codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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ALINORM 81/26

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Fourteenth Session

Geneva, 29 June - 10 July 1981

REPORT OF THE TWELFTH SESSION OF THE

CODEX COMMITTEE ON FOODS FOR SPECIAL DIETARY USES

Bonn-Bad Godesberg, 29 September-3 October 1980

INTRODUCTION

1. The Codex Committee on Foods for Special Dietary Uses held its Twelfth Session in Bonn-Bad Godesberg from 29 September to 3 October 1980 by courtesy of the Government of the Federal Republic of Germany under the Chairmanship of Dr. H. Drews, Ministerialrat in the Federal Ministry of Youth, Family and Health. Professor Dr. D. Eckert, Chairman of the Codex Alimentarius Commission, opened the Session on behalf of the Federal Minister of Youth, Family and Health, Mrs. Antje Huber. He emphasized the change in direction of the work of the Commission; the increased attention to the needs of developing countries, the continuation of the importance of health aspects of Codex Standards and the contribution of Codex activities in general to facilitating international understanding and trade.

2. The Committee observed a minute's silence in memory of Dr. Elisabeth Hufnagel of the Federal Republic of Germany. The Chairman recalled Dr. Hufnagel's valuable contribution in the field of international food standards, her dedication to her work and the many personal contacts which linked her with colleagues from all over the world.

3. The Session was attended by representatives from the following 23 countries:

Australia
Austria
Belgium
Canada
Chile
Denmark
Finland
France
Germany, Fed. Rep. of
Hungary
Ireland
Japan
Mexico
Netherlands
New Zealand
Norway
Panama
Spain
Sweden
Switzerland
United Kingdom
United States of America
Yugoslavia

Observers were present from the following international organizations:

- Association of Official Analytical Chemists (AOAC)
- European Economic Community (EEC)
- International Association for Cereal Chemistry (ICC)
- International Federation of Glucose Industries (IFG)

- International Secretariat for the Industries of Dietetic Food Products (ISDI)
- International Federation of Margarine Associations (IFMA)
- International Union of Nutritional Sciences (IUNS)
- Marinalg International
- Food and Agriculture Organization (FAO)
- World Health Organization (WHO)
- United Nations Children Fund (UNICEF)

The list of participants, including officers from FAO and WHO, is contained in Appendix I to this report.

ADOPTION OF THE AGENDA

4. The Agenda was adopted with one amendment: that the order of Items 7 and 8 be reversed, since it was thought that the prior consideration of the draft standard for the Labelling of and Claims for Prepackaged Foods claimed to be suitable for Incorporation in a Prescribed Dietary Regimen for Diabetics would facilitate discussion on the draft standard for the Labelling of Low Calorie and Calorie-reduced Foods.

5. The Committee noted that the ad hoc Working Groups on the Methods of Analysis and on the Advisory Lists for Mineral Salts and Vitamin Compounds for Foods for Infants and Children would meet during the session and would report back to the Committee.

6. The delegation of Norway suggested that a Working Group be established to consider the latest version of the WHO/UNICEF Code of Marketing of Breastmilk Substitutes. It was pointed out that representatives of WHO and UNICEF would be attending the Committee's session on 1 October 1980 to report progress on the latest consultations. The Committee therefore decided against setting up a Working Group.

APPOINTMENT OF RAPPORTEURS

7. Mr. J.L. Allain (France) and Dr. S.J. Darke (United Kingdom) kindly agreed to serve as rapporteurs for the session.

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

8. The Committee had before it document CX/FSDU 80/2 which contained information on matters of interest which resulted from other Codex activities.

9. The Committee noted that, at any stage of the development of Codex Standards, government comments could be made on the possible economic implications of these standards for their countries.

10. The Committee also noted with interest that the Codex Alimentarius Commission had given careful consideration to the nutritional aspects of Codex standards such as those for infant formula and processed baby foods. A paper on the nutritional aspects of Codex work was being prepared for the next session of the Commission. The Commission had also requested Commodity Committees to pay special attention to the nutritional aspects of those standards for which they were responsible. Attention was also drawn to the on-going work of the Codex Committee on Food Labelling on the Guidelines on Nutrition Labelling, currently at Step 3. The Committee was of the opinion that many of the aspects covered by these guidelines relate to matters which were of a highly specialised scientific nature which was well within the expertise and competence of this Committee. The Secretariat was instructed to arrange for the Guidelines on Nutrition Labelling to be referred to this Committee after the next session of the Codex Committee on Food Labelling.

11. In discussing whether or not nutritional considerations for all foods were within the Committee's terms of reference, the Committee expressed its wish to be consulted on all nutritional matters related to Codex work and to exercise a similar advisory function in nutritional aspects of Codex Standards as other General Subject Committees had on certain other aspects. The Secretariat was requested to submit these views to the next session of the Commission and to consider an appropriate revision of the Committee's term of reference (see also para. 55).

12. The Committee agreed that the other matters mentioned in the document CX/FSDU 80/2 would be taken up under the appropriate items of the Agenda.

13. Concerning the progress report on government acceptances of standards elaborated by the Committee, delegations were requested to advise the Secretariat of any information which related to the formal acceptance of these standards. Members of the Codex Alimentarius Commission were also interested to know of any action either taken or contemplated in this regard. In instances where governments were unable to accept a standard, information as to whether or not products which complied with that standard were permitted to circulate freely within their countries, was of particular interest.

CONSIDERATION OF DRAFT GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES AT STEP 7

14. The Committee had before it the above standard as contained in CX/FSDU 80/3 and government comments received thereon in CX/FSDU 80/3, Addendum 1, (Canada, Denmark, Finland, Netherlands, New Zealand, Poland, Sweden and Switzerland), and Addendum 2 (France). The Committee noted that the above standard had been endorsed by the Codex Committee on Food Labelling at Step 5 subject to certain amendments set forth in CL 1980/10. The Commission had subsequently advanced the standard to Step 6. The Committee decided to consider the above standard in detail, section by section.

Section 1 - Scope

15. No changes were made to the Scope section.

Section 2 - Definitions

Foods for Special Dietary Uses (Section 2.1)

16. It was pointed out that the present definition was intended to cover all foods for special dietary uses including foods for infants and young children. Some delegations felt that this should be stated explicitly in the definition; others considered that such a clause would be superfluous. The Committee decided not to amend this part of the definition but to introduce an appropriate footnote to the effect that Foods for Special Dietary Uses included those for infants and young children.

17. In compliance with the proposal of the Codex Committee on Food Labelling, the Committee agreed to introduce the term "particular" immediately before the phrase "physical and physiological conditions" and amended the definition accordingly.

18. There was an extensive discussion about whether foods for special dietary uses should be specially processed or formulated and should differ singificantly from the comparable normal foods. Some delegations held the view that such modifications were essential to justify the classification of these foods as Foods for Special Dietary Uses. The delegation of the United States expressed the view that certain ordinary foods were, by their nature, suitable for inclusion in special diets. It was pointed out that the appropriate claims and labelling information to be permitted for these foods was set out in section 6.1.3 of the draft standard. The Committee did not amend the second sentence of section 2.1 except that the word "ordinary"

was substituted for "normal" as a more suitable adjective for the description of those foods which were not Foods for Special Dietary Uses.

19. The delegation of the United States also drew attention to the need for a definition of "medical foods". A discussion on this matter had taken place at the previous session of the Committee. The delegation provided a slightly amended text 1/ to that contained in para. 75 of ALINORM 79/26 and reiterated the view that it was important to permit special provisions to be made for these foods. The Committee noted the proposal but decided, however, not to include a definition of medical foods. Further consideration of "medical foods" could occur during the discussions of sections 4 and 6.1.4.

20. Attention was drawn to a suggestion by the Codex Committee on Food Labelling that the definitions contained in sections 2.2 to 2.9 of the draft standard be deleted so that a reference to the relevant definitions in the General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969) and the General Guidelines on Claims could be introduced. The Committee, however, decided to retain the definition 2.2 to 2.9 in extenso. Members agreed that it was preferable to have a complete document since this would be easier to understand, and would facilitate the work of governments in deciding whether to accept the standard. Furthermore, the Committee felt that to refer to the documents quoted above might also include amendments to those documents which would not be appropriate to this standard in all cases.

Section 3 - General Principles

21. The Committee recognized that Section 3.2 of the General Principles, which had been taken from the General Standard, was not applicable to foods for specific dietary uses and decided therefore to delete this section.

22. The Committee was reminded that it had considered, at its last session, a proposal from the United States to introduce two new provisions under this section but had deferred any decision on the proposed text and its inclusion in the standard (see para. 79 of ALINORM 79/26). No written comments had been received on this matter and the delegation of the United States was of the opinion that the Committee might limit its considerations to the proposed section 3.4 which would read as follows:

> "3.4 Nothing in the labelling and advertizing of the foods to which this standard applies shall imply that the food, because of the presence or absence of certain vitamins and/or minerals, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptoms, although the label may state that the food is a source of an essential nutrient which is important for good nutrition and health. This prohibition does not apply to "Medical Foods" represented for use solely under medical supervision in the dietary management of specific diseases or disorders."

23. The delegation of the United States supported the proposed exemption from the general prohibition of certain claims, as indicated in the first sentence of the text 3.4, by giving details about the specific characteristics of "medical foods" such as:

(a) indiscriminate use of these products might be a hazard to health;
(b) they should be administered therefore under strict medical supervision; advertisement and information about these foods should be permitted only to the medical profession.

Detailed additional labelling provisions would be required to ensure proper use of these foods.

1/ Medical Foods: "This is a category of Foods for Special Dietary Uses that includes all foods which are intended for use under medical supervision in the dietary management of individuals with specific diseases or disorders or medical conditions where the existence of special nutritional requirements related thereto are established by medical diagnosis".

24. Several other delegations agreed that such foods existed, for example specific foods for renal insufficiency, for phenylketonuria and other abnormal metabolic conditions. It was also noted that these specially prepared "medical foods" could either provide the whole or a part of a complete diet.

25. The Committee agreed with the view expressed by several delegations that it would be more appropriate to elaborate an entirely new standard or preferably guidelines to cover these products in more detail. If desired, the guidelines could be annexed to this standard in due course.

26. The delegation of the United States was asked to prepare a first draft of suitable guidelines, which would be limited to aspects of labelling and claims for "medical foods" for consideration by the Committee at its next session.

27. In view of the foregoing the Committee decided not to include the proposed section 3.4 (see para. 22) into the standard.

Section 4 - Mandatory Labelling of Prepackaged Foods for Special Dietary Uses

28. The Committee agreed to amend editorially the preamble to this section, to make it clear that the reference to specific Codex Standards for Foods for Special Dietary Uses applied to those standards which had already been elaborated by this Committee. The list of Codex Standards for Foods for Special Dietary Uses will be included in the final version of this Report. The list would be up-dated periodically as new standards were formulated.

29. The Committee did not change any of the provisions contained in section 4.1 "The Name of the Food" except that section 4.1.2 was amended to permit the use of an "appropriate equivalent term", and in section 4.1.3 "may" was altered to "shall" because it was agreed that the declaration of the essential features which characterize the food should be mandatory.

30. Several delegations indicated that they had difficulties in understanding exactly what was meant by the term "component" in section 4.2.2 (List of Ingredients). The secretariat pointed out that similar difficulties had arisen in Codex Commodity Committees when they had considered the labelling requirements for many foods under their jurisdiction. It had therefore been proposed in the working paper on the "Revision of the General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969)" submitted for consideration to the forthcoming session of the Codex Committee on Labelling, to reword this provision. In reality the provision was meant to require declaration of individual ingredients of a composite food which was used as an ingredient itself. The Committee agreed that the proposed text of the section (4.2.2) as contained in working paper CX/FL 80/7 should replace the present section 4.2.2. Consequently, the definition of the term "component" was deleted from section 2.

31. With regard to the requirement to declare the energy value in both kJ and kcal, the Committee decided not to amend the section and not to permit an alternative declaration in either kJ or kcal. The declaration in kcal was more readily understood by consumers although international agreements required the expression of energy in kJ.

32. Several different versions for section 4.3.2 had been proposed in the written comments and were supported by the delegations present. However, in view of the widely divergent opinions the Committee decided to delete the section entirely as it would complicate the standard unduly without contributing any meaningful information to the consumer. It was also proposed to include in section 4.3.1(b) a provision which would permit macronutrients, if present in amounts of less than 1 gramme per 100 grammes, not to be declared. The Committee did not amend section 4.3.1(b).

33. The Committee agreed that consumers would be interested in, and had a right to be informed of, the amounts of those nutrients which were declared as characterizing the essential feature of the product. A new section 4.3.1(c) was included in the draft for this purpose (see Appendix II to this report).

34. The Committee did not make any changes in sections 4.4 (Net Contents), 4.5 (Name and Address) and 4.7 (Lot Identification). Several delegations expressed the view that the text of section 4.6.1 (Country of Origin) should be the same as in the General Standard for the Labelling of Prepackaged Foods. Consumers were often interested in knowing which was the country of origin of any particular food. However, there were difficulties sometimes in deciding which was the country of origin. The Committee retained section 4.6.1 unchanged.

35. The Committee noted that the Codex Committee on Food Labelling was in the process of revising the Guidelines on Date Marking for Use in Codex Commodity Committees and welcomed comments from these Committees. In particular advice was sought on the shelf-life of the products for which standards were elaborated.

36. The Committee decided to retain the principle that to give the date of minimum durability should be mandatory.

37. Several delegations drew attention to the fact that foods for special dietary uses belonged to virtually all groups of products and that this Committee would not be able to express its opinion on the shelf-life of all of these groups. It was also recognized that the processes of modification used in the production of foods for special dietary uses, for example, reduction in sugar content, decrease in sodium content, increase in water content, could change the shelf-life of the final product.

38. The Committee agreed to amend section 4.8.2 to require a declaration of the minimum durability by day, month and year for all foods covered by the standard; except that only the month and year could be declared for products with a shelf-life of more than three months. This provision might be reviewed when further advice from the Codex Committee on Food Labelling was available.

39. Section 4.9.1 (Storage Instructions for Unopened Food) was amended by replacing "essential" for "of importance".

Section 6 - Additional Requirements

40. The Committee accepted the recommendations of the Codex Committee on Labelling at its 13th Session and made editorial amendments to sections 6.1.2 and 6.1.3 (see Appendix II to this report) and the provision contained in section 6.1.1 was made mandatory.

41. The Secretariat was requested to seek advice on the implications of including Codes of Practice or other texts of an advisory nature, or parts thereof, into mandatory provisions in Standards. The Committee noted that this matter would be considered at the next Session of the Executive Committee.

42. Full discussion took place on Section 6.1.4 in view of the recommendation of the Codex Committee on Labelling to delete this section. One delegation, supported by others held the view that, if the second sentence were to be retained, the prohibitions of certain claims stipulated in the first sentence would be meaningless. However, several delegations, including the delegation of Japan, suggested and the Committee recognized that, for certain specific foods, additional label information which indicated the specific purpose of the food was essential for the consumer and should be permitted.

43. The Committee therefore agreed that a wording, which in principle upheld the above-mentioned prohibition, be permitted. However, exemptions would be allowed in cases where Codex Standards had already been elaborated for the food in question or where, in the absence of a Codex Standard or Guideline, national legislation did permit such exemption (see Appendix II to this Report). The delegation of Switzerland did not agree with the amendment and wished to retain the section unchanged.

STATUS OF THE STANDARD

44. Some delegations held the view that, since substantial changes had been made in the standard, governments should have an opportunity to re-examine the amendments in the light of further comments. The majority of the delegations present decided to retain the standard

at Step 7 for further consideration at the next session of the Committee. The Draft Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses, as amended, is contained in Appendix II to this Report.

CONSIDERATION OF THE PROPOSED DRAFT STANDARD FOR FOLLOW-UP OR SUPPLEMENTARY FOODS AT STEP 4

45. The Committee had before it the above draft standard in Appendix IV to ALINORM 79/26 and comments received thereon in documents CX/FSDU 80/6 (Canada, Finland, Germany, Fed. Rep.of, Netherlands, New Zealand, Norway, Philippines, Poland, Sweden, Switzerland, United Kingdom), Addendum 1 (Czechoslovakia, France, Italy, Marinalg International), Addendum 2 (Norway), a Conference Room Document (Hungary) and comments from the Coordinating Committees for Asia and Africa in document CX/FSDU 80/2.

46. In view of the written comments the Committee decided to reconsider the need for the elaboration of this standard.

47. Several delegations emphasized that no standard should be developed for the products covered by the present draft for two reasons. They felt that the products covered by the standard were based on compositional requirements which were oversophisticated if the products were to be used as weaning foods or to supplement breastmilk in the weaning period of the infant. This had resulted in very expensive products which were not within the economic means of consumers from low-income populations. On the other hand, it was pointed out, that there was a potential danger that these products which were cheaper than infant formula would be used instead of infant formula at an early age of the infant when they were nutritionally inadequate.

48. The Committee noted a report on infant nutrition of the European Society for Pediatric Gastroenterology and Nutrition (ESPGAN), Committee on Nutrition.

49. One delegation expressed the view that it was not possible to cover in one standard all products which were suitable under different socio-economic conditions and for infants of different age groups.

50. The Committee agreed that Breastmilk Substitutes should be adequate to cover the nutritional needs of a healthy infant up to 4-6 months if given as the sole food. Breastmilk supplements would, however, be administered to older infants as a complementary food and not as the sole source of nutrients.

51. Attention was drawn to the comments from the Coordinating Committee for Asia which had been in favour of a standard for such foods. However, that Committee had emphasized the need for a low-cost product which could provide those nutrients in which the local, normally carbohydrate-rich staple food of the diet was deficient. In this context it was pointed out that the emphasis on locally produced, low-cost weaning foods was in agreement with the recommendations to the UNICEF/WHO Meeting on Infant and Child Feeding and with earlier recommendations by various UN agencies.

52. The Committee recalled that it had considered at an earlier meeting that the data contained in the PAG Guideline No. 8 (PAG Guideline on Protein-Rich Mixtures for Use as Supplementary Foods) was very useful for the consideration of these supplementary products. It was noted that this Guideline had been published in 1972 and that scientific and technological developments in the field of infant feeding would justify its review and possible up-dating.

53. One delegation drew attention to a discussion of follow-up milk at the 10th Session of this Committee, where the Committee had been informed that large quantities of the product covered by the standard were moving in international trade and that the product therefore complied with the Codex Work Priority Criteria for elaborating a standard.

54. In view of the above considerations, the Committee agreed that it was not feasible to cover both types of products within one standard and did not consider the present text of the standard in detail. It was also agreed to proceed as follows:

A Working Group would be established to meet, prior to the next session, or, preferably, in conjunction with the session to consider:

(a) the Proposed Draft Standard for Follow-up and Supplementary Foods with the aim to amend it in such a way as to apply to follow-up foods only, taking into account further information from governments on the type of products.

(b) the PAG Guideline No. 8 with the view to a possible up-dating in the light of recent scientific and technological developments in infant and child feeding. Efforts should be made to provide the Working Group with as much data as possible.

It was also agreed that the Working Group might give consideration to the adaptation of the PAG Guideline to the Codex Format.

55. The Committee noted that revised terms of reference (see para. 11) were necessary for the Committee to commence work on the PAG Guidelines and reiterated its recommendation to the Commission to approve the revised terms of reference at its next session.

56. Professor Rey, France, will act as coordinator for the preparations for the session of the Working Group. It was agreed that the Secretariat should invite member countries to the meeting of the Working Group which would be convened in conjunction with the next session of this Committee and that membership of the ad hoc Working Group was open to all members of the Codex Alimentarius Commission who wished to participate in the work of that group.

Report on the Second Session of an ad hoc Working Group on Foods for Use in a Diet for Diabetics

57. The ad hoc Working Group on Foods for Use in a Diet for Diabetics had held its second meeting on 25 and 26 September 1980 in Bad Godesberg to consider in the light of government comments the "Draft Guidelines of Foods Specially Modified for Incorporation in a Prescribed Dietary Regimen for Certain Diabetics" (CX/FSDU 80/5), which had been prepared by the delegation of Australia. The comments had been contained in Addenda 1 and 2 to the above document.

58. The Session had been attended by twenty six representatives from seven countries and two international organizations. The detailed Report of the Session of the Working Group is contained in Appendix III to this Report.

59. The Chairman of the Working Group, Dr. W. Hölzel, introduced the report and pointed out that the Group had confirmed its view that diabetics could satisfy their nutritional requirements by proper selection of ordinary foods. However, the products under discussion provided the possibility for a more diversified diet.

60. The Working Group had agreed with the delegate from Australia that in view of the comments on the scope, purpose and format of the proposed text, it was more appropriate to elaborate a standard for the labelling of and claims for foods for use in a diet for diabetics which would be complementary to the general standard on labelling and claims elaborated by this Committee. The Working Group had therefore proceeded to consider the proposed draft for such a standard submitted by the United Kingdom in their written comments (CX/FSDU 80/5 Addendum 1) and to use the Australian paper as a background document.

Consideration of a First Draft of a Standard for the Labelling of and Claims for Prepackaged Foods claimed to be suitable for incorporation in a Prescribed Dietary Regimen for Diabetics

61. The Working Group had considered the above draft in detail (see paras 4-21 of Appendix III). Agreement had been reached on all provisions of the draft standard with the exception of two provisions included in section 4 on claims. These two provisions dealt with the carbohydrate content (section 4.3(f)) in general and with a more detailed description of requirements for modification of certain carbohydrates (section 4.1). These sections had been placed in square brackets.

62. The Working Group had recommended that this Committee should consider the further development of the above standard taking into account the deliberations of the Working Group.

63. The Chairman of the Committee thanked the Working Group for its valuable work and suggested that the Committee might place the above proposed draft standard at Step 3 of the Procedure so that government comments would be requested with particular emphasis on the sections in square brackets.

64. The delegation of France expressed the view that, whereas the entire standard was well drafted as such, it was not sufficient to limit it to a definition of the products concerned. If no compositional criteria were included to substantiate these definitions, the delegation of France would oppose the development of this standard. The need for certain compositional requirements was supported by another delegation, especially in view of the fact that many diabetics were obese and required restrictions in energy intake. It was proposed that governments submit detailed comments on these matters for the next session.

Status of the Standard

65. The Committee advanced the 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 to Step 3 of the Procedure. The above standard is contained in Annex II to Appendix III to this report.

FIRST DRAFT OF A PROPOSED DRAFT STANDARD FOR THE LABELLING OF "LOW CALORIE AND REDUCED CALORIE" FOODS

66. The Committee had before it a first draft of the above standard prepared by the United States (Appendix V, ALINORM 79/26) and government comments (CX/FSDU 80/4, Add. 1, 2, and a Conference Room Document from Hungary).

67. Several delegations considered that the draft covered a wider remit than had been established by the Committee at its earlier sessions. The draft covered foods which by their nature were low in calories and which in the opinion of a number of delegations should not be regarded as special dietary foods. These delegations considered that the standard should cover only calorie-reduced foods, i.e. foods which had been modified in such a way as to reduce significantly their energy value. The definitions of foods for special dietary uses in standards such as those for gluten-free or low-sodium foods were cited in support of this view. In this connection Mr. Beacham of the US delegation recalled that the name of the Committee had been changed at an early stage from the Committee on Special Dietary Foods to the Committee on Foods for Special Dietary Uses. This had been done in recognition of the fact that a significant feature of the foods under consideration by this Committee was that they were presented to the public as being of value for some particular dietary purpose. These may include ordinary foods so presented, because of some aspect of their natural composition. It was the Committee's purpose to ensure that they were truthfully and informatively labelled.

68. The delegation of the United States explained that the maximum caloric value for low-calorie foods was established at 40 calories per serving to include foods of distinctly low calorie value. The Food and Drug Administration analysed the caloric values of foods included in the current edition of the USDA Handbook No. 8 and found that a 40 calories per serving maximum included a reasonable number of foods, e.g. soups, juices, fruits and vegetables. In view of this fact, at approximately twenty foods as consumed during a day, the use of low calorie foods in the diet would contribute to a significant reduction of calorie intake and would be useful to those on a weight reduction programme.

69. Attention of the Committee was drawn to the written comments of the delegations of New Zealand, Hungary and Czechoslovakia, proposing that the term "calorie" in the naming of "low calorie" and "reduced calorie" foods be replaced by "energy" in recognition of the increasing use of the SI. System. The Committee agreed to the use of the term "energy" in order to resolve the problem of the dual use of joule and calorie as units of measurement of food energy. The Committee agreed to consider the development of a standard which would apply only to energy-reduced foods but which would contain a definition for "low-energy foods". In the claims section of the standard an appropriate provision could be included which would be consistent with the principle contained in Section 6.1.3 of the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses. This Section 6.1.3 permitted claims such as: "this food is naturally X" but would not allow the food to be described as "special dietary" or "special dietetic".

70. The Committee decided to restrict the discussion of the draft to major considerations which would assist the delegation of the USA to prepare a revised text; this text would be sent to governments for comments prior to the next session of the Committee: the standard should be for Energy-Reduced Foods. It would be necessary to develop an appropriate definition, and to determine the extent to which the energy content of any foods had to be reduced, compared with the comparable ordinary food, before the food could be regarded as a special dietary food and described as being energy-reduced. A number of delegations indicated that in their countries regulations existed which prescribed the extent to which such a reduction in energy was required before the food could be marketed as an energy-reduced food. The reduction was normally related to a base reference food and the reduction varied from one-third to 50 percent of the normal energy content. The delegation of France pointed out that limitation of the energy value only could lead to nutritional imbalances and that it would therefore be desirable to indicate requirements for the content of certain nutrients. Some delegations drew attention to the need also to cover specially formulated products for which there was no base reference food. It was agreed that countries should supply the delegation of the USA (Dr. Robert Weik) with as much information as possible on the regulations or practices in their countries relating to energy-reduced foods. The delegation of the USA undertook to prepare a redraft of the standard and to circulate it for government comments prior to the next session of the Committee.

DISCUSSION ON THE USE OF THE TERM "PREPACKAGED" IN CODEX STANDARDS FOR FOODS FOR SPECIAL DIETARY USES

71. The Secretariat informed the Committee of the work undertaken by Codex Committee on Labelling on Draft Guidelines for the Labelling of Non-Retail Containers. The Commission, at its 13th Session, had recognized that Codex Committees could provide valuable information on this matter and in particular on the definitions of those types of container to which the guidelines should apply and which were not covered by the General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969).

72. The Committee noted that containers for foods destined for catering purpose, which would include the use in hospitals, were, at present, not considered to be "prepackaged" products for the purpose of Codex Standards, but were one of the types of non-retail containers which were to be covered by the above guidelines. It was further noted that for certain products,

a large proportion of the total production was consumed under catering arrangements; e.g. hospitals, institutional feeding or restaurants and canteens.

73. The Committee felt that in addition to labelling considerations there might be more far-reaching implications concerning the scope of those standards which were intended to apply only to prepackaged foods for special dietary uses.

74. The Committee decided to defer consideration of the labelling implications until such time when the Codex Committee on Labelling has made progress on both the Guidelines on the Labelling of Non-Retail Containers and the revision of the General Labelling Standard for Prepackaged Foods.

75. The Committee further agreed that governments should be requested to express their opinion on the appropriateness of restricting some of the standards to cover Prepackaged Products only.

MATTERS RELATED TO FOODS FOR INFANTS AND CHILDREN

76. The Committee had before it document CX/FSDU 80/7 which contained information related to two matters: the Advisory Lists of Mineral Salts and Vitamin Compounds for Foods for Infants and Children (Part I) and the Code of Hygienic Practice for Foods for Infants and Children (Part II).

ADVISORY LISTS OF MINERAL SALTS AND VITAMIN COMPOUNDS FOR FOODS FOR INFANTS AND CHILDREN

77. The Committee noted that the 13th Session of the Codex Alimentarius Commission had agreed that (a) the lists were of advisory nature, (b) could be amended by the Committee in accordance with the criteria for such amendments laid down by this Committee and (c) should be appended to the finalized Codex Standards for Foods for Infants and Children, (d) appropriate editorial amendments to Codex Standards for Foods for Infants and Children (CAC/RS 72/74- 1976) should be made as proposed in Appendix III to ALINORM 79/26.

78. The Committee noted that the Commission had approved the inclusion of ferric ammonium citrate into the list.

79. The Committee had agreed earlier in the session that the ad hoc Working Group dealing with the above lists should review them in the light of the Report of the 13th Session of the Codex Alimentarius Commission and report back to the Committee.

REPORT OF THE WORKING GROUP ON MINERAL SALTS

80. The Working Group included representatives from Federal Republic of Germany, France, Netherlands, Switzerland, United Kingdom and United States. Dr. R.W. Weik (USA) acted as Chairman and presented the following report:

(a) The Working Group discussed the list of proposed amendments to the approved Advisory List of Mineral Salts for Use in Foods for Infants and Children (Annex 3 to Appendix III, ALINORM 79/26) in the light of the decisions of the 13th Session of the Codex Alimentarius Commission.

(b) The U.S. delegation pointed out that several mineral compounds which were in the original list submitted by the Working Group at the 11th Session had been omitted from the Advisory List in Annex 1 to Appendix III. The reason for the omission was that their purity requirements were listed in the Merck Index as "used in food" and neither in Food Chemicals Codex nor JECFA specifications which were used for the other compounds.

(c) These mineral salts in question met the other three criteria and many of them had been used for years in infant formula and other foods for infants and children. All of these mineral salts were known to be safe and biologically available and had been shown to meet the purity requirements required by the new paragraph 3(i)d adopted by the Commission at its 13th Session.

(d) The following mineral salts have therefore been included in the final list:

Magnesium gluconate	Cupric carbonate
Ferrous citrate	Cupric citrate
Ferrous lactate	Cupric sulphate
Ferrous carbonate	Zinc acetate
Ferrous succinate	Zinc chloride
Ferric citrate	Zinc oxide
Ferric gluconate	Manganese carbonate
Sodium ferric pyrophosphate	Manganese citrate
	Potassium gluconate

(e) Other salts on the proposed list appeared to require further review before they could be moved to the approved advisory list.

(f) The representative from Switzerland advised the Working Group that ferrous phosphate was used in some foods in his country but the compound had never been submitted for approval. The Working Group recommended that the representative from Switzerland submit to the Chairman of the Working Group the necessary data to demonstrate that all the criteria for amendment of the advisory list had been met.

81. The Chairman of the Committee thanked the Working Group for the valuable work on these lists. It was noted that the Advisory Lists for Mineral Salts and for Vitamin Compounds would be published in the next edition of the booklet of Codex Standards for Foods for Infants and Children (CAC/RS 72/74-1976) together with other already adopted amendments.

82. It was further noted that the list containing those substances for which further information was needed and the criteria for amendment of the lists was included as Appendix IV in the report. The review of the Advisory List would be a standing item on the Agenda of Sessions of this Committee.

PROPOSED AMENDMENT TO THE CODEX STANDARD FOR INFANT FORMULA (CAC/RS 72/74-1976)

83. The Committee recalled that it had decided that no food additive should be carried over into Infant Formula from ingredients or raw materials. This provision had been adopted by the Commission subject to elaboration of an appropriate wording by the Codex Committee on Food Additives which reads as follows:

"No food additives shall be present as a result of carry-over from raw materials and other ingredients".

84. The delegation of Switzerland had considered that this provision would prohibit the use of certain special vitamin forms in infant formula as it did not allow for minute quantities of stabilizers and carrier substances listed in the Advisory List of Vitamin Compounds. Therefore Switzerland had submitted a proposed amendment to the 13th Session of the Codex Alimentarius Commission, which would exempt these substances from the general prohibition stipulated in the provision on carried-over additives.

85. The 13th Session of the Codex Alimentarius Commission had given its approval to an amendment of the standard in principle and had referred the matter to this Committee for consideration (paras 437-438 of ALINORM 79/38).

86. Several delegations felt that the proposed amendment was not specific enough, particularly with regard to the maximum amounts of these substances which could be present if such an exemption was to be accepted.

87. The Committee agreed that the following text of the Proposed Amendment of the Standard for Infant Formula should be submitted to governments for comments at Step 3:

> 5.3 No food Additives shall be present as a result of carry-over from raw materials and other ingredients with the exception:
>
> (a) of the food additives listed under 5.1 to 5.4 of this standard within the limits of the maximum levels stipulated in this standard, and
>
> (b) of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children.

REPORT OF AN AD HOC WORKING GROUP ON METHODS OF ANALYSIS AND SAMPLING FOR FOODS FOR INFANTS AND CHILDREN

88. The Committee received a report from the Chairman of the above Working Group, Professor Dr. W. Krönert, which had met during the session. The meeting had been attended by members of the delegations from the Federal Republic of Germany, the United Kingdom, the United States and the Secretariat.

89. The Working Group had considered several methods of analysis which had to be finalized and concluded as follows:

(a) Classification of Codex Methods of Analysis

The Working Group took note of the "Classification of Codex Methods of Analysis" approved by the Codex Alimentarius Commission at its 13th Session. In principle the Working Group considered this classification as useful. However, the Working Group emphasized that defining methods (I) must be elaborated before figures for the respective criteria were laid down in the standards.

(b) Determination of Nitrogen (Kjeldahl method)

The Working Group supported the efforts of the Codex Committee on Methods of Analysis and Sampling to replace the mercury catalysts by other chemicals, e.g. potassium and copper sulphate. However, the Working Group was unable to decide in which cases this might be possible without changing the results of analysis. The delegate of the United States was asked to make available a comparative study by Dr. J.C.D. White, Hannah Research Inst., Ayr, Scotland to the members of this Working Group for information in the light of methods used for the determination of nitrogen in infant formula and baby foods.

(c) Loss on Drying

The Chairman of the Working Group was asked to contact Dr. Schuller of the National Institute of Public Health, Bilthoven, Netherlands, for further information on developments concerning this matter.

(d) Determination of Crude Fibre in Infant Formula

The Working Group considered the amount of crude fibre in infant formula as analytically irrelevant. At the present time, an error in the amount of carbohydrates (as determined by difference) caused by neglecting the crude fibre content, could be less than the analytical error in the determination of crude fibre in the presence of thickeners.

(e) Determination of Vitamin K

No proposals for suitable methods were available as yet.

(f) Determination of Vitamin D and E

No suitable methods could be proposed at the present time. However, methods for the determinations based on HPLC were in preparation.

(g) Determination of Linoleic Acid

The Commission for Fats and Oils of IUPAC had elaborated a method for the determination of cis-cis 1:4 polyene acids. The quantity of linoleic acid could be determined by this method in combination with a G.L.C. method.

The Chairman of the Working Group was asked to make these methods available to the members of the Working Group.

The Chairman of the Committee thanked the Working Group for its valuable work. The Committee agreed with the conclusions of the Working Group and recommended that matters be followed up as indicated in the above report of the Working Group.

CODE OF HYGIENIC PRACTICE FOR FOODS FOR INFANTS AND CHILDREN

90. At the 13th Session of the Codex Alimentarius Commission, this Code was adopted at Step 8 except for the microbiological specifications contained in Annex I to the Code and the methods for microbiological analysis contained in Annex II (see also Appendix VII to ALINORM 79/26). The Commission deferred any decision concerning Annexes I and II but gave due regard to the views of the Committee about the advisory nature of the specifications.

91. Several delegations informed the Committee that, in their countries, microbiological end-product specifications for infant foods were mandatory. They were therefore in favour of the specifications being mandatory rather than advisory. The majority of delegations expressed the opinion that the specifications should be advisory for the time being. One delegation expressed the view that the specifications were too strict and that they would want to see some revision of the limits for bacterial counts. (Part II, para. 4 of CX/FSDU 80/7). The Committee agreed that the specifications included in the Code were of advisory nature. It was noted that countries having mandatory provisions for these microbiological specifications could specify this as a deviation when accepting the Codex Standards for Foods for Infants and Children. In view of the deviations notified, this Committee could reconsider at a future session, whether the microbiological specifications should be advisory or mandatory.

92. The Committee noted that a Circular Letter had been sent in August 1980 to Codex Contact Points for comments on the two annexes at Step 6 and that the comments would be considered by the next session of the Codex Committee on Food Hygiene (November 1980) which would also have before it the views of this Committee.

WHO/UNICEF INTERNATIONAL CODE OF MARKETING OF BREASTMILK SUBSTITUTES AND RELATED PRODUCTS

93. The representative of WHO outlined briefly the history of the proposed Draft International Code of Marketing of Breastmilk Substitutes. In October 1979, WHO and UNICEF had held a meeting at WHO Headquarters of representatives from all governments and organizations who were interested in the feeding of Infants and Young Children. The Meeting had recommended that an international code of marketing of infant formula and products used as breastmilk supplements should be developed by WHO/UNICEF. A first draft of the Code of Practice had been considered at a series of consultation meetings convened by WHO and UNICEF. A second draft had been examined by the World Health Assembly in May 1980 and a resolution had been adopted by the Assembly in which WHO was instructed to prepare a further draft Code in consultation

with other interested parties for review by the WHO Executive Board and Assembly in 1981. This third draft had been reviewed at two recent consultation meetings. The first consultation had been attended by experts in infant feeding and by representatives of UN agencies, non-governmental organizations and industry. The second consultation had been attended by representatives of 28 Member Governments of WHO. The representatives of WHO and UNICEF informed the Committee that a fourth version of the Code was being currently drafted for submission to the Executive Board of WHO in January 1981 and then to Member Nations of WHO for consideration at the World Health Assembly in May 1981. In reply to questions from delegates, the Committee was informed that this time schedule would not permit a further round of consultations with interested parties prior to submission of the Code to the Executive Board and the Assembly.

94. Some delegations were disappointed that the Committee would have no opportunity to discuss the Code before it was finalized and adopted by the World Health Assembly. The Code could have important implications for the future work of the Committee. These delegations favoured the creation of a Working Group to examine this aspect of the Code and thought that the Committee should examine this matter at its next session in the light of the review to be undertaken by the Working Group. The Code could have implications for the Committee's work on standards for foods for infants and children as well as for the possible updating of the PAG Guideline No. 8.

95. The representative of ISDI informed the Committee that whilst the major part of the Infant Food Industry had endorsed the recommendations of the WHO/UNICEF Meeting, October 1979, there were now serious misgivings within the industry concerning the content of the Code and manner in which it was being developed. The representative listed both the positive and the negative features of the Code from the industry's point of view.

96. Several delegations expressed the view that the scope and coverage of the Code concerning Infant Foods should be carefully delineated and that regard should be paid to the differing social, economic and environmental circumstances existing in different countries. Parts of the Code which might be appropriate in a developing country might not be of relevance in a developed country and vice versa.

97. The Committee concluded that it would be important for the adopted WHO/UNICEF International Code of Marketing of Breastmilk Substitutes and Related Products to be distributed to Members of this Committee for their examination and comments. The comments would be collated and put before the next session of the Committee and this Committee would be requested to examine in particular any implications of the Code for the Committee's work on standards for products covered by the Code.

FUTURE PROGRAMME OF WORK

98. The Committee briefly reviewed the principal items of business for its next session and other items on the Schedule of Future Work. The principal matters to be considered at the 13th Session would be:

(a) General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses at Step 7 (para. 44).

(b) Guidelines on "Medical Foods" which are advertized to the medical profession only. (Prepared by the delegation of the United States, para. 26).

(c) Standard for the Labelling of and Claims for Prepackaged Foods claimed to be suitable for Incorporation in a Prescribed Dietary Regimen for Diabetics at Step 4, (para. 65).

(d) Standard for the Labelling of and Claims for Low-energy and Energy-reduced Foods (Redraft by the United States in light of government comments) (para.70).

(e) Implications of the WHO/UNICEF "International Code of Marketing of a Breastmilk Substitute and Related Products" on the Committee's work on standards for products covered by the Code (para. 97).

(f) Report of the Working Group on Follow-up and Supplementary Foods based on the Proposed Draft Standard for Follow-up Foods (Appendix IV to ALINORM 79/26) and the PAG Guideline No. 8, "Protein-Rich Mixtures for Use as Supplementary Foods" (para. 54).

(g) Guidelines on Nutrition Labelling and the Committee's revised Terms of Reference (paras 11 and 55).

(h) Proposed Amendments to the Standard for Infant Formula at Step 3 concerning carry-over food additives and carrier substances of special vitamin forms (para. 87).

(i) Consideration of the coverage of standards for products in non-retail containers (paras 71-75).

(j) Methods of Analysis and Sampling (para. 89).

(k) Possible amendments to the Advisory Lists of Vitamin Compounds and Mineral Salts (para. 82).

DATE AND PLACE OF NEXT MEETING

99. The Chairman informed the Committee that the Federal Republic of Germany would be pleased to host the Thirteenth Session of the Committee at Bonn-Bad Godesberg in September 1982.

SUMMARY STATUS OF WORK

Standard/Code/Document	Status Step	To be dealt with by	ALINORM/App. Document
Standard for Foods with Low Sodium Content (including salt substitutes)	9	Governments	CAC/RS 53-1971
Standard for Infant Formula 1/	9	Governments	CAC/RS 72-1976
Standard for Canned Baby Foods 1/	9	Governments	CAC/RS 73-1976
Standard for Processed Cereal-based Foods for Infants and Children 1/	9	Governments	CAC/RS 74-1976
List of Vitamin Compounds for Use in Foods for Infants and Children (see paras 81-82)	-	Governments	Annex to Codex Standards for Foods for Infants and Children
List of Mineral Salts for Use in Foods for Infants and Children (see paras 81-82)	-	Governments	
Standard for Gluten-free Foods	9	Governments	CAC/RS 118-1979

1/ New edition of CAC/RS 72/74-1976 will include all amendments to these standards so far adopted.

Standard/Code/Document	Status Step	To be dealt with by	ALINORM/App. Document
Draft General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses	7	13th FSDU	ALINORM 81/26 Appendix II
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	13th FSDU	ALINORM 81/26 Appendix III
Proposed Draft Standard for Follow-up Foods and Review of PAG - Guideline No. 8 - Protein-Rich Mixtures for Use as Supplementary Foods	4 -	WG (see paras 54-56) 13th FSDU	ALINORM 79/26 Appendix IV ALINORM 81/26 Appendix V
First Draft of a Standard for Energy-reduced Foods (including definition of "low-energy" foods)	-	13th FSDU (see para.70)	CX/FSDU 82/... 1/
First Draft of Guidelines on Labelling of and Claims for "Medical Foods"	-	13th FSDU (see para.26)	CX/FSDU 82/... 1/
Proposed Draft Amendment to Codex Standard for Infant Formula CAC/RS 72-1976	3	13th FSDU	ALINORM 81/26 para. 87
Review of adopted UNICEF/WHO International Code of Marketing of Breastmilk Substitutes and Related Products	-	13th FSDU	CX/FSDU 82/... 1/
Review of Draft Guidelines on Nutrition Labelling	(5)	13th FSDU	ALINORM 81/22 Appendix ... 1/
Review of Status of Microbiological End Product Specifications and related Methods of Analysis and Sampling Plans	-	See para.91	ALINORM 79/26 Appendix VII
Proposed Draft Standard for Consumer-Packaged Protein Foods	4	ALINORM 78/26 see para.86	ALINORM 71/26 Appendix VII
Cholesterol-reduced Foods	-	Postponed, ALINORM 78/26 see para.83	-
Medium-chain Triglycerides	-	Postponed, ALINORM 78/26 see para.84	-
Low-lactose Products	-	Postponed, ALINORM 78/26 see para.100	-
General Principles concerning the Fortification of Foods	-	Postponed, ALINORM 78/26 see para.100	-
Revision of Standard for Infant Formula (CAC/RS 72-1976)	-	ALINORM 78/26 see para. 85	-

1/ To be distributed separately, in due course.

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DRAFT GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES

(Retained at Step 7)

1. SCOPE

This standard applies to the Labelling of all Prepackaged Foods for Special Dietary Uses as defined in Section 2.1 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 Label includes any tag, brand, mark, pictorial or other descriptive matter written, printed, stencilled, marked, embossed or impressed, on, or attached to a container of food.

2.3 Labelling includes the label and any written, printed or graphic matter relating to and accompanying the food.

2.4 Advertising includes any statement written,visual or oral, related to the food, including in promotional literature except those mentioned under 2.2 and 2.3.

2.5 Claims means any representation which states, suggests or implies that the food has particular qualities relating to its origin, nutritional properties, nature, processing, composition or any other quality which render it suitable for a special dietary use. The inclusion of substances mentioned only on a list of ingredients or as part of nutritional labelling shall not constitute a claim.

2.6 Container means any form of packaging of food for sale as a single item whether by completely or partially enclosing the food in such a way that the contents cannot be altered without opening or changing the packaging and includes wrappers.

2.7 Prepackaged means packaged or made up in advance, ready for retail sale in a container.

2.8 Ingredient means any substance, including a food additive, used in the manufacture or preparation of a food and present in the final product.

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.

1/ This includes foods for infants and young children.

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 sub-sections 4.1 to 4.9 of this section as applicable to the food being labelled, except to the extent otherwise expressly provided in specific Codex Standards for Foods for Special Dietary Uses. (See Annex I).

4.1 The Name of the Food

4.1.1 The name of the food shall indicate the true nature of the food and normally be specific and not generic.

4.1.1.1 Where a name or names have been established for a food in a Codex Standard, at least one of these names shall be used.

4.1.1.2 In other cases, a common or usual name shall be used, if one exists.

4.1.1.3 Where no common or usual name exists, an appropriate descriptive name shall be used.

4.1.1.4 A "coined" or "fanciful" name, however, may be used provided it is not misleading and is accompanied by an appropriate descriptive term.

4.1.2 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

4.1.3 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.

4.2 List of Ingredients

4.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion by weight, except that in the case of dehydrated foods which are intended to be reconstituted by the addition of water or milk, the ingredients may be listed in order of proportion in the reconstituted product provided that the list of ingredients is headed by a statement such as "Ingredients when reconstituted in accordance with the directions on the label".

4.2.2 Where an ingredient of a food is itself the product of two or more ingredients, the latter shall be declared in brackets, in descending order of proportion by weight (m/m), following the name of the actual ingredient of which they form a part.

4.2.3 A specific name shall be used for ingredients in the list of ingredients except that class titles for ingredients may be used in accordance with General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969).

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 (kJ) and kilojoules (kCal).

(b) The number of grammes of protein, 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 foodstuffs 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

4.4.1 The net contents shall be declared in either the metric ("Système International" units) or avoirdupois or both systems of measurement as required by the country in which the food is sold. 1/ The declaration shall be made in the following manner:

(a) for liquid foods, by volume;
(b) for solid foods, by weight, except that when such foods are usually sold by number a declaration by count may be made;
(c) for semi-solid or viscous foods, either by weight or volume.

4.4.2 Foods packed in a liquid medium normally discarded before consumption shall carry a declaration of the drained weight of the food.

4.5 Name and Address

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

4.6 Country of Origin

4.6.1 The country of origin of the food shall be declared.

4.6.2 Where a 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 purpose of labelling.

4.7 Lot Identification

Each container shall be embossed or otherwise permanently marked, in code or in clear, to identify the producing factory and the lot.

4.8 Date Marking

4.8.1 The date of minimum durability shall be declared.

4.8.2 The date shall consist of the day, month and year in uncoded chronological order except that:

Where the product will keep for more than three months, an uncoded indication of the month and the year only will suffice.

4.9 Storage Instructions and Directions for Use

4.9.1 Storage of Unopened Food

Storage instructions for unopened special dietary food packages shall be included on the label if such information is essential for the keeping qualities of the food.

4.9.2 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/ Governments communicating acceptance of this standard are requested to indicate specifically their country's requirements concerning the system of measurement.

4.9.3 Directions for Use

Directions for use shall be included on the label if necessary to ensure correct utilization. In particular, directions for reconstitution shall be included on the label if applicable.

5. PRESENTATION OF MANDATORY INFORMATION

5.1 General

Statements required to appear on the label by virtue of this standard or any other Codex Standard shall be clear, prominent and readily legible by the consumer under normal conditions of purchase and use. Such information shall not be obscured by designs or by other written, printed or graphic matter and shall be in contrasting colour to that of the background. The letters in the name of the food shall be in a size reasonably realted to the most prominent printed matter on the label. Where the container is covered by a wrapper, the wrapper shall carry the necessary information, or the label on the container shall be readily legible through the outer wrapper or not obscured by it. In general, the name and net contents of the food shall appear on that portion of the label normally intended to be presented to the consumer at the time of sale.

5.2 Language

The language used for the declaration of the statements referred to in para. 5.1 shall be a language acceptable to the country in which the food is intended for sale. If the language on the original label is not acceptable, a supplementary label containing the mandatory information in an acceptable language may be used instead of relabelling.

6. ADDITIONAL REQUIREMENTS

6.1 Claims

6.1.1 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.

6.1.2 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.

6.1.3 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", such a food may, however, 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.

6.1.4 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.

6.2 Irradiated Foods

Foods which have been treated with ionizing radiation, shall be so designated.

6.3 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. (See Annex 1).

7. OPTIONAL LABELLING

Any information or pictorial device may be displayed in labelling provided that it is not in conflict with the mandatory requirement nor would mislead or deceive the consumer in any way whatsoever in respect of the food.

ANNEX 1 To
APPENDIX II

LIST OF RECOMMENDED INTERNATIONAL 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)	CAC/RS 53-1971
(b)	Infant Formula 1/	CAC/RS 72-1976
(c)	Canned Baby Foods 1/	CAC/RS 73-1976
(d)	Processed Cereal-based Foods for Infants and Children 1/	CAC/RS 74-1976
(e)	"Gluten-free" Foods	CAC/RS 118-1979

ALINORM 81/26
APPENDIX III

REPORT OF THE SECOND MEETING OF AN AD HOC WORKING GROUP ON FOODS FOR USE IN A DIET FOR DIABETICS

INTRODUCTION

The 11th session of the Committee on Foods for Special Dietary Uses accepted the recommendations made by an ad hoc Working Group and decided to commence work on guidelines for foods for use in a diet for diabetics (paras 97-98 of ALINORM 79/26).

A First Draft of Guidelines for Foods Specifically Modified for Incorporation in a Prescribed Dietary Regimen for Certain Diabetics, kindly prepared by the delegation of Australia, was circulated to members of the above working group for comments. The Government of the Federal Republic of Germany kindly offered to host a second session of the Working Group prior to the 12th session of this Committee in order to discuss the guidelines and to evaluate the comments received from the Netherlands, Norway, Sweden, United Kingdom, United States, WHO and the International Diabetes Federation.

1/ These standards are published as one booklet "Recommended International Standards for Foods for Infants and Children" (CAC/RS 72/74-1976). The revised edition (1980) includes all amendments to these standards adopted by the Codex Alimentarius Commission.

APPENDIX III

The ad hoc Working Group met in Bonn-Bad Godesberg from 25 to 26 September 1980 under the Chairmanship of Dr. W. Holzel, Regierungsdirektor, Ministry for Youth, Family and Health of the Federal Republic of Germany.

The meeting was attended by representatives from the following countries and international organizations:

Australia	Switzerland	ISDI
Germany, Fed. Rep. of	United Kingdom	FAO
Netherlands	United States	
Sweden		

The List of Participants is contained in Annex I.

CONSIDERATION OF FIRST DRAFT OF PROPOSED DRAFT GUIDELINES FOR FOODS SPECIALLY MODIFIED FOR INCORPORATION IN A PRESCRIBED DIETARY REGIMEN FOR CERTAIN DIABETICS

1. The Working Group had before it the above guidelines as contained in CX/FSDU 80/5 and comments thereon in CX/FSDU 80/5, Addenda 1 and 2. The Working Group expressed its thanks to the delegation of Australia for the excellent paper which had succeeded in covering all important points discussed at the previous session of the group.

2. The Working Group agreed with the delegate from Australia that (a) the regulations should deal with labelling aspects and claims only; (b) many of the provisions applicable to the foods for use for diabetics were contained in the General Standard for the Labelling of and Claims for Foods for Special Dietary Uses; (c) any additional provisions excluding compositional requirements for these products should be presented in the form of a standard.

3. The Working Group therefore agreed with a proposal to continue the discussion on an appropriate proposed draft standard submitted by the United Kingdom and to use the Australian paper as a background document.

CONSIDERATION OF A FIRST DRAFT OF A PROPOSED DRAFT STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS CLAIMED TO BE SUITABLE FOR INCORPORATION IN A PRESCRIBED DIETARY REGIMEN FOR CERTAIN DIABETICS (Pages 10-13 of CX/FSDU 80/5, Add. 1)

4. The Working Group agreed that it was possible to meet the nutritive needs of diabetics by proper selection from ordinary foods.

5. It was further agreed that ordinary foods not suitable for diabetics might become suitable after appropriate modification. In this case they were special dietary foods covered by the General Labelling Standard for these foods. However, it was recognized that additional provisions were necessary to ensure proper consumer information and to provide for specific provisions on claims.

6. The Working Group than proceeded to discuss the draft proposal in detail. The amended text is contained in Annex II.

Section 1 - Scope

7. The Working Group agreed that all diabetics needed a specific diet; but that the exact dietary regimen had to be prescribed by qualified persons to meet the needs of the individual diabetic. Therefore the term "certain" in connection with "diabetic" was deleted wherever it appears in the standard.

8. It was pointed out that not all modified foods were suitable for all types of diabetics and it was suggested to include an explanatory paragraph which would deal with the principles of suitable modifications. This was not included in Section 1 (see para. 18).

Section 2 - Definitions

9. The following preamble was introduced: "For the purpose of this standard", and the text of Section 2 was appropriately modified:

10. On Section 2.2 it was pointed out that the term "appropriately qualified person" was open to misinterpretation. "Authorized" was substituted for "qualified" to allow for the diverging practices of health administration in different countries.

11. Concerning Sections 2.4, 2.5 and 2.6, the Working Group felt that these definitions for carbohydrates, sugar substitutes and non-nutritive sweeteners were not really defining these substances well and were furthermore not suitable for use as reference in the following provisions on labelling and claims.

12. It was agreed that carbohydrates should include all carbohydrates.

13. After extensive discussion on the metabolic pathway of fructose it was decided that for the purpose of this standard fructose was a sugar substitute. A modification for nutritive sweeteners was introduced including sugars and "glucoplastic" 1/sugar substitutes; i.e. sugar substitutes which in one way or the other entered into the glucose metabolism.

14. It was agreed that these "glucoplastic" sugar substitutes, e.g. polyols and fructose, were used to replace glucose, sucrose and other glucose containing low molecular weight carbohydrates. The definition for non-nutritive sweeteners was amended to relate to sweeteners which were not, or virtually not, utilized as source of energy. Consequential amendments to these definitions were made in Section 3.

Section 3 - Mandatory Labelling

15. The Working Group agreed in principle with Section 3.1 but suggested that the statement to be declared in close proximity to the name should read "May be suitable for diabetics subject to advice from a qualified person".

16. It was decided that the sugar substitutes and non-nutritive sweeteners were to be declared in descending order of proportion by weight, by their specific names in the List of Ingredients (Section 3.2.1), and to give in addition their classname in brackets in order to provide further information for the consumer.

17. The Working Group agreed that in the nutrient labelling section a quantitative declaration should be required for starches; glucose, sucrose and other glucose containing low molecular weight carbohydrates and "glucoplastic" sugar substitutes. These substances would also have to be included in the calculation of total carbohydrates.

Section 4 - Claims

18. The Working Group felt that Section 4.1, suitably amended, would provide an opportunity to include the statement on the principles of modification (see also para. 8), and at the same time provided advice on this basis for the claims that an appropriately modified food of this nature was suitable for diabetics. To this effect the Working Group accepted the part of a proposal made by the Netherlands (see para. 1, CX/FSDU 80/5, Add. 1) that glucose, sucrose and other glucose containing low molecular weight carbohydrates not be added to the modified foods and the added sweetness of the products be derived from sugar substitutes and/or non-nutritive sweeteners or the products not be sweetened at all.

1/ Due to the opinion of several English speaking delegates that an equivalent term to glucoplastic might be more suitable, it was agreed to place the term glucoplastic within quotation marks wherever it appeared in the standard.

19. No consensus could be reached on Section 4.3(f) which required the modified products to contain significantly less carbohydrates than the ordinary food. It was pointed out that current scientific evidence did not justify such a requirement. Sections 4.1 and 4.3(f) were placed in square brackets to request specific comments on this matter.

20. It was agreed that Section 4.3(c) expressed an important principle of the dietary management of diabetics; and the wording was clarified accordingly.

21. The delegation of the Federal Republic of Germany felt that the statement related to Section 4.2(b) did not apply in all circumstances and wished therefore to delete it from the standard. The Working Group preferred to retain Section 4.2(b).

22. The view was expressed that in addition to the provisions contained in the draft there should be a requirement to place a worning statement in close proximity to the name of the food about the content of non-nutritive sweeteners (reason: possible carcinogenic properties), and about the content of polyols (reason: laxative properties). It was however noted that the investigations of these substances had not yet been finalized and that it was not possible to relate the requirements to the ADI which was calculated per kg body weight and related to the total diet. The Working Group did not include, at this time, any provisions dealing with such warning statements including also the reference to the content of these substances.

RECOMMENDATION

23. The Working Group recommended that the Committee should consider the further development of the "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" in the light of the comments made.

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PROPOSED DRAFT STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKGED FOODS CLAIMED TO BE SUITABLE FOR INCORPORATION IN A PRESCRIBED DIETARY REGIMEN FOR DIABETICS

1. SCOPE

This standard applies to the labelling of all those foods for special dietary uses, as defined in the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses, which are claimed to be suitable for incorporation in a prescribed dietary regimen for diabetics, and to claims made for such foods.

2. DEFINITION OF TERMS

For the purpose of this standard:

2.1 Diabetics are those diabetic individuals who have been advised, by a qualified person, that particular prepackaged foods specifically modified for diabetics and marketed for this purpose, may be included in their dietary regimen within the limits prescribed by the qualified person.

2.2 Qualified Person means a medically qualified person or other person appropriately authorized to advise diabetics regarding their dietary regimen as part of the treatment and control of their diabetes.

2.3 Prescribed Dietary Regimen is that dietary regimen prescribed by a qualified person to meet the specific nutritional requirements of an individual diabetic.

2.4 Carbohydrates means metabolisable carbohydrates and include nutritive sweeteners and starches.

2.5 Nutritive Sweeteners are those sugars, except fructose, which are defined by the Codex Alimentarius Commission and "glucoplastic" sugar substitutes.

2.6 "Glucoplastic" Sugar Substitutes are substances such as sorbitol, mannitol, xylitol and other polyols, and fructose which are intended to replace glucose, sucrose and other glucose containing low molecular weight carbohydrates.

2.7 Non-nutritive Sweeteners are sweetening substances which are not utilized in the metabolism as a source of energy or which are contributing only a negligible amount of energy as normally consumed.

3. MANDATORY LABELLING

3.1 Foods to which this standard applies shall be labelled in conformity with the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses, except that the condition for which the food is intended may be stated in close proximity to the name of the food, provided that it is accompanied by the following statement, or some similar statement:

"May be suitable for diabetics, subject to advice from a qualified person".

3.2 The following additional material shall also be shown on the labels of foods to which this standard applies:

3.2.1 Sugar substitutes and non-nutritive sweeteners shall be identified in the List of Ingredients by their specific names together with the appropriate classname in brackets in descending order of proportion.

3.2.2 In addition to the declaration of nutritional information required to be shown on the label in compliance with Section 4.3.1 of the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses, the following nutritional information shall be given on the label:

(a) the total combined weight in grammes of glucose, sucrose and other glucose containing molecular weight carbohydrates; and
(b) of "glucoplastic" sugar substitutes per 100 grammes of the food, and where appropriate, per specified quantity of the food as suggested for consumption. The amounts of these substances present in the food shall also be included in the calculation of the total amount of carbohydrate present in the food, and this should be made clear in the labelling.

4. CLAIMS

/4.1 No claim that a food is suitable for incorporation in a prescribed dietary regimen for diabetics shall be made unless the food is a special dietary food as defined in the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses which is prepared in accordance with the following principles:

(a) no glucose, sucrose or other glucose containing low molecular weight carbohydrates are added as ingredients in these foods;
(b) added sweetners is derived from "glucoplastic" sugar substitutes and/or non-nutritive sweeteners;
(c) or they are not sweetened./

4.2 Any claims made for foods covered by this standard shall be in accordance with the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses.

4.3 Nothing in the labelling or advertising of foods covered by this standard shall claim, either expressly or by implication:

(a) that such foods may be taken by diabetics without reference to the limits of a dietary regimen prescribed by a qualified person;
(b) that such foods are suitable for the use of all diabetics;
(c) that the nutritive needs of diabetics cannot be met by proper selections from ordinary food;
(d) that a particular ingredient or componenet has a particular suitability for incorporation in a dietary regimen for diabetics in general or for any particular type of diabetic;
(e) that the use of such foods is essential or necessary for incorporation in a dietary regimen for diabetics in general or for any particular type of diabetic;
[(f) that a food has been specially modified and is suitable for incorporation in a dietary regimen for diabetics in general or for any particular type of diabetic if the food does not contain substantially less carbohydrate than a similar food for normal consumption.]

4.4 In the labelling and advertising of foods to which this standard applies, statements or claims may be made that such foods may afford a greater variety of foods for the diabetic within the limits of the dietary regimen prescribed by a qualified person.

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

PART I: ADVISORY LISTS OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR INFANTS AND CHILDREN

The 13th Session of the Codex Alimentarius Commission approved the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children for inclusion in Codex Standards for Foods for Infants and Children (A) and agreed with the proposed criteria for amendments of the list (B) which applied to the proposed amendments (C) and any other amendment proposed at a future date:

A.

Vitamin	Vitamin Form	Purity Requirements
1. Vitamin A	Retinyl acetate	USP, BP, Ph. Eur., FCC
	Retinyl palmitate	USP, BP, Ph. Eur., FCC
	Retinyl propionate	USP, BP, Ph. Eur., FCC
2. Provitamin A	Beta-carotene	FAO/WHO, FCC
3. Vitamin D		
3.1 Vitamin D_2	Ergocalciferol	USP, BP, Ph. Eur., FCC
3.2 Vitamin D_3	Cholecalciferol	USP, FCC
	Cholecalciferol-cholesterol	DAB
4. Vitamin E	d-alpha-tocopherol	NF, FAO/WHO
	dl-alpha-tocopherol	NF, FAO/WHO, FCC
	d-alpha-tocopheryl acetate	NF, FCC
	dl-alpha-tocopheryl acetate	NF, FCC
	d-alpha-tocopheryl succinate	FCC
	dl-alpha-tocopheryl succinate	NF
5. Thiamin (Vitamin B_1)	Thiamin chloride hydrochloride	USP, BP, Ph. Eur., FCC
	Thiamin mononitrate	USP, FCC
6. Riboflavin (Vitamin B_2)	Riboflavin	USP, BP, Ph. Eur., FAO/WHO, FCC
	Riboflavin 5'-phosphate sodium	BPC, FCC
7. Niacin	Nicotinamide	USP, BP, Ph. Eur., FCC
	Nicotinic acid	NF, BP, Ph. Eur., FCC
8. Vitamin B_6	Pyridoxine hydrochloride	USP, BP, Ph. Eur., FCC
9. Biotin (Vitamin H)	d-biotin	FCC
10. Folacin	Folic acid	USP, BP
11. Pantothenic acid	Calcium pantothenate	USP, Ph. Eur., FCC
	Panthenol	FCC
12. Vitamin B_{12}	Cyanocobalamin	USP, BP, Ph. Eur.
	Hydroxocobalamin	NF, BP
13. Vitamin K_1	Phytylmenaquinone	USP, BP
14. Vitamin C	Ascorbic acid	USP, BP, Ph. Eur., FAO/WHO, FCC
	Sodium ascorbate	USP, FAO/WHO, FCC
	Calcium ascorbate	FCC
	Ascorbyl-6-palmitate	NF, FAO/WHO, FCC
15. Choline	Choline bitartrate	DAB, FCC
	Choline chloride	FAO/WHO, DAB, FCC
16. Inosotol		FCC

Special Vitamin Forms

For reasons of stability and easier handling, some vitamins have to be converted into suitable preparations, e.g. stabilized oily solutions, gelatine coated products, fat embedded preparations. For this purpose, the edible materials and the additives included in the respective Codex Standard may be used.

Abbreviations

USP = **United States Pharmacopoeia XIX.**
NF = **United States National Formulary XIV.**
BP = **British Pharmacopoeia 1973, including addenda.**
BPC = **British Pharmaceutical Codex 1973.**
Ph.Eur. = **European Pharmacopoeia Vol.I - 1969, II-1971 and III-1975.**
FAO/WHO = Guide to the Safe Use of Food Additives (CAC/FAL 5-1979)
DAB = **Deutsches Arzneibuch 7. Ausgabe 1968.**
FCC = **Food Chemicals Codex, 2nd ed. 1972.**
JSFA = Japanese Standards of Food Additives, 4th Ed., 1979.

B. 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.

C. 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 below:

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**	
Pantothenic Acid	**Sodium pantothenate**	
Vitamin C	**Potassium ascorbate** **Ascorbyl stearate**	**JSFA**
Choline	**Choline hydrogen citrate**	

2. Special Vitamin Forms

In addition to the substances listed in List A it has been proposed that the following substances should be permitted: (see also paras 83-87)

Substance	Purity Requirements
Gum arabic (gum acacia)	**FAO/WHO**
Silicon dioxide, as anticaking agent, not more than 10 g/kg	**FAO/WHO**

PART II: ADVISORY LISTS OF MINERAL SALTS FOR USE IN FOODS FOR INFANTS AND CHILDREN

The 13th Session of the Codex Alimentarius Commission approved the Advisory List of Mineral Salts for Use in Foods for Infants and Children for inclusion in Codex Standards for Foods for Infants and Children (as amended (A)) and agreed with the proposed criteria for amendments of the list (B) which applied to the proposed amendments (C) and any other amendment proposed at a future date:

A.

Salts	Purity Requirements	Use in Foods for Infants and Children
1. Source of Calcium (Ca)		
1.1 Calcium carbonate	FCC; FAO/WHO	Milk substitute formulae; Infant cereals
1.2 Calcium chloride	FCC, FAO/WHO	Milk-based and milk substitute formulae
1.3 Calcium citrate	FCC, FAO/WHO	Milk-based, milk substitute, protein hydrolysate and meat-based formulae
1.4 Calcium gluconate	FCC, FAO/WHO	Protein hydrolysate formulae
1.5 Calcium glycerophosphate	FCC	
1.6 Calcium lactate	FCC, FAO/WHO	Electrolyte mixture supplement
1.7 Calcium phosphate, monobasic	FCC, FAO/WHO	Milk substitute and low sodium formulae
1.8 Calcium phosphate, dibasic	FCC	Milk substitute and protein hydrolysate formulae
1.9 Calcium phosphate, tribasic	FCC, FAO/WHO	Milk substitute, protein hydrolysate and premature formulae; infant cereals
1.10 Calcium oxide	FCC, FAO/WHO	Protein supplement formulae
1.11 Calcium sulphate	FCC, FAO/WHO	Infant cereals
2. Source of Phosphorus (P)		
2.1 Calcium phosphate, monobasic	FCC, FAO/WHO	Milk substitute and low sodium formulae
2.2 Calcium phosphate, dibasic	FCC	Milk substitute and protein hydrolysate formulae
2.3 Calcium phosphate, tribasic	FCC, FAO/WHO	Milk substitute, protein hydrolysate and premature formulae; infant cereals
2.4 Magnesium phosphate, dibasic	FCC	Milk substitute and lactose-free formulae
2.5 Magnesium phosphate, tribasic	FCC, FAO/WHO	
2.6 Potassium phosphate, monobasic	FCC, FAO/WHO	Protein hydrolysate formulae
2.7 Potassium phosphate, dibasic	FCC, FAO/WHO	Milk-based, milk substitute and protein hydrolysate formulae
2.8 Sodium phosphate, dibasic	FCC, FAO/WHO	Electrolyte mixture supplement

APPENDIX IV

Salts	Purity Requirements	Use in Foods for Infants and Children
3. Source of Chloride (Cl)		
3.1 Calcium chloride	FCC, FAO/WHO	Milk-based, milk substitute and protein supplement formulae; electrolyte mixture supplement
3.2 Choline chloride	FCC, FAO/WHO	Milk-based, milk substitute and protein hydrolysate formulae
3.3 Magnesium chloride	FCC, FAO/WHO	Milk-based, milk substitute and lactose-free formulae
3.4 Manganese chloride	FCC	Milk-based formulae
3.5 Potassium chloride	FCC, FAO/WHO	
3.6 Sodium chloride	FCC, FAO/WHO	Milk substitute formulae, baby foods and electrolyte mixture supplement
3.7 Sodium chloride, iodized	FCC	Milk substitute formulae
4. Iron (Fe)		
4.1 Ferrous carbonate, stabilized	*	
4.2 Ferrous citrate	*	Milk and soy-based liquid infant formulae
4.3 Ferrous fumarate	FCC	Vitamins, iron supplement
4.4 Ferrous gluconate	FCC, FAO/WHO	
4.5 Ferrous lactate	*	Milk and soy-based liquid infant formulae
4.6 Ferrous succinate		
4.7 Ferrous sulphate	FCC	Milk-based, milk substitute and protein hydrolysate formulae
4.8 Ferric ammonium citrate	FAO/WHO	
4.9 Ferric citrate	*	Milk and soy-based liquid infant formulae, not allowed in powdered formulae, cereals or canned baby foods
4.10 Ferric gluconate	*	
4.11 Sodium ferric pyrophosphate	*	
4.12 Hydrogen reduced iron	FCC	Infant cereals; protein supplement formulae
4.13 Electrolytic iron	FCC	Infant cereals
4.14 Carbonyl iron	*	
4.15 Ferric pyrophosphate	FCC	Milk-based formulae
5. Source of Magnesium (Mg)		
5.1 Magnesium carbonate	FCC, FAO/WHO	Baked products
5.2 Magnesium chloride	FCC, FAO/WHO	Milk-based, milk substitute and lactose-free formulae
5.3 Magnesium oxide	FCC, FAO/WHO	Milk substitute, protein hydrolysate and premature formulae
5.4 Magnesium phosphate, dibasic	FCC	Milk substitute, lactose-free formulae

* See para. 80 b-d.

Salts	Purity Requirements	Use in Foods for Infants and Children
5.5 Magnesium phosphate, tribasic	FCC, FAO/WHO	
5.6 Magnesium sulphate	FCC	Electrolyte mixture supplement

6. Source of Sodium (Na)

6.1 Sodium bicarbonate	FCC, FAO/WHO	Milk-based formulae, gazed products
6.2 Sodium carbonate	FCC, FAO/WHO	Protein hydrolysate formulae
6.3 Sodium chloride	FCC, FAO/WHO	Milk substitute formulae, baby foods, electrolyte mixture supplement
6.4 Sodium chloride, iodized	FCC	Milk substitute formulae
6.5 Sodium citrate	FCC, FAO/WHO	Milk-based, milk substitute and protein hydrolysate formulae, electrolyte mixture supplement
6.6 Sodium gluconate	FCC	
6.7 Sodium lactate	FAO/WHO	
6.8 Sodium phosphate, monobasic	FCC, FAO/WHO	Milk substitute formulae
6.9 Sodium phosphate, dibasic	FCC, FAO/WHO	Electrolyte mixture supplement
6.10 Sodium phosphate, tribasic	FCC, FAO/WHO	
6.11 Sodium sulphate	FCC	
6.12 Sodium tartrate	FCC, FAO/WHO	

7. Source of Potassium (K)

7.1 Potassium bicarbonate	FCC, FAO/WHO	
7.2 Potassium carbonate	FCC, FAO/WHO	
7.3 Potassium chloride	FCC, FAO/WHO	
7.4 Potassium citrate	FCC, FAO/WHO	
7.5 Potassium glycerophosphate	FCC	
7.6 Potassium gluconate	*	
7.7 Potassium phosphate, monobasic	FCC, FAO/WHO	Protein hydrolysate formulae
7.8 Potassium phosphate, dibasic	FCC, FAO/WHO	Milk-based, milk substitute and protein hydrolysate formulae

8. Source of Copper (Cu)

8.1 Copper gluconate	FCC	
8.2 Cupric carbonate	*	Baked products, protein supplement formulae
8.3 Cupric citrate	*	Milk-based, protein hydrolysate and meat-based formulae
8.4 Cupric sulphate	*	

9. Source of Iodine (I)

9.1 Potassium iodide	FCC	Milk-based, milk substitute, meat-based formulae
9.2 Sodium iodide	FCC	Milk-based, milk substitute and protein hydrolysate formulae

* See para. 80 b-d.

Salts	Purity Requirements	Use in Foods for Infants and Children
10. Source of Zinc (Zn)		
10.1 Zinc acetate	*	
10.2 Zinc chloride	*	
10.3 Zinc oxide	*	Protein hydrolysate formulae
10.4 Zinc sulphate	FCC	Milk-based, milk substitute and protein hydrolysate formulae
11. Source of Manganese (Mn)		
11.1 Manganese carbonate	*	
11.2 Manganese chloride	FCC	Milk-based formulae
11.3 Manganese citrate	*	
11.4 Manganese sulphate	FCC	Milk-based, milk substitute and protein hydrolysate formulae

Abbreviations

FAO/WHO = Guide to the Safe Use of Food Additives (CAC/FAL 5-1979)
FCC = Food Chemicals Codex, 2nd Ed., 1972.

* See para. 80 b-d.

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 below:

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

1/ Used in animal feeding studies.

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

PAG - GUIDELINE ON PROTEIN-RICH MIXTURES FOR USE AS SUPPLEMENTARY FOODS

(PAG - Guideline No. 8 - published 1972)

INTRODUCTION

The serious and widespread problem of malnutrition during the weaning period in tropical and subtropical countries and the inability of lower income groups to purchase sufficient animal protein foods or high-cost special children's foods calls for marketing of nutritious, low-cost mixtures based mainly on vegetable proteins mixed with other proteins where appropriate. In addition to low cost, satisfactory tolerance and acceptability on the part of the child and acceptability to the adult(s) responsible for providing the child's food are important factors. Of paramount importance, however, if the primary purpose is to be achieved, is the maintenance of minimal nutritional and sanitary standards, even though this may mean constraints in relation to cost.

Ideally, the protein food mixture should be a supplement which is patterned in accordance with the child's diet in the home and which fills the gaps with respect to calories, proteins and other nutrients. In order to be certain that the minimal needs are covered even under unfavorable dietary conditions, the supplementary food mixture should provide protein, vitamins and minerals corresponding to recommended allowances when consumed at the recommended level. The recommended daily intake of the supplement is usually of the order of 100g dry weight. These products should not be recommended for infants below six months of age unless they are specifically treated to ensure complete digestibility.

1. LEVEL OF PROTEIN

The provision of adequate protein generally presents a difficult problem during the weaning period and special attention should be given to the quality and quantity of protein in supplementary weaning foods. With protein of nutritional quality equivalent to cow's milk (NPU = 80); the level of protein in the supplementary food should be at least 15% w/w. If the quality of protein is lower, i.e. NPU less than 80, the quantity of protein should be increased as follows:

NPU	% Weight/Weight
80	15.0
75	16.0
70	17.1
65	18.5
60	20.0

In any case the NPU value of the protein should not be less than 60 and preferably nearer 65 and correspondingly the PER not less than 2.1 and preferably above 2.3 (casein = 2.5; the value for casein varies with different casein products and the strain of the rat used for testing.

2. CALORIES

The mixture should provide as many calories as possible and this may be achieved by adding fat. Poorly-digestible carbohydrate, including fiber, should be held to a practical minimum. The starchy portion of mixtures may be modified through various combinations of heat and mechanical processing or enzyme treatment, so that when prepared with water and ready for feeding, the food has minimal bulk and maximal protein availability and maximum calorie density.

3. FAT

Present knowledge does not permit specifying with certainty a dietary allowance of fat. Even so, it will be of great advantage to incorporate into protein-rich food mixtures as much fat as is technologically feasible without compromising the keeping qualities of the food. The fat will increase the calorie density of the mixture. A level of fat contributing 25% of calories to the mixture would be desirable. The linoleic acid content should be at least 1%. Without any addition of extra fat, the protein food may contain nearly 2 to 3% fat derived from the basic ingredients used in the formula. If the cost, including the need for special packaging to ensure adequate shelf-life, is found prohibitive, the addition of food fat or oil when the mixture is prepared for consumption is recommended as a possible approach.

4. VITAMINS AND MINERALS

Protein-rich mixtures should be fortified with vitamins and minerals sufficient to satisfy recommended allowances. Special attention should be given to vitamin A, riboflavin, niacin, folate, vitamin B_{12}, ascorbic acid, vitamin D, calcium, iron and iodine. Minimal quantities of various vitamins and minerals as proposed in Section 6 are recommended. However, some adjustment in the light of local nutritional problems may be considered. There may be no need to provide additional vitamins or minerals as medication to the child if the high-protein mixture is fed at recommended levels.

5. PHYSICAL CHARACTERISTICS, FLAVOUR AND TASTE

Acceptability of formulated foods can be enhanced by modern industrial processing such as precooking and roller drying, extrusion cooking and enzyme treatment. The food mixture should be formulated and processed so that by the addition of minimal amounts of freshly boiled water or by boiling after adding water it is easily and quickly prepared as a gruel or porridge of the proper consistency for feeding.

Consideration should be given to the processing of starchy components with amylases or by extrusion cooking which will (a) reduce the cooking time in the home and (b) reduce the viscosity and water retention capacity ("bulkiness") of the mixture, thus allowing the feeding of a more concentrated preparation. The addition of sugar to protein-rich food mixtures is permissible provided the cost is not unduly increased, since such an additive enhances acceptability. In general, however, the sweetening of the products should be carried out in the home. There is no evidence that sucrose intolerance is a problem of importance.

There is no need to add ordinary salt to formulated supplentary foods.

6. GUIDELINES FOR COMPOSITION EXPRESSED ON DRY WEIGHT BASIS

	Units per 100 calories*	Units per 100 grams
Protein	5.4 g	Not less than 20 g**
Fat	-	As much as feasible, up to 10 g
Crude fiber	-	Not more than 5 g***
Moisture	-	Preferably 5-10 g
Total ash	-	Not more than 5 g
Acid-insoluble ash		Not more than 0.05 g

* Calculated on the basis of 370 calories per 100 grammes.

** This protein level assumes an NPU not less than 60 and a PER not less than 2.1. If these values are higher, the level of protein may be reduced accordingly (see Section 1).

*** Crude fiber higher than this may be acceptable although it would require clinical testing.

APPENDIX V

	Units per 100 calories *	Units per 100 grams
Vitamin A, retinol equivalent	108 mcg	400 mcg**
Thiamine	80 mcg	0.3 mg
Riboflavin	108 mcg	0.4 mg
Niacin	1330 mcg	5.0 mg
Folate	54 mcg	0.2 mg
Vitamin B_{12}	0.54 mcg	2.0 mcg
Ascorbic acid	5400 mcg	20 mg
Vitamin D	108 IU	400 IU
Calcium	80 mg	300 mg (as phosphate or carbonate)
Iron	2.7 mg	10 mg (as food-grade compound of adequate iron availability)
Iodine	28 mcg	100 mcg (as iodate or iodide)

NOTE: Under certain local conditions, the addition of vitamin B_6 (to approximately the level of thiamine) and of alphatocopherol should be considered.

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.

7. FOOD ADDITIVES

The use of excessive amounts of flavouring agents should be avoided. If any food additives are used, they should be those which have been cleared by the Joint FAO/WHO Expert Committee on Food Additives. The amounts used should not exceed the minimum necessary to produce the desired effect. Necessary information must be given on the label on the nature and quantities of food additives used in the product.

8. STANDARDS AND PURITY

8.1 The ingredients in the formula should meet national and/or international standards with regard to purity. The Protein Advisory Group has prescribed quality guidelines for some common ingredients.

8.2 Legumes and oilseeds may frequently contain tryptic inhibitors and other undesirable factors which must be reduced by processing before use in high-protein foods. Since all toxic factors may not be eliminated by processing, it is essential that only grain legumes which are nutritionally wholesome and toxicologically safe be used.

8.3 The preparation of a protein concentrate from oilseeds may require solvent extraction. Adequate procedures requiring food-grade solvents are described in the Joint FAO/WHO Expert Committee Report No. 14. It is necessary to eliminate the dangers of toxicity from solvents by using food-grade products.

8.4 Cereals, oilseeds and other source materials to be used in the basic mixture may be contaminated with toxic molds. The Protein Advisory Group has reviewed this problem and issued a statement (PAG Statement No. 2) on the subject.

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* Calculated on the basis of 370 calories per 100 grammes.

** 1300 International Units as vitamin A palmitate.

9. MICROBIOLOGICAL AND SANITARY STANDARDS

Guidelines for microbiological and sanitary requirements are available as PAG Guideline No. 11.

10. PACKAGING

Packages and the containers in which they are shipped should provide protection from the inroads of insects, microorganisms, moisture and contaminants. If foods are dispensed from bulk containers, proper sanitary procedures should be observed. Simple but effective information with respect to the correct use of the product should be on the package.

11. SHELF-LIFE

The packaged product should remain acceptable for food use in terms of retention of palatability, nutritional availability and freedom from toxic or other deleterious changes for a period of six months under tropical conditions.