

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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ALINORM 99/26

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-third Session
Rome, 28 June – 3 July 1999

REPORT OF THE TWENTY-FIRST SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Berlin, Germany
21 – 25 September 1998

Note: This document incorporates Codex Circular Letter 1998/35-NFSDU.

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CX 5/20.2

CL 1998/35 – NFSDU
October 1998

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-FIRST SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (ALINORM 99/26)**

The report of the Twenty-first Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses will be considered by the 23rd Session of the Codex Alimentarius Commission to be held in Rome from 26 June–3 July 1999.

PART A. MATTERS FOR ADOPTION OR APPROVAL BY THE 23RD SESSION OF THE CODEX ALIMENTARIUS COMMISSION

DRAFT TEXTS AT STEP 8

- 1. DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (PART B) (GUIDELINES FOR USE OF NUTRIENT CLAIMS) (ALINORM 99/26, Appendix II);**

Governments and International Organizations are invited to comment on the above draft Table and should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 of the Procedure for the Elaboration of Codex Standards Including Consideration of Any Statements Relating to Economic Impact (*Codex Alimentarius Procedural Manual*, Tenth Edition, pp. 24-25) to the Chief, 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 1 April 1999**.

DRAFT TEXTS AT STEP 5:

- 2. PROPOSED DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN (ALINORM 99/26, Appendix IV)**

Governments and International Organizations are invited to comment on the proposed draft Standard at Step 5 of the Procedure for the Elaboration of Codex Standards Including Consideration of Any Statements Relating to Economic Impact (*Codex Alimentarius Procedural Manual*, Tenth Edition, pp. 24-25) and should do so in writing to the Chief, 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 1 April 1999**.

PART B. REQUEST FOR COMMENTS AND INFORMATION

3. DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (PART B, CONTAINING PROVISIONS ON FIBRE) (Guidelines FOR USE OF NUTRITION CLAIMS) AT STEP 6 (ALINORM 99/26, para. 30 and Appendix III)

Governments wishing to comment on the proposed draft Table at Step 6 should do so in writing to the Chief, 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 1 April 1999**.

4. Proposed Draft Revised Standard for Gluten-Free Foods at Step 6 (ALINORM 99/26, para.40)

Governments wishing to comment on the proposed draft Standard which is presented in the document CX/NFSDU 98/4 should do so in writing to the Chief, 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 1 April 1999**.

5. Proposed Draft Revised Standard for Infant Formula at Step 3 (ALINORM 99/26, paras 106 and Appendix V)

Governments are invited to comment on the proposed draft Standard especially on parts which are left in square brackets and should do so in writing to the Chief, 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 1 April 1999**.

6. VITAMIN C FORTIFICATION (ALINORM 99/26 para. 7-8)

While considering Vitamin C Fortification issue the Committee took note that there might be a need for a review of the General Principles for the Addition of Essential Nutrients for Foods (CAC/GL 09-1987) in order to address the issue of fortification in commodity standards. Governments are invited to comment on the above subject matter and should do so in writing to the Chief, 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 1 April 1999**.

SUMMARY AND CONCLUSIONS

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

MATTERS FOR CONSIDERATION BY THE COMMISSION

The Committee:

- ☛ Recommended the adoption at Step 8, the Table of Conditions for Nutrient Contents (Part B) containing provisions on Protein and Vitamins and Minerals for inclusion into Guidelines for Use of Nutrition Claims (para. 30 and Appendix II);
- ☛ advanced the Proposed Draft Revised Standard for Cereal-Based Foods for Infants and Young Children for adoption at Step 5 (para. 82 and Appendix IV);
- ☛ initiated a new work on Advisory Lists of Mineral Salts and Vitamin Compounds, subject to approval by the 23rd Session of the Codex Alimentarius Commission (para. 121).

OTHER MATTERS OF INTEREST TO THE COMMISSION

The Committee:

- ☛ Returned the Draft Table of Conditions for Nutrient Contents (Part B) containing provisions on fibre to Step 6 for further comments and consideration by the next session of the Committee (para. 30 and Appendix III);
- ☛ returned Proposed Draft Standards for Infant Formula to Step 3 for further comments and consideration (para. 106 and Appendix V);
- ☛ agreed to further consider the Proposed Draft Guidelines on Vitamin and Mineral Supplements as well as a working paper prepared in order to facilitate discussion on this issue (para. 49);
- ☛ agreed to leave the text of the Draft Revised Standard for Gluten-Free Foods as it was in CX/NFSDU 98/4 at Step 6 and give further consideration at the next session (para. 40);
- ☛ agreed that provisions for Vitamins and Minerals in Foods for Special Medical Purposes deserved further consideration and that the Delegation of Germany would revise the discussion paper including the Table as required in square brackets for further comments and consideration (para. 113);
- ☛ agreed to postpone considering the Nutrient Reference Values for Labelling Purposes until the recommendations of the Expert Consultation in Bangkok became available (para. 115); and
- ☛ agreed that the question regarding the proprietary techniques should be referred to the Codex Committee on Methods of Analysis and Sampling as a general matter (para. 40).

LIST OF ABBREVIATIONS

(Used in this Report)

AAC	Association des Amidonnières de Céréales de L'U.E.
AESGP	Association Européenne des Spécialités Pharmaceutiques Grand Public
ALINORM	Reports of Codex Committees and other working papers submitted to the Codex Alimentarius Commission
AOAC	AOAC International
AOECS	Association of European Coeliac Societies
CAC	Codex Alimentarius Commission
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCFL	Codex Committee on Food Labelling
CI	Consumers International
CIAA	Confederation of the Food and Drink Industries of the EU
CISDA	Confederation of International Soft Drinks Associations
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCPFV	Codex Committee on Processed Fruits and Vegetables
CCPR	Codex Committee on Pesticide Residues
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
GMP	Good Manufacturing Practice
EC	European Commission of the European Union
EHPM	European Federation of Associations of Health Product Manufacturers
ENCA	European network of Childbirth Association
IBFAN	International Baby Food Action Network
ICGMA	International Council of Grocery Manufacturers Association
IDF	International Dairy Federation
IFMA	International Federation of Margarine Associations
ILCA	International Lactation Consultant Association
IOCCC	International Organization for Cocoa, Chocolate and Confectionery
ISDI	International Special Dietary Food Industries
ISDC	International Soft Drink Council
JECFA	Joint FAO/WHO Expert Committee on Food Additives
NRV	Nutrient Reference Values
UNICEF	United Nations Children's Fund
WHO	World Health Organization of the United Nations

INTRODUCTION

1. The Twenty-first Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses was held from 21 to 25 September 1998 in Berlin, Germany at the kind invitation of the Government of Germany. The Session was chaired by Prof. Dr. Rolf Grossklaus, Director and Professor of the Federal Institute for Health Protection of Consumers and Veterinary Medicine. The Session was attended by 200 delegates, advisors and observers from 42 Member countries and 21 international organizations.

OPENING OF THE SESSION (AGENDA ITEM 1)

2. The Session was opened by Mrs Dr Sabine Bergmann-Pohl, Parliamentary Under-secretary of the Federal Ministry of Health. On behalf of the Federal Minister of Health she extended a very warm welcome to the delegates attending the Session. She highlighted the importance of the work of Codex in providing standards for protecting consumers' health and facilitating international food trade while improving international competitiveness. Mrs Bergmann-Pohl noted especially that the record attendance of delegations at the Session was a recognition of the great importance of Codex, due to the reference to Codex standards, guidelines and recommendations under the relevant World Trade Organization Agreements. She also pointed out that some misinformation existed on medical claims and on the introduction of restrictions concerning the accessibility of vitamins and minerals. In conclusion, she expressed the hope that, despite all difficulties, the decisions of the Committee would be taken by consensus and based on available scientific data and wished the delegates all success in their work.

3. The Delegation of Spain expressed regret at the lack of interpreting into the Spanish language and requested the Secretariat of the host country to consider additional means of ensuring the possibility to work in all official languages at the meeting.

ADOPTION OF THE AGENDA (AGENDA ITEM 2)¹

4. The Committee **adopted** the Provisional Agenda as proposed, and **agreed** to discuss the proposals of Australia (CRD 10) concerning the Proposal to Define the Basis for Derivation of Energy Conversion Factors in the Codex Guidelines on Nutrition Labelling and New Zealand (CRD 20) concerning the revision of the Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979) under Other Business and Future Work (Agenda Item 10).

MATTERS REFERRED TO THE COMMITTEE FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (AGENDA ITEM 2)²

5. The Committee noted matters arising from the 22nd Session of the Codex Alimentarius Commission (CAC; June 1997; 45th Session of the Executive Committee of the Codex Alimentarius Commission (CCEXEC), the 29th Session of the Codex Committee on Pesticide Residues (CCPR; 7-12 April 1997) and decided to discuss specific concerns under the relevant Agenda Items.

PROVISIONS OF FORTIFICATION ON IODINE, IRON AND VITAMIN A IN THE GUIDELINES OF NUTRITION CLAIMS³

6. The Committee **accepted** the kind offer of the delegation of Thailand to prepare a discussion paper for consideration at the next Session of CCNFSU.

¹ CX/NFSU 98/1.

² CX/NFSU 98/2; CX/NFSU 98/2 Addendum; CRD 11 (Comments from USA); CRD 22 (CIAA); CRD 36 (ILSI).

³ ALINORM 97/15, paras 69-74.

VITAMIN C FORTIFICATION⁴

7. It was pointed out by several delegations that this issue was already covered by the “General Principles for the Addition of Essential Nutrients to Foods” (CAC/GL 09-1987) in which there were provisions for nutrient fortification. The Committee discussed the need for a clear distinction between use of vitamin C as an additive and for fortification purposes: when used as an additive it should be declared as such and when used for fortification purposes it should be declared in accordance with the General Guidelines on Claims.

8. The Committee took note that there might be a need for a review of the General Principles in order to address the issue of fortification in commodity standards and **agreed** that a Circular Letter should be prepared in order to ask for governments comments on the necessity of the review.

CONSIDERATION OF METHOD OF ANALYSIS FOR NUTRITION LABELLING⁵

9. The Committee took note that a new method became available and **agreed** to add the method AOAC 996.06 for the determination of polyunsaturated and saturated fats to the current list of methods.

MATTERS RELATED TO HEALTH AND NUTRITION CLAIMS

10. The Committee noted that the Coordinating Committee for Europe had stressed the importance of matters relating to nutrition and health claims and the need to proceed with work in these areas. In this perspective, the Committee discussed the following matters arising from the Committee on Food Labelling (CCFL).

PROPOSED DRAFT AMENDMENT TO THE GUIDELINES ON NUTRITION LABELLING

11. The Committee considered the request from the CCFL to determine if public health needs required the mandatory labelling of sugars, fibre, saturated fats and sodium when nutrition labelling was applicable. This would be in addition to the current provisions of the Guidelines for Nutrition Labelling, whereby energy value, protein, available carbohydrate and fat must be declared when a nutrient declaration is made.

12. Several delegations supported the current requirements in the Guidelines, pointing out that the declaration of four additional nutrients would be difficult to apply in practice and might confuse the consumer without providing useful information. They pointed out that, from a public health point of view, additional labelling was not the only means to improve the nutritional status of the population, and stressed the need for developing nutrition education so that consumers could actually benefit from nutrition labelling and be able to make an informed choice.

13. The Observer from the European Community, recalled that the approach in the EC was consistent with the current Guidelines, and that the declaration of energy, protein, carbohydrate and fat was mandatory only when a claim was made. Further, if a claim was made on any of sugar, fibre, saturated fat and sodium, the declaration of all four additional nutrients was also becoming compulsory. The Observer proposed that the Committee considered this approach and he was supported by Canada and other delegations.

14. The Delegation of India and the Observer from CI supported mandatory comprehensive labelling for consumers information and education. It could be further expanded including the fibre, sugar, saturated fat and sodium. Some delegations expressed the view that it should be left to national authorities to determine whether additional nutrition labelling was required. The Delegation of the United States supported the inclusion of the four additional nutrients and proposed that further consideration should be given to this matter as it would be useful to provide guidance to governments on the declaration of additional nutrients even on an optional basis.

⁴ ALINORM 99/27, para. 29

⁵ ALINORM 97/23A, paras 43-48, Appendix IV, CX/MAS 97/9; CRD 4 (Comments from Canada, Uruguay, CSPI).

15. The Committee recognized that there was general support for retaining the current provisions in the Guidelines and **agreed** to consider this question further at its next session and ask for further comments on this matter.

PROPOSED DRAFT RECOMMENDATIONS ON THE USE OF HEALTH CLAIMS

16. The Committee had an exchange of views on the request from the CCFL concerning the scientific basis for health claims, and recognized that one of the major issues was the definition of health claims, as the approach to this concept greatly differed from one country to another.

17. Several delegations indicated that they did not support any claim relating to the prevention, cure and treatment of disease but that further consideration could be given to claims relating to the contribution of specific nutrients to health, provided the scientific basis for such claims was clearly established.

18. The Observer from Consumers International expressed its view that health claims should not be permitted. Health claims generally created confusion for consumers, and it was very difficult to define them satisfactorily. The Observer from the Council for Responsible Nutrition (CRN) pointed out that many such claims, some of which were misleading to consumers, were found on the market and that the Committee should seek to address this complex issue as an urgent matter.

19. The Delegation of France indicated that it had prepared a document on the scientific criteria to be used as basis of health claims and offered to communicate it to interested delegations. The Delegation of the United States referred to their experience with health claims at the national level and proposed to gather information from member countries on their experience with the definition of criteria.

20. The Committee recognized that criteria for scientific evidence should be defined in order to substantiate the basis of health claims and **agreed** to continue its work on this important issue. The Committee welcomed the offer of the delegations of France and the United States to coordinate the preparation of a working document, with the participation of the delegations of Brazil, Denmark, Germany and other interested delegations, for consideration at the next session.

DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (PART B) (DRAFT GUIDELINES FOR USE OF NUTRIENT CLAIMS (AGENDA ITEM 3)⁶

FIBRE

21. The Committee recognized that the following issues should be addressed when defining the condition for claims on fibre: the definition of fibre, the method of analysis, the reference to the Nutrient reference Values (NRV); and the discrepancies in the results obtained when declaration was made per 100 g or per 100 kcal.

22. Some delegations were in favour of setting a condition for making a claim on fibre per 100 kcal as this would include many foods which were recognized as sources of fibre, especially fruit and vegetables, whereas they might be excluded under another system. Other delegations supported the condition for claim per 100 g, which would be consistent with the expression of nutrients included in part A of the Table. It was also proposed by Brazil to include a reference to fibre figures at “source” 1.5 g and “high” 3.0 g per 100 ml to take into account liquids such as fruit juices. Some delegations proposed to refer to the serving size in order to avoid the inconsistencies identified when referring to 100 kcal or 100 g.

23. The Committee recognized that since there was no agreement on the definition of fibre and the method of determination, no decision could be taken at this stage but it would be useful to proceed with

⁶ CX/NFSDU 98/3; CX/NFSDU 98/3-Add.1 (Comments from Australia, Cuba, Kuwait, Mexico, New Zealand, South Africa, Spain); CX/NFSDU 98/3-Add.2 (Germany); CRD 2 (Uruguay); CRD 12 (USA); CRD 27 (Thailand); CRD 34 (ISDC); CRD 40 (India); CRD 53 (USA).

consideration of this issue. The Committee **agreed** to establish an informal Working Group⁷ chaired by the United Kingdom to consider the comments and proposals received from governments and determine how to progress further as regards claims related to fibre. The Committee noted that the informal Working Group had not come to a conclusion but had initiated work to identify the areas which required further consideration and **agreed** to pursue its consultations as required by correspondence, with a view to establishing a scientific basis for the fibre levels in the Table.

PROTEIN - VITAMINS AND MINERALS

24. Some delegations indicated that the classification of certain foods as liquid or solid created some difficulties to determine whether they were sources of some nutrients; other delegations pointed out that the reference to energy (100 kcal) instead of quantity (100 g or ml) would solve that problem.

25. The Delegation of South Africa proposed to combine the references to energy and to quantity in order to avoid, foods which are not recognized sources of protein or high in protein to be classified as such.

26. The Committee discussed the use of the value for “high” and generally agreed that it should be two times the values for “source”. The Observer from Consumers International expressed the view that the value for high protein should correspond to three times the value for “source” as this would correspond to consumer perception. The Delegation of Spain while agreeing with a scientific basis of condition for claim noted that this information was not always sufficiently clear to consumers. Other delegations pointed out that the current ratio between “high” and “source” was consistent with scientific studies based on food consumption surveys in their countries.

27. Some delegations expressed the view that the NRV should be updated, as the values in the Table referred to them. However the Committee agreed that as regards nutrition claims, the issue to be addressed was not the actual figures for NRVs but the principles for the establishment of conditions in the Table.

28. Some delegations pointed out that the expression per serving should be taken into account as it was current practice in their countries; this should be reflected in the conditions for claims in the Table, as agreed at the last session of the Committee and noted in the Commission’s report. The Committee recognized that it was not possible to determine the size of servings as this differed widely according to the countries and the foods considered, but agreed that a reference to expression per serving should be included in the Table. In order to facilitate discussion on the values for both protein and vitamins and minerals, the Committee agreed to establish an informal Working Group chaired by France, especially to consider the proposal of the Delegation of the United States for a reference to servings and direct from the Codex Alimentarius Commission to undertake further work on the serving sizes (ALINORM 97/37 paras 50).

29. Findings of the informal working Group were presented by Professor Rey (France) who informed the Committee that the Working Group, except for South Africa and France, had reached consensus on the issue raised. The Committee expressed its appreciation to the Working Group and agreed with its recommendations to include the following values, in addition to the expression per 100 kcal and per 100 g/ml:

- 10% of the NRV per serving for “source of protein”
- 15% of NRV per serving for “source of vitamins and minerals”

with a footnote to the effect that the serving size was to be determined at national level. The reference to “high” as two times the value for “source” was also confirmed both for protein and vitamins and minerals. South Africa and France agreed to a revised footnote, but did not agree to a revised conditions for protein.

⁷ Australia, Brazil, Canada, Denmark, France, Germany, Hungary, Korea, New Zealand, South Africa, USA.

STATUS OF THE DRAFT TABLE OF CONDITIONS (GUIDELINES ON USE OF NUTRITION CLAIMS)

30. The Committee **agreed** to advance the provisions on Protein and Vitamins and Minerals in the Table to Step 8 for adoption by the 23rd Session of the Commission (see Appendix II) and to return the provisions on Fibre to Step 6 for further comments and consideration by the next session (see Appendix III).

DRAFT REVISED STANDARD FOR GLUTEN-FREE FOODS (AGENDA ITEM 4)⁸

31. The Committee recalled that the Twenty-second Session of the CAC adopted the Proposed Draft Standard for Gluten-Free Foods at Step 5 while recommending that comments on methods of analysis and on amounts of gluten in gluten free foods should be taken into account when finalizing the standard. The Committee noted that without an appropriate method of analysis it was not scientifically justified to advance the Draft further.

32. The Delegation of Sweden introduced its recent study on gluten determination in foods by an enzyme immunoassay using a monoclonal antibody against omega-gliadin (CRD 33), noting that the detection limit of the method (AOAC 991.19) was about 20-40 ppm and the repeatability was acceptable. Some Delegations pointed out that the method presented, raised some technical concerns: it was performed only on wheat and due to this uncertainty exists as regards its applicability to other cereals. It measured only omega-gliadin and other gliadins should also be taken into account. There were also concerns about variability of results using this method. The need of further improvement was raised. The Spanish Delegation, referring to its written comments (CRD 21), expressed concerns about establishing limits without having a method to detect all prolamins.

33. The Committee noted that in some cases a proprietary method was the most specific way to detect an analyte, such as in the case of gluten detection. Since Codex had not endorsed these techniques as methods of analysis of Codex, the CCMAS should consider this problem.

34. Several delegations suggested that the Committee should ask FAO and WHO to convene an Expert Consultation to address the issue of the level and the method of analysis. Other delegations proposed to consult the CCMAS on this issue. The Secretariat informed the Committee that on the request of the CCFL, JECFA was prepared to consider the question of hypersensitivity at its 53rd Session (June 1999) and the intolerance to gluten might be discussed in this context. The Secretariat recalled that the role of the CCMAS was to endorse methods of analysis proposed by specialized Committees and the CCNFSU needed to specify the method.

35. Spain presented its position about fixing a level at 200 ppm indicating that in the interest of protecting health, consumers' safety and their legitimate economic concerns is unwarranted to classify foods with a gluten content of 200 ppm as gluten free. Several delegations and the Observer from the AAC proposed that the discussion of this draft should be adjourned until a reliable method of analysis became available. Other delegations were in favour of continuing work on it in order to meet the urgent need of patients suffering from coeliac disease and proposed to advance a proposal for a single level at 200 ppm to Step 8. A new preamble would suggest revision of a standard when improved analytical methodology become available. Taking into account the absence of an appropriate and accurate method of analysis, it was proposed to maintain the gluten free level at 200 ppm for all foods and to include a new preamble suggesting the future amendment of the standard when new scientific evidence became available.

36. Several delegations pointed out that the current definition proposing two levels of "gluten-free" foods was confusing and misleading for the consumer and that the single level should be set. However, other delegations and the Observer from AO ECS stressed the need for two levels with regard to the

⁸ CX/NFSU 98/4; CX/NFSU 98/4-Add.1 (Comments from Australia, Spain, UK, AAC; ISDI); CX/NFSU 98/4-Add.2 (AO ECS); CRD 3 (Uruguay, ISDI); CRD 13 (USA); CRD 21 (Spain); CRD 33 = CRD 43 (Sweden); CRD 44 (India); CRD 51 (Norway).

naturally gluten free foods and the products which had been rendered gluten free. The Committee noted that the proposed term “gluten-free” might mislead the consumer and recognized that the term “low or reduced in gluten” should be considered.

37. The Observer from AO ECS, supported by some delegations, expressed the view that the level of 200 ppm for all gluten-free foods was too high to protect coeliacs and the gluten level should refer only to the end product for better consumer protection.

38. The Delegation of Finland proposed to remove *oats* from the list as recent clinical scientific research showed that oats could be tolerated by coeliac disease patients as it allows to provide dietary fibres for coeliacs. The Observer from AO ECS, supported by some delegations, stressed that the square bracket on oats should be removed as oats might have negative impact on the health of coeliacs and that the medical experts had not reached consensus on this issue.

39. The Committee recognized that the development of reliable method of analysis for gluten was the key point in this discussion and that the development of the method should be encouraged by all means.

STATUS OF THE DRAFT REVISED STANDARD FOR GLUTEN-FREE FOODS

40. The Committee **agreed** to leave the text of the draft as it was in CX/NFSDU 98/4 and to return it to Step 6 for further consideration. The Committee also **agreed** that the question regarding the proprietary techniques should be raised to the CCMAS as a general matter.

PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL SUPPLEMENTS AT STEP 4 (AGENDA ITEM 5)⁹

41. The Chairman recalled that the last Session of the CAC (June 1997) discussed this issue and agreed to return the Proposed Draft to Step 3 for further comments and consideration by the CCNFSDU, including a fundamental reconsideration of the need for the Guidelines, and invited the Committee to exchange views on the fundamental question raised.

42. The Committee considered the matter and recognized that two approaches existed to this question. Several countries and the Observer from CI were in favour of further elaboration of these Guidelines without delay as vitamin and mineral supplements were widely marketed and the unregulated usage of some supplements might harm the health of consumers. Moreover, since national legislation could not always address the problems and trade barriers already existed, it was essential to provide an international reference in the framework of the Codex and to ensure fair trade practices. Some delegations pointed out that a clear distinction should be established between vitamins and minerals for therapeutic purposes, and dietary supplements which should be classified as foods and therefore within the mandate of the Committee.

43. The Delegation of Canada, supported by the United States strongly objected to further elaboration of the guidelines as this would interfere with the trade of products which could benefit certain consumers, as recent scientific data¹⁰ indicate that diet may not be sufficient to meet the requirements for some nutrients of some population subgroups; in addition, many consumers felt that the consumption of vitamin and minerals was a “right”, and products which were safe and presented no health risk should be freely available. The Delegation stressed that, since the attitude and perception of consumers greatly differed from one country to another, the regulation of supplements should be left to national authorities.

⁹ CX/NFSDU98/5; CX/NFSDU 98/5-1-Corrected Version (Comments from Australia, Denmark, Spain, CSPI; CRN; ISDI); CX/NFSDU 98/5-Add.2 (Germany); CRD 1(USA: Abridged Internet Version of A Risk Assessment Model for Establishing Upper Uptake Levels for Nutrients); CRD 4 (Canada, Uruguay, CSPI); CRD 14 (USA); CRD 25 (Thailand); CRD 44 (India); CRD 52 (Norway).

¹⁰ Food and Nutrition Board, NAS.

44. The Committee was reminded that in some countries vitamin and/or mineral supplements were regulated as pharmaceuticals or therapeutic goods entirely and in some countries it depended on the amount of dosage in excess of the RDI. It was therefore considered necessary first to solve the key principles of the problem. The Delegation of South Africa, supporting the written comments of Australia, stated that as the Guidelines would not apply to those countries where supplements were regulated as drugs, they would have a limited effect on the current situation in South Africa.

45. The Committee had an extensive debate on the basis for the establishment of upper limits in the light of currently available scientific evidence; some delegations supported a science based risk model approach for developing upper safe limits while other delegations stressed that decision should be based essentially on nutritional considerations. It was also noted that official authorities had to address questions related to unsubstantiated claims, control and monitoring of products, which should be taken into account when discussing the establishment of limits.

46. The Chairman proposed that in order to facilitate consensus, efforts should be made to combine the different approaches as it should be possible to integrate both safety and nutrition concerns on the following basis: the establishment of a science based risk assessment model to develop safe upper limits, taking into account all sources of nutrients and adequate safety factors to make recommendations for vitamin and mineral daily intake for vitamin and mineral supplements. The Committee could not come to a conclusion at this stage but agreed to continue its discussions at the next session in the light of the above proposal and the issues raised during the debate.

47. The Secretariat drew the attention of the Committee to the Joint FAO/WHO Expert Consultation on Human Vitamin and Mineral Requirements, currently being held in Bangkok (21-30 September 1998). The intention of the Consultation was to review the full scope of food-based vitamin and minerals requirements, including their role in normal human physiology and metabolism and in deficiency disease conditions and it might provide the basis for the solution of this issue.

48. The Observer from the EC indicated that the question of dietary supplements was currently under consideration in the EC, where no legislation existed as yet, and informed the Committee that a paper on this matter had been prepared by the EC services. This paper provided a neutral and objective presentation on the issues that should be considered on this subject and aimed to help understand the rationale behind the different approaches. The Observer pointed out that this paper currently discussed had been developed in the EU context but that it might be further developed in the international context with the participation of interested countries; it would be useful to study in depth the principles justifying each particular position in order to find a common ground for discussion. The Committee **agreed** that, before proceeding further in the elaboration of the Guidelines a discussion paper, taken as a basis the above mentioned paper, should be prepared jointly by Canada, USA and the EC on the issues raised above.

STATUS OF THE PROPOSED DRAFT GUIDELINES ON VITAMIN AND MINERAL SUPPLEMENTS

49. The Committee decided to retain the Proposed Draft Guidelines for Vitamin and Mineral Supplements at Step 4 and **agreed** to consider a discussion paper prepared by Canada, the United States and the EC at its next session in order to facilitate consideration of this issue.

PROPOSED DRAFT REVISED STANDARD FOR PROCESSED CEREALS-BASED FOODS FOR INFANTS AND YOUNG CHILDREN (AGENDA ITEM 6)¹¹

50. The Committee, recalling that the Proposed Draft had been considered in detail at its last session and circulated for additional comments, considered the text section by section and made the following amendments.

¹¹ CX/NFSDU 98/6; CX/NFSDU 98/6 (corrigendum trilingual); CX/NFSDU 98/6-Addi.1 (Comments from Cuba, Kuwait, Mexico, CI, ISDI); CX/NFSDU 98/6-Add.2 (Comments from Germany, Spain, AOECs, EC); CRD 5 (Uruguay, Canada, ISDI); CRD 15 (USA); CRD 23 (ENCA); CRD 26 (Thailand); CRD 31 (IBFAN); CRD 37 (Japan); CRD 45 (India); CRD 49 (ILCA).

SCOPE

51. The Delegation of Bolivia proposed to amend the Scope to refer to “the age of about 6 months” instead of “4 to 6 months”, stressing the health problems associated with complementary feeding when introduced too early, especially in developing countries. This view was supported by the Delegations of Egypt, Hungary, Norway, Korea, India, Brazil, Venezuela, Uruguay, by the Representative of UNICEF (who referred to WHA resolution 47.5), and the Observers from Consumers International, IBFAN, ENCA, ILCA. They pointed out that the use of a range (4 to 6 months) would be confusing to health workers and parents, and that a precise limit for the introduction of cereal-based foods provided better guidance in order to address problems related to microbial contamination and intolerance.

52. The Delegation of France, supported by several delegations and the Observer from the EC, supported the current text and stressed the scientific basis for the range of 4 to 6 months, as it allowed to take into account the health and nutrition status of the population in different countries and the growth needs of the infant, whereas a limit of six months did not allow any flexibility in this respect. The Delegation also noted that the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children referred to older infants after 6 months and it had been decided to keep the Standard and the Guidelines separate because they applied to different age ranges and had different purposes.

53. The Representative of WHO indicated that there was no change in the current WHO position concerning the introduction of complementary feeding between four and six months, as current scientific evidence did not support an amendment at this stage; the range was an essential element as it reflected the need to take into account the diversity of needs of the individual infant. The Representative informed the Committee that a comprehensive study, to be concluded in 2002, had been initiated to revise the current International Growth Reference Standards, on the basis of data collected in several regions on breast-fed children (representing ideal nutrition); the results of this study would provide the scientific basis for reconsidering this issue in the future. The Representative also pointed out that the Scope should be considered in conjunction with Section 8.5.4 concerning Information for Utilization, whereby the decision to introduce complementary feeding should be made in consultation with a health worker on the basis of the specific needs of the infants, and additional requirements could be established at the national level.

54. Some delegations including India the Representatives from UNICEF and CI drew attention to the recent WHA resolution where “about six month” was adopted instead of “four to six month” in view of the global nature of the standard.

55. Some delegations stressed the fact that a decision on this issue had already been taken at the last session on the recommendation of WHO representative¹² and that the current text should be retained as there was no scientific basis to amend it. India and other delegations were opposed to this. The Committee, recognizing that there was no consensus at this stage, agreed with the proposal of the Delegation of Canada to include the current text in square brackets for further comments and consideration at the next session.

56. As a consequential amendment, all related references to the age of introduction in the standard were put in square brackets: sections 3.8.1 (optional ingredients), 8.5.3 (gluten declaration), 8.5.4 (use of the product).

2.1 PRODUCT DEFINITIONS

57. The Committee agreed to delete the first sentence of this section as it repeated the text of Section 2. Description.

58. Some delegations proposed to delete the reference to biscuits, rusks and pasta as specific foods for young children since there was no need for special regulation of these products for children, because these products, as defined for infants and young children, were not different from products used by other age groups. This view was supported by the Observers from Consumers International and ENCA.

¹² ALINORM 97/26, para. 67.

The Representative of WHO indicated that, the fact that the products were not necessary did not mean that the products could not be regulated. Other delegations indicated that these products were used and regulated by legislation in their countries and that it was useful to provide nutritional criteria for their composition at the international level and as guidance for governments. This view was supported by the Observer from ISDI.

59. The Committee noted the proposal from the Delegation of India to delete the reference to starchy roots as they did not provide protein and all countries should be able to use cereals for their babies. It was however noted that starchy roots had been included in the standard to take into account the needs of countries where no other raw materials were available. The Committee recognized that the standard was intended to cover all types of foods and raw materials used in different regions and agreed to retain the text as currently drafted.

2.2. OTHER DEFINITIONS

60. The Committee had an exchange of views on point 2.2.3 referring to milk, and discussed whether sweetened condensed milk, evaporated milk and skim milk should be excluded. Some delegations pointed out that confusion should be avoided between composition requirements which were relevant for the manufacturer and the instructions for use provided to consumers in the labelling. The Committee recognized that nutritional requirements, as defined in Section 3, would ensure that the end-product would not be too high in fat or sugars and that additional requirements concerning different types of milk were not necessary; it was also noted that a definition for milk, recently revised by the Committee on Milk and Milk Products, existed within Codex. The Committee therefore agreed to delete section 2.2.3.

3.1 ESSENTIAL COMPOSITION

61. The Committee agreed to delete the reference to peanut “arachis” in view of allergenicity risks.

3.3 PROTEIN

62. The Committee agreed to retain the second option proposed in the current text, referring to 80% of the reference protein, for the expression of protein contents. The Delegation of Japan proposed to indicate that the values for protein could be set at the national level in the light of dietary habits. This view was supported by the Delegation of Norway, who proposed to lower current values in order to avoid excessive protein intake. The Committee however retained the current text as it was intended to provide a common approach at the international level, including the inclusion of Annex 1 on casein. The Committee agreed that only natural forms of L-amino acids can be used.

3.4 CARBOHYDRATES

63. The Committee agreed to change the amount of added carbohydrates in para. 3.4.2 from 1.2 - 2.0 g per 1 kJ as suggested by the Delegation of Spain.

3.5 LIPIDS

64. The reference to the products covered in point 2.1.4 (biscuits) was deleted as the provisions of section 3.5.1 concerned only simple cereals to be reconstituted.

65. Some delegations pointed out that the provisions for (a) lauric acid and (b) myristic acid were not considered essential and the Committee agreed to delete them.

3.6 MINERALS

66. The reference to the expression of sodium per 100 kcal was introduced in square brackets for further consideration. In section 3.6.1, the Committee agreed to retain reference to products intended for children over one year with an editorial change for clarification purposes. The Committee agreed to delete section 3.6.2 referring to products covered by 2.1.4 (biscuits) and to transfer this reference to section 3.6.1.

3.7 VITAMINS

67. Some delegations supported the deletion of section 3.7.2 on the addition of vitamins A and D as fortification with these vitamins was not necessary in some countries and could even result in excessive intake and serious health hazards; decisions on fortification should be left to national authorities, as indicated in section 3.7.3. Other delegations recalled that these provisions were already included in the standard for infant formula and that they applied only to cereals with an added high protein food (2.1.2). Some delegations pointed out that fortification should not be mandatory.

68. The Committee also noted that the provisions for vitamins A and D should be consistent with section 3.7.3 whereby the addition of vitamins and minerals was left to national legislation. Some delegations proposed that section 3.7.3 should not mention specifically vitamin A, iodine and iron, while other delegations stressed the importance of such a reference in view of public health concerns related to micronutrient deficiencies.

69. The Committee, with the exception of the Delegation of Norway, **agreed** 1) to retain the current values for Vitamins A and D in section 3.7.2 and 2) to amend section 3.7.3 to specify that derogations to these maximum values and the addition of other vitamins and minerals, for which no provisions were set in the standard, was left to national legislation.

3.8 OPTIONAL INGREDIENTS - 3.8.3 COCOA

70. The Committee, while noting the suggestion of some delegations to delete this section and the proposal of the Delegation of Korea to refer to one year of age for the introduction of cocoa, agreed to retain the current text, which referred to nine months.

3.10 CONSISTENCY AND PARTICLE SIZE

71. Several delegations and observers proposed to introduce a reference to “spoon feeding”, which would ensure that these products were not marketed as breast milk substitutes which could be fed by bottle, and to current practice for infants above six months. Other delegations pointed out that this requirement was conditional on the decision relative to the age of introduction of supplementary feeding. The Committee recognized that no conclusion could be reached at this stage and agreed to include “spoon feeding” in square brackets for further comments. The Observer from ILCA noted that the additional word “spoon” before feeding was consistent with this draft as these products are not breast milk substitutes.

4. FOOD ADDITIVES

72. The Committee noted that a number of proposals had been made for amendments to the additives section and recalled that appropriate technological justification should be provided when submitting additives for endorsement to the Committee on Food Additives and Contaminants. The Committee recognized that these provisions should be considered carefully taking into account all relevant technical aspects, which was not feasible at the current session due to time constraints; it was therefore proposed that a Working Group¹³ coordinated by the Delegation of the Netherlands should work by correspondence in order to provide a revised Section on Food Additives for consideration by the next session.

5. CONTAMINANTS

73. The Delegation of Spain expressed the view that the current reference to “practically free” (from contaminants) was not acceptable as it did not provide the legal and practical basis for official control of foodstuffs nor guarantee the free circulation of goods. This view was supported by other

¹³ The Working Group includes the following participants: Canada, China, France, Germany, Romania, Spain, Switzerland, UK, USA, Uruguay, Slovakia, EC, ISDI.

delegations, who proposed the inclusion of precise figures for pesticides, heavy metals and other contaminants.

74. The Committee recalled that the Committee on Pesticide Residues had asked for clarification on its earlier request for the establishment of MRLs for foods for infants and children, and recognized that justification should be provided. The Committee therefore agreed to request the CCPR to consider the feasibility of establishing specific MRLs for cereal based foods and infant formula. In setting MRLs for each pesticide residue in these foods, the CCPR should describe the general principles for risk assessment that have been taken into account. These principles should include, but not be limited to, consideration of:

- the physiological and developmental characteristics of infants and young children who would be consuming these products;
- the relative contribution of these foods to the total daily intake of these infants and children; and
- the types of ingredients used in these foods.

6. HYGIENE

75. The Committee noted that the reference statements on food hygiene had been amended by the last Session of the Commission and agreed to amend the current section accordingly.

8. LABELLING

76. The Committee had an exchange of views on the reference to labelling in the appropriate language of the country and noted that a reference to Language was included in the General Standard for the Labelling of Packaged Foods. However, some delegations and observers supported a specific statement in the standard to this effect and the Committee retained the current text.

8.3 DECLARATION OF NUTRITIVE VALUE

77. In order to clarify and simplify this section, the Committee agreed to replace the current section with the text proposed in the comments of Canada, whereby the energy value was expressed in kcal or kJ, and protein, carbohydrate and fat were “expressed in grams per 100 g of the food sold as well as per specified quantity of the food as suggested for consumption”. The text of the Section 8.3 was amended as proposed by the Observer from EC.

8.5 INFORMATION FOR UTILIZATION

78. In Section 8.5.2, the Committee agreed to delete the reference to protein and to refer to “products covered by point 2.1.1” for clarification purposes.

79. In Section 8.5.3, the Committee had an exchange of views on the declaration of gluten and recognized that questions relating to gluten-free foods were addressed in the relevant standard and should be compatible with the reference to gluten in foods for infants. The Committee agreed that “the presence or absence” of gluten should be declared, in order to provide flexibility. The sentence was left in square brackets. The Observer of AOACS expressed the view that a sufficient declaration of gluten including gluten containing processing aids the “75% rule” should be extended to all processed cereal-based foods for infant and young children for better information of gluten intolerant consumers. The Observer from ISDI remarked that there was no need for this request because the presence of gluten containing cereals was indicated on the list of ingredients.

80. Section 8.5.4 was left in square brackets pending a decision on the Scope, since it included the reference to age. Some delegations and the Representative of WHO noted that this section would not be necessary if a precise limit was introduced for the age of introduction; other delegations stated that the decision should be taken with a health worker even in the framework of a recommendation for “about six months” which was not absolute.

81. The Delegation of India and of Consumers International proposed to include the following additional provisions: a reference to the need for breast feeding to continue when supplementary foods were introduced; a prohibition of pictures representing children or suggesting an inappropriate age of introduction; a prohibition of health and nutrition claims. The Committee noted that under the current provisions of the General Guidelines on Claims, health claims were allowed only in conformity with national legislation.

STATUS OF THE PROPOSED DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN

82. The Committee, recognizing the progress made on the revision of the text, **agreed** to forward the Proposed Draft to the Commission for adoption at Step 5 (see Appendix IV).

PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA AT STEP 4 (AGENDA ITEM 7)¹⁴

83. The Delegation of Netherlands introduced the proposed draft. The Committee recalled that the 20th session of the Committee briefly discussed the proposed draft and in view of the importance of the standard and the short time available agreed to return the text to Step 3 for further consideration.

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

1. SCOPE

85. Canada and other delegations pointed out that all infant formula, including those for special dietary uses, should meet all the requirements under the standard, except those related to any nutrient that needs to be modified to meet the special nutritional requirement, to ensure that formulas were safe and nutritionally adequate in all other respects (additives, contaminants, hygiene). The Committee noted that although some requirements on an infant formula for specific health conditions might deviate from the provisions in the proposed draft, other aspects of the formula should comply with requirements in the proposed draft. The first paragraph of the proposed draft was amended. The Observer from the EC expressed serious concerns about the consequences of including products intended for infants not in good health in this standard. As regards of applicability of provisions of use of additives and labelling, taking into account that different such provisions might be set in other standards and notably the standard on Foods for Special Medical Purposes.

86. Regarding the reference to the International Code of Marketing of Breast Milk Substitutes and relevant World Health Assembly (WHA) resolutions, the Committee noted the proposed text submitted by the Delegation of Canada (CRD 6). Several delegations and the Observer from the EC opposed reference to WHA resolutions because it would bind the standard to future resolutions which contents are unknown. Other delegations and the Representative of UNICEF supported the reference. The Committee agreed to include the words “and relevant World Health Assembly resolutions” in square bracket.

87. The Delegation of Spain expressed the view that the legal implications of the reference should be carefully examined.

2. DESCRIPTION

Section 2.1.1

88. The Committee agreed to add “safe, potable and previously boiled” immediately before “water”, as the safety of water in preparation of infant formula was essential.

¹⁴ CX/NFSDU 98/7; CX/NFSDU 98/7-Add.1 (Comments from Australia - version disregarded, Costa-Rica, Egypt, Lithuania, New Zealand, South Africa, Turkey, CI, ISDI); CX/NFSDU 98/7-Add.2 China, EC); CRD 6 (Australia-correct version, Canada, Mexico, Uruguay); CRD 16 (USA); CRD 24 (ENCA); CRD 46 (India); CRD 48 (Argentina); CRD 50 (ILCA).

Section 2.1.2

89. Several delegations proposed to delete the text after “its directions for use” while others were opposed. The Committee noted that the words “four to six months” should be considered in conjunction with the discussion of Agenda Item 6 (see paras. 51-56).

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

Section 3.1

90. The Committee had an extensive exchange of views. Many relevant suggestions on this section, including those written in CX/NFSDU 98/6-Add. 1; Add. 2 and CRDs, were provided.

91. Referring to their comments in CRD 46, the Delegation of India opposed the current section 3.1.1, as the composition of infant formula should be in conformity with their national legislation.

92. The Committee noted that maximum values in the tables of vitamins and minerals should be based on scientific risk analysis and data. Further examination of individual figures for both minimum and maximum values should be done in the next session.

93. Regarding the footnote of the Vitamins and Minerals Table: the text in brackets in the first footnote was deleted, as scientific basis of the specified maximum needed further consideration; the proposed maximum ratio of Ca to P was replaced by 2.0 with square brackets; the fourth footnote was deleted, as Iron deficiency was a serious problem in some countries and Infant formula should always be fortified.

94. The words “protein partial hydrolysates” was added after the words “cow’s milk protein” in the section (e) to make it consistent with the provisions for soya protein.

95. The proposed title of section (f) “Fat and Linoleate” was replaced by the new title “Fat and Fatty Acids”, as this section deals with various fat components in addition to linoleate. The provisions for content of lauric and myristic acid were deleted, as the scientific justification of these provisions required further consideration. Several delegations raised concerns about proposed limits to trans fatty acids. The Observer from CRN asked that the recommendations or concerns of several delegates on DHA and ARA be specifically mentioned in the draft of the report in order to focus scientific discussion regarding what may be compelling and emerging data regarding benefit.

Section 3.2

96. In section 3.2.2, “and safety” were included after “usefulness”.

4. FOOD ADDITIVES

97. The Delegation of the United States suggested to add Diacetyl Tartaric Acid Esters of Mono- and Diglycerides and Citric acid esters of mono- and diglycerides in the list of emulsifiers (CRD 16). Some delegations proposed to delete the thickening agents from the list.

98. The Committee noted that scientific justification should be provided when submitting additives for endorsement of the CCFAC. The Committee agreed that the Working Group which examines the section of food additives in the Proposed Draft Revised Standard for Cereal-Based Foods for Infant and Children (paras 72) should cover this task.

5. CONTAMINANTS

99. Regarding section 5.2, the Delegation of Spain repeated the concerns expressed in para. 72 and the view that the extent of “other contaminants” should be clarified. Some delegations proposed to include contaminants such as heavy metals, PCB, dioxins or radioactive elements. The Committee agreed that the discussion of this section should follow that of the section of contaminants in the Proposed Draft Revised Standard for Cereal-Based Foods for Infant and Children (Agenda Item 6)

6. HYGIENE

100. The Committee noted that the reference statements on food hygiene had been amended by the last Session of the Commission and agreed to amend the current section accordingly.

9. LABELLING

Section 9.1

101. In section 9.1.5, the Committee agreed to include the second sentence in square brackets, as the discussion of health claim had not yet been finalized.

102. In section 9.1.6, both paragraphs were put in square brackets.

Section 9.5

103. In section 9.5.2, the words “over six months of age” were put in square brackets.

Section 9.6

104. The Committee agreed that the entire paragraph of section 9.6.1 and 9.6.2 were put in square brackets for further consideration.

Annex 1

105. The Committee agreed to take the figures proposed by the Delegation of Canada (CRD 6).

STATUS OF THE PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA

106. The Committee **agreed** to return the Proposed Draft Revised Standard to Step 3 for further consideration. (see Appendix V).

REVIEW OF PROVISIONS FOR VITAMIN AND MINERALS IN CODEX STANDARDS

(A) VITAMINS AND MINERALS IN FOODS FOR SPECIAL MEDICAL PURPOSES (AGENDA ITEM 8A)¹⁵

107. The Delegation of Germany introduced document CX/NFSDU 98/8 which had been prepared upon the request of the 19th Session of the Committee.

108. The Committee thanked the Delegation of Germany for the paper and had an exchange of views regarding the scientific basis of nutrient requirements for diseased people and the age groups to be considered when setting minimum and maximum levels of vitamins and minerals. It was agreed to express nutrient density criteria both in kcal and in kilojoules as the latter expression was used in a number of countries. The Committee accepted the view that, when elaborating the provisions in the future, the age ranges should be based on the following three age groups: 0-12 months, 1-11 years, and over 11 years.

109. The Delegation of United States objected to the establishment of maximum limits except on the basis of science based risk assessment when safety concern existed and pointed out that some of the ranges for the electrolytes were not adequate. Some delegations questioned the usefulness of prescribing nutrient content based on the requirements for healthy adults. It was also suggested to amend the reference energy intake to 1500 kcal.

110. The Delegations of Denmark and Norway proposed to extend the scope of the Table and to include requirements for energy, protein contents and essential fatty acids. The Delegation of Romania pointed out that patients with severe burns had special requirements as regards fatty acids. The Committee however did not come to a conclusion on the addition of other nutrients to the Table.

¹⁵ CX/NFSDU 98/8; CX/NFSDU 98/8-Add.1 (Comments from Australia, Denmark, Egypt, Norway, Singapore, UK; ISDI); CRD 7 (Uruguay); CRD 19 (USA); CRD 29 (Thailand); CRD 42 (Denmark); CRD 47 (India).

111. It was suggested that the Table, when further developed, should be included in the Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses. The Committee however noted that the standard did not apply to composition requirements but only to labelling and claims; its revision and the amendment of its scope was a different issue which had not been raised so far and could not be considered at this stage, especially as it had not yet been decided how to proceed with the Table.

112. The Delegation of Switzerland drew the attention of the Committee to the fact that the FAO/WHO Expert Consultation on Human Vitamin and Mineral Requirements was being held in Bangkok and its conclusions might be useful in this regard.

113. The Committee **agreed** that the issues identified above deserved additional consideration and agreed that the Delegation of Germany would revise the discussion paper including the Table, as required, in square brackets for further comments and consideration at the next session.

NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES (AGENDA ITEM 8B)¹⁶

114. The Committee recalled that at its 20th Session it had considered this issue and it was agreed that the paper should be circulated for comments on the general approach to the values, and further action, if needed.

115. The Committee noted that it was difficult to deal with this matter as there is no foreseen possibility to have the Expert Consultation similar to the one that was held in Helsinki. The Delegation of Switzerland recalled that the Joint FAO/WHO Expert Consultation is being held in Bangkok and it might provide data necessary for the further elaboration of this document. The Committee **agreed** to stop considering this issue until the recommendations of the Expert Consultation become available.

CONSIDERATION OF DIETARY MODELLING (AGENDA ITEM 9)¹⁷

116. The Delegation of Australia recalled that a discussion paper on Dietary Modelling for nutrient intake had been presented at the last session and circulated for comments to seek the views of member countries on how to proceed in this area. The Delegation recognized that this document had been superseded as further development of the matter had occurred through the recommendations of the FAO/WHO Consultation on Food Consumption and Exposure Assessment of Chemicals (Geneva, 1997)¹⁸. In this perspective, the Delegation proposed that the Committee might consider how to integrate the recommendations of the Consultation in its work on nutrition issues, as the Consultation had been concerned essentially with exposure to chemicals.

117. The Committee **agreed** with this view and decided to discontinue consider the discussion on Consideration of Dietary Modelling. It welcomed the offer of the Delegation of Australia to develop a discussion paper on the application of the Consultation's recommendations to the work of the Committee, for consideration at the next session.

¹⁶ CX/NFSDU 98/9; CX/NFSDU 98/9-Add.1 (Comments from Singapore, UK); CRD 8 (Uruguay); CRD 17 (US); CRD 30 (Thailand); CRD 35 (ISDC).

¹⁷ CX/NFSDU 98/10; CX/NFSDU 98/10-Add.1 (Comments from Egypt, Slovak Republic); CRD 9 (Uruguay); CRD 17 (USA); CRD 18 (USA).

¹⁸ WHO/FSF/FOS.975, Geneva, 1997.

OTHER BUSINESS AND FUTURE WORK (AGENDA ITEM 10)¹⁹

118. The Committee expressed its appreciation to Prof Dr Dr h.c Arpad Somogyi who chaired the Committee for a long time for his important contribution to the work of the Committee and wished him all success in his new position.

(A) PROPOSAL TO DEFINE THE BASIS FOR DERIVATION OF ENERGY CONVERSION FACTORS IN THE CODEX GUIDELINES ON NUTRITION LABELLING

119. The Delegation of Australia introduced CRD 10 which highlighted the need for a clear definition of the basis on which energy factors were derived. It proposed consideration of a definition of metabolisable energy in the Guidelines on Nutrition Labelling to allow a review of the existing factors in the light of the new definition. This would be especially useful for regulatory authorities when developing provisions for nutrition labelling relating to energy. The Delegation indicated that consideration could also be given to reviewing the energy values currently listed in the Guidelines, taking into account the recommendations of the Joint FAO/WHO Expert Consultation on Carbohydrates.

120. The Committee expressed its appreciation to the Delegation of Australia for this interesting study and some delegations indicated that due to the technical nature of the document and the significant changes proposed, they needed to study it further and could not take a position at this stage. It was agreed to circulate the document to member countries, as it had been available only as a CRD at the current session, and to discuss it further at the next session with a view to make a decision whether this matter would be supported as a new work.

(B) 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)

121. The Delegation of New Zealand introduced CRD 20, recalling that the latest amendments to the Lists had been made in 1991, and that many nutrient sources permitted for use in at the national level were not included in the lists, which could create barriers to trade. The Delegation proposed that in order to take into account the importance of public health and safety, new scientific and technological developments, and the work of JECFA on specifications, the revision of the Lists should be initiated as new work.

122. The Committee, recalling that the lists had been kept regularly under review in the past, recognized that it was necessary to ensure its consistency with current practice in member countries and agreed to propose the revision of the Lists as new work to the Commission. It was further agreed that subject to the approval of the Commission, a Circular Letter would be issued to ask for comments on the current Lists, for consideration at the next Session.

FUTURE WORK

123. The Committee noted that its future work would include:

- Part B of the Table of Conditions (containing provisions on Fibre)
- Revision of Standard for Gluten-Free Foods
- Vitamin and Mineral Supplements
- Revision of Standard for Processed Cereal-Based Foods for Infants and Young Children
- Revision of Standard on Infant Formula
- Vitamins and Minerals in Foods for Special Medical Purposes
- Advisory Lists of Mineral Salts and Vitamin Compounds

¹⁹ CRD 10 (Australia); CRD 18 (USA) CRD 20 (New Zealand).

- Discussion paper on Application of the FAO/WHO Expert Consultation's Recommendations to the work of the Committee (paras 117)
- Discussion paper on Criteria for scientific evidence relative to health claims
- Discussion paper on Energy Conversion Factors
- Discussion paper on Fortification Issues (Provisions of Fortification of Iodine, Iron and Vitamin A in the Guidelines of Nutrition Claims)
- Date and place of the Next Session

123. Some delegations pointed out that in view of the heavy workload of the Committee in considering both specific commodity standards and general nutrition issues, it should meet more frequently, as did most general subject Committees, and especially the Committee on Food Labelling.

124. The Chairman indicated that the host government would consider the feasibility of convening the sessions on an 18 months basis. The Committee noted that the next session would be held in Berlin in 2000, the exact arrangements to be determined by the host government and the Codex Secretariat.

SUMMARY STATUS OF WORK

Subject Matter	Step	For Action by	Document Reference (ALINORM 99/26)
Draft Table of Conditions for Nutrient Contents (Part B, containing provisions on Protein and Vitamin and Minerals) (Guidelines for Use of Nutrition Claims)	8	23 rd CAC, Governments	para. 30, Appendix II
Draft Table of Conditions for Nutrient Contents (Part B, containing provisions on Fibre) (Guidelines for Use of Nutrition Claims)	6/7	Governments, 22 nd CC NFSDU	para. 30, Appendix III
Proposed Draft Revised Standards for Gluten-Free Foods	6/7	Governments, 22 nd CCNFSDU	paras 84-88 CX/NFSDU 98/4
Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infant	5/6/7	23 rd CAC, Governments, 22 nd CCNFSDU	para. 82 Appendix IV
Discussion paper in order to facilitate consideration on: Proposed Draft Guidelines for Vitamin and Mineral Supplements	4	Canada, USA, EC 22 nd CCNFSDU	paras 41-49
Proposed Draft Revised Standard for Infant Formula	3/4	Governments, 22 nd CCNFSDU	paras 83-106, Appendix V
Review of Provisions for Vitamins and Minerals in Codex Standards in: (a) Vitamins and Minerals in Foods for Special Medical Purposes	3	Germany, Governments, 22 nd CCNFSDU	paras 107-113
(b) Nutrient Reference Values for Labelling Purposes	3	22 nd CCNFSDU	paras 114-115
Proposals for new work:			
A review of the Advisory Lists of Mineral Salts and Vitamin Compounds, subject to approval by the 23 rd Session of the Codex Alimentarius Commission	1,2,3	23 rd CAC New Zealand, Codex Secretariat, 22 nd CCNFSDU	paras 121-122
Discussion paper on Proposal to Define the Basis for Derivation of Energy Conversion Factors in the Codex Guidelines on Nutrition Labelling		Australia, 22 nd CCNFSDU	paras 119-120
Discussion paper on Criteria for Scientific Evidence Relative to Health Claims	-	France, USA 22 nd CCNFSDU	paras 16-20
Discussion paper on Provisions of Fortification on Iodine, Iron and Vitamin A in the Guidelines of Nutrition Claims	-	Thailand 22 nd CCNFSDU	para. 6
Proposals for discontinuation of work: Consideration of Dietary Modelling		46 th CCEXEC	para. 117
Matters of Interest of other Codex Committees:			
MRLs for Foods for Infant and Children		CCCPR	para. 74
Proprietary Techniques in Codex Methodology		CCMAS	para. 40

ALINORM 99/26
APPENDIX I

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LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES

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APPENDIX II

DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (Part B)
(GUIDELINES FOR USE OF NUTRITION CLAIMS)²⁰
(At Step 8 of the Procedure)

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

²⁰ Serving size to be determined at national level.

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APPENDIX III

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

COMPONENT	CLAIM	CONDITIONS
B.		
NOT LESS THAN		
Fibre	Source High	3 g per 100 g or 1.5 g per 100 kcal or per serving ²¹ 6 g per 100 g or 3 g per 100 kcal or per serving

²¹ Serving size to be determined at national level

**PROPOSED DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS
FOR INFANTS AND YOUNG CHILDREN
(At Step 5 of the Procedure)**

1. SCOPE

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

2. DESCRIPTION

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

2.1. PRODUCT DEFINITIONS

Four categories are distinguished:

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

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

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

2.1.4 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

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

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

3.2 ENERGY DENSITY

The energy density of cereal-based foods should not be less than 0.8 kcal/g (3.3 kJ/g).

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 (casein as defined in Annex 1) 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 Sections 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 Section 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 Section 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 Sections 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 Section 2.1.2

- the amount of added carbohydrates from these sources shall not exceed 0.48 g/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

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

- 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 Section 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 Section 2.1.4 containing milk.

3.7 VITAMINS

3.7.1 The amount of vitamin B1 (thiamin) shall not be less than [15 µg/100 kJ] [(60 µg/100 kcal)].

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

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

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

3.7.3 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 practice

4.2.3 Calcium carbonate |

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 combination

4.3.2 Alpha-tocopherol |

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/100g on an as consumed basis
4.4.3	Vanillin	

4.5 Enzymes

4.5.1 Malt carbohydrases GMP

4.6 Leavening Agents

4.6.1	Ammonium carbonate	Limited by GMP
4.6.2	Ammonium hydrogen carbonate	

5. CONTAMINANTS

5.1 PESTICIDE RESIDUES

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

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

5.2 OTHER CONTAMINANTS

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

6. HYGIENE

6.1 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 the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979).

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

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

- (a) shall be free from microorganisms in amounts which may represent a hazard to health;
- (b) shall be free from parasites which may represent a hazard to health; and
- (c) shall not contain any substance originating from microorganisms in amount which may represent a hazard to health.

7. PACKAGING

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

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

8. LABELLING

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

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

8.1 THE NAME OF THE FOOD

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

8.2 LIST OF INGREDIENTS

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

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

8.3 DECLARATION OF NUTRITIVE VALUE

8.3.1 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 were appropriate per specified quantity of the foods as suggested for consumption.

8.4 DATE MARKING AND STORAGE INSTRUCTIONS

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

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

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

8.5 INFORMATION FOR USE

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

8.5.2 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.

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

[8.5.4 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.]

8.6 ADDITIONAL REQUIREMENTS

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

9. METHODS OF ANALYSIS AND SAMPLING

See Codex Alimentarius Volume 13.

**ALINORM 99/26
APPENDIX V****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 healthy 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 consideration the recommendations given to countries under the International Code of Marketing of Breast-milk Substitutes [and relevant World Health Assembly Resolutions].

2. DESCRIPTION**2.1 PRODUCT DEFINITIONS**

2.1.1 Infant formula, when in liquid form, may be used either directly or diluted with safe, potable, and previously boiled water before feeding, as appropriate. In powdered form it requires safe, potable, and previously boiled water for preparation.

2.1.2 Infant formula shall be nutritionally adequate to promote normal growth and development when used in accordance with its directions for use [and to satisfy by itself the nutritional requirements of infants during the first four to six months of life].

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

2.2.1 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 maximum levels of vitamins, minerals in an available form, choline, protein, fat and fatty acid, carbohydrates and energy:

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	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 (α-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 m	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

	Amounts per 100 kilocalories		Amounts per 100 kJ	
	Minimum	Maximum	Minimum	Maximum
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	1.5 mg	0.12 mg	0.6 mg
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)	N.S. ¹	3 µg	N.S. ¹	0.7 µg
(c) Choline	N.S. ¹	N.S. ¹	1.7 mg	N.S. ¹

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* 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 their partial hydrolysates.

Protein content = nitrogen content x 6.25 for soya protein isolates and their 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 forms of L-amino acids shall be used.

(e) **Fat and Fatty Acid**

The product shall contain:

- linoleic acid (in the form of triglycerides) 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

3.2.1 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 significant amounts of these nutrients, based on levels in human milk.

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

3.3 VITAMIN COMPOUNDS AND MINERAL SALTS

3.3.1 Vitamins and minerals added in accordance with Sections 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 being fed through a soft rubber or plastic teat.

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	
4.1.1 Guar gum	0.1 g in all types of infant formula
4.1.2 Locust bean gum ²²	0.1 g in all types of infant formula

²² Temporarily endorsed.

4.1.3	Distarch phosphate	0.5 g singly or in combination in soy- based infant formulae only
4.1.4	Acetylated distarch phosphate	
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 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
4.2.3	Mono- and diglycerides	0.4 g in all types of infant formulae

4.3 pH-ADJUSTING AGENTS

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

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

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

6. HYGIENE

6.1 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 the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979).

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

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

- (a) shall be free from microorganisms in amounts which may represent a hazard to health;
- (b) shall be free from parasites which may represent a hazard to health; and
- (c) shall not contain any substance originating from microorganisms in amount which may represent a hazard to health.

7. PACKAGING

7.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. 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° 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) Codex Alimentarius Volume 1), 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 90% or more of the protein is derived from whole or skim milk, as such or with minor modification, 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 [may] 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 Formula 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 millilitre of the food ready for use, when prepared according to the instructions on the label.
- (b) the total quantity of each vitamin, mineral, choline and any optional ingredient as listed in paragraphs 3.1.2 and 3.2 of this Standard per 100 grammes of the food as sold as well as per 100 millilitre of the food ready for use, when prepared according to the instructions on the label. In addition, the declaration 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.

9.5.2 Information that infants [over six months of age] should receive supplemental foods in addition to the formula shall appear on the label.

9.6 ADDITIONAL LABELLING REQUIREMENTS

[9.6.1 Labels should not discourage breast feeding. 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 breast-feeding [or: the statement: Breast milk is the best food for your baby, it protects against diarrhoea and other illnesses]; c) a statement that the product should only be used on advice of a health worker as to the need for its use and the proper method of use; d) instructions for appropriate preparation; and e) a warning against the health hazards of inappropriate preparation.

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

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

10. METHODS OF ANALYSIS AND SAMPLING

See Codex Alimentarius Volume 13.

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