

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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ALINORM 93/26

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX ALIMENTARIUS COMMISSION
20th Session
Geneva, Switzerland, 28 June - 7 July 1993

REPORT OF THE 18TH SESSION OF THE CODEX COMMITTEE ON
NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Bonn-Bad Godesberg, Germany, 28 September - 2 October 1992

N.B.: This Report incorporates Circular Letter
CL 1992/27-NFSDU.

W/z9605

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CX 5/20

CL 1992/27-NFSDU
October 1992

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

FROM: Secretary, Codex Alimentarius Commission,
Joint FAO/WHO Food Standards Programme,
FAO, Via delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: Distribution of the Report of the 18th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), Bonn-Bad Godesberg, Germany, 28 September - 2 October 1992, ALINORM 93/26

The Report of the 18th Session of the CCNFSDU is attached. It will be presented at the 20th Session of the Codex Alimentarius Commission to be held in Geneva, 28 June - 7 July 1993.

A. MATTERS FOR CONSIDERATION BY THE COMMISSION

1. Adoption at Step 5 of the Proposed Draft Standard for Formula Foods for Use in Very Low Energy Diets (Para. 48, Appendix II)
2. Terms of Reference of the Committee

The Committee recommended that the phrase, "and where specifically referred to the Committee" be deleted from the last indent of its terms of reference in the Procedural Manual and agreed to ask the Commission to consider revising the terms of reference of the Committee with a view toward strengthening its horizontal functions (para. 24).

3. Proposals for New Work

While discussing its future activities, the Committee agreed to initiate work on the following documents subject to the approval by the Commission:

- (a) A Proposed Revised Draft Standard for Gluten-Free Foods, to be circulated for comments at Step 3 (para. 83).
- (b) Guidelines on the Fortification Requirements of Lower Fat Products (para. 25).
- (c) Guidelines on the Use of Non-Nutritive Fat Replacers (paras 25 and 108).
- (d) A Revision of the Guidelines for Use by Codex Committees on Inclusion of Nutrition Provisions on Nutritional Quality in Food Standards (ALINORM 87/26, Appendix IV), (paras 25 and 108).

B. REQUEST FOR INFORMATION

During the review of provisions for vitamins and minerals in Codex standards and guidelines, the Committee noted that there were significant developments in recommendations for nutrition labelling at national and regional level. The Committee agreed to ask the Secretariat to prepare a background document on that subject, for consideration at its next session.

Comments, suggestions and recommendations on this subject are invited. They should be sent to this Office preferably before 30 June 1993.

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INTRODUCTION

1. The Codex Committee on Nutrition and Foods for Special Dietary Uses held its Eighteenth Session in Bonn-Bad Godesberg, from 28 September to 2 October 1992, under the Chairmanship of Professor Arpad Somogyi, Head of the Max von Pettenkofer Institute of the Bundesgesundheitsamt (Federal Health Office). The session was attended by 113 delegates and observers from 24 Member Countries and 9 International Organizations. A complete list of participants is given in Appendix I to the present report.

OPENING OF THE SESSION (AGENDA ITEM 1)

2. The Session was opened by Mrs. J. Peters, Chief of the Division Consumer Affairs, Federal Ministry of Health, on behalf of the Secretary of State for the Ministry of Health. Mrs. Peters welcomed the participants and recalled the objectives of Codex, which are protection of consumer health and safety and facilitation of international trade. She stressed the importance of the work achieved so far by the Commission to produce internationally accepted standards. She noted that the Committee had extended its scope in 1983, and that it was the principal adviser of the Commission for nutrition. She stressed the importance of the forthcoming FAO/WHO International Conference on Nutrition, in view of the widespread problems of malnutrition and food-related diseases, and noted that its outcome would have implications for the work of this Committee.

3. In thanking Mrs. Peters for her address, the Chairman recalled the wide field and many tasks which are covered by the Committee. He stated that major consideration is to be given to health, safety and consumer protection and pointed out that the review of Codex Standards had been initiated as recommended by the Commission.

ADOPTION OF THE AGENDA (AGENDA ITEM 2)

4. The Committee had before it document CX/NFSDU 92/2, the Provisional Agenda for the Session. The Chairman highlighted the agenda items relating to the standards review process, or which had a bearing on the work of the other Codex Committees. It was noted that under Agenda Item 12 "Review of Provisions for Vitamin A, Folate, Iron and Vitamin B12 in Standards Elaborated by the Committee", the issue of methods of analysis would be considered, on the basis of document CX/NFSDU 92/1-Addendum 1.

5. In order to facilitate discussions on Methods of Analysis in NFSDU Standards and on the Review of Provisions for Vitamins and Minerals (Agenda Item 12), the Committee agreed to establish two Working Groups under the Chairmanship of Dr. J. Chopra (USA) and Professor J. Rey (France), respectively.

6. The Delegate from Argentina expressed regret at the lack of interpretation into Spanish language at the session.

7. The Committee adopted the agenda as proposed in CX/NFSDU 92/1.

APPOINTMENT OF RAPORTEURS (AGENDA ITEM 3)

8. The Committee agreed to appoint the following delegations as rapporteurs:

- United States: English text
- Switzerland: French text
- Germany: German text.

MATTERS OF INTEREST TO THE COMMITTEE ARISING FROM THE 19TH SESSION OF THE COMMISSION, THE 39TH SESSION OF THE EXECUTIVE COMMITTEE AND OTHER CODEX COMMITTEES (AGENDA ITEM 4)

9. The Committee had before it document CX/NFSDU 92/2, containing matters of interest of particular importance to the Committee and introduced by the Secretariat. The Committee noted the recommendations of the FAO/WHO Food Standards Conference, as endorsed by the Commission, regarding improvement of consumer participation, the review of Codex standards and procedures and horizontal approach to food standardization. The Committee also noted the clarification given by the Executive Committee, at its 38th Session, on the responsibilities of CCNFSDU, CCMAS and CCFL as to methodology. The Committee took note of the activities of CCFAC regarding the proposed General Standard for Food Additives. Certain delegations questioned the decision of CCFAC to discontinue work on limits for aflatoxin M1 in milk destined for baby foods.

10. The main general conclusions of the last 25th session of CCFH were presented, especially the advancement to Step 8 of the Draft General Provisions Relating to Hygiene

in Codex Standards, the Draft Principles and Applications of the Hazard Analysis Critical Control Point (HACCP) and the revision of the General Principles of Food Hygiene. In reply to questions on the incorporation of HACCP in the General Principles, it was indicated that the revised version, which was currently being prepared, would be circulated for government comments and be considered in detail by the next session of CCFH.

11. The Committee was further informed of the recommendations made to the Commission by the last session of the Committee on General Principles. These recommendations include deletion of "target acceptance" and extension of acceptance under the "free distribution" principle to all Codex Standards; possible adoption of standards at Steps 5 and 8 by a two-thirds majority of votes cast; alignment of elaboration procedures and establishment of a "fast track" procedure; and recommendations for "revised" Codex Standards to include only essential provisions.

12. The delegate from Argentina agreed with the priority attention given to problems of hygienic food production and with the horizontal approach to food standardization, and the recommendation on speeding up the elaboration of amendments.

13. In reply to a question regarding the terms of reference of the Committee, the Secretariat recalled that CCNFSDU is a commodity committee with its terms of reference extended to nutrition and that no change in its terms of reference had been proposed by the Commission or the Committee on General Principles. This matter was discussed in further detail under Agenda Item 5 (paras 22-24).

14. The Committee was informed of the extensive preparations for the International Conference on Nutrition at the regional and international levels, and of the considerable participation and input at the Preparatory Committee Meeting for the ICN held in Geneva from 18-24 August 1992. The representative of WHO indicated that the report of this meeting would be distributed in the near future.

REVIEW OF NUTRITIONAL CONSIDERATIONS IN THE WORK OF THE CODEX ALIMENTARIUS COMMISSION (AGENDA ITEM 5)

15. The Committee had before it documents CX/NFSDU 92/3 containing the report of Dr. N. Tape (Canada), CX/NFSDU 92/3-Add. 1 containing the written comments of Denmark and New Zealand and CX/NFSDU 92/3-Add. 2 containing the written comments of the USA.

16. The Chairman reviewed the background to this agenda item. At the 16th Session of the CCNFSDU, it was suggested that the Committee should consider ways of addressing the concern over excessive intakes of fat; sugars and sodium and inadequate intake of fibre which is particularly acute in developed countries. The Committee agreed at its 17th Session that consideration should be given to the recruitment of a consultant who would examine current nutrition recommendations and guidelines and Codex standards and prepare recommendations for the Committee's future action. The Commission endorsed this procedure (ALINORM 91/40, para. 275) and accordingly, FAO recruited the services of a consultant, Dr. Norman W. Tape of Canada, who prepared a working paper for consideration by the Committee.

17. The Committee expressed appreciation to the author for the scope and quality of the paper, and thanked him for his very informative and valuable contribution to a very complex and important problem.

18. The Committee agreed that the paper was a useful document in defining the future direction and programme of work of the Committee. While generally agreeing with the recommendations made in the document, the Committee noted the statement of the Delegation of the United States that this should not be taken as an endorsement by the Committee of the Report of a Study Group on Diet, Nutrition and Chronic Diseases (WHO Tech. Rep. Series No. 497, 1990) referred to extensively in the document prepared by the Consultant. The Delegation of the United States further stated that it does not support the adoption of global guidelines because there is still considerable variation in the nutritional needs and problems of population world-wide. The Committee also noted that the draft Plan of Action being prepared for the International Conference on Nutrition also urges adoption of dietary targets at the national level rather than the global level.

19. The Committee agreed with the statements of several delegations that regional aspects should be taken into consideration when defining dietary recommendations and that the principle of subsidiarity should be respected. The Committee also agreed that dietary guidelines do not generally apply to infants and young children.

20. The Committee agreed with the paper's conclusion that food standards cannot by themselves promote healthy diets or serve for implementation of dietary goals although they can have a supporting role.

21. Several delegations expressed general and serious reservations about claims and statements concerning diet/disease relationship, and the Committee agreed that more scientific information is needed in support of these relationships.

22. Several delegations and the observer from IOCU stated that the exact status and terms of reference of the Committee were not clear. It was noted that the terms of reference imply that it also has horizontal functions in endorsing nutritional provisions in other committee standards and advising the Commission on matters of nutrition.

23. One delegation proposed that the Committee move away from rigid vertical new standards toward more collaboration with CCFL on labelling which would allow the consumer an informed choice. The delegate also noted the implications of the International Conference on Nutrition for the future work of the Committee and suggested that the Codex Alimentarius Commission should reconsider and clarify its status.

24. The Committee recommended that the phrase, "and where specifically referred to the Committee" be deleted from the last indent of its terms of reference in the Procedural Manual and agreed to ask the Commission to consider revising the terms of reference of the Committee with a view toward strengthening its horizontal functions.

25. The Committee also agreed to include in its future work the following subjects proposed in the document.

- Development of guidelines on the fortification requirements of lower fat products and consideration of the need for and nature of guidelines on the use of non-nutritive fat replacers. The Committee accepted the offer of the Delegations of Germany and France to prepare a draft paper for discussion at the next meeting.
- Consideration of a revision of the Guidelines for Use by Codex Committees on Inclusion of Nutrition Provisions on Nutritional Quality in Food Standards. A Circular Letter will be sent to obtain government comments and the Delegation of Canada agreed to prepare a draft for consideration at the next meeting.

26. The Committee noted that an extensive review of nutritional aspects of fats is being organized jointly by FAO/WHO for 1993.

PROPOSAL FOR A REVISION OF THE CODEX STANDARD FOR CEREAL-BASED INFANT FOODS (CODEX STAN 74-1981) IN RELATION TO THE GUIDELINES ON FORMULATED SUPPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN (AGENDA ITEM 6)

27. The Committee had before it the following documents: CX/NFSDU 92/4 containing the proposed draft and CX/NFSDU 92/4-Add. 1 containing the written comments of Canada and USA.

28. The Chairman presented a brief background to the document. The CCNFSDU had elaborated Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (ALINORM 91/26, App. II) in response to a wish expressed by developing countries through FAO and WHO for guidance in preparing foods for infants and children from locally available raw material. The Guidelines were adopted by the Codex Alimentarius Commission at its Nineteenth Session in 1991.

29. In order to avoid any possible overlap between the Codex Standard for Processed Cereal-Based Foods and the Guidelines, the Commission had requested that CCNFSDU integrate the Standard and the Guidelines into a single document. It was also necessary to consider amendments of the Standard itself.

30. Many delegations questioned the usefulness of the merging of the two documents since they cover distinctly different types of food products. A question was also raised about the interpretation of the intention of the Commission in recommending the integration of the two texts.

31. Many delegations also expressed concern that the original intention and purpose of the Guidelines might become lost in a combined standard. Many delegations were of the opinion that the integrated document could be considerably improved.

Status of the Standard

32. The Committee agreed that a proposed revised standard would be redrafted by the Delegation of Switzerland in collaboration with France, the USA and the Netherlands, with the understanding that the original concept and objectives of the Guidelines would be preserved in the merged document. The revised Standard will be circulated for comments at Step 3 before the next session of the Committee.

PROPOSED DRAFT STANDARD FOR FORMULA FOODS FOR USE IN VERY LOW ENERGY DIETS (AGENDA ITEM 7)

33. The Committee had for its consideration the Proposed Draft Standard for Formula Food for Use in Very Low Energy Diets for Weight Control, as contained in Appendix VI of ALINORM 91/26. The Committee also had before it comments of governments and international organizations in reply to CL 1992/9-NFSDU contained in documents CX/NFSDU 92/5 (Denmark, Germany, New Zealand, Norway, Sweden, ISDI), CX/NFSDU 92/5-Add. 1 (new proposed draft standard by ISDI), CX/NFSDU 92/5-Add. 2 (Canada, United States).

34. Some delegations indicated that such formula foods can be used in their countries only under medical supervision, and in one case even under prescription. These formula foods would therefore be considered as medical foods. The observer from the EC informed the Committee that this was also the approach taken by the EEC Scientific Committee for Food.

35. The Delegations of the Netherlands and the United Kingdom and the observer from ISDI were of the opinion that very low energy diets present no health hazard if used for a limited period of time, for example less than six weeks, and that they should therefore not be regarded as medical foods. It was pointed out by several delegations that the use of such diets, for whatever period of time, was never without adverse consequences to health, as it entailed not only the loss of fat, but of lean body mass. Several delegations remarked that weight was often likely to increase rapidly after losing weight by means of such foods. It was reported that such body weight variations are hazardous as they might increase long-term obesity and increase the risk of cardiac disease. Several delegations pointed out that frequent use of such diets is contrary to current nutritional recommendations, and that they are sold freely in many countries, where they might be used without any medical advice. The Delegation of the United Kingdom thought that the labelling of these products should provide advice on their recommended period of use.

36. After an extensive exchange of views, the Committee agreed that the question of medical prescription was the responsibility of national governments, and that adequate labelling is of major importance to prevent improper use of these foods in order to ensure consumer protection.

37. The Committee agreed with the proposal of the Delegation of Australia to amend Section 1 - Scope, by adding the statement that those foods are intended for special medical purposes and should be used under medical supervision, irrespective of the duration of the diet. A statement that the issue of medical prescription should be decided by national authorities should also be included. It was further agreed that in Section 9 - Labelling, the first statement in Point 9.6 would read "to be used only under medical supervision".

38. The Committee agreed that the proper term to be used in the title and the relevant sections was "very low energy diet" instead of "very low calorie diets" in order to make use of current SI terminology. The Committee also agreed that these are diets for weight reduction" rather than "weight control" in the dietary management of obesity.

39. After a wide exchange of views, the Committee agreed that these diets would cover a daily energy intake of 450 to 800 kcal, instead of 600 kcal, in order to avoid a gap in the daily energy intake categories covered by other Codex standards. For example the Standard for Formula Foods for Use in Weight Control Diets (adopted by the last session of the Commission) applies to diets providing no less than 800 kcal.

40. The Committee also agreed to change the definition of protein quality in Section 3.2.1 to make it consistent with the recommendations of the FAO/WHO Expert Consultation on Protein Quality Evaluation (December 1989). (FAO Food and Nutrition Paper 51, 1991).

41. A proposal to describe such formula foods as "nutritionally complete" was not accepted by the Committee, as these foods are low in energy, contain only certain nutrients and such labelling could deceive the consumer.

42. The Committee discussed whether the composition and quality factors apply to these foods as sold or as prepared (ready-to-eat). The Committee noted that various nutritive liquids other than water can be used to reconstitute these foods and thereby increase their energy content. Some delegations were of the opinion that the standard applied to the formula food itself as it is marketed, regardless of the instructions for its preparation. Other delegations were of the opinion that consideration should be given to the end-product as consumed. The Committee decided that composition and quality factors apply to the product as sold, and that the product as prepared according to instructions shall not exceed a daily energy intake of 800 kcal.

43. There was an extensive exchange of views on the minimum level of carbohydrates, including scientific arguments to the effect that the minimum level should be lowered to 40 g. The Committee agreed to retain the level of 50 g and to redefine these as "available" carbohydrates. The Committee also accepted the proposal that a document reviewing this subject would be prepared by ISDI for consideration at its next meeting.

44. Some delegations were of the opinion that a positive list of vitamins, minerals and other essential nutrients should be included. In this respect the Committee had to take into account the conclusions of the Working Group on the Review of Provisions for Vitamins and Minerals which met during the session (see paras 88-93).

45. In the course of the discussion on Section 9 - Labelling, the Committee noted that detailed labelling provisions had been given for these foods, but that it had now decided that these are foods for special medical purposes. Consequently, these foods should be labelled in accordance with the Standard for the Labelling of and Claims for Foods for Special Medical Purposes. In addition, the Committee also agreed that certain specific labelling requirements relating particularly to very low energy diets should be included in this section. After a detailed discussion on 9.6 - Information for Utilization, the Committee agreed that provisions in this section will include a statement on the necessity of medical supervision, a statement that the purpose of the product is for dietary management of obesity, a warning that these foods should not be used by certain sensitive population groups, and a statement concerning precautions and contraindications.

46. The Delegation of the Netherlands expressed the view that the contraindications should be specified in the standard since it may be expected that a general agreement on these, even among experts, may not be always present. The Committee however agreed that the contraindications need not be enumerated in the section on information, as the appropriate statements are the responsibility of the manufacturers, in accordance with national legislation in each country. It was therefore decided in order to achieve consistency with the Standard for Labelling of and Claims for Foods for Special Medical Purposes to use the general wording of paragraph 4.5.2 of the said standard. It was moreover pointed out that as it was specified that these foods would be used under medical supervision, the issues of precautions and contraindications would be better left to the medical supervision, on a case by case basis.

47. The Delegation of Argentina pointed out that the declaration of country of origin should be mandatory, as it is in Argentina.

Status of the Standard

48. The Committee agreed to advance the Proposed Draft Standard to Step 5 of the Codex Procedure. The revised text of the Proposed Draft Standard is attached to the present report as Appendix II.

CONSIDERATION OF A PROPOSED DRAFT APPENDIX ON SALT IODIZATION TO THE CODEX STANDARD FOR FOOD GRADE SALT (CODEX STAN 150-1985) (AGENDA ITEM 8)

49. At its 16th and 17th Sessions, the Committee agreed that it would be possible to prepare advice on the iodization of salt as the main approach to control iodine deficiency disorders, which affect millions of people, predominantly in developing countries.

50. The Commission being aware of the extensive regional and worldwide activities and of a World Health Assembly Resolution (WHA 43.2) concerning the elimination of iodine deficiency disorders and recognizing the importance of salt iodization, requested the Secretariat to arrange for the development of an Annex on Iodization to the existing

Codex Standard for Food Grade Salt (CODEX STAN 150-1985). Comments and suggestions were requested with CL 1991/12-NFSDU.

51. The Chairman introduced the papers for this item CX/NFSDU 92/6 containing the comments of Denmark, Finland, Germany, New Zealand, Norway, Poland, Sweden and Zimbabwe, and CX/NFSDU 92/6-Add. 1 containing the comments of Canada and the United States.

52. One delegation briefly outlined its country's experience with salt iodization and pointed out that worldwide harmonization of the addition of iodine could be done with potassium and sodium iodate which have proved safe over a period of many years.

53. The Delegation of Argentina stated that the addition of potassium iodate to any food should be avoided because of its chemical composition.

54. Another delegation discussed problems encountered when an iodization vehicle other than salt is used and pointed out that while there are adequate technologies for iodization, the levels of iodine to be added should be discussed. The Committee recognized that global standardization may be difficult due to the variety of salt consumption patterns, severity of iodine deficiency disorders and other factors.

55. The representative of WHO informed the Committee about concerns raised on the safety of potassium iodate in the 43rd WHA and referred the Committee to Annex 5 of the 37th Report of the Joint FAO/WHO Committee on Food Additives which addressed this issue (WHO Tech. Rep. Ser. 806, 1991). JECFA concluded that use of potassium iodate for fortifying salt to control iodine deficiency should be continued and states that potassium iodate is more suitable for this purpose than potassium iodide. The representative also gave a brief description of salt iodation programmes in developing countries and of the extensive expertise gained during the last 2-3 decades.

56. The Committee accepted the proposal of the German Delegation to draft an Annex to the Codex Food Grade Salt Standard and noted that the Annex would be prepared in time to be circulated for comments before the next session of the Committee.

CONSIDERATION OF UPPER AND LOWER LIMITS FOR NUTRIENT QUANTITY DESCRIPTORS IN THE PROPOSED DRAFT GUIDELINES FOR HEALTH AND NUTRITION CLAIMS ON FOOD PRODUCT LABELLING (AGENDA ITEM 9)

57. The Committee had for its consideration document CX/NFSDU 92/7 containing Appendix I to CX/FL 91/9 with the proposed limits for Nutrient Quantity Descriptors. Government comments were presented in documents CX/NFSDU 92/7-Add. 1 (Denmark, Germany, New Zealand) and CX/NFSDU 92/7-Add. 2 (United States).

58. The Delegation of Canada recalled that the 21st Session of the Committee on Food Labelling had considered in detail Proposed Draft Guidelines on Nutrition and Health Claims for Food Labelling and had agreed to solicit advice from CCNFSDU on levels of nutrients to qualify for use of nutrition descriptors (ALINORM 91/22, para. 125). This procedure had been approved by the Commission.

59. Some delegations questioned the inclusion of health claims in the proposed Guidelines. The Chairman reminded the Committee that its mandate was not to discuss the Guidelines in their entirety, as this was the responsibility of CCFL, but to examine specifically the levels for nutrient content, claims as proposed in Table I of CX/NFSDU 92/7.

60. With respect to the general aspects of the proposed claims, some delegations were of the opinion that conditions for claims should not refer to "per serving" but only to a level for 100 g or 100 ml, while other delegations and the observer from IOCU thought that the idea of "per serving" was more appropriate in some cases, especially for liquids.

61. The Committee agreed to delete all references to "per serving" in the Table. The Delegations of the USA and the United Kingdom expressed their reservation on this deletion. The Committee agreed that as servings of liquids are generally larger, the level of energy or a nutrient for 100 ml of a liquid, would be 50% of the corresponding level allowed for 100 g of solids.

62. The Delegations of Argentina and Australia expressed their view that when the term "free" was used, no trace of the relevant component should be found in the food. The Committee however agreed that such a requirement would not be practical, and that nutritionally negligible traces could be present.

Energy

63. Several delegations pointed out that it would be difficult to agree on a satisfactory definition for reference foods and a "reduced" level of energy. The Committee agreed that Section 7 - Comparative Claims of the Proposed Draft Guidelines adequately covered claims for reduction, and decided to delete the reference to reduced energy in the table. The Committee also decided to recommend that 7.3 be revised to include a defined minimum reduction necessary to qualify for a claim.

64. The Committee did not accept a proposal to lower the value for liquids from 20 kcal per 100 ml to 10 kcal/100 ml, but agreed to adopt the conditions for "low energy" as proposed in the Table of the document CX/FL 91/9.

Fat

65. The Committee agreed on the values of 3 g/100 g (solids) and 1.5 g/100 ml (liquids) for "low" fat and 0.15 g per 100 g or ml for "fat free". The Committee was also of the opinion that no claim should be made for the absence of fat or any other nutrient in foods which naturally did not contain the said nutrient.

Saturated Fat

66. The Committee agreed on the value of [1.5 g/100 g] for solids or [10% of energy], as this level was recommended in many guidelines. It was pointed out, however, that the recommendation of 10% of energy from saturated fat applied to the entire diet, not to individual foods. The Committee decided to put both definitions in square brackets, while noting that they would be considered again in the future.

Cholesterol

67. The Committee accepted the view expressed by several delegations that claims for "cholesterol free" foods were of no significance in many cases. It therefore agreed to delete the reference to "cholesterol free". The Delegations of the Netherlands and the United Kingdom were of the view that cholesterol claims in general are of no significance and should therefore not be used.

68. The Committee noted that the level of cholesterol in a food should be considered in relation to the amount of saturated fat and the energy percentage derived therefrom. It agreed to describe "low" in cholesterol by a maximum level of 20 mg/100 g for solids, 10 mg/100 ml for liquids, together with a limit of 1.5 g saturates/100 g for solids, 0.75 g/100 ml for liquids or a requirement that saturates would provide no more than [10%] of the energy intake.

Sugars

69. The Committee decided that this section should refer to all sugars and not to "sugar". It further agreed to delete the reference to "low" as such a definition was not nutritionally relevant and to define "free" as containing no more than 0.5 g/100 g or 0.25 g/100 ml, following the previous agreement on the term "free". (See paragraph 62).

70. One delegation expressed the view that the presence of sugars even in trace amounts would not be compatible with a claim for dental benefit.

Sodium

71. The Committee agreed to delete the reference to "and at least 50% less sodium" and concentrate on the levels per 100 g. Some delegations were of the opinion that three categories were not needed and that only claims for "low" and "free" should be considered. It was also pointed out that confusion should be avoided with the Standard for Low Sodium Foods. The Committee agreed to maintain the three categories proposed in the Table and to put "Very low" and "Free" in square brackets.

Fibre

72. The Committee agreed to delete the reference to "Very High" and leave the levels proposed in the Table for "Source" and "High" in square brackets.

Protein

73. The Committee agreed to delete the reference to "Very High" and to specify that the percentage of the RDA applies to 100 g of the food.

Vitamins and Minerals

74. The Committee agreed to delete the reference to "except Vitamin C" and to "Very High", thereby incorporating the conditions for Vitamin C into the Section on Vitamins and Minerals. The Committee also noted that consideration should be given to the hazard caused by an excessive intake of these nutrients.

75. Several delegations were of the opinion that the value of 5% for "Source" should be raised to 10 or 15% of the reference RDA. The observer from the EEC informed the Committee that Community legislation allowed nutrition claims for vitamins and minerals only if the amounts present per specified quantity of the food (100 g or 100 ml) were not less than 15% of the reference RDA. The Delegation of the United Kingdom proposed a level of [20-50%] for source. The Committee agreed to propose the levels of 10-15% for "Source" and [20-30%] for "High" in square brackets. These amounts refer to 100 g or 100 ml of the food.

76. The Committee agreed to annex the revised Table to this report as Appendix III and to make it available for consideration by the Codex Committee on Food Labelling.

CONSIDERATION OF A PROPOSED REVISED DRAFT STANDARD FOR GLUTEN-FREE FOODS (CODEX STAN 118-1981) (AGENDA ITEM 10)

77. The Committee had before it documents CX/NFSDU 92/8 and CX/NFSDU 92/8-Add. 1 which contained the comments of Canada, Germany, USA and ISDI respectively.

78. The Chairman introduced the item by recalling that at the last session of the Committee it was agreed that developments in the chemical characterization of gluten and human intolerance to it justify the review and updating of the standard.

79. The Chairman also pointed to increasing concern over the wide use of gluten containing ingredients in foods which do not contain gluten naturally, such as meat, fish, poultry, sausages, cheese, ice-cream, margarine, mayonnaise, milk products, etc. This development is likely to create problems for persons with gluten intolerance. The issue has been mentioned at the 15th Session of the CCNFSDU (ALINORM 89/26, paras 103-104) and has recently been raised with the Codex Secretariat by the Association of European Celiac Societies and clinicians.

80. One delegation informed the Committee that serious problems with gluten-based additives in foods have been successfully addressed with appropriate labelling, including clear statements of ingredients.

81. The observer from the Association of European Celiac Societies informed the Committee that better labelling and monitoring are needed in order to avoid the hazard to celiac patients from the extended use of gluten containing ingredients in foods. The observer reported on important advances in analytical methodology of gluten, and on the proposed value of 10 mg prolamin/100 g wheat starch. The observer also indicated that a limit of 1 mg/100 g for gluten-free foods should be considered and regulations for good manufacturing practices under special care are necessary to avoid cross-contamination of gluten-free foods by traces of gluten. Several delegations were of the opinion that the definition of "gluten-free food" in the Standard should be amended to include only those foods which do not contain any wheat, oats, barley, rye or triticale or any parts thereof. The Committee noted that a new definition has been proposed for gluten as the protein (prolamin) fraction commonly found in wheat, oats, barley, rye and triticale.

82. The Committee agreed that the level of gluten and the methods for its determination are the crucial points in the revision of the standard. Several delegations were of the opinion that the limit of 10 mg prolamin/100 g product was acceptable at present, but the Committee decided that the figure should remain in square brackets pending the adoption of an appropriate method. The Committee was aware of important developments in gluten methodology, but did not want to delay the revision of the entire standard because of lack of validated methods. Also the Committee was informed about extensive inter-laboratory studies of two methods that have been carried out by the Netherlands.

83. The Committee accepted with appreciation the offer of the Delegations of the Netherlands and USA to prepare a revised draft which would include a limit of [10 mg prolamin/100 g]. The revised draft should be circulated for comments at Step 3 and reviewed at the next session of the Committee.

REVISION OF THE CODEX STANDARD FOR LOW SODIUM FOODS (CODEX STAN 53-1981)
(AGENDA ITEM 11)

84. The Committee had before it the written comments of Denmark and Germany in document CX/NFSDU 92/9 and CX/NFSDU 92/9-Add. 1 with the comments of Canada, USA and ISDI.

85. The Committee noted that the problem of reducing sodium intake is now addressed through labelling and consumer education. The Committee also noted that the need for special dietary foods low in sodium has been reduced except for certain consumers who are under medical supervision.

86. The Committee noted that several delegations had proposed that work on the revision should be discontinued and the standard eliminated, while other delegations and the observer from ISDI were of the opinion that such action was premature.

87. The Committee agreed to reconsider the standard at its next session in the light of the progress in the elaboration of the Guidelines for Nutrition and Health Claims for Food Product Labelling.

REVIEW OF PROVISIONS FOR VITAMIN A, FOLATE, IRON AND VITAMIN B12 IN STANDARDS ELABORATED BY THE COMMITTEE (AGENDA ITEM 12)

88. The Committee had before it a document CX/NFSDU 92/10 which contained background information on recent FAO/WHO Expert Advice on Nutrient Intake. At its last session in 1991, the Committee had been aware of the need to review and update provisions for nutrients, vitamins and minerals in several special food standards. Therefore, it agreed to include in the agenda of its future meetings a continuing item on the changes in the scientific advice provided by FAO/WHO on nutrient intakes (ALINORM 91/26, paras 46-47, 53-58).

89. The Committee decided to establish an Ad-Hoc Working group to advise the plenary on the provisions for vitamins and trace elements for Codex Standards for Special Foods (para. 5). The Working Group was composed of delegates from Australia, Canada, France, Netherlands, Norway, Sweden, Switzerland, United Kingdom, United States and WHO and was chaired by Prof. Jean Rey (France).

90. The Chairman of the Working Group stated that the Group had reviewed the provisions of the draft Standard Formula Food for Use in Very Low Energy Diets and proposed that the provisions be the same as those in the Codex Standard for Weight Control Diets. The Working Group recommended that these amounts be those proposed by the FAO/WHO Consultation on Vitamins and Minerals for Male Adults, except in the case of iron where the value for the lower limit of the range for women should be used.

91. The Committee accepted the recommendation of the Working Group that Pantothenic Acid, Vitamin K1, Biotin and Chloride, should be added to the existing list in both standards. The Group also discussed the addition to the list of Manganese, Selenium, Molybdenum and Chromium, but no consensus was reached.

92. In reviewing the Infant Formula Standard (CODEX STAN 72-1981), the Working Group agreed that the amounts of vitamins and minerals provided for in this standard agree with present FAO/WHO recommendations with the exception of Vitamin B12. The Codex Standard provides for an amount of Vitamin B12 per day up to 10 times the 1988 FAO/WHO recommended safe level of intake*. The Committee agreed to request the French Delegation to prepare an updated review paper on Vitamin B12 for its next session.

93. The Working Group also reviewed the list of Vitamins and Minerals in the Guidelines on Nutrition Labelling (CAC/GL 2-1985). In light of the current recommendations for nutrition labelling which are being developed in various countries, the Committee requested the Secretariat to send out a Circular Letter requesting information on this subject and prepare a document for the next session.

* Requirements of Vitamin A, Iron, Folate and Vitamin B12, Report of a Joint FAO/WHO Expert Consultation, FAO Food and Nutrition Series No. 23, 1988.

Review of Methods of Analysis in the Codex Standards for Special Foods

94. Under Agenda Item 2, the Committee appointed a Working Group to review some analytical methods for use in standards elaborated by the Committee (see para. 5). Document CX/NFSDU 92/10-Add. 1 was available as a basis for the work of the Ad-Hoc Working Group attended by representatives of the Netherlands, USA, ISDI and AOAC and chaired by Dr. Chopra (USA).

95. The Delegation of the United Kingdom said that the inclusion of a method for the determination of dietary fibre in infant formula and follow-up formula was unnecessary, and that the amount of carbohydrate should be measured directly. The Delegation of France noted that dietary fibre was unlikely to be present in infant formula. The Committee welcomed the offer of the United Kingdom to propose a method for measuring carbohydrate before the next meeting of the Committee.

96. The Committee endorsed the recommendations of the Working Group which are presented in Appendix IV, agreed to include a method for carbohydrates in addition to that for dietary fibre, and agreed to forward the list to the CCMAS for consideration and endorsement.

97. It was agreed that methods 16-19 in Appendix IV should not be further elaborated since they refer to nutrition labelling.

GUIDELINES FOR DIETARY SUPPLEMENTS WITH SPECIAL REFERENCE TO VITAMINS AND MINERALS
(AGENDA ITEM 13)

98. The Committee had before it the working paper CX/NFSDU 92/11 prepared by Germany containing the Draft Guidelines for Dietary Supplements, CX/NFSDU-Add. 1 containing the comments of Canada, CX/NFSDU 92/11-Add. 2 containing comments from Malaysia.

99. The Chairman recalled that at its 17th Session, the Committee reviewed the comments from several countries on whether or not work on vitamin and mineral supplements should be undertaken within Codex. There was general support for the development of guidelines for those vitamin and mineral supplements which could be identified as foods. The Commission agreed that work on the Guidelines should continue (ALINORM 91/40, para. 274).

100. In discussing the Sections on Scope and Definition, the Committee agreed that the supplements should be treated as foods within the Codex system. The view was also expressed that the matter of whether or not to regulate them as drugs should be left to the discretion of national authorities. The Australian Delegate maintained the view that vitamin and mineral supplements should not be treated as foods. Another Delegation was of the opinion that if vitamin and mineral supplements were not regulated as drugs, they should be at least regulated as foods for special dietary uses.

101. The Section on Composition was discussed in some detail. One delegation suggested that Vitamin K1 should be excluded. In connection with Section 3.3, one delegation was in favour of establishing a positive list for nutrients and ingredients.

102. Several delegations expressed concern that the consumption of 100% RDA from a supplement alone was not a good recommendation. The observer from IOCU was of the opinion that for some trace elements the safety margin between the RDA and toxicity is narrow.

103. One delegation pointed out that the guidelines should clearly define the supplements as mixtures of individual vitamins and minerals in order to exclude extracts and concentrates prepared from common food products.

104. One delegation found that the list of about 24 nutrients included in the document was too long and suggested that subsets of various combinations be developed. One delegation proposed that supplements be packed in child-resistant packaging because of possible intoxication of children with iron contained in the preparation.

105. The observer of ISDI noted that the document was structured like a standard and suggested that it be redrafted as guidelines.

106. The Committee noted that there was extensive recent scientific information on vitamins and minerals which should be considered in the preparation of the document and agreed to request the German Delegation to redraft the Guidelines and make them available in time to be circulated for comments at Step 3.

OTHER BUSINESS AND FUTURE WORK (AGENDA ITEM 14)

107. The Committee noted that no proposals have been submitted under Other Business and agreed that the agenda for its next session would include the following matters:

- Development of Guidelines on the Fortification Requirements of Lower Fat Products. (Subject to endorsement by the Commission).
- Consideration of the Need for and Nature of Guidelines on the Use of Non-Nutritive Fat Replacers. (Subject to endorsement by the Commission).
- Review of the Guidelines for Use by Codex Committees on Inclusion of Nutrition Provisions on Nutritional Quality in Food Standards. (Subject to endorsement by the Commission).
- Revised Proposed Standard for Cereal-Based Infant Foods.
- Draft Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction, at Step 7.
- Proposed Draft Annex on Salt Iodization to the Standard on Food Grade Salt.
- Proposed Revised Draft Standard for Gluten-Free Foods.
- Consideration of Revision of the Standard for Low-Sodium Foods.
- Review of Provisions for Vitamins and Minerals in Codex Standards.
- Proposed Draft Guidelines for Dietary Supplements, at Step 4.

DATE AND PLACE OF NEXT SESSION (AGENDA ITEM 15)

108. The Committee was informed that the 19th Session of the Committee would be held in Bonn-Bad Godesberg tentatively between the last week of September and the last week of October 1994.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by	Document Reference
Proposed Draft Standard for Formula Foods for Use in Very Low Energy Diets	5	20th CAC, Governments	ALINORM 93/26, para. 48 Appendix II
Proposed Draft Standard for Cereal-Based Infant Foods	3	Switzerland, France, USA, Governments, 19th NFSDU	ALINORM 93/26, para. 32
Proposed Draft Guidelines for Dietary Supplements	3	Germany, Governments, 19th NFSDU	ALINORM 93/26, para. 103
Appendix on Salt Iodization to Codex Standard on Food Grade Salt	3	Germany, Governments, 19th NFSDU	ALINORM 93/26, para. 56
Proposed Draft Standard for Gluten-Free Foods	3	Netherlands, USA, Governments, 19th NFSDU	ALINORM 93/26, para. 83
Provisions for Vitamins and Minerals in Codex Standards	-	France, Governments, Secretariat, 19th NFSDU	ALINORM 93/26, paras 92-93
Proposed Conditions for Descriptors of Claims for Nutrient Contents	-	CCFL	ALINORM 93/26, para. 76 Appendix III
Methods of Analysis for Use in NFSDU Standards	-	CCMAS	ALINORM 93/26, paras 96-97 and Appendix IV

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**PROPOSED DRAFT STANDARD FOR FORMULA FOODS FOR USE IN
VERY LOW ENERGY DIETS FOR WEIGHT REDUCTION
(At Step 5, Paras 33-48)**

1. **SCOPE**

This standard applies to formula foods for use in very low energy diets for weight reduction as defined in Section 2. These foods are defined as foods for special medical purposes and should be used under medical supervision. The matter of sale on prescription should be a decision made at national level.

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

2. **DEFINITION**

A formula food for use in very low energy diet is a food specially prepared to supply a minimum amount of carbohydrates and the daily requirements of the essential nutrients in 450-800 kcal which represents the sole source of energy intake.

3. **ESSENTIAL COMPOSITION AND QUALITY FACTORS**

The product as sold should comply with the following composition and quality factors:

3.1 **Energy Content**

A formula food for very low energy diets shall provide when prepared according to instructions a daily energy intake of 450-800 kcal as the only source of energy.

3.2 **Nutrients Contents**

3.2.1 **Protein**

- Not less than 50 g protein with a nutritional quality¹ equivalent to a protein-digestibility-corrected aminoacid score of 1 shall be present in the recommended daily intake of energy.
- Essential amino acids may be added to improve protein quality only in amounts necessary for this purpose. Only L-forms of amino acids shall be used, except that DL-methionine may be used.

3.2.2 **Fats**

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

3.2.3 **Carbohydrates**

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

¹ Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation, Bethesda, MD USA, 4-8 December 1989, FAO Food and Nutrition Paper No. 51, 1991, Rome, p. 23.

3.2.4 **Vitamins and Minerals**

Very low energy diets shall provide the vitamins and minerals in the recommended daily intake of energy as given below. Other essential nutrients not specified below may also be included.

Vitamins

Vitamin A	600	µg
Vitamin D	2.5	µg
Vitamin E	10	mg
Vitamin C	30	mg
Thiamin	0.8	mg
Riboflavin	1.2	mg
Niacin	11	mg
Vitamin B-6	2	mg
Vitamin B-12	1	µg
Folic Acid (as monoglutamate)	200	µg

Minerals

Calcium	500	mg
Phosphorus	500	mg
Iron	16	mg
Iodine	140	µg
Magnesium	350	mg
Copper	1.5	mg
Zinc	6	mg
Potassium	1	g
Sodium	1.6	g

3.3 **Ingredients**

Very low energy diets shall be prepared from protein constituents of animal and/or plant which have been proved suitable for human consumption and from other suitable ingredients necessary to achieve the essential composition of the product as set out in Sections 3.1 and 3.2 above.

4. **FOOD ADDITIVES**

Food additives cleared by the Joint FAO/WHO Expert Committee on Food Additives shall be permitted at levels endorsed by the Codex Committee on Food Additives and Contaminants.

5. **CONTAMINANTS**

5.1 **Pesticide Residues**

The product shall be prepared with special care under good manufacturing practices, so that no residues of pesticides, which may be required in the production, storage or processing of the raw materials or the finished food ingredient, remain in the product, or, if technically unavoidable, are reduced to the maximum extent possible, and shall comply with those maximum residue limits established by the Codex Committee on Pesticide Residues for this commodity.

5.2 **Other Contaminants**

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

6. **HYGIENE**

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

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

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

7. **PACKAGING**

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

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

8. **FILL OF CONTAINER**

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

- (a) Not less than 80% v/v for products weighing less than 150 g (5 oz);
- (b) not less than 85% v/v for products in the weight range of 150-250 g (5-8 oz); and
- (c) not less than 90% v/v for products weighing more than 250 g (8 oz) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.

9. **LABELLING**

In addition to the appropriate Sections of the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) and the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (in print, ALINORM 91/26, Appendix IV), the following specific provisions apply:

9.1 The name of the food shall be "Formula Food for Use in Very Low Energy Diets".

9.2 **List of Ingredients**

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

9.3 **Declaration of Nutritive Value**

9.3.1 The nutritive value shall be declared on the label per 100 grammes or 100 ml of the food as sold and, where appropriate, for a specified quantity of the food as suggested for consumption:

- (a) The amount of energy expressed in kilocalories (kcal) and kiloJoules (kJ);
- (b) the amounts of protein, available carbohydrates and fat expressed in grammes;
- (c) the amounts of vitamins and minerals in Section 3.2.4 expressed in metric units;
- (d) the amounts of other nutrients may also be declared.

9.3.2 If the fatty acid composition is declared on the label, it should be done in accordance with the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985).

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

9.4 Date Marking

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

9.5 Storage Instructions

9.5.1 Un-opened Food

Any special conditions for the storage of the food shall be declared on the label if the validity of the date depends thereon. Storage instructions of opened packages of the food shall be included on the label to ensure that the opened food maintains its wholesomeness and nutritive value. A warning should be included on the label if the food is not capable of being stored after opening or is not capable of being stored in the container after opening.

9.6 Information for Utilization

In addition to the appropriate sections of the Codex Standard on the Labelling of and Claims for Foods for Special Medical Purposes, the following directions should be provided:

- The statement "for the dietary treatment of obesity" shall be declared on the label, in close proximity to the name of the food.
- Reference to the importance of maintaining adequate daily fluid intake.
- A statement that the product should not be used by pregnant, nursing and lactating women or by infants, children, adolescents and elderly.

9.7 Additional Provisions

A statement that the product may not be recommended for use for purposes other than the dietary management of obesity.

The statements with respect to the name of the food and the indications for use as given in Sections 9.1 and 9.6 shall appear on the label of the package and/or sachet for use by the consumer. Other statements, as required under Section 9.6 above and Section 4.5 of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes, may appear on an accompanying leaflet in which case reference shall be made to this fact on the label of the package and/or sachet.

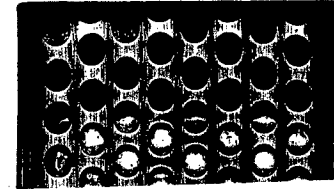
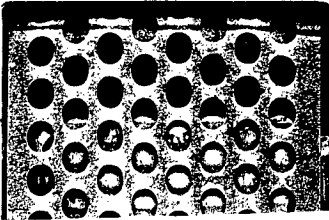
**PROPOSED CONDITIONS FOR DESCRIPTORS OF CLAIMS FOR
NUTRIENT CONTENT
(Paras 57-76)**

<u>COMPONENT</u>	<u>CLAIM</u>	<u>CONDITIONS</u>
A. Energy	Low	Less than: 40 kcal (170 kJ) per 100 g. (solids) or 20 kcal (80 kJ) per 100 ml (liquids)
Fat	Low	Less than: 3 g per 100 g solid 1.5 g per 100 ml liquid
	Free	0.15 g per 100 g or ml
Saturated Fat	Low	[Less than: 1.5 g Saturates/100 g solid] [0.75 g Saturates/100 ml liquid] [10% of energy]
Cholesterol	Low	Less than: 20 mg/100 g. product solid 10 mg/100 ml product liquid
		Together with Less than: 1.5 g Saturates/100 g solid 0.75 g Saturates/100 ml liquid [10%] of energy derived from saturates
Sugar	Free	Less than: 0.5 g per 100 g 0.5 g per 100 ml
Sodium	Low	Less than: 120 mg per 100 g
	[Very Low]	[40 mg per 100 g]
	[Free]	[5 mg per 100 g]
B. Fibre	Source High	Not less than: [2 g. per serving] [4 g. per serving]
Protein	Source High	Not less than: [10% of reference RDA/100 g of food] [20% of reference RDA/100 g of food]
Vitamins and Minerals	Source High	Not less than: [10-15% of reference RDA/100 g of food] [20-30% of reference RDA/100 g of food]

ANALYTICAL METHODS FOR WHICH FURTHER ACTION IS INDICATED (Paras 94-97)

	PROVISION	STANDARD(S)	METHOD/REFERENCE	TYPE/STATUS
1.	<u>BIOTIN VITAMIN H</u> 1.5µg/100Cal	Infant Formula (72-1981) and Follow-up formula (156-1987)		To be developed
2.	<u>CHOLINE</u> 7mg/100Cal	Infant formula and Follow-up formula		To be developed
3.	<u>DIETARY FIBER</u> (Total) <u>3.1-Carbohydrates</u> Direct	Infant formula and Follow-up formula	AOAC 991.43 ¹ - Enzymatic, Gravimetric.	To be developed
4.	<u>IODINE</u> 5µg/100Cal 150µg/100g	Infant and follow-up formula, Weight control diet (CAC/181) Cereal-based foods (CX/NFSDU 92/4)	AOAC 992.24 ¹ - (milk based)	To be developed
5.	<u>LOSS ON DRYING</u>	All special Foods Standards	AOAC 925.23 ¹ - (milk)	Others to be developed
6.	<u>PANTOTHENIC ACID</u>	Infant formula and Follow-up formula	1. AOAC 992.07. 2. The Analyst 89 (1964) (1); 3-6; ibid, 232; or U.S. Dept. of Agr. Agr. Handbook 97 (1965) (non-enriched)	IV
7.	<u>VITAMIN A</u> 75-150µg/100Cal (400-100µg/100g)	Infant Formula, Follow-up formula	AOAC 992.06 Retinol 992.04 Retinol-isomers AOAC 941.15 (where carotenes have been used as source) (spectrophotometric)	IV
8.	<u>VITAMIN D</u> 40-80mg/100Cal	All special Foods Standards	AOAC 974.29 (colorimetric) Vit. D2 AOAC 992.26 Vit. D3, Milk Based Infant Formula	IV. To be developed.

¹ AOAC (15th Ed.).



	PROVISION	STANDARD(S)	METHOD/REFERENCE	TYPE/STATUS
9.	<u>VITAMIN E</u>	All special Food Standards	AOAC 971.30 992.03 - Milk Based Infant Formula	IV, (Matrix effects)
10.	<u>VITAMIN K₁</u>	Infant formula Follow-up formula	AOAC 992.27	
11.	<u>CALCIUM AND MAGNESIUM CONTENT</u>	Foods with low sodium content including salt substitutes (CODEX STAN 53-1981)		To be developed
12.	<u>AMMONIUM CONTENT</u>	Provisions 11-14 refer <u>exclusively</u> to salt substitutes		To be developed
13.	<u>PHOSPHORUS CONTENT</u>			To be developed
14.	<u>CHOLINE</u>			To be developed
15.	<u>GLUTEN CONTENT</u>	Gluten-free Foods (118-1981)		See para. 97
16.	<u>POLYUNSATURATED FAT</u>	Guidelines for Nutrition Labelling (CAC/GL 2-1985)		See para. 97
17.	<u>SATURATED FAT</u>			See para. 97
18.	<u>SUGARS</u>			See para. 97
19.	<u>ORGANIC ACIDS</u>			