codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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ALINORM 95/26

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-first Session
Rome, 3 - 8 July 1995

REPORT OF THE NINETEENTH SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Bonn-Bad Godesberg, Germany
27 - 31 March 1995

Note: This document incorporates Circular Letter 1995/12-NFSDU

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CX 3/15.2

CL 1995/12-NFSDU
April 1995

TO:
- Codex Contact Points
- Participants at the 19th 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, 00100 Rome, Italy

SUBJECT: Distribution of the Report of the Codex Committee on Nutrition and Foods for Special Dietary Uses

A) MATTERS FOR ADOPTION BY THE 21st SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Draft Standard at Step 8 of the Procedure

1. Draft Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction (para. 31, Appendix II)

Governments wishing to propose amendments or comments should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 (see Procedural Manual of the Codex Alimentarius Commission, pp.33-35) to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, via delle Terme di Caracalla, 00100 Rome, Italy, **before 15 June 1995**.

Name of the Committee

2. Proposal to change the name of the Committee into "Codex Committee on Nutrition" (para. 80)

Governments wishing to comment on this proposal should do so in writing to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO via delle Terme di Caracalla, 00100 Rome, Italy, **before 15 June 1995**.

Proposed Draft Guidelines at Step 5 of the Procedure

3. Table of Conditions for Claims for Nutrient Contents, to be included in the Proposed Draft Guidelines for Use of Health and Nutrition Claims (para. 14, Appendix III)

Governments wishing to submit comments on the implications which the above document may have for their economic interests should do so in writing in conformity with the Procedure for the Elaboration of Worldwide Standards at Step 5 to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, via delle Terme di Caracalla, 00100 Rome, Italy, **before 15 June 1995**.

Note: The text of the Proposed Draft Guidelines, elaborated by the CCFL was circulated in November 1994 for comments at Step 5

In relation with the values proposed in the Table for fat content and in the light of the discussions of the Committee (para. 88), governments are also invited to present information and comments on issues associated with the presence of trans-fatty acids, for further consideration by the CCNFSDU and CCFL.

B. REQUEST FOR COMMENTS AND INFORMATION

Proposed Draft Amendment at Step 3 of the Accelerated Procedure

4. Proposed Draft Amendment to the Standard for Infant Formula: Amount of Vitamin B_{12} (para. 60, Appendix IV)

Subject to confirmation by the 21st Session of the Commission, the Proposed Draft Amendment is hereby circulated for comments at Step 3 of the Accelerated Procedure. Governments wishing to submit comments on all aspects of the Amendment, including possible implications for their economic interests should do so in writing to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, via delle Terme di Caracalla, 00100 Rome, Italy, **before 15 June 1995**.

Proposed Draft Standards and Guidelines at Step 3 of the Procedure

5. Proposed Draft Revised Standard for Food Grade Salt (para. 42)

6. Proposed Draft Revised Standard for Gluten-Free Foods (para. 54)

7. Proposed Draft Guidelines for Dietary Supplements (para. 49)

8. Proposed Draft Revised Guidelines on the Inclusion of Provisions on Nutritional Quality in Codex Standards (para. 72)

Note: A specific Circular Letter inviting comments at Step 3 on the document will be issued separately (CL 1995/18-NFSDU)

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 19th Session of the Committee on Nutrition and Foods for Special Dietary Uses are as follows:

Matters for adoption by the Commission:

The Committee:

- agreed to advance to Step 8 the Draft Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction (para. 31, Appendix II)

- agreed to propose that the name of the Committee become "Codex Committee on Nutrition" (para. 80)

- agreed to use the Accelerated Procedure for a Proposed Draft Amendment to the Standard for Infant Formula (Vitamin B_{12}) (para. 60, Appendix IV)

- agreed on a Table of Conditions for Claims for Nutrient Content, to be included in the Proposed Draft Guidelines for Use of Health and Nutrition Claims (para. 14, Appendix III)

Other Matters of Interest to the Commission

The Committee:

- proposed that the Guidelines for Formulated Foods and the Standard for Processed Cereal-Based Foods remain separate and that the Standard be revised (para. 36)

- proposed to proceed with the revision of the Guidelines for the Inclusion of Provisions on Nutritional Quality (para. 72) and to initiate work on the following matters:

  - Revision the Standard for Infant Formula (para. 90)
  - Dietary modelling (para. 91)
  - Vitamins and minerals in foods for medical purposes (para. 92)

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INTRODUCTION

1. The Codex Committee on Nutrition and Foods for Special Dietary Uses held its Nineteenth Session in Bonn-Bad Godesberg, from 27 to 31 March 1995 by courtesy of the Government of Federal Republic of Germany. The Session was chaired by Professor Dr. Dr. h.c. Arpad Somogyi, Director of the Federal Office for Consumer Protection and Veterinary Medicine (BgVV). The Session was attended by 150 participants representing 34 member countries and 16 international organizations. The list of participants is attached to this report as Appendix I.

OPENING OF THE SESSION (Agenda item 1)

2. Dr. W. Hölzel, Director, Federal Ministry of Health, opened the Session, welcoming the participants on behalf of the Federal Minister of Health, and stressed that the Codex Alimentarius Commission was the only international organization in the field of food standardization, providing a forum where Member Countries could exchange information, and furthering the harmonization of food legislation. He recalled that specific reference was made to Codex in the GATT/WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS); it was essential that Codex standards and related texts should be based on science and integrate the latest technological developments, while taking into account consumer protection.

ADOPTION OF THE AGENDA (Agenda item 2)

3. The Committee adopted the Provisional Agenda (CX/NFSDU 95/1), and agreed to allow the presence of the press and one industry observer.

MATTERS REFERRED TO THE COMMITTEE BY THE COMMISSION AND OTHER CODEX COMMITTEES (Agenda item 3)[1]

Proposed Draft Guidelines for Use of Health and Nutrition Claims

4. The Committee recalled that the last session had considered the conditions for claims for nutrient content (such as "low", "high" or "source"), as this was its specific responsibility in the development of the Guidelines, and proposed a tentative list of values for certain nutrients (Appendix III, ALINORM 93/26). Following the decision of the 23rd CCFL Session to advance the Proposed Draft Guidelines to Step 5, the Committee reviewed and amended the Conditions for Claims for Nutrient Content as follows.

Saturated fats: "low"

5. The Committee agreed to require both a maximum level of saturated fats and a maximum percentage of total energy.

Cholesterol : "low"

6. The Committee confirmed its earlier decision to set a maximum level of cholesterol together with a maximum level of saturated fats.

7. The Delegation of Canada proposed to reintroduce the claim "cholesterol free", which had been deleted at the last session (ALINORM 93/26, para. 67) and the Committee had an extensive exchange of views on the inclusion of this claim in the Table. Some Delegations were of the view that a definition was needed as the claim was commonly used on the market and should be regulated; other delegations and the Observer from Consumers International considered that the claim was not significant from the nutritional point of view and likely to mislead the consumer. It was also noted that Section 4.2 of the Proposed Draft

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[1] CX/NFSDU 95/2

Guidelines addressed the question of claims for foods inherently free or low in a nutrient. The Committee agreed to keep the Table as currently drafted and to retain an open list of claims for nutrient content. The Chairman pointed out that questions concerning labelling provisions should be referred to the CCFL.

Sodium

8. Some delegations questioned the need for the "very low" claim. The Delegation of the United Kingdom expressed the view that the claim for "low" should correspond to 40 mg/100g. However, the Committee agreed to keep the current definitions as a compromise solution.

Fibre - Protein

9. The Committee had an exchange of views on the levels to be proposed, and also noted the difficulties associated with the definition of fibre and the methods of analysis for its determination.

10. The Committee proposed to describe "source" (of fibre) as a minimum of 3 g/100 g or 1.5 g/ 100 kcal and "high" as 6 g/100 g or 3 g/100 kcal.

11. The Committee agreed to describe "source" (of protein) as 10% of the NRV/100 g for solids or 5% of the NRV for liquids and products with a high water contents (75-80%), or 5% of the NRV/100 kcal.

12. The Committee agreed to retain both sets of values in square brackets. The Delegation of the United States expressed its disagreement with the values proposed for Fibre and Protein.

Vitamins and Minerals

13. The Committee proposed to describe "source" as not less than 15% of the NRVs/100 g for solids, 7.5%/100 ml (liquids) or 5% of the NRV/100 kcal; the values for "high" should be in the range of 2 to 3 times the "source" value. As further consideration of these proposals would be required, it was agreed to keep them in square brackets.

14. The Committee agreed to propose the amended Table, attached as Appendix III, for inclusion in the Proposed Draft Guidelines on Health and Nutrition Claims.

Comparative Claims

15. The Committee noted that the CCFL had asked for advice on Section 5.4 of the Guidelines referring to numerical values for "reduced" or "increased".

16. Some delegations expressed the view that a reduction of 25% was not significant and proposed a higher figure. Other delegations felt that the level proposed was only a minimum and did not preclude the possibility to base the comparison on a higher level if needed; a higher value would also reduce the availability of foods with reduced or increased levels of specific nutrients.

17. In reply to a question on conditions for comparative claims, the Secretariat indicated that the CCFL had considered these issues in detail and included relevant provisions in Sections 5.1 to 5.3. The Committee noted that the figures for reduction or increase should be based on a specific quantity of foods.

18. The Committee agreed to retain the values of 25% (energy or macronutrient) and 10% (micronutrient) when a claim for "reduced" or "increased" was made. The Committee noted that in certain countries "light" implied a greater reduction and was equivalent to "low". It was, however, noted that the mandate of the Committee was to consider numerical values and that comments on the labelling aspects of the Guidelines should be made to the CCFL. The Committee therefore proposed to the CCFL the deletion of the term "light" in conjunction with "reduced" as these terms were not equivalent and their interchangeable use might mislead the consumer.

19. The Committee noted that, following the decisions taken by the CCFL, there was no specific action required concerning the Standard for Low Sodium Foods.

20. It was noted that the CCFL had referred to the Committee the request of the Delegation of Malaysia for the declaration of trans-fatty acids (see Agenda item 15 - Other Business).

Labelling of Foods which can cause hypersensitivity

21. The Committee was informed of the work of CCFL on the Labelling of Foods which can Cause Hypersensitivity; a proposal for the revision of the General Labelling Standard ("25% rule") and a list of substances that can cause severe reactions were under consideration. An information paper on the subject, prepared by the Delegation of Sweden, was also available. The CCFL had agreed to seek the advice of the Committee on the substances to be included in the list and the criteria for them to be included. The Committee, feeling that further consideration of this complex issue was required, welcomed the offer of the Delegation of France to prepare a paper for circulation and consideration by the next session.

DRAFT STANDARD FOR FORMULA FOODS FOR USE IN VERY LOW ENERGY DIETS FOR WEIGHT REDUCTION (Agenda item 4)

22. The Committee considered the comments received at Step 6 in reply to CL 1992/27 and 1993/27[2] and agreed to the following amendments.

1. Scope

23. The Committee agreed that these foods *must* be used under medical supervision (instead of "should") and to add "by individuals with moderate or severe obesity" at the end of the second sentence. The Committee, however, decided not to include a reference to BMI and to contraindications for use as the amended wording adequately covered these issues.

2. Definition

24. The Delegation of Germany preferred the energy range of 600-800 kcal, considering that products providing less than 600 kcal had caused sudden deaths due to cardiac failure in young women and increased the risk of osteoporosis. Several other delegations pointed out that nutritionally complete products with high quality protein in a range of 450-600 kcal were not associated with serious hazards. These delegations also noted that the products causing serious illness were nutritionally incomplete and contained protein of low biological quality. While noting differences in interpretation of the same data, the Committee was informed that calcium depletion occurred with weight loss regardless of the energy value of the diet. The Committee agreed to maintain the current range. The Delegation of Germany expressed its reservation on this decision.

3.2.1 Protein

25. The Committee noted that high quality protein should be used and decided to maintain the original text on protein. The Delegation of Canada stated that as high quality protein was required, supplementation with essential amino acids would not necessarily result in high quality protein and should not be included. The Committee however decided to retain the current text on amino acids to allow flexibility in formulation.

3.2.2 Fat

26. The Committee agreed to add a reference to α-linolenic acid (one of the essential fatty acids) as well as a ratio of linoleic acid to α-linolenic acid, and to delete the word "of energy" after "dietary intake".

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[2] CX/NFSDU 95/3 (Australia, Spain, Mexico, Germany, Thailand, Denmark, Sweden, Norway, IDF) and Add.1 (ISDI), CRD 1-rev (USA), CRD 4 (CI), CRD 9 (Canada)

3.2.3 Carbohydrates

27. Although some delegations proposed to change the minimum level to 30 g of available carbohydrates, the original value of 50 g was retained.

3.2.4 Vitamins and Minerals

28. The values for potassium and sodium were corrected to 1.6 g and 1 g respectively. The Committee noted that other micronutrients may need to be included in the list. It was noted that, as very low energy diets may be the only source of energy for a relatively long period, they should provide 100% of the Nutritional Reference Values (NRV). The Delegation of the USA indicated that NRVs were usually higher than nutritional requirements and therefore preferable. The Committee however recalled that NRVs were defined for nutritional labelling purposes only and not for the formulation of foods. The Representative of WHO indicated that WHO would shortly publish *Trace Elements in Human Nutrition* (in press) and *Report of WHO/FAO Consultation on Development of Food Based Dietary Guidelines* (including an Annex on Vitamins and Minerals) (in preparation). The Committee decided to include a reference to 100% of the recommended daily intakes and to keep the current list with a footnote stating that the values should be reviewed when new WHO/FAO recommendations became available. Some delegations expressed the view that maximum levels should be set for vitamins and minerals and it was agreed that this issue would be discussed again in the future.

4. Food Additives

29. The Observer of ISDI stated that a list of food additives was needed. The Committee decided to retain the present wording.

9.6 Information for Utilization

30. The Committee decided to change the term "dietary treatment" to "dietary management" to agree with section 4.5.1 of the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 189-1991). After extensive discussion on whether to delete the third indent in view of the requirement for medical supervision, the Committee decided to add at the end "except when medically indicated".

Status of the Draft Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction

31. The Committee decided to advance the Draft Standard to Step 8 (attached as Appendix II) for adoption by the 21st Session of the Commission, with the understanding that Section 3.2.4 Vitamins and Minerals should be reviewed when new WHO/FAO recommendations became available.

PROPOSED DRAFT REVISED STANDARD FOR FORMULATED SUPPLEMENTARY FOODS AND IN PARTICULAR PROCESSED CEREAL-BASED FOODS (Agenda item 5)

32. The Delegation of Switzerland presented the revised document and recalled the decision of the Commission to combine the Guidelines for Formulated Supplementary Foods for Older Infants and Young Children and the Standard for Processed Cereal-Based Foods for Infants and Children. Following consideration of the first draft by the 18th CCNFSDU Session, the text had been redrafted by Switzerland (CX/NFSDU 94/4), and circulated for comments at Step 3.[3]

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[3] CX/NFSDU 95/4-Add.1 (Denmark, Germany, ISDI) and Add. 2 (France, Hungary), CRD 1 (USA), CRD 2 (Costa Rica), CRD 5 (EC), CRD 7 (Mexico), CRD 8 (Australia), CRD 10 (Canada)

33. Although the Committee generally agreed on the need to revise the current Standard, there was extensive discussion on the Scope of the revised text. Several delegations felt that no mention should be made of the use of cereal-based foods before 6 months, in view of the resolution of the World Health Assembly that exclusive breast-feeding should be recommended until the age of 4-6 months, and from the age of about 6 months appropriate complementary feeding practices should be introduced, emphasizing continued breast-feeding and frequent feeding with safe and adequate amounts of local foods. The Delegation of India, supported by several countries, indicated that intensive national campaigns for breast-feeding were under active implementation and no possibility should be left to alter the interpretation of the WHO recommendation concerning the weaning age.

34. Several delegations pointed out that the purposes of the Guidelines and Standard were different, resulting in different ages for the introduction of foods, as indicated in the Description. The Representative of WHO indicated that because different objectives and population groups were targeted, two separate texts were clearly required.

35. Other delegations and the Observer from Consumers International suggested that as health concerns for allergies were identical for all groups, a general limit of 6 months should be applied, in which case the Guidelines and Standard could be integrated. The Observer from the EC stated that cereal-based foods could be used from 4 months of age in the EC, and that labelling information was required concerning gluten content if the product was marketed for use below the age of six months. The Observer from AOECS pointed out that cereal-based foods should not be introduced before 6 months in view of the risks of gluten intolerance, as the hazard would be greater at 4 months.

36. The Committee agreed to propose to the Commission that the Guidelines and the Standard remain separate, and that the Standard be revised. Should the Commission confirm this decision, a Circular Letter would be sent to request comments on the current standard.

PROPOSED DRAFT APPENDIX ON SALT IODIZATION TO THE STANDARD ON FOOD GRADE SALT (Agenda item 6)

37. The Committee recalled that its last Session had considered the iodization of salt to prevent iodine deficiency disorders and accepted the proposal of the German Delegation to draft an Annex to the Codex Standard for Food Grade Salt (CODEX STAN 150-1986) which had been developed by the Codex CCFAC. While introducing the Amendment of the Codex Standard for Food Grade Salt to Include the Iodization of Salt (CX/NFSDU 95/5) and government comments[4], the Delegation of Germany stated that as the rates of iodine deficiency and salt consumption differed from country to country, the establishment of maximum and minimum levels should be left to national authorities. For the purpose of salt iodization, the 37th JECFA Session had concluded that potassium iodate was more suitable than potassium iodide. The German Delegation further indicated that studies conducted in Germany and in the Wageningen Agricultural University (Netherlands) showed that, so far, iodization with potassium iodate did not cause significant negative effects on the taste or colour of salt.

38. In relation to the safety of iodate and iodide, the Representative of WHO informed the Committee that WHO had recently published a booklet, "Iodine and Health", to assist countries in setting an adequate level of fortification, and mentioned a UNICEF/University of Wageningen project, currently collecting data on the effect of iodate or iodide on certain processed foods.

3.4 Iodization of food grade salt

39. The Committee agreed to switch the positions of "in iodine-deficient areas" and "for public health reasons" in order to avoid suggesting that salt iodization was required everywhere, and to change the term "endemic goitre" to "iodine deficiency disorders".

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[4] CX/NFSDU 95/5-Add.1 (France), CRD 1-rev. (USA)

40. The Delegation of France proposed to include minimum and maximum iodine levels of 75 and 150 μg/day. The Committee decided not to do so as the level of fortification should be established by the national health authorities.

41. In response to an inquiry from the Delegation of Indonesia on the technological aspects of iodized salt in fats and oils the Delegation of the Netherlands indicated that this issue was under study by Wageningen University and invited governments to send available information to the University. The Delegation of India informed the Committee that the marketing of non-iodized salt was banned in many states in India, which ensured successful prevention of iodine deficiency. As smaller manufacturers found it extremely difficult to meet the minimum level of 97% sodium chloride, the Delegation raised the possibility of lowering the level to 96%. However, as the mandate of the Committee only covered salt iodization, whereas composition and quality criteria were under the responsibility of the Committee on Food Additives and Contaminants, it was agreed to forward the suggestion from India to the CCFAC.

Status of the Proposed Draft Revised Standard for Food Grade Salt

42. The Committee agreed to circulate the amended Proposed Draft Standard for government comments at Step 3, and to forward it to the CCFAC.

PROPOSED DRAFT GUIDELINES FOR DIETARY SUPPLEMENTS (VITAMINS AND MINERALS) (Agenda item 7)

43. The Delegation of Germany introduced document CX/NFSDU 95/6[5] which had been prepared following extensive discussions held at previous sessions, and included a background paper giving the rationale for the actual Guidelines.

44. The Committee accepted the proposal of the Observer from Consumers International to include a Preamble to the effect that most people have access to a balanced diet, and should be encouraged to select such a diet from food before considering any supplements.

45. The Delegations of the United States and the United Kingdom were not favourable to the development of such guidelines, as they felt a prescriptive text was not needed in this area. Many delegations however stressed the necessity for an international reference for dietary supplements, as they were widely traded, and the Committee agreed to proceed with its work on the Guidelines.

46. The Committee agreed to delete the reference to nutrients, as the Guidelines should apply only to vitamins and minerals presented as such. The Committee discussed the classification of dietary supplements, as some delegations regarded them as foods, which should be regulated as such, while other delegations felt that they would be more adequately described as drugs or foods for special dietary uses. This also raised questions of competence as to the monitoring of such products by regulatory authorities. As drugs were not covered by the mandate of the Commission, the Committee agreed to delete the reference to drugs in the definition (2.3). The Delegations of Denmark and the United States did not agree to this deletion as they felt the distinction between foods and drugs should be made clear.

47. The Committee agreed to delete Section 8.5 concerning claims for the prevention or curing of a disease, as this was already covered by the General Guidelines on Claims (Prohibited Claims).

48. It was pointed out that the text was in the format of a standard; however, the Committee confirmed its earlier decision to develop it as guidelines. The Committee agreed that the CL requesting comments at Step 3 should ask for specific information on the additives used in such foods and their technological justification.

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[5] Comments in CRD 1 (USA) and 4 (CI)

Status of the Proposed Draft Guidelines for Dietary Supplements (Vitamins and Minerals)

49. The Committee agreed to circulate the amended Proposed Draft Guidelines and background document for government comments at Step 3.

PROPOSED DRAFT REVISED STANDARD FOR GLUTEN-FREE FOODS (Agenda item 8)

50. The Committee recalled that its last session had accepted the offer of the Delegations of the Netherlands and USA to prepare a revised draft of the current standard, which would include a limit of [10mg prolamin/100 g].

51. While introducing the Proposed Draft Revised Standard[6], the Delegation of the Netherlands indicated that the limits for gluten applied to the end product because contamination was a major source of gluten in these foods. The maximum level of 200 ppm of gluten had been selected as 200 ppm was equivalent to 100 ppm of gliadin; the intake of 10 mg prolamin/day should not be exceeded by susceptible groups; no validated methods existed with a limit of determination below 160 ppm. It was noted that the determination of total nitrogen in the end product was not useful because of the possible presence of various nitrogen compounds, ELISA methods should therefore be used to determine gluten/gliadin.

2.1 Definition

52. The Committee discussed two sets of definitions: one contained in CX/NFSDU 95/7 and the other proposed by AOECS, which included foods naturally free from gluten. Some delegations were in favour of the AOECS proposal whereas other delegations were of the view that "gluten-free foods" should only include foods which had been rendered "gluten-free". The Committee decided to include both definitions in square brackets for further consideration, and noted that the AOECS definition would entail consequential changes to the Standard.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

53. Several delegations considered that the maximum level of 200 ppm was too high to protect susceptible populations and supported lower values, and in one instance, zero. The Delegation of Sweden indicated that reactions in extreme cases could be due to other hypersensitivity reactions (e.g. wheat allergy) and not gluten intolerance. Other delegations preferred to keep the current level (0.3% protein in dry matter) as products manufactured according to the Standard had not generally caused serious adverse effects in celiac patients, and 200 ppm was technologically difficult to meet. The Committee also noted differences in the interpretation of "0.3 g protein", and in the tolerance to gluten of celiac patients. After extensive discussion, the Committee decided to put 200 ppm in square brackets.

Status of Proposed Draft Revised Standard for Gluten-Free Foods

54. The Committee decided to return the Proposed Draft Revised Standard to Step 3 for further comments.

REVIEW OF PROVISIONS FOR VITAMINS AND MINERALS IN CODEX STANDARDS (Agenda item 9)

55. The Committee recalled that the last session had decided to review and update the provisions for vitamins and minerals in the light of new data and international recommendations, and considered government comments in reply to Cls 1992/27 and 1993/27-NFSDU[7]

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[6] CX/NFSDU 95/7, Step 3 comments in CX/NFSDU 95/7-Add.1 (France, AOAC, AOECS), CRD 1-rev. (USA), 4 (CI), 11 (Canada), 12 (Sweden), 16 (Thailand)

[7] CX/NFSDU 95/8-I (Australia, Germany, Hungary, New Zealand, Spain, Thailand, USA)

56. The Observer from the EC informed the Committee that the Scientific Committee for Foods had established values for reference intakes for nutrients and lower values for labelling purposes, as the objectives were different. Some delegations pointed out that a document was needed for discussion, in view of the existing data and recommendations existing at the national and international levels.

57. The Committee discussed the purpose of the review of vitamins and minerals and identified two separate issues: the establishment of nutrient requirements, which would be achieved through an Expert Consultation at the international level, and the definition of NRVs for labelling purposes. The Representative of WHO recognized there was an urgent need to update the recommendations, and it was agreed to draw the attention of FAO and WHO to this issue. The Secretariat pointed out that joint FAO/WHO expert consultations were subject to the Rules of the parent organizations, and such a request was not within the competence of the Committee.

58. It was agreed that the updating of NRVs could be addressed within the framework of the Committee, through the establishment of criteria for the definition of NRVs and consideration of the existing data on their values. The Committee welcomed the offer of the Delegation of France to prepare a paper for consideration by the next session, in cooperation with interested delegations. It was agreed that an informal Working Group would meet during the session to consider this question.

Vitamin B_{12}: Comment paper of France

59. While introducing document CX/NFSDU 95/8-II, Professor Rey (France) pointed out that the FAO/WHO recommendation to lower the safe level of intake from 0.3 to 0.1 μg/day for infants was based on limited and outdated evidence concerning correction of the deficiency, and did not provide an adequate safety margin. In view of more recent studies and recommendations in different countries, the present level applying to Infant Formula (0.15 μg/100 kcal) could be reduced to 0.05 μg/100 kcal. Other delegations and the Observer from the EC did not support this value for vitamin B_{12} and recommended 0.1 μg/100 kcal. The Delegation of France agreed to this proposal. The Committee agreed on the value of 0.1 μg/100 kcal and decided to amend the Standard for Infant Formula accordingly.

Status of the Proposed Draft Amendment to the Standard for Infant Formula

60. As it was noted that the Accelerated Procedure was applicable in the case of new scientific information or revision of standards and in view of the non-controversial nature of the proposal, the Committee agreed to circulate the Proposed Draft Amendment (attached as Appendix IV) at Step 3 of the Accelerated Procedure, subject to confirmation by the Executive Committee and the Commission.

DEVELOPMENT OF GUIDELINES ON THE FORTIFICATION REQUIREMENTS OF LOWER FAT PRODUCTS (Agenda item 10)

61. The Committee recalled that its 18th Session had agreed to develop guidelines on the fortification requirements of lower fat products and accepted the offer of the Delegations of Germany and France to prepare a paper for comments[8] and consideration by the present session.

62. While introducing the document it had prepared (CX/NFSDU 95/10), the Delegation of Germany pointed out that in developed countries, it was generally recommended to reduce the intake of fat in order to reduce energy intake and to shift the intakes of protein, fat and carbohydrates toward a more balanced ratio. It was suggested that because obese persons might generally prefer a high fat diet, it would be more effective to reduce fat intake rather than carbohydrate intake for weight loss purposes, and lower fat products may therefore be helpful. Notwithstanding, technological limitations and nutritional considerations limited the use of nutritive fat replacers to certain foods.

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[8] CX/NFSDU 95/10-Add.1 (France, Hungary), CRD 1-rev. (USA), CRD 4 (Consumers International), CRD 16 (Thailand)

63. The Delegation of Germany indicated that there was no reason to fear that the population in developed countries would suffer from an inadequate intake of necessary nutrients due to the consumption of lower fat products, and concluded that it seemed premature at this stage to elaborate general guidelines. There was wide support for this conclusion. While not opposing it, the Observer from Consumers International supported the recommendation for further studies of consumer behaviour (section II E). Some delegations stressed the need to consider the situation in developing countries. The Observer from AOECS pointed out the risk of increased gluten intake due to the replacement of fat with carbohydrates in reduced-fat foods.

CONSIDERATION OF THE NEED FOR AND NATURE OF GUIDELINES ON THE USE OF NON-NUTRITIVE FAT REPLACERS (Agenda item 11)

64. The Committee recalled that its 18th Session had agreed to consider the need for and nature of guidelines on the use of non-nutritive fat replacers and accepted the offer of the Delegations of Germany and France to prepare a paper for comments[9] and consideration by the present session.

65. While introducing document CX/NFSDU 95/10, which it had prepared, the Delegation of Germany indicated that although the document was one year old and did not reflect the latest information on toxicological evaluation of some fat replacers, its basis was still valid. The Delegation recommended that guidelines for nutritive fat replacers already marketed be elaborated; the use of fat replacers should be limited to certain population groups which could benefit from reduced-fat diets, while sufficient information about the importance of low fat diets should be provided to consumers at the national level; and products as formulated and consumed should be thoroughly examined. The Delegation concluded that the elaboration of guidelines for non-nutritive fat replacers should be postponed.

66. There was wide support for the conclusion presented by Germany as most delegations were of the opinion that there were insufficient data for the elaboration of such guidelines. It was however agreed that this issue should be reviewed when further information became available. The Delegation of Malaysia and the Observer from Consumers International pointed out that some products were already under development and would soon be marketed and traded internationally, and guidelines were needed in order to protect consumers. The Delegation of Thailand indicated that there was no problem of excessive fat intake in Thailand and therefore fat replacers would prove more detrimental than beneficial if marketed there.

67. The Committee had an exchange of views to determine whether non-nutritive fat replacers were novel foods or food additives and noted that it was within the competence of JECFA to evaluate such substances.

68. The Committee decided to postpone the elaboration of guidelines on the use of fat replacers until sufficient information became available.

DRAFT REVISED GUIDELINES FOR THE USE OF CODEX COMMITTEES ON THE INCLUSION OF PROVISIONS ON NUTRITIONAL QUALITY IN FOOD STANDARDS AND OTHER CODEX TEXTS (Agenda item 12)

69. The Delegation of Canada introduced document CX/NFSDU 95/11 prepared at the request of the last session and outlined the amendments proposed to allow for more flexibility in the elaboration of standards to address nutritional concerns. The Committee agreed on the importance of referring to the total diet when considering the nutritional quality of foods.

70. The Committee decided not to include a new Section 1.4 on nutritional quality of modified versions of standardized foods, as this was adequately covered by other provisions. In Section 3.3 Nutritional Quality, the Committee agreed to add "taking into account the role of the food in the diet

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[9] CX/NFSDU 95/10-Add.1 (France, Hungary), CRD 1-rev. (USA), 4 (CI), 16 (Thailand)

of the population and national dietary guidelines". In Section 4.1.2, it was further agreed to include micronutrients and other nutrients.

71. In reply to a question, the Representative of WHO informed the Committee that the report of a Joint WHO/FAO Consultation on Development of Food-Based Dietary Guidelines would soon be published.

Status of the Proposed Draft Revised Guidelines on the Inclusion of Provisions for Nutritional Quality

72. The Committee agreed to circulate the Proposed Draft Guidelines, as amended during the session, for comments at Step 3 and to inform the Executive Committee and Commission of this new work.

TERMS OF REFERENCE AND PROGRAMME OF WORK OF THE COMMITTEE (Agenda item 13)

73. The Secretariat recalled that the last session of the Commission had agreed to amend the Terms of Reference of the Committee to strengthen its horizontal work, and had also agreed that the Secretariat should draft simplified Terms of Reference, which were presented in document CX/NFSDU 95/12. The 41st CCEXEC Session had proposed a reorganization of the work of the Committee to encompass general aspects of nutrition in Codex work, and suggested to rename it as the Committee on Nutrition and Food Composition. With reference to biotechnology, the CCFL had expressed the view that it should take the lead on all matters related to food labelling.

74. The Delegation of Germany supported the decision of the Commission to amend the Terms of Reference to allow the Committee to address all nutrition-related issues including biotechnology and novel foods, and stressed its responsibility to ensure consumer protection in this area. These views were supported by the Delegation of Canada.

75. The Committee had an exchange of views on the issue of a name which would reflect the extension of its mandate in the area of nutrition. There was general support to rename the Committee as the Committee on Nutrition. The Delegation of Poland stated that, if the name was changed, it should be made clear how the work of the Committee would be considered in the framework of Codex. The Observer from ISDI expressed the view that the current name should be retained.

76. The Delegation of Australia expressed the view that the strengthening of the horizontal work of the Committee would allow it to address more effectively issues related to consumers' health protection from the nutritional perspective in the setting of food standards. The Committee, however, noted that it should not go beyond the mandate of the Commission since issues such as public health and nutrition policy were responsibilities of WHO, FAO and national governments.

77. The Committee noted that a number of proposals had been made for the amendment of the Terms of Reference[10] and that no time had been allowed to study them. The Delegation of Canada supported the written comments of Germany to the effect that the Terms of Reference should use the same wording as other general committees. The Delegation of France pointed out that the terms of reference presented in document 95/12 should serve as a basis for discussion but that detailed discussion should be deferred until the next session, in view of the importance of this matter.

78. The Delegation of the United Kingdom, supported by the United States, Sweden, and France, expressed the view that the Committee should not be generally responsible for biotechnology, except for those issues where nutritional aspects were essential.

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[10] CX/NFSDU 95/12 (Australia, Denmark, Germany), CRD 1 (USA), CRD 4 (Consumers International), CRD 13 (France)

79. For the motives noted above, the Committee could not conduct a thorough discussion of the terms of reference and related matters; no decision could therefore be reached at this stage.

80. The Committee agreed to refer its decision to change its name into **Committee on Nutrition** to the CCEXEC and to the Commission. It was noted that comments would be requested by CL on matters referred to the Commission according to the usual procedure.

METHODS OF ANALYSIS IN STANDARDS FOR FOODS FOR SPECIAL DIETARY USES (Agenda item 14)

81. The conclusions of the *ad hoc* Working Group on Methods of Analysis (Netherlands, Sweden, UK, USA, AOAC), were presented by Mrs. Lauwaars (AOAC).

82. Although many methods had been proposed in the comments[11], most of them were either not validated or applicable only to limited matrices. The Committee proposed for endorsement by CCMAS the following validated methods: AOCS Ce 1c-89 for saturated and polyunsaturated fat for nutrition labelling, and an enzymatic method for total dietary fibre in infant formula and follow-up formula. Denmark was invited to submit the NMKL methods for nitrogen in gluten-free foods and for phosphorus in foods with low sodium content.

83. As many commodity/provision combinations still required methods of analysis, governments were encouraged to submit relevant methods to facilitate validation. The Observer from AOAC expressed her willingness to collaborate with governments and international organizations in inter-laboratory studies of the determination of gliadin/gluten.

84. The Committee noted that the Working Group on Endorsement of the Codex Committee on Methods of Analysis and Sampling had expressed the view that levels of analytes should be on a weight or volume basis rather than on a energy basis, or else that energy/weight (or volume) ratios should be specified so as to avoid interpretation problems.

85. The methods proposed for endorsement by the CCMAS are attached as Appendix V, as well as a list of commodity/provision combinations requiring methods of analysis.

OTHER BUSINESS AND FUTURE WORK (Agenda item 15)

Supplementary Foods

86. The Delegation of Norway asked for written information on the recommended age for the introduction of supplementary foods, and the Representative of WHO agreed to submit a written statement by the end of 1995, which would also reflect any new information resulting from a state-of-the-art review currently ongoing.

Trans-fatty Acids

87. The Delegation of Malaysia informed the Committee that, as presented in CRD 6, studies conducted in several countries established the health risks associated with trans-fatty acids and expressed the view that labelling of trans-fatty acids should be required; the Delegation proposed that the Committee recommend that this issue be considered by the CCFL.

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[11] CX/NFSDU 95/13 (Germany, Poland, USA, AOAC) and Add.1 (Denmark), CRD 3 (UK), CRD 17 (Thailand), in reply to CL 1994/30-NFSDU

88. The Representative of WHO informed the Committee of the conclusions of the FAO/WHO Expert Consultation on Fats and Oils in Human Nutrition[12]: "claims concerning saturated fatty acids in foods should be restricted to foods with appropriately low or limited levels of trans isomers of fatty acids". Although there had been no agreement on recommendations, the Consultation also noted that it may be useful to consider other concerns relative to labelling: "Declarations for the amount of trans isomers of fatty acids in a food, either as a separate listing or as a component of the saturated fat listing is another concern. Finally, declarations for the amount of n-3, n-6 and monounsaturated fatty acids should be considered". The Committee agreed that specific comments on this issue should be requested in the section of the Circular Letter concerning the Table of Conditions for Claims for Nutrient Content.

Health and Nutrition Claims

89. The Delegation of France recalled that the CCFL had sought the advice of the Committee on Sections 6. Nutrient Function Claims and 7. Health Claims of the Guidelines for Use of Health and Nutrition Claims, and pointed out that their validity needed to be evaluated to protect consumers against misleading claims. The Delegation suggested that specific guidelines would be useful in this respect. The Committee, however, felt that it was too early to take a decision as the Proposed Draft Guidelines were still under discussion.

Future Work

90. In addition to future work arising from the items previously discussed, the Committee agreed that a revision of the **Standard for Infant Formula** was necessary and welcomed the offer of the Delegation of the Netherlands to undertake the revision, subject to approval by the 21st Session of the Commission. A CL asking for comments on the current standard would be issued after the Commission to facilitate the revision.

91. The Delegation of Australia proposed that the Committee consider **dietary modelling**, especially the methodology for forecasting the impact of change in food composition on the potential consumption of nutrients and non-nutrients in the diet, and the Committee agreed that Australia would prepare a paper for consideration by the 20th session. The Delegations of Germany and the United States also offered to provide data on their experience to assist Australia in this task.

92. The Delegation of Germany proposed to consider the **levels of vitamins and minerals in foods for special medical purposes**, as their specific nutritional requirements should be addressed, and agreed to prepare a document on this issue for consideration by the 20th Session of the Committee.

DATE AND PLACE OF NEXT SESSION (Agenda item 16)

93. The Committee was informed that its 20th Session would be held in Bonn from 7 - 11 October 1996, subject to approval by the 21st Session of the Commission.

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[12] CRD 14 (Chapters 10 and 15 of the Report of the FAO/WHO Expert Consultation on Fats and Oils in Human Nutrition, Rome, 1993)

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by	Document Reference in ALINORM 95/26
Draft Standard for Formula Foods for Use in Very Low Energy Diets	8	Governments 21st CAC	para. 30 Appendix II
Table of Conditions for Claims for Nutrient Contents	5	Governments 21st CAC 24th CCFL	paras. 14, 88 Appendix III
Name of the Committee		42nd CCEXEC 21st CAC	para. 80
Vitamin B_{12} in Infant Formula (Proposed Draft Amendment)	3	21st CAC Governments	para. 60 Appendix IV
Proposed Draft Revised Standard for Food Grade Salt (Salt Iodization)	3	Governments CCNFSDU 28th CCFAC	para. 42
Proposed Draft Revised Standard for Gluten-Free Foods	3	Governments CCNFSDU	para. 54
Proposed Draft Guidelines for Dietary Supplements (Vitamins and Minerals)	3	Governments CCNFSDU	para. 49
Proposed Draft Revised Guidelines on the Inclusion of Provisions on Nutrition	3	Governments CCNFSDU	para. 72
Provisions for Vitamins and Minerals - as NRVs - in foods for medical purposes		 France Germany CCNFSDU	 para. 58 para. 92
Methods of Analysis		CCMAS	para. 82 Appendix V
Other matters - Dietary modelling - Revision of the Standard for Infant Formula		Australia, USA, Germany CCNFSDU Netherlands	para. 91 para. 90

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DRAFT STANDARD FOR FORMULA FOODS FOR USE IN VERY LOW ENERGY DIETS FOR WEIGHT REDUCTION
(At Step 8 of the Procedure)

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 must be used under medical supervision by individuals with moderate or severe obesity. 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 diets 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 quality [1] 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 and less than 0.5 g α-linolenic acid in the recommended daily intake with the linoleic acid/α-linolenic acid ratio between 5 and 15.

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.

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[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 100% of the recommended daily intakes for vitamins and minerals. Other essential nutrients not specified below may also be included.

Vitamins[2]

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	1.6 g
Sodium	1 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.

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[2] These lists should be reviewed when new FAO/WHO recommendations become available.

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 (CODEX STAN 180-1991), 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 management 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, except when medically indicated.

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.

TABLE OF CONDITIONS FOR CLAIMS FOR NUTRIENT CONTENT
(Proposed Draft Guidelines for Use of Health and Nutrition Claims)
(At Step 5 of the Procedure)

COMPONENT	CLAIM	CONDITIONS
A.		**Less than**
Energy	Low	40 kcal (170 kJ) per 100 g (solids) 20 kcal (80 kJ) per 100 ml (liquids)
Fat	Low	3 g per 100 g (solids) 1.5 g per 100 ml (liquids)
	Free	0.15 g per 100 g/ml
Saturated Fat	Low	1.5 g per 100 g (solids) 0.75 g per 100 ml (liquids) and 10% of energy
Cholesterol	Low	20 mg per 100 g (solids 10 mg per 100 ml (liquids) 10% of energy and less than: 1.5 g saturates per 100 g (solids) 0.75 g saturated per 100 g (liquids)
Sugars	Free	0.5 g per 100 g/ml
Sodium	Low Very Low Free	120 mg per 100 g 40 mg per 100 g 5 mg per 100 g
B.		**NOT LESS THAN**
Fibre	Source	[3 g per 100 g or 1.5g per 100 kcal]
	High	[6 g per 100 g or 3 g per 100 kcal]
Protein	Source	[10% of NRV/100 g (solids)] [5% of NRV/100 ml (liquids)] [5% of NRV/100 kcal]
	High	[20% of NRV/100 g (solids)] [10% of NRV/100 ml (liquids)] [10% of NRV/100 kcal]
Vitamins and Minerals	Source	[15% of NRV/100 g (solids)] [7.5% of NRV/100 g (liquids)] [or 5% of NRV/100 kcal]
	High	[2 or 3 times the values for "source"]

PROPOSED DRAFT AMENDMENT TO THE STANDARD FOR INFANT FORMULA (CODEX-STAN 72-1981)
(At Step 3 of the Accelerated Procedure)[1]

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

Table

Vitamin B_{12} : 0.1 μg/100 kcal (Minimum)

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[1] Subject to confirmation by the Commission

A. METHODS OF ANALYSIS FOR FOODS FOR SPECIAL DIETARY USES PROPOSED BY THE CCNFSDU

Serial No.	Commodity Standard No.	Provision Level	Method	Principle
580	Guidelines for nutrition labelling CAC/GL 2-1985	Polyunsaturated fat	AOCS Ce 1c-89	GLC
581	Guidelines for nutrition labelling CAC/GL 2-1985	saturated fat	AOCS Ce 1c-89	GLC
635	Infant formula and follow-up formula 72-1981 & 156-1987	Total dietary fibre	J. Publ. Analysts (1993) 29(2)	Enzymatic Englyst method

B. COMMODITY/PROVISION COMBINATIONS FOR WHICH METHODS SHOULD BE DEVELOPED

575	Infant formula and follow-up formula 072-1981 & 156-1987	Carbohydrate (direct)	TBD	
574	Infant formula and follow-up formula 072-1981 & 156-1987	Choline 7 mg/100 kcal	TBD	
242	Special foods 980	Biotin > 1.5 µg/100 kcal	TBD	
226	Special foods 980	Choline > 7 mg/100 kcal	TBD	
250	Special foods 980	Iodine > 5 µg/100 kcal	TBD Proposed AOAC 992.24	
585	Special foods 980	Vitamin D (D2) [40-100 i.u./100 kcal]	TBD	
241	Special foods 980	Vitamin K1 > 4 µg/100 kcal	TBD Proposed AOAC 992.27	
443	Wheat gluten 163-1987	Heavy metals	TBD Proposed AOAC 986.15	Atomic absorption spectrophotometry

B. COMMODITY/PROVISION COMBINATIONS FOR WHICH METHODS OF ANALYSIS SHOULD BE DEVELOPED

Serial No.	Commodity Standard No.	Provision Level	Method	Principle
577	Foods with low sodium content (including salt substitutes) 053-1981	Ammomium (salt substitutes)	TBD	
576	Foods with low sodium content (including salt substitutes) 053-1981	Calcium and magnesium (salt substitute)	TBD	
255	Foods with low sodium content (including salt substitutes) 053-1981	Choline (salt substitutes) < 3 % (m/m)	TBD	
578	Foods with low sodium content (including salt substitutes) 053-1981	Phosphorus (salt substitutes)	TBD	
255	Foods with low-sodium content (including salt substitutes) 053-1981	Choline < 3 % (m/m)	TBD	
579	Gluten-free foods 118-1981	Gluten	TBD	
258	Gluten-free foods 118-1981	Nitrogen No limit	TBD	
583	Guidelines for nutrition labelling CAC/GL 2-1985	Organic acids	TBD	
582	Guidelines for nutrition labelling CAC/GL 2-1985	Sugars	TBD	
573	Infant formula and follow-up formula 072-1981 & 156-1987	Biotin 1.5 µg/ 100 kcal	TBD	