codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

ALINORM 03/26

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-fifth Session
Rome, 30 June– 5 July 2003

REPORT OF THE 23rd SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Berlin, Germany
26 – 30 November 2001

Note: This document incorporates Codex Circular Letter 2001/45-NFSDU.

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CX 5/20.2 CL 2001/45 – NFSDU
December 2001

TO: Codex Contact Points
Interested International Organizations

FROM: Chief, Joint FAO/WHO Food Standards Programme, FAO
Viale delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: **DISTRIBUTION OF THE REPORT OF THE TWENTY-THIRD SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (ALINORM 03/26)**

The report of the Twenty-third Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses will be considered by the 25th Session of the Codex Alimentarius Commission to be held in Rome, 30 June - 5 July 2003.

PART A. REQUEST FOR COMMENTS AND INFORMATION

1. PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL SUPPLEMENTS AT STEP 3 (ALINORM 03/26, PARAS 18-40 AND APPENDIX II)

Governments are invited to comment on the proposed Draft Guidelines and should do so in writing to: Dr Rolf Grossklaus, Director and Professor, Federal Health Institute of Consumer Protection and Veterinary Medicine (BgVV), P.O. Box 33 00 13, 14191 Berlin, Germany, Fax: +49 1888 412 - 37 15, e-mail: ccnfsdu@bgvv.de with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org), **not later than 15 June 2002**.

2. PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA AT STEP 3 (ALINORM 03/26, PARAS 41-90 AND APPENDIX III)

Governments are invited to comment on the proposed Draft Revised Standard and should do so in writing to: Dr Rolf Grossklaus, Director and Professor, Federal Health Institute of Consumer Protection and Veterinary Medicine (BgVV), P.O. Box 33 00 13, 14191 Berlin, Germany, Fax: +49 1888 412 - 37 15, e-mail: ccnfsdu@bgvv.de with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org), **not later than 31 August 2002**.

Comments on Food Additive Section should be directed to: Mrs Awilo **Ochieng Pernet**, lic iur, Codex Contact Point of Switzerland, Main Unit Food Safety, Swiss Federal Office of Public Health, 3003 Bern, Switzerland, Fax:+41 (31) 3 22 95 74, email:awilo.ochieng@bag.admin.ch with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org), **not later than 15 June 2002**.

3. PROPOSED DRAFT REVISED STANDARD FOR CEREAL - BASED FOODS FOR INFANTS AND YOUNG CHILDREN (ALINORM 03/26, PARAS 91-117 AND APPENDIX IV)

Governments are invited to comment on the proposed Draft Revised Standard and should do so in writing to: Dr Rolf Grossklaus, Director and Professor, Federal Health Institute of Consumer Protection and Veterinary Medicine (BgVV), P.O. Box 33 00 13, 14191 Berlin, Germany, Fax: +49 1888 412 - 37 15, e-mail: ccnfsdu@bgvv.de with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org), **not later than 31 August 2002**.

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SUMMARY AND CONCLUSIONS

The Twenty-third Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses reached the following conclusions:

MATTERS OF INTEREST FOR THE EXECUTIVE COMMITTEE/COMMISSION

The Committee:

- ☛ Supported the conclusions of the 49th Session of the Executive Committee that the Revised Standard for Gluten-Free Foods be held until such time as the scientific basis for the establishment of gluten levels and the method of gluten determination were clarified (paras 9-10);
- ☛ Recognized that no progress could be expected on the Amendment to the Guidelines for the Use of Nutrition Claims at this stage and agreed to retain the Draft Condition for Claims on Dietary Fibre for consideration at its next session with the understaning that it would decide how to proceed further in the light of the new scientific evidence that would become available (paras 11-17);
- ☛ Returned the Proposed Draft Guidelines on Vitamin and Mineral Supplements, as amended during the session, for further comments and consideration by the next session of the Committee (paras 18-40);
- ☛ Returned the Proposed Draft Standard for Infant Formula to Step 3 for further comments and consideration by the next session of the Committee (paras 41-90);
- ☛ Recognized that despite the progress made on the Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infant and Young Children, some important provisions were left in square brackets and some sections needed to be up-dated in the light of new scientific evidence, therefore agreed to return the Proposed Draft Standard for further comments and consideration at the next session of the Committee (paras 91-117);
- ☛ Requested the Delegation of Germany to revise the Advisory List(s) of Mineral Salts and Vitamin Compounds for the Use in Foods for Infants and Young Children in view of the comments provided at the current session with the understanding that the revised version would be circulated for comments before the next session of the Committee (paras 118-129);
- ☛ Agreed to ask additional information from Member Governments on:
    - The Lists of Additives to be used in the Proposed Draft Revised Standard for Infant Formula and the Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infant and Young Children (paras 63-69 and 113);

MATTERS OF INTEREST TO OTHER COMMITTEES

CCFAC

- ☛ Expressed its concern on the large number of additives and levels of use proposed for infant formula and foods for infants and children in the Draft Sections of the General Standard for Food Additives, and asked the Committee on Food Additives and Contaminants to defer finalization of these levels until the CCNFSDU had carried out a thorough review of the current additives in the standards for foods for infants and children (para. 69);

CCPR

- ☛ Amended pesticide residue provisions in the Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children in order to provide additional protection of infants and young children (para. 113).

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LIST OF ABBREVIATIONS

AAA	Association Des Amidonneries de Cereales de L'U.E.
AESGP	Association of the European Self-Medication Industry
ALINORM	Reports of Codex Committees and other working papers submitted to the Codex Alimentarius Commission
AOAC	AOAC International
AOECS	Association of European Celiac Societies
CAC	Codex Alimentarius Commission
CCFL	Codex Committee on Food Labelling
CIAA	Confederation of the Food and Drink Industries of the EU
CISDA	Confederation of International Soft Drinks Associations
CRD	Conference Room Document
CX/NFSDU	Working papers for the Codex Committee on Nutrition and Foods for Special Dietary Uses
CRN	Council for Responsible Nutrition
CSPI	Center for Science in Public Interest
EC	European Commission of the European Union
EFLA	European Food Law Association
EHPM	European Federation of Associations of Health Product Manufacturers
ENCA	European Network of Childbirth Associations
IACFO	International Association of Consumer Food Organizations
IADSA	International Alliance of Dietary/Food Supplement Associations
IBFAN	International Baby Food Action Network
ICA	International Cooperative Alliance
ICGMA	International Council of Grocery Manufacturers Association
IDF	International Dairy Federation
IFMA	International Federation of Margarine Associations
IFT	Institute of Food Technologists
IFU	International Federation of Fruit Juice Producers
ISDC	International Soft Drink Council
ISDI	International Special Dietary Food Industries
NRV	Nutrient Reference Values
UNICEF	United Nations Children's Fund
WHO	World Health Organization of the United Nations

INTRODUCTION

1. The Twenty-third Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held from 26 to 30 November 2001 in the Federal Institute for Health Protection of Consumers and Veterinary Medicine, Berlin, by courtesy of the Government of Germany. The Session was chaired by Dr Rolf Grossklaus, Director and Professor at the above Institute. The Session was attended by 209 delegates, observers and advisors representing 49 Member countries, one Observer country and 25 International Organizations.

OPENING OF THE SESSION

2. The Session was opened by Dr Gerald Thalheim, Parliamentary State-Secretary to the Federal Minister of Consumer Protection, Food and Agriculture, who welcomed the participants on behalf of the Minister. Dr Thalheim noted the lessons learned from the earlier food crisis in Europe and emphasized the importance of the work of the Codex Alimentarius Commission in providing worldwide standards to protect the health of consumers, especially infants and young children and ensuring fair practices in food trade. He stressed the importance of the work in ensuring that children under five years are protected from malnutrition and are supplied with enough safe and good quality food, as still there were cases in the world when ten million children under five years suffered from food and nutrient deficiencies. Dr Thalheim also emphasized the importance of sound food labelling in ensuring the protection of consumers from misleading and unsubstantiated claims. Finally Dr Thalheim wished every success to the meeting and the delegates in their important work.

ADOPTION OF THE AGENDA (AGENDA ITEM 1)[1]

3. The Committee noted that the paper regarding justification of the Consideration of the Necessity for Review of the General Principles for the Addition of Essential Nutrients to Food under Agenda Item 12 had not been prepared, therefore the matter was deleted from the Provisional Agenda. The Committee adopted the Provisional Agenda as the Agenda for the Session with the above amendment.

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES (AGENDA ITEM 2)[2]

4. The Committee noted matters arising from the 48th and 49th Sessions of the Executive Committee; the 24th Session of the Codex Alimentarius Commission (CAC), 2-7 July 2001; the 33rd Session of the Codex Committee on Pesticide Residues (CCPR); the 25th Session of the Codex Committee on Food Labelling (CCFL) and the 1st session of the *Ad Hoc* Codex Intergovernmental Task Force on Fruit Juices and Nectars as follows:

Proposed Draft Revised Standard for Processed Cereal - Based Foods for Infants and Young Children

5. The Committee decided to take into account the conclusions of the 48th Session of the Executive Committee on the above subject matter in conjunction with Agenda item 6 (see paras 91 – 117).

Recommendations of the FAO Conference on International Trade Beyond 2000

6. The Committee noted that the following recommendations directed from the Melbourne Conference to the Codex Alimentarius Commission and endorsed by the 23rd Session of the Commission[3] were most

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1 CX/NFSDU 01/1.

2 CX/NFSDU 01/2; CX/NFSDU 01/2-Add.1; CRD 9 (comments of India).

appropriate for application in its work: the Recommendation 14 regarding the consideration of special needs of developing countries and Recommendation 17 stating that standards should not to be over-prescriptive or unnecessary stringent.

Draft Medium-Term-Plan

7. The Committee concluded that it had no comments on the Proposed Draft-Medium-Term Plan and noted that Governments could provide their additional comments to the Codex Secretariat by the end of November.

Risk Analysis Policies in the Committee

8. The Delegation of Australia stressed the importance of basing all Codex food safety standards on risk analysis and the Committee noted that this question would be specifically discussed under Agenda item 10.

Draft Revised Standard for Gluten Free Foods

9. The Committee generally supported the conclusions of the 49th Session of the Executive Committee that the Revised Standard be held at Step 7 until such time as the scientific basis for the establishment of a level and the method of determination were clarified.

10. Some delegations, however indicated the importance of this matter in relation to protection of consumers' health and were of the view that it should be placed on the Provisional Agenda for the next session of the Committee.

GUIDELINES FOR THE USE OF NUTRITION CLAIMS: DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (PART B CONTAINING PROVISIONS ON DIETARY FIBRE (AGENDA ITEM 3)[4]

11. The Committee recalled that it had not been possible to reach consensus on the definition, method of analysis and conditions for claims for dietary fibre at the last session. The Draft Condition for Claims had therefore been returned to Step 6 for additional comments and further consideration.

12. The Delegation of the United States informed the Committee that its National Academy of Science had undertaken a comprehensive review of dietary fibre definitions and related methods of analysis and that a dietary reference intake would be defined on that basis. The Committee noted that the final report would be published in early 2002 and that it could be used as a basis for further discussion at the next session.

13. The Delegation of Sweden informed the Committee that studies were also underway in the Nordic countries on the reference intake for fibre and new information resulting from these studies would probably be available in 2002. The Committee noted that any new scientific information published prior to its next session would be made available to delegates through the usual distribution channels, including the Codex or host country website.

14. The Committee noted that the current definition included in the Guidelines on Nutrition Labelling covered "edible plant and animal material". Some delegations supported a definition of fibre including only products of plant origin as this corresponded to the messages used for the purposes of nutrition education and was commonly understood by consumers. It was noted that this would require an amendment to the current Guidelines on Nutrition Labelling but it was not possible to reach a conclusion on this question at this stage.

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[3] ALINORM 01/41, paras 42-44.

[4] ALINORM 01/26, Appendix III, CX/NFSDU 01/3 (comments of Australia, Germany, Malaysia, New Zealand, South Africa, Spain, United States), CRD 7 (comments of Uruguay), CRD 8 (comments of Thailand).

The Observer from IDF expressed the view that oligosaccharides from milk and breast milk should be taken into account due to their important physiological functions.

15. As regards the expression of the conditions for claims, the Committee noted the proposals to address the following issues: the expression of conditions per serving and per energy; the need for a third category with a higher fibre content; the definition of conditions for liquids, in addition to solids. However the Committee agreed that the conditions for claims could not be discussed in detail until the questions of the definition and the methods of analysis had been addressed.

16. The Committee also noted that the Spanish translation of "dietary fibre" should be corrected to avoid confusion with special dietary foods.

Status of the Guidelines for Use of Nutrition Claims – Draft Table of Condition for Nutrient Contents Claims (Dietary Fibre)

17. The Committee recognized that no progress could be expected from additional comments at this stage and agreed to retain the Draft Condition for Claims on dietary fibre at Step 7 for further consideration at the next session. The Committee agreed that it would decide how to proceed further in the light of the new scientific evidence that would become available.

PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL SUPPLEMENTS (AGENDA ITEM 4)[5]

18. The Committee recalled that at its last session it had returned the Proposed Draft Guidelines to Step 3 for further comments and consideration by the next session. It was noted that the current Guidelines contained some prescriptive text that could be more relevant to a standard.

19. The Committee discussed the Proposed Draft Guidelines Section by Section and made the following amendments.

Preamble, Scope and Definitions

20. The Delegation of the United States drew the attention of the Committee to the fact that none of the Codex Guidelines had Preambles and that the text of the Scope could be reworded to accommodate the wording from the Preamble in order avoid duplication.

21. The Delegation of Malaysia, supported by several delegations objected to such proposal and was of the view that the current Preamble was important, especially for countries which were promoting a dietary based approach and therefore should be retained as it was written, or incorporated into the Scope entirely.

22. After an extensive debate on the content and the location of Preamble, the Committee concluded that it needed more consideration especially as the Preamble, Scope and the Section on Definitions were interrelated and therefore the issue should be discussed in its entirety. The Committee agreed to request additional comments on the wording and the location of Preamble.

23. The Committee amended the second sentence in section 1.2 in order to emphasize the applicability of the Proposed Draft Guidelines to foods only.

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[5] ALINORM 01/26, Appendix IV; CX/NFSDU 01/4 (comments of Australia, Malaysia, Mexico, New Zealand, South Africa, Spain, CRN, IADSA, ISDI); CX/NFSDU 01/4 –Add.1 (comments of Denmark and Germany), CX/NFSDU 01/4 –Add.2 (comments of China, Cuba and Norway); CRD 7 (comments of Uruguay); CRD 8 (comments of Thailand); CRD 9 (comments of India).

24. The Committee amended the second sentence in section 2.1 by substituting "concentrated sources" with "forms" and deleted the square brackets from "concentrated".

25. The Committee deleted Section 2.2 as supplements serving special nutritional purposes were taken out from the Scope of these Guidelines.

26. In order to clarify the applicability of the Proposed Draft Guidelines for Vitamin and Mineral Supplements, the Committee agreed to delete the square brackets from Section 1.3.

27. Regarding the proposal to extend the Scope to cover herbs traditionally used for supplementation purposes or as a medicine, the Secretariat recalled that the Committee and the CAC had considered this matter in the past and that the 21st session of the Commission in 1997, concurred with the view of this Committee and deleted this matter from the Commission's work Programme. It left this matter to national authorities to decide since the regulation and practices in this area greatly differed from one country to another[6]. The Observer from the EC suggested to indicate that provisions on vitamins and minerals included in these Guidelines should also be applicable to supplements containing vitamins and minerals together with other ingredients.

Section 3. Composition

28. The sentence in section 3.1.1 was amended in order to make the Proposed Guidelines less prescriptive and to clarify that status of vitamins and minerals should be recognized by FAO/WHO.

29. Section 3.1.2 was amended to clarify the nature and requirements for nutrient sources and the wording "and national legislation, where applicable" at the end of the second sentence put in square brackets.

30. While considering section 3.1.3 regarding provisions limiting the use of individual vitamins and minerals, some delegations were of the view that those limitations should be based on science. Other delegations stressed the need to take into account other factors such as regional or national peculiarities in supplying population with vitamins and minerals. The Committee was unable to reach agreement on the wording at this stage and decided to retain this paragraph in square brackets for further comments and consideration.

31. Section 3.1.4 was amended to replace the wording " nutrients" by "vitamins and minerals".

32. To be consistent with the previous decision regarding the Scope of the Guidelines, the sentence in square brackets with reference to supplements for special nutritional purposes was deleted.

33. The Committee noted the proposal from the Observer of CRN suggesting to clarify the Section on composition by adding new sub-section 3.1.4 to read:

> *"Nothing in the Scope of this guideline is intended to exclude from later consideration, additional guidelines for other food ingredients, such as fiber and amino acids.*
>
> *Further, nothing in this guideline is intended to exclude the use of other food ingredients in supplements that contain vitamins and minerals".*

Section 3.2 Contents of Vitamins and minerals

34. While considering section 3.2.1 regarding the minimum level of nutrients in vitamin and mineral supplements and the basis for its expression, different opinions were expressed. Some delegations indicated that the level of 15% was acceptable, while other delegations were of the view that such level was too low therefore some of them proposed a level of 25%. Some other delegations favoured establishing a level of

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6 ALINORM 97/37, para. 151.

33%. It was noted that instructions of the manufacturer regarding recommendations for consumption should be taken into consideration.

35. The Committee decided to delete the square brackets from this section and to express the level of vitamin and mineral supplements per daily portion of consumption on the basis of the recommended daily intake established by FAO/WHO. The Committee agreed to put provisions regarding minimum levels ranging from 15% to 33% in square brackets for further comments.

36. The Committee had a lengthy debate regarding the maximum level to be contained in vitamin and mineral supplements and the basis for its establishment. Some delegations proposed to retain the maximum level at 100% of the recommended daily intake, while some other delegations and observers were of the opinion that this level should be higher in order to provide more benefits for consumers; that the upper level should be established on the basis of risk assessment and should consider all sources of the nutrients.

37. As a compromise, the Committee agreed to retain the Section 3.2.2 and amend the Section 3.2.3 by clarifying the nature and the requirements for the setting of upper safe limits for vitamin and mineral supplements and to keep both options in square brackets for further comments.

38. Due to time constraints the Committee did not discuss Section 4.

Section 5. Labelling

39. In view of its previous decision on the Scope, the Committee agreed to delete provisions regarding the supplementation for special nutritional purposes contained in Section 5.2

Status of the Proposed Draft Guidelines on Vitamin and Mineral Supplements

40. The Committee agreed to return the Proposed Draft Guidelines, as amended during the session, to Step 3 for further comments and consideration by next session of the Committee (see Appendix II).

PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA (AGENDA ITEM 5)[7]

41. The Chairman recalled that the proposed Draft had been returned to Step 3 for further comments and consideration due to lack of consensus on a number of important issues and especially the Scope. As it had not been possible due to time constraints to discuss the composition requirements, it had been agreed that a Working Group coordinated by the United States would work by correspondence to prepare revised requirements for vitamins and minerals in that section. The Committee discussed the standard section by section and made the following amendments.

Section 1. Scope

42. The Delegation of Germany presented the discussion paper that had been prepared at the request of the Committee to address the issue of infant formula for special medical purposes, and proposed three options: A) revising the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (FSMP) to include provisions for special medical purposes for infants; B) excluding FSMP from the Standard for Infant Formula without elaborating specific provisions in another standard; and C) including provisions for medical foods in the Standard for Infant Formula.

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[7] ALINORM 01/26 - Appendix V, CX/NFSDU 01/5 (discussion paper prepared by Germany), CX/NFSDU 01/5-Add.1 (comments of China, Cuba, IBFAN), CRD 4 (Report of the Working Group on Composition Requirements), CRD 5 (comments of the EC), CRD 6 (comments of UNICEF), CRD 7 (Uruguay), CRD 8 (Canada, Thailand), CRD 9 (India).

43. The Delegation of India, supported by several delegations and the Observers of IBFAN and IACFO, supported the deletion of the term "healthy" since it was not clearly defined and as the standard should cover the needs of all infants. Other delegations expressed the view that it should be retained as the standard should apply only to the general population. After a detailed discussion, the Committee agreed to delete the term "healthy" as it was not necessary in the first sentence, and discussed the second sentence.

44. The Committee noted that according to the original text[8], the provisions of the standard were "also intended for infants with special nutritional requirements" and the word "also" was reintroduced in the English version as it had been omitted.

45. The Committee had an extensive discussion on whether the standard should cover foods for special medical purposes, as defined in the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes*.

46. The Observer from the EC stressed the importance of a separate standard for medical foods to address the health hazards affecting specific groups of infants, while the current standard should cover normal requirements; this was also necessary to prevent misrepresentation of ordinary infant formula as medical foods. This view was supported by several delegations, some of which referred to similar provisions in their national regulations, and the Observer from ISDI.

47. The Delegation of Canada proposed to develop a single standard for all types of infant formula, as the current standard was generally suitable and flexible enough to allow some modifications for special medical uses, and this was consistent with the provisions of the International Code of Marketing of Breast-milk Substitutes. The Delegation of India stressed the importance of promoting breastfeeding and ensuring compliance with the Code. These positions were supported by several other delegations.

48. The Representative of WHO indicated that the International Code of Marketing of Breast-milk Substitutes covered all types of formula, including those for infants with special nutritional requirements or medical needs, intended as a partial or total replacement for breast milk.

49. After an extensive debate, the Committee recognized that no consensus could be reached at this stage and that Section 1.1 would require further discussion. The first sentence was retained with the deletion of "healthy" and the second sentence was retained in square brackets for further comments and consideration at the next session.

50. The Observer from the EC proposed that as a follow-up to the discussion paper, the Delegation of Germany should prepare alternative simulation versions corresponding to the options discussed, in order to facilitate discussion. Some delegations opposed the development of an additional discussion paper as the Committee should concentrate on the text of the standard. The Committee noted that as this section would be returned to Step 3 for further comments, all governments and observers would have the opportunity to provide additional comments and proposals on the section under discussion and the standard as a whole.

51. In Section 1.3 referring to the World Health Assembly Resolutions, the Committee agreed that the text should refer to WHA resolution WHA54.2 (2001) on Infant and Young Child Nutrition and deleted the current footnote concerning previous resolutions.

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[8] ALINORM 99/26, Appendix V.

Section 2. Description

Product Definitions

52. Some delegations pointed out that the paragraphs under Definitions were not really definitions but description of the products. The Committee noted that it would be possible to retain only the definition of "infant" under " Definitions" and rename section 2.1 as "Description", but did not come to a conclusion at this stage.

53. In section 2.1.1, the Committee agreed that "infant formula, when in liquid form, may be used either directly or prepared" with water, rather than "diluted" with water for clarification purposes, and to add a reference to directions for use.

54. In section 2.1.2, the Committee had an extensive debate on the reference to "normal growth" and the nutritional requirements of infants. Some delegations pointed out that the term "normal" was not clearly defined and the Committee therefore agreed to put it in square brackets.

55. Some delegations and observers stressed that only products complying with all the requirements of the standard should be presented as infant formula, in order to avoid misleading claims, and the Committee agreed to add a sentence to this effect at the end of the section.

56. As regards nutritional requirements, some delegations proposed to mention the first six months of life in view of WHA resolution WHA54.2 (2001). Other delegations supported a general formulation such as "the nutritional requirements of infants" to allow more flexibility. Some delegations and the Representative of WHO pointed out that this would imply suitability during the first 12 months of life as the sole source of nourishment, according to the definition of "infant" and might prevent the introduction of complementary feeding between 6 and 12 months.

57. After some discussion, the Committee agreed to refer to "the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding" as a compromise and for further consideration at the next session.

58. Several delegations expressed the view that infant formula could not satisfy "by itself" the nutritional requirements of infants as this would imply that it had the same nutritional value as breast milk. Other delegations supported this wording as it would make it clear that infant formula should satisfy all nutritional requirements of infants. The Committee noted that the term "sole source of nutrients" might be more generally acceptable but did not reach a conclusion on this question.

59. As it was not possible to reach a consensus on this section, it was retained in square brackets for further comments and consideration at the next session.

Section 3. Essential Composition and Quality Factors

60. The Delegation of the United States informed the Committee that the Working Group established at the last session had postponed consideration of macronutrients as new recommendations in this area were expected from the FAO/WHO Expert Consultation on Human Protein Requirements (April 2002), and from a report of the National Academy of Sciences on dietary reference intakes. The WG had recommended general principles for establishing maximum and minimum values for the essential composition of infant formula, and proposed revised levels of vitamins and minerals on this basis.

61. The Committee expressed its appreciation to the United States and to the Working Group for their considerable work. As it was not possible to discuss composition requirements at the current session due to time constraints, it was agreed that the proposals in CRD 4 would be circulated separately for comments and

further consideration at the next session. The Observer of AOECS underlined the importance to use constituents of gluten-free plant origin for infant formula.

62. The Committee agreed with the proposal of the Chairman to convene a Working Group immediately prior to the next session on Saturday, 2 November 2002, in order to review the comments submitted before 31 August 2002 and prepare proposals for revision to facilitate the discussion in the plenary session.

Section 4. Additives

63. The Secretariat informed the Committee of the status of the additives currently allowed in the standard as related to the Codex General Standard for Food Additives (GSFA). Only Ascorbyl Palmitate was included in the final text of the General Standard with a level of 50 mg/kg. The draft sections of the General Standard[9] included the other additives with higher maximum levels of use, and additional thickeners and emulsifiers. Several colours were listed for use in infant formula (such as Brilliant Blue, Brilliant Black, Beet Red, Sunset Yellow FCF, Quinoline Yellow, Ponceau 4R, Indigotine) whereas the current standard did not allow the use of any colour.

64. The Committee noted that all additives proposed in the draft GSFA for infant formula were also proposed for cereal-based foods, and that sweeteners were allowed under the category "Dietetic Foods intended for special medical purposes, including those for infants and children".

65. The Secretariat also indicated that member countries could provide their comments directly to the CCFAC as the draft sections of the GSFA would be considered at Step 7 by the next session of the Committee (March 2002) with a view to their adoption by the Commission in 2003.

66. Many delegations expressed the view that the additives allowed in infant formula and generally in foods for infants and children should be kept to the minimum necessary, on the basis of adequate technological justification. The additives included in the GSFA should take into account the advice provided by the CCNFSDU as regards foods for special dietary uses. It was noted that according to the procedure, the Committee was responsible for developing a section on food additives, which had to be forwarded to the CCFAC for endorsement.

67. Some delegations proposed to define criteria for the establishment of a list of additives for infant formula. The Committee however recalled that the ADIs established by JECFA for additives took into account all population groups and that the *General Principles for the Use of Food Additives* provided guidance for establishing lists of additives for all foods.

68. As it was not possible to consider the additives section at the present session the Committee agreed that specific comments would be requested and that a Working Group[10] chaired by Switzerland and working by correspondence would revise the additives section on the basis of the comments. The Proposed Draft List of additives will be considered by the next session of the Committee.

69. The Committee expressed its concern on the large number of additives and levels of use proposed for infant formula and foods for infants and children in the Draft Sections of the General Standard, and asked the Committee on Food Additives and Contaminants to defer finalization of these levels until the CCNFSDU had carried out a thorough review of the current additives in the standards for foods for infants and children.

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[9] ALINORM 01/12, Appendices III and IV.

[10] Thailand, Germany, India, Sweden, Romania, United States, France, Turkey, Canada, Tanzania, Slovakia, United Kingdom, Nigeria, Poland, Denmark, China, Japan. Netherlands, Indonesia, EC, ISDI, CRN, ENCA, ALACTA, IBFAN.

Section 5. Contaminants

Pesticide Residues

70. The Delegation of Kenya, supported by other countries, proposed to set a level of 0.01 mg/kg for each pesticide and expressed the view that the current paragraph did not allow sufficient protection from contamination by pesticides.

71. The Secretariat recalled that the question of specific maximum residue limits for pesticides in infant formula and foods for infants and children had been discussed at earlier sessions, that the Committee on Pesticide Residues did not set MRLs for composite products but only in raw agricultural commodities, and that the establismnent of MRLs for composite products required new internationally agreed methodology. It was also pointed out that a large number of MRLs had been established for products of plant and animal origin entering into the composition of infant formula and foods for infants and children. The 32nd Session of the CCPR (2000) had endorsed the current section on pesticide provisions after careful consideration in order to minimize the presence of pesticide residues in foods for infants and children. It was noted that any amendment to the current text would require endorsement by the CCPR. In addition, the Committee was informed that the Joint Meeting on Pesticide Residues (JMPR) intends to address increased vulnerability of infants and children at its meeting in 2002.

72. The Delegation of Nigeria proposed that pesticides "that have been used" should be reduced "to the safest level possible". Other delegations pointed out that the safest level could not be defined precisely and that the reference to pesticides "which may be required" was preferable for the purposes of health protection.

73. The Delegation of India stressed the importance of implementation at the national level and in the absence of international recommendations, proposed to include a reference to national legislation.

74. The Delegation of Turkey proposed to include a reference to the MRLs established by the Commission after the wording "raw materials"and to delete the rest of the sentence.

75. Other delegations supported the current text and as the Committee could not agree on any of the changes proposed, the section was left unchanged.

Other contaminants

76. The Committee noted that the 24th Session of the Commission had adopted maximum levels for lead including a level of 0.02 mg/kg in infant formula in the product (ready to use) and it was agreed to include it at the end of the section.

Section 9. Labelling

77. In section 9.1.4 the Committee deleted the square brackets and agreed that products which contain neither milk nor milk derivative "shall be labelled" as such, rather than "may be labelled".

78. In section 9.1.5, the Delegation of India, supported by some delegations and the Observer from IACFO pointed out that health claims were used to promote infant formula and proposed to prohibit health claims, nutrient function claim and nutrient contents claims.

79. The Delegation of Germany proposed to defer discussion of this section as the Committee had not yet decided whether or not to include foods for special medical uses in the Scope of the standard. The Committee could not come to a consensus and left the section unchanged with square brackets around the entire text and the last sentence.

80. The Committee discussed section 9.1.6 on the declaration of iron and noted some proposals for amendments. The Delegation of Tanzania proposed to delete both alternative sentences as they were not necessary and the range of iron levels was specified in the composition Table. The Delegation of Norway pointed out that it was difficult to reach a conclusion at this stage since the composition of the product had not been finalized. The Committee retained both sentences in square brackets for further consideration.

Declaration of Nutritive Value

81. The Delegation of the United States proposed to add a declaration of nutrients per 100 kcal for macronutrients, in addition to 100 g or 100 ml. As this was already allowed for other nutrients and ingredients in paragraph (b), the text was reordered to make this provision applicable to all nutrients.

82. In paragraph (b), the Committee clarified the reference to nutrients defined under 3.1.2 and to ingredients defined under 3.2. It was also agreed to refer to "other ingredients" rather than "optional ingredients" for clarification purposes. The Delegation of Uruguay objected to this decision as the declaration of nutritive value refers to kcal and nutrients. The ingredients which are not nutrients (3.2.4) should be included in the corresponding list of ingredients.

83. In section 9.6.1, many delegations proposed to delete the square brackets in point b) and retain the statement "Breastmilk is the best food for your baby, it protects against diarrhea and other illnesses", while other delegations proposed to delete that sentence as it was not in conformity with the provisions of the Code of Marketing for Breast-milk Substitutes. Some delegations pointed out that not all illnesses were covered and that breast feeding "helps protect against some illnesses".

84. After an extensive discussion, the Committee agreed to include the following alternative texts in square brackets for further consideration: 1) the current text as amended by the Delegation of Uruguay to present the statement as an example; and 2) "the statement "Breastfeeding is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breastmilk", as proposed by the Observer from the EC.

85. In section 9.6.2, the Committee agreed to prohibit pictures of infants "and women" idealizing the use of infant formula. The Delegation of India proposed to refer to "artificial feeding" instead of "infant formula". However it was pointed out that "artificial feeding" had a specific meaning in medicine and that it was totally different from infant feeding with infant formula; in addition the standard applied only to infant formula and did not cover other type of products or feeding.

86. The Committee agreed that the label "shall have graphics" to illustrate the methods of preparation of the products and methods of feeding. Some delegations and observers proposed to refer to the use of cups for feeding rather than bottles, since bottle feeding was prohibited under some national regulations. The Committee however noted that the present text referred to "methods of feeding" in a general sense for the purposes of labelling; the standard did not prescribe any specific method of feeding and this was left to national authorities to decide.

87. In section 9.6.4, the Committee agreed to clarify that infants should receive complementary feeding "from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker and in any case from the age over six months", as proposed by the Observer from the EC.

88. The Committee discussed whether section 9.6.5 concerning the distinction between infant formula and follow-up formula should be retained or deleted, and could not come to a conclusion. The section was retained in square brackets for further consideration.

Section 10. Methods of Analysis and Sampling

89. The Secretariat informed the Committee that the Commission had adopted five Codex general methods for the detection of irradiated foods, which were relevant in view of the provisions in Section 3.6. It was

noted that the entire section on methods of analysis would be presented in the standard to allow for further comments and updating if necessary.

Status of the Proposed Draft Revised Standard for Infant Formula

90. The Committee agreed to return the Proposed Draft Standard to Step 3 for further comments and consideration at the next session (see Appendix III).

PROPOSED DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN AT STEP 4 (AGENDA ITEM 6)[11]

91. The Committee recalled that the Proposed Draft Revised Standard was retained at Step 4 as the 22nd session of the Committee was unable to reach an agreement on the wording in the Scope regarding the introduction of the complementary feeding and therefore requested the Commission advice on how to proceed on this matter.

92. The Committee decided to consider the Proposed Draft Revised Standard section by section and made the following changes.

Scope

93. The Committee recalled that this matter was considered by the 48th session of the Executive Committee[12] which noted that the Fifty-fourth World Health Assembly (Geneva, 14 to 22 May 2001) adopted a comprehensive resolution on infants and young child feeding[13] and that the Executive Committee recommended that the World Health Assemble resolution be taken into account by the Committee. It agreed that the Committee should proceed to a conclusion of the revision of the standard as quickly as possible in order to satisfy the need for an adequate standard ensuring the quality and the safety of these products in international trade.

94. The Committee discussed the wordings proposed by the European Community, UNICEF and WHO for the Scope. The Delegation of Brazil emphasized that the spirit of WHA resolution WHA54.2 (2001) should be fully reflected as a primary aspect of the Scope, in line with a population or public health approach.

95. The Observer from the EC pointed out that their proposal took full account of the resolution of WHA and of the conclusions and recommendations of the WHO Expert Consultation (Geneva, 28-30 March, 2001). The Committee had a lengthy and extensive debate regarding the wording that should be taken as a basis for the Draft Revised Standard.

96. The Delegation of the United States suggested to amend the text proposed by the EC to clarify that when breast feeding or infant formula was not sufficient to satisfy individual nutritional requirements complementary feeding might be given upon advice of independent health professional. This proposal was supported by several delegations and the Observer from ENCA.

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[11] CL 1999/20-NFSDU; CXNFSDU 01/7 (comments of Australia, Brazil, Cuba, France, Germany, Hungary, Indonesia, Italy, Korea, Republic of, Mexico, Norway, Paraguay, Poland, Senegal, Singapore, South Africa, Sri Lanka, Switzerland, United Kingdom, European Commission, AOECS, ENCA, IBFAN, ISDI, WHO, The use of Additives in Processed Cereal-Based Foods for Infants and Young Children, prepared by the Netherlands, Canada, China, France, Germany, Romania, Slovakia, Spain, Switzerland, United Kingdom, the USA, Uruguay, EC and ISDI); CX/NFSDU 01/6-Add.1 (Note from the WHO Secretariat); CX/NFSDU 01/6-Add.2 (comments of ISDI, IBFAN, ENCA; CRD 5 (comments of European Community); CRD 6 (comments of UNICEF); CRD 7 (comments of Uruguay); CRD 8 (comments of Canada, Thailand); CRD 9 (comments of India).

[12] ALINORM 01/4, paras 38-39.

[13] Resolution 54.2 Infant and Young Child Nutrition.

97. The Delegation of Uruguay pointed out that the reference to independent health workers could be understood and interpreted in various countries differently and that it might create difficulties in the application of this standard. In addition, the Delegation of Uruguay did not support the text in principle for the following reasons: according to its food legislation since 1994, these foods were regulated as complementary foods for infants of 6 months and above and young children; the World Health Assembly was the only adequate and representative framework to give recommentations on infant feeding; and finally the legislation in Uruguay, in addition to protecting the health of infants and breastfeeding, did not consider cereal-based foods adequate to be used during the first six months of life, due to the risk of early gluten intolerance. The Delegation pointed out that this risk did not only concern cereals containing gluten, but all this food group due to the possibility of contamination during processing, and this well known fact should be taken into account.

98. The WHO Representative stated that, in light of the Committee' s discussion on the Draft Revised Standard for Infant Formula, the juxtaposition of breast milk and infant formula in Scope was inappropriate. The present wording appeared to imply a degree of nutritional equivalence between breast milk and infant formula – that both were adequate to meet the nutritional requirements of six months – that was not at all supported by scientific evidence. To remedy this, he suggested shortening the wording for the Scope to read; "This standard covers processed cereal-based foods intended for feeding infants from the age of six month onwards, and for feeding young children as part of their progressively diversified diet".

99. Some Observer organizations proposed to use the wording as suggested by UNICEF. The Delegation of India pointed out that the wording proposed by WHO was more appropriate especially in ensuring that complementary foods are not marketed in a way to undermine the prevalence of breastfeeding, that was very important for developing countries. This view was supported by a number of delegations and some Observers.

100. The Observer of the EC drew the attention of the Committee to the fact that from the recommendations of the WHO Expert Consultation it was clear that exclusive breast feeding might cause some problems for some children, therefore suggested to amend its initial proposal by deleting the reference to breast feeding alone or by infant formula being sufficient.

101. The Representative of WHO agreed with this reformulation which, in addition to being in conformity with WHO Health Assembly resolution WHA54.2 (2001), removed any suggestion of nutritional equivalence between breast milk and infant formula.

102. In addition, it was proposed to amend the EC proposal by inserting at the end of the sentence the reference to the WHA resolution WHA54.2 to make it clear that the spirit of that resolution could not be lost.

103. The Committee noted that it was not possible to come to an agreement at this stage. Due to time constraints and in order to progress with the revision of the rest of the document, the Committee decided to put both the EC and WHO proposals for the Scope in square brackets for further comments and consideration.

Section 2 Description

104. The Committee noted proposals to amend the title of the Proposed Draft Standard and/or to delete the reference to the use of starchy root and stem products as they could lower nutritional value of the cereal-based products, and to increase the percentage of cereals to reflect the title of the Proposed Draft Standard.

105. The Committee recalled that starchy roots and stems were introduced because those products were traditionally used in some developing countries.

106. The Representative of FAO stated that FAO makes a clear distinction between cereal crops and root crops and that carbohydrates derived from cereals are differentiated from those derived from starchy roots

by the FAO/WHO Expert Consultation[14], therefore the description under Section 2, which reads, "Processed cereal-based foods 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" was technically incorrect. The Representative indicated that either the term 'cereal-based' should be deleted from the title or the description should state clearly that the 'cereal-based foods are primarily prepared from one or more milled cereals' only.

107. The Delegation of India proposed that in respect of cereal based foods the minimum percentage of cereals needs to be higher than 25% in case products has to be reconstituted with milk or other appropriate nutritious liquids.

108. The Committee decided to clarify the wording of Description by indicating that cereals should constitute at least 25% of final mixture of the product on dry weight basis and made the relevant clarification in Section 3.1.1 regarding the use of legumes, starchy roots and stems as suggested by the Delegation of Malaysia.

Section 2.1 Product Definitions

109. The Observer from ENCA proposed to adopt 2.2.1 to the wording of Scope and to take the definition of older infants of Guidelines on Formulated Supplementary Foods for Older Infants and Young Children to read: "The term older infants means persons from the 6^{th} month and not more than 12 month of age". Some delegations opposed to this proposal.

110. The Committee amended Section 2.1.1 to clarify the nature of cereals.

Section 3. Essential Composition and Quality factors

111. Due to time constraints and in view of the fact that some provisions of this section needed to be up-dated to take into account the latest scientific findings, the Committee decided to establish a Working Group[15] working by electronic mail to be chairedby the Delegation of Malaysia.

112. The Representative of FAO supported such approach and indicated that an up-dating of the section on composition of the cereal-based foods for infants and children would benefit from the FAO/WHO/UNU Consultations on macronutrients (Human Energy Requirements, Rome, October 2001 and Human Protein Requirements scheduled in Geneva for April 2002) as well as the deliberations of the Food and Nutrition Board of the US National Academy of Sciences. The Representative indicated that the two Working Groups would also benefit from the reports and recommendations of the Consultations concerning requirements for fats and oils, carbohydrates and vitamins and minerals in human nutrition.

Section. Food Additives

113. Based on the discussion which had taken place as regards the additives section while considering the infant formula standard (see paras 63 –69), the Committee decided to extend the mandate of the Working Group led by Switzerland, so that it would also revise the additives section in this standard based on additional comments received. The revised section on food additives will be considered by the Committee at its next session.

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[14] Carbohydrates in Human Nutrition, FAO Food and Nutrition Paper 65.

[15] Bulgaria, Canada, China, Denmark, Germany, Egypt, France, India, Indonesia, Japan, Mexico, Nigeria, Norway, Singapore, South Africa, Thailand, Turkey, UK, Uruguay, ALACTA, ENCA, IBFAN, IACFO, ISDI, IOCCC and the EC.

Section 5. Contaminants

114. The Committee agreed with the suggestion of the Observer of the EC to amend the pesticide residue provisions endorsed by the CCPR (ALINORM 01/24, para.74) in order to provide additional protection of infants and young children by inserting the following text (subject for endorsement by the Committee on Pesticide residues):

> *"These limits shall take into account the specific nature of the products concerned and the specific population group for which thy are intended".*

Section 8. Labelling

115. The Committee accepted the proposal of the Delegation of India in section 8.2.3 regarding the presentation of pictures or texts on the label that could idealize the use or could suggest an inappropriate age of introduction of cereal-based products and decided to put the wording in square brackets. The Delegation of India referring to its written comments (CRD 9), and supported by some delegations, proposed two other amendments regarding the prohibition for these products health claims and the declaration of genetically modified ingredients on the label. The Committee did not include these amendments, as the Committee could not agree at this stage since there was no time for discussions and these matters were still the subject of debate in the Committee on Food Labelling. There was insufficient time to discuss this entire section.

Section 9. Methods of Analysis and Sampling

116. Following the earlier decision taken on the relevant Section of the Proposed Draft Revised Standard for Infant Formula (see also para 89), the Committee decided to reinsert provisions for methods of analysis for comments and further up-dating, if necessary.

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

117. The Committee recognized that despite the progress made, some important provisions were left in square brackets and some sections needed to be up-dated, therefore agreed to return the Proposed Draft Standard to Step 3 for further comments and consideration at the next session of the Committee (see Appendix IV).

DISCUSSION PAPER ON THE PROPOSED DRAFT REVISION OF THE ADVISORY LIST(S) OF MINERAL SALTS AND VITAMIN COMPOUNDS FOR THE USE IN FOODS FOR INFANTS AND CHILDREN (CAC/GL 10-1979) (AGENDA ITEM 7)[16]

118. The Delegation of Germany introduced the item and recalled that following the decision of the last session of the Committee a Circular Letter had been prepared to request comments regarding the criteria for inclusion and/or deletion of vitamin compounds and mineral salts to the List(s), the title and structure of the List(s).

119. The Delegation indicated that on the basis of comments received it was proposed that the Committee consider the addition of some amendments to the existing sections a), c) and d) of the list of criteria[17] that were highlighted in bold in document CX/NFSDU 01/7.

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[16] CL 2001/-NFSDU , CXNFSDU 01/7 (comments of Australia, Cuba, Hungary, Malaysia, Mexico, Spain, USA, EU and ISDI), CRD 3 (comments to the CL 2001/7-NFSDU of China); CRD 7 (comments of Uruguay).

[17] ALINORM 89/69, para. 193.

120. The reference to ADI was deleted from section b) as this concept was already covered by section a).

121. The Delegation pointed out that a new section e) containing the provisions on the demonstration of stability of nutrients and new provisions in section 2 which clarified the process of deletion from the List had been introduced.

122. The Delegation informed the Committee that the structure of the List(s) had been amended to cover not only vitamin compounds and minerals salts but also other nutrients such as amino acids and food additives for special vitamin forms and that requirements regarding all suggested classes of nutrients were clarified as presented in CX/NFSDU 01/7.

123. The Committee expressed its appreciation to the Delegation of Germany for their valuable work on the revision of this document.

124. The Delegation of the United States, while supporting the proposed new structure and pointing out the usefulness of these proposals, expressed concern regarding the scientific rationale for the inclusion of some nutrients into the List(s) and their suitability for different products such as Infant Formula or Cereal Based-Foods.

125. The Committee noted the clarification of the Delegation of Germany that the basis for inclusion of nutrients were their evaluation by FAO/WHO, EC or in some cases, by national authorities.

126. Regarding the proposal to extend the scope of the List(s) and to amend the title to cover a wider range of age and also foods for special medical purposes, the Committee concluded that at this stage the scope should be limited to infants and young children. Some delegations were of the view that the List(s) should cover Foods for Special Medical Purposes, while the Delegation of the United States pointed out that there was no compositional Codex Standard for Foods for Special Medical Purposes, therefore before expanding the List(s) there should be criteria set for the inclusion of nutrients for this type of products. The Committee was informed that nutrient sources for Foods for Special Medical Purposes included in the list went through an evaluation process in the European Community. The Committee noted that it was not able to reach consensus on this matter at this stage and decided to put Foods for Special Medical Purposes in the title in square brackets for further comments and consideration.

127. The Committee generally supported the proposed structure of the List(s).

128. The Committee agreed to delete Section 2 regarding source of phosphorus and Section 3 regarding source of chloride in the Table A.

Status of the Proposed Draft Revision of the Advisory List(s) of Mineral Salts and Vitamin Compounds for the Use in Foods for Infants and Young Children (CAC/GL 10-1979)

129. The Committee requested the Delegation of Germany to revise the Lists in view of the comments provided at the current session with the understanding that the revised version would be circulated for comments at Step 3 before the next session of the Committee.

DISCUSSION PAPER ON REVIEW OF PROVISIONS FOR VITAMINS AND MINERALS IN CODEX STANDARDS: VITAMINS AND MINERALS IN FOODS FOR SPECIAL MEDICAL PURPOSES (AGENDA ITEM 8)[18]

130. The Delegation of Germany presented the discussion paper prepared in the light of the discussions of the last session of the Committee, and indicated that few comments had been received concerning the criteria used in member countries for the selection of vitamins and minerals. The Delegation also pointed out that only provisions for vitamins and minerals were proposed, not requirements for medical foods as such, and recalled that such provisions might be useful if the Committee decided to include foods for special medical purposes in the standard for infant formula.

131. The Committee recalled that the current *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* addressed only labelling and claims, and discussed whether additional provisions should be developed for such foods.

132. As there was no support for further work, the Committee agreed not to proceed with the discussion of provisions for vitamins and minerals in foods for special medical purposes.

DISCUSSION PAPER ON ENERGY CONVERSION FACTORS (AGENDA ITEM 9)[19]

133. The Delegation of Australia introduced the document and recalled that this matter had been considered by the Committee during the last two sessions and that comments indicated that some support had been received from member countries concerning further work on this agenda item. The Delegation indicated that from the replies to a previously distributed Codex Circular Letter, it was evident that there were considerable differences across member countries in relation to energy conversion factors used for some food components, and therefore proposed to consider initiating new work on this matter.

134. The Committee noted that the current differences in assigning different energy conversion factors to the same food component might create a problem in international trade; however it also noted that scientific advice was necessary to solve the problems with the assigning energy conversion factors.

135. The Representative of FAO pointed out that, FAO in preparation for the Joint Consultation on Human Energy Requirements (Rome, October 2001) had already obtained a background document of Energy Conversion factors and had organized a Working group in the area related to analytical aspects of energy and protein. The Representative also pointed out that the above Consultation had strongly endorsed the wish of FAO to convene Expert Consultations/Technical Working Groups on Applications of Requirements and Harmonization of Definitions and Approaches to arriving at Human Nutritional Requirements. As a part of the former it was the decision of the FAO to include consideration of the problem of energy conversion factors. Taking into acoount the work done by Australia in producing a very valuable document for this Committee, FAO was of the view that providing scientific advice on this topic to the Committee was important and urgent.

136. The Secretariat recalled that without a solid scientific basis there might be difficulties and delays in the development of work, and therefore proposed that the Committee should await scientific findings and recommendations of the FAO/WHO Expert consultation on Energy Conversion factors before initiating new work.

137. The Committee welcomed the work of FAO/WHO on this matter and was of the view that request for new work was premature at this stage and decided that it would return to consideration of this matter as

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[18] CX/NFSDU 01/8, CRD 1 (comments of Cuba).

[19] CX/NFSDU 01/09; CRD 7 (comments of Uruguay); CRD 8 (comments of Canada).

soon as the results of the above Expert consultation became available. It agreed that the next session should be kept informed of the progress achieved by FAO/WHO and national scientific bodies in this area, in order to facilitate its further work in this area.

DISCUSSION PAPER ON THE APPLICATION OF METHODOLOGY OF RISK ASSESSMENT FOR NUTRITION ISSUES: THE INCORPORATION OF NUTRIENT RISK ASSESSMENT IN A RISK-BASED APPROACH TO ASSIST DECISION-MAKING PROCESS OF CCNFSDU (AGENDA ITEM 10)[20]

138. The Committee recalled that following earlier discussions, it had been agreed at the last session that the Delegation of Australia would revise its initial discussion paper on the basis of the comments received on risk assessment for nutrition issues. The Delegation of Australia recalled the recommendations of the Commission concerning the application of risk analysis principles in the development of Codex food safety standards and noted the work undertaken by several committees on risk analysis. Several aspects of the Committee's work were related to food safety, as it appeared from recent discussions on the safe levels of vitamins and minerals and these issues should be addressed on the basis of scientific risk assessment. The Delegation recalled that several countries followed a risk-based approach for nutrient assessment at the national level, and some studies were underway to establish safe upper levels of consumption for vitamins and minerals (United States, EC). It was therefore proposed that the Committee should request FAO/WHO to extend their current work on Reference recommended nutrient intakes to include ULs for vitamins and minerals.

139. The Representative of FAO indicated that FAO had already decided to call an Expert Consultation to update the scientific developments related to some vitamins and minerals since the Bangkok meeting in 1998. As a part of this exercise the remit of this expert group would be broadened to the extent possible to consider the possibility to look into the issue of Upper Limits and safety with regard to some micronutrients.

140. The Observer form the EC informed the Committee of the work of the Scientific Committee for Food on the establishment of upper limits for vitamins and minerals and stressed that this was a long term exercise and that it might not be possible to address this question through an international consultation.

141. The Representative of FAO indicated that the Expert Consultation would consult and draw upon the experiences of the Food and Nutrition Board/US National Academy of Sciences and the European Community SCF's work in this area, in order to develop recommendations that could provide the scientific basis for further work in the Committee.

142. The Observer from CRN, referring to its written comments supported further work on risk assessment taking into account the most updated scientific data in order to ensure the scientific basic of decision making.

143. The Committee expressed its appreciation to the Delegation of Australia for its work in this important area and agreed that a risk-based approach should be followed for the establishment of upper limits for micronutrients. It agreed that the next session should be kept informed of the progress achieved by FAO/WHO and national scientific bodies in this area, in order to facilitate its further work on vitamins and minerals.

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[20] CX/NFSDU 01/10, CRD 2 (comments of CRN), CRD 7 (comments of Uruguay), CRD 8 (comments of Thailand).

DISCUSSION PAPER ON SPORTS AND ENERGY DRINKS (AGENDA ITEM 11)[21]

144. The Committee recalled that the Committee on Food Labelling had initially discussed this question and asked the advice of the CCNFSDU on the opportunity of developing conditions for a "high energy" claim and the need for a standard for sports drinks as foods for special dietary uses. The last session of the Committee had discussed this question briefly and agreed to ask for comments on these proposals in order to facilitate further discussion. The Secretariat presented a discussion paper highlighting the issues raised in earlier discussions and in the comments received, and the applicability of current labelling texts to the claims for "sports and energy drinks". The Chairman recalled that the main problems with these products related to misleading claims and possible adverse effects to health, and proposed to discuss the following issues: the definition of a "high energy" claim; the need for a standard for "sports drinks/foods"; and the question of pharmacologically active substances.

145. Some delegations supported the definition of conditions for "high energy" as such claims were currently found on the market. Other delegations pointed out that there was no real need for such criteria as the main problem was the misuse of the term "energy" and misleading claims, which were already covered in general Codex labelling texts and in the national regulations of many countries. The Delegation of Uruguay considered that the definition of "high energy" is necessary for consumers as documented in its comments (CRD 7) and expressly asked the Committee to work on this subject, for solids as well as for liquids.

146. As regards the opportunity to develop a standard for sports drinks as foods for special dietary uses, the Committee recognized that it was within its mandate. Some delegations and Observers supported new work in this area, since these products were regulated in several countries and traded internationally. Other delegations expressed the view that sports foods were not foods for special dietary uses and did not warrant the development of a specific standard and enough information on current problems of these products in consumer health and international trade was not shared among member countries at this moment, and the Committee could not come to a consensus on this question.

147. As regards the establishment of maximum levels for pharmacologically active substances in beverages, some delegations agreed that this might be considered on the basis of scientific risk assessment, while other delegations objected to work on setting levels for pharmacologically active substances as food ingredients as it was not within the mandate of the Committee. In addition, the term "pharmacollogically active substances" was not appropriate to some delegations to designate those substances.

148. The Committee therefore concluded that there was no need for further consideration of "sports drinks/foods" and "energy drinks" and that no further work was required in this area.

OTHER BUSINESS AND FUTURE WORK: CONSIDERATION OF THE NECESSITY FOR REVIEW OF THE GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 09-1987) (AGENDA ITEM 12)

149. The Committee noted that the paper on this Agenda Item had not been prepared, therefore there was no other business for this Committee.

DATE AND PLACE OF THE NEXT SESSION (AGENDA ITEM 13)

150. The Committee was informed that the next session of the Committee would be held in Berlin, from 4 to 8 November 2002, subject to confirmation by the host Government and the Codex Secretariat.

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[21] CX/NFSDU 01/11, CX/NFSDU 01/11-Add.1, CRD 1 (comments of Cuba), CRD 7 (comments of Uruguay).

SUMMARY STATUS OF WORK

Subject Matter	Step	For Action by	Reference in ALINORM 03/26
Proposed Draft Revised Standards for Gluten-Free Foods	7	Prolamin Working Group	paras 9-10
Guidelines for Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents (Part B, containing provisions on Dietary Fibre)	7	Defer consideration until new scientific information became available	paras 11-17
Proposed Draft Guidelines for Vitamin and Mineral Supplements	3	Governments 24th CCNFSDU	paras 18-40 and Appendix II
Proposed Draft Revised Standard for Infant Formula	3	Governments, 24th CCNFSDU	paras 41-90 and Appendix III
Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children	3	Governments, 24th CCNFSDU	paras 91-117 Appendix IV
Proposed Draft Revision of the Advisory List(s) of Mineral Salts and Vitamin Compounds for the Use in Foods for Infants and Young Children (CAC/GL 10-1979)	2	Germany Governments 24th CCNFSDU	paras 118-129
Discussion Paper on Energy Conversion Factors	-	FAO/WHO, CCNFSDU	paras 132-136

Appendix/Annexe/Apéndice I

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Appendix II

PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL SUPPLEMENTS

(At Step 3 of the Procedure)

PREAMBLE

Most people who have access to a balanced diet can usually obtain all the nutrients they require from their normal diet. Because foods contain many substances that promote health, people should therefore be encouraged to select a balanced diet from food before considering any vitamin and mineral supplement. In cases where the intake from the diet is insufficient or where consumers consider their diet requires supplementation, vitamin and mineral supplements serve to supplement the daily diet.

1. SCOPE

1.1 These guidelines apply to vitamin and mineral supplements intended for use in supplementing the daily diet [if and where necessary] with vitamins and/or minerals. These Guidelines apply to vitamin and mineral supplements which are regulated as foods.

1.2 It is left to national authorities to decide whether vitamin and mineral supplements are drugs or foods. These Guidelines do apply in those jurisdictions where products defined in 2.1 are regulated as foods.

1.3 Foods for special dietary uses as defined in the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) are not covered by these Guidelines.

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. Vitamin and mineral supplements are sources in concentrated forms of those nutrients alone or in combinations, marketed in capsules, tablets, powders, solutions etc., not in a conventional food form and do not provide a significant amount of energy. [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.]

3. COMPOSITION

3.1 SELECTION OF VITAMINS AND MINERALS

3.1.1 Vitamin and mineral supplements should contain vitamins/provitamins and minerals whose nutritional value for human beings has been proven by scientific data and whose status as vitamins and minerals is recognised by FAO and WHO.

3.1.2 The selection of admissible vitamin and mineral sources should be based on criteria such as safety and bioavailability. In addition, purity criteria should take into account the FAO/WHO or Pharmacopoeias [and national legislation, where applicable].

[3.1.3 The use of individual vitamins and minerals in supplements 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 vitamin and/or mineral or an appropriate combination of vitamins and/or minerals.

3.2 CONTENTS OF VITAMINS AND MINERALS

3.2.1 The minimum level of each vitamin and/or mineral contained in a vitamin and mineral supplement per daily portion of consumption as suggested by the manufacturer should be [15% to 33%] of the recommended daily intake as determined by FAO/WHO.

3.2.2 [The maximum level of each vitamin and/or mineral contained in a vitamin and mineral supplement per daily portion of consumption as suggested by the manufacturer should not exceed [100%] of the recommended daily intake as determined by FAO/WHO .]

or

3.2.2 [Maximum amounts of vitamins and minerals in vitamin and mineral supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following criteria into account:

(a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;

(b) the daily intake of vitamins and minerals from other dietary sources.

When the maximum levels are set, due accont should be taken to the reference intake values of vitamins and minerals for the population.]

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

4. PACKAGING

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

4.2 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.

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

5. LABELLING

5.1 Vitamin and mineral supplements are labelled according to the Codex Standard for the Labelling of Prepackaged Foods (Codex-Stan 1-1985, Rev. 1-1991) as well as according to the General Guidelines on Claims (CAC/GL 1-1979).

[5.2 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.

[5.3 The amount of the vitamins and minerals present in the product shall be declared in the labelling in numerical form. The units to be used shall be units of weight.

5.4 The amounts of the vitamin and minerals declared shall be those per portion of the product as recommended for daily consumption on the labelling and per unit dose form, as appropriate.

5.5 Information on vitamins and minerals shall also be expressed as a percentage of the reference values mentioned, as the case may be, in the Codex Guidelines on Nutrition Labelling.]

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

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

[5.8 The label must contain a statement: supplements can not be used for the replacement of meals on long term basis.

5.9 All labels shall bear a statement that the supplement should be taken on an advice of a nutritionist, a dietician or a medical doctor.]

Appendix III

PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA (CODEX STAN 72-1981)

(At Step 3 of the Procedure)

1. SCOPE

1.1 This standard applies to infant formula in liquid or powdered form intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants. [The provisions in this standard are also intended for infants with special nutritional requirements, except for certain provisions which must be modified to meet those special requirements.]

1.2 The standard contains compositional, quality and safety requirements to ensure a safe and nutritionally adequate product.

1.3 The application of the Standard should take into account the recommendations given to countries under the International Code of Marketing of Breast-milk Substitutes and the World Health Assembly resolution WHA54.2 (2001).

2. DESCRIPTION

2.1 PRODUCT DEFINITION

2.1.1 Infant formula, when in liquid form, may be used either directly or prepared with safe, potable, and previously boiled water before feeding according to directions for use. In powdered form it requires safe, potable, and previously boiled water for preparation.

2.1.2 [Infant formula shall be nutritionally adequate to ensure [normal] growth and development when used in accordance with its directions for use to meet the nutritional requirements of infants by itself during the first months of life up to the introduction of appropriate complementary feeding. Only products that comply with the criteria laid down in the provisions of this standard would be accepted for marketing as infant formula.]

2.1.3 Infant formula is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

2.2 OTHER DEFINITIONS

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

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 ESSENTIAL COMPOSITION

3.1.1 Infant formula is a product based on milk of cows or other animals and/or other edible constituents of animal, including fish, or plant origin, which have been proved to be suitable for infant feeding.

3.1.2 Infant formula shall contain per 100 kilocalories (or 100 kilojoules) of intake, the following minimum and maximun levels of vitamins, minerals in an available form, choline, protein, fat and fatty acid, carbohydrates and energy:

[

	Amounts per 100 kilocalories		Amounts per 100 kJ	
	Minimum	**Maximum**	**Minimum**	**Maximum**
(a) Vitamins				
Vitamin A*	60 µg	180 µg	14 µg	43 µg
Vitamin D	40 I.U. or 1 µg	100 I.U. or 2,5 µg	10 I.U. or 0.25 µg	25 I.U. or 0.63 µg
Vitamin E (a-tocopherol equivalent TE)	0,5 mg/g linoleic acid[2], but in no case less than 0.5 mg/100 kcal	N.S.[1]	0.5 mg/g linoleic acid[2] but in no case less than 0.1 mg /100 kJ	N.S.[1]
Ascorbic Acid (Vitamin C)	8 mg	N.S.[1]	1,9 mg	N.S.[1]
Thiamine (Vitamin B_1)	40 µg	N.S.[1]	10 µg	N.S.[1]
Riboflavin (Vitamin B_2)	60 µg	N.S.[1]	14 µg	N.S.[1]
Niacin, niacin equivalents	0,8 mg	N.S.[1]	0,2 mg	N.S.[1]
Vitamin B_6	15 µg/g protein but in no case less than 35 µg/100 kcal	N.S.[1]	15 µg/g protein but in no case less than 9 µg/100 kJ	N.S.[1]
Folic acid	4 µg	N.S.[1]	1 µg	N.S.[1]
Pantothenic acid	300 µg	N.S.[1]	70 µg	N.S.[1]
Vitamin B_{12}	0.10 µg	N.S.[1]	0.025 µg	N.S.[1]
Vitamin K_1	4 µg	N.S.[1]	1 µg	N.S.[1]
Biotin (Vitamin H)	1.5 µg	N.S.[1]	0.4 µg	N.S.[1]
(b) Minerals				
Sodium (Na)	20 mg	60 mg	5 mg	15 mg
Potassium (K)	60 mg	145 mg	15 mg	35 mg
Chloride (Cl)	50 mg	125 mg	12 mg	29 mg
Calcium (Ca)[3]	50 mg	N.S.[1]	12 mg	N.S.[1]
Phosphorus (P)[3]	25 mg	90 mg	6 mg	22 mg
Magnesium (Mg)	5 mg	15 mg	1.2 mg	3,6 mg
Iron (Fe)	0.5 mg	1.5 mg	0.12 mg	0.36 mg
Iron (Fe)[4]	1 mg	2 mg	0.25 mg	0.5 mg
Iodine (I)	5 µg	N.S.[1]	1.2 µg	N.S.[1]
Copper (Cu)	20 µg	80 µg	4.8 µg	19 µg
Zinc (Zn)	0.5 mg	N.S.[1]	0.12 mg	N.S.[1]
Zinc (Zn)[4]	0.75 mg	2.4 mg	0.18 mg	0.6 mg
Manganese (Mn)	5 µg	N.S.[1]	1,2 µg	N.S.[1]
Selenium (Se)	7 µg	3 µg	N.S.[1]	0,7 µg
(c) Choline	N.S.[1]	N.S.[1]	1.7 mg	N.S.[1]

]

* expressed as retinol equivalent

[1] N.S. = Not specified

[2] Or per g polyunsaturated fatty acids, expressed as linoleic acid.

[3] The Ca: P ratio shall be not less than 1.2 and not more than [2.0].

4 In formula manufactured from soya proteins, alone or in a mixture with cow's milk protein.]

(d) Protein

(i) Protein content = nitrogen content x 6.38 for cow's milk proteins and protein partial hydrolysates.

Protein content = nitrogen content x 6.25 for soya protein isolates and protein partial hydrolysates.

The "chemical index" shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein (breast milk, as defined in Annex 1).

(ii) The product shall contain protein at a level of not less than 1.8 g/100 kcal (0.45 g/100 kJ) and not more than 3 g/100 kcal (0.7 g/100 kJ).

For an equal energy value, the formula must contain an available quantity each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex 1); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together.

[The minimum value set for quality and the maximum for quantity of the protein may be modified by national authorities according to their own regulations and/or local conditions.]

(iii) Isolated amino acids may be added to Infant Formula only to improve its nutritional value for infants. Essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only natural L forms of amino acids shall be used.

(e) Fat and Fatty Acid

The product shall contain:

- linoleic acid (in the form of glycerides) at a level of not less than 300 mg/100 kcal (or 70 mg/100 kJ) and not more than 1200 mg/100 kcal (285 mg/100 kJ);
- fat at a level not less than 4.4 g/100 kcal (1.05 g/100 kJ) and not more than 6.5 g/100 kcal (1.5 g/100 kJ);
- the alpha-linolenic acid content shall not be less than 50 mg/100 kcal (12 mg/100 kJ);
- the linoleic/alpha-linolenic acid ratio shall not be less than 5 nor greater than 15;
- the trans fatty acid content shall not exceed 4% of the total fat content;
- the erucic acid content shall not exceed 1% of the total fat content;

(f) Carbohydrates

The product shall contain carbohydrates at a level of not less than 7 g/100kcal (1.7 g/100 kJ) and not more than 14 g/100kcal (3.4 g/100 kJ).

(g) Energy content

The energy content of the product shall not be less than 60 kcal/100 ml (250 kJ/100 ml) and not more than 75 kcal/ 100 ml (315 kJ/100 ml).

3.2 OPTIONAL INGREDIENTS

4.2.1 In addition to the vitamins and minerals listed under 3.1.2(a), (b) and (c), other nutrients may be added when required in order to provide nutrients ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrients of the infant.

3.2.2 The usefulness and safety of these nutrients shall be scientifically shown.

3.2.3 When any of these nutrients is added, the formula shall contain sufficient amounts of these nutrients to achieve the intended effect, based on levels in human milk.

3.2.4 Only L(+) producing lactic acid cultures may be used**.**

3.3 VITAMIN COMPOUNDS AND MINERAL SALTS

3.3.1 Vitamins and minerals added in accordance with Section 3.1.2 (a,b,c,d) and 3.2.1 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).

3.4 CONSISTENCY AND PARTICLE SIZE

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

3.5 PURITY REQUIREMENTS

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

3.6 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 Infant Formula, as described in Section 1 of this Standard, and with the restrictions stated below:

[		**Maximum level in 100 ml of the ready-to-drink product**
4.1	**THICKENING AGENTS**	
5.1.1	Guar gum	0.1 g in all types of infant formula
4.1.2	Locust bean gum[23]	0.1 g in all types of infant formula
4.1.3	Distarch phosphate	} 0.5 g singly or in combination in soy-
4.1.4	Acetylated distarch phosphate	} based infant formulae only
4.1.5	Phosphated distarch phosphate	}
4.1.6	Hydroxypropyl starch	} 2.5 g singly or in combination in
		} hydrolyzed protein and/or amino acid

[23] Temporarily endorsed.

		}	acid-based infant formulae only
4.1.7	Carrageenan	}	0.03 g in regular, milk- and soy-
		}	based liquid infant formulae only
		}	
		}	0.1 g in hydrolyzed protein and/or amino acid-based liquid infant formulae only

4.2 EMULSIFIERS

4.2.1	Lecithin	0.5 g in all types of infant formulae
4.2.2	Mono- and diglycerides	0.4 g in all types of infant formulae

4.3 pH-ADJUSTING AGENTS

4.3.1	Sodium hydroxide	}	
4.3.2	Sodium hydrogen carbonate	}	
4.3.3	Sodium carbonate	}	Limited by good manufacturing practice
4.3.4	Potassium hydroxide	}	and within the limits for sodium and
4.3.5	Potassium hydrogen carbonate	}	potassium in Section 3.1.2 (c) in all
4.3.6	Potassium carbonate	}	types of infant formulae
4.3.7	Calcium hydroxide	}	
4.3.8	Sodium citrate	}	
4.3.9	Potassium citrate	}	
4.3.10	L(+) Lactic acid	}	Limited by good manufacturing practice
4.3.11	Citric acid		in all types of infant formulae

4.4 ANTIOXIDANTS

4.4.1	Mixed tocopherols concentrate	}	1 mg in all types of infant formulae
4.4.2	L-Ascorbyl palmitate	}	**]**

4.5 CARRY-OVER OF FOOD ADDITIVES

No food additives shall be present as a result of carry-over from raw materials and other ingredients with the exception:

(a) of the food additives listed under Sections 4.1 to 4.4 of this standard within the limits of the maximum levels stipulated in this standard; and

(b) of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children within the limits of the maximum levels stipulated in that List.

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.

5.2 OTHER CONTAMINANTS

Infant formula shall not contain contaminants or undesirable substances (e.g. biologically active substances) in amounts which may represent a hazard to the health of the infant

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

	Maximum level
Lead	0.02 mg/kg (in the ready-to-use product)

6. HYGIENE

6.1 It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1 1969, Rev. 3- 1997), and other relevant Codex texts such as the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979).

6.2 The products should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997)

7. PACKAGING

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

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 substance 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 container shall be:

(i) not less than 80% v/v for products weighing less than 150 g (5 oz.);

(ii) not less than 85% v/v for products in the weight range 150-250 g (5-8 oz.); and

(iii) 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^{o} C which the sealed container will hold completely filled.

9. LABELLING

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

9.1 THE NAME OF THE FOOD

The text of the label and all other information accompanying the product shall be written in the appropriate language**.**

9.1.1 The name of the product shall be either "Infant Formula" or any appropriate designation indicating the true nature of the product, in accordance with national usage.

9.1.2 The sources of protein in the product shall be clearly shown on the label.

9.1.3 If cow's milk is the only source of protein, the product may be labelled "Infant Formula Based on Cow's Milk".

9.1.4 A product which contains neither milk or any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase.

[9.1.5 A product intended for infants with special nutritional requirements shall be labelled to show clearly the special requirement for which the formula is to be used and the dietary property or properties on which this is based. [No health claims shall be made regarding the dietary properties of the product.]]

9.1.6 [Products containing not less than 0.5 mg Iron (Fe)/ 100 kilocalories shall be labelled "Infant Forumula with added Iron"].

or

[Products containing less than 0.5 mg Iron (Fe)/ 100 kcal shall be labelled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources.]

9.2 LIST OF INGREDIENTS

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

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

9.3 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 kilocalories (kcal) and/or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes of the food as sold as well as per 100 milliliter of the food ready for use, when prepared according to the instructions on the label.

(b) the total quantity of each vitamin, mineral, choline as listed in paragraph 3.1.2 and any other ingredient as listed in paragraph 3.2 of this Standard per 100 grammes of the food as sold as well as per 100 milliliter of the food ready for use, when prepared according to the instructions on the label.

(c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.

9.4 DATE MARKING AND STORAGE INSTRUCTIONS

9.4.1 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.

9.4.2 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.

9.5 INFORMATION FOR USE

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

9.6 ADDITIONAL LABELLING REQUIREMENTS

9.6.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

a) the words "important notice" or their equivalent;

b) [a statement of the superiority of breastfeeding or breastmilk, for example the statement: Breastmilk is the best food for your baby, it protects against diarrhea and other illnesses];

or:

b) [The statement "Breastfeeding is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breastmilk.]

c) a statement that the product should only be used on advice of a independent health worker as to the need for its use and the proper method of use;

d) instructions for appropriate preparation;

e) a warning against the health hazards of inappropriate preparation; and a warning that formula remaining after each feeding should be discarded.

9.6.2 The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of infant formula. The label shall have graphics illustrating the method of preparation of the product and methods of feeding.

9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.

9.6.4 Information shall appear on the label to the effect that infants should receive supplemental foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.

9.6.5 [The products shall be labelled in such a way as to avoid any risk of confusion between infant formula and follow-up formula.]

10. METHODS OF ANALYSIS AND SAMPLING

Dietary fibre, total	AOAC 991.43
Iodine (milk based formula)	AOAC 992.24
Pantothenic acid	AOAC 992.07
Pantothenic acid	*The Analyst* 89 (1964)(1) 3-6, 232 US Dept Agr., *Agr. Handbook* 97 (1965)
Vitamin A	AOAC 974.29
Vitamin A (retinol isomers)	AOAC 992.04
Vitamin A (retinol)	AOAC 992.06
Vitamin A in foods in which carotenes have been added as a source of vitamin A	AOAC 942.15
Vitamin K_1	AOAC 992.27
Vitamin D (D_3, milk based infant formula)	AOAC 992.26
Vitamin E	AOAC 971.30
Vitamin E (milk based infant formula)	AOAC 992.03
Vitamin B_{12}	AOAC 952.20
Vitamin B_6	AOAC 961.15
Vitamin C	AOAC 967.22; AOAC 967.21
Determination of choline	AOAC 999.14 (Enzymatic method)
Determination of Vitamin K	AOAC 999.15 (LC method)
Detection of Irradiated Foods	Codex General Methods
Determination of Lead	Codex General Methods
Calcium	AOAC 984.27
Chloride	
Carbohydrates	Method described in CAC/VOL IX-Ed.1, Part III
Crude protein	Method described in CAC/VOL IX-Ed.1, Part III
Fat	CAC/RM 55-1976
Fill of containers	CAC/RM 46-1972
Folic acid	AOAC 944.12
Linoleate (in the form of glycerides)	AOAC 922.06; 969.33; 963.22; 979.19
Loss of drying	AOAC 934.01; AOAC 925.23
Nicotinamide for foods not based on milk	AOAC 961.14
Nicotinamide for milk- based foods	AOAC 944.13
Phosphorus	AOAC 986.24
Protein efficiency ratio (PER)	AOAC 960.48
Riboflavin	AOAC 970.65
Sodium and potassium	AOAC 984.27
Sodium and potassium	ISO 8070:1987 IDF 119A/1987
Thiamine	AOAC 942.23
Total dietary fibre	AOAC 985.29

ANNEX 1

Essential and semi-essential amino acids in breast milk

For the purpose of this Standard the essential and semi-essential amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

	per 100 kJ	**per 100 kcal**
Arginine	25	107
Cystine	11	44
Histidine	12	47
Isoleucine	20	83
Leucine	40	167
Lysine	28	119
Methionine	6	23
Phenylalanine	18	75
Threonine	18	77
Tryptophan	7	31
Tyrosine	20	85
Valine	24	99

Appendix IV

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 complementary food from the age of 6 months onwards, or when upon the advice of an independent health worker it is required to satisfy their individual nutritional requirements, and for feeding young children as part of a progressively diversified diet, in accordance with World Health Assembly resolution WHA54.2 (2001).]

or:

[This standard covers processed cereal-based foods intended for complementary feeding of infants from the age of 6 months onwards, or for feeding young children as part of their progressively diversified diet in accordance with the World Health Assembly resolution WHA54.2 (2001).]

2. DESCRIPTION

Processed cereal-based foods are prepared primarily from one or more milled cereals,,which should constitute at least 25% of the final mixture on a dry weight basis.

2.1. PRODUCT DEFINITIONS

Four categories are distinguished:

2.1.1 Products consisting only of 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).

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 ESSENTIAL COMPOSITION

3.1.1 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. It may also contain legumes

(pulses), starchy roots (such as arrow root, yam or cassava) or starchy stems or oil seeds in smaller proportions.

3.1.2 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/100g (3.3/kJ/100g).

3.3 PROTEIN

3.3.1 The chemical index of the added protein shall be equal to at least 80% of that of the reference protein or the Protein Efficiency Ratio (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. Only natural forms of L-amino acids should be used.

3.3.2 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)]

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

3.3.4 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 0.48g/100 kJ (2.0 g/100 kcal
- the amount of added fructose shall not exceed 0.6 g/100 kJ (2.5 g/100 kcal)]

3.5 LIPIDS

For products mentioned in point 2.1 the lipid content shall not exceed 1.1g/100 kJ (4.5 g/100 kcal) If the lipid content exceeds 0.8g/100kJ (3.3g/100kcal):

- the amount of linoleic acid (in the form of triglycerides=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 2.1.4 of this Standard shall not exceed [100 mg/100 kcal] of the ready-to-eat product, except in the case of products intended for children over one year of age, where the sodium content shall not exceed [200 mg/100 kcal].

3.6.2 The calcium content shall not be less than 20 mg/100 kJ (80 mg/100 kcal) for products mentioned in points 2.1.2.

3.6.3 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 [15µg/100 kJ] [(60µg/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 Derogations to the maximum amounts for vitamin A referred to in 3.7.2 and the addition of vitamins and minerals for which specifications are not set above 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 prepared according to the label directions for use, processed cereal-based foods should have a texture appropriate for the [spoon 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		50 mg, expressed as ascorbic acid and within the limits for sodium

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 limit shall take into account the specific nature of the products concerned and the specific population group for which they are intended.

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

It is recommended that the product covered by the provision of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice – General Principle of Hygiene (CAC/RCP 1 1969, Rev. 3, 1997), and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

The product should comply with any microbiological criteria established in accordance with the Principles for the Establishment and application of microbiological Criteria for Foods (CAC/GL 21-1997).

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

8.1 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:

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

8.3 [The label shall have no pictures of infants or young children or text, which idealizes the use or suggests an inappropriate age of introduction of these products.]

8.2 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.

8.3 LIST OF INGREDIENTS

8.3.1 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.

8.3.2 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.

8.4 DECLARATION OF NUTRITIVE VALUE

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

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

(c) the average quantity of the vitamins and minerals when their declaration is not covered by the provisions of section 8.3.1 (b) expressed in numerical form per 100 g or 100 ml of the product as sold and where appropriate per specified quantity of the foods as suggested for consumption.

8.5 DATE MARKING AND STORAGE INSTRUCTIONS

8.5.1 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.

8.5.2 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.

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

8.6 INFORMATION FOR UTILIZATION

8.6.1 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.

8.6.2 For products covered by 2.1.1, directions on the label shall state “Milk or formula but no water shall be used for dilution or mixing” or an equivalent statement.

8.6.3 The presence or absence of gluten should be indicated on the label, if the intended age of use is below [six months].

[8.6.4 The label shall indicate clearly from which age the product is intended for use. The label shall clearly state that the product is not recommended for use below 4 to 6 months. In addition, the label shall include a statement indicating that the decision when precisely to begin complementary feeding should be made in consultation with a health worker, based on the infant specific growth and development needs. Additional requirements in this respect may be made in accordance with the legislation of the country in which the product is sold.]

8.7 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 Section on methods in the Proposed Draft Revised Standard for Infant Formula.

In addition:

Detection of Irradiated Foods

Codex General Methods