codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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REPORT OF THE ELEVENTH SESSION OF THE CODEX COMMITTEE ON FOODS FOR SPECIAL DIETARY USES

Bonn-Bad Godesberg, 23-27 October 1978

INTRODUCTION

1. The Codex Committee on Foods for Special Dietary Uses held its Eleventh Session in Bonn-Bad Godesberg from 23 to 27 October 1978 by courtesy of the Government of the Federal Republic of Germany and under the Chairmanship of Dr. H. Drews. Professor Dr. D. Eckert, Vice-President of the Codex Alimentarius Commission opened the Session on behalf of the Federal Minister of Health and emphasized the increasing influence of the Codex work on national policies and the growing interest of developing countries which examine closely the results of the Commission's work in relation to international trade.

The Committee observed a minute's silence in memory of Mr. H.U. Pfister of the delegation of Switzerland. Professor Dr. Eckert welcomed in particular the delegation of Nicaragua which was participating for the first time.

2. The Session was attended by representatives from the following 20 countries:

Australia	Netherlands
Austria	New Zealand
Belgium	Nicaragua
Czechoslovakia	Norway
Finland	Sweden
France	Switzerland
Germany, Fed.Rep. of	Thailand
Hungary	United Kingdom
Ireland	United States of America
Japan	Yugoslavia

Observers were present from the following international organizations:

- Association of Official Analytical Chemists (AOAC)
- European Economic Community (EEC)
- European Federation of Associations of Health Product Manufacturers (EHPM)
- International Association for Cereal Chemistry (ICC)
- International Federation of Glucose Industries (IFGI)
- International Organization of Consumers' Unions (IOCU)
- International Secretariat for the Industries of Dietetic Food Products (ISDI)
- International Union of Nutritional Sciences (IUNS)
- Institut Européen des Industries de la Pectine (IEIP)
- United Nations Children Fund (UNICEF)
- International Federation of Margarine Associations (IFMA)
- World Health Organization (WHO)
- Food and Agriculture Organization of the United Nations (FAO)

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

ADOPTION OF THE PROVISIONAL AGENDA

3. It was noted that during the Session of the Committee the Working Groups on Methods of Analysis and Sampling for Infant Foods and on Mineral Salts for Infant Foods would meet and report to the Committee. The Committee therefore agreed to the necessary re-arrangement of the Agenda.

APPOINTMENT OF RAPPORTEURS

4. Mr. A. Duran (France) and Dr. S.J. Darke (United Kingdom) agreed to serve as rapporteurs for the Session.

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

5. The Committee had before it document CX/FSDU 78/2 which contained information on the above matters. The Committee noted that the Commission had reviewed its programmes of work and its working procedures with the view to giving more attention to the needs of developing countries.

6. New Committees had been established for Cereals and Cereal Products and for Vegetable Proteins.

7. The Committee was informed that the Commission had adopted among others the Guidelines on Date Marking, the Standard for Fructose and Amendments concerning food additives to the standards for Foods for Infants and Children at Step 9.

8. The Committee noted that the Commission had requested the Codex Committee on Food Labelling to reconsider certain sections of the General Guidelines on Claims. It further noted that section 4.2 of these Guidelines contained a general prohibition of claims which relate to matters of health or medical conditions. After discussion the Committee agreed to make a recommendation to the Committee on Food Labelling that the last sentence of section 4.2 of the General Guidelines on Claims be deleted.

9. The Committee was informed that the Codex Committee on Food Hygiene had advanced the Code of Hygienic Practice on Foods for Infants and Children to Step 8. The Chairman expressed the view that when the Code had been finalized, the Committee would have to consider whether any of its provision and in particular the microbiological specifications should be made mandatory in the standards for foods for infants and children. The Committee decided to request government comments on the matter and instructed the Secretariat to append the Code to this Report (See Appendix VII).

10. The Committee also noted that the Codex Committee on Food Additives had recommended that the application or otherwise of the "Carry-over Principle" should be mentioned explicitly in all standards, and had proposed a form of words to this effect to be adopted by the Commission at its next session.

11. The attention of the Committee was drawn to a report by a Joint FAO/WHO Expert Committee on Fats and Oils in Human Nutrition (FAO/WHO, Food and Nutrition Paper No. 3, 1978) on a number of matters which would be of interest in relation to foods for special dietary purposes, for example, infant formula.

12. The Committee was further informed on the current position concerning governmental acceptances of the standards for foods for infants and children.

13. The Chairman drew attention to the discussion of the Codex Committee on Food Labelling on the elaboration of guidelines for the control of advertizing and promotional literature concerning infant formula. A large number of delegations expressed themselves in favour of preparing such guidelines not only for infant formula but for all foods for infants and children.

14. Reference was made to the Code of Ethics drawn up by the International Council of Infant Food Industries. However, it was generally felt that this Code was not fully satisfactory. The Code had also been criticized by the former Protein-Calorie Advisory Group (PAG). WHO also criticized the Code in one of its reports and advocated a ban on the advertizing of breast milk substitutes by radio and television.

15. The Representative of IOCU reminded the Committee that in 1972 IOCU had prepared a draft code for consideration by the Codex Committee on Food Labelling. The membership of IOCU had emphasized on a number of occasions the importance of the elaboration of such a code by the Codex Alimentarius Commission. The Representative of IOCU indicated the organization's willingness to assist in the preparation of a code.

16. The delegation of Sweden informed the Committee that in his country a Code of Ethics had been established for the marketing of infant foods which might be of use when drafting an international code. He also drew attention to certain sections of a Draft Code on Ethics for the International Trade in Foodstuffs which had been prepared by an FAO Consultant for the Commission.

17. The Representative of FAO reported on arrangements which had been made by UNICEF in collaboration with other UN Agencies for the "International Year of the Child". It was considered in FAO, WHO and UNICEF that, as part of these activities, it would be highly desirable for a Code of Ethics concerning the marketing, advertising, etc. of infant foods to be elaborated within the Codex framework.

18. The Committee expressed general support for the development of a code of practice in view of its special importance in developing countries. The Committee agreed to consider what arrangements should be made for the preparation of a code under Item 11 of the Agenda "Other Business" (see para 99).

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

19. The Committee had before it document CX/FSDU 78/3 which contained a revised list of vitamin compounds for use in foods for infants and children drawn up by the delegation of Switzerland, and document CX/FSDU 78/4 containing a list of mineral salts for use in foods for infants and children which had been revised by the delegation of the United States.

List of Vitamin Compounds

20. It was pointed out that this list had been revised taking into account the comments made by the 10th Session of this Committee and additional government comments concerning the inclusion of other vitamin compounds. Several delegations made proposals for further amendments of the list.

List of Mineral Salts

21. The delegation of the United States explained to the Committee that this list had also been revised in the light of government comments and that any proposals for the inclusion of additional mineral salts should be made only in accordance with specific criteria. Suggestions as to these criteria had been made in the document. Compounds which did not fulfil or no longer fulfilled these requirements should be deleted from the list.

22. The delegation of the United States pointed out that not all salts could be used equally successfully in the different types of foods for infants and children and therefore an appropriate differentiation had been introduced in the list. Another section, which dealt with information concerning purity requirements, had also been included.

Status of the List of Vitamin Compounds and Mineral Salts

23. The Committee agreed that the lists should be advisory. It further discussed the concepts of open and closed lists and concluded that the lists were by their nature "closed", but that it would be possible for the Committee to add or delete compounds as and when there were new developments in the light of new knowledge. For this purpose it was agreed that appropriate criteria should be established and that amendments to the lists should only be made when these criteria were met.

24. The development of these criteria was assigned to the Working Group on Mineral Salts under the chairmanship of Dr. Robert Weik. The Working Group proposed to use the criteria contained in CX/FSDU 78/4 amended by one new provision concerning the deletion of substances and the Committee agreed to the following wording which would, when appropriately modified, also apply to vitamin compounds:

"i. Mineral salts may be added to the list only when:

(a) they are shown to provide technological and 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.

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."

25. The Committee decided to establish additional lists of vitamins and minerals respectively for which more information was needed (e.g. references on purity requirements) in the same way as this had been done in the case of food additives.

26. The Committee thanked the Working Group for its advice and agreed that the lists should be attached to the booklet containing the Standards for Foods for Infants and Children at Step 9. A reference to the lists as source of minerals and vitamins should be included in all standards for foods for infants and children. This would require editorial amendments to the Step 9 standards, and the Secretariat was instructed to arrange for these amendments to be submitted to the next session of the Commission.

27. The lists of vitamin compounds and mineral salts for use in foods for infants and children are contained in Appendix III to this Report.

WORKING GROUP ON METHODS OF ANALYSIS AND SAMPLING FOR FOODS FOR INFANTS AND CHILDREN

28. The above Working Group had continued its work on methods of analysis and sampling for foods for infants and children by correspondence between sessions, and also met during this session to prepare document CX/FSDU 78/5 - a progress report.

29. The Working Group had discussed several sampling plans and methods of analysis for the determination of crude and dietary fibre, vitamins D, E, K, iodine and linoleic acid on the basis of comments received from members of the Working Group. However, none of these methods had yet been finalized and several of them would have to be circulated again for comments.

30. The Chairman thanked Professor Krönert, the Chairman of the Working Group, for the valuable work of the Group.

31. The report of the Working Group is contained in Appendix VI to this Report.

CONSIDERATION OF THE PROPOSED DRAFT STANDARD FOR FOLLOW-UP FOODS FOR OLDER INFANTS AND CHILDREN AT STEP 4

32. The Committee considered the above standard (document CX/FSDU 78/6), which had been revised by the delegation of Switzerland, and government comments on the standard (Addenda 1 and 2 to CX/FSDU 78/6).

33. In introducing the document the delegation of Switzerland pointed out that the revision of the standard was based on comments made by this Committee at its 10th Session. In particular, the scope section and other relevant provisions had been amended to include as basic ingredients suitable protein sources other than milk. In view of the fact that the product was not the sole source of food for infants and children but was intended as part of a diversified diet the requirements for vitamins and minerals had been restricted to four vitamins, maximum levels for sodium and minimum levels for calcium and iron. Some of the thickening agents contained in the Standard for Infant Formula had been included. The Secretariat was requested to correct several printing errors in the document.

34. The delegation of Switzerland suggested some additional amendments to the Standard and the Committee agreed to discuss these under the relevant sections of the Standard.

35. Several delegations questioned the need for the elaboration of the standard. The view was expressed that cow's milk with certain vitamins added could be used for older infants and children and that there was a danger that such follow-up products might be selected instead of infant formula for the feeding of small infants because they were likely to be cheaper than infant formula. It was, however, pointed out by the delegation of France that the proportion of iron, calcium and protein contained in the products made them specifically suitable for older infants and children.

36. Several delegations stated that the product should be suitable for use as a supplement to weaning food especially in developing countries to provide energy, protein and those nutrients in which the staple foods were deficient. Attention was drawn to the PAG-Guidelines No. 8 concerning "Protein-rich mixtures for use as supplementary foods".

37. Emphasis was placed on the inclusion of other protein sources, e.g. vegetable proteins which could be available locally, and were well suited to meet the dietary needs of infants and children. Considerable discussion took place about an appropriate title for the standard and whether or not it was possible to elaborate a scope section to cover products from a wide range of raw materials.

38. The Committee agreed that a working group should redraft the scope section to indicate the range of products covered by the standard and to establish an age limit for their use. The Working Group was further requested to redraft Section 2 "Description" in the light of the discussion and to include the function of the product, its true nature and matters related to processing. It was further agreed that Section 4.1.1 should be transferred to the section on description whereas certain provisions contained in Section 2.1 dealing with directions for use should be included in the section on labelling. Professor J. Ray and Dr. R.H.C. Fleming reported on the revision of the proposed draft standard, and the Chairman expressed the Committee's appreciation for the work carried out by the Working Group.

39. The Committee agreed in principle with the revised Sections 1 and 2 as contained in Appendix IV to this Report and amended the title to read "Proposed Draft Standard for Follow-up or Supplementary Foods".

Essential Composition and Quality Factors

40. The Committee discussed extensively whether the provisions contained in Section 4.1.2 were applicable to products which were milk-based as well as to those which were derived from protein sources other than cow's milk. It was pointed out that cow's milk as raw material provided a great number of vitamins and minerals which would have to be added to products prepared with other raw materials, e.g. isolated soy proteins. It was therefore proposed to establish different specifications for different types of products and the Working Group was requested to revise the provisions in Section 4.1.2 accordingly.

41. The Committee agreed to a minimum level of 3 g protein per 100 available Calories for all products, and that a product which contained at least 3 g milk protein should be described as a milk based product.

42. It was further agreed that the product should contain fat at a level of not less than 3.3 grammes or more than 6 grammes per 100 available Calories, or not less than 0.8 grammes and not more than 1.5 grammes per 100 available kilojoules.

43. The provision on linoleic acid was revised to apply only to products containing vegetable fats. Several delegations were of the opinion that this restriction was not justified since also animal fats not containing linoleic acid could be used in the product and the Committee placed the provision in brackets with the view to request government comments on it.

44. In addition to the substances in Section 4.1.2 the Committee included several other substances in the list of essential nutrients. Some of these, however, would only need to be added to the non-milk based products. Doubt was expressed by several delegations as to whether it was necessary to establish specifications for the following nutrients: choline, vitamin K_1, biotin, potassium, chloride, phosphorus, magnesium, iodine and copper. In the case of zinc it was recommended that the minimum level should be reviewed. The provisions for the above nutrients were all placed in brackets to be considered in government comments.

Optional Ingredients

45. The Committee discussed Section 4.2.1 dealing with the addition of other nutrients than those mentioned under 4.1.2 and agreed that it should be left to national legislation to permit the use of these additional nutrients. It was pointed out that the Committee had already made a similar decision in the Standards for Canned Baby Foods and for Cereal-Based Foods for Infants and Children. The wording of 4.2.1 was amended accordingly.

46. Section 4.2.2 was amended to apply only to these additional nutrients.

47. Concerning Section 4.2.3 the Committee decided to establish a provision for optional ingredients. The purpose of the use of cocoa was discussed and it was agreed that more information was needed on the type of cocoa to be permitted in these products.

Consistency and Particle Size

48. The Committee agreed to delete reference to bottle feeding.

Food Additives

49. The Committee noted that the revised draft contained provisions for two thickening agents which had also been permitted in infant formula. The delegation of Switzerland proposed and the majority of the delegations agreed to include all thickening agents which were permitted in infant formula with the restrictions stated in that standard.

50. The delegation of the Federal Republic of Germany expressed the view that in the light of toxicological data available thickening agents and in particular carrageenan should not be permitted in foods for infants and children. The delegation of France was opposed to the inclusion of thickening agents in both the Standard for Infant Formula and the Standard for Follow-up or Supplementary Foods. The Committee decided to request specifically government comments on the section on thickening agents.

51. The Committee noted that the sections on contaminants, hygiene, packaging and fill of container corresponded to those in the Standard for Infant Formula. These sections were accepted unchanged.

Labelling

52. The Working Group had reviewed Section 10 on Labelling and revised it in the light of the changes made in Sections 1.2 and 4. The Committee agreed to the proposals of the Working Group, made a minor editorial amendment to Section 10.1.2 and placed the last sentence in brackets.

53. The Committee accepted the redrafted version of Section 10.9 - Information for Utilization - which had been proposed by the Working Group.

Status of the Standard

54. The Committee decided to return the above standard to Step 3 of the Procedure in view of the substantial changes which had been made to it. In order to better take into account the possible role of such products in developing countries in relation to products covered by other Codex standards for infants and children, the Committee was concerned to obtain the views of developing countries on the Standard and recommended that it should be considered by the Regional Coordinating Committees for Africa, Asia and Latin America. The Secretariat undertook to ensure that the standard would be on the agenda of the next session of these Committees. The Standard is contained in Appendix IV to this Report.

CONSIDERATION OF THE DRAFT STANDARD FOR "GLUTEN-FREE" FOODS AT STEP 7

55. The Committee had before it the above Standard (Appendix II to ALINORM 78/26) and government comments on the Standard contained in CX/FSDU 78/7 and Conference Room Document No. 2.

Definition of "gluten-free" and Method of Analysis for the Determination of Gluten

56. The Chairman recalled that at the last session considerable progress had been made in the elaboration of this standard. However, the Committee still had to agree on a figure for the maximum level of total protein content of gluten containing cereal grains and their derivatives in "gluten-free" foods.

57. He pointed out that this figure was linked to a suitable method of analysis and invited the delegation of the Netherlands to report on the progress made in developing such a method. The delegation of the Netherlands gave an overall view on the state of research concerning the relation of gluten to coeliac disease and said that improved methods were available for separating different protein fractions and differentiating between different types of cereals. He also reported on a method for the quantitative measurement of the antibodies against gliadin present in the serum of coeliac patients. The Elisa-Method of Engrall and Perlman had been adopted for this purpose. This opened up possibilities for easier diagnosis and better "in-vitro" characterization of the toxic substances in certain grains. However, no acceptable quantitative "in-vitro" method would be available in the near future, due to a great number of problems which would have still to be resolved.

58. In view of the above the delegation of Finland proposed a total residual protain for cereals in "gluten-free" foods of not more than 0.3% in the dry matter. This could be achieved technologically and was generally acceptable in his country for patients with coeliac disease. The proposal was supported by other delegations.

59. The delegate from the United Kingdom considered that a figure (0.8%) for residual protein would be appropriate for products made from wheat flour since such products had been used for many years in the United Kingdom without any evidence of harm.

60. Several delegations expressed themselves in favour of a very low residual protein content because it was not yet known whether the toxic factor was still present in this residue or not.

61. It was suggested that each delegation should obtain information about manufacturing practice and analysis of residual protein in their own country before the next meeting.

62. There was also a suggestion that a smaller residual protein could be achieved by permitting the use of wheat starch only in conjunction with other cereal starches which have a naturally lower gluten content.

63. The Committee agreed to a figure of 0.3% for the total protein content in section 2.2.2 and to the proposal that total residual protein would be better expressed as nitrogen (g%) since the residual material was not gliadin but possibly consisted of other nitrogen compounds which might be tolerated by patients with coeliac disease. The delegate of Australia asked that residual nitrogen be expressed on a dry-weight-basis.

64. The Committee decided to amend section 2.2.2 to read as follows:

> "2.2.2 For the purpose of this standard, "gluten-free" means that the total nitrogen content of the gluten containing cereal grains used in the product does not exceed 0.05 g per 100 grammes of these grains on a dry weight basis."

Labelling

65. The attention of the Committee was drawn to the fact that the present wording of the preamble of the Section on labelling did not provide for the mandatory labelling provisions contained in Section 3 of the General Standard for the Labelling of Prepackaged Foods. In view of Section 1.2 which stipulated that the standard referred only to the specific provisions related to the special dietary purpose for which gluten-free foods are intended, the Committee decided to amend the preamble along the lines of that contained in the standard for low sodium foods as follows:

> "In addition to the general labelling provisions contained in the General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969) and any specific labelling provisions set out in a Codex standard applying to the particular food concerned, the following provisions for the labelling of "gluten-free" foods shall apply".

66. The Committee considered that a declaration of the nature and source of the starch or starches on the label would provide useful information to coeliac patients and decided to add a relevant provision to Section 4.2, List of Ingredients (new provision 4.2.2) as follows:

> "The nature and source of the starch or starches shall be declared on the label. In the case of starch prepared from gluten-containing cereal grains the declaration of this starch shall be accompanied by a statement "containing not more than 0.3% protein in the dry matter".

67. A proposal was made to indicate the proportion of individual starches in the product, however, it was decided not to make any further change to section 4.2.2.

68. Section 4.3.2 concerning the declaration of nutritional value was amended editorially to make reference to Section 3.2 dealing with the vitamin and mineral content of "gluten-free" foods.

Claims

69. The Committee agreed not to revise the Section on Claims until the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses had been finalized.

Status of the Standard

70. The Committee decided to advance the Draft Standard for "Gluten-free" Foods to Step 8 of the Codex Procedure. The delegation of the United Kingdom expressed its opposition to advancing the draft standard to Step 8 because in its opinion the proposed limit of residual protein was too low and more information about manufacturing processes and analysis of residual protein was required before the limit could be fixed. The standard is contained in Appendix II to this Report.

PROPOSED DRAFT GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES AT STEP 4

71. The Committee had before it document CX/FSDU 78/9 which contained a redrafted standard prepared by the delegation of the United Kingdom and the Codex Secretariat, and government comments (CX/FSDU 78/9, Add.I and Conference Room Documents No. 2 and 3). The Committee noted that a number of provisions of the standard were identical to those in the General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969) dealing with the normal food.

72. The Committee decided to confine its discussions to those aspects of the text which were specifically concerned with foods for special dietary uses. The question of how to include the relevant provisions of the General Labelling Standard and other commodity standards was left to the Secretariat.

Title of the Standard

73. The Committee considered whether the title of the standard should include a reference to claims. It was agreed that the purpose of the standard was to include provisions for labelling and for claims as described in the scope section. It was further pointed out that the provisions concerning claims related to both labelling and advertizing. The Committee therefore agreed to leave the title unchanged.

Definition of Terms

74. Considering the definition of terms in Section 2 of the standard the Committee made the following amendments.

Section 2.1: It was agreed that the definition should make it clear that foods complying with this definition should be called foods for special dietary uses only when they were presented as such. The provision was amended accordingly. The Committee considered whether a specific reference to foods for infants and children was necessary and concluded that this was not the case as these products were already covered by the present text.

Section 2.4: The Committee agreed to revise the text of this provision as follows: "Advertizing includes any statement, visual or oral, related to the food, including those appearing in promotional literature, except that mentioned under Sections 2.2 and 2.3". Reference to different provision applying to literature provided solely to qualified persons was deleted as it was felt that this type of literature also constituted a form of advertizing.

Section 2.5: It was agreed to make specific reference in this section to advertizing as well as to other representations.

Definition of "medical foods"

75. The delegation of the United States drew the attention of the Committee to another category of foods which were prepared to take care of the nutritional requirements of persons under very special circumstances, e.g. under stress in pre- and post-operational period. The U.S.A. suggested that a definition for these "medical foods" should be included in the Standard to avoid confusion with food for special dietary uses as defined in Section 2.1. The proposed wording by the U.S.A. for the new paragraph reads as follows:

"Medical Foods are foods that are specially formulated or prepared products consumed or administered enterally under direct or indirect medical supervision in the dietary management of individuals with specific diseases, disorders, or medical conditions in which the existence of associated special nutritional requirements is established by medical evaluation".

76. The delegations of the Netherlands and of Switzerland stated that they were opposed to the proposal made by the United States.

77. The Committee agreed to request government comments on the proposal made by the delegation of the United States. However, the text was not yet included in the revised version of the standard.

General Principles

78. Section 3.3: The Committee thought that the reference to a physician was too restrictive and substituted the term by "qualified person".

79. The delegation of the United States suggested the addition of two new paragraphs to Section 3 to avoid false and misleading claims 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 foods represented for use solely under medical supervision in the dietary management of specific diseases or disorders (Medical Foods)."

"3.5 Nothing in the labelling and advertizing of the foods to which this standard applies shall imply that the food has dietary properties when such properties are of no significant value in human nutrition, e.g. rutin and other bioflavonoids, para-amino benzoic acid, have been represented as having nutritional properties but have not been shown to be essential in human nutrition."

80. The Committee thought that Section 6.1.1, which recommended that claims should be made in accordance with the General Guidelines on Claims would suffice to protect the consumer against misleading or false claims.

81. It was decided to request government comments on the above proposal but not to include the above new paragraphs in the Standard.

Nutritional Labelling

82. The view was expressed that the declaration of nutritional information should be made for 100 grammes or 100 ml of the food as sold, and where appropriate also per specified quantity of the food suggested for consumption. This would provide more useful information to the consumer. The Committee concurred with this view and amended sections 4.3.1(a) and (b) accordingly.

83. The delegation of Australia proposed that the phrase "food as sold" should read "food as consumed". The delegation of the Federal Republic of Germany was of the opinion that the amount of energy should be expressed in available kilocalories and kilojoules. The Committee did not change the provisions on either of these matters.

84. Considerable discussion took place on section 4.3.2 dealing with foods of a very low energy value. Several delegations thought that no separate provision should be established for these foods. Other delegations pointed out that the declaration of nutritional information under 4.3.1(b) was meaningless since the quantities of protein, carbohydrate and fat contained in foods with an energy value of less than 12 kcal per 100 grammes were negligible.

85. The opinion was expressed that the declaration of the energy value could be made by using the phrase "under 12 kcal". Several delegations stated that in their countries the energy value of foods with a very low energy value was declared in steps of 5 or 10 kcal. The Committee concluded that no decision could be reached at present and that governments should be required to comment specifically on 4.3.2. The provision was therefore placed in brackets.

Date Marking

86. Several delegations pointed out that section 4.8.2 as drafted appeared not so clear as it could mean that the requirements for date marking for products with a long shelf life were more restrictive than those for less stable products. The Secretariat was requested to redraft the section and to request specific government comments on it.

Storage Instructions and Directions for Use

87. The Committee agreed that storage instructions were useful for both unopened and opened foods. However, concern was expressed about the present text which implied that the storage instructions alone would ensure that the product would conform with the standard at the time that it is opened for use.

88. It was pointed out that the Committee on Food Labelling had discussed the matter extensively and had decided that the storage instructions could not guarantee the quality of the product. However, these instructions were of importance for the keeping qualities of the food if they were exactly followed. The Committee agreed to amend sections 4.9.1 and 4.9.2 accordingly.

Claims

Section 6.1.3

89. The Committee agreed that this provision should apply to foods which by their nature possessed essential characteristics on which the consumer would wish to receive information and deleted the brackets from the word "naturally".

Section 6.1.4

90. It was noted that the above provision consisted of two parts which could be construed to have contradicting meanings. The Committee agreed fully with the wording of the first sentence. The provision prohibited claims as to the suitability of a special dietary food for use in the prevention, alleviation, treatment or cure of a disease, disorder or physiological condition.

91. Several delegations were of the opinion that a provision should be included in this section which would correspond to the second sentence of 4.2 of the General Guidelines on Claims. To do so would permit exemption from the above prohibition for certain foods including certain dietary foods. The Committee was informed that the Commission had referred the Guidelines back to the Codex Committee on Food Labelling so that this matter could be reconsidered.

92. Other delegations expressed the view that the second sentence of 6.1.4 should be deleted as they considered that such a provision could be misused and could detract from the prohibition of certain claims in the first sentence.

93. The Committee therefore agreed to place the last sentence of 6.1.4 within brackets and to request government comments on this matter.

Status of the Standard

94. The majority of delegations agreed to advance the standard to Step 5 of the Procedure. The revised text of the standard will be issued separately prior to the next session of the Codex Alimentarius Commission.

GUIDELINES ON TERMINOLOGY FOR THE ELABORATION OF A STANDARD FOR FOODS OF LOW ENERGY (CALORIE) CONTENT

95. The Committee at its previous session had accepted an offer of the delegation of the U.S.A. to prepare a paper which would "provide guidelines for terminology of use in the elaboration of any standard for foods to control energy intake" (ALINORM 78/26, page 11). The Committee had before it document CX/FSDU 78/8, tabled by the U.S.A., entitled "Proposed Draft Standard for Labelling of Low Calorie and Reduced Calorie Foods".

96. When introducing the paper the delegation of the U.S.A. informed the Committee that it was based on new regulations published in their country in September 1978 concerning this category of foods. A number of questions and points of clarification were raised by members of the Committee, and because of the need for further discussion and explanation it was agreed to append the document to the report of the session and to invite government comments before the next meeting. The document is contained in Appendix V to this Report.

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

97. The Chairman outlined the principal matters considered by the ad hoc Working Group and drew the Committee's attention to the recommendations contained in paras 15 and 16 of the report (Document CX/FSDU 78/10). Whilst there had been a general consensus that no standard for foods for use in a diet for diabetics should be elaborated, the Working Party had suggested that guidelines for these foods might be elaborated. The Working Group had further recommended that there was no need to develop a standard for carbohydrate-reduced foods.

98. The Committee expressed its appreciation for the document prepared by the Working Group and agreed with the recommendations of the Working Party and accepted an offer of the delegation of Australia to prepare a first draft of suitable guidelines. This would be circulated to members of the Working Group prior to the next session of the Committee.

OTHER BUSINESS

CODE OF ETHICS CONCERNING THE MARKETING AND ADVERTIZING OF INFANT FOODS

99. A suggestion that a code of ethics should be prepared was made in the opening session of the meeting, and the Committee returned to this subject under "Other Business". After receiving information concerning the new arrangements for nutrition within the U.N. System - namely that the Protein Advisory Group had been replaced by the ACC Sub-Committee on Nutrition and its Advisory Group on Nutrition - the Committee recommended that a first draft for a Code of Ethics be prepared by these bodies. The draft would then be considered by the Committee at the next session.

FUTURE WORK

100. The delegation of Australia proposed that the Committee should consider the elaboration of standards for low-lactose products. The delegation of the U.S.A. also proposed that the Committee should develop general principles concerning the fortification of foods. In view to the Committee's current heavy work-load it was agreed to place these items on the Committee's list of future work in the knowledge that it was unlikely that these proposals could be considered at the next meeting.

DATE AND PLACE OF THE NEXT SESSION

101. The Chairman informed the Committee that the Federal Republic of Germany would be pleased to host the next session at the Stadhalle, Bad Godesberg in the autumn of 1980.

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	9	Governments	CAC/RS 72-1976
Standard for Canned Baby Foods	9	Governments	CAC/RS 73-1976
Standard for Processed Cereal-based Foods for Infants and Children	9	Governments	CAC/RS 74-1976
List of Vitamin Compounds	-	13th CAC	ALINORM 79/26 paras 19-27 Appendix III
List of Mineral Salts	-	13th CAC	
Draft Standard for Gluten-free Foods	8	13th CAC	ALINORM 79/26, Appendix II
Proposed Draft General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses	5	13th CAC	CX/FSDU 80/... 1/
Proposed Draft Standard for Follow-up or Supplementary Foods	3	12th FSDU Coordinating Cttees for Asia, Africa & Latin America	ALINORM 79/26, Appendix IV & CX/ASIA 79/2-Add.1
First Draft of a Proposed Draft Standard for Low Calorie and Reduced Calorie Foods	2	12th FSDU	ALINORM 79/26, Appendix V
Code of Hygienic Practice for Foods for Infants and Children	8	13th CAC 12th FSDU see para 9	ALINORM 79/26, Appendix VII & ALINORM 79/13, Appendix V
Microbiological Specifications for Foods for Infants and Children including Sampling Plan	8		
First Draft of Proposed Draft Guidelines for Foods for Use in a Diet for Diabetics (prepared by Australia)	-	12th FSDU see paras 97-98	CX/FSDU 80/... 1/
Code of Ethics on the Marketing and Advertizing of Infant Foods (to be prepared by ACC/Sub-Committee on Nutrition and its Advisory Group on Nutrition)	-	12th FSDU see paras 13-18; 100	CX/FSDU 80/... 1/
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 STANDARD FOR "GLUTEN-FREE FOODS"

(Advanced to Step 8)

1. SCOPE

1.1 This standard applies to those processed foods which have been specially prepared to meet the dietary needs of persons intolerant to gluten.

1.2 The standard refers only to the specific provisions related to the special dietary purpose for which these foods are intended.

1.3 This standard does not apply to foods which in their normal form do not contain gluten.

2. DESCRIPTION

2.1 Definition

"Gluten-free food" is a food so described:

(a) consisting of or containing as ingredients such cereals as wheat, triticale, rye, barley or oats or their constituents, which have been rendered "gluten-free", or

(b) in which any ingredients normally present containing "gluten" have been substituted by other ingredients not containing "gluten".

2.2 Subsidiary Definitions

2.2.1 For the purpose of this standard, "gluten" is defined as those proteins, commonly found in wheat, triticale, rye, barley or oats to which some persons are intolerant.

2.2.2 For the purpose of this standard, "gluten-free" means that the total nitrogen content of the gluten-containing cereal grains used in the product does not exceed 0.05 g per 100 grammes of these grains on a dry matter basis.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 A "gluten-free" food shall be based on or shall contain:

(a) gluten-containing cereals such as wheat, triticale, rye, barley or oats or their constituents, which have been rendered "gluten-free" according to section 2.2.2; or

(b) ingredients which do not contain gluten in substitution for the ingredients containing gluten which are normally used in a food of that kind; or

(c) any mixture of two or more ingredients as in (a) and (b).

3.2 Gluten-free foods, substituting important basic foods like flour or bread, must supply approximately the same amount of vitamins and minerals as the original foods they replace in accordance with the national legislation of the country in which the food is sold.

4. LABELLING

In addition to the general labelling provisions contained in the General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969) and any specific labelling provisions set out in a Codex standard applying to the particular food concerned, the following provisions for the labelling of "gluten-free" foods shall apply:

4.1 The Name of the Food

The term "gluten-free" shall be given in the immediate proximity to the name of the product.

4.2 List of Ingredients

4.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and added minerals, these shall be arranged as separate groups of vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

4.2.2 The nature and source of the starch or starches shall be declared on the label. In the case of starch prepared from gluten-containing cereal grains the declaration of this starch shall be accompanied by a statement "containing not more than 0.3% protein in the dry matter".

4.3 Declaration of Nutritive Value

The label shall include the following nutritional information:

4.3.1 The amount of energy, expressed in Calories (Kcal) or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes of the food and where appropriate per specified quantity (e.g. one biscuit) of the food as suggested for consumption.

4.3.2 In addition to any other nutritional information required by national legislation, the total quantity in the final product of those vitamins and minerals which have been added in accordance with Section 3.2 shall be declared per 100 g as well as according to the serving size of the food suggested for consumption.

4.4 Date Marking and Storage Instructions

The date of minimum durability of the food shall be declared in clear.
Storage instructions shall appear on the label or on the accompanying leaflet.

5. CLAIMS

5.1 A food prepared according to Section 3.1 may be called a "gluten-free" food.

5.2 A food which naturally has no gluten may not be called "gluten-free"; however, a cereal or a food product containing a cereal which naturally has no gluten, may be labelled to show that it is naturally free of gluten and is suitable for use in gluten-free diet.

6. PACKAGING

6.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food.

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

7. METHODS OF ANALYSIS AND SAMPLING

7.1 Determination of Nitrogen Content (to be developed)

REPORT OF THE WORKING GROUP ON MINERAL SALTS

1. The Working Group was requested to consider the list of both mineral salts and vitamin compounds for use in infant foods. The Group included representatives from Australia, Federal Republic of Germany, France, Netherlands, Switzerland, United States and United Kingdom. Dr. Robert Weik of the delegation of the United States acted as Chairman.

2. The Working Group noted that the Committee had concluded that both lists would be "closed" with the possibility of amending by either adding to the lists or deleting from the lists.

3. The Working Group considered criteria necessary to amend the lists of mineral salts and vitamin compounds and agreed with the criteria as stated in paragraph 33 of ALINORM 78/26 as amended in CX/FSDU 78/4. It was decided that a further paragraph should be added to provide for deleting substances from the lists. The criteria are as follows:

"i. Mineral salts may be added to the list only when:

(a) they are shown to provide technological and 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.

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."

4. The Working Group also agreed to use the above criteria, editorially amended to replace the term mineral salt by the term vitamin, as a basis for additions to or deletions from the list of vitamins.

5. The Working Group agreed to use the food additives concept in providing for two lists for each classification. List A would be the approved list and List B would be a listing of recommended mineral salts or vitamin compounds which did not yet meet the criteria for being added to the approved List A.

6. The Working Group considered the lists of vitamin compounds and mineral salts in CX/FSDU 78/3 and 78/4 together with requests from governments for additions and prepared two lists for each classification. The lists are contained in Annexes 1 to 4 to this Appendix.

7. The Working Group noted that the intent of the Committee had always been to refer to the final lists in some manner and concluded that the approved lists for mineral salts and vitamin compounds would be advisory and not form part of each standard for foods for infants and children. However, the approved list would have to be published together with the above standards as Part 3 of the booklet CAC/RS 72/74-1976.

8. The Working Group recommended that the Codex standards for foods for infants and children at Step 9 (CAC/RS 72/74-1976) should be amended editorially to make reference to the approved advisory lists for mineral salts and vitamin compounds for use in foods for infants and children. Furthermore reference to the above lists as appropriate should be made in any other standard for foods for infants and children which may be elaborated.

9. The following amendments have been proposed for the:

(a) Recommended International Standard for Infant Formula (CAC/RS 72-1976)

Introduce a new paragraph 4.3 as set out below and renumber existing paragraphs 4.3; 4.4 and 4.5:

"4.3 Mineral Salts and Vitamin Compounds

Minerals and vitamins added in accordance with paragraphs 4.1.2 (a, b, c, d) and 4.2.1 should be selected from the Advisory Lists for Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children as shown in Part 3.

The amount of Na and K derived from the added minerals and/or vitamins shall be within the limits for Na and K in Section 4.1.2."

(b) Recommended International Standard for Canned Baby Foods (CAC/RS 73-1976)

Add to paragraph 3.1.2, after existing text the following:

"Such additions should be selected from the Advisory Lists for Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children as shown in Part 3.

The amount of Na derived from the added minerals and/or vitamins shall be within the limits for Na in Section 3.1.3."

(c) Recommended International Standard for Processed Cereal-based Foods for Infants and Children (CAC/RS 74-1976)

Add to paragraph 4.2.2, after existing text the following:

"Such additions should be selected from the Advisory List for Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children as shown in Part 3".

The amount of Na derived from the added minerals and/or vitamins shall be within the limits for Na in Section 4.1.4 and 4.1.5 as appropriate."

(d) Add new Part 3 to the Recommended International Standards for Foods for Infants and Children (CAC/RS 72/74-1976) containing an:

(i) Advisory List of Mineral Salts for Use in Foods for Infants and Children;

(ii) Advisory List of Vitamin Compounds for Use in Foods for Infants and Children.

ANNEX 1 to
Appendix III

ADVISORY LIST OF MINERAL SALTS FOR USE IN FOODS FOR INFANTS AND CHILDREN 1/

(LIST A)

Source of/ Salts	Food Chemicals Codex	FAO/WHO (CAC/FAL 1-1973)	Use in Animal Feeding Studies	Use in Foods for Infants and Children
CALCIUM (Ca)				
Calcium carbonate	x	x	x	Milk substitute formulae; Infant cereals
Calcium chloride	x	x	x	Milk-based and milk substitute formulae
Calcium citrate	x	x	x	Milk-based, milk substitute, protein hydrolysate and meat-based formulae
Calcium gluconate	x	x	x	Protein hydrolysate formulae
Calcium glycerophosphate	x			
Calcium lactate	x	x	x	Electrolyte mixture supplement
Calcium phosphate, monobasic	x	x	x	Milk substitute and low sodium formulae
Calcium phosphate, dibasic	x		x	Milk substitute and protein hydrolysate formulae
Calcium phosphate, tribasic	x	x	x	Milk substitute, protein hydrolysate and premature formulae; infant cereals
Calcium oxide	x	x		Protein supplement formulae
Calcium sulphate	x	x		Infant cereals
PHOSPHORUS (P)				
Calcium phosphate, monobasic	x	x	x	Milk substitute and low sodium formulae
Calcium phosphate, dibasic	x		x	Milk substitute and protein hydrolysate formulae
Calcium phosphate, tribasic	x	x	x	Milk substitute, protein hydrolysate and premature formulae; infant cereals
Magnesium phosphate, dibasic	x			Milk substitute and lactose-free formulae
Magnesium phosphate, tribasic	x	x		
Potassium phosphate, monobasic	x	x	x	Protein hydrolysate formulae
Potassium phosphate, dibasic	x	x	x	Milk-based, milk substitute and protein hydrolysate formulae
Sodium phosphate, dibasic	x	x	x	Electrolyte mixture supplement

1/ See paragraphs 5 and 7 of Appendix III.

Source of/ Salts	Food Chemicals Codex	FAO/WHO (CAC/FAL 1-1973)	Use in Animal Feeding Studies	Use in Foods for Infants and Children
MAGNESIUM (Mg)				
Magnesium carbonate	x	x	x	Baked products
Magnesium chloride	x	x	x	Milk-based, milk substitute and lactose-free formulae
Magnesium oxide	x	x	x	Milk substitute, protein hydrolysate and premature formulae
Magnesium phosphate, dibasic	x		x	Milk substitute, lactose-free formulae
Magnesium phosphate, tribasic	x	x		
Magnesium sulphate	x		x	Electrolyte mixture supplement
SODIUM (Na)				
Sodium bicarbonate	x	x	x	Milk-based formulae, gazed products
Sodium carbonate	x	x		Protein hydrolysate formulae
Sodium chloride	x	x	x	Milk substitute formulae, baby foods, electrolyte mixture supplement
Sodium chloride, iodized	x		x	Milk substitute formulae
Sodium citrate	x	x		Milk-based, milk substitute and protein hydrolysate formulae, electrolyte mixture supplement
Sodium gluconate	x			
Sodium lactate		x		
Sodium phosphate, monobasic	x	x	x	Milk substitute formulae
Sodium phosphate, dibasic	x	x	x	Electrolyte mixture supplement
Sodium phosphate, tribasic	x	x		
Sodium sulphate	x			
Sodium tartrate	x	x		
POTASSIUM (K)				
Potassium bicarbonate	x	x	x	
Potassium carbonate	x	x		
Potassium chloride	x	x	x	
Potassium citrate	x	x	x	
Potassium glycerophosphate	x			
Potassium phosphate, monobasic	x	x	x	Protein hydrolysate formulae
Potassium phosphate, dibasic	x	x	x	Milk-based, milk substitute and protein hydrolysate formulae

Source of/ Salts	Food Chemicals Codex	FAO/WHO (CAC/FAL 1-1973)	Use in Animal Feeding Studies	Use in Foods for Infants and Children
CHLORIDE (Cl)				
Calcium chloride	x	x	x	Milk-based, milk substitute and protein supplement formulae; electrolyte mixture supplement
Choline chloride	x	x	x	Milk-based, milk substitute and protein hydrolysate formulae
Magnesium chloride	x	x		Milk-based, milk substitute and lactose-free formulae
Manganese chloride	x			Milk-based formulae
Potassium chloride	x	x	x	
Sodium chloride	x	x	x	Milk substitute formulae, baby foods and electrolyte mixture supplement
Sodium chloride, iodized	x		x	Milk substitute formulae
IRON (Fe)				
Ferrous fumarate	x			Vitamins, iron supplement
Ferrous gluconate	x	x	x	
Ferrous sulphate	x		x	Milk-based, milk substitute and protein hydrolysate formulae
Reduced iron:				
Hydrogen reduced iron	x			Infant cereals; protein supplement formulae
Electrolytic iron	x			Infant cereals
Carbonyl iron				
Ferric pyrophosphate 1/2/	x		x 3/	Milk-based formulae
COPPER (Cu)				
Copper gluconate	x			
IODINE (I)				
Potassium iodide	x		x	Milk-based, milk substitute, meat-based formulae
Sodium iodide	x		x	Milk-based, milk substitute and protein hydrolysate formulae
ZINC (Zn)				
Zinc sulphate	x		x	Milk-based, milk substitute and protein hydrolysate formulae
MANGANESE (Mn)				
Manganese chloride	x			Milk-based formulae
Manganese sulphate	x		x	Milk-based, milk substitute and protein hydrolysate formulae

1/ Not allowed in powdered formulae, cereal-based products or baby foods.
2/ Not allowed in foods not subject to heat and pressure treatment during manufacture.
3/ Milk- and soy-based liquid infant formulae.

ANNEX 2 to
Appendix III

ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR INFANTS AND CHILDREN 1/
(LIST 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= List of Additives evaluated for their Safety-in-use in Food (CAC/FAL 1-1973).
DAB = Deutsches Arzneibuch 7. Ausgabe 1968.
FCC = Food Chemicals Codex, 2nd ed. 1972.

1/ See paragraphs 5 and 7 of Appendix III.

ANNEX 3 to
Appendix III

LIST OF PROPOSED AMENDMENTS TO ADVISORY LIST OF MINERAL SALTS FOR USE IN FOODS FOR INFANTS AND CHILDREN 1/ (LIST B)

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

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.

(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.

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 carbonate, stabilized Ferrous citrate 2/ Ferrous glucuronate Ferrous glycerophosphate 3/ Ferrous lactate 2/ Ferrous saccharate Ferrous succinate Ferric citrate 2/4/ Ferric gluconate 2/4/ Ferric lactate 4/ Ferric ammonium citrate Ferric tartrate Sodium ferric pyrophosphate 2/ 4/ 5/	

1/ See paragraph 5 of Appendix III.
2/ Used in animal feeding studies: milk and soy-based liquid infant formulae.
3/ Used in animal feeding studies.
4/ Not allowed in powdered formulae, cereals or baby foods.
5/ Not allowed in foods.

Source of	Salts	Use in Foods for Infants and Children
Copper (Cu)	Cupric acetate Cupric carbonate Cupric citrate 1/ Cupric sulphate 1/	) Baked products, protein) supplement formulae Milk-based, milk substitute) Protein hydrolysate and) meat-based formulae
Iodine (I)	Calcium iodostearate Sodium iodine 1/	) Milk-based, milk substitute) protein hydrolysate formulae
Zinc (Zn)	Zinc acetate Zinc chloride 1/ Zinc lactate Zinc oxide 1/	Protein hydrolysate formulae
Manganese (Mn)	Manganese carbonate Manganese citrate 1/ Manganese lactate	
Sodium (Na)	Sodium glucuronate Sodium glycerophosphate Sodium malate	
Potassium (K)	Potassium gluconate Potassium glucuronate Potassium malate	
Chloride (Cl)	Zinc chloride 1/	

1/ Used in animal feeding studies.

ANNEX 4 to
Appendix III

LIST OF PROPOSED AMENDMENTS TO ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR INFANTS AND CHILDREN 1/ (LIST B)

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

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.

(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.

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:

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

Abbreviations

FAO/WHO = List of Additives evaluated for their Safety-in-use in Foods (CAC/FAL 1-1973).
FCC = Food Chemicals Codex, 2nd ed. 1972.
JSFA = Japanese Standards of Food Additives, 1974.
USP = United States Pharmacopoeia XIX.

1/ See paragraph 5 of Appendix III.

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APPENDIX IV

PROPOSED DRAFT STANDARD FOR FOLLOW-UP OR SUPPLEMENTARY FOODS
(Returned to Step 3)

1. SCOPE

1.1 This standard applies to foods intended for use as part of the weaning or follow-up diet of the infant from the age of 4 to 6 months, and of the child.

1.2 This standard does not include foods covered by the Standards for Infant Formula, for Processed Cereal-based Foods for Infants and Children, and for Canned Baby Foods.

2. DESCRIPTION

2.1 These foods are not intended to serve as the sole source of nourishment. They are intended to supply, as part of the infant's increasingly diversified diet, at least the minimum requirements of those nutrients which are most likely to be deficient in the diet of infants who may not be receiving infant formula or adequate amounts of breast milk and of children.

2.2 These foods are based on the milk of cows or other animals and/or other edible constituents of animal origin and/or plant origin, which have been proved to be suitable for infants from the age of 4 to 6 months, and children.

2.3 These foods are so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution.

3. DEFINITION

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

3.2 The term "child" means a person from the age of more than 12 months up to the age of three years.

3.3 The term "Calorie" means "kilocalorie" or "large calorie" (1 kilojoule is equivalent to 0.239 kilocalories).

4. ESSENTIAL COMPOSITION AND QUALITY FACTORS

4.1 Essential Composition

Follow-up or Supplementary Food shall contain, per 100 available Calories (100 kilojoules) of intake the following minimum and maximum levels of protein, fat, vitamins, and minerals in an available form [according to the legislation of the country in which they are sold].

(a) Protein

(i) Shall not be less than 3.0 g per 100 available Calories (or 0.7 g per 100 kilojoules) of protein of nutritional quality equivalent to that of casein or a greater quantity of other protein in proportion to its biological value. The quality expressed in PER (Protein Efficiency Ratio) of the protein shall not be less than 85% of that of casein. The total quantity of protein shall not be more than 5.5 g per 100 available Calories (or 1.3 g per 100 available kilojoules). The minimum value set for quality and the maximum for quantity of the protein may be modified by national authorities according to their own regulations and/or local conditions.

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

(iii) For the purpose of the present standard, only those foods containing a minimum of milk protein of 3 g per 100 available Calories (or 0.7 g per 100 kilojoules) are considered as foods "based on milk".

(b) Fats

(i) The product shall contain fat at a level of not less than 3.3 g or not more than 6 g per 100 available Calories (or not less than 0.8 g and not more than 1.5 g per 100 available kilojoules).

(ii) [Whenever the product contains vegetable fats, the level of linoleic acid (in the form of glycerides) shall not be less than 300 mg per 100 available Calories (or 70 mg per 100 available kilojoules).]

(c) Vitamins

	Amounts per 100 available Calories	
	Minimum	Maximum
Vitamin A	250 I.U. or 75 µg expressed as retinol	750 I.U. or 225 µg expressed as retinol
Vitamin D	40 I.U.	100 I.U.
Vitamin E (α tocopherol compounds)	0.7 I.U./g linoleic acid 1/ but in no case less than 0.7 I.U./100 available calories	not specified
Ascorbic acid (Vitamin C)	8 mg	not specified
Thiamine 2/ (Vitamin B_1)	40 µg	" "
Riboflavin 2/ (Vitamin B_2)	60 µg	" "
Nicotinamide 2/	250 µg	" "
Vitamin B_6 2/	45 µg 3/	" "
Folic acid 2/	4 µg	" "
Pantothenic acid 2/	300 µg	" "
Vitamin B_{12} 2/	0.15 µg	" "
[Vitamin K_1 2/	4 µg	" "]
[Biotin 2/ (Vitamin H)	1.5 µg	" "]
(d) [Choline 2/	7 mg	" "]
(e) Mineral Salts		
Sodium (Na)	20 mg	100 mg
[Potassium (K) 2/	80 mg	200 mg]
[Chloride (Cl) 2/	55 mg	150 mg]
Calcium (Ca) 4/	90 mg	200 mg
[Phosphorus (P) 2/	60 mg	not specified]
[Magnesium (Mg) 2/	6 mg	" "]
Iron (Fe)	1 mg	" "
[Iodine (I) 2/	5 µg	" "]
[Copper (Cu) 2/	60 µg	" "]
Zinc (Zn) 2/	[0.5 mg]	" "

1/ Or per g polyunsaturated fatty acids, expressed as linoleic acid.
2/ Specification only applicable to goods which are not "based on milk".
3/ Products with a higher protein content than 3 g protein/100 Calories should contain a minimum of 15 µg Vitamin B_6 per gramme of protein.
4/ The Ca:P ratio shall not be less than 1.1.

4.2 Optional Ingredients

4.2.1 In addition to the vitamins and minerals listed under 4.1(c), (d) and (e), other nutrients may be added in conformity with the legislation of the country in which the food is sold.

4.2.2 The usefulness of these other nutrients shall be scientifically shown.

4.2.3 In addition to the raw materials used to obtain the essential composition the following substances may be used:

[Cocoa: Only in products to be consumed after 9 months of age, and at the maximum level of 5% on a dry basis.]

4.3 Consistency and Particle Size

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

4.4 Purity Requirements

All ingredients shall be clean, of good quality, safe and suitable for ingestion by infants. They shall conform with their normal quality requirements, such as colour, flavour and odour.

4.5 Specific Prohibition

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

5. FOOD ADDITIVES (Subject to endorsement by the Codex Committee on Food Additives)

The following additives are permitted in the preparation of Follow-up Food:

		In 100 g of product ready-to-eat (unless otherwise indicated)
5.1	Thickening Agents	
5.1.1	Guar gum	0.1 g } in all types of the product
5.1.2	Locust bean gum	0.1 g }
5.1.3	Distarch phosphate	0.5 g singly or in combination in soy-based products only
5.1.4	Acetylated distarch phosphate	
5.1.5	Phosphated distarch phosphate	2.5 g singly or in combination in hydrolyzed protein and/or amino acid-based products only
5.1.6	Hydroxypropyl starch	
5.1.7	Carrageenan	0.03 g in milk - and soy-based products only 0.1 g in hydrolyzed protein and/or amino acid-based liquid products only
5.2	Emulsifiers	
	Lecithin	0.5 g
	Mono- and Diglycerides	0.4 g
5.3	pH-Adjusting Agents	
	Sodium hydrogen carbonate Sodium carbonate Sodium citrate Potassium hydrogen carbonate Potassium carbonate Potassium citrate	Limited by GMP within the limits for Na and K in section 4.1(e)
	L (+) Lactic acid L (+) Lactic acid producing cultures Citric acid	Limited by GMP (see also section 4.1 (e))

		In 100 g of product ready-to-eat (unless otherwise indicated)
5.4	Antioxidants	
	Mixed tocopherols concentrate	300 mg/kg fat
	L-ascorbyl palmitate	200 mg/kg fat
	L-ascorbic acid and its Na and K salts	50 mg expressed as ascorbic acid (within the limits for Na and K in section 4.1.2(c))
5.5	Flavours	
	Vanilla extract	Limited by GMP
	Ethyl vanillin	7 mg
	Vanillin	7 mg
5.6	Enzymes	
	Malt carbohydrases	Limited by GMP

6. CONTAMINANTS (Subject to endorsement by the Codex Committee on Food Additives)

6.1 Pesticide Residues

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

6.2 Other Contaminants

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

7. HYGIENE (Subject to endorsement by the Codex Committee on Food Hygiene)

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

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

(a) shall be free from pathogenic microorganisms;

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

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

7.3 The product shall be prepared, packed, and held under sanitary conditions and should comply with the Code of Hygienic Practice for Foods for Infants and Children (to be prepared by the Committee on Food Hygiene).

8. PACKAGING

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

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

9. FILL OF CONTAINER

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

(i) not less than 80% v/v for products weighing less than 150 g (5½ oz.);

(ii) not less than 85% v/v for products in the weight range 150-250 g (5½-9 oz.); and

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

10. LABELLING (Subject to endorsement by the Codex Committee on Food Labelling)

In addition to sections 1, 2, 4 and 6 of the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969), the following specific provisions apply (subject to endorsement by the Codex Committee on Food Labelling).

10.1 The Name of the Food

10.1.1 The name of the product shall be either "Follow-up Food or Supplementary Food for Older Infants and Children" or any appropriate designation indicating the true nature of the food, in accordance with national usage.

10.1.2 Only those products which contain a minimum of 3 g of milk protein per 100 available Calories (or 0.7 g per 100 available kilojoules) may be described as "based on milk". /If 90% or more of the total protein contained in the product is provided by milk protein the product may be labelled as "Follow-up Milk" or "Supplementary Milk"./

10.1.3 The label must state that the food is only suitable for infants over the age of 4 months, and this instruction shall be included in all descriptive literature.

10.2 List of Ingredients

10.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and added minerals, these ingredients shall be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

10.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate class names for these ingredients and additives may be included on the label.

10.3 Declaration of Nutritive Value

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

10.3.1 The amount of energy, expressed in Calories (kcal) and/or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes of the food as sold as well as per specified quantity of the food as suggested for consumption.

10.3.2 The total quantity of each vitamin, mineral, and any optional ingredient as listed in paragraphs 4.1.2 and 4.2 of this standard per 100 grammes of the food as sold as well as per specified quantity of the food as suggested for consumption. In addition, the declaration per 100 Calories (or per 100 kilojoules) is permitted.

10.4 Net Content

The net content of the product shall be declared by volume if it is in liquid form, or by weight if it is in powdered form. The declaration of weight or volume shall be made in either the metric ("Système international" units) or in a system of measurement as required by the country in which the food is sold, or in both systems.

10.5 Name and Address

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

10.6 Country of Origin

10.6.1 The country of origin of the food shall be declared if its omission would mislead or deceive the consumer.

10.6.2 When the food undergoes processing in a second country which changes its nature, the country in which the processing is performed shall be considered to be the country of origin for the purpose of labelling.

10.7 Lot Identification

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

10.8 Date Marking and Storage Instructions

10.8.1 The date of minimum durability of the food shall be declared in clear.

10.8.2 Storage instructions shall appear on the label or on the accompanying leaflet.

10.9 Information for Utilization

The product may be a liquid which is ready-to-feed or a concentrated liquid or a powder to which water is added. Directions as to the preparation and use of the food, and its storage and keeping after the container has been opened shall appear on the label or on the accompanying leaflet.

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APPENDIX V

FIRST DRAFT OF A

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

(prepared by the United States)

1. SCOPE

This standard applies to any food that purports to be, or is represented for special dietary use, because of usefulness in maintaining or reducing caloric intake, or body weight, including, but not limited to any food that bears representation that is low or reduced in calories. Both processed and unprocessed foods may bear appropriate claims under this standard.

2. DEFINITIONS

a. Low calorie foods:

A food may purport to be or be represented as "low calorie" only if:

A serving of the food supplies no more than 40 kcal, and

The food does not provide more than 0.4 kcal per gramme as consumed, or is a sugar substitute.

Foods that are low calorie within the meaning of the paragraph (a) of this section, as naturally occurring, without having any fabrication or alteration, may be labelled as a low calorie food, e.g. "celery, a low calorie food". They may not be labelled with the term "low calorie" immediately preceding the name of the food, because such terminology would imply that the food has been altered to lower its calories with respect to other foods of the same type.

b. Reduced calorie food:

A food may be labelled as "reduced calorie", or with other terms representing or suggesting special dietary usefulness, on the basis of a fabrication or alterations, that makes the food lower in calories than the food that it can substitute for in the diet, only if:

A comparison of the calorie content of a specified serving of the food with the calorie content of an equivalent serving of the same food without fabrication or alteration of special dietary significance reveals a calorie reduction of at least one third.

The food bears on its label, a statement that clearly and concisely describes the comparison upon which the claim of special dietary usefulness is made. The statement shall either identify a specific food having at least one and a half times as many calories per serving for which the food can substitute, or indicate that the claim of special dietary usefulness is based on a comparison with the same food without the fabrication, or alteration of special dietary significance. The statement shall also include a comparison between the caloric content of a specified serving of the food, and an equivalent serving of a food it substitutes for, or the same food without the fabrication, or alteration of special dietary significance.

c. Artificial sweetener:

The term "artificial sweetener" means a sweetening substance not used in normal metabolism as a source of calories.

3. QUALITY FACTORS

a. Nutritional:

The Low Calorie or Reduced Calorie food must not be nutritionally inferior, except in respect of calories, to the food for which it substitutes, or the same food without the fabrication or alteration of special dietary significance.

b. Non-nutritive ingredients:

A Low Calorie or Reduced Calorie Food may contain a non-nutritive sweetener, or other ingredient only if the ingredient is safe for use in the food, under the applicable national laws and regulations.

Any food that achieves its special dietary usefulness as a Low Calorie or Reduced Calorie Food by use of a non-nutritive ingredient other than an artificial sweetener (not utilized in normal metabolism), shall bear on its label a statement that it contains a non-nutritive ingredient, and the percentage by weight of the non-nutritive ingredient.

Any food that achieves its special dietary usefulness in reducing or maintaining caloric intake or body weight through use of non-nutritive sweetener shall bear on its label a statement that it contains a non-nutritive ingredient, but need not state the percentage by weight of the non-nutritive sweetener.

If a nutritive as well as a non-nutritive sweetener is added the statement shall indicate the presence of both types of sweeteners, e.g. sweetened with nutritive sweetener(s), and non-nutritive sweetener(s).

c. Organoleptic properties:

A Low Calorie or Reduced Calorie Food must be similar in all its organoleptic properties to the food it is represented as substituting for, or to the food without the fabrication or alteration of special dietary significance.

Any food that does not resemble in all its organoleptic properties, the specific food for which it substitutes, e.g. canned pears packed in unsweetened water, in comparison with pears in heavy syrup, may be labelled with appropriate terms to indicate its dietary usefulness, but in immediate proximity such labelling shall indicate material differences in organoleptic properties, between it and the food to which it is compared. The food shall not bear terms in juxtaposition with its name, or in the labelling that represent or suggest that the food is essentially the same as the other food in all its organoleptic properties except for a reduction of calories.

4. LABELLING

In addition to the appropriate sections of the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969), the following specific provisions shall apply, subject to the endorsement by the Codex Committee on Food Labelling.

The label shall include the following information:

a. Descriptive name of the product.
b. Common or usual name of each ingredient listed in descending order of proportion by weight.
c. Complete nutrition labelling (as required by national legislation) per serving of the food as normally consumed (per 100 g optional).
d. Directions for use and storage, and date of minimum durability, or expiration date (as required by national legislation).
e. Any other information required by national legislation, and the Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses.
f. Availability of additional information from manufacturers.

5. CLAIMS

Label terms suggesting usefulness as low calorie or reduced calorie foods:

a. Consumers may reasonably be expected to regard terms representing that the food contains no sugars, or sweeteners, e.g. "sugar free", "sugarless", "no sugar", as indicating a product which is low in calories or significantly reduced in calories. Consequently a food may not be labelled with such terms unless:

It is labelled "low calorie" or "reduced calorie" or the "sugarless" term is immediately accompanied each time it is used by a statement "not a reduced calorie food" or "not a low calorie food", or "not for weight control" or "useful only in not promoting tooth decay", or other terms indicating that the sole special usefulness of the food is for a specified purpose, other than weight control.

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

b. A food may be labelled with terms such as "diet", "dietetic", "artificially sweetened", "sweetened with non-nutritive sweetener", or other terms representing or suggesting that the food is low calorie, reduced calorie, or a food that may make a comparative claim of special dietary usefulness only if:

The food is labelled "low calorie" or "reduced calorie" or bears a comparative claim of special dietary usefulness in compliance with the criteria established for "low calorie" or "reduced calorie" foods.

c. Paragraph (b) of this section will not apply to:

Any use of such terms that is specifically authorized by a Codex Standard governing a particular food.

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

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

6. OTHER FACTORS

It may not be technologically feasible to manufacture a "reduced calorie" food under the criteria set forth in paragraph 2(b) for all foods that are significant dietary sources of calories and for which it would be useful, to those on calorie-restricted diets, to have a reduced calorie substitute. Accordingly, the Codex Committee on Foods for Special Dietary Uses may establish (by standard) acceptable alternative criteria for a specific "reduced calorie" food. Under no circumstances shall a food be permitted to be labelled as "reduced calorie" unless:

The available data demonstrates that it is not feasible to attain a greater caloric reduction to meet the established criteria than that for which approval is sought.

The available data demonstrates that the use of the food with the caloric reduction attained, will result in a significant reduction in calories in the diet, and be useful to those on weight control programmes.

7. METHOD OF ANALYSIS AND SAMPLING (To be developed later).

8. PACKAGING

Shall be in compliance with the Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses.

REPORT OF THE AD HOC WORKING GROUP ON METHODS OF ANALYSIS AND SAMPLING

(CX/FSDU 78/5)

MEMBERS: Delegates from France
Germany, Federal Republic of (Chairman)
United Kingdom
United States

The Working Group discussed the following items:

1. Sampling
   1.1 Sampling Plan in the Code of Hygienic Practice for Foods for Infants and Children
   1.2 Other Sampling Plans
2. Determination of Crude Fibre and Dietary Fibre
3. Determination of Vitamin D
4. Determination of Vitamin E
5. Determination of Vitamin K
6. Determination of Iodine
7. Determination of Linoleic Acid

1. Sampling

1.1 Sampling Plan in the Code of Hygienic Practice for Foods for Infants and Children

The Working Group is of the opinion that the Sampling Plan which is part of the Code of Hygienic Practice could not be discussed separately from this Code. An acceptance of the Code implicates the acceptance of the Sampling Plan.

1.2 Other Sampling Plans

The Working Group stressed the dependence of sampling plans on the parameters of the criteria, i.e. distribution, frequency, etc. There are no proposals for other sampling plans which seem applicable to infant formula or food for infants and children.

2. Determination of Crude Fibre and Dietary Fibre

The Working Group had before it a Synopsis prepared by the German delegate. It also took note that there is a joint group from EEC and IARC which will also deal with the determination and definition of dietary fibre during its next session in December 1978.

The Working Group is of the opinion that the method of Southgate is too complicated for the determination of fibre in foods for babies and infants, when the determination is only necessary for the indirect determination of digestible carbohydrates. The Group proposed to wait for the results of the next session of the aforementioned EEC/IARC Group.

3. Determination of Vitamin D

The Working Group had before it three methods for the determination of Vitamin D, two of them by GLC, supplied by Denmark and the United Kingdom, and a colorimetric one, supplied by Switzerland. In addition, the determination of Vitamin D by HPLC was discussed.

In principle the Working Group would prefer the determination by means of HPLC, but it was noted that HPLC is not a common method as yet. Therefore, the three other methods should be circulated for comments.

4. Determination of Vitamin E

The Group had before it two methods for the determination of Vitamin E, as supplied by Denmark and the United Kingdom. Again, the HPLC-method was discussed and preferred. But the Group decided to proceed in the same way as mentioned under 3. above.

5. Determination of Vitamin K

The United States delegate stressed the need for a method for the determination of Vitamin K and proposed to ask all delegates of the Committee for methods used in their countries.

6. Determination of Iodine

The Working Group had before it two methods as supplied by Denmark and the United Kingdom. Since the other members of the Working Group had a lack of experience in the determination of small amounts of iodine, the Working Group decided to circulate both methods for comments.

7. Determination of Linoleic Acid

The Chairman informed the Working Group that IUPAC is still developing a method. As soon as this method is available it will be circulated.

ALINORM 79/26
APPENDIX VII
(ALINORM 79/13, App. V)

REVISED DRAFT OF

CODE OF HYGIENIC PRACTICE FOR FOODS FOR INFANTS AND CHILDREN

(UP TO THREE YEARS)

(Advanced to Step 8)

SECTION I - SCOPE

SECTION II - DEFINITIONS

SECTION III - HYGIENE REQUIREMENTS IN PRODUCTION/HARVESTING AREAS

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3.1.3 Irrigation control

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SECTION V - ESTABLISHMENT: HYGIENE REQUIREMENTS

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CODE OF HYGIENIC PRACTICE FOR FOODS FOR INFANTS AND CHILDREN
(UP TO THREE YEARS)
(Advanced to Step 8)

Sideline positions indicate material which is particular to this Code of Hygienic Practice and therefore does not appear in the "General Principles of Food Hygiene"

SECTION I - SCOPE

1.1 This Code of Hygienic Practice applies to all prepackaged foods produced, represented, or purported to be for the special use of infants and/or children.

It contains the minimum hygienic requirements for the handling (including production, preparation, processing, packaging, storage, transport, distribution and sale) of such food to ensure a safe, sound and wholesome product.

SECTION II - DEFINITIONS

2. For the purposes of this Code the following expressions have the meaning stated:

Adequate	Sufficient to accomplish the intended purpose of this code.
Children	persons from the age of more than 12 months up to the age of three years.
Cleaning	the removal of soil, food residues, dirt, grease or other objectionable matter.
Contamination	the occurrence of any objectionable matter in the product.
Disinfection	The reduction without adversely affecting the food by means of hygienically satisfactory chemical agents and/or physical methods of the number of micro-organisms to a level that will not lead to harmful contamination of food.
Edible Product	product fit for human consumption.
Establishment	any building(s) or area(s) in which food is handled after harvesting and the surroundings under the control of the same management.
Food Handling	any operation in the growing and harvesting, preparation, processing, packaging, storage, transport, distribution, and sale of food.
Food Hygiene	all measures necessary to ensure the safety, soundness and wholesomeness of food at all stages from its growth, production or manufacture until its final consumption.

Hermetically sealed containers	containers which are designed and intended to protect the contents against the entry of microorganisms during and after heat processing.
Infant	a person not more than 12 months of age
Low acid food	any food , other than alcoholic beverages, where any component has a pH value greater than 4.6 after heat processing.
Packaging Material	any containers such as cans, bottles, cartons, boxes, cases, and sacks, or wrapping and covering material such as foil, film, metal, paper, waxpaper, and cloth.
Pests	any animals capable of directly or indirectly contaminating food.
Potable Water	water fit for human consumption. Standards of potability should not be lower than those contained in the latest edition of the "International Standards for Drinking Water", World Health Organization.
Protective Clothing	special garments intended to prevent the contamination of food and used as outer wear by persons in an establishment and includes head coverings and footwear.
Unfit for human consumption	an article that would normally be edible but is inedible because of disease, decomposition or any other reason.

SECTION III - HYGIENIC REQUIREMENTS IN PRODUCTION/HARVESTING AREAS

3.1 Environmental Hygiene in areas from which raw materials are derived

3.1.1 Unsuitable growing or harvesting areas

Food should not be grown or harvested when the presence of potentially harmful substances would lead to an unacceptable level of such substances in the food.

3.1.2 Protection from contamination by wastes

3.1.2.1 Raw food materials should be protected from contamination by human, animal, domestic, industrial and agricultural wastes which may be present at levels likely to be a hazard to health. Adequate precautions should be taken to ensure that these wastes are not used and are not disposed of in a manner which may constitute a public health hazard through the food.

3.1.2.2 Arrangements for the disposal of domestic and industrial wastes in areas from which raw materials are derived should be acceptable to the official agency having jurisdiction.

3.1.3 Irrigation control

Food should not be grown or produced in areas where the water used for irrigation might constitute a health hazard to the consumer through the food.

3.1.4 Pest and disease control

Control measures involving treatment with chemical, physical or biological agents should only be undertaken by or under direct supervision of personnel who have a thorough understanding of the potential hazards to health, particularly those which may arise from residues in the food. Such measures should only be carried out in accordance with the recommendations of the official agency having jurisdiction.

3.2 Harvesting and production

3.2.1 Techniques

Methods and procedures associated with harvesting and production should be hygienic, and such as not to constitute a potential health hazard or result in contamination of the product.

3.2.2 Equipment and containers

Equipment and containers used for harvesting and production should be so constructed and maintained as not to constitute a hazard to health. Containers which are re-used should be of such material and construction as will permit easy and thorough cleaning. They should be cleaned and maintained clean and where necessary, disinfected. Containers previously used for toxic materials should not subsequently be used for holding foods or food ingredients.

3.2.3 Removal of obviously unfit materials

Raw materials which are obviously unfit for human consumption should be segregated during harvesting and production. Those which cannot be made fit by further processing should be disposed of in such a place and in such a manner as to avoid contamination of the food and/or water supplies or other food materials.

3.2.4 Protection against contamination and damage

Suitable precautions should be taken to protect the raw products from being contaminated by pests or by chemical, physical or microbiological contaminants or other objectionable substances. Precautions should be taken to avoid damage.

3.3. Storage on the place of production/harvesting

Raw materials should be stored under conditions that will protect against contamination and minimize damage and deterioration.

3.4. Transportation

3.4.1 Conveyances

Conveyances for transporting the harvested crop or raw product from the production area or place of harvest or storage should be adequate for the purpose intended, and should be of such material and construction as will permit easy and thorough cleaning. They should be cleaned and maintained clean and where necessary disinfected and disinfested.

3.4.2 Handling procedures

All handling procedures should be such as will prevent raw materials from being contaminated. Care should be taken to prevent spoilage, to protect against contamination and to minimize damage. Special equipment - such as refrigeration equipment - should be used if the nature of the product or distances involved so indicate. If ice is used in contact with the product it should be of the quality required in paragraph 4.4.1.2

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

4.1 Location

Establishments should be located in areas which are free from objectionable odours, smoke, dust or other contaminants and are not subject to flooding.

4.2 Roadways and Areas used by wheeled traffic

Such roadways and areas serving the establishment and which are within its boundaries or in its immediate vicinity should have a hard paved surface suitable for wheeled traffic. There should be adequate drainage, and provision should be made to allow for cleaning.

4.3 Buildings and facilities

4.3.1 Construction

Buildings and facilities should be of sound construction and maintained in good repair.

4.3.2 Working space

Adequate working space should be provided to allow for satisfactory performance of all operations.

4.3.3 Design: cleaning

The design should be such as to permit easy and adequate cleaning and to facilitate proper supervision of food hygiene.

4.3.4 Design: pests

The buildings and facilities should be designed to prevent the entrance and harbouring of pests and the entry of environmental contamination such as smoke, dust etc..

4.3.5 Design: cross contamination

Buildings and facilities should be designed to provide separation between those operations which may cause cross-contamination, by partition, location or other effective means. Separate rooms or areas should be provided for unpacking, washing or peeling of raw materials, as the case may be.

4.3.6 Design: operation flow

Buildings and facilities should be designed to facilitate hygienic operations by means of a regulated flow in the process from the arrival of the raw material at the premises to the finished product, and should provide for appropriate temperature conditions for the process and the product. Where appropriate, separate rooms or areas suitably equipped for the required purpose, should be provided for cooking or sterilization of food.

Where cooling is required, the establishments should provide sufficient capacity in cooling and freezer space to handle maximum product flow.

4.3.7 In food handling areas:

- Floors where appropriate, should be of water-proof, non-absorbent, washable, non-slip and non-toxic materials, without crevices, and should be easy to clean and disinfect. Where appropriate, floors should slope sufficiently for liquids to drain to trapped outlets.

- Walls where appropriate, whould be of water-proof, non-absorbent, washable and non-toxic materials and should be light coloured. Up to a height appropriate for the operation they should be smooth and without crevices, and should be easy to clean and disinfect. Where appropriate, angles between walls, between walls and floor and between walls and ceilings should be sealed and coved to facilitate cleaning.

- Ceilings should be so designed, constructed and finished as to prevent the accumulation of dirt and minimize condensation, mould development and flaking, and should be easy to clean.

- Windows and other openings should be so constructed as to avoid accumulation of dirt and those which open should be fitted with screens. Screens should be easily movable for cleaning and kept in good repair. Internal window sills, if present, should be sloped to prevent use as shelves.

- Doors should have smooth, non-absorbent surfaces, and, where appropriate, be self-closing and close fitting.

- Stairs, lift cages and auxiliary structures such as platforms, ladders, chutes, should be so situated and constructed as not to cause contamination to food. Chutes should be constructed with inspection and cleaning hatches.

4.3.8 Overhead structures

In food handling areas all overhead structures and fittings should be installed in such a manner as to avoid contamination directly or indirectly of food and raw materials by condensation and drip, and should not hamper cleaning operations. They should be insulated where appropriate and be so designed and finished as to prevent the accumulation of dirt and to minimize condensation, mould development and flaking. They should be easy to clean.

4.3.9 Living quarters etc.

Living quarters, toilets and areas where animals are kept should be completely separated from and not open directly on to food handling areas.

4.3.10 Access control

If the establishment is not in its own building or buildings, the layout and control of access should be to prevent unauthorized persons from entering the establishment.

4.3.11 Materials

The use of material which cannot adequately be cleaned and disinfected such as wood, should be avoided, unless their use would clearly not be a source of contamination.

4.4 Sanitary Facilities

4.4.1 Water supply

4.4.1.1 An ample supply of potable water under adequate pressure and of suitable temperature should be available with adequate facilities for its storage where necessary and distribution, and with adequate protection against contamination and pollution. The standard or potability should not be less than those contained in the latest edition of "International Standards of Drinking Water" (WHO). An adequate supply of hot potable water not less than +80°C should be available at all times during the working hours.

4.4.1.2 Ice should be made from potable water and should be manufactured, handled and stored so as to protect it from contamination.

4.4.1.3 Steam used in direct contact with food or food contact surfaces should contain no substances which may be hazardous to health or may contaminate the food.

4.4.1.4 Non-potable water should be carried in completely separate lines, identified preferably by colour and used for steam production, refrigeration, fire control and other similar purposes not connected with food with no cross-connection with or back-siphonage into the system carrying potable water. (See also 7.3.2.)

4.4.2 Effluent and waste disposal

Establishments should have an efficient effluent and waste disposal system which should at all times be maintained in good order and repair. All effluent lines (including sewer systems) should be large enough to carry peak loads and should be so constructed as to avoid contamination of potable water supplies.

4.4.3 Changing facilities and toilets

Adequate, suitable and conveniently located changing facilities and toilets should be provided in all establishments. Toilets should be so designed as to ensure hygienic removal of waste. These areas should be well lit, ventilated and, where appropriate, heated and should not open directly into food handling areas. Hand washing facilities with warm or hot and cold water and with suitable hand-cleaning preparations with suitable hygienic means of drying hands should be provided near toilets and in such a position that the employee must pass them when returning to the processing area. Where hot and cold water is available mixing taps should be provided. Where paper towels are used, a sufficient number of dispensers and receptacles should be provided adjacent to each washing facility. Taps should be of a non-hand operable type. Notices should be posted directing personnel to wash their hands after using the toilet.

4.4.4 Hand washing facilities in processing areas

For the use of personnel during operations adequate and conveniently located facilities for hand washing and drying should be provided wherever the process demands, especially in all areas where unpacked edible material is handled, and, where appropriate, facilities for hand disinfection. The facilities should be full view of the production area. Warm or hot and cold water and suitable hand-cleaning preparations should be provided. **Where hot and cold water is available mixing taps should be provided.** There should be suitable hygienic means of drying hands. **Where paper towels are used, a sufficient number of dispensers and receptacles should be provided adjacent to each washing facility. Taps of a non-hand operable type are desirable. The facilities should be furnished with waste pipes leading to drains.**

4.4.5 Disinfection facilities

In all processing areas wherever the process demands, adequate facilities for cleaning and disinfection of working implements and equipment should be provided. These facilities should be of such nature as to permit proper cleaning and disinfection. They should be constructed of corrosion-resistant materials and should be easy to clean. Facilities for cleaning and disinfection of implements should be fitted with suitable means of supplying hot and cold water in sufficient quantity. The temperature of the hot water should be not less than +82°C at all times while food is being handled in that part of the establishment.

4.4.6 Lighting

Adequate natural or artificial lighting should be provided throughout the establishment. Where appropriate the lighting should not alter colours and the intensity should not be less than:

540 lux (50 foot candles)	at all inspection points or points requiring otherwise close examination
220 lux (20 foot candles)	in work rooms
110 lux (10 foot candles)	in other areas

Light bulbs and fixtures suspended over food materials in any stage of production should be of a safety type and protected to prevent contamination of food in case of breakage.

4.4.7 Ventilation

Adequate ventilation should be provided to prevent excessive heat, steam, condensation and dust and to remove contaminated air. The direction of the air flow should never be from a dirty area to a clean area. Ventilation openings should be provided with a screen or another protecting enclosure of non corrodable material. Screens should be easily removable for cleaning.

In areas where dry powdered materials are handled, special provisions such as suction hoods or room partitions should be used to prevent the speading of dust.

4.4.8 Facilities for storage of waste and inedible material

Facilities should be provided for the storage of waste and inedible material prior to removal from the establishment. These facilities should be designed to prevent access to waste or inedible material by pests and to avoid contamination of food, potable water, equipment, buildings or roadways on the premises.

4.5 Equipment and Utensils

4.5.1 Materials

All equipment and utensils used in food handling areas and which may contact food should be made of material which does not transmit toxic substances, odour or taste, is non-absorbent, is resistant to corrosion and is capable of withstanding repeated cleaning and disinfection. Surfaces should be smooth and free from pits and crevices. The use of wood and other materials which cannot be adequately cleaned and disinfected should be avoided, except when their use would clearly not be a source of contamination.

The use of different materials in such a way that contact corrosion can occur should be avoided.

4.5.2 Sanitary design, construction and installation

4.5.2.1 All equipment and utensils should be so designed and constructed as to prevent hygienic hazards and permit easy and thorough cleaning and disinfection, and where practicable, be visible for inspection. Stationary equipment should be installed in such a manner as to permit easy access and thorough cleaning.

4.5.2.2 Containers for inedible material and waste should be leak proof, constructed of metal or other suitable impervious material which is easy to clean or disposable and able to be closed accurately.

4.5.2.3 All refrigerated spaces should be equipped with temperature measurement or recording devices.

4.5.3 Equipment identification

Equipment and utensils used for inedible materials or waste should be so identified and should not be used for edible products.

4.5.4 Tanks and vessels

All surfaces which may come in contact with food should be visible for inspection and readily accessible for manual cleaning. Bottoms of fixed vessels may be of the cone type or may be flat and inclined at an angle of 3-5° for easy drainage. In either case, a drain cock should be provided at the lowest point.

Mixing, blending and homogenizing equipment should be of a type which does not allow food to come into direct contact with seals and bearings which are often a serious source of contamination.

4.5.5 Piping

The piping system should be designed so as to permit free drainage and prevent the occurrence of blind sections in pipes, joints, valves and gauges.

Pipe runs should be kept as short as possible; right-angled joints should be avoided and pipes should slope to a drainage point with a recommended fall of at least 1 in 120.

Cocks, valves and gauges should be accessible and easily dismantled for inspection and cleaning.

4.5.6 Pumps

Pumps should be so designed as to be readily dismantled for cleaning.

Shaft seals should be of the mechanical type and accessible for inspection, and maintenance.

Bearings should be located outside the food zone and be of sealed or self-lubricating type.

SECTION V - ESTABLISHMENT: HYGIENE REQUIREMENTS

5.1 Maintenance

The buildings, equipment, utensils and all other physical facilities of the establishment, including drains, should be maintained in good repair and in an orderly condition.

As far as practicable, rooms should be kept free from steam, vapour and surplus water.

5.2 Cleaning and disinfection

5.2.1 Cleaning and disinfection should meet the requirements of this code. For further information on these procedures see Annex I of the Code of Practice "General Principles of Food Hygiene".

5.2.2 To prevent contamination of food, all equipment and utensils should be cleaned as frequently as necessary and disinfected whenever circumstances demand.

They should also be cleaned and disinfected at the conclusion of the work shift.

5.2.3 Adequate precautions should be taken to prevent food from being contaminated during cleaning or disinfection of rooms, equipment or utensils by water and detergents or by disinfectants and their solutions. Detergents and disinfectants should be suitable for the purpose intended and should be acceptable to the official agency having jurisdiction.

Any residues of these agents should be removed by thorough rinsing with potable water from any area or equipment that comes into contact with the food before the area or equipment is again used for handling food.

5.2.4 Either immediately after cessation of work for the day or at such other times as may be appropriate, floors, including drains, auxiliary structures and walls of food handling areas should be thoroughly cleaned.

5.2.5 Changing facilities and toilets should be kept clean at all times.

5.2.6 Roadways and yards in the immediate vicinity of and serving the premises should be kept clean.

5.3 Hygiene Control Programme

A permanent cleaning and disinfection schedule should be drawn up for each establishment to ensure that all areas are appropriately cleaned and that critical areas, equipment and material are designated for special attention. A single individual who should preferably be a permanent member of the staff of the establishment and whose duties should be independent of production, should be appointed to be responsible for the cleanliness of the establishment. He should have athorough understanding of the significance of contamination and the hazards involved. All cleaning personnel should be well-trained in cleaning techniques. Completion of each task in the cleaning and disinfection schedule should be signed and dated in an appropriate record.

5.4 By-Products

By-products should be stored in such a manner as to avoid contamination of food. They should be removed from the working areas as often as necessary and at least daily.

5.5 Storage and Disposal of Waste

Waste material should be handled in such a manner as to avoid contamination of food or potable water. Care should be taken to prevent access to waste by pests. Waste should be removed from the food handling and other working areas as often as necessary and at least daily. Immediately after disposal of the waste, receptacles used for storage and any equipment which has come into contact with the waste should be cleaned and disinfected. The waste storage area should also be cleaned and disinfected.

5.6 Exclusion of Domestic Animals

Animals that are uncontrolled or that could be a hazard to health should be excluded from establishments.

5.7 Pest Control

5.7.1 There should be an effective and continuous programme for the control of pests. Establishments and surrounding areas should be regularly examined for evidence of infestation.

5.7.2 Should pests gain entrance to the establishment, eradication measures should be instituted. Control measures involving treatment with chemical, physical or biological agents should only be undertaken by or under direct supervision of personnel who have a thorough understanding of the potential hazards to health resulting from the use of these agents, including those which may arise from residues retained in the product. Such measures should only be carried out in accordance with the recommendations of the official agency having jurisdiction.

5.7.3 Pesticides should only be used if other precautionary measures cannot be used effectively. Before pesticides are applied, care should be taken to safeguard all food, equipment and utensils from contamination. After application, contaminated equipment and utensils should be thoroughly cleaned to remove residues prior to being used again.

5.8 Storage of Hazardous Substances

5.8.1 Pesticides or other substances which may represent a hazard to health should be suitably labelled with a warning about their toxicity and use. They should be stored in locked rooms or cabinets used only for that purpose, and dispensed and handled only by authorized and properly trained personnel or by persons under strict supervision of trained personnel. Extreme care should be taken to avoid contaminating food.

5.8.2 Except when necessary for hygienic or processing purposes, no substance which could contaminate food should be used or stored in food handling areas.

5.9 Personal effects and clothing

Personal effects and clothing should not be deposited in food handling areas.

SECTION VI - PERSONNEL HYGIENE AND HEALTH REQUIREMENTS

6.1 Hygiene training

Managers of establishments should arrange for adequate and continuing training of every food handler in hygienic handling of food and in personal hygiene so that they understand the precautions necessary to prevent contamination of food. Instruction should include relevant parts of this Code. Attendance records should be kept.

6.2 Medical examination

Persons who come in contact with food in the course of their work should have a medical examination prior to their employment if the official agency having jurisdiction, acting on medical advice, considers that this is necessary, either because of epidemiological considerations, the nature of the food prepared in a particular establishment, or the medical history of the prospective food handler. Medical examination of a food handler should be carried out at other times when clinically or epidemiologically indicated.

6.3 Communicable diseases

The management should take care to ensure that no person, while known or suspected to be suffering from, or to be a carrier of a disease likely to be transmitted through food, or while afflicted with infected wounds, skin infections, sores or with diarrhoea, is permitted to work in any food handling area in any capacity in which there is any likelihood of such a person directly or indirectly contaminating food with pathogenic micro-organisms. Any person so affected should immediately report to the management that he is ill.

6.4 Injuries

Any person who has a cut or wound should not continue to handle food or food contact surfaces until the injury is completely protected by a waterproof covering which is firmly secured, and which is conspicuous in colour. Adequate first-aid facilities should be provided for this purpose.

6.5 Washing of hands

Every person engaged in a food handling area should wash his hands frequently and thoroughly with a suitable hand-cleaning preparation under running warm, potable water while on duty. Hands should always be washed before commencing work, immediately after using the toilet, after handling contaminated material and whenever else necessary. After handling any material which might be capable of transmitting disease, hands should be washed and disinfected immediately. Notices requiring hand-washing should be displayed. There should be adequate supervision to ensure compliance with this requirement.

6.6 Personal cleanliness

Every person engaged in a food handling area should maintain a high degree of personal cleanliness while on duty, and should at all times while so engaged wear suitable protective clothing including head covering and footwear, all of which articles should be cleanable unless designed to be disposed of, and should be maintained in a clean condition consistent with the nature of the work in which the person is engaged. Aprons and similar items should not be washed on the floor. During periods where food is manipulated by hand any jewellery that cannot be adequately disinfected should be removed from the hands. Personnel should not wear any insecure jewellery when engaged in food-handling.

6.7 Personal Behaviour

Any behaviour which could result in contamination of food, such as eating, use of tobacco, chewing (e.g. gum, sticks, betel nuts, etc.) or unhygienic practices such as spitting, should be prohibited in food handling areas.

6.8. Gloves

Gloves, if used in the handling of food products, should be maintained in a sound, clean and sanitary condition. The wearing of gloves does not exempt the operator from having thoroughly washed hands. Gloves should be made of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

6.9 Visitors

Precautions should be taken to prevent visitors to food handling areas from contaminating food. These may include the use of protective clothing. Visitors should observe the provisions recommended in paras 5.9, 6.3, 6.4, 6.7.

6.10 Supervision

Responsibility for ensuring compliance by all personnel with all requirements of paragraphs 5.9.1 - 5.9.10 inclusive should be specifically allocated to competent supervisory personnel.

SECTION VII - HYGIENIC PROCESSING REQUIREMENTS

7.1 Raw material requirements in the establishment

Raw materials used for the production of food for infants and children should, where applicable, comply with their appropriate Codes of Hygienic Practice. If no appropriate Code of Hygienic Practice exists, the "General Principles of Food Hygiene" should apply.

7.1.1 Acceptance

No raw material or ingredient should be accepted by the establishment if known to contain parasites, microorganisms, or toxic, decomposed or extraneous substances which will not be reduced to acceptable levels by normal plant procedures of sorting and/or preparation or processing.

Raw materials used for the production of food for infants and children should not contain pesticide residues or other objectionable substances in a concentraion in the final product believed to constitute a health hazard for infants and children.

Raw materials destined for the production of food for infants and children should be of high hygienic condition.

Food of animal origin should only be derived from healthy stock.

7.1.2 Inspection and sorting

Raw materials or ingredients should be inspected and sorted prior to being moved into the processing line, and where necessary, laboratory tests should be made. Only clean sound raw materials or ingredients should be used in further processing.

7.1.3 Storage of raw materials and ingredients

Raw materials and ingredients stored on the premises of the establishment should be maintained under conditions that will prevent spoilage, protect against contamination and minimize damage. Stocks of raw materials and ingredients should be properly rotated, and should be stored under cool conditions.

7.2 Prevention of cross-contamination

7.2.1 General remarks

Effective measures should be taken to prevent contamination of food material by direct or indirect contact with material at an earlier stage of the process.

7.2.2 Personal behaviour

Persons handling raw materials or semi-processed products capable of contaminating the end product should not come into contact with any end product unless and until they discard all protective clothing worn by them during the handling or raw materials or semi-processed products which have come into direct contact with or have been soiled by raw material or semi-processed products and have changed into clean protective clothing.

7.2.3 Hand washing

If there is a likelihood of of contamination, hands should be washed thoroughly between handling products at different stages of processing.

7.2.4 Equipments

All equipments which has been in contact with raw materials or contaminated material should be thoroughly cleaned and disinfected prior to being used for contact with end products.

7.3 Use of water

7.3.1 General requirements

As a general principle, only potable water as defined in the latest edition of "International Standards of Drinking Water" (WHO) should be used in food handling.

7.3.2 Non-potable water

Non-potable water may be used with the acceptance of the official agency having jurisdiction for steam production, refrigeration, fire control and other similar purposes not connected to food. However non-potable water may, with special acceptance of the official agency, be used in certain food handling areas, when this does not constitue a hazard to health.

7.3.3 Re-circulated water

Water recirculated for reuse within an establishment should be treated and maintained in a condition so that no health hazard can result from its use. The treatment process should be kept under constant surveillance. Alternatively, recirculated water which has received no further treatment may be used in conditions where its use would not constitute a health hazard, and will not contaminate either the raw material or the end product. Recirculated water should have a separate distribution system which can be readily identified. The acceptance of the official agency having jurisdiction should be required for any treatment process and for the use of recirculated water in any food process.

7.4 Processing

7.4.1 Processing should be supervised by technically competent personnel.

7.4.2 All steps in the production process, including packaging, should be performed without unnecessary delay and under conditions which will prevent the possibility of contamination, deterioration, or the development of pathogenic and spoilage micro-organisms.

7.4.3 Rough treatment of containers should be avoided to prevent the possibility of contamination of the processed product.

7.4.4 Methods of preservation should be such as to protect against contamination or development of a public health hazard and against deterioration within the limits of good commercial practice.

7.5 Packaging

All food for infants and children should be packed in in containers which protect the food from contamination and deterioration.

7.5.1 Packaging material

All packaging materials should be stored in a clean and sanitary manner. The material should be appropriate for the product to be packed and for the expected conditions of storage, and should not transmit to the product objectionable substances beyond the limits acceptable to the official agency having jurisdiction. The packaging material

should be sound and should provide appropriate protection from contamination.
Vacuum packed containers sealed with quick-twist, screw-on or snap-on lids, which have an annular space between the inner edge of the lid's rim and the container itself, should have such space eliminated by lid or container design or be made inaccessible by sealing.

7.5.2 Inspection

Product containers should not have been used for any purpose which may lead to contamination of the product. Containers should be inspected immediately before use to ensure that they are in a satisfactory condition and where necessary cleaned and/or disinfected; no water, other than potable water, should be used for washing empty containers. When washed they should be well drained before filling. Only packaging material required for immediate use should be kept in the packing or filling area.

7.5.3 Precluding contamination

Packing should be done under conditions that preclude the introduction of contamination into the product.

7.5.4 Lot identification

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

A lot is a quantity of food produced under identical conditions, all packages of which should bear a lot number that identifies the production during a particular time interval, and usually from a particular "line" or other critical processing unit.

7.5.5 Storage instructions

Instructions for proper storage and use should be given on the label.

7.6. Storage and transport of the end product

The end product should be stored and transported under such conditions as will preclude the contamination with and/or proliferation of micro-organisms and protect against deterioration of the product or damage to the container. During storage, periodic inspection of the end product should take place to ensure that only food which is fit for human consumption is despatched and that end product specifications should be complied with. The product should be despatched in the sequence of the lot numbers.

7.6.1 Thermally processed low acid canned food should be produced according to the Code of Hygienic Practice for Low Acid Canned Foods.

7.6.2 Checking for defects

Each lot should be checked after filling. Containers showing defects which may affect product quality, should be rejected.

7.6.3 Vacuum checking

In case of thermally processed vacuum packed containers, the vacuum of all containers should be checked after heat processing.

7.7 Sampling and Laboratory Control Procedures

7.7.1 Each establishment should have access to laboratory control of the products processed. Such control should reject all food that is unfit for human consumption or that does not comply with the end product specifications.

Laboratories checking for pathogenic microorganisms should be well separated from food processing areas.

7.7.2 Sampling

Representative samples of the end product should be taken to assess the safety and quality.

SECTION VIII - END PRODUCT SPECIFICATIONS

8.1 General

The food for infants and/or children should be free from foreign and other objectionable matter to the extent possible in good manufacturing practice, as well as free from toxic substances in a concentration believed to constitute a health hazard for infants and children.

8.2 Pesticide residues and food additives

The food for infants and/or children should comply with the requirements for pesticide residues and food additives laid down by the Codex Alimentarius Commission.

8.3 Microbiological specifications

The food should comply with the microbiological specifications laid down in Annex I. For the microbiological analysis, the methods contained in Annex II should be used.

MICROBIOLOGICAL SPECIFICATIONS FOR FOODS FOR INFANTS AND CHILDREN (UP TO THREE YEARS)

Product	Test	Case	Class Plan	n	c	Limit per g m	Limit per g M
a) Dried biscuit type product[1]							
1. plain	none	-	-	-	-	-	-
2. coated	coliform	5	3	5	2	<3[2]	20
	Salmonella[3)9)]	11	2	10	0	0	-
b) Dried and instant products[4)5)]	mesophilic aerobic bacteria[6)]	6	3	5	2	10^3	10^4
	coliform	6	3	5	1	<3[2]	20
	Salmonella[9)]	12	2	60	0	0	-
c) Dried products requiring heating before consumption[5)7)]	mesophilic aerobic bacteria	4	3	5	3	10^4	10^5
	coliform	4	3	5	2	10	100
	Salmonella[9)]	10	2	5	0	0	-
d) Thermally processed products packaged in hermetically sealed containers[8)]	These products: a) shall be free of microorganisms capable of growth in the product under normal nonrefrigerated conditions of storage and distribution; and b) shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health; and c) if they have a pH above 4.6 shall have received a processing treatment which renders the products free of viable forms of microorganisms having public health significance.						

1) Dry shelf-stable products
2) <3 means no positive tube in the standard-3-tube MPN method
3) Applies only to products containing one or more Salmonella sensitive ingredients, e.g: chocolate coatings
4) Products intended for consumption after addition of liquid; includes dried infant formulas, instant infant cereals, etc.; microbial limits apply to dry product
5) Includes supplementary products, e.g. sweetening agents, starches, texturizers and similar products, singly or in combination
6) Not applicable to products which are produced by a microbial fermentation process
7) Products intended for consumption after addition of liquid and which are specified to be heated to boiling before consumption; microbial limits apply to dry product
8) Includes aseptically canned products and liquid infant formulas; assumes these products are manufactured in accordance with the respective Codes of Good Manufacturing Practice
9) For the examination of such foods for the presence of Salmonella, 25 g samples shall be used and these may be pooled.

METHODS FOR MICROBIOLOGICAL ANALYSIS FOR FOODS FOR INFANTS AND CHILDREN (UP TO THREE YEARS)

Mesophilic aerobic bacteria

Draft International Standard ISO/DIS 4833
Refer to ICMSF (1974) chapter 7, page 83-91 for collection and preparation of samples for analysis; in all instances 25 g shall constitute a sample unit (analytical unit); incubation of agar plates shall be at 30°C.

Coliform count

Draft International Standard ISO/DIS 4831
Collection and preparation of samples, sample unit and incubation as in viable colony count above.

Salmonellae

According to the "Report of the 13th Session of the Codex Alimentarius Committee on Food Hygiene, Rome, 10 - 13 May, 1976, Appendix VI, para 9".
Collection and preparation of samples, sample unit and incubation as in viable colony count above.

Labour and cost of testing may be reduced by testing pooled sample units (analytical units). Studies have shown[1)] that salmonellae may be detected with equal accuracy, and that there is no significant difference in sensitivity when testing a large sample versus multiple subsamples. Therefore, 25 g sample units may be composited to a quantity not to exceed 400 g. Analysis may then proceed as for a 25 g unit with appropriate change in equipment, media volume, etc.

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1) American Public Health Association, 1976. Compendium of Methods for the Microbiological Examination of Foods, M. L. Speck (ed), chapter 25, page 313. American Health Association, 1015 18th St., N.W. Washington D.C. 20036