods covered by the standard. Several delegations stated that infants

from 4-6 months onwards had the physiological capabilities to digest a more diversified diet of which the products covered by the standard were intended to supply a liquid part. Experts in paediatric nutrition had agreed that in many circumstances after the age of 4-6 months the amount of breastmilk or its substitute consumed did not supply all the nutrients needed for health and optimal growth of infants. Other delegations stated that they could agree with 6 months and 9 months (Japan) respectively, since these limits reflecting infant feeding practices in their countries. The Committee agreed to replace the term "6 months" by "4-6 months" and to delete the square brackets. The Secretariat was instructed to make the consequential amendments to the other sections of the standard.

39. The Committee noted proposals for the name of the product the replacement of "food" by "formula". The Committee felt that the term "formula" could be misleading since it could be confused with infant "formula" and agreed that the term "food" was more appropriate.

40. Several delegations were of the opinion that the part of the definition "replacing breast milk or infant formula" did not add significantly to the definition and might even be misleading. The Committee agreed to delete this part of the sentence. The delegation of Sweden, supported by Norway, requested clarification whether the products covered by the standard were also covered by the WHO Code on the Marketing of Breast-Milk Substitutes. The Chairman of the Committee referred to Article 2 of the Code and an interpretation of this article on page 33 of the WHO publication. For further discussions see also paras 125-133.

41. There was a considerable discussion as to the function of follow-up foods in the diet of infants from 4-6 months on. The Committee noted a written proposal submitted by the United States, requiring that the product should supply all the essential nutrients to older infants and young children when they were weaned from breastmilk or from infant formula. The Committee was informed that follow-up foods were intended to be used as a complementary food together with other complementary foods (e.g. fruits, vegetables, cereal based foods) after the initial period of 4-6 months when breastmilk and/or its substitutes had been the only sources of nourishment. The Committee decided not to introduce the US proposal since the other complementary foods also supplied a considerable amount of certain essential nutrients. The Committee also did not agree to introduce the following additional wording at the end of the sentence: "and the composition of which makes it possible to satisfy the need for nutrients which were supplied by breastmilk or infant formula". The Committee agreed on the following definition: "Follow-up food means a food intended for use as a liquid part of the weaning diet for the infant from the age of 4-6 months on and the young child".

42. The Secretariat was instructed to ensure that the definition as well as the other provisions in the standard were identical in English, French and Spanish.

Sections 2.2, 2.3 and 2.4

43. The Committee noted a proposal to transfer those sections into Section 3 since they were more appropriate as requirements for the essential composition of the products. The Committee also noted that, as presently worded, these three sections contained descriptive aspects of follow-up foods and decided to retain them as such in Section 2.

Section 3 - Essential Composition and Quality Factors

Section 3.2.1 - Protein per 100 Available Kilocalories (or Kilojoules)

44. The Committee noted the proposal of the Netherlands to lower the minimum requirement for protein to 2.25 g/100 kcal or 0.5 g/100 kJ. This view was shared by the observer from the EEC. There was no further support for the above proposal and the Committee retained the present values of 3.0 g/100 kcal or 0.7 g/100 kJ and deleted the square brackets.

Section 3.2.2.2 - Fat per 100 Available Kilocalories (or Kilojoules)

45. The Secretariat was instructed to correct the value of fat/100 available kilojoules to read 71.7 mg.

Section 3.2.4 - Vitamins other than Vitamin E

Vitamin A

46. The Committee noted a proposal to increase the maximum levels of vitamin A to 750 I.U. and 180 I.U. per 100 available Kcal respectively. These proposed values were three times the minima laid down in the standard and in view of the widespread deficiency of vitamin A in large parts of the population in developing countries it seemed to be more appropriate to introduce the higher maximum limits. The Committee agreed to introduce the higher values of 750 I.U. and 180 I.U. for the maximum levels of vitamin A.

Vitamin D

47. A proposal similar to that for vitamin A was also made for vitamin D, i.e. an increase of the maximum to three times of the minimum (120 I.U. and 30 I.U. respectively). The Committee noted that Hungary, in its written comments, had opposed the addition of vitamin D to infant formula. Several delegations considered that the maximum level in the standard was too high thus having a negative health effect. The Committee noted that the need for vitamin D depended on the exposure of infants to sunlight and might therefore vary according to climatic conditions. It was also pointed out that in many countries large doses of vitamin D were given to infants as drugs for prophylactic purposes. The Committee noted that the danger of vitamin D deficiency existed not only in Nordic countries but was evident also in other countries as shown in a recent survey in North African countries and Ethiopia. The Committee agreed to retain the higher values, noting that this did not represent a toxicological risk.

Vitamin B Group

48. The Committee noted a proposal to delete all vitamins of the B group (except B₁) from the standard or to make these provisions optional since these vitamins were also supplied by other complementary foods such as cereal based products in the recommended diversified diet for older infants and young children; requirements for these vitamins complicated the formulation of the product and made it more costly.

49. The Committee recalled that the standard for follow-up foods had originally contained only provisions for products based on milk, fortified with those nutrients which might be at risk in the diversified diets of infants from 4-6 months on (Vitamins A and D, Calcium and Iron). At a later stage products based on other protein sources had also been included in the standard and, therefore, provision had been made to achieve nutritional equivalence with the former.

50. The delegation of Norway drew attention to the need to take into account possible changes in the vitamin content of foods for infants and children stored under unfavourable conditions and to support WHO in its effort on preparing documentation and guidance on the effect of unfavourable storage conditions.

Vitamin B₂ - Riboflavin

51. Several delegations proposed to lower the value to 60 µg which was also included in the standard for infant formula. This was agreed and the square brackets were deleted.

Vitamin B₆

52. The Committee confirmed that the vitamin B₆ content should be related to the protein content of the product; namely 15 µg/g of protein. The Committee noted a proposal from the United States to retain the above requirement, but to introduce a minimum of 35 µg.

The Committee agreed to retain the level of 45 µg and the footnote and to delete the square brackets.

Section 3.2.5 - Vitamin E

53. The Secretariat was instructed to correct the minimum per 100 available kilojoules to read 0.15 I.U..

Section 3.2.6 - Minerals

Sodium, Potassium and Chloride

54. The Committee was informed that it was not possible to comply in all cases with the maximum levels for sodium, potassium and chloride in products which were based on protein sources other than milk. The Committee agreed that, for health reasons, the maximum levels for sodium should be retained. The Committee did not object to increasing the maxima for potassium and chloride and decided to retain the values in the standard, in square brackets, in order to obtain Government comments and proposals for the actual figures for inclusion in the standard. The observer from the EEC stated that no levels for sodium and potassium should be included in the standard.

Calcium and Phosphorus

55. The Committee noted a written proposal to lower the minimum values for calcium and phosphorus to be similar to those contained in the standards for infant formula, maintaining the footnote on the calcium/phosphorus ratio. In this connection attention was also drawn to the fact that the weaning period represented in many countries an adaptation to a low calcium diet and that therefore the lower levels (50 mg Ca/25 mg P) were more appropriate.

56. The Committee was also informed that calcium absorption from foods other than breastmilk was only in the range of 25-30% and that calcium requirements for infants of 1 year of age were 400-600 mg Ca per day; most of the calcium was obtained from the milk-based portion of the diet. It was proposed that the recommendation of ESPGAN (90 mg Ca) should be followed for follow-up foods and that the lower levels of 50 mg Ca/25 mg P were not acceptable. The Committee decided to leave the present wording of the provision unchanged and retain square brackets to obtain further comments on this matter.

Iron, Iodine and Zinc

57. No changes were made to the provisions for iron, iodine and zinc.

Section 3.3.1.1. - Essential Ingredients

58. The Committee instructed the Secretariat to amend this section editorially in accordance with its earlier decisions.

Section 3.3.1.2

59. The Committee noted that this section contained compositional requirements for follow-up foods based on milk which had to be seen in connection with the labelling provisions in Section 9.1.3. The Committee agreed that the two sections should be consistent and that any amendments to Section 9.1.3 should be reflected in Section 3.3.1.2. The Committee also agreed to retain a minimum of 3 g per 100 available calories (or 0.7 g per 100 kilojoules) of protein which should be derived from whole or skimmed milk which represented a minimum of 90% of the total protein. The Committee noted written comments which required that the total protein should be derived from milk or milk products.

60. The Secretariat was instructed to align the French version of this provision with the English text.

Section 3.4 - Purity Requirements

61. No changes were made to this section except an editorial amendment concerning the age range 4-6 months.

Section 3.5 - Consistency and Particle Size and

Section 3.6 - Specific Prohibitions

62. No changes were made to the above two sections.

Section 4 - Food Additives

63. Following proposals from the floor the Committee decided to consider the addition of certain additives. The deletion of hydroxypropyl starch, guar gum and locust bean gum was also proposed. The delegation of France was of the opinion that the Committee should not consider changes to the section on food additives in the absence of appropriate information and comments. In order to expedite the work of the Committee, it was agreed to set up a small Working Party consisting of delegates from Switzerland, France and the United States and a member of the Codex Secretariat to study the proposals in detail.

64. Dr. G.A. Purvis (USA), reporting on behalf of the Working Party, subsequently informed the Committee that, having considered all available information, the Working Party recommended the amendment of the section on food additives as follows:

- (a) hydroxypropyl starch should be replaced by acetylated distarch in order to reflect current good manufacturing practices;
- (b) α -tocopherol to be included with mixed tocopherols concentrate at a maximum level of 3 mg/100 ml;
- (c) L-ascorbic acid and its Na and Ca salts to be included with L-ascorbyl palmitate at a maximum level of 5 mg/100 ml, singly or in combination, expressed as ascorbic acid;
- (d) alginates, Na, K, Ca and NH_4 to be included in addition to carrageenan;
- (e) pectins (amidated and non-amidated) to be included at a maximum level of 1 g/100 ml;
- (f) natural fruit extracts and vanilla extracts to be included at levels governed by GMP;
- (g) vanillin and ethyl-vanillin to be included at maximum levels of 5 mg singly or in combination; and
- (h) caramel colour (plain) to be included at a level governed by GMP.

65. The Working Party had also recommended that the Carry-over Principle should be applied to this standard as in the case of canned baby foods and cereal-based baby foods, since the foods covered by this standard were intended for infants over 4-6 months of age.

66. The Committee agreed with the recommendations of the Working Party, noting that most of the food additives included in Section 4 were already in the Codex Standard for Infant Formula. The use of other additives were justified on the basis of technological effects already recognized in the standard. However, in compliance with the guidelines of the Codex Committee on Food Additives (CCFA) it was agreed that a working paper should be prepared for the next session of the CCFA on the basis of information received by the end of July 1985 justifying the use of the additives, especially those added during the present session. The delegation of the United States undertook to prepare the paper on the basis of information received. It was also agreed to amend the term "ready-to-drink" to "ready-for-consumption".

Sections 5 - 8

67. The Committee made no changes to these sections.

Section 9 - Labelling

68. The Committee requested the Secretariat to relate the section on labelling to the revised General Standard for the Labelling of Prepackaged Foods, as appropriate.

Section 9.1 - The Name of the Food

69. In order to remove any ambiguity as to the meaning of "older infants and young children" in Sub-section 9.1.1, and in the interest of brevity, the Committee agreed that the name of the food should simply be "follow-up food". The second sentence of this sub-section was left unchanged.

70. In discussing Sub-section 9.1.3 a number of objections were raised to a product containing 3 g protein derived from milk/100 available calories being referred to as "follow-up milk". It was suggested that the wording at para. 10.1.3 in the standard for infant formula be followed requiring 90% of the protein being derived from milk. Other products conforming with Section 3.3.1.2 might be called "follow-up milk" or "follow-up food, milk-based".

71. The Committee, in discussing Section 9.1.4, was informed of a possible inconsistency between this section and Section 9.1.2. Furthermore, the point was made that claims related to allergies and other pathological conditions in addition to milk protein and lactose intolerance should be covered in a more generally phrased Section 9.1.4. The Committee decided to retain Section 9.1.4, but to place it in square brackets in order to request additional comments from Governments on this matter.

72. In order to expedite the examination of the various points raised, the Committee decided to convene a small Working Party consisting of members of delegations of France, Norway, Switzerland, United Kingdom and the United States, to study the above sections and to propose a revised text of Sections 9.1.2 - 9.1.4.

73. On the recommendation of the Working Party the Committee adopted the following texts to replace Sections 9.1.2 - 9.1.3, except that it decided to place 90% in square brackets so that this figure could be discussed on the basis of comments. It was also agreed that Section 3.3.1.2 should be brought in line with the new Section 9.1.2. The adopted Sections 9.1.2 and 9.1.3 were as follows:

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

"9.1.3 The sources of protein shall be clearly shown on the label in close proximity to the name of the food in descending order of proportion by weight, except for those products which are labelled in accordance with Section 9.1.2. "

Section 9.2 - List of Ingredients

74. There was a discussion as to whether this provision should follow the Standard for Infant Formula or the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CX/FSDU 85/10). The Secretariat pointed out that in order to follow the General Standard with regard to this and other provisions in the labelling section, it would be necessary to study carefully the implications for various sections of the standard, requiring a working paper for the next session. The delegation of the United Kingdom suggested deleting reference to the declaration of vitamins and minerals in Section 9.2.1 and also considered that in Section 9.2.2 it would be desirable

to clarify what is meant by a "specific name" for ingredients of animal or plant origin. This point was answered by reference to the General Standard for the Labelling of Prepackaged Foods.

Section 9.3 - Declaration of Nutritive Value

75. The delegation of the United States was of the opinion that this section should be in line with the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CX/FSDU 85/10). The delegation of the Netherlands was of the opinion that as some nutrients were not subject to maximum limits, this section should contain a clause prohibiting misleading claims concerning the addition of vitamins, etc., in higher amounts than nutritionally required. The delegation of Argentina pointed out that it would be better to refer to 100 ml of food on an as consumed basis. The representative of the EEC was of the opinion that presenting information on a quantity suggested for consumption would not be practical and the Committee agreed to replace the phrase by reference to 100 ml ready-for-consumption.

Sections 9.4 - 9.8

76. The Committee decided to include these provisions by reference to the General Standard for the Labelling of Prepackaged Foods. As regards Section 9.6 - Country of Origin, the delegation of Argentina wished the declaration of country of origin to be always mandatory. (See also para. 74).

77. As regards Section 9.8 - Date Marking and Storage Instructions, the delegation of France was of the opinion that the date of minimum durability could not apply to certain unstable vitamins and should be replaced by the expiry date. The delegation of Argentina requested the inclusion of the date of minimum durability generally, not limited to vitamins. The Committee decided to leave the section unchanged.

Section 9.9 - Information on Utilization

78. The Committee agreed to consequential changes, i.e. reference to 4-6 months and removal of square brackets. It also agreed to delete in Section 9.9.1 reference to "accompanying leaflet". Concerning Section 9.9.2 it was discussed whether the term "shall" should replace "should". It was agreed to request the views of Governments on this matter and to rediscuss it at the next session. The Committee agreed to change in Section 9.9.3 the term "supplemental" to "other" in order to prevent confusion with supplementary foods.

Status of the Standard

79. A number of delegations were in agreement with the opinion of the delegation of the United Kingdom that such a fundamental issue, as whether there was a real need for the standard, had not been adequately discussed. Moreover there was still doubt over whether follow-up foods should contain all essential nutrients or only some. For these reasons the standard might not be ready to be advanced to Step 5. Other delegations were of the opinion that the standard should be advanced to Step 5. The delegation of Norway pointed out that the question as to whether the WHO Code of Marketing of Breast-Milk Substitutes covered follow-up foods should have to be clarified before a decision on advancing the standard could be taken.

80. The Committee agreed to advance the Standard Proposed Draft for Follow-up Foods for Older Infants and Young Children to Step 5 of the Codex Procedure. The Standard is contained in Appendix IV to this report.

CONSIDERATION OF THE PROPOSED DRAFT GUIDELINES ON THE DEVELOPMENT OF SUPPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN AT STEP 4 (Item 8)

81. The Committee had before it the above guidelines as contained in Appendix X to ALINORM 83/26 and comments received thereon in working paper CX/FSDU 85/13 (Egypt, Hungary,

New Zealand, Spain, Switzerland, Thailand, United States and ISDI).

Section 1 - Purpose

82. The delegation of Sweden questioned whether the above guidelines should cover technological aspects as presently included in Section 5 - Processing. It was of the opinion that this Committee should limit its considerations to nutritional aspects and delete reference to technological matters for which it did not have sufficient expertise. This view was supported by the delegation of the United States which referred to the discussions at earlier sessions that the document should be based on an up-dated version of PAG Guideline No. 8; furthermore the technology required varied from region to region.

83. The Committee was reminded that the guidelines had been intended to provide guidelines to developing countries on the nutritional as well as the technological aspects of the production of suitable weaning foods based on locally available raw materials. The delegation of Norway supported the need to provide information on appropriate technology of such aspects, e.g. reducing water absorbing capacity of cereals and generally bulk of the food, increase of nutrient density and other aspects of carbohydrate technology. The Committee agreed to retain Section 1 unchanged.

Section 2 - Scope

84. Several delegations expressed the opinion that it was not well defined in the scope which products were covered by the standard. In this context attention was drawn to the written comments submitted by the United States which proposed a more comprehensive text. The Committee agreed that the US proposal was more appropriate for inclusion in Section 3 - Definitions, and could be combined with the already existing definition under Section 3.1. Section 2.1 was left unchanged.

85. Concerning Section 2.2 an editorial amendment was made to clarify the text by replacing "these" by "those".

Section 3 - Definitions

Section 3.1

86. The Committee recognized that the key to elaborating meaningful guidelines for supplementary foods for older infants and young children was the elaboration of a definition which left no opportunity for ambiguities. The Committee agreed that it was paramount to separate in the definition supplementary foods from those covered by other Codex standards for foods for infants and children; this reflected also the view of the delegation of Kuwait.

87. In this context, the Committee recalled that it had initiated these guidelines on the request of countries which felt that there was a need for complementary foods, based, where possible, on local raw materials, which would provide during the weaning period, in addition to breastmilk or its substitute, those nutrients in which the local staple food were lacking or insufficient. These products were needed during the transition to the normal family diet; the products should therefore be designed to complement high carbohydrate staple foods and should provide nearly the daily required quantities of protein and other essential nutrients. To provide for a sufficiently high nutrient density in the total diet, the addition of fat and even soluble carbohydrates had been proposed.

88. The Committee recognized that it was necessary to establish a definition which was not in conflict with those of other infant foods nor with the definition of complementary foods in the WHO Code for the Marketing of Breastmilk Substitutes.

89. The Committee agreed that Governments and Coordinating Committees should be requested to submit proposals for an appropriate definition having regard to the definitions of other foods for infants and children mentioned above and the following two definitions: (a) as presently drafted in the standard; and (b) as proposed in the written comments of the United States (as amended):

- "(a) "Supplementary Foods for Older Infants and Young Children" are foods for use for infants from 4-6 months on as a supplement to breastmilk or breastmilk substitutes or other foods available in the country where the product is sold. These foods are intended to provide those nutrients which are lacking in the basic staple food."
- "(b) "Supplementary Foods for Older Infants and Young Children" are foods other than infant formula or milk for infants from 4-6 months on and young children, which will complete the supply of essential nutrients for breast-, formula- or milkfed infants. Supplementary foods are designed and used as complementary foods."

90. It was also agreed that specific comments on raw materials suitable for these foods and on the provisions of the guidelines as presently drafted, should be sought from the Coordinating Committees for Africa, Asia and Latin America.
91. The Committee further agreed that a Working Group should be established to meet prior to the next session of the Committee to examine the comments and elaborate a suitable definition of supplementary foods for older infants and young children. After having agreed on a suitable definition the Working Group should also review the whole text of the guidelines, taking into account comments from Governments and Coordinating Committees and prepare a revised text for the next session of the Committee.
92. The delegations of Australia, Canada, France, Kuwait, Mexico, the Netherlands, Norway, Switzerland, United Kingdom and the observer from EEC offered to participate at the Working Group under the Chairmanship of the United States. The Committee agreed that the Working Group was open to any other country wishing to attend.
93. The Committee agreed not to proceed with a further consideration of the guidelines at this session. The amended text of the above guidelines is contained in Appendix XII to this report.

CONSIDERATION OF THE REPORT OF WORKING GROUP I (Item 9)

94. The Committee had before it Conference Room Documents CRD 5, 6 and 12 which related to nutritional aspects referred to the Committee, as well as the Proposed Draft Guidelines for the Use of Codex Committees on the Inclusion of Provisions on Nutritional Quality in Food Standards and Other Codex Texts (Appendix IV to ALINORM 83/26) and General Principles for the Addition of Nutrients to Food (CRD 7). The Conference Room Documents were introduced by the Chairman of Working Group I Dr. Pia Noble (Federal Republic of Germany).

PROPOSED DRAFT GUIDELINES FOR THE USE OF CODEX COMMITTEES ON THE INCLUSION OF PROVISIONS ON NUTRITIONAL QUALITY IN FOOD STANDARDS AND OTHER CODEX TEXTS (AT STEP 4) (Item 9(a))

95. The Committee noted that detailed discussions had taken place on these guidelines especially with reference to the manner of fortification and restoration, the use of the term "nutrient" or "essential" nutrient, and whether fortification should be permitted only where a demonstrated dietary deficiency existed. The Working Group had adopted an amended text of the guidelines and had recommended that they be advanced to Step 5.
96. The Committee expressed its appreciation for the work carried out by Working Group I and concurred with the conclusions included in Report of WG I given in Appendix V. It decided to advance the above Guidelines to Step 5, as contained in Annex 2 to Appendix V.

Matters Referred to the Committee

97. The Committee noted that WG I had dealt with all questions referred to it. It had commented in detail, through a special Working Party under the Chairmanship of Dr. F.C. Gran (Norway) on: (a) the Proposed Draft Guidelines for the Utilization of Vegetable Protein Products in Foods being developed by the Codex Committee on Vegetable Proteins; and (b) the need for specific guidelines on the restoration of nutrients in wheat flour requested by the Codex Committee on Cereals, Pulses and Legumes. The report of the special Working Party is given in Appendix VI.

98. The Committee concurred with the conclusions of the Working Party and expressed its appreciation for the work done by the Working Party.

Name of the Committee

99. The Committee agreed with the conclusions of WG I that it was premature to change the name of the Committee (see para. 33, Appendix V).

GENERAL PRINCIPLES FOR THE ADDITION OF NUTRIENTS TO FOODS (Item 9(b))

100. The Committee decided to discuss in detail the above General Principles as amended by Working Group I (see CRD 7). The delegation of Canada pointed out that the revised General Principles had been prepared by the delegations of Canada, Norway, Sweden, Switzerland, United Kingdom and United States on the request of WG I. The Committee noted the view expressed by the delegation of France that the addition of nutritive elements to food should be optional.

Section 1 - Purpose

101. It was agreed that reference should not be made to national authorities since the Principles were directed to all those responsible for the development of guidelines, etc., concerning the addition of essential nutrients to food.

Section 3 - Definitions

102. The delegation of the United Kingdom was of the opinion that reference to prevention or correction of demonstrated nutritional deficiency should be deleted from the definition in Section 3.5. This reference appeared also in Section 7.2.1 which the delegation of the United Kingdom believed was the appropriate place for it. Considering that the same wording had been adopted in the Guidelines on Nutritional Aspects for Codex Committees (Appendix II, CRD 5), it was decided to leave Section 3.5 unchanged. As regards Section 3.6, the delegation of Norway pointed out that good manufacturing practices did not necessarily include provisions which ensured maintenance of nutritive value. It, therefore, recommended the inclusion of the following provision: "All processing should be carried out in a manner that minimizes loss of nutritive value". The Committee noted the suggestion of the delegation of Norway.

Section 4 - Basic Requirements

103. As regards Section 4.9 the delegations of Switzerland and the Federal Republic of Germany suggested that it should be deleted. The Committee accepted the explanation of the delegation of Canada that this section was needed to prevent frustrating the policy of improving the nutritional status of populations through an increased cost of the food product and retained the text unchanged.

104. In Section 4.11 reference to national food standards was deleted.

Section 5 - Nutrient Addition for Purposes of Restoration

105. In relation to the expression "strongly recommended", the Committee agreed that the intention was to stress the desirability of restoring essential nutrients without making it a mandatory requirement.

106. The delegation of France was strongly of the opinion that Section 5.2 was not practical as a number of terms such as "edible portion" and "reasonable daily intake" were subject to varying interpretation. The delegation of France proposed the following text to replace that in Section 5.2:

"A food should be considered a significant source of an essential nutrient if it contains, for 100 kcal, prior to processing, storage or handling, at least 5% of the recommended daily allowance for this nutrient (nutritional density)."

107. The Committee noted the above proposal and also noted para. 18 of the Report of WG I in this connection. It was agreed that comments should be invited also on the proposal of France. Similar considerations also applied to Section 6.2.

Status of the General Principles

108. The Committee discussed whether the text should be elaborated as Guidelines or General Principles and whether the Codex Step Procedure should be followed.

109. It was agreed that, rather than guidelines, general principles should be elaborated. The Committee adopted the General Principles, as amended, and referred them to the Commission for consideration (see Appendix VII). It was expected to finalize the General Principles after one more round of comments. The delegation of Argentina reserved its position on the General Principles until they had been studied by experts in that country.

110. The Committee expressed its appreciation to the Chairman and Members of Working Group I and the associated Working Parties for their work.

REPORT OF THE AD HOC WORKING GROUP ON THE:

- A. PROPOSED DRAFT STANDARD FOR LABELLING OF AND CLAIMS FOR LOW ENERGY AND ENERGY REDUCED FOODS (AT STEP 4); AND
- B. PROPOSED DRAFT GUIDELINES FOR THE COMPOSITION AND LABELLING OF AND CLAIMS FOR MEAL REPLACERS FOR WEIGHT REDUCTION (Item 10)
- C. PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF AND CLAIMS FOR / MEDICAL FOODS / (AT STEP 4) (Item 11)

111. The Committee had before it the above report as contained in Conference Room Documents No. 8 and 8(a). The Chairman thanked the delegation of the United States for having prepared working papers CX/FSDU 85/5 and 85/6 which had served as a basis for the discussion of the above items. The Chairman also expressed the appreciation of the Committee to the Chairman of the WG, Dr. J. Chopra (USA), the rapporteurs Dr. M.C. Cheney (Canada) and Dr. D.H. Buss (UK) as well as all members of the group for their valuable work.

112. Several delegations regretted that the Working Group had not been in a position, due to time constraint, to adopt the two above reports and suggested that in future, whenever possible, the Working Group reports should be adopted before being submitted to the plenary.

Comments on the Proposed Draft Standard for the Labelling of and Claims for Low Energy and Reduced Energy Foods and the Relevant Section of the Working Group Report

113. Several delegations were opposed to the inclusion in the standard of the notion of "specified servings" which was not acceptable as an entity to which energy or nutrient content should be related; the principle of nutrient density should be further considered instead (Section 3.1 of Appendix I and para. 8). The Committee agreed to place the term in square brackets.

114. It was also agreed that special provisions should be made for sugar substitutes which excluded the maximum levels for energy.

115. It was noted that several delegations had proposed an increase in the maximum energy level to 50 kcal. It was also suggested that a distinction should be made between solid and liquid foods by including different energy maximum levels.

116. The Committee agreed that the definitions under Sections 3.4 to 3.6 should be examined with the view to deleting them since no corresponding provisions were present in the standard.

117. The Committee further agreed to place Sections 1 and 6 into an Appendix since they were outside the established format for Codex standards.

118. It was pointed out that the first sentence of Section 3.3 should also include reduction of carbohydrate content.

119. The Committee noted that the standard excluded foods which were naturally low in energy and agreed that all sections referring to such foods should be deleted from the standard. The Committee could not decide whether all foods covered by the standard were indeed foods for special dietary uses. For sake of uniformity the Committee included "... for special dietary uses" in the title and placed these terms in square brackets for further comments.

120. The Committee noted that substantial amendments had been made to Section 4 and that, due to the complexity of the matter, a number of inconsistencies had been introduced. The Committee agreed in this context that a thorough review should be carried out of this standard as well as the two comments mentioned under (B) and (C) above in order to resolve the inconsistencies, taking into account the comments of the Committee, the two reports of the Working Group and the drafts concerned in working papers CX/FSDU 85/5 and 85/6. The Committee agreed that this work should be carried out by the Secretariat in cooperation with the two rapporteurs. The delegation of the United States agreed to assist in the review. The Secretariat informed the Committee that the revised texts together with explanatory notes would be issued as an Addendum to the final Report.

Comments on Proposed Draft Guidelines for the Composition and Labelling of and Claims for Meal Replacers for Weight Reduction

121. The Committee noted that the Working Group had amended the title to refer to "meal replacements for weight control and reduction".

122. The Committee agreed that Table 1 should refer to two alternative proposals. In this context it was pointed out that the minima in proposal I related to single portions whereas the maxima represented the figures for the total daily ration. The view was also expressed that the standard should distinguish two categories: single meal replacers and total daily rations.

Comments on the Proposed Draft Guidelines on the Labelling of and Claims for Medical Foods

123. The Chairman of the Working Group informed the Committee that the Working Group had felt that it was most important to establish a fully agreed definition and that the guidelines should be revised according to the definition. The delegation of Kuwait expressed the view that a clear distinction should be made between medical foods and other foods for special dietary uses. This was agreed by the Committee.

Conclusions

124. The Committee agreed with the matters expressed in paras 112 and 120 and decided that the three documents should be placed at Step 3 of the Procedure for a further round of Government comments. It was also agreed that a Working Group would meet in connection with the next session to examine the redrafts in the light of Government comments. The two reports of the Working Group (Conference Room Documents No. 8 and 8(a)) are attached as Appendix VIII to this report.

CONSIDERATION OF WORKING PAPER ON IMPLICATIONS FOR CODEX STANDARDS OF THE WHO INTERNATIONAL CODE FOR THE MARKETING OF BREASTMILK SUBSTITUTES (Item 12)

125. The Committee recalled that, following a recommendation of the Commission, it had, at its thirteenth session, discussed in some detail the relation between the provisions on labelling, advertising and instructions for use contained in the standards for foods for infants and young children and the relevant corresponding sections of the International Code of Marketing of Breast-Milk Substitutes as adopted by the World Health Assembly (ALINORM 83/26, paras 133-137). Differing views having been expressed on the question whether the relevant provisions were compatible or whether a harmonization was necessary or desirable, the Committee had suggested that a consultant be appointed "for the preparation of a review paper for the next session of the Committee" (para. 137).

126. The review paper submitted to the Committee (CX/FSDU 84/9) analysed in some detail the origin, structure, nature, purpose and scope of the various provisions and the institutional setting in which they had been adopted. Special attention was given to Codex instruments on the subject of labelling and to the labelling provisions of Codex Commodity Standards, in particular those relating to foods for infants and young children. As a result of this analysis, the review paper reached the conclusion that none of these instruments or provisions were incompatible with the WHO Code and that existing differences in coverage and emphasis resulted in complementarity rather than inconsistency. Accordingly, it did not seem necessary from a strictly legal point of view, to amend any of the Codex instruments in question.

127. However, the paper suggested that there might be practical or policy considerations in favour of establishing closer links between the WHO Code and the labelling provisions of the Codex Standards on Infant Formula, on Canned Baby Foods and on Cereal-based Foods for Infants and Children.

(a) Infant Formula

If it were felt that the attention of national authorities preparing laws or regulations to implement this Codex standard should be directed to the WHO Code, this could be achieved by the addition to Section 10.10 of the standard, of a sentence containing cross-reference to that code. The section as amended (with the addition underlined) would then read as follows:

"An indication that Infant Formula is intended to replace or supplement breast-feeding, where breast-feeding is not possible or is insufficient, may be given on the label. In this case, the provisions of Article 9 of the International Code of Marketing of Breast-Milk Substitutes of the World Health Organization should be duly taken into account".

(b) Canned Baby Foods and Processed Cereal-Based Foods

While the products covered by these standards normally constitute complementary foods used during and after weaning, it could probably not be excluded a priori that they might fall within the scope of the WHO Code in particular circumstances, especially if they were "marketed or otherwise represented to be suitable ... for use as a partial or total replacement of breast-milk". (WHO Code, Article 2 "Scope of the Code"). If this were to cause any problems of implementation at the national level, the situation might be met by adding a subsection, under a suitable sub-heading, to Section 9 of both these standards. The subsection (as subsequently modified in the light of the Committee's deliberation) would read as follows:

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

128. The Chairman expressed the thanks of the Committee to the consultant, Dr. J.P. Dobbert, for the excellent paper which provided the necessary background material for consideration of the complex issue.

129. The Committee agreed with the conclusion that, in principle, there was no inconsistency between the WHO Code and the relevant provisions of the aforementioned Codex standards and that it was therefore not indispensable, from a legal point of view, to amend these standards. With respect to the question whether it would be desirable, on policy or practical grounds, to introduce the amendments tentatively proposed in the working paper, one delegation expressed doubts as to the incorporation in a potentially mandatory text (i.e. a Codex standard) of a provision referring to provisions of a text that was only a recommendation (i.e. the WHO Code). The author of the working paper pointed out that the mandatory provisions were generally characterized by the use of the term "shall", while in recommendations or guidelines the less binding term "should" was normally used. The latter term also appeared in the proposed draft amendments which would therefore be no more binding on governments than the WHO Code.

130. The Committee approved by consensus the proposed amendment to Section 10.10 of the Infant Formula Standard as reproduced in paragraph 127(a) above, and decided to recommend to the Commission to consider it at Step 5 of the Procedure for the Elaboration of Codex Standards.

131. As regards the amendment envisaged for the Standards for Canned Baby Foods and Cereal-based Foods (reproduced in paragraph 127(b) above), several delegations stated that they could not support that amendment since it could give the misleading impression that these foods were generally embraced by the WHO Code. They considered that these products were not appropriate for feeding to infants below the age of 4-6 months as a breast-milk substitute or in a bottle, and that it was therefore unlikely that such foods would be marketed as breast-milk substitutes within the terms of the Code. On the other hand, the view was also expressed that the adoption of the amendment would facilitate the implementation of the WHO Code and assist governments in taking suitable measures designed to avoid abuses. Many delegations refrained from stating their position.

132. Among the few delegations who took the floor on the proposed amendment (given in para 127(b) above), the prevailing view was that the amendment could be subject to misinterpretation. In order to be able to consider the matter further, the Committee decided to defer the question until a subsequent session, taking into account, as appropriate, any guidance that may be provided by the Commission.

133. The Chairman expressed the Committee's appreciation for the valuable advice provided by the Legal Counsel of WHO, Dr. C.H. Vignes and by the consultant in the course of the discussion.

AMENDMENTS TO CODEX STANDARDS FOR FOODS FOR INFANTS AND CHILDREN (Item 13)

134. The Committee had before it Appendix XIII to ALINORM 83/26 containing proposed amendments at Step 3 and government comments in document CX/FSDU 85/14.

135. There was discussion on the proposed amendment of the maximum limit for vitamin D. A number of delegations were of the opinion that the proposed level of 120 I.U. was higher than necessary. Some delegations expressed their preference for a limit of 100 I.U., while others preferred to leave the maximum limit at 80 I.U.. The Committee adopted a maximum limit of 100 I.U.

136. As there was agreement on the various other proposed amendments, the Committee decided to refer the proposed amendments, with the change to the maximum limit for Vitamin D, to the Commission at Step 5 with the recommendation that Steps 6 and 7 be omitted. The above proposed amendments are contained in Appendix IX to this report.

REPORT OF THE AD HOC WORKING GROUP IV ON AMENDMENTS TO ADVISORY LISTS FOR MINERAL SALTS AND VITAMIN COMPOUNDS (CAC/VOL. IX) (Item 14)

137. The above Working Group met during this session of the Committee and the Chairman of the Working Group, Dr. R.W. Weik of the United States introduced the following report:

- (a) The Working Group considered document CX/FSDU 85/8, and an unnumbered document consisting of two reprints submitted by Italy in support of the inclusion of pyridoxine dipalmitate in the advisory list of vitamin compounds.
- (b) The Working Group agreed to delete pyridoxine palmitate from the list of proposed vitamin compounds as proposed in document CX/FSDU 85/8. The Working Group also concluded that the documentation submitted by Italy for pyridoxine dipalmitate did not meet the criteria for amendment of the advisory list of vitamin compounds. The Working Group requested further supporting information to meet the criteria requirements particularly on availability and use.
- (c) The Netherlands representative requested that potassium iodate, manganese gluconate and zinc gluconate be added to the list of proposed mineral salts to be included in the advisory list. The Working Group agreed to place these compounds on the list of proposed mineral salts and requested data to support the criteria for amendment of the advisory list of mineral salts.
- (d) The Netherlands representative also requested that the citric acid esters of mono- and di-glycerides be permitted to be used in infant formula and follow-up food. The Working Group requested supporting information to be considered at the next session.
- (e) The Swedish representative requested that starch hydroxypropyl be removed from the list of additives approved for use in infant formula and canned baby foods. The Working Group requested information to support the request for deletion."

138. The Chairman of the Working Group proposed that Appendix XII of ALINORM 83/26 containing proposed substances for inclusion in the List and Criteria be also appended to the report of this session.

139. The Committee approved the report of WG IV and agreed with its conclusion as well as with the proposal in para. 138 above. (See also Appendix XI). The Chairman expressed the Committee's appreciation for the valuable work of the Working Group.

140. The Committee noted additional proposals for amendments to the section on food additives in the Codex Standards for Foods for Infants and Children. The Committee proposed and the Chairman of the Working Group agreed that the terms of reference of the Working Group should be extended to permit examination of additives which were proposed as amendments to the Codex Standards for Foods for Infants and Children. The procedure was for governments to submit their proposals and supporting material to the Working Group which could examine the matter and make recommendations to the plenary. The plenary in turn would seek the Commission's approval to initiate the amendment procedure provided it was satisfied that the amendment was necessary.

141. The delegation of the Netherlands indicated that it would submit amendment proposals for vanillin in the Standards for Canned Baby Foods and for Processed Cereal-based Foods for Infants and Children. The Committee agreed that the above proposals should be considered according to the procedure outlined in para. 140.

142. WG IV agreed to convene again in connection with the 15th Session of this Committee.

REPORT OF WORKING GROUP III - METHODS OF ANALYSIS AND SAMPLING FOR FOODS FOR INFANTS AND CHILDREN (Item 15)

143. The Committee had before it the report of Working Group III (CRD No. 9). Prof. Dr. W. Krönert (Federal Republic of Germany) introduced the report of the Working Group and highlighted those aspects in which action by the Committee was needed. He informed the Committee that WG III had examined all information available to it (i.e. documents CX/FSDU 85/7, 85/7-Add. 1 and the reports of the Codex Committee on Methods of Analysis and Sampling).

144. The Working Group had reached certain conclusions concerning sampling, but did not discuss the problem raised by the Codex Committee on Food Additives concerning sampling for contaminants, since no such provisions were incorporated in any of the standards elaborated by the CC/FSDU. As regards the determination of available carbohydrate, the Working Group had considered the measurement of crude fibre. The determination of "crude fibre" as against "dietary fibre" had been noted to influence the results of analysis in certain types of baby foods. As this matter related not only to analysis but represented a nutritional question, the Working Group had referred the matter to the Committee for discussion at its next session.

145. The Working Group had examined the working paper prepared by Canada (as Coordinator) for the Working Group on Methods of Analysis of CCFL and had noted that there was some inconsistency of approach to the determination of nutrients. This should be examined in greater detail by a future session.

146. As regards the revision and classification of methods of analysis, the Working Group had completed its task. The exercise revealed that a number of methods were not satisfactory for the intended purpose, while others required further elaboration or study. The Working Group had identified these methods in a Table. Where further information on collaborative effort was needed in the elaboration of methods, the Working Group (through the Chairman, Secretary or the AOAC) would contact the Secretariat of the Inter-Agency Meeting.

147. The Committee endorsed the recommendations of the Working Group as contained in the report of WG III (see Appendix XI). On the recommendation of the Working Group it was agreed that Working Group III should continue to function between sessions of the Committee and should hold a session during the next session of the Committee. The membership of the present Working Group was open to other interested countries or organizations. The Chairman of the Committee thanked the Working Group for its valuable work.

FUTURE WORK PROGRAMME (Item 16)

148. The Chairman of the Committee expressed doubt whether the Committee could take on any further work in view of its already heavy work programme. This view was supported by a number of delegations.

149. The delegation of the Netherlands was of the opinion that the elaboration of a standard for products sweetened with sugar substitutes (whether low calorie or not) should be considered. The delegation of France, thought that this might be a way of overcoming problems in connection with foods for diabetics. The delegation of the Federal Republic of Germany was of the opinion that there was insufficient scientific knowledge to enable the Committee to embark on work in this field. The delegation of the United States preferred to wait and see how matters would develop in connection with the low-energy foods. The Committee finally agreed to examine this question on the basis of a working paper to be prepared by the Netherlands.

150. The delegation of Kuwait proposed that the Committee look into the question of "natural" and "health" foods which were being marketed in increasing amounts with various claims. The Committee agreed with the Secretariat that the marketing of foods and various other products, such as herbs, was either not within its terms of reference or was a matter of enforcement of the relevant labelling standards developed by Codex.

151. The Committee agreed to delete from its current programme of work the following items: cholesterol-reduced foods, medium-chain triglycerides and low-lactose products.

152. In reply to a query by the delegation of France, the Chairman of the Committee stated that it was the intention to convene Working Groups prior to the next session of the Committee and to provide more time for them for their discussions. The exact mechanism for doing this would be worked out and Governments would be informed in good time. Countries at present not listed as members of the various Working Groups were welcome to attend.

OTHER BUSINESS (Item 17)

Recommended Dietary Intakes

153. The delegation of Sweden recommended that FAO/WHO through appropriate expert groups make recommendations for dietary intakes as this would facilitate the work of the Codex; the available data on nutrient requirements (elaborated by FAO/WHO) were rather old and might require up-dating. The Chairman of the Committee pointed to great discrepancies in national recommended dietary intakes and wondered whether common international recommendation could be arrived at.

154. The Secretariat drew the Committee's attention to a summary of such recommended dietary intakes prepared by the IUNS which had been mentioned during the discussion of the Guidelines on Nutrition Labelling by CCFL. The delegation of Australia pointed to the existence of the UN Advisory Group on Nutrition which might be approached. The Secretariat indicated that close cooperation already existed between Codex and the UN Advisory Group. The delegation of Switzerland offered to make available to the Codex Secretariat tables of recommended daily intakes for various countries.

155. The Committee strongly supported the recommendation of the Codex Committee on Food Labelling that "the specific recommendations made by FAO/WHO Expert Groups for daily intakes of energy and nutrients needed periodic revision in the light of new knowledge and that some essential vitamins and minerals had not yet been examined. It was of the opinion that human nutritional requirements should be kept under constant review and strongly recommended to FAO/WHO to re-activate work on nutritional requirements".

Food Irradiation

156. The Secretariat informed the Committee of a communication received from the IAEA in connection with the irradiation of foods. The IAEA was of the opinion that the prohibition included in the standards for infant formula, canned baby foods and cereal-based foods regarding the irradiation of these foods or the use of irradiated food components in the preparation of these foods, was not consistent with the Codex General Standard for Irradiated Foods (Vol. XV of the Codex Alimentarius) which contained a general upper limit for absorbed radiation dose for all foods. IAEA wished this matter to be considered by the next session of the Commission.

157. The Committee noted the above comments and agreed that the conclusions of the Commission should be awaited before taking further action.

Use of Spanish Language

158. The delegations of Argentina, Cuba, Mexico and Spain, drew attention of the Codex Committee on Foods for Special Dietary Uses to the following points:

(a) The Contact Points of Argentina, Cuba, Mexico and Spain, have, unfortunately, not received the complete official papers in due time to make it possible to study and deal with the subjects of the agenda of the Fourteenth Session of this Committee.

(b) Apart from this, no Spanish version of the said papers was, in some cases, available. For this reason the delegations of Argentina, Cuba, Mexico and Spain, would appreciate it if all the documents of this Committee were translated into Spanish, in conformity with the working method adopted by the Codex Alimentarius Commission.

(c) Thus the above delegations requested the Chairman of the Committee to consider the possibility that the simultaneous interpretation at the plenary sessions of the Committee be conducted in the three working languages adopted by the Codex Alimentarius Commission, i.e. English, French and Spanish.

159. The Secretariat pointed out that the rules of the Commission provided for the use of only two of the working languages of the Commission at Sessions of Codex Committees. Nonetheless the availability of all working papers and other documents in all three languages would be highly desirable. As provision of a third language as regards working documents involved extra costs, the Secretariat undertook to explore all possibilities to make Spanish working documents available for the next session.

160. Since the Host Government provided for interpretation and the translation of working documents during sessions of Codex Committees, Mr. Hauser, speaking on behalf of the Technical Secretariat informed the Committee that the question of the provision of a third language had already been pursued in the past. The provision of interpretation and translation into Spanish would entail considerable extra problems. He stated that the matter would be examined again and that the results would be communicated to the Spanish speaking delegations prior to the next meeting of the Committee.

TIME AND PLACE OF NEXT SESSION (Item 18)

161. The Committee was informed that the next Session of the Committee would be held after September 1986.

SUMMARY STATUS OF WORK

Standard/Code/Document	Status Step	To be dealt with by	ALINORM/App. Document
Standard for Foods with Low Sodium Content (Including Salt Substitutes)	9	Governments	CODEX STAN 53-1981
Standard for Infant Formula	9	Governments	CODEX STAN 72-1981
Standard for Canned Baby Foods	9	Governments	CODEX STAN 73-1981
Standard for Processed Cereal-Based Foods for Infants and Children	9	Governments	CODEX STAN 74-1981
Advisory List of Vitamin Compounds for Use in Foods for Infants and Children	-	Governments	CODEX ALIMENTARIUS Volume IX
Advisory List of Mineral Salts for Use in Foods for Infants and Children	-	Governments	

SUMMARY STATUS OF WORK (Cont.)

Standard/Code/Document	Status Step	To be dealt with by	ALINORM/App. Document
Standard for Gluten-Free Foods	9	Governments	CODEX STAN 118-1981
Draft General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses	8	16th CAC	ALINORM 85/26 Appendix III
Proposed Draft Standard for Follow-up Foods	5	16th CAC	ALINORM 85/26, App.IV
Proposed Draft Guidelines for Use by Codex Committees on the Inclusion of Provisions on Nutritional Quality in Food Standards and other Codex Texts	5	16th CAC	ALINORM 85/26 Annex 2 to Appendix V
General Principles for the Addition of Nutrients to Foods	-	16th CAC	ALINORM 85/26 Appendix VII
Proposed Draft Standard for the Labelling of and Claims for Prepackaged Foods Claimed to be suitable for Incorporation in a Prescribed Dietary Regimen for Diabetics	3	Work suspended. See para. 33 of ALINORM 85/26	ALINORM 83/26 Appendix V
Proposed Draft Standard for Low Energy and Energy-Reduced Foods	3	15th CCFSDU	ALINORM 85/26 Addendum 1
Proposed Draft Guidelines for the Composition and Labelling of and Claims for Meal Replacers for Weight Reduction	3	15th CCFSDU	ALINORM 85/26 Addendum 1
Proposed Draft Guidelines for "Medical Foods"	3	15th CCFSDU	ALINORM 85/26 Addendum 1
Proposed Draft Guidelines on the Development of Supplementary Foods for Older Infants and Young Children	3	WG + 15th CCFSDU	ALINORM 85/26 Appendix XII
Proposed Draft Amendment to Codex Standard for Infant Formula CAC/RS 72-1976	5	16th CAC	ALINORM 85/26 para. 127(a)
Proposal for Amendment of Codex Standards 73-1981 and 74-1981	-	16th CAC 15th CCFSDU	ALINORM 85/26 para. 127(b)
Proposed Amendments to Codex Standards for Foods for Infants and Children	5 <u>1/</u>	16th CAC	ALINORM 85/26 Appendix IX
WG on Advisory Lists for Vitamin Compounds and Mineral Salts	-	15th CCFSDU	ALINORM 85/26 paras 137-142
WG on Methods of Analysis and Sampling	-	15th CCFSDU	ALINORM 85/26 paras 143-147 and Appendix XI
Products Sweetened with Sugar Substitutes (Paper to be prepared by the Netherlands)	-	15th CCFSDU	CX/FSDU 86/...

1/ . With a recommendation to the Commission to omit Steps 6 and 7 and adopt the amendments at Step 8.

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OPENING ADDRESS

14th Session of the Codex Committee on "Foods for Special Dietary Uses"

Bonn - Bad Godesberg, 28 January, 1985

Mister President,
Ladies and Gentlemen,

On behalf of the Federal Republic of Germany I would like to welcome you most sincerely to the 14th session of the Codex Committee on "Foods for Special Dietary Uses", taking place here in the Stadthalle Bonn - Bad Godesberg.

I am glad to convey to you the greetings of the Federal Minister Dr. Heiner Geissler who regrets not being able to attend the meeting because of pressing official engagements. He therefore asked me to transmit to you his best wishes for a positive and successful session.

I am very happy to see that you followed our invitation in such large numbers, in spite of the present bad weather conditions. More than eighteen years have passed since the first session of this Committee, and since that time the number of participating countries and International Organizations has more than tripled and that of participants has grown up to nearly four times the original number.

In my opinion, this illustrates the importance of the work of this Committee. I can today welcome representatives of more than 30 states and of 8 International Organizations. I would particularly like to welcome the representatives of Bahrein, the Dominican Republic and Kuwait, who participate in the discussions of the Committee for the first time.

I would especially like to welcome Dr. Ladomery and Mrs. Dix from the Codex Secretariat in Rome, Mr. Dobbert as the former legal adviser to the FAO, and finally Dr. Keller, representative of the WHO.

Ladies and Gentlemen,

On this occasion, I would like to say a few words from the view of the Federal Republic of Germany on the importance of the work of the Codex Alimentarius Commission and particularly the work of the Codex Committee on Foods for Special Dietary Uses. From the very beginning, the Federal Government has taken part, in a very intensive way, in the work of the Codex Alimentarius Commission and its numerous Committees, recognizing that the consumer can effectively be protected against health risks caused by foods as well as against deceptions by means of a global standardization of foods. On the other hand, standardization of foods is a way of ensuring fair manufacturing and trade practices.

The activities of the Codex Alimentarius Commission over more than twenty years have represented an important assistance for African, Asian and Latin American countries, since the standards and codes of hygienic practice constitute the basis for the development or improvement of their own food legislation and for an efficient food quality control. Through this, it is intended to enable them not only to supply raw materials but also to manufacture finished products according to standard and to offer them on the world market.

In future, the task of industrialized nations will be more and more to become aware of the problem of acceptance of Codex standards and codes in order to enforce them by harmonizing their regulations.

Ladies and Gentlemen,

the attention of the Federal Government is particularly drawn to the Codex Committee on Foods for Special Dietary Uses which from the very beginning was chaired by the Federal Republic of Germany. Up to now, the Committee has elaborated five standards that have been adopted by the Commission and submitted to governments for approval.

Several crucial points, too, besides further discussion of different fields of action, range among the items of the agenda of this 14th session, especially:

- (i) the subject already provisionally discussed by the newly formed Working Group I (Nutritional Aspects in Codex Standards and Related Matters) on the 24th and 25th of January, 1985,
- (ii) the final discussion in view of the definitive adoption of the Revised Draft of the General Standard for the Labelling of and Claims for prepackaged Foods for Special Dietary Uses, and
- (iii) the consideration of the Proposed Draft Standard for Follow-up Foods for Infants and Young Children.

In its 15th Plenary Session in 1983, the Codex Alimentarius Commission approved a considerable extension of the terms of reference of this Committee as to nutritional aspects. This means:

- (a) the elaboration of provisions for nutritional aspects of all foods,
- (b) the discussion in the Codex Commodity Committees for General Questions of nutritional aspects related to the standards falling under their terms of reference,
- (c) the examination and approval of the provisions on nutritional aspects in draft standards or other Codex texts that are submitted to the Codex Alimentarius Commission by other subsidiary bodies.

Due to this enlargement of terms of reference the Committee will be obliged to set certain priorities. It will have to decide on whether special dietary questions should still continue to be a priority matter or whether, in view of the importance for the world population, problems of nutrition should be given preference.

It is an essential task of public health policy, also in industrialized nations, to extend and improve nutritional information. It is up to them to strengthen the responsibility of each individual and to point out how to consolidate and maintain health and efficiency by means of self-help and preventive measures. The transfer of knowledge has to achieve changes in behaviour, in particular in order to reduce the enormous cost of nutrition-related diseases and to provide those concerned with more quality of life. In this respect, the Committee will eventually be able to give more impetus.

Ladies and Gentlemen,

I come to the end of my opening address. I hope that your discussions during the strenuous sessions will be successful and that you will enjoy your stay in Bonn. I also hope that beside the expert discussions you will find time for talking to each other and cultivating often long-standing relationships. Thank you.

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DRAFT GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR
PREPACKAGED FOODS FOR SPECIAL DIETARY USES
(At Step 8)

1. SCOPE

This standard applies to the Labelling of all Prepackaged Foods for Special Dietary Uses as defined in Section 2.1 to be offered as such to the consumer or for catering purposes and certain aspects relating to the presentation thereof and to claims made for such foods.

2. DEFINITION OF TERMS

For the purpose of this standard:

2.1 Foods for Special Dietary Uses are those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such 1/. The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist.

2.2 The definitions laid down in the Codex General Standard for the Labelling of Prepackaged Foods 2/ apply.

3. GENERAL PRINCIPLES

3.1 Prepackaged foods for special dietary uses shall not be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding their character in any respect.

3.2 Nothing in the labelling and advertising of foods to which this standard applies shall imply that advice from a qualified person is not needed.

4. MANDATORY LABELLING OF PREPACKAGED FOODS FOR SPECIAL DIETARY USES

The label of all prepackaged foods for special dietary uses shall bear the information required by Section 4 of the Codex General Standard for the Labelling of Prepackaged Foods 2/ and Sub/sections 4.1 to 4.8 of this section as applicable to the food being labelled, except to the extent otherwise expressly provided in a specific Codex standard.

4.1 The Name of the Food

In addition to the declaration of the name of the food in accordance with Sections 4.1.1 and 4.1.2 of the Codex General Standard for the Labelling of Prepackaged Foods 2/ the following provisions apply:

4.1.1 The designation "special dietary", "special dietetic" or an appropriate equivalent term, may be used in conjunction with the name only where the product corresponds to the definition of such foods in Section 2.1.

4.1.2 The characterizing essential feature but not the condition for which the food is intended, shall be stated in appropriate descriptive terms in close proximity to the name of the food.

1/ This includes foods for infants and young children.

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

4.2 List of Ingredients

4.2.1 The declaration of the list of ingredients shall be in accordance with Sections 4.2.1, 4.2.2 and 4.2.3 of the Codex General Standard for the Labelling of Prepackaged Foods. 1/

4.3 Nutritional Labelling

4.3.1 The declaration of nutritional information on the label shall contain the following:

(a) The amount of energy per 100 grammes or 100 ml of the food as sold and where appropriate per specified quantity of the food as suggested for consumption, expressed in kilocalories (Kcal) and kilojoules (kJ).

(b) The number of grammes of protein, available carbohydrate and fat per 100 grammes or 100 ml of the food as sold and where appropriate per specified quantity of the food as suggested for consumption.

(c) The total quantity of those specific nutrients or other components which provide the characterizing essential feature for the special dietary use for which the food is intended per 100 grammes or 100 ml of the food as sold and, where appropriate, per specified quantity of the food as suggested for consumption.

4.4 Net Contents and Drained Weight

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

4.5 Name and Address

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

4.6 Country of Origin

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

4.7 Lot Identification

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

4.8 Date Marking and Storage Instructions

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

4.8.1 Storage of Opened Food

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

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

5. ADDITIONAL MANDATORY REQUIREMENTS FOR SPECIFIC FOODS

5.1 Quantitative Labelling of Ingredients

5.1.1 The quantitative labelling of ingredients shall be in accordance with Sections 5.1.1 to 5.1.4 of the Codex General Standard for the Labelling of Prepackaged Foods. 1/

5.2 Claims

5.2.1 Any claims made for the foods covered by this standard shall be in accordance with the General Guidelines on Claims elaborated by the Codex Alimentarius Commission.

5.2.2 Where a claim is made that the food is suitable for "special dietary uses" that food shall comply with all provisions of this standard except otherwise provided in a specific Codex Standard for Foods for Special Dietary Uses.

5.2.3 A food which has not been modified in accordance to Section 2.1 but is suitable for use in a particular dietary regimen because of its natural composition shall not be designated "special dietary" or "special dietetic" or any other equivalent term. However, such a food may bear a statement on the label that "this food is by its nature X" (X means the essential distinguishing characteristic) provided that such statement does not mislead the consumer.

5.2.4 Claims as to the suitability of a food as defined in Section 2.1 for use in the prevention, alleviation, treatment or cure of a disease, disorder or particular physiological condition are prohibited unless they are:

(a) in accordance with the provisions of Codex Standards or Guidelines for Foods for Special Dietary Uses, and following the principles set forth in such standards or guidelines;

(b) or, in the absence of an applicable Codex standard or guideline, permitted under the laws of the country in which the food is distributed.

5.3 Irradiated Foods

5.3.1 Irradiated foods for special dietary uses shall be labelled in accordance with Section 5.2 of the Codex General Standard for the Labelling of Prepackaged Foods. 1/

5.4 Nothing in this standard shall preclude the adoption of additional or different provisions in a Codex Standard for Foods for Special Dietary Uses, in respect of labelling, where the circumstances of a particular food would justify their incorporation in that standard.

6. EXEMPTIONS FROM MANDATORY LABELLING REQUIREMENTS

6.1 Exemptions from mandatory labelling requirements shall be in accordance with Section 6.1 of the Codex General Standard for the Labelling of Prepackaged Foods. 1/

7. OPTIONAL LABELLING

7.1 Optional labelling of foods for special dietary uses shall be in accordance with Sections 7.1 and 7.2 of the Codex General Standard for the Labelling of Prepackaged Foods. 1/

8. PRESENTATION OF MANDATORY INFORMATION

8.1 The presentation of the mandatory information shall be in accordance with Sections 8.1.1 to 8.1.5 and Sections 8.2.1 and 8.2.2 of the Codex General Standard for the Labelling of Prepackaged Foods. 1/

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

LIST OF CODEX STANDARDS FOR FOODS
FOR SPECIAL DIETARY USES

The following standards have been adopted by the Codex Alimentarius Commission and sent to Member Governments for acceptance:

(a)	Food with Low-Sodium Content (Including Salt Substitutes)	CODEX STAN 53-1981
(b)	Infant Formula	CODEX STAN 72-1981
(c)	Canned Baby Foods	CODEX STAN 73-1981
(d)	Processed Cereal-Based Foods for Infants and Children	CODEX STAN 74-1981
(e)	"Gluten-free" Foods	CODEX STAN 118-1981

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APPENDIX IV

PROPOSED DRAFT STANDARD FOR FOLLOW-UP FOOD FOR OLDER
INFANTS AND YOUNG CHILDREN
(At Step 5)

1. SCOPE

1.1 This standard applies to the composition and labelling of follow-up foods for infants from 4-6 months on and young children.

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

2. DESCRIPTION

2.1 Definitions

2.1.1 "Follow-up Food" means a food intended for use as a liquid part of the weaning diet for the infant from the age of 4-6 months on and for the young child.

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

2.1.3 The term "young child" means a person of 1-3 years of age.

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

2.2 "Follow-up Food" is prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin, which have been proved to be suitable for infants from the age of 4-6 months on and for young children.

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

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

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Energy Content

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

3.2 Nutrient Content

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

3.2.1 Protein per 100 Available Calories (or Kilojoules)

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

3.2.1.2 Essential amino acids may be added to Follow-up Food only to improve its nutritional value. Essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L forms of amino acids shall be used.

3.2.2 Fat per 100 Available Calories (or Kilojoules)

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

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

3.2.3 Carbohydrates

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

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

3.2.4 Vitamins other than Vitamin E

	<u>Amounts per 100 available Calories</u>		<u>Amounts per 100 available kilojoules</u>	
	<u>Minimum</u>	<u>Maximum</u>	<u>Minimum</u>	<u>Maximum</u>
Vitamin A	250 I.U. or 75 µg expressed as retinol	750 I.U. or 225 µg expressed as retinol	60 I.U. or 18 µg expressed as retinol	180 I.U. or 54 µg expressed as retinol
Vitamin D	40 I.U. or 1 µg	120 I.U. or 3 µg	10 I.U. or 0.25 µg	30 I.U. or 0.75 µg
Ascorbic acid (Vitamin C)	8 mg	N.S. <u>1/</u>	1.9 mg	N.S. <u>1/</u>
Thiamine (Vitamin B ₁)	40 µg	N.S. <u>1/</u>	10 µg	N.S. <u>1/</u>
Riboflavin (Vitamin B ₂)	60 µg	N.S. <u>1/</u>	14 µg	N.S. <u>1/</u>
Nicotinamide	250 µg	N.S. <u>1/</u>	60 µg	N.S. <u>1/</u>
Vitamin B ₆ <u>2/</u>	45 µg	N.S. <u>1/</u>	11 µg	N.S. <u>1/</u>
Folic acid	4 µg	N.S. <u>1/</u>	1 µg	N.S. <u>1/</u>
Pantothenic acid	300 µg	N.S. <u>1/</u>	70 µg	N.S. <u>1/</u>
Vitamin B ₁₂	0.15 µg	N.S. <u>1/</u>	0.04 µg	N.S. <u>1/</u>
Vitamin K ₁	4 µg	N.S. <u>1/</u>	1 µg	N.S. <u>1/</u>
Biotin (Vitamin H)	1.5 µg	N.S. <u>1/</u>	0.4 µg	N.S. <u>1/</u>
3.2.5 <u>Vitamin E</u> (<u>α</u> -tocopherol compounds)	0.7 I.U./ g linoleic acid <u>3/</u> but in no case less than 0.7 I.U./100 available Calories	N.S. <u>1/</u>	0.15 I.U./g linoleic acid <u>3/</u> but in no case less than 0.15 I.U./100 available kilojoules	N.S. <u>1/</u>

1/ N.S. = Not specified.

2/ Formulas should contain a minimum of 15 µg Vitamin B₆ per gramme of protein. See Section 3.2.1.1.

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

3.2.6 Minerals

	<u>Amounts per 100 available Calories</u>		<u>Amounts per 100 available kilojoules</u>	
	<u>Minimum</u>	<u>Maximum</u>	<u>Minimum</u>	<u>Maximum</u>
Sodium (Na)	20 mg	85 mg	5 mg	21 mg
Potassium (K)	80 mg	[200 mg]	20 mg	[50 mg]
Chloride (Cl)	55 mg	[150 mg]	14 mg	[35 mg]
Calcium (Ca) ^{1/}	[90 mg]	N.S. ^{2/}	[22 mg]	N.S. ^{2/}
Phosphorus (P) ^{1/}	[60 mg]	N.S. ^{2/}	[14 mg]	N.S. ^{2/}
Magnesium (Mg)	6 mg	N.S. ^{2/}	1.4 mg	N.S. ^{2/}
Iron (Fe)	1 mg	2 mg	0.25 mg	0.50 mg
Iodine (I)	5 ug	N.S. ^{2/}	1.2 ug	N.S. ^{2/}
Zinc (Zn)	0.5 mg	N.S. ^{2/}	0.12 mg	N.S. ^{2/}

3.3 Ingredients

3.3.1 Essential Ingredients

3.3.1.1 Follow-up Food shall be prepared from the milk of cows or of other animals and/or other protein constituents of animal and/or plant origin which have been proved suitable for infants from the age of 4-6 months on and for young children and from other suitable ingredients necessary to achieve the essential composition of the product as set out in Sections 3.1 and 3.2 above.

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

3.3.2 Optional Ingredients

3.3.2.1 In addition to the vitamins and minerals listed under 3.2.4 to 3.2.6, other nutrients may be added when required in order to ensure that the product is suitable to form part of a mixed feeding scheme intended for use from 4-6 months on.

3.3.2.2 The usefulness of these nutrients shall be scientifically shown.

3.3.2.3 When any of these nutrients is added, the food shall contain significant amounts of these nutrients, based on the requirements of infants from 4-6 months on and young children.

3.4 Purity Requirements

3.4.1 General

All ingredients shall be clean, of good quality, safe and suitable for ingestion by infants from 4-6 months on and young children. They shall conform with their normal quality requirements, such as colour, flavour and odour.

3.4.2 Vitamin Compounds and Mineral Salts

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

^{1/} The Ca:P ratio shall be not less than 1.0 and not more than 2.0.

^{2/} N.S. = Not specified.

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

3.5 Consistency and Particle Size

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

3.6 Specific Prohibition

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

4. FOOD ADDITIVES

The following additives are permitted:

		<u>Maximum Level in 100 ml of Product Ready-for-Consumption</u>
4.1	<u>Thickening Agents</u>	
4.1.1	Guar gum)	0.1 g
4.1.2	Locust bean gum)	
4.1.3	Distarch phosphate)	0.5 g singly or in combination
4.1.4	Acetylated distarch phosphate)	in soy-based products only
4.1.5	Phosphated distarch phosphate)	
4.1.6	Acetylated distarch adipate <u>1/</u>)	2.5 g singly or in combination
)	in hydrolyzed protein and/or
)	amino acid-based products only
4.1.7	Carrageenan)	0.03 g singly or in combination
4.1.8	Alginates, Na, K, Ca, NH ₄ <u>2/</u>)	in milk and soy-based products
)	only
)	
)	0.1 g singly or in combination
)	in hydrolyzed protein and/or
)	amino acid-based liquid
)	products only
4.1.9	Pectins (amidated and non-amidated) <u>2/</u>	1 g
4.2	<u>Emulsifiers</u>	
4.2.1	Lecithin	0.5 g
4.2.2	Mono- and Diglycerides	0.4 g
4.3	<u>pH-Adjusting Agents</u>	
4.3.1	Sodium hydrogen carbonate)	
4.3.2	Sodium carbonate)	
4.3.3	Sodium citrate)	
4.3.4	Potassium hydrogen carbonate)	
4.3.5	Potassium carbonate)	Limited by Good Manufacturing
4.3.6	Potassium citrate)	Practices within the limits for
4.3.7	Sodium hydroxide)	Na and K in Section 3.2.6
4.3.8	Potassium hydroxide)	
4.3.9	Calcium hydroxide)	
4.3.10	L (+) Lactic acid)	
4.3.11	L (+) Lactic acid producing cultures)	
4.3.12	Citric acid)	

1/ Technological justification for replacement of hydroxypropyl starch to be supplied to the CCFA.

2/ Technological justification to be supplied to the CCFA and maximum levels to be confirmed.

4.4 Antioxidants

		<u>Maximum Level in 100 ml of Product Ready-for-Consumption</u>
4.4.1	Mixed tocopherols concentrate)	
4.4.2	α-Tocopherol <u>1/</u>)	3 mg singly or in combination
4.4.3	L-Ascorbyl palmitate <u>1/</u>)	5 mg singly or in combination,
4.4.4	L-Ascorbic acid and its Na, Ca salts <u>1/</u>)	expressed as ascorbic acid (See Section 3.2.6)

4.5 Flavours

4.5.1	Natural Fruit Extracts <u>1/</u>	GMP
4.5.2	Vanilla extract <u>1/</u>	GMP
4.5.3	Ethyl vanillin <u>1/</u>	5 mg
4.5.4	Vanillin <u>1/</u>	5 mg

4.6 Colours

4.6.1	Caramel colour, plain <u>1/</u>	GMP
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4.7 Carry-Over Principle

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

5. CONTAMINANTS

5.1 Pesticide Residues

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

5.2 Other Contaminants

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

6. HYGIENE

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

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

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

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

1/ Technological justification to be supplied to the CCFA and maximum levels to be confirmed.

7. PACKAGING

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

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

8. FILL OF CONTAINERS

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

(i) not less than 80% v/v for products weighing less than 150 g (5 1/2 oz.);

(ii) not less than 85% v/v for products in the weight range 150-250 g (5 1/2 - 9 oz.); and

(iii) not less than 90% v/v for products weighing more than 250 g (9 oz) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20° C which the sealed container will hold when completely filled.

9. LABELLING *

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

9.1 The Name of the Food

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

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

"9.1.3 The sources of protein shall be clearly shown on the label in close proximity to the name of the food in descending order of proportion by weight, except for those products which are labelled in accordance with Section 9.1.2."

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

9.2 List of Ingredients

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

* See para. 74.

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

9.3 Declaration of Nutritive Value

The declaration of nutrition information shall contain the following:

9.3.1 The amount of energy per 100 ml of the food ready-for-consumption expressed in kiloCalories (kcal) and kilojoules (kJ).

9.3.2 The number of grammes of protein, available carbohydrate and fat per 100 ml of the food ready-for-consumption.

9.3.3 The total quantity of each vitamin, mineral and any optional ingredient, as listed in Section 3.3.2 of this standard per 100 ml of the food ready-for-consumption.

9.4 Net Contents and Drained Weight

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

9.5 Name and Address

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

9.6 Country of Origin

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

9.7 Lot Identification

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

9.8 Date Marking and Storage Instructions

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

9.8.1 Storage of Opened Food

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

9.9 Information for Utilization

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

9.9.2 The labelling of a Follow-up Food shall include a statement that Follow-up Food should be introduced only from 4-6 months on.

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

10. METHODS OF ANALYSIS AND SAMPLING

See Appendix XIII to this Report.

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

REPORT OF THE AD-HOC WORKING GROUP ON NUTRITIONAL ASPECTS
IN CODEX STANDARDS AND RELATED MATTERS

INTRODUCTION

1. The 13th Session of CCFSU established an ad-hoc Working Group on Nutritional Aspects in Codex Standards and Related Matters to consider the following items:

- Proposed Draft Guidelines for the Use of Codex Committees on the Inclusion of Provisions on Nutritional Quality in Food Standards and other Codex Texts (At Step 4);
- First Draft of General Principles for the Addition of Nutrients to Foods;
- Need to amend the name of the Committee; and
- Other matters related to nutritional aspects.

2. The above Working Group met on 24-25 January 1985 in Bonn-Bad Godesberg in conjunction with the 14th Session of CCFSU. The meeting was chaired by Dr. P. Noble, Regierungsratin, Federal Ministry of Youth, Family and Health of the Federal Republic of Germany. A list of participants is attached as Annex I.

PROPOSED DRAFT GUIDELINES FOR THE USE OF CODEX COMMITTEES ON THE INCLUSION OF PROVISIONS
ON NUTRITIONAL QUALITY IN FOOD STANDARDS AND OTHER CODEX TEXTS (At Step 4)

3. The Working Group considered the above guidelines as contained in Appendix IV to ALINORM 83/26 in the light of comments from the United States, and the International Union of Nutritional Sciences (IUNS).

Section 1 - Purpose

4. No change was made to this section.

Section 2 - Scope

5. The Working Group noted the written proposal from the United States to include general principles for the addition of nutrients to food and decided to postpone a decision on this matter until Section 4 had been discussed (see para. 20).

Section 3 - Definitions

6. The Working Group noted that these guidelines as well as the first draft of the General Principles for the Addition of Nutrients to Foods (Appendix to CX/FSDU 85/4-Part II), and other Codex texts (e.g., Guidelines on Nutrition Labelling) contained definition of terms, and agreed that, in principle, only one Codex definition for each of the terms should be developed.

(a) Fortification (3.1)

7. General proposals were made to amend the definition for fortification with the intent to distinguish it clearly from the term "restoration". It was pointed out that only the addition of nutrients over and above the level normally contained in the food or after restoration, should be defined as fortification. Several delegations indicated that the requirement that a deficiency of nutrients be demonstrated was too restrictive and created a difficulty with the fortification of foods such as breakfast cereals. Other delegations were of the opinion that the deficiency had to be demonstrated to avoid fortification for promotional purposes only.

8. The Working Group agreed that the definition of "fortification" should be very clear and informative for the use by Codex Committees and should read as follows:

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

9. The Working Group considered the feasibility of including the term "enrichment" as an alternative. It was noted that in many countries the term enrichment was not equivalent to fortification. It was decided to include the term in square brackets and to obtain specific government comments.

10. The Working Group agreed that, instead of following an alphabetical order, it was more appropriate to group terms in order of significance and that the term "restoration" should follow that for "fortification" after the present definitions in Sections 3.2 to 3.5.

Nutrient (3.2)

11. The Working Group noted several proposals to amend this definition, in particular with reference to "healthy life" instead of "life" (b) and "patho-physiological changes" or "nutritional disturbances" instead of "physiological changes". The view was also expressed that it might not be necessary to include a definition of "nutrient" since most of the provisions related to "essential nutrients" which were defined in Section 3.3. The Working Group decided to include the definition of "nutrient" as contained in the Guidelines on Nutrition Labelling, including reference to "healthy life", but excluding reference to chemical substance.

Essential Nutrient (3.3)

12. It was agreed to use the definition for "essential nutrient" as contained in the General Principles for the Addition of Nutrients to Foods; however the term "chemical" was deleted. Similar to the decision on Section 3.2, reference to "healthy life" was included.

Nutritional Equivalence (3.4)

13. The Working Group did not agree with a proposal of the United States to exempt energy, fat and sodium content from the requirement of equivalence and agreed that this was better discussed under Section 4.3.1. The Working Group agreed that such an exemption should be of a more general nature as provided in Section 6.1 of the General Principles for Food Fortification. The Working Group agreed that in the French version the term "comparable" should be used instead of "égal". The definition was left unchanged.

Nutritional Quality (3.5)

14. The Working Group noted comments which indicated that this definition was too comprehensive in its present version. It agreed, however, that these guidelines were intended to provide Codex Committees with advice on nutritional quality and that this definition provided a summary of aspects pertaining to nutritional quality. The Working Group decided to place the improved version submitted by IUNS in a preamble to the guidelines, deleting reference to environmental contaminants and drugs.

Restoration (3.6)

15. The Working Group recalled its earlier decision to place the definition for fortification and restoration in close proximity. The view was expressed that restoration should only be permitted if the loss of nutrients resulted in a deficiency. If generally applied there could be a confusion between foods in which nutrients had been restored and those to which no nutrients had been added. The requirement for levels at least as high as those in the pre-processed food might lead to a higher addition of the nutrients concerned than intended. The Working Group agreed that restoration meant only the addition of nutrients to the level originally contained in the food.

16. The Working Group noted the proposal in the written comments of the USA and decided that the proposed amendment referring to measurable contribution should be

considered under Section 4.3.1.1. The Working Group was in favour of adopting Section 3.8 of the General Guidelines for the Addition of Nutrients to Foods, placing the term "unavoidably" in square brackets. The Working Group noted a proposal to limit restoration to essential nutrients and agreed that this again was a matter for Section 4.

Substitute Food (3.7)

17. The Working Group noted the view that this definition did also apply to products resembling foods of non-animal origin and placed the term "in particular foods of animal origin" in square brackets. The Working Group considered also a proposed amendment which referred to claims of nutrient addition to substitute foods and decided that the matter of claims did not belong to a definition and should be covered somewhere else.

Nutrient Density (New Section)

18. The Working Group noted a proposal to include a definition of nutrient density, a concept which was gaining more importance. The Working Group also noted that CCFL had developed such a definition. The Working Group did not include the definition of nutrient density since it did not appear in the guidelines.

Section 4 - Instruction to Codex Committees

Section 4.1 - No change.

Section 4.2

19. As a consequence of earlier decisions, Section 4.2(a) was amended to read: "The food is a major source of energy and nutrients in the diets of populations or specific population groups"; and Section 4.2(b) to read: "The food has sustained significant [and unavoidable] losses of [essential] nutrients during processing, storage and handling". There was an extensive discussion on whether anyone of the points (a) to (e) individually would require the establishment of provisions and advisory uniformation on nutritional aspects. The view was expressed that: (a) together with anyone of the circumstances described in (b) to (e) was more appropriate. The Working Group concluded that more comments were needed on this point and decided to add after each of the subsection the word "or" in square brackets.

Section 4.3 - Addition of Nutrients to Foods

20. The Working Group noted the extensive comments on this section submitted by the United States. The view was expressed that this additional material pertaining to the section on addition of nutrients was more valuable and appropriate in the General Principles for the Addition of Nutrients to Foods. The Working Group agreed to replace the present Section 4.3.1 by a reference to the General Principles for the Addition of Nutrients to Foods and to refer the US comments to the plenary for discussion of the General Principles.

21. The view was expressed that in Sections 4.3.2, 4.3.3 and 4.3.4, it should be decided whether the term "nutrient" or "essential nutrient" was applicable. No changes were made at present to Sections 4.3.2, 4.3.3 and 4.3.4.

22. With regard to Section 4.3.4.1 there was a discussion challenging the appropriateness of requiring a mandatory provision to specifying the amounts of nutrients to be contained in the food. As the Working Group was not in a position to decide on this matter, it agreed to place the whole provision in square brackets. The Working Group agreed, however, that the "general agreement" referred to in the text of 4.3.4.1 and 4.3.4.3 related to agreement within the Codex Committee concerned, rather than to the view of the scientific community in general.

23. The Working Group agreed that the material in Section 4.3.5 was more appropriate for the General Principles for the Addition of Nutrients to Foods and transferred it to the latter document.

24. Several delegations felt that it was not appropriate to include a requirement for the establishment of advisory lists for vitamin compounds and mineral salts in these guidelines. Dr. Cheney of Canada, the author of the guidelines, explained that the meaning of Section 4.3.6 was that Codex Committees should develop such lists for the products they were standardizing, since they had the necessary expertise. It was noted that approved lists existed already for infant foods and that these would be useful as a starting point for drawing up similar lists for other foods. The Working Group decided that the present text should be amended accordingly.

Section 4.4

25. There was a proposal to include also reference to micro-nutrients besides the existing provisions for macro-nutrients and to biological availability. The author explained that this section was intended to cover compositional aspects, e.g. minimum meat protein content. The Working Group decided to refer to "nutrients" rather than "macro-nutrients".

Section 4.5

26. No change was made to this section.

Section 4.6

27. The Working Group discussed whether it should be mandatory for Codex Committees to submit all provisions on nutritional aspects for endorsement by the CCFSU. The Working Group noted that the revised terms of reference could be interpreted to this effect. However, the 15th Session of the Commission had amended the relevant clause to require that such provisions should be specifically referred to this Committee, leaving the decision with the Codex Committee concerned as regards the need to consult the CCFSU. The Working Group was of the opinion that this Committee should examine all provisions on nutritional aspects in order to coordinate the approach taken by Codex Committees. The Working Group decided to delete the square brackets from the last sentence.

Conclusion

28. The Working Group recommended to the Committee that the above guidelines, as amended, be advanced to Step 5 of the Procedure. The amended text is contained in Annex II to this paper.

FIRST DRAFT OF GENERAL PRINCIPLES FOR THE ADDITION OF NUTRIENTS TO FOODS

29. The Chairman expressed the thanks of the Working Group to Dr. Cheney of Canada for preparing an excellent first draft of General Principles for the Addition of Nutrients to Foods (CX/FSU 85/4-Part II). Referring to its earlier decision to review the above document in the light of the comments from the United States, the Working Group accepted the kind offer of the delegations of the United States and Canada to revise the paper in cooperation within other interested countries. The revised document would be referred to the plenary for consideration.

OTHER MATTERS OF INTEREST

30. The Working Group had before it documents CX/FSU 85/4-Parts I and III. The Working Group noted the discussions which took place at the 6th Session of the Coordinating Committee for Africa and the 17th Session of the Codex Committee on Food Labelling concerning matters relating to nutritional aspects.

General Guidelines for the Utilization of Vegetable Protein Products in Foods (Appendix II to ALINORM 85/30)

31. The Working Group was informed that the above guidelines at Step 5 had been referred to this Committee for consideration (para. 76, ALINORM 85/30). The Working Group noted that most of the sections of the guidelines contained provisions on nutritional aspects of a complex nature, requiring a considerable amount of attention. The Working Group decided, therefore, to establish a specific working party to prepare written

comments on the guidelines and advice to CCVP, which would be submitted to the plenary for approval. The working party, under the Chairmanship of Norway, consisted of delegations of Thailand, United Kingdom, France, USA, Canada, Cameroon, the Netherlands, Kuwait and the Federal Republic of Germany.

Restoration of Nutrients in Wheat Flour (Paras 216-218 of ALINORM 85/29)

32. The Working Group was informed that CC/CPL had requested this Committee to advise on the need for separate guidelines on restoration of nutrients in wheat flour and decided that the working party should also give consideration to this matter (see para. 31 above).

Name of the Committee (Para. 22 of ALINORM 83/26)

33. The Chairman recalled that the CC/FSDU, at its previous Session, had considered amending its name to reflect the extended terms of reference. It was noted that no additional proposals for an amended name had been submitted. Following discussions, the Working Group decided that it was premature to change the name of the Committee and so recommended to the Committee.

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PROPOSED DRAFT GUIDELINES FOR THE USE OF CODEX COMMITTEES ON THE
INCLUSION OF PROVISIONS ON NUTRITIONAL QUALITY IN
FOOD STANDARDS AND OTHER CODEX TEXTS
(At Step 5)

Nutritional quality as applied to food means the presence of essential nutrients and energy-yielding substances, and other aspects of food, consideration of which is traditionally considered as part of the science of nutrition.

These other aspects include non-essential amino-acids; specific types of fatty acids and carbohydrates; dietary fibre (plant material not digested by human enzymes); cholesterol; lipotropic substances; all components of human milk (except drugs, other contaminants); the quantity and quality of fats and proteins; nutrient bioavailability; nutrient interactions with other nutrients and with food additives, natural toxicants; nutrient excesses; and the effects of food processing, both positive and negative, on such nutritional quality.

These aspects of nutritional quality must be evaluated in terms of modern nutritional principles, standards and guidelines aimed at meeting human nutritional needs. These include recommended nutrient intakes, nutrient density, the role of the food in the diet of the population and the role of diet and nutrition in disease prevention and health promotion.

1. PURPOSE

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

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

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

2. SCOPE

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

3. DEFINITIONS

For the purpose of these guidelines:

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

- (a) Which provides energy; or
- (b) which is needed for the growth and development and maintenance of healthy life; or
- (c) a deficit of which will cause characteristic biochemical or physiological changes to occur.

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

3.3 Nutritional equivalence means of equal nutritive value in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients.

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

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

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

4. INSTRUCTIONS TO CODEX COMMITTEES

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

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

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

(b) the food has sustained significant [and unavoidable] losses of [essential] nutrients during processing, storage and handling; [or]

(c) the food is destined for use as a substitute for, or the principal ingredient in a substitute for a common food [particularly of animal origin]; [or]

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

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

4.3 Addition of Nutrients to Foods

4.3.1 Provision for the addition of nutrients to foods should be made, where appropriate, in conformity with the General Principles for the Addition of Nutrients to Foods (Appendix VII to ALINORM 85/26).

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

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

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

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

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

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

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

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

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

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

ALINORM 85/26

APPENDIX VI

REPORT OF WORKING PARTY ON REVIEW OF SPECIFIC MATTERS
REFERRED TO WORKING GROUP I

1. The Working Party was chaired by Professor Fredrik Gran of Norway, Dr. M.C. Cheney, Canada, Mme. M. Astier-Dumas, France, and Dr. Gunter Pahlke, Federal Republic of Germany, acted as rapporteurs. The following countries and International Organizations are represented: Cameroon, Canada, Federal Republic of Germany, France, Iran, Kuwait, Mexico, Netherlands, Norway, Sweden, Switzerland, Thailand, United Kingdom, United States, EEC, FAO (Codex Secretariat).

2. The Working Party had before it the document, CX/FSDU 85/4-Part III. Its attention was drawn in particular to Appendix I containing the Proposed Draft Guidelines for the Utilization of Vegetable Protein Products (VPP) in Foods at Step 5.

3. The Working Party noted that the Codex Committee on Vegetable Proteins (CCVP) had indicated that CCFSDU should at some time review the nutritional aspects of the above guidelines. It was further noted that this was an appropriate time since the guidelines would be at Step 6 when CCVP will be meeting again later in 1985.

4. Initially there was some discussion of the need to amend Section 2 - Scope to exclude foods for infants and children, however, it was decided that no revision to this section was necessary.

5. It was agreed to submit the following comments on the guidelines to CCFSU for transmittal to CCVP.

COMMENTS ON PROPOSED DRAFT GUIDELINES FOR THE UTILIZATION OF VEGETABLE PROTEIN PRODUCTS (VPP) IN FOODS

General Comments

6. The Working Party noted that the guidelines will be used by other Codex Committees, Governments and manufacturers who have not had the benefit of the background papers and expert advice and discussion which went into their development. CCVP should consider expanding the guidelines where necessary to ensure that their intent will be fully understood by those using them.

7. The Working Party requested that the Proposed Draft Guidelines for the Use of Codex Committees on the Inclusion of Provisions on Nutritional Quality in Food Standards and Other Codex Texts and the General Principles on the Addition of Nutrients to Foods be drawn to the attention of the CCVP and that the CCVP be asked to consider these two texts in the further development of these guidelines.

Specific Comments

8. Section 3 - Definitions

- 1) Definitions should be developed for the following terms: protein quality, anti-nutritional factors, nutritional quality.
- 2) The following definitions require clarification: complementation, supplementation, utilizable protein.
- 3) The definition of vegetable protein products (VPP) should be expanded to include reference to different forms of VPP such as concentrates and isolates.
- 4) The reference "protein" used in determining the amino acid score should be the amino acid pattern described by FAO/WHO, 1984.

9. Section 5 - Uses of VPP for Functional and Optional Purposes

Since this section does not, for practical reasons, mention maximum levels of use, greater emphasis should be placed on the need to ensure that no replacement of the principal protein source and associated nutrients occurs.

10. Section 6 - Uses of VPP to Increase Content of Utilizable Protein

- 1) The following sentence should be added to Subsection 6.1: "It should be noted that increasing the protein quantity and/or quality of a diet will be ineffective if energy requirements are not met".
- 2) The following sentence should be added to Subsection 6.4: "Only L forms of amino acids should be used".
- 3) The requirements discussed in Subsection 6.6 should be reviewed and re-formulated in accordance with the General Principles on the Addition of Nutrients to Foods.
- 4) The word "endemic" in Subsection 6.6 should be changed to "demonstrated".
- 5) Subsection 6.7 requires clarification with respect to supplementation and complementation in light of a review of the definitions for these terms.

- 6) The square brackets should be removed in Subsection 6.8.
11. Section 7 - Uses of VPP in Partial or Complete Substitution of the Animal Protein in Foods
- 1) The reference protein in subparagraph 7.2(i) should be standard casein.
 - 2) The conversion factor (N x 6.25), in subparagraph 7.2(ii) should be reconsidered.
12. Section 8 - Uses of VPP as Sole Protein Source in Products with New Identities
- Requirements pertaining to the nutrient content and nutrient labelling of these products should be developed.

COMMENTS ON PROPOSED DRAFT GUIDELINES FOR TESTING SAFETY AND NUTRITIONAL QUALITY OF VEGETABLE PROTEIN PRODUCTS

13. Subsection 1.2 Nutritional Value should be re-titled Protein Quality.
14. The criteria outlined in Section 2 have not been fully developed especially with respect to anti-nutritional factors and bioavailability.
15. Subsection 2.1.1.4 - Carbohydrates should be reworded as follows:
- "Analysis should be carried out to characterize both the available (digestible) and the unavailable carbohydrates."
16. In Subsection 2.4.2 - Other Studies the word "carcinogenic" should be inserted.

CODEX COMMITTEE ON CEREALS, PULSES AND LEGUMES

17. The Working Party noted the report of the 4th Session of the CC/CPL at which the Committee had considered the need for guidelines on the restoration of nutrients to wheat flour.
18. It was agreed that the CC/CPL should be asked to consider the Proposed Draft Guidelines for the Use of Codex Committees on the Inclusion of Provisions on Nutritional Quality in Food Standards and Other Codex Texts with particular attention to the provisions respecting restoration and advisory lists of vitamins and minerals. It was suggested that the CC/CPL might wish to consider the development of advisory information on the restoration of nutrients to wheat flour in the light of this document.

WORKING PARTY ON REVIEW OF SPECIFIC MATTERS
REFERRED TO THE WG I

List of Participants

<u>Name</u>	<u>Country</u>
M.C. Cheney	Canada
Jean-Claude Lowe	Cameroon
R.M. Tomarelli	USA
Duane Benton	USA
John Bushnell	USA
Joginder Chopra	USA
R.W. Weik	USA
George A. Purvis	USA
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Karin Winberg	Sweden
Lennart Hellving	Sweden
Günter Pahlke	Federal Republic of Germany
Rolf Grossklaus	Federal Republic of Germany
Wegdan M.H. Elhelw	Kuwait
R.W. Taplin	UK
David H. Buss	UK
Basil Mathioudakis	Commission of the EEC
Hadi Djahanschiri	Iran
Irina du Bois	Switzerland
Jorge Ramirez Caso	Mexico
Pracha Boonyasirikool	Thailand
M. Astier-Dumas	France
A.M.M. Abdellatif	Netherlands
Fredrik C. Gran	Norway

GENERAL PRINCIPLES FOR THE ADDITION OF NUTRIENTS TO FOODS

1. PURPOSE

- 1.1 To provide guidance to those responsible for developing guidelines and legal texts pertaining to the addition of essential nutrients to foods.
- 1.2 To establish a uniform set of principles for the rational addition of essential nutrients to foods.
- 1.3 To maintain or improve the overall nutritional quality of foods.
- 1.4 To prevent the indiscriminate addition of essential nutrients to foods thereby decreasing the risk of health hazard due to essential nutrient excesses, deficits or imbalances. This will also help to prevent practices which may mislead or deceive the consumer.
- 1.5 To facilitate acceptance in international trade of foods which contain added essential nutrients.

2. SCOPE

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

3. DEFINITIONS

For the purpose of these guidelines:

- 3.1 Nutrient means any substance normally consumed as a constituent of food:
- (a) which provides energy; or
 - (b) which is needed for growth and development and maintenance of healthy life; or
 - (c) a deficit of which will cause characteristic bio-chemical or physiological changes to occur.
- 3.2 Essential nutrient means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life and which cannot be synthesized in adequate amounts by the body.
- 3.3 Nutritional equivalence means being of equal nutritive value in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients.
- 3.4 Substitute food is a food which is designed to resemble a common food [particularly a food of animal origin] in appearance, texture, flavour and odour, and is intended to be used as a complete or partial replacement for the food it resembles.
- 3.5 Fortification [or enrichment] means the addition of one or more essential nutrients to a food over and above the levels normally contained in the food or the levels after restoration for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups.
- 3.6 Restoration means the addition to a food of essential nutrient(s) which are [unavoidably] lost during the course of good manufacturing practice, or during normal storage and handling procedures, in amounts which will result in the presence in the food of the levels of the nutrient(s) present in the edible portion of the food before processing, storage or handling.

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

4. BASIC PRINCIPLES

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

4.1.1 restoration;

4.1.2 nutritional equivalence of substitute foods;

4.1.3 fortification;

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

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

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

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

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

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

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

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

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

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

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

5. NUTRIENT ADDITION FOR PURPOSES OF RESTORATION

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

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

6. NUTRIENT ADDITION FOR PURPOSES OF NUTRITIONAL EQUIVALENCE

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

6.2 A food being substituted or partially substituted should be considered a significant source of an essential nutrient if the food contains the essential nutrient in amounts equal to or greater than [10%] of the recommended nutrient intake in a reasonable daily intake (or in the case of an essential nutrient for which there is no recommended intake, [10%] of the average daily intake).

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

7. NUTRIENT ADDITION FOR PURPOSES OF FORTIFICATION

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

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

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

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

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

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

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

8. NUTRIENT ADDITION TO SPECIAL PURPOSE FOODS

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

REPORT OF WORKING GROUP II ON CERTAIN STANDARDS AND GUIDELINES

INTRODUCTION

1. The Ad-hoc Working Group II met twice, on both occasions under the Chairmanship of Dr. Joginder Chopra of the United States. It consisted of members of the following delegations: Australia, Canada, France, Federal Republic of Germany, Norway, Netherlands, United Kingdom, Switzerland. On 28 January 1985 it discussed the Proposed Draft Standard for the Labelling of and Claims for Low Energy and Energy-Reduced Foods at Step 4 as in Appendix VII of ALINORM 83/26 and in the light of Government comments and the redraft contained in CX/FSDU 85/5 (Appendix I); and the Proposed Draft Guidelines for the Composition and Labelling of and Claims for Meal Replacements for Weight Reduction as contained in CX/FSDU 85/5 (Appendix II). On 29 January 1985 it discussed the Proposed Draft Guidelines for the Labelling of and Claims for [Medical Foods] at Step 4, as in Appendix VI of ALINORM 83/26 in the light of Government comments and the redraft contained in CX/FSDU 85/6.

PROPOSED DRAFT STANDARD FOR THE LABELLING OF AND CLAIMS FOR LOW ENERGY AND ENERGY-REDUCED FOODS (AT STEP 4)

2. Comments had been received from the Governments of Canada, Denmark, the Federal Republic of Germany, Hungary, New Zealand, and the United Kingdom. The United States had kindly redrafted the proposals to incorporate these comments, and the discussions of the Group concentrated on the revised version in CX/FSDU 85/5. It was noted that Appendix I was a proposed Standard while Appendix II was a proposed guideline. It was agreed that both would be Standards, but that the Secretariat should retain the present guideline format during the 14th Session of the Committee.

Section 1 - Purpose

3. No change was made to this section.

Section 2 - Scope

4. The Working Party wished to restrict the scope of the Standard to those foods that were specially formulated to be low or reduced in energy. The Secretariat was requested to redraft this section to make it clear that foods naturally low in energy were to be excluded from the provisions of the Standard.

5. It was noted that a number of the proposed labelling provisions were already covered in the Draft General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses, and it was agreed to restrict the labelling provisions to matters over and above these general provisions.

6. The delegation of the Netherlands requested the development of a separate standard for foods sweetened with sugar substitutes. The delegation of the Federal Republic of Germany also noted that there were a number of dietetic foods that were not covered by the draft standard or even by the Committee on Foods for Special Dietary Uses, but there was no detailed discussion of these suggestions.

7. It was noted that, in the French text, the distinction between 'energy' and 'calorie' required clarification.

Section 3 - Definitions

8. The Working Party discussed the concept of 'a serving' and made a number of proposals which required different qualifying energy values for different foods under definition 3.1. It was eventually agreed that the most practical solution was to insert the word 'specified' before 'serving' and to delete Section 3.7. It was also noted that the conversion from 40 kilo-calories was incorrect: the value should be 167 kilojoules, but there was a further suggestion that the rounded value of 170 kilojoules could be used.

9. The delegation of the United Kingdom reminded the Working Party that intense sweeteners bulked with, for example, lactose would contain 400 kilocalories per 100 g and

therefore fall outside the present definition of 'low energy food'. It was agreed that this should be corrected.

10. It was suggested that a food with 75% of the energy of the normal food, or, more stringently, with only 50% of the original energy content should qualify the food to be a 'reduced energy food'. It was agreed that the present suggestion of 66 2/3% in definition 3.2 should be retained, but in square brackets. It was also noted that the definition would include, for example, normal foods sold in smaller portions; and that the proposal (which is not a definition) in the second sentence of 3.2 and in 3.3 would not be possible for foods manufactured with added bulking agents or water or with less carbohydrate. It was agreed to replace these with the proposed definition of nutritional equivalence from the Proposed Draft Guidelines for the Use of Codex Committees on the Inclusion of Provisions of Nutritional Quality in Food Standards and Other Codex Texts (Appendix IV of ALINORM 83/26) and that foods with up to 30% less of the essential nutrients might be acceptable.

11. As the present definition of non-nutritive ingredient (3.4) includes essential minerals and vitamins, and the present definition of non-nutritive sweetener (3.5) excludes aspartame, the Secretariat was requested to consolidate definitions 3.4, 3.5 and 3.6. Proposals from France are as below, and alternative proposals in English are in the Annex.

- 3.4 "Non-nutritive ingredient(s)" means bulk substances (dietary fibre) little or not utilized in normal metabolism as a source of energy.
- 3.5 "Non-nutritive sweetener(s)" means intense sweeteners which, in view of the amounts used, are contributing only in a negligible way to the energy intake.
- 3.6 "Nutritive sweetener(s)" means bulk sweeteners partly or fully utilized in normal metabolism as a source of energy.

Section 4 - Labelling

12. Further to the discussion under 'Scope', it was agreed that foods naturally low in energy should be specifically stated to be covered by the General Standard for the Labelling of and Claims for Prepackaged Foods.

It was also agreed that as paragraphs 4.3 and 4.4 were already covered in the General Standard, they could be deleted, and that because paragraphs 4.2 and 4.5 added little they might also be considered for deletion.

Finally, the example of a 'reduced energy' food in paragraph 4.6 and the whole of paragraph 4.7 (which had amplified 4.6) should also be deleted.

Section 5 - Claims

13. A number of delegations expressed reservations about paragraph 5.1 (a). The Codex Secretariat noted that a paper on "negative claims" was being prepared by the delegation of Australia for the meeting of the Codex Committee on Food Labelling in Ottawa in March 1985. It would be circulated to the Committee on Foods for Special Dietary Uses, and the Working Party agreed that paragraph 5.1 (a) should be re-considered in the light of that paper. The delegation from France also expressed reservations with respect to paragraph 5.1 (b).

14. No changes were made to paragraphs 5.2(a), (b) and (c).

Section 6 - General Considerations

15. A number of delegations argued for the deletion of this Section. The Codex Secretariat pointed out that if this draft was to be a standard and not a guideline, it would not be appropriate to include such a section. It could, however, be placed in an Appendix after suitable re-wording, and it was agreed that this and the other changes that would be required after drafting in the form of a Standard would make it necessary for this draft to be re-considered. Accordingly Section 6 was placed in square brackets.

PROPOSED DRAFT GUIDELINES FOR THE COMPOSITION AND LABELLING OF AND CLAIMS FOR MEAL REPLACEMENTS FOR WEIGHT REDUCTION

16. Several delegations suggested that a distinction needed to be made between meal replacements that substituted for only one or two meals in the day, and meal replacements which constituted the entire diet. Both compositional and labelling requirements could be governed by the intended use of the product.

17. The Netherlands supported by the U.K. proposed that nutritional requirements for meal replacements used to replace single meals be less stringent than those for products constituting the total diet.

18. The German delegation proposed that labels of products used as the total diet should carry a warning statement cautioning against their use for more than 4 weeks without medical supervision and against their use by children.

19. The French delegation stated that meal replacements which are used once or twice a day should be accompanied by directions for use that ensure a daily energy intake of 1000 kcals. If meal replacements are used as the sole source of nourishment, this should be done only under medical supervision which by definition would make the meal replacements a medical food. This would be particularly important in the case of products represented for use in Very Low Calorie Diets.

Section 1 - Purpose

20. It was proposed that the words "weight control" be inserted both here and in the title of the Draft Standard.

Section 3 - Definitions

21. It was proposed that the word "single" be deleted.

Section 4 - General Principle of Description

22. No change was made to this Section.

Section 5 - Nutritional Aspects

23. Subsection 5.1. The Swiss delegation proposed that the figures in (a) and (b) be changed to 200 kcal and 750 kcal respectively. Other delegations did not agree, pointing out that these products are sold over the counter and are used without medical supervision. There is general agreement that individuals on diets providing less than 800 - 900 kcal per day require close medical supervision.

24. The Chairman pointed out that the Canadian proposal listed in Table I was incorrect and should be ignored.

25. It was not possible in the time available for discussion to continue beyond Section 5.2 - Protein. It was, however, noted that if this Guideline is to be re-drafted by the Secretariat in the form of a Standard (which was the course favoured by the delegations from the Federal Republic of Germany, France, and the Netherlands but not by the United Kingdom), then the format of the Standard for infant foods would be an appropriate one to follow.

PROPOSED DRAFT STANDARD FOR LABELLING OF AND CLAIMS FOR PREPACKAGED "LOW ENERGY"
AND "REDUCED ENERGY" FOODS 1/
(At Step 3)

1. PURPOSE

1.1 To insure that adequate information is provided to consumers regarding the nutritional value of foods for special dietary uses that purport to be or are represented as being useful in controlling or reducing energy intake or body weight.

1.2 To prevent deception of purchasers of foods for special dietary uses in controlling or reducing energy intake.

1.3 To provide appropriate criteria for labelling of and claims for "low energy" and "reduced energy" foods.

1.4 To restrict the use of label statements and to require certain disclosures on foods which are not of special dietary usefulness in controlling or reducing energy intake or body weight.

2. SCOPE

This standard applies to the labelling of and claims for foods manufactured to be low in energy or reduced in energy, and which are intended for controlling or reducing energy intake or body weight. It does not apply to foods naturally low in energy.

3. DEFINITIONS

3.1 A low energy food is: (a) a manufactured food which provides a maximum of 40 kilocalories or [167/170] kilojoules per specified serving and which has an energy density of no more than 40 kilocalories or [167/170] kilojoules per 100 g. (b) An intense sweetener, or (c) A product which consists of a mixture of an intense sweetener with other substances and which, when compared on a weight for weight basis, is significantly sweeter than sucrose.

3.2 A reduced energy food is a food which provides not more than [66 2/3%] of the energy that would be normally provided in that food if it were not energy (calorie)-reduced. [A "reduced energy food" should be nutritionally equivalent, except with respect to energy content, to the food for which it substitutes].

[3.3 Either insert definition of "Nutritional equivalence" or: Nutritional inferiority includes: Any reduction in the content of an essential nutrient that is present in measurable amount, but does not include a reduction in the energy or fat content. For the purpose of this standard a measurable amount of an essential nutrient in a food shall be considered to be [2] percent of RDA of protein or any vitamin or mineral per 100 ml or 100 gm and where appropriate per specified quantity in food as suggested for consumption or where the food is customarily not consumed directly per average or usual portion as expressed in 3.7(b)].

3.4 Non-nutritive ingredient is an ingredient consisting largely or completely of dietary fibre.

3.5 Intense sweetener is a substance which, weight for weight, is significantly sweeter than sucrose.

3.6 Nutritive sweetener is a sweetening substance which is utilized in the metabolism as a source of energy and contributes a significant amount of energy as normally consumed.

1/ No comments are requested on this version. The revised text will be issued as Addendum to ALINORM 85/26 in due course.

4. LABELLING

4.1 Foods to which this standard applies shall be labelled in conformity with the appropriate sections of the "General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses". Where foods are naturally low in energy they should also be labelled in conformity with the General Standard, and if possible in conformity with the specific labelling provisions for low-energy foods that have been specially prepared for special dietary uses.

[4.2 Foods to which this standard applies shall be permitted to bear in its labelling the term "Calorie" as an alternative for the term "Energy".]

4.5 The term "low energy" or a "low energy food" may be used on the label to characterize products that are "low energy" as defined in section 3, but should not precede the name of a food naturally low in energy because such terminology would imply that the food had been altered to lower its energy with respect to other foods of the same type.

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

4.7 The term "reduced energy" or a "reduced-energy food" may be used on the label to characterize products that are reduced in energy as defined in section 3.

4.9 The label of "low energy" or "reduced energy" food shall carry a statement of the content of polyhydric alcohols, e.g., mannitol, sorbitol, if they are present in the food, in g per 100 g or 100 ml of the food as sold and per specified quantity of the food as suggested for consumption.

5. CLAIMS

[5.1 (a) Terms such as "sugar free", "sugarless", "no sugar", and "no fat" may be interpreted by consumers as indicating a product that is low in energy or significantly reduced in energy. Consequently, a food not in accordance with the definition of Section 3, may not be labelled with such terms unless such term is immediately accompanied each time it is used by a statement "not a reduced energy food", or "not a low energy food" or "not for energy control", or "useful only in not promoting tooth decay", or other terms indicating that the sole special usefulness of the food is for a specific purpose other than energy control or weight reduction.

Paragraph (a) of this section shall not apply to a factual statement that a food is unsweetened or contains no added sweeteners in the case of a food that contains an apparent substantial sugar content, e.g., fruit juices.]

(b) A food may be labelled with such terms as "diet", "dietetic", "artificially sweetened", "sweetened with non-nutritive sweetener", or other such terms representing or suggesting that the food is low in energy or reduced in energy, or that the label of the food may carry a comparative claim of special dietary usefulness only if the food is labelled low in energy or reduced in energy or bears a comparative claim of special dietary usefulness.

5.2 Paragraph 5.1 (a) and (b) of this section will not apply to:

(a) Any use of such terms that is specifically authorized by the Codex standard governing a particular food.

(b) Any use of the term "diet" which clearly shows that the food is offered solely for dietary use(s) other than controlling or reducing energy intake or body weight, e.g., "for low sodium diets."

(c) Any use of such terms on a formulated meal replacement, low energy meal, or other food that is represented to be of special dietary use as a whole meal, pending the issuance of a Codex standard governing the use of such terms on such foods.

[6. GENERAL CONSIDERATIONS

It may not be technologically feasible to manufacture a "reduced energy" food under the criteria set forth in Section 3 for all foods that are significant dietary sources of energy and for which it would be useful to those on energy-restricted diets to have a reduced energy substitute. Accordingly, the Committee on Foods for Special Dietary Uses, may establish (by issuance of a Codex standard) acceptable alternative criteria for a "reduced energy" food if:

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

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

ALINORM 85/26

ANNEX 2 TO APPENDIX VIII

PROPOSED DRAFT STANDARD FOR THE COMPOSITION AND LABELLING OF AND CLAIMS FOR MEAL REPLACEMENTS FOR WEIGHT CONTROL AND REDUCTION 1/

1. SCOPE

These guidelines apply to the composition and labelling of and claims for meal replacements for controlling or reducing energy intake to achieve weight loss.

2. DEFINITION

A MRWR is a food that when sold ready-to-serve or when diluted with water, milk or a combination thereof, as directed, meets the compositional requirements of this guideline, and is represented as a replacement for one or more meals or as the total diet.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Energy

3.1.1 A serving of the food when ready to serve shall contain at least [250 kcal (1050 kJ)]; and

3.1.2 A meal replacement that is sold or advertised for sale as a replacement for all meals in a diet shall be accompanied by directions for use that, if followed, will result in a daily energy intake of at least [1000 kcal or 4.2 MJ].

3.2 Protein

3.2.1 A minimum of 20% but less than 50% of the energy available from the food shall be derived from its protein content.

3.2.2 The protein present in the foods shall be: (i) of a nutritional quality equivalent to casein or (ii) where a protein has a PER less than 100% that of casein, the levels should be increased to compensate for the lower PER. No product with a PER less than 85% that of casein should be used as a MRWR.

1/ No comments are requested on this version. The revised text will be issued as Addendum to ALINORM 85/26 in due course.

3.2.3 Essential amino-acids may be added to MRWR to improve the protein quality. Only L-forms of amino-acids shall be used in meal replacements.

3.3 Fat and Linoleate

3.3.1 Not more than 30% of the energy available from the food shall be derived from fat; and

3.3.2 Not less than 3% of the energy available from the food shall be derived from linoleic acid in the form of a glyceride.

3.4 Carbohydrates

Except in the case of a MRWR that is to be consumed as a liquid, not more than 30% of the available carbohydrates in a food shall be in the form of sugars (mono-, di- and/or oligosaccharides up to four units) and sugar alcohols.

3.5 Vitamins and Minerals

A serving of a MRWR shall contain the minimum amounts of all vitamins and minerals listed in Table 1.

3.6 Ingredients

3.6.1 Essential Ingredients

3.6.1.1 MRWR shall be prepared from protein of animal and/or of plant origin which have proven to be 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 - 3.5.

3.6.2 Non-essential Ingredients

To be elaborated.

4. FOOD ADDITIVES

To be elaborated.

5. PACKAGING

5.1 The MRWR 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.

5.2 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.

6. 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.

7. LABELLING

7.1 MRWR shall comply with the appropriate section of:

7.1.1 Recommended International General Standard for the Labelling of Prepackaged Foods (Ref. No.: CAC/RS 1-1969);

7.1.2 The Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses; and

7.1.3 Proposed Draft Standard for the Labelling of and Claims for Prepackaged Low Energy and Reduced Energy Foods.

7.1.4 Foods to which this standard applies shall be permitted to bear in its labelling the term "Calorie" as an alternative for the term "Energy".

7.1.5 A MRWR which uses a non-nutritive ingredient must declare on its label the presence of the non-nutritive ingredient(s) and its percentage by weight.

7.1.6 A MRWR which uses a non-nutritive sweetener(s) shall bear a statement on its label that it contains a non-nutritive sweetener(s) but need not state the percentage by weight of the non-nutritive sweetener(s). If a nutritive sweetener(s) as well as a non-nutritive sweetener(s) is added to the MRWR the label statement shall indicate the presence of both types of sweetener, e.g., sweetened with nutritive sweetener(s) and non-nutritive sweetener(s).

7.2 Name of the Food

7.2.1 The name of the product shall be "Meal Replacement for Weight Reduction" for controlling or reducing energy intake to achieve weight loss; and

7.2.2 A common or usual name must be used or an appropriate descriptive name that is not false or misleading.

7.3 List of Ingredients

A complete list of ingredients shall be declared on the label in descending order of predominance by weight.

7.4 Declaration of Nutritive Value

The following nutrition information shall be declared on the label per 100 gm or 100 ml of the food as sold and where appropriate for a specified quantity of foods as suggested for consumption (per serving):

(a) The amount of energy expressed in kilocalories (kcal) Calories or Kilojoules (kJ).

(b) The amount of protein, carbohydrate and fat expressed in grammes.

(c) The amount of vitamins and minerals expressed in International Units, mcg, mg, g.

(d) Fatty acid composition, cholesterol and/or sodium may also be declared in mg or g as appropriate.

If the food is commonly combined with another ingredient(s) before eating and directions for such combinations are provided, another column of figures may be used to provide a list of the nutrient content for the final combination.

7.5 Directions for Use

Instructions for preparation and use applicable before and after the product is opened that will ensure stability of the product throughout the expected shelf-life shall be declared on the label.

7.6 Date Marking

Both inner and outer labels, if applicable, must bear an expiration date indicating the "use by" or "use before" date prior to which all nutrients specified on the label or labelling will meet the level specified and product quality will be assured.

7.7 Net Contents

The net contents of the MRWR shall be declared by volume if it is in liquid form, or by weight if it is in solid or powdered form. The declaration of weight or volume shall be made in either the metric or in a system of measurement as required by the country in which the food is sold, or both systems.

7.8 Pertinent Reference Material

The package may contain information such as scientific references, sources of information for diet counselling, and information for obtaining supplies of the product.

7.9 Lot Identification

The container or label must bear a code to identify the producing factory and the lot.

7.10 Name and Address

The name and address of the manufacturer, packer, distributor, importer, exporter or vendor of the food shall be declared.

7.11 Country of Origin

The country of origin of the food shall be declared if its omission would mislead or deceive the consumer. When the food undergoes processing in a second country, which changes its nature, the country in which the processing is performed shall be considered to be the country of origin for the purposes of labelling.

TABLE 1

NUTRITIONAL REQUIREMENTS FOR MEAL REPLACEMENT FOR WEIGHT REDUCTION

Nutrients	German Proposal ¹			U.S.A. Proposal ²
	Min.	Max.	Per 1000 Kcal	Per 1000 kcal
Protein (gm)	25/meal	(50/day)		65 (or 45) ³
Carbohydrates	20/meal	(90/day)		
	(45 gm Lactose)			
Pat (gm)				
% of cal				30
Essential Fatty Acids	3.0/meal	(7.0/day)		3.0
% of cal				
<u>Vitamins</u>				
Vitamin A (IU)	1000	2997	2497	5000
Vitamin D (IU)	30	100	80	400 (optional)
Vitamin E (IU)	6	18	20	30
Vitamin C (mg)	25	75	62	60
Thiamine (mg)	0.5	1.6	1.3	1.5
Riboflavin (mg)	0.7	2.0	1.7	1.7
Niacin (mg)	-	-	-	20.0
Vitamin B-6 (mg)	0.6	1.8	1.5	2.0
Vitamin B-12 (µg)	-	-	-	6.0
Folic acid (mg)	-	-	-	0.4
Biotin	-	-	-	0.3
d-panthothenic acid (mg)	-	-	-	10.0
<u>Minerals</u>				
Calcium (gm)	0.3	0.8	-	1.0
Phosphorus (gm)	0.0	0.9	0.8	1.0
Iron (mg)	6.0	18.0	15.0	18.0
Iodine (µg)				150
Magnesium (mg)				400
Copper (mg)				2.0
Zinc (mg)				15.0
Potassium (gm)				1.2
Manganese (mg)				2.0
Sodium (g)				1.0

Footnotes:

¹ German proposal recommends an intake of 400 kcal (1675 kJ) per meal and a maximum of 1200 (5025 kJ) per day.

² USA proposal recommends an intake of 250 kcal (1050 kJ) per meal and a maximum intake of 1000 kcal (4200 kJ) per day. The amounts of nutrients per 1000 kcal of meal replacement for weight reduction (MRWR) proposed by USA are at levels at which there is a reasonable assurance that the consumption of 1000 kcal of MRWR will not result in excessive intake of the nutrients considering the cumulative amount from other sources.

³ The requirement for protein is 45 gm if the PER is equal to or greater than casein, and 65 gm if the PER is less than that of casein.

PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF AND
CLAIMS FOR [MEDICAL] FOODS 1/

TITLE

1. It was suggested that the term "medical food" be replaced by "special enteral dietary formula". No conclusions were reached.

STANDARD OR GUIDELINE?

2. There was also discussion on whether the document should be a guideline or a standard. A guideline was favoured but no conclusion was reached.

PURPOSE

3. It was agreed to delete "marketed worldwide" from Section 1.1.

4. It was noted that the word "effective" implies therapy and cure and is a term usually reserved for drugs. It was proposed that Section 1.1 be reworded as follows:

"To ensure that [medical] foods are safe when appropriately used, suitable for the intended purpose and ...

To ensure that [medical] foods are safe and appropriate for the intended purpose ..."

SCOPE

5. Delegations agreed that the Scope needs clarification and shortening. Among the points raised were the need to consolidate the definitions into Section 3, the possibility of removing foods that are nutritionally complete for normal individuals even if they may be used in tube-feeding regimes and the fact that the guidelines should address the foods rather than the medical conditions.

DEFINITION

6. It was agreed that the definition of a medical food was crucial to the entire guideline. It was further agreed that medical foods are a particular category of foods for special dietary uses.

7. It was noted that the definition contained statements of principle which should be re-located in Section 4.

8. Several delegations proposed definitions for medical foods and factors to be considered within a definition. For example, it was proposed that medical foods could be defined as foods for special dietary uses which can only be used under medical supervision; which do not appear in normal channels of trade; which require special labelling regarding indications and contraindications for their use which go beyond those provided for in the Draft General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses.

9. It was noted that a food taken under medical supervision did not automatically become a medical food. The definition must therefore clearly set out how these products differ from other foods for special dietary uses.

10. The delegation of the EEC submitted the following proposed definition which incorporated a number of other delegations' proposals and which was supported by a number of delegations. [Medical] foods are a category of foods for special dietary uses intended for enteral use either exclusively or in supplementation when the normal oral feeding is impossible, insufficient, or contraindicated and also for renutrition in the case of malnutrition. [Medical] foods may only be used under medical supervision in an appropriate diet designed to be beneficial for a specific disease, disorder or medical condition related to a disease.

1/ No comments are requested on this version. The revised text will be issued as Addendum to ALINORM 85/26 in due course.

11. The Chairman then asked all delegations to provide written comments on the purpose, scope, definitions, principles and labelling of [medical] foods in the light of the discussion. It would also be appreciated if delegations could provide the Secretariat with examples of foods in use in their countries which they regard as medical foods, and of particular problems in their use which require specific control.

ALINORM 85/26
APPENDIX IX

PROPOSED AMENDMENTS TO CERTAIN PROVISIONS OF THE CODEX STANDARD
FOR FOODS FOR INFANTS AND CHILDREN 1/
(At Step 5)

A. LEAVENING AGENTS

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

"5.6 Leavening Agents

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

B. DEFINITION OF 'CHILDREN'

Standards concerned: Codex Standards for Canned Baby Foods (CODEX STAN 73-1981) and Processed Cereal-based Foods for Infants and Children (CODEX STAN 74-1981). To make the following amendment to Sections 2.3 and 3.3 of the above standards:

"2.3 - 3.3

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

C. GUAR GUM

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

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

Guar Gum	0.2 g "
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D. MAXIMUM LEVELS FOR VITAMIN D CONTENT

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

	"Amount per 100 available Calories		Amount per 100 available Kilojoules	
	<u>Minimum</u>	<u>Maximum</u>	<u>Minimum</u>	<u>Maximum</u>
Vitamin D	40 I.U.	120 I.U.	10 I.U.	30 I.U. "

1/ It is proposed to recommend to the 16th Session of the Commission to omit Steps 6 and 7 and to adopt the amendment at Steps 5 and 8.

MATTERS RELATED TO THE ADVISORY LISTS FOR MINERAL SALTS
AND VITAMIN COMPOUNDS FOR USE IN FOODS FOR
INFANTS AND CHILDREN

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

B. CRITERIA FOR AMENDMENTS OF THE ADVISORY LIST OF MINERAL SALTS FOR USE IN FOODS FOR INFANTS AND CHILDREN

- (i) Mineral salts may be added to the list only if:
- (a) they are shown to provide technological and/or nutritional improvements;
 - (b) the anion of the salt (or the acids from which the anion is derived) is an approved additive and its use would not exceed the ADI;
 - (c) it is demonstrated by appropriate studies in animals and/or infants that the mineral element is biologically available from the salt;
 - (d) the purity requirements for the mineral salt are established in an internationally recognized specification.
- (ii) Mineral salts shall be deleted from the list if they are found no longer to meet the above criteria or if there is no evidence of their continued commercial application.

C. LIST OF PROPOSED MINERAL SALTS TO BE INCLUDED IN THE ADVISORY LIST OF MINERAL SALTS FOR USE IN FOODS FOR INFANTS AND CHILDREN

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

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

1/ Used in animal feeding studies.

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

D. CRITERIA FOR AMENDMENTS OF THE ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR INFANTS AND CHILDREN

- (i) Vitamin Compounds may be added to the list only if:
- (a) they are shown to provide technological and/or nutritional improvements;
 - (b) the anion of the compound (or acids from which the anion is derived) is an approved additive and its use should not exceed the ADI;
 - (c) it is demonstrated by appropriate studies in animals and/or infants that the vitamin element is biologically available from the compound;
 - (d) the purity requirements for the vitamin compound are established in an internationally recognized specification.
- (ii) Vitamin Compounds shall be deleted from the list if they are found no longer to meet the above criteria or if there is no evidence of their continued commercial application.

E. LIST OF PROPOSED VITAMIN COMPOUNDS TO BE INCLUDED IN THE ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR INFANTS AND CHILDREN

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

Vitamin	Vitamin Compound	Purity Requirements
Provitamin A	Beta-apo-8'-carotenal Vitamin A Alcohol	FAO/WHO USP, FCC
Vitamin B ₂	Riboflavin tetrabutyrate	JSFA
Vitamin B ₆	Pyridoxal 5'-phosphate Pyridoxine di-palmitate	
Pantothenic Acid	Sodium pantothenate	
Vitamin C	Potassium ascorbate Ascorbyl stearate	JSFA
Choline	Choline hydrogen citrate	

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

The above Working Group met on 28-29 February 1985 in Bonn-Bad Godesberg in conjunction with the 14th Session of the CCFSDU, under the Chairmanship of Prof. Dr. W. Kronert (Federal Republic of Germany), Mr. J.R. Cooke (UK) acting as Rapporteur. A list of participants is given in Annex I to this Appendix.

SAMPLING

1. The Working Group noted the General Principles for the Establishment or Selection of Codex Sampling Procedures elaborated by CCMAS in Appendix IV to ALINORM 83/23. It was considered that sampling plans for commodity defects were not needed and those for net contents were not a problem for this particular Committee, but were a general problem for all prepackaged foods. However, the elaboration of sampling plans for compositional criteria was relevant to the work of the Committee. It would be necessary at the next meeting to decide how to sample a load and how to interpret whether the analytical results complied with the specification. The Working Group considered that specific sampling plans for health related microbiological properties should be left to the Codex Committee on Food Hygiene. As the present standards did not contain any provisions for pesticide residues or other contaminants, it was concluded that it would be inappropriate to consider the question of sampling plans and acceptance criteria for environmental or other contaminants. The Committee might, on the other hand, consider the establishment of provisions for contaminants especially for canned baby foods.

2. The Working Group noted the new interpretation of the Classification of Codex Methods of Analysis, elaborated by CCMAS in Appendix II to ALINORM 85/23. The information was used in allocating classifications to the present methods of analysis; some problems were encountered in respect of the classification.

3. The Working Group also noted that the CCMAS had endorsed methods for the determination of ash, loss on drying and crude fibre in foods for infants and children.

4. The Working Group next considered the table of methods of analysis in Codex Standards for Foods for Special Dietary Uses (CX/FSDU 85/7-Add. I), and the methods still in need of development (CX/FSDU 85/7). The methods or the requirement for methods were listed in one of the five groups (see Annex II). Those methods now considered to be satisfactory were classified. Many of the methods given in the standards are now considered to be less than satisfactory and these were either replaced by new proposals or will be amended or replaced at a later date. Some methods have yet to be elaborated. Methods of analysis in the present standards now listed in groups 2 and 3 should not be subject to acceptance as part of the standard, since they were not considered to be fully satisfactory. They should remain in the Codex standards concerned in the absence of satisfactory methods. Two methods are now given for the determination of crude fibre. This determination is needed for the calculation of energy. The Working Group was of the opinion that the Committee should consider whether this is still a satisfactory alternative to the determination of dietary fibre.

5. The Working Group took note of the revised Guidelines for Methods of Analysis for Nutritional Labelling prepared by the Canadian delegation. In many cases the methods were noted to be the same as those put forward by this Committee. Consideration should be given to such differences as do exist.

6. It was recommended by the Working Group that an intersession Working Group should be set up to combine working between the sessions. It was agreed that the Secretary, Chairman and Representative of the AOAC, would contact the Secretary of the Inter-Agency Meeting (see ALINORM 85/23) to ask for its assistance in gathering information to help in the completion of the work, as appropriate.

LIST OF PARTICIPANTS

W. Krönert	Germany, Fed. Rep. of (Chairman)
H. Guelard	France
Cr. C.J. Olling	Netherlands
J.R. Cooke	UK (Rapporteur)
R.M. Tomarelli	USA
M. Tuinstra-Lauwaars	AOAC
E. Rabe	ICC
L.G. Ladomery	FAO (Secretary)

REVIEW OF METHODS OF ANALYSIS IN CODEX STANDARDS ELABORATED BY CCFSU

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

METHOD/TITLE	STANDARD REFERENCE	PRESENT METHOD	PROPOSED METHOD	CLASSIFICATION
1.1 Silica Content (5.8)	CODEX STAN 53-1981	AOAC, XI, 1970, 35.049	Unchanged	III ⁽¹⁾
1.2 Iodine Content (5.9)	CODEX STAN 53-1981	AOAC, XI, 1970, 33.056-33.058	AOAC, XIII, 1980, 33.147-33.150 Same method, revised reference	III ⁽²⁾ (1)
1.3 (a) Fat in Infant Foods (2.2) containing starch, meat or vegetable products	CODEX STAN 72/74-1981	CAC/RM 55-1976 (Vol. IX) n-Hexane extraction	Unchanged	I
1.4 (b) Fat in Infant Foods not containing starch, meat or vegetable products	"	B-2 of Code of Principles for Milk and Milk Products, CAC/RM 1-1973	Method unchanged New Reference. Vol. XVII	I
1.5 Ash (4)	"	AOAC, XIII, 1980, 7.009	Unchanged	I
1.6 Crude Protein (6)	"	Kjeldahl method for total nitrogen, text in Vol. IX	Unchanged	II ⁽³⁾
1.7 Loss on Drying (8)	"	AOAC, XIII, 1980, 7.003 Moisture Drying in Vacuo 95-100°C	Unchanged	I
1.8 Vitamin C (13) (L-Ascorbic Acid)	"	AOAC, XI, 1970, 2,6 Dichloroindophenol, 39.051-39.055 or 39.056.39.062 (Microfluorometric)	AOAC, XIII, 1980, 43.056-43.060 or 43.061-43.067, same methods, revised references	II
1.9 Thiamine (14) (Vitamin B ₁)	"	AOAC, XI, 1970, 39.024-39.030 (Fluorometric method)	AOAC, XIII, 1980, 43.024-43.030 (Fluorometric method)	II
1.10 Riboflavin (15) (Vitamin B ₂)	"	AOAC, XI, 1970, 39.039-39.042 (Fluorometric method)	AOAC, XIII, 1980, 43.039-43.042 (Fluorometric method)	II

1.11	(a) Nicotinamide for Milk-based Foods (16.2)	"	AOAC, XI, 1970, 39.101-39.109 Titrimetric/Turbidimetric methods	AOAC, XIII, 1980, 43.150- 43.158 Titrimetric/Turbidimetric methods (4)	II
1.12	(b) Nicotinamide for Foods not based on Milk (16.2)	"	AOAC, XI, 1970, 39.044-39.046	AOAC, XIII, 1980, 43.044-43.046 Colorimetric method	II
1.13	Vitamin B ₆ (17)	"	AOAC, XI, 1970, 39.142-39.147	AOAC, XIII, 1980, 43.188-43.193	II
1.14	Folic acid (18)	"	AOAC, XI, 1970, 39.093-39.097 Titrimetric method	AOAC, XIII, 1980, 43.142-43.146 Titrimetric method	II
1.15	(a) Pantothenic acid for enriched Foods (19.1)	"	AOAC, XI, 1970, 39.110-39.118 Titrimetric and Turbidimetric methods	AOAC, XIII, 1980, 43.159-43.167 Titrimetric and Turbidimetric methods (4)	II
1.16	Vitamin B ₁₂ (20)	"	AOAC, XI, 1970, 39.085-39.092 Titrimetric and Turbidimetric methods	AOAC, XIII, 1980, 43.134-43.141 (4) Same methods	II
1.17	Chloride (25)	"	Codex General Method. Appendix IV ⁽⁵⁾ of ALINORM 76/23	Unchanged	II
1.18	Water Capacity of Containers (31)	"	CAC/RM 46-1972. CA Vol. II	Unchanged	I

REVIEW OF METHODS OF ANALYSIS IN CODEX STANDARDS ELABORATED BY CCFSU

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

METHOD/TITLE	STANDARD REFERENCE	PRESENT METHOD ⁽⁶⁾	PROPOSED METHOD	CLASSIFICATION OF THE NEW METHOD
2.1 Nitrogen Content (7.1)	CODEX STAN 118-1981		A radio immunoassay for α - and β -gliadins Clinical Science (1983) 64, 655-659	
2.2 Calcium (26)	CODEX STAN 72/74-1981	AOAC, XII 1970, 14.014	IDF 119/1984:ISO DIS 80740 ⁽⁷⁾	II
2.3 Sodium and Potassium (24)	"	US Flame photometric method	IDF 119/1984; ISO DIS 80740 ⁽⁷⁾	II

REVIEW OF METHODS OF ANALYSIS IN CODEX STANDARDS ELABORATED BY CCFSDU

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

METHOD/TITLE	STANDARD REFERENCE	PRESENT METHOD (6)	PROPOSED METHOD	CLASSIFICATION
3.1 Sodium Content (5.1)	CODEX STAN 53-1981	US Flame photometric method	To be further discussed at 14th S. CCFSDU	
3.2 Potassium Content (5.2) 2/	CODEX STAN 53-1981	US Flame photometric method	To be further discussed at 14th S. CCFSDU	
3.3 Calcium Content (5.3)	CODEX STAN 53-1981	AOAC, XI, 1970, 2.097-2.102 Atomic Absorption Spectrophotometry	AOAC, XIII, 1980, 2.109-2.113 (AAS) Revised Reference	
3.4 Magnesium Content (5.4) 3/	CODEX STAN 53-1981	AOAC, XI, 1970, 2.097-2.102 Atomic Absorption Spectrophotometry	AOAC, XIII, 1980, 2.109-2.113 (AAS) Revised Reference	
3.5 Ammonium Content (5.5)	CODEX STAN 53-1981	AOAC, XI, 1970, 2.057 Ammoniacal Nitrogen	AOAC, XIII, 1980, 2.065. Same method, revised reference	
3.6 Phosphorus Content (5.6) 3/4/	CODEX STAN 53-1981	AOAC, XI, 1970, 8.025-8.028	AOAC, XIII, 1980, 8.031-8.033 Same method, revised reference	
3.7 Protein Efficiency Ratio (PER) (7)	CODEX STAN 72/74-1981	AOAC, XII, 1975, 43.183-43.187	AOAC, XIII, 1980, 43.212-43.216 Same method, revised reference	
3.8 Vitamin A (11)	"	AOAC, XI, 1970, 39.001-39.007, 39.008-39.013, 39.014-39.017	AOAC, XIII, 1980, 43.001-43.007, 43.008-43.013, 43.014-43.017 Revised references	
3.9 Vitamin D (12)	"	AOAC, XI, 1970, 39.149-39.162	AOAC, XIII, 1980, 43.195-43.208 Revised reference	
3.10 Pantothenic acid for non-enriched Foods (19.2)	"	USDA Handbook 97 or "The Analyst" 89, 1, 1964	--	
3.11 Vitamin E (23)	"	AOAC, Journal of the AOAC, 54, 485-490, 1971	AOAC, XIII, 1980, 43.087-43.105	
3.12 Phosphorus (27)	"	AOAC, XI, 1970, 22.044-22.046 Gravimetric Quinoline Molybdate Method	AOAC, XIII, 1980, 22.046-22.048 Same method	
3.13 Copper, Manganese Zinc, Magnesium (28)	"	AOAC, XI, 1970, 2.097-2.102 Atomic Absorption Spectrophotometric	AOAC, XIII, 1980, 2.109-2.113	
3.14 Iron (29)	"	AOAC, XI, 1970, 14.011-14.013	AOAC, XIII, 1980, 14.011-14.013	

4. Methods proposed but more information needed

METHOD/TITLE	STANDARD REFERENCE	PRESENT METHOD	PROPOSED METHOD	CLASSIFICATION
4.1 Choline Content (5.7) <u>3/ 5/</u>	CODEX STAN 53-1981	To be elaborated	Saucerman et al. JAOAC <u>67</u> (1984), page 982-985	-
4.2 Linoleate (3) see para. 90 of ALINORM 76/23	CODEX STAN 72/74-1981	To be elaborated	IUPAC Standard Methods ⁽⁸⁾ For the Analysis of Fats and Oils No 2.209 in con- nection with 2.312	-
4.3 Crude Fibre (5) See para. 88 of ALINORM 76/23	"	To be elaborated	ISO 5498 ISO 6541	I
4.4 Choline (10)	"	To be elaborated	See under 4.1	-

REVIEW OF METHODS OF ANALYSIS IN CODEX STANDARDS ELABORATED BY CCFSU

5. Method to be elaborated

METHOD/TITLE	STANDARD REFERENCE	PRESENT METHOD	PROPOSED METHOD	CLASSIFICATION
5.1 Vitamin K _I (20)	CODEX-STAN 72/74	To be elaborated. See para. 118 of ALINORM 83/26	To be elaborated	-
5.2 Biotin (Vitamin H) (22)	"	Growth Response, Lactobacillus plantarum ATCC, 8014	To be elaborated	-
5.3 Iodine (30)	"	To be elaborated. See para. 118 of ALINORM 83/26	To be elaborated	-

- (1) No evidence of relevance to Codex.
- (2) Optional additive to conform with national legislation.
- (3) The calculation factors are classified: I
- (4) Further informations needed whether both methods are equivalent.
- (5) The FAO Secretariat is asked to publish the method.
- (6) The methods in the standards should not be part of the acceptance of the standards.
- (7) For infant formula only, for other methods to be elaborated.
- (8) To be published.

GUIDELINES FOR DEVELOPMENT OF SUPPLEMENTARY FOODS
FOR OLDER INFANTS AND YOUNG CHILDREN

(At Step 3) 1/

1. PURPOSE

To provide guidance, on nutritional and technical aspects, for the development of supplementary foods for infants from 4-6 months onwards and young children, including:

- Formulation of supplementary foods, based on the nutritional requirements of older infants and young children.
- Processing techniques
- Instructions for use
- Hygiene, packaging and labelling

2. SCOPE

2.1 The provisions of the guideline apply to supplementary foods as defined in Section 3.1 below.

2.2 Foods covered by the Codex Standards for Cereal-based Foods (CODEX STAN 74-1981) and for Follow-up [Foods] (Appendix IX), should comply with those standards in the first instance. However, additional requirements may be recommended in accordance with the appropriate provisions of these guidelines.

3. DEFINITIONS

3.1 "Supplementary Foods of Older Infants and Young Children" means a food for use from the beginning of infant's weaning period from [4-6 months] on as a supplement to breastmilk or, breastmilk substitutes, or other foods available in the country where the product is sold. [These foods should provide such nutrients which are lacking in the basic staple food].

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

3.3 The term "young child" means a person of 1-3 years of age.

4. RAW MATERIALS USED IN SUPPLEMENTARY FOODS

4.1

4.1.1 Cereals

4.1.1.1 All milled cereals used as foodstuffs may be used in the formulation of supplementary foods.

4.1.1.2 Cereals such as: oats, barley, sorghum, millet and teff which by simple milling yield flours with high crude fibre content not suitable for infant feeding, should be processed in such way as to reduce their fibre content,

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

4.1.2 Pulses

4.1.2.1 Pulses, including chick peas, lentils, peas, cow peas, green gram (Cajanus cajan), mung beans, kidney beans, appropriately processed, have been found suitable for feeding older infants and young children.

1/ Subject to approval by the 15th Session of the Commission.

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

4.1.2.3 Anti-nutritional factors present in edible pulses are mainly lectins (haemagglutinins) as well as trypsin and chymotrypsin inhibitors. While lectins can be destroyed by heating (boiling, toasting), trypsin inhibitory activity can be reduced at higher temperatures (pressure cooking), or through prolonged boiling.

4.1.2.4 Faba beans (*Vicia fava*), while having a very good nutritional quality and being a high yield crop, should not be used in the formulation of supplementary foods because of the danger of favism. Heating (boiling, pressure cooking, toasting) does not inactivate the toxic principles vicin and co-vicin.

4.1.3 Oil Seeds and Oils Seed Protein Products

4.1.3.1 Oil seed flours, protein concentrate and protein isolates which have been found suitable for feeding older infants and young children include:

Soya bean: flour (full fat and defatted), concentrate, isolate

Groundnuts: defatted flour and isolate

Sesame: whole ground and defatted flour

Cottonseed: defatted flour

Sunflower seed: defatted flour

4.1.3.2 Oils seed flours and protein products are a rich source of protein (50% for flours to 95% for isolates). Produced under appropriate conditions they can constitute the main protein component in the formulation of supplementary foods.

4.1.3.3 Appropriate conditions for the production of edible flours from soya beans, groundnuts, cottonseed and sesame are proposed in the PAG Guidelines No. 5, No. 2, No. 4 and No. 14 respectively. 1/

4.1.4 Fish and Fish Protein Concentrates

4.1.4.1 Dried, ground edible fish species and edible fish protein concentrates, produced under appropriate conditions have been found very suitable for the feeding of infants and young children. Such conditions are proposed in the PAG Guideline No. 9. 1/

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

4.1.5 Fats

4.1.5.1 Fats and especially vegetable fats and oils are added in the formulation of supplementary foods both for increasing the energy density of the food and for meeting physiological requirements of the older infant and the young child.

4.1.5.2 Vegetable oils and fats containing polyunsaturated fatty acids are to be preferred to those containing large amounts of saturated fatty acids.

4.2 Other Ingredients

4.2.1 Milk and Milk Products

Milk and Milk Products, when available, contribute to improving the nutritional quality of the product.

1/ 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. 9: Fish protein concentrates for human consumption; PAG Guideline No. 14: Preparation of defatted edible sesame flour.

4.2.2 Sweeteners

Sugar and other nutritive sweeteners enhance acceptability of the food and contribute to reducing the bulkiness.

4.2.3 Flavours

Vanilla and traditional flavours may be added to supplementary foods to enhance acceptability.

4.2.4 Others

Other ingredients may be used, provided they have been proven to be suitable for their intended purpose.

5. PROCESSING

5.1 General Aspects

Regardless of the type and level of processing the raw materials should be preliminarily treated to obtain a wholesome and clean starting material. Such treatments include:

5.1.1 Cleaning and washing to eliminate dirt, damaged grains, insects and insect excreta and any adhering material.

5.1.2 Dehulling. Pulses and oilseeds should be dehulled as completely as feasible. Dehulling reduces the crude fibre content of the product to acceptable levels and eliminates tannins and other phenolic materials which can lower the protein digestibility. The same applies to certain cereals and in particular to those mentioned in Section 4.1.1,2.

5.2 Simple Processing

5.2.1 Milled Products

5.2.1.1 Ingredients suitable for the formulation of supplementary foods without further processing may be milled together or individually followed by the addition of other ingredients for the required formulation of the product.

5.2.1.2 Supplementary foods based on dry milled ingredients require thorough boiling in the prescribed quantity of water in order to sterilize the product, to destroy toxic substances and anti-nutritional factors which may be present, to gelatinize starch and generally improve the digestibility and absorption.

5.2.1.3 The bulkiness of preparations of feeds from supplementary foods consisting of dry milled ingredients, can be reduced by adding during the formulation adequate amounts of α -amylase which, during the slow heating to boiling, pre-digest partially the starch and reduces the amount of water needed for the preparation of the food.

5.2.2 Toasting (Roasting)

5.2.2.1 Pulses as well as oilseeds (soya, groundnuts and sesame) can be toasted as whole grains directly or after pre-soaking. Pre-soaking results in puffed grains with a light texture. Toasting enhances the flavour and the taste of the product, through dextrinization of starch, improves digestibility and contributes to reducing bulkiness.

5.2.2.2 The toasted ingredients, after dehulling, are milled and mixed with the other ingredients required for the formulation of the product.

5.2.2.3 The supplementary food based on toasted and milled ingredients require adequate boiling in the prescribed quantity of water prior to feeding.

5.2.3 Sprouting and Malting

5.2.3.1 Cereals and pulses can be induced to germinate by soaking or humidifying. The seed coat of the grains splits during the process and is removed by washing. The malted product after drying is milled and mixed with the other ingredients of the supplementary foods.

5.2.3.2 The action of natural amylases results in the predigestion of the starchy component (dextrinization), thus in a reduction of bulk and increase of the nutrient density of the products.

5.3 Advanced Processing Technology

5.3.1 Extrusion Cooking 1/

5.3.1.1 The milled main ingredients (cereals, pulses, oilseed flours) mixed together may be processed by extrusion-cooking in one step. The extruded product after drying (if necessary) is milled to the desired particle size and formulated by addition of the minor ingredients.

5.3.1.2 The effects of this technology are: gelatinization of the starchy component of the mixture with minimal quantities of water; inactivation of lectins and simultaneous reduction of trypsin inhibitor activity; need of reduced quantities of water for preparation i.e. increase in nutrient density.

5.3.1.3 The extrusion-cooking processed supplementary foods do not require, for nutritional reasons, boiling during reconstitution in water.

5.3.2 Enzymatic Pre-digestion 1/

5.3.2.1 The milled main ingredients (cereals, pulses, oilseed flours) with 1-2 volumes of water and 0.05-0.1% of the dry mixture of α -amylase are heated, under continuous stirring, in a converter slowly up to 60°-70° C until the mixture acquires the desired fluidity, which indicates the splitting of the starch molecule into dextrans and reducing sugars. Then the temperature is raised to 85-90° C to inactivate the enzyme, and the resulting slurry is drum dried and reduced to flour or to small flakes. Then the minor constituents and fat are added to complete the formulation.

5.3.2.2 The product when reconstituted with the prescribed quantity of water does not require boiling.

5.3.2.3 The product displays improved organoleptic characteristics, higher digestibility, good solubility and requires minimal quantities of water for preparation thus having a high nutrient density.

6. FORMULATION OF SUPPLEMENTARY FOODS

1/ These products are also covered by the Codex Standard for Processed Cereal-based Foods. However, the standard does not include detailed provisions on nutrient content.

6.1 Nutritional Aspects

6.1.1 Energy

6.1.1.1 The energy content of the main components of supplementary foods (cereals, pulses, defatted oilseed flours) is relatively low.

6.1.1.2 The energy density can be increased by: adding fat and/or nutritive sweeteners and/or by processing the main ingredients as proposed in Sections 5.2 and 5.3.

6.1.1.3 100 g of supplementary food should provide about 400 kcal.(1.7 Mj).

6.1.2 Protein

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

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

6.1.2.3 In order to cover 75% of the protein recommended intake through the supplementary food, its protein content should be adjusted at $16 \times 0.75 = 12$. With an amino acid score of 65 its protein content should be $12:65 \times 100 = 18.5$ g or 20g/100 g.

6.1.3 Fat

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

6.1.3.2 Where this is economically not feasible in the formulation of the supplementary 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 food.

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

1/ The safe level of protein intake is the amount of protein considered necessary to meet the physiological needs and maintain the health of nearly all persons in a specified group. (This level is higher than the average requirement for protein).

2/ The energy requirement of persons is the energy intake that is considered adequate to meet the energy needs of the average healthy person on a specified category. .

6.1.4 Carbohydrates

6.1.4.1 Carbohydrates, in the form of nutritive sweeteners, increase the energy density, are easier digested and absorbed than starch, and enhance acceptability.

6.1.4.2 Where this is economically not feasible in the formulation of the supplementary food, the instructions for use on the label should recommend the addition of a specified quantity of sugars, syrups or similar sweeteners during the preparation of the food.

6.1.4.3 As dietary fibres are slowly absorbed and fermented by the intestinal flora, thus causing laxative effect, the crude fibre content of the product should not exceed 5% per 100 g of product. Higher levels may be acceptable, although it would require clinical testing.

6.1.5 Vitamins and Minerals

6.1.5.1 The addition of vitamins and minerals should be conditioned by local nutrition and health problems as well as by national legislation.

6.1.5.2 The vitamin and mineral content of the ingredients of the supplementary foods should be taken into account when deciding on the type of vitamin-mineral premix to be added during the formulation.

6.1.5.3 In cases that older infants and young children are given vitamins and minerals through MCH centres or other health agencies, their addition in supplementary foods may be redundant.

6.1.6 Proposed Model Composition for Supplementary Foods

6.1.6.1 On the basis of the above considerations Table 1 proposes a model composition of supplementary foods for older infants and young children.

6.1.6.2 The model might not be applicable under all conditions prevailing in different countries and appropriate modifications can be made for adapting it to specific socio-economic conditions. (See also Sections 6.1.3.2, 6.1.4.2 and 6.1.5).

7. PREPARATION FOR USE

7.1 Products consisting of non-heat processed mixtures of raw ingredients should be adequately boiled during preparation in the prescribed quantity of water.

7.2 Products consisting of heat-processed mixtures may be prepared by addition cold or warm water and mixing. Boiling may not be required.

7.3 Where for technological and economic reasons the addition of high energy ingredients - fats, nutritive sweeteners - was not feasible their addition during preparation may be desirable and recommended.

8. HYGIENE

8.1 To the extent possible in good manufacturing practice, supplementary foods for older infants and young children should be free from objectionable matter.

8.2 When tested by appropriate methods of sampling and examination, the product; 1/

1/ Further consideration should be given to these sections,

Table 1. Proposed Model Composition for Supplementary Foods

	Amounts per 100g.	Amounts per 100 kcal.	Amounts per 100 Kj
Protein <u>1/</u> g.	20	5.2	1.21
Fat, g.	10	2.6	0.6
Crude fiber <u>2/</u> g.	5	1.3	0.3
Acid-insoluble ash, g.	0.05	-	-
4.6.4. <u>Vitamin Content</u> <u>3/</u>			
Vitamin A, as retinol, μg	400	100	24
Vitamin D, (cholecalciferol), μg	10	2.5	0.6
Vitamin E, (α -tocopherol), μg	5	1.25	0.3
Ascorbic acid, mg	20	0.52	0.12
Thiamine, μg	500	125	32
Riboflavin, μg	800	200	48
Niacin, mg	9	2.20	0.57
Vitamin B ₆ , μg	900	220	57
Folic acid, μg	100	27	6
Vitamin B ₁₂ , μg	2	0.52	0.12
4.6.5. <u>Minerals Content</u>			
Calcium, mg	800	200	48
Phosphorus, mg	800	200	48
Iron, mg	10	2.7	0.6
Iodine, μg	70	18	4.5

1/ Protein with a Score of 65 and PER 2.2 (Casein: 2.5)

2/ Crude fiber higher than this may be acceptable, although it would require clinical testing

3/ The values for vitamins and minerals are considered minimal, except in the case of Vitamin D, where no further increase is desirable. The excess of each vitamin added during processing should be no greater than that needed to maintain label requirements over the expected shelf-life of the product.

General Aspects

(a) For the purpose of calculating the energy and nutrient requirements, the child of one year of age is taken as a reference.

(b) The recommended daily protein intake 1/ is 16 g of egg/milk quality.

(c) The energy requirement 2/ is 1200 kcal. (5 Mj)/day.

(d) 100 g of supplementary food in powder, grits or flake form, when prepared with the prescribed quantity of water, is considered a reasonable quantity that an older infant or young child can ingest easily in two or more feedings.

(e) This quantity can provide only about one third of the energy requirements, but it can provide 75-100% of the recommended protein intake.

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

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

9. PACKAGING

9.1 The product should be packed in containers which will safeguard the hygienic and other qualities of food,

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

10. LABELLING

10.1 The Name of the Food

10.1.1 The name of the product should be "Supplementary Food for Older Infants and Young Children". In addition thereto any appropriate designation which may be used in accordance with national usage,

10.1.2 The sources of protein in the product should be clearly shown on the label in proximity to the name of the food, 1/

10.2 List of Ingredients

10.2.1 A complete list of ingredients should be declared on the label in descending order of proportion. The added vitamins and minerals should be arranged as separate groups for vitamins and minerals.

10.3 Declaration of Nutritive Value

The declaration of nutrition information should contain the following information in the following order: 1/

(a) The amount of energy, expressed in Kilocalories and/or Kilojoules, and the number of grammes of protein, carbohydrates and fat per 100 g of the food as sold.

(b) The total quantity of each vitamin and mineral per 100 g of the food as sold.

10.4 Net Content

The net content of the product should be declared by weight, in either the metric ("Système International" units) or in a system of measurement as required by the country in which the food is sold, or in both systems.

10.5 Name and Address

The name and address of the manufacturer, packer, distributor or vendor of the food should be declared.

10.6 Date Marking and Storage Instructions

10.6.1 The "date of minimum durability" (preceded by the words "best before") should be declared by the day, month and year in uncodded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer.

1/ Further consideration should be given to these sections.

In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

10.6.2 In addition to the date, any special conditions for the storage of the food should be indicated if the validity of the date depends thereon.

10.6.3 Where practicable, storage instructions should be in close proximity to the date marking.

10.7 Information for Utilization

10.7.1 Directions as to the preparation and use of the food should appear on the label, preferably accompanied by appropriate sketches. These directions for use should include appropriate information in accordance with Section 7.

10.7.2 Instructions for the storage and keeping of the food after the container has been opened should appear on the label.

10.7.3 The label should include a statement that the food should not be introduced before [four to six months] of age.