codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME Tel.: 52251 Telex: 625825-625853 FAO I Cables: Foodagri Rome Facsimile: (6)5225.4593

ALINORM 97/26

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-second Session
Geneva, 23-28 June 1997

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

Bonn-Bad Godesberg, Germany
7-11 October 1996

Note: This document incorporates Circular Letter 1996/41-NFSDU

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CX 3/15.2 **CL 1996/41-NFSDU**
November 1996

TO: - Codex Contact Points
- Participants at the 20th 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 22nd SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Draft Guidelines at Step 8 of the Procedure

1. Table of Conditions for Claims for Nutrient Contents, to be included in the Draft Guidelines for Use of Health and Nutrition Claims (para. 26, Appendix II).

Proposed Draft Standard at Steps 5 and 8 of the Procedure

2. Proposed Draft Revised Standard for Food Grade Salt (para. 32, Appendix III)

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) to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, via delle Terme di Caracalla, 00100 Rome, Italy, **before 30 April 1997**.

Proposed Draft Standard at Step 5 of the Accelerated Procedure

3. Proposed Draft Amendment to the Standard for Infant Formula: Vitamin B_{12} (para. 94, Appendix IV)

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 30 April 1997**.

Terms of Reference of the Committee

4. Proposal to amend the Terms of Reference of the Committee (para. 6).

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 30 April 1997**.

Proposed Draft Standard and Guidelines at Step 5 of the Procedure

5. Proposed Draft Revised Standard for Gluten-Free Foods (para. 41, Appendix V)

6. Proposed Draft Guidelines for Vitamin and Mineral Supplements (para. 64, Appendix VI)

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 30 April 1997**.

Proposal to discontine work

7. Proposed Draft Guidelines on the Inclusion of Nutrition Provisions on Nutritional Quality in Food Standards (para. 102)

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 30 April 1997**.

B. REQUEST FOR COMMENTS AND INFORMATION

Draft Guidelines at Step 6 of the Procedure

8. Part B of the Table of Conditions for Claims for Nutrient Contents, to be included in the Draft Guidelines for Use of Health and Nutrition Claims (para. 27, Appendix VII).

Governments are invited to submit comments on the values in the Table and on the expression of the conditions for claims per serving.

Proposed Draft Standard at Step 3 of the Procedure

9. Proposed Draft Revised Standard for Cereal-Based Foods for Infants and Young Children (para. 89, Appendix VIII)

Governments are invited to provide comments especially on the new sections and the provisions in square brackets.

Governments and inernational organizations wishing to comment points 8. and 9. above 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 30 July 1997**.

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 20th Session of the Committee on Nutrition and Foods for Special Dietary Uses are as follows:

Matters for adoption by the Commission:

The Committee:

- advanced to Step 8 Part A of the Table of Conditions for Claims for Nutrient Content, to be included in the Draft Guidelines for Use of Health and Nutrition Claims (para. 26, Appendix II)

- advanced to Step 5/8 the Proposed Draft Revised Standard for Food Grade Salt (para. 32, Appendix III)

- advanced to Step 5 of the Accelerated Procedure the Proposed Draft Amendment to the Standard for Infant Formula (Vitamin B_{12}) (para. 94, Appendix IV)

- proposed to revise its Terms of Reference (para. 6)

- advanced to Step 5 the Proposed Draft Guidelines for Vitamins and Minerals Supplements (para. 64, Appendix VI)

- advanced to Step 5 the Proposed Draft Standard for Gluten Free Foods (para. 41, Appendix V)

- proposed to discontinue work on the revision of the Guidelines for the Inclusion of Provisions on Nutritional Quality (para. 102)

Other Matters of Interest to the Commission

The Committee:

- returned to Step 6 Part B. of the Table of Conditions for Claims (para. 26, Appendix VII)

- returned to Step 3 the Proposed Draft Revised Standard for Cereal-Based Foods for Infants and Young Children (para. 89, Appendix VIII)

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INTRODUCTION

1. The Codex Committee on Nutrition and Foods for Special Dietary Uses held its Twentieth Session in Bonn-Bad Godesberg, from 7 to 11 October 1996 by courtesy of the Government of the 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. The Session was attended by 187 participants representing 39 member countries and 19 international organizations. The list of participants is attached 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. He noted that the increasing interest and attendance at the Sessions of the Committee were a recognition of the importance of its work in providing worldwide standards and guidance on the nutritional aspects of food in international trade. Dr. Hölzel outlined the key role assumed by the Codex Alimentarius Commission within the framework of the World Trade Organization, expressed the hope that the vast experience of the Committee would contribute to the successful solution of the important and difficult issues on the Agenda.

ADOPTION OF THE AGENDA (Agenda Item 2)

3. The Committee adopted the Provisional Agenda as proposed in document CX/NFSDU 96/1.

4. The Committee agreed to establish two informal Working Groups to consider 1) Nutrient Reference Values for Labelling Purposes (chaired by France) and 2) Methods of Analysis (chaired by the United States).

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

Terms of Reference of the Committee

5. The Committee recalled that its last session had not come to a conclusion on the request of the Commission to consider simplified Terms of Reference, but had proposed to shorten its name to "Codex Committee on Nutrition". The 42nd Session of the Executive Committee had recommended that the name of the Committee remain unchanged until so far as appropriate Terms of Reference were available. The mandate should reflect that Codex should deal only with nutritional aspects of foods.

6. The Committee considered the simplified version proposed by the Secretariat and agreed to the following Terms of Reference:

(a) to study specific nutritional problems assigned to it by the Commission and advise the Commission on general nutrition issues

(b) to draft general provisions, as appropriate, concerning the nutritional aspects of all foods

(c) to develop standards, guidelines or related texts for foods for special dietary uses, in cooperation with other committees where necessary

(d) to consider, amend as necessary and endorse provisions on nutritional aspects proposed for inclusion in Codex standards, guidelines and related texts

7. The Committee had an exchange of views on the opportunity of changing the name of the

[1] CX/NFSDU 96/2

Committee in the light of the revised terms of reference. Although some delegations supported the shorter name as it was clear from the terms of reference that the Committee dealt with foods, the Committee agreed to retain the current name as it reflected both the horizontal aspects of the work and food standardization activities.

Biotechnology

8. The Committee noted that the CCEXEC had recommended that a paper containing proposed draft guidelines be prepared for the next session of the CCFL to address the labelling issues associated with biotechnology. The Chairman informed the Committee that the Joint FAO/WHO Expert Consultation on the Food Safety Aspects of Biotechnology had been held from 30 September to 4 October 1996 and that its conclusions would be taken into account in the elaboration of the Guidelines and other relevant aspects of Codex work.

Food Fortification

9. The Committee noted that the report of the FAO Technical Meeting on Food Fortification - Technology and Quality Control (20-23 November 1995, Rome) had been distributed to participants.

DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (DRAFT GUIDELINES FOR USE OF NUTRITION CLAIMS) (Agenda Item 4)[2]

10. The Committee recalled that the Draft Guidelines had been advanced to Step 8 and that the Committee on Food Labelling had asked the CCNFSDU to consider conditions for the expression of nutrients on the basis of servings and to define the conditions for ”cholesterol free”, ”low sugars”, ”energy free” and ”saturated fat free”.

11. In order to facilitate the discussion of these issues, the Committee established an informal Working Group chaired by the Delegation of the United Kingdom[3]. The Committee considered the conditions in the Table and made the following amendments and additions.

Energy Free

12. The Committee agreed to define the claim for energy free for liquids as 4 kcal/100 ml, recognizing that it was not applicable to solids, although some delegations and the Observer from Consumers International felt that the value should be lower or at the limit of quantification.

Fat

Low Fat

13. Some delegations and the Observers from the EC and IFMA expressed the view that a specific exception should be made for products with a natural high fat content, where the current values did not allow for a "low" claim, even with a significant reduction in fat contents. The Committee however recalled that the CCFL had considered this question in detail and confirmed that there should be no exception to the general applicability of the Guidelines. Comparative claims (”reduced” or ”light”) were allowed when a significant reduction in nutrient contents had been made, and could be used in the case of high fat products. The Observer from Consumers International stressed that no exceptions should be made in order to provide reliable nutritional information to consumers.

14. The Committee did not accept a suggestion to include a footnote indicating that commodity

[2] CX/NFSDU 96/3 and CRD 3 (comments of New Zealand, France, Thailand, European Dairy Association, International Dairy Federation and International Federation of Margarine Associations)

[3] CRD 14 (Conclusions of the Working Group)

committees might establish standards diverging from the conditions in the Table and agreed that such a proposal would detract from the overall horizontal approach followed in Codex, while noting that general provisions in specific standards were subject to endorsement by the relevant general committees. The Observer from IDF expressed his disagreement with this decision.

Fat Free

15. The Committee discussed a proposal to increase the level for ”fat free” to 0.5g/100 g or ml, taking into account the sensitivity of methods for the determination of fat. Some delegations pointed out that the current level of 0.15 g was very low and too restrictive, preventing claims for products such as cereals. The conditions for claims should also be considered in the context of general nutritional policy to help consumers to make informed choices. Other delegations expressed the view that fat should be below the limit of quantification and the same condition should apply all claims for "free". The Committee amended the conditions for "fat free" to not more than 0.5 g/ 100g or 100ml.

Saturated Fats

Low

16. The Delegation of Malaysia expressed the view that a claim for trans-fatty acids should be included in the Table and the Committee recalled that the CCFL had sought its advice on nutrition aspects of this issue in relation to claims for saturated fats. Some delegations felt that it was premature to include any reference to trans-fatty acids as scientific evidence was not entirely conclusive, while other delegations proposed to add them to saturated fats for the purpose of making claims.

17. The Committee recognized that, in view of current scientific evidence, it was premature to request a separate declaration of trans-fatty acids and recalled that the FAO/WHO Expert Consultation on Fats and Oils in Human Nutrition had recommended that claims concerning saturated fats should be restricted to foods with appropriately low or limited levels of trans-fatty acids. As suggested by the Delegation of France, the Committee agreed to include a footnote indicating that ”In the case of the claim for ”low in saturated fats”, trans-fatty acids should be taken into account where applicable. This provision consequently applies to foods claimed to be ”low in cholesterol” or "cholesterol free".

Free

18. The Committee agreed that the condition for this claim should be "not more than 0.1 g of saturated fat per 100g of solids or 100 ml of liquids".

Cholesterol Free

19. The Committee agreed that this claim could be made when the level of cholesterol was not higher than 0.005 g/100 g (solids) or 100 ml (liquids) and the saturated fat contents was the same as for ”low cholesterol”. The Committee did not accept a proposal to link the level of cholesterol to the total energy value of the food. The Committee did not accept the view of the Delegation of Malaysia that claims for cholesterol (low and free) should not be linked to saturated fats.

Low Sugars

20. Several delegations and the Observers from Consumers International and IFGMA stressed that this claim was not relevant from the nutritional point of view, while a claim for ”reduced” sugars would be more appropriate if applicable. The Committee agreed to recommend to the CCFL not to include ”low sugars” in the list and to retain only the ”sugar free” claim.

Fibre

21. Some delegations pointed out that the expressions of fibre content per 100 kcal and per 100 g did not correspond. For some foods, the expressions were consistent when calculated on the basis of servings while they may be consistent for other foods on the basis of 100g. In view of the difficulties to establish a definition of fibre as well as a suitable method of analysis, the Committee could not reach a conclusion at this stage and agreed that this issue required further consideration, in conjunction with the expression of claims per servings.

Protein

22. The Committee agreed that further consideration should be given to the values proposed.

Vitamins and Minerals

23. The Committee noted the difficulties associated with the definitions of levels for vitamins and minerals per 100g or per 100 kcal and agreed that further consideration should be given to the values proposed.

Expression of nutrient contents per serving

24. The Committee, recognizing that servings were used as reference in a number of countries, agreed that this issue required further consideration, in order to establish conditions for claims on the basis of servings, to be added to the Table at a later date. It was further agreed to require specific government comments by Circular Letter, for consideration by the next session. The correlation between the expression of nutrient contents per 100g/100ml or 100 kcal and per serving should be examined carefully in order to provide clear and comparable information to consumers.

25. The Committee agreed that, as consensus had been reached on part A of the Table, with the amendments and additions noted above, it should be included in the Draft Guidelines, while further work was still required on part B (Fibre, Protein, Vitamins and Minerals) and on the expression of conditions for claims per serving.

Status of the Table of Conditions for Nutrient Contents

26. The Committee agreed to forward part A of the Table to the Commission for adoption at Step 8 as part of the Draft Guidelines for Use of Nutrition Claims (see Appendix II) and to return part B to Step 6 for further comments and discussion at the next session (Appendix VII).

PROPOSED DRAFT REVISED STANDARD FOR FOOD GRADE SALT (Agenda Item 5)[4]

27. The Committee agreed with the proposal of France to reinsert the sodium iodides and iodates in the list of iodizing agents along with the widely used potassium salts.

28. The Committee reasserted its position that the choice of the iodizing agent and level of iodization should remain under the responsibility of the national authorities.

29. The Committee noted the proposal of the delegation of Malaysia to include a provision concerning appropriate packaging in order to maintain the stability of iodized salt, which might be altered particularly in hot and humid climates. The Committee agreed that this general question should be referred to the Committee on Additives and Contaminants.

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[4] **CL 1995/18-NFSDU and CX/NFSDU 96/4 (comments of Cuba, France, Germany, Malaysia, Poland, Spain), CRD 4 (Thailand, Malaysia, European Salt Producers Association,)**

30. The Committee noted the concern of the Delegation of Indonesia regarding the effects of iodized salt on fats and oils and was informed that studies carried out in the framework of the UNICEF/Wageninen University project, in Germany and in Poland, had not demonstrated any detrimental effect of iodized salt on several processed foods.

31. The Representative of WHO informed the Committee that revised Recommended Iodine Levels in Salt and Guidelines for Monitoring their Adequacy and Effectiveness[5] had recently been prepared by WHO on the basis of a study carried out in seven African countries.

Status of the Proposed Draft Revised Standard for Food Grade Salt

32. The Committee agreed to advance the Proposed Draft Standard to Step 5 and, in view of the extensive review of the document, to recommend that the Commission omit Steps 6 and 7 to adopt it at Step 8 (see Appendix III).

PROPOSED DRAFT STANDARD FOR GLUTEN FREE-FOODS[6] (Agenda Item 6)

33. The Committee considered the Proposed Draft section by section and made the following amendments.

2. Description

34. Some delegations and the Observer from AOECS, as well as some written comments, supported the definition covering all gluten free foods. Other delegations stressed that the standard should apply exclusively to cereal-based foods and that it was not necessary to include products which were gluten-free by nature.

35. The Committee decided to specify that all Triticum species were covered, mentioning specifically *Triticum polonicum* (kamut), spelt and durum wheat as examples. The Committee did not accept a proposal to delete oats from the list of gluten containing species, as no conclusive evidence from longterm studies and reliable medical data existed at this stage, and the reference to oats was put in square brackets for further comments.

36. Some delegations proposed that gluten free foods should contain no detectable gluten, while others pointed out that there were varying degrees of intolerance and that celiacs did ingest very low amounts of gluten in their diets. The Observer from AOECS expressed the view that the level of 200 ppm of gluten on a dry matter basis for all gluten-free foods was too high to protect coeliacs and that the gluten level should refer to the end-product for better consumer information.

37. After an extensive discussion, the Committee agreed to define three groups according to their gluten content in the end product, with all figures in square brackets for further comments:
- naturally gluten free foods (20 ppm of gluten),
- products which had been rendered "gluten free" (200 ppm)
- any mixture of the two ingredients (200 ppm).

38. The Committee recognized the difficulty of defining and enforcing any limits in the absence of reliable validated methods for the quantification of gluten, although qualitative detection at low levels was possible, and noted that specific methods were used in practice, especially the AOAC immuno assay method and qualitative tests with limits of detection between 5 and 30 ppm.

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[5] WHO/NUT/96.13 (WHO/UNICEF/ICCIDD consultation, WHO Geneva, 8-9 July 1996), Nutrition Unit, WHO, 1211 Geneva 27, Switzerland

[6] CL 1995/18-NFSDU, Appendix III and CX/NFSDU 96/5 (comments from Cuba, France, Germany, Poland, Spain), CX/NFSDU 96/5-Add.1 (Sweden), CRD 5 (Canada)

39. The Committee agreed to transfer the definition of "gluten free" in 2.2.2 to section 3.1 as it belonged more adequately in the provisions on Composition and should not be repeated.

5. Claims

40. The Committee noted a proposal for distinct claims for "gluten free" and "low or reduced in gluten", as it would reflect more accurately the current definitions. The Committee deleted section 5.2 (gluten-free by nature) as it was covered by the amended definition in section 2.

Status of the Proposed Draft Revised Standard for Gluten Free Foods

41. The Committee agreed to advance the Proposed Draft Standard to Step 5 of the Procedure for adoption by the 22nd Session of the Commission (see Appendix V).

PROPOSED DRAFT GUIDELINES FOR DIETARY SUPPLEMENTS (Agenda Item 7)[7]

42. The Committee had an exchange of views on the opportunity of proceeding with work on Dietary Supplements in view of the difficulty to reach consensus on the approach to be followed. The Delegation of the United States, supported by the Delegation of the United Kingdom and Japan, did not agree with the development of the guidelines as the provisions therein were inconsistent with their national regulations and would unnecessarily restrict consumer access to dietary supplements. Some delegations however stressed the need for international guidelines as these products were widely traded and should be regulated. Other delegations, although not opposed to the development of guidelines, pointed out that several issues remained to be addressed and that further scientific data would be needed. The Delegation of Canada emphasized the importance of applying risk assessment methodology if maximum levels of intake were to be established. The Delegation of the Netherlands stressed the need for a safety based approach in setting upper limits.

43. The Committee agreed to concentrate on safety considerations based on scientific evidence and proceeded with the consideration of the text, with the understanding that some questions could not yet be settled.

Preamble

44. Some delegations felt that the Preamble was not necessary and should be deleted, as the promotion of balanced diets concerned nutrition policy and was therefore outside the Scope. Other delegations and the Observer from Consumers International felt that the importance of a balanced diet should be highlighted as it was essential to place the guidelines in their proper context. The Committee retained the Preamble with an amendment to the first sentence to make it more general.

45. The Committee did not accept the proposal of the Delegation of India to indicate that "However people who do not have access to balanced diets may need vitamins and minerals supplements to safeguard their health".

Scope

46. The Committee discussed the opportunity of referring to "dietary supplements". It was suggested to establish a distinction between food supplements intended for general use and dietary supplements for specific dietary purposes. The Observer from the EC indicated that "dietary" applied only to foods for special dietary uses in the EC Directive and that confusion should be avoided between these two categories of products.

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7 CL 1995/18-NFSDU and CX/NFSDU 96/6 (comments of Cuba, Denmark, France, Germany, Malaysia, Spain, European Federation of Associations of Health Product Manufacturers), CX/NFSDU 96/6-Add 1 (Consumers for Health Choice), CRD 6 (Canada, Thailand)

47. The Committee agreed to refer to "Vitamins and Minerals Supplements" in the scope, the title and throughout the text as it would clarify that the guidelines did not apply to other nutrients.

48. Some delegations indicated that supplements were regulated as drugs in their legislation. After an exchange of views on the applicability of the guidelines, the Committee agreed to amend the second paragraph to clarify that the classification of supplements was left to national legislation and the guidelines did not apply where supplements were regulated as drugs.

2. Definitions

49. The Committee deleted current sections 2. Definitions and 3. Nutrients to replace them with new sections as proposed by the Delegation of Germany.

Section 2.1

50. Some delegations pointed out that other nutrients might be included in the supplements, and it was clarified that they derived their nutritional relevance primarily from minerals and/or vitamins. The Committee did not agree to include a maximum level of energy to distinguish supplements from other products such as fortified foods, as the definition was sufficiently explicit.

51. The different forms of presentation were mentioned in the definition without any reference to "pharmaceutical dosage" which could create confusion on the nature of the product.

52. The Committee agreed to specify that supplements were used when the intake of food was insufficient to meet vitamins and minerals requirements or when the consumers considered that their diet required supplementation.

Section 2.2

53. While recognizing that supplements were regulated as drugs in some countries, the Committee agreed that for the purpose of the Guidelines, they were considered as foods.

Section 2.3

54. The Committee agreed to indicate that supplements could also be used for specific dietary purposes.

3. Composition

Section 3.1

55. Some delegations were in favour of a positive list while other delegations stressed that no comprehensive list could be established and that no limitations should be set except on the basis of safety; moreover, an "adequate intake" was not clearly defined. The Committee agreed that only vitamins/provitamins and those minerals which were recognized as essential on a scientific basis should be included. The Committee did not come to an agreement on the proposal of the Delegation of Germany concerning recommendations for intake, which was left in square brackets. The Delegation of France expressed the view that toxicological and nutritional aspects should be distinguished when safety limits were considered, and the Committee should primarily address nutritional concerns.

56. The Committee agreed to refer to nutrient selection criteria (3.1.2), to limitations of use for health protection reasons (3.1.3) and to the suitability of nutrients for specific purposes on the basis of scientific data (3.1.4).

Section 3.2

57. In section 3.2.1, the Committee could not agree on a minimum level set and left "15% of the recommended daily intake" square brackets.

58. In section 3.2.2, some delegations were opposed to the definition of a maximum level of 100% of the recommended daily intake. The Committee agreed to a proposal by the Delegations of the United Kingdom and Canada referring to a safe level set on the basis of risk assessment, taking into account all sources of the nutrients in the diet, as well as nutrient interaction. Both proposals were put in square brackets for further consideration.

59. In section 3.2.3, it was agreed that when a narrow margin existed between the RDA and the adverse level, different maximum limits might be established at the national level.

8. Labelling

60. The Committee agreed to refer to the name of the product instead of "commercial name".

61. In section 8.3, the Committee agreed that the label should indicate "the biologically active part of the vitamins and minerals". As it was suggested that "recommended daily intake" be replaced by "nutrient reference value", the current wording was retained in square brackets for further comments.

62. The Committee agreed that section 8.4 should only mention recommendations for use while section 8.5 should refer to a warning statement when a risk of toxicity existed.

Status of the Proposed Draft Guidelines for Vitamins and Minerals Supplements

63. The Delegation of the United States, supported by other delegations, pointed out that since there was no consensus on many aspects of the Guidelines and further detailed consideration of the proposals put forward at the session would be required, the text should be returned to Step 3 for additional comments on the amended version. Several delegations however noted that significant progress had been made through extensive discussion and that guidelines were urgently needed.

64. The Committee agreed to forward the Proposed Draft Guidelines to the Commission for adoption at Step 5 (see Appendix V). The Delegations of Australia, Canada, Japan, Netherlands, New Zealand, United States and United Kingdom objected to this decision.

PROPOSED DRAFT REVISED STANDARD FOR CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN (Agenda Item 8)[8]

65. The Committee recalled that following the decision of the last session, the current standard was revised by the Secretariat in the light of the comments received and circulated for comments at Step 3 prior to the session. The Committee considered the text section by section and made the following amendments.

1. Scope

66. The Committee discussed the opportunity of replacing "weaning" with another wording, as some delegations felt that it was clearly associated with a progressive adaptation, while for other delegations, it might create confusion in languages other than English. The Representative of WHO indicated that the

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[8] CX/NFSDU 96/7-I and Parts II to V (comments of Denmark, France, Malaysia, Spain, Switzerland, Uganda, CI, EC, ISDI), CRD 7 (Australia, Brazil, Canada, France, Malaysia, Norway, Thailand, WHO, IBFAN, Biopolymer, ISDI, CI), CRD 12 (Indonesia)

use of "complementary feeding" had been proposed in order to avoid confusion in some languages, and to clarify that breast feeding should continue while other foods were introduced. This wording also corresponded to the International Code of Marketing for Breast Milk Substitutes.

67. The Delegation of Venezuela, supported by other delegations and the Observer from Consumers International, proposed a recommended age of "about six months", referring to World Health Assembly resolutions of 1992 (WHA 45.34) and 1994 (WHA 47.5). The Representative of WHO recalled that this issue had been discussed repeatedly, and that the words "about six months" should be seen in the overall context of WHO's infant feeding recommendation. The first part concerned the four to six months duration of exclusive breast feeding while the second part referred to the approximate timing of the introduction of complementary foods. The age range was an essential element of WHO's recommendation and starting complementary feeding too early or too late were both undesirable. Further scientific evidence on the variable impact of individual and population circumstances may warrant a change in the future, but present data confirmed WHO's long-standing recommendation.

68. Some delegations stressed the health hazards resulting from inadequate complementary feeding, especially when introduced too early. The Committee reiterated that the application of specific measures was left to national authorities in accordance with their health policy. The Representative of WHO emphasized that the decision to start complementary feeding depended on the growth needs of the infant, the foods available including the amount of breast milk and environmental and social conditions.

69. The Committee adopted the WHO proposal for rewording the Scope, adding a reference to infant formula.

2. Description

70. Notwithstanding the view of the Delegation of India that starchy roots should not be included as they did not provide good quality protein, the Committee agreed to retain them and to add starchy stems which were a staple food in some regions (sago). It was noted that this provision had been included to take into account the needs of countries where no other raw materials were available for the preparation of complementary foods. It was further agreed to include arachis in square brackets in view of allergenicity risks.

2.1 Definitions

71. The Committee agreed to amend and simplify the definitions as suggested by several delegations and the Observer from the EC, with the understanding that the same products were covered.

2.2.2 Other Definitions

72. In the definition of "young children" a reference to "36 months" was added and the reference to kilojoule and kilocalorie was deleted (2.2.3). The Committee accepted a proposal of Malaysia to exclude sweetened condensed milk (in square brackets). The Observer from IDF referred to the ongoing review of the Code of Principles concerning Milk and Milk Products, where "milk" was defined.

3. Essential Composition and Quality Factors

73. A general statement was included to indicate that requirements for energy and nutrients referred to the product ready for use, unless otherwise specified.

3.2 Energy Density

74. Some delegations felt that this provision was not necessary as other criteria adequately defined nutritional value; the Committee discussed the need to retain it and noted that this addressed a concern expressed by countries where insufficient energy density was a cause of malnutrition. Although the Delegation of India supported a higher value, the Committee agreed that the level should be raised from

0.6 to 0.8 kcal/g.

3.3 Protein

75. The Committee discussed several proposals for the expression of protein content, especially whether the minimum contents of 15% and 12% should be retained. As the categories had been amended in the definitions, the Committee agreed that further consideration should be given to protein contents, as expressed in the following proposals: the current sections 3.3.1 and 3.3.2 (the rest of the section being deleted) and the alternative EC proposal, both in square brackets. The corresponding Labelling section (8.5.2) was retained in square brackets.

3.4 Carbohydrates and 3.5 Lipids

76. The Committee agreed in principle to include new sections on carbohydrate and lipids, leaving the actual figures in square brackets for further consideration.

3.6 Minerals

77. The Committee agreed to include in square brackets a proposal from Indonesia for a maximum sodium content of 200 mg/100 kcal in savoury products for children over one year (3.6.1).

78. Section 3.6.2 concerning sodium in biscuits was retained in square brackets altough some delegations felt that it might duplicate the provisions in 3.6.1.

79. The Delegation of Malaysia, supported by India and some delegations, proposed to include a provision for iron as iron deficiency was a serious concern in their countries. Other delegations stressed the difficulty of setting recommended levels; as that fortification requirements differed greatly according to the country, such provisions should not be mandatory.

3.5 Vitamins

80. In section 3.5.2, the Delegation of Norway, supported by Canada and New Zealand, expressed the view that supplementation should not be mandatory for vitamins A and D in countries where deficiency was not a problem, as the high levels proposed might pose a risk to health. The Committee noted that the approach followed for vitamins and for minerals should be consistent as the standard was intended for application at the international level, and fortification should be applied in accordance with national legislation as indicated section 3.5.3. The Committee agreed to put the section in square brackets.

81. In section 3.5.3, an indicative reference to the addition of vitamin A, iron and iodine was included.

3.6 Optional ingredients

82. In section 3.6.1, the Committee included the general wording proposed by WHO. In Section 3.6.3, the Committee noted a suggestion to increase the age where cocoa could be used while some delegations proposed to delete the section, and it was put in square brackets.

4. Additives

83. The Committee noted that several proposals for amendments had been made and agreed that detailed consideration of this issue would be required at the next session. It was recalled that food additives should be proposed on the basis of the Preamble of the General Standard for Food Additives, especially regarding technological justification.

5. Contaminants

84. The Delegation of Germany proposed to include specific requirements for pesticide residues, in view of the health risks for infants and children. Although there was consensus on the inclusion of a general statement concerning the precautions needed, the Committee recognized that the establishment of MRLs was outside its competence and agreed that this question should be referred to the Committee on Pesticide Residues, while encouraging countries to provide specific information on this issue.

8. Labelling

85. A statement was included in square brackets to the effect that all required information should be given in the appropriate language, in view of some countries' concerns.

86. The Committee did not accept the proposal of the Delegation of Hungary, supported by some delegations, to prohibit nutrient function claims regarding dietary properties.

87. In section 8.5.4 (declaration of gluten), the reference to six months was left in square brackets, as no conclusion could be reached.

88. The Committee had an extensive exchange of views on the requirements for the age of introduction and agreed to specify: the intended age of use; that products should not be used before 4 to 6 months; that the decision should be made with a health worker.

Status of the Proposed Revised Draft Standard on Cereal-Based Foods for Infants and Young Children

89. The Committee recognized that further consideration should be given to the extensive amendments proposed and agreed to return the Proposed Draft Standard to Step 3 for further comments (see Appendix VIII).

PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA (Agenda Item 9)[9]

90. Following the decision of the last session concerning the revision, the Codex Standard for Infant Formula was revised by the Netherlands in the light of the comments received and circulated at Step 3 prior to the session.

91. The Committee expressed its appreciation to the Delegation of the Netherlands for its valuable work and, while noting that some technical corrections should be made (such as provisions for amino acid and certain vitamins), decided to concentrate on matters of principle.

92. It was noted that the Proposed Draft referred to WHO resolutions and that the WHO Statement on Infant Feeding was included in Codex Volume 4 in conjunction with relevant Codex standards but not as part of them. The Representative of WHO indicated that his Organization was prepared to undertake the revision of the statement on the basis of current scientific evidence in this area.

Status of the Proposed Draft Revised Standard for Infant Formula

93. In view of the importance of this standard and the insufficient time available to examine it, the Committee agreed to return the Proposed Draft to Step 3 for further comments and consideration by the next session.

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[9] CL 1995/33-NFSDU, CX/NFSDU 96/8, CRD 8 (comments from Malaysia)

REVIEW OF PROVISIONS FOR VITAMINS AND MINERALS IN CODEX STANDARDS (Agenda Item 10)

Vitamin B_{12}: Proposed Draft Amendment to the Standard for Infant Formula (Agenda Item 10 a)

94. As no comments had been made at Step 3 in reply to CL 1995/11-NFSDU and in view of the consensus on this issue, the Committee agreed to forward the Proposed Draft Amendment to Step 5 of the Accelerated Procedure for adoption by the Commission (Appendix IV).

NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES (Agenda Item 10b) [10]

95. The Committee recalled that the last session had agreed to review the Nutrient Reference Values for labelling purposes, and a discussion paper had been prepared by France, under the direction of Professor Rey, who presented it to the session.

96. The Committee expressed its appreciation of the document which provided a comprehensive review of a very complex and important issue. Codex NRVs had been compared with those applied in certain countries (United States, United Kingdom, India) and those recommended recently by the EC Scientific Committee for Foods.

97. Some delegations and the Observer from Consumers International supported further consideration of this issue. It was noted that the CCFL was also considering the opportunity of reviewing the Guidelines on Nutrition Labelling. The Committee agreed that the paper should be circulated for comments on the general approach to the values, and further action, if any was required, and that a Working Group would facilitate discussions of this issue at the next session.

VITAMINS AND MINERALS IN FOODS FOR SPECIAL MEDICAL PURPOSES [11] (Agenda Item 10c)

98. The Committee recalled that its last session had agreed that the Delegation of Germany would prepare a paper reviewing the recommended levels of vitamins and minerals in foods for special medical purposes.

99. The Committee noted that in the absence of specific daily recommendations concerning intake for sick people, recommendations had been based on the intakes for adults proposed by the EC Scientific Committee for Foods. Those for children of 0-12 months of age were based on the Codex Standard for Infant Formula and RDAs from the USA National Research Council were also included.

100. The Committee expressed its appreciation of the document for its clear presentation and valuable information, which would be useful for both patients and manufacturers. Some delegations suggested that the scope of the work should be extended to include protein intake and essential fatty acids, and the Committee agreed that the document should be circulated for detailed review and comments.

REVIEW OF THE GUIDELINES ON THE INCLUSION OF NUTRITION PROVISIONS ON NUTRITIONAL QUALITY IN FOOD STANDARDS[12]

101. The Secretariat introduced the document, recalling that the Committee on General Principles and CCEXEC had recommended to redraft it as General Guidelines directed to governments instead of instructions to Codex Committees.

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10 CX/NFSDU 96/10

11 CX/NFSDU 96/11

12 **CX/NFSDU 96/12, CX/NFSDU 96/12-Add 1 (comments from Cuba, France, Malaysia, Spain), CRD 11 (Australia, France, Thailand, ILSI)**

102. Although it was suggested that advice directed to Codex committees might still be needed, the Committee noted the clear request of the CCGP and CCEXEC and recognized that many definitions and objectives of the Guidelines were already covered by the General Principles for the Addition of Essential Nutrients to Foods. It was also pointed out that advice on nutrition policy was outside the mandate of the Committee and that the context had changed since the adoption of the current guidelines. In view of these considerations, the Committee came to the conclusion that the document was not needed and that work in this area should be discontinued, and agreed to refer this proposal to the Executive Committee.

METHODS OF ANALYSIS IN STANDARDS FOR FOODS FOR SPECIAL DIETARY USES (Agenda Item 12)[13]

103. The Delegation of the United States informed the Committee that no new methods had been put forward and no new developments had taken place since the last session. The Committee noted that in the only comment received, Germany proposed that AOAC method 991.43 for dietary fibre replace the recommended Englyst method.

104. The Committee agreed that a regular review of methods of analysis was not warranted and that work in this area should be discontinued at its next session, to be considered again only if new developments took place.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 13)

Dietary Modelling

105. The Committee recalled that its last session had agreed that Australia would prepare a paper on dietary modelling of nutrient intake. The 42nd Session of the CCEXEC had expressed the view that consideration of dietary models for nutrient intake did not appear to be consistent with the Commission's mandate and requested clarification from the CCNFSDU.

106. The Delegation of Australia introduced the paper (CRD 10) which covered current approaches to dietary modelling of intakes and its role in exposure assessment and risk assessment. The Committee took note of the forthcoming FAO/WHO Consultation on Food Consumption and Exposure Assessment of Chemicals (Geneva, 10-14 February 1997).

107. The Committee noted that dietary modelling could be relevant to its work, particularly in conjunction with the establishment of upper limits for supplementation and fortification, and agreed to circulate the paper for comments, in order to determine future work in this area at the next session.

Consideration of Potentially Harmful Herbs and Botanical Preparations sold as Foods[14]

108. The Committee recalled that, following a proposal by the Coordinating Committee for North America and the South West Pacific, the CCEXEC proposed that work in this area be allocated to CCNFSDU, which should consider the matter and report its findings to the next CCEXEC, in the light of the comments provided by governments.

109. Several delegations pointed out that the toxicity of herbs was essentially a safety problem and had no nutritional implications; moreover, it was the responsibility of national authorities to establish lists of potentially harmful plants on a toxicological basis. The Committee was not therefore competent to deal with this issue, and did not appear to be concerned. It was however suggested that this issue may be considered in the framework of the work undertaken on dietary supplements.

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[13] **CX/NFSDU 96/13; CRD 15 (Report of WG)**

[14] CL 1996/20-NFSDU, CRD 2 (comments from Australia, New Zealand, Denmark, Germany, Hungary, France, Spain)

110. Some delegations expressed the view that the establishment of a negative list at the international level would be useful and suggested that an Expert Consultation could deal with this question.

Allergens

111. The Committee recalled earlier discussions concerning the establishment of criteria for a list of allergens, in conjunction with the work of CCFL concerning labelling issues related to hypersensitivity. The Committee however noted that the FAO Technical Consultation on Food Allergies had proposed such criteria and agreed that there was no need for specific consideration of this issue at this stage.

DATE AND PLACE OF NEXT SESSION (Agenda Item 14)

112. The Committee was informed that its next session would be held in Germany from 21-25 September 1998.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by	Document Reference in ALINORM 95/26
Table of Conditions for Claims for Nutrient Contents (Part A)	8	Governments 22nd CAC	para. 26 Appendix II
Part B	6	Governments CNFSDU	Appendix VII
Proposed Draft Revised Standard for Food Grade Salt (Salt Iodization)	8	Governments 22nd CAC	paras. 32 Appendix III
Vitamin B_{12} (Proposed Draft Amendment)	5	Governements 22nd CAC	para. 94 Appendix IV
Proposed Draft Revised Standard for Gluten Free Foods	5	Governments 22nd CAC	para. 41 Appendix V
Proposed Draft Guidelines for Vitamins and Minerals Supplements	5	Governments 22nd CAC	para. 64 Appendix VI
Proposed Draft Revised Standard for Cereal Based Foods	3	Governments CCNFSDU	para. 89 Appendix VIII
Proposed Draft Revised Standard for Infant Formula	3	Governments CCNFSDU	para. 93
Proposed Draft Revised Guidelines on the Inclusion of Provisions on Nutrition		22nd CAC	para. 102
Vitamins and Minerals in foods for medical purposes		Governments CCNFSDU	para. 100
NRVs for labelling purposes		Governments CCNFSDU	para. 97
Dietary modelling		Governments CCNFSDU	para. 107

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PROPOSED DRAFT REVISED STANDARD FOR FOOD GRADE SALT
(At Steps 5 and 8 of the Procedure)[1]

1. **SCOPE**

This standard applies to salt used as an ingredient of food, both for direct sale to the consumer and for food manufacture. It applies also to salt used as a carrier of food additives and/or nutrients. Subject to the provisions of this standard more specific requirements for special needs may be applied. It does not apply to salt from origins other than those mentioned in Section 2, notably the salt which is a by-product of chemical industries.

2. **DESCRIPTION**

Food grade salt is a crystalline product consisting predominantly of sodium chloride. It is obtained from the sea, from underground rock salt deposits or from natural brine.

3. **ESSENTIAL COMPOSITION AND QUALITY FACTORS**

3.1 Minimum NaCl Content

The content of NaCl shall not be less than 97% on a dry matter basis, exclusive of additives.

3.2 Naturally Present Secondary Products and Contaminants

The remainder comprises natural secondary products, which are present in varying amounts depending on the origin and the method of production of the salt, and which are composed mainly of calcium, potassium, magnesium and sodium sulphates, carbonates, bromides, and of calcium, potassium, magnesium chlorides as well. Natural contaminants may also be present in amounts varying with the origin and the method of production of the salt.

3.3 Use as a Carrier

Food grade salt shall be used when salt is used as a carrier for food additives or nutrients for technological or public health reasons. Examples of such preparations are mixtures of salt with nitrate and/or nitrite (curing salt) and salt mixed with small amounts of fluoride, iodide *or iodate*, iron, vitamins, etc., and additives used to carry or stabilize such additions.

3.4 *Iodisation of food grade salt*

In iodine-deficient areas, food grade salt shall be iodised to prevent iodine-deficiency disorders (IDD) for public health reasons.

3.4.1 Iodine compounds

For the fortification of food grade salt with iodine, use can be made of sodium and potassium iodides or iodates.

[1] Amendments are printed in italics

3.4.2 Maximum and minimum levels

The maximum and minimum levels used for the iodisation of food grade salt are to be calculated as iodine (expressed as mg/kg) and shall be established by the national health authorities in the light of the local iodine deficiency situation.

3.4.3 Quality Assurance

The production of iodised food grade salt shall only be performed by reliable manufacturers having the knowledge and the equipment requisite for the adequate production of iodised food grade salt, and specifically, for the correct dosage and even intermixing.

4. FOOD ADDITIVES

4.1 All Additives used shall be of food grade quality.

4.2 Anticaking Agents

		Maximum Level in the Final Product
4.2.1	Coating agents; Carbonates, calcium and/or magnesium; Magnesium oxide; Phosphate, tricalcium; Silicon dioxide, amorphous; Silicates, calcium, magnesium, sodium alumino, or sodium calcium alumino	20 g/kg singly or in combination
4.2.2	Coating hydrophobic agents; aluminium, calcium magnesium, potassium or sodium salts of myristic, palmitic or stearic acids	
4.2.3	Crystal modifiers: ferrocyanides, calcium, potassium** or sodium*	10 mg/kg* singly or in combination expressed as $[Fe(CN_6)]^{3-}$

4.3 Emulsifiers

Polysorbate 80	10 mg/kg

4.4 Processing Aid

Dimethylpolysiloxane	10 mg of residue/kg

5. CONTAMINANTS

Food grade salt may not contain contaminants in amounts and in such form that may be harmful to the health of the consumer. In particular the following maximum limits shall not be exceeded:

5.1 Arsenic - not more than 0.5 mg/kg expressed as As
5.2 Copper - not more than 2 mg/kg expressed as Cu
5.3 Lead - not more than 2 mg/kg expressed as Pb

** Sodium and potassium ferrocyanides, maximum level may be 20 mg/kg when used in the preparation of "dendritic" salt.

5.4 Cadmium - not more than 0.5 mg/kg expressed as Cd
5.5 Mercury - not more than 0.1 mg/kg expressed as Hg

6. HYGIENE

In order to ensure that proper standards of food hygiene are maintained until the product reaches the consumer, the method of production, packaging, storage and transportation of food grade salt shall be such as to avoid any risk of contamination.

7. LABELLING

In addition to the requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) the following specific provisions apply:

7.1 The Name of the Product

7.1.1 The name of the product, as declared on the label shall be "salt".

7.1.2 The name "salt" shall have in its close proximity a declaration of either "Food Grade" or "Cooking Salt" or "Table Salt".

7.1.3 Only when salt contains one or more ferrocyanide salts, added to the brine during the crystallization step, the term "dendritic" could be included accompanying the name.

7.1.4 Where salt is used as a carrier for one or more nutrients, and sold as such for public health reasons, the name of the product shall be declared properly on the label, for example "salt fluoridated", "salt iodated", "salt iodized", "salt fortified with iron", "salt fortified with vitamins" and so on, as appropriate.

7.1.5 An indication of either the origin, according to the description on Section 2, or the method of production may be declared on the label, provided such indication does not mislead or deceive the consumer.

7.2 Labelling of Non-Retail Containers

Information for non-retail containers shall either be given on the container or in accompanying documents, except that the name of the product, lot identification and name and address of the manufacturer or packer shall appear on the container. However, lot identification and the name and address of the manufacturer or packer may be replaced by an identification mark, provided that such mark is clearly identifiable with the accompanying documents.

8. METHODS OF ANALYSIS AND SAMPLING

8.1 Sampling (See Appendix in Volume 13)

8.2 Determination of Sodium Chloride Content

This method allows the calculation of sodium chloride content, as provided for in Section 3.1, on the basis of the results of the determinations of sulphate (Method 8.4), halogens (Method 8.5), calcium and magnesium (Method 8.6), potassium (Method 8.7) and loss on drying (Method 8.8). Convert sulphate to $CaSO_4$ and unused calcium to $CaCl_2$, unless sulphate in sample exceeds the amount necessary to combine with calcium, in which case convert calcium to $CaSO_4$ and unused sulphate first to $MgSO_4$ and any remaining sulphate to Na_2SO_4. Convert unused magnesium to $MgCl_2$. Convert potassium to Kcl. Convert unused halogens to NaCl. Report the NaCl content on a dry matter basis, multiplying the percentage NaCl by 100/100-P, where P is the percentage loss on drying.

8.3 Determination of Insoluble Matter

According to ISO 2479-1972 "Determination of matter insoluble in water or in acid and preparation of principal solutions for other determinations".

8.4 Determination of Sulphate Content

According to ISO 2480-1972 "Determination of sulphate content. Barium sulphate gravimetric method".

8.5 Determination of Halogens[1]

According to ISO 2481-1973 "Determination of halogens, expressed as chlorine. Mercurimetric method" (for the recovery of mercury from the laboratory waste, see Annex of ECSS/SC 183-1979).

8.6 Determination of Calcium and Magnesium Contents

According to ISO 2482-1973 "Determination of calcium and magnesium contents. EDTA complexometric methods".

8.7 Determination of Potassium Content

According to ECSS/SC 183-1979 "Determination of potassium content by sodium tetraphenylborate volumetric method" or alternatively according to ECSS/SC 184-1979 "by flame atomic absorption spectrophotometric method".

8.8 Determination of the Loss on Drying (Conventional Moisture)

According to ISO 2483-1973 "Determination of the loss of mass at 110^{o}C".

8.9 Determination of Copper Content

According to ECSS/SC 144-1977 "Determination of copper content, Zinc dibenzyldithiocarbamate photometric method".

8.10 Determination of Arsenic Content

According to method ECSS/SC 311-1982 "Determination of arsenic content. Silver diethyldithiocarbamate photometric method".

8.11 Determination of Mercury Content

According to method ECSS/SC 312-1982 "Determination of total mercury content. Cold vapour atomic absorption spectrometric method".

8.12 Determination of Lead Content

According to method ECSS/SC 313-1982 "Determination of total lead content. Flame atomic absorption spectrometric method".

8.13 Determination of Cadmium Content

According to method ECSS/SC 314-1982 "Determination of total cadmium content. Flame atomic absorption spectrometric method".

8.14 Determination of iodine content

According to method ESPA/CN 109/84 "Determination of total iodine content. Titrimetric method using sodium thiosulfate".

[1] An alternative method for the determination of halogens by using silver nitrate is being studied.

PROPOSED DRAFT AMENDMENT TO THE STANDARD FOR INFANT FORMULA
(CODEX-STAN 72-1981)
(At Step 5 of the Accelerated Procedure)

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

Table

Vitamin B_{12} : 0.1 1g/100 kcal (Minimum)

PROPOSED DRAFT REVISED STANDARD FOR GLUTEN-FREE FOODS
(At Step 5 of the Procedure)

1. SCOPE

1.1 This standard applies to those foodstuffs and ingredients which have been especially processed or prepared to meet the dietary needs of persons intolerant to gluten.

1.2 The standard refers only to the special dietary purpose for which these foodstuffs and ingredients are intended.

2. DESCRIPTION

2.1 Definition

"Gluten-free" foods are foodstuffs so described:

a) consisting of or made only from ingredients which do not contain any prolamins from wheat or all *Triticum* species such as spelt (*Triticum spelta* L.), kamut (*Triticum polonicum* L.) or durum wheat, rye, barley, [oats] or their crossbred varieties with a gluten level not exceeding [20 ppm]; or

b) consisting of ingredients from wheat, rye, barley, oats, spelt or their crossbred varieties, which have been rendered "gluten-free"; with a gluten level not exceeding [200 ppm]; or

c) any mixture of the two ingredients as in a) and b) with a gluten level not exceeding [200 ppm]

2.2 Subsidiary Definitions

2.2.1 Gluten
For the purpose of this standard "gluten" is defined as a protein fraction from wheat, rye, barley, [oats] or their crossbred varieties and derivatives thereof, to which some persons are intolerant and that is insoluble in water and 0.5M NaCl.

2.2.2 Prolamins
Prolamins are defined as the fraction from gluten that can be extracted by 40 - 70% of ethanol. The prolamin from wheat is gliadin, from rye is secalin, from barley hordein and from oats avenin.
It is however an established custom to speak of glutensensitivity. The prolamin content of gluten is generally taken as 50%

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Gluten-free

For the purpose of this standard "gluten-free" means that the total content of gluten in products defined in 2.1a) shall not exceed [20 ppm], that the total content of gluten from wheat, rye, barley, [oats] or crossbred varieties of these does not exceed [200 ppm] in these foodstuffs or ingredients defined in 2.1 b) and c) on a dry matter basis. The prolamin content of liquid food products is in the same way expressed in ppm of the original product.

3.2 "Gluten-free" foodstuffs, substituting important basic foodstuffs should supply approximately the same amount of vitamins and minerals as the original foodstuffs they replace.

3.3 The product shall be prepared with special care under Good Manufacturing Practice (GMP) to avoid contamination with prolamins.

4. LABELLING

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

5. CLAIMS

5.1 A foodstuff or ingredient that meets the requirement set out in Section 3.1 may be labelled "gluten-free".

6. GENERAL OUTLINE OF THE METHOD OF ANALYSIS AND SAMPLING

6.1 Introduction

To enforce the compliance to the limits for gluten-free products set in the preceding paragraphs an analytical method is needed which has a high level of accuracy. Up till now it has not been possible to design such a method in detail, as several factors impair its performance:

- the extend of compositional mismatch between contaminating or residual proteins and a gluten standard,
- the availability of a gluten standard,
- the selectivity of the antiserum,
- the effect of heating of the product on the extractability and epitope integrity.

As the proposed limit is near to the level which might be toxic for coeliacs, a more comprehensive investigation to address these questions has to be carried out. The general outline of the method of analysis and sampling presented below will constitute the framework for such an investigation.

When a standard is generally accepted as a point of reference, the general outline can be used as a basis for the determination of gliadin until all reagents and equipment necessary for the determination has been standardized and evaluated.

6.2 **Determination of gluten in foodstuffs and ingredients**

The determination of gluten in foodstuffs and ingredients shall be based on an immunologic method.The antibody to be used should react with the cereals that are toxic for persons sensitive to gluten and should not cross-react with the other cereals or other constituents of the foodstuffs and ingredients.

6.3 **The extraction of prolamins**

6.3.1 Pretreatment of solid foodstuffs and ingredients

Depending on the fat-content of the product, either of two pretreatments is used:

a) Products with a fat-content higher than 10%: Five grams of the product are homogenized with a blender in 50 ml hexane. The suspension is centrifuged for 30 min at 1500xg; the supernatant discarded and the extraction step is repeated until the sample is fat-free. The pellet is dried at 600C, weighed, milled and an aliquot is used for analysis.
b) In products with a fat-content lower than 10% an extraction is generally not necessary. Five grams of the product are dried at 600C, milled and an aliquot is used for analysis.

6.3.2 Extraction

a) solid foodstuffs and ingredients
An aliquot of the dried sample is homogenized with 60% aqueous ethanol in a volume 10 times its weight; homogenized for 2 minutes and after 15 minutes centrifuged for 10 min at 1500xg. The supernatant is taken

off and stored if necessary at 40C before determination. When a precipitate is formed this is spun down and discarded.

b) liquid foodstuffs and ingredients
An aliquot of a liquid product is diluted with ethanol; the added volume of ethanol being calculated to yield 60% ethanol in the resulting mixture. The mixture is homogenized and further treated like solid food extracts.

6.4 **Determination of gliadin.**

6.4.1 Plate preparation

Microtiter plates are coated overnight with an antibody against gliadin in an appropriate dilution (e.g. 1 in 600) in a sodium carbonate buffer. The plate is washed three times with phosphate-buffered saline with 0.05% Tween (PBS-T) and once more with deionised water containing 0.03% Na-azide.
Plates can be stored at 40C in a sealed plastic bag.

6.4.2 Standard

It is necessary to use a gliadin standard in order to minimize interassay variation. Apart from that a "golden standard" should be used to make comparison of the results from different laboratories with different ELISA-techniques and with different antisera possible. This "golden standard" should be prepared by one laboratory under strictly standardized conditions.

6.4.3 Determination

After appropriate dilution of the extract the samples and the necessary standard dilutions to obtain a standard curve are brought into the wells of the plate. After incubation for 2 hours, the plates are washed three times with cold PBS-T. To the wells the monoclonal or polyclonal antibody against gliadin conjugated with an enzyme is added and after incubation for 2 hours the plates are emptied and washed three times with PBS-T. Then a substrate for the enzyme is added. After an appropriate time the reaction is stopped. The absorption is measured directly in the microtiter plates.

6.4.4 The gliadin concentration is determined from the standardcurve obtained. The result is multiplied by 2 to obtain the gluten content and expressed in ppm of the original product.

7. REMARKS

7.1 The method determines the amount of prolamin in a product. It is however important to stress that the total daily intake of prolamin for coeliac patients should not exceed 10 mg per day.

7.2 The method is sensitive for native prolamins. The sensitivity for heated products is - depending on the temperature and time of heating - lower. It may be reduced to 10% of the original sensitivity. The reduction in sensitivity is related to the amount of a-gliadin in the sample and the sensitivity of the antibody for the different subfractions in the gliadin.

7.3 Depending on the specificity of the antibody, the method determines also the prolamins from rye, barley and oats as gliadin equivalents. The response in the assay however can be different from that for gliadin and must in that case be determined separately with an appropriate standard.

7.4 If the method gives a positive result and there is some doubt about the specificity, a blot after electrophoretic separation of the sample can be performed.

7.5 Products from partial hydrolysis of prolamins can, depending on the degree of hydrolysis, not always been determined by the method described.

7.6 Polyphenols such as those from tea, hops or cocoa decrease the yield of the extraction of prolamins by binding to the latter. Addition of casein as a competing protein as well as urea is necessary in that case.

7.7 The detection limit of the method should be at least 10 ppm in the product on a dry matter basis.

PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL SUPPLEMENTS
(At Step 5 of the Procedure)

Preamble

Most people who have access to a balanced diet should usually obtain all the nutrients they require from their normal diet. People should therefore be encouraged to select such a balanced diet from food before considering any dietary supplement.

1. Scope

These guidelines apply to vitamin and mineral supplements intended for use in supplementing the daily diet with vitamins and/or minerals.

It is left to national regulations to decide whether vitamin and mineral supplements are drugs or foods. These Guidelines do not apply in those jurisdictions where products defined in 2.1 are regulated as drugs.

2. Definitions

2.1 Vitamin and mineral supplements for the purpose of these guidelines derive their nutritional relevance primarily from the minerals and/or vitamins they contain. They can be marketed in capsules, tablets, powders, liquids etc..[They serve to supplement the daily diet with these nutrients in cases when the intake from food is insufficient or where the consumers consider their diet requires supplementation.]

2.2 For the purpose of the Guidelines, vitamin and mineral supplements are considered as foods (as defined in the Procedural Manual of the Codex Alimentarius, 9th edition, 1995, p.59), if not otherwise stated in national regulations.

2.3 Vitamin and mineral supplements can serve special nutritional purposes, if their composition and contents of minerals and vitamins corresponds to particular dietary requirements that result from certain physical or physiological conditions and they are marketed for that particular purpose.

3. Composition

3.1 Selection of vitamins and minerals

3.1.1 Vitamin and mineral supplements shall contain vitamins/provitamins and only minerals in conjunction with the relevant Codex standards whose indispensability for human beings has been proven by scientific data [up to a level considered safe as determined by risk analysis] [and which are covered by recommendations for the daily intake or estimated values for safe and adequate intake established by recognized scientific authorities]

3.1.2 The selection of admissible nutrient compounds may be based on nutrient criteria of the FAO/WHO or Pharmacopoeias and national legislation.

3.1.3 The use of supplements of individual vitamins and minerals can be [limited] for reasons of health protection and consumer safety,taking into account regional or national peculiarities concerning the supply situation of the population.

3.1.4 Vitamin and mineral supplements may contain all vitamins and minerals that comply with the criteria in 3.1.1, a single nutrient or an appropriate combination of nutrients.
[The suitability of a single nutrient or a combination of several nutrients in a vitamin and mineral supplement for the special nutritional purpose for which it is marketed should be proven by scientific data.]

3.2 Contents of vitamins and minerals

3.2.1 The minimum level of each nutrient contained in a vitamin and mineral supplement should be [15%] of the recommended daily intake or the estimated safe and adequate daily intake.

3.2.2 [The maximum level of each nutrient contained in a vitamin and mineral supplement should not exceed [100%] of the recommended daily intake or the estimated safe and adequate intake per daily dose.]

[Alternatively for 3.2.1 and 3.2.2, vitamin and mineral supplements should contain nutritionally relevant nutrient levels. The daily dose shall not exceed the physiological quantity. These dosages shall remain below the dose range that produces pharmacological effects]

or

[3.2.1 Supplements may contain vitamins and minerals up to a level that is considered safe on the basis of risk assessment considerations, as determined by appropriate risk assessment methodology, taking into account all sources of nutrients in the diet.]

3.2.3 For vitamins and minerals with a narrow safety margin between the recommended daily intake and the adverse effect level, difference maximum limits for the daily dose may be established at the national level.

4. Food Additives

The additives authorized by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) are permissible, provided they are necessary for technological reasons and do not exceed the equivalent of their acceptable daily intakes (ADI).

5. Contaminants

The product shall be prepared with special care under good manufacturing practices and shall be free of pesticides and other contaminants to the maximum extent possible.

6. Hygiene

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

6.3 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 the hygienic and other qualities of the food.

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

7.3 Vitamin and mineral supplements should be distributed in child-resistant packagings, if necessary.

8. Labelling

8.1 Dietary supplements are labelled according to the Codex Standard for the Labelling of Prepackaged Foods (Codex-Stan 1-1985) as well as according to the General Guidelines on Claims (CAC/GL 1-1979), the Guidelines on Nutrition Labelling (CAC/GL 2-1985).

8.2 The name of the product shall be "vitamin and mineral supplement" or "dietary mineral/vitamin preparation to supplement the diet with..", with an indication of the nutrients contained therein or
" vitamin and mineral supplement in cases of...", with an indication of the special nutritional purposes for products that meet the criteria of 2.2 and 3.1.4.

8.3 The label must indicate the biologically active part of all vitamins and minerals in units of weight per product unit and in the case of liquids per recommended dose unit. Additionally, the percentage of the [recommended daily intake] of the vitamin or mineral that is covered by the consumption of the recommended daily dose of the product must be indicated.

8.4 The label must indicate the recommendations on how to take the product (quantity, frequency, special conditions).

8.5 The label must contain a warning statement [if the product contains a significant amount of a nutrient with respect to the toxicity level.]

DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (Part B)
(DRAFT GUIDELINES FOR USE OF NUTRITION CLAIMS)
(At Step 6 of the Procedure)

COMPONENT	CLAIM	CONDITIONS
B.		**NOT LESS THAN**
Fibre	Source	3 g per 100 g or 1.5 g per 100 kcal
	High	6 g per 100 g or 3 g per 100 kcal
Protein	Source	10% of NRV per 100 g (solids) 5% of NRV per 100 ml (liquids) or 5% of NRV per 100 kcal
	High	20% of NRV per 100 g (solids) 10% of NRV per 100 ml (liquids) or 10% of NRV per 100 kcal
Vitamins and Minerals	Source	15% of NRV per 100 g (solids) 7.5% of NRV per 100 ml (liquids) or 5% of NRV per 100 kcal
	High	2 or 3 times the values for "source"

ALINORM 97/26
APPENDIX VIII

PROPOSED DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN
(At Step 3 of the Procedure)

1. SCOPE

This standard covers processed cereal-based foods intended for feeding infants as a complement to breast milk or infant formula when, from the age of 4 to 6 months onwards, breast feeding alone or infant formula is no longer sufficient to satisfy nutritional requirements and for feeding young children as part of their progressively diversified diet.

2. DESCRIPTION

Processed cereal-based foods are prepared primarily from one or more milled cereals and/or legumes (pulses) and/or starchy root or stem products which constitute at least 25% of the final mixture on a dry weight basis.

2.1. Product Definitions

Processed cereal-based foods are prepared primarily from one or more milled cereals and/or legumes (pulses) and/or starchy root or stem products which constitute at least 25% of the final mixture on a dry weight basis. Four categories are distinguished:

2.1.1 simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids;

2.1.2 Cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid

2.1.3 Pasta which are to be used after cooking in boiling water or other appropriate liquids;

2.1.5 Rusks and biscuits which are to be used either directly or, after pulverization, with the addition of water, milk or other suitable liquids.

2.2 Other Definitions

2.2.1 The term **infant** means a person not more than 12 months of age.

2.2.2 The term **young children** means persons from the age of more than 12 months up to the age of three years (36 months).

[2.2.3 The term milk above does not include sweetened condensed milk, evaporated milk and skim milk.]

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

Dry cereal, rusk, biscuits and pasta are prepared primarily from one or more milled cereal products, such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat and/or legumes (pulses) and/or starchy roots (such as arrow root, yam or cassava) or starchy stems and also, sesame, [arachis] and soybean.

The requirements concerning energy and nutrients refer to the product ready for use as marketed or prepared according to the instructions of the manufacturer, unless otherwise specified.

3.2 Energy Density

The energy density of cereal-based foods should not be less than 0.8 kcal/g.

3.3 Protein

[3.3.1 Where the product is intended to be mixed with water before consumption, the minimum content of protein shall not be less than 15% on a dry weight basis and the quality of the protein shall not be less than 70% of that of casein. However, when the chemical index of the protein is at least equal to 80% of that of casein, the minimum protein content shall not be less than 12%.]

[3.3.2 The addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose. Only natural L forms of amino acids shall be used.]

or

[3.1.4 The chemical index of the added protein shall be equal to at least 80% of that of the reference protein (casein as defined in Annex 1) or the protein energy ration (PER) of the protein in the mixture shall be equal to at least 70% of that of the reference protein. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose.]

[3.1.1 For products mentioned in points 2.1.2 and 2.1.4, the protein content shall not exceed 1.3 g/100 kJ (5.5 g/100 kcal)]

[3.1.2 For products mentioned in point 2.1.2 the added protein content shall not be less 0.48 g/100 kJ (2 g/100 kcal)]

[3.1.3 For biscuits mentioned in point 2.1.4 made with the addition of a high protein food, and presented as such, the added protein shall not be less than 0.36 g/100 kJ (1.5 g/ 100 kcal).]

3.4 Carbohydrates

[3.4.1 If sucrose, fructose, glucose, glucose syrup or honey are added to products mentioned in points 2.1.1 and 2.1.4

- the amount of added carbohydrates from these sources shall not exceed 1.8 g/100 kJ (7.5 g/100 kcal)
- the amount of added fructose shall not exceed 0.9 g/100 kJ (3.75 g/100 kcal)

3.4.2 If sucrose, fructose, glucose, glucose syrup or honey are added to products mentioned in point 2.1.2

- the amount of added carbohydrates from these sources shall not exceed 1.2 g/100 kcal
- the amount of added fructose shall not exceed 0.6 g/100 kJ (2.5 g/100 kcal)]

3.5 Lipids

3.5.1 For products mentioned in points 2.1.1 and 2.1.4 the lipid content shall not exceed 0.8 g/100 KJ (3.3 g/100 kcal)

3.5.2 For products mentioned in point 2.1.2 the lipid content shall not exceed 1.1 g/100 KJ (4.5 g/100 kcal):

(a) the amount of lauric acid shall not exceed 15% of the total lipid content;
(b) the amount of myristic acid shall not exceed 15% of the total lipid content;
(c) the amount of linoleic acid (in the form of glycerides = linoleates) shall not be less than 70 mg/100 kJ (300 mg/100 kcal) and shall not exceed 285 mg/100 kJ (1200 mg/100 kcal).

3.6 Minerals

3.6.1 The sodium content of the products described in Sections 2.1.1 to 2.1.3 of this Standard shall not exceed 100 mg/100 g of the ready-to-eat product.[However, for products intended for children over one year of age, the sodium content shall not exceed 200 m/100 kcal.]

[3.6.2 The sodium content of the products described in Section 2.1.4 of this Standard shall not exceed 300 mg/100 g of the product as sold.]

3.6.3 The calcium content shall not be less than 20 mg/100 kJ (80 mg/100 kcal) for products mentioned in points 2.1.1 to 2.1.3

3.4.4 The calcium content shall not be less than 12 mg/100 kJ (50 mg/100 kcal) for products mentioned in point 2.1.4 containing milk.

3.7 Vitamins

3.7.1 The amount of vitamin B1 (thiamin) shall not be less than 25 µg/100 kJ (100 µg/100 kcal)

[3.7.2 For products mentioned in 2.1.2, the amount of vitamin A and vitamin D expressed in µg/100 kcal shall be within the following limits:

- vitamin A (µg retinol equivalents) : 60 - 180
- vitamin D : 1 - 3

These limits are also applicable to other processed cereal-based foods when vitamin A or D are added.]

3.7.3 The addition of vitamins and minerals, especially vitamin A, iodine and iron shall be in conformity with the legislation of the country in which the product is sold.

3.7.4 Vitamins and/or minerals added should be selected from the Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979).

3.8 Optional Ingredients

3.8.1 In addition to the ingredients listed under 3.1, other ingredients suitable for infants who are more than four to six months of age and for young children can be used.

3.8.2 Products containing honey or maple syrup should be processed in such a way as to destroy spores of Clostridium botulinum, if present.

[3.8.3 Cocoa can be used only in products to be consumed after nine months of age, and at the maximum level of 1.5% m/m in the ready-to-eat product.]

3.9 Quality Factors

3.9.1 All ingredients, including optional ingredients, shall be clean, safe, suitable and of good quality.

3.9.2 All processing and drying should be carried out in a manner that minimizes loss of nutritive value, particularly protein quality.

3.9.3 The moisture content of the products shall be governed by good manufacturing practice for the individual product categories and shall be at such a level that there is a minimum loss of nutritive value and at which microorganisms cannot multiply.

3.10 Consistency and Particle Size

3.10.1 When reconstituted according to the label directions for use, processed cereal-based foods should have a texture appropriate for the feeding of infants or young children of the age for which the product is intended.

3.10.2 Rusks and biscuits may be used in the dry form so as to permit and encourage chewing or they may be used in a liquid form, by mixing with water or other suitable liquid, that would be similar in consistency to dry cereals.

3.11 Specific Prohibition

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

4. FOOD ADDITIVES

The following additives are permitted in the preparation of processed cereal-based foods for infants and children, as described in Section 2.1 of this Standard (in 100 g of product, on a dry weight basis unless
otherwise indicated)

4.1 Emulsifiers

4.1.1	Lecithin	1.5 g
4.1.2	Mono- and diglycerides	1.5 g

4.2 pH Adjusting Agents

4.2.1	Sodium hydrogen carbonate	GMP, within the limits for sodium
4.2.2	Potassium hydrogen carbonate	} Good manufacturing
4.2.3	Calcium carbonate	} practice
4.2.4	L(+) Lactic acid	1.5 g
4.2.5	Citric acid	2.5 g

4.3 Antioxidants

4.3.1	Mixed tocopherols concentrate	} 300 mg/kg fat, singly or in
4.3.2	Alpha-tocopherol	} combination
4.3.3	L-Ascorbyl palmitate	200 mg/kg fat
4.3.4	L-Ascorbic acid and its sodium and potassium salts and within the limits for sodium	50 mg, expressed as ascorbic acid

4.4 Flavours

4.4.1	Vanilla extract	GMP
4.4.2	Ethyl vanillin	} 7 mg on an as consumed basis
4.4.3	Vanillin	}

4.5 Enzymes

4.5.1	Malt carbohydrates	GMP

4.6 Leavening Agents

4.6.1	Ammonium carbonate	} Limited by
4.6.2	Ammonium hydrogen carbonate	} GMP

5. CONTAMINANTS

5.1 Pesticide Residues

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

The products covered by the provisions of the Standard shall comply with those maximum residue limits established by the Codex Alimentarius Commission.

5.2 Other Contaminants

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

6. HYGIENE

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

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

6.3 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 the hygienic and other qualities of the food.

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

8. LABELLING

In addition to the requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991), Codex Alimentarius Volume 1), the following specific provisions apply:

[Any indication required in the labelling should be made in the appropriate language of the country in which the product is sold.]

8.1 The Name of the Food

The name of the food shall be "Dry Cereal for Infants (and/or Young Children)", "Rusks for Infants (and/or Young Children)" or "Biscuits (or "Milk Biscuits") for Infants (and/or Young Children)" or "Pasta for Infants (and/or Young Children)", or any appropriate designation indicating the true nature of the food, in accordance with national legislation.

8.2 List of Ingredients

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

8.2.2 The specific name shall be declared for ingredients and food additives. In addition, appropriate class names for these ingredients and additives may be included on the label.

8.3 Declaration of Nutritive Value

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

(a) The amount of energy, expressed in calories (kcal) or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes of the food as sold as

well as per specified quantity of the food as suggested for consumption;

(b) in addition to any other nutritional information required by national legislation, the total quantity in the final product of each vitamin and mineral added according to Section 3.2.2 shall be declared per 100 g as well as according to the serving size of the food suggested for consumption.

8.4 Date Marking and Storage Instructions

8.4.1 The date of minimum durability (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer. In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

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

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

8.5 Information for Utilization

8.5.1 Directions as to the preparation and use of the food, and its storage and keeping before and after the container has been opened, shall appear on the label or on the accompanying leaflet.

[8.5.2 When the product contains less than 15% protein and the quality is less than 70% that of casein, or less than 12% protein of a quality equivalent to 80% of that of casein, directions on the label shall state "Milk or formula but no water shall be used for dilution or mixing" or an equivalent statement.]

8.5.4 The presence of gluten should be indicated in the label, if the intended age of use is below six months.

8.5.5 The label shall indicate clearly from which age the product is intended for use. In any case no reference shall be made to use of these products before 4 months. Additional requirements in this respect may be made in accordance with the legislation of the country in which the product is sold.

8.6 Additional Requirements

The products covered by this standard are not breast-milk substitutes and shall not be presented as such.

9. METHODS OF ANALYSIS AND SAMPLING

See Codex Alimentarius Volume 13.