codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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

ALINORM 03/27/26

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-seventh Session
Geneva, Switzerland, 28 June– 4 July 2004

REPORT OF THE 25th SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Bonn, Germany
3 – 7 November 2003

Note: This document incorporates Circular Letter CL 2003/42-NFSDU

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CX 5/20.2 **CL 2003/42-NFSDU**
November 2003

TO: Codex Contact Points
Interested International Organizations

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

SUBJECT: **Distribution of the Report of the 25th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (ALINORM 04/27/26)**

A. REQUEST FOR COMMENTS AND INFORMATION AT STEP 5 OF THE PROCEDURE:

1. Proposed Draft Guidelines for Vitamin and Mineral Supplements, para. 61 and Appendix II

2. Proposed Draft Revised Standard for Infant Formula (para. 100 and Appendix V)

3. Proposed Draft Revised Standard for Cereal - Based Foods for Infants and Young Children (para. 130 and Appendix VI)

Governments and international organizations wishing to comment on the above texts should do so in writing, preferably by email to: the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org), **before 31 March 2004**.

B. REQUEST FOR COMMENTS AND INFORMATION AT STEP 6 OF THE PROCEDURE:

1. Guidelines for the Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents (Part B) Dietary Fibre

Governments and international organizations are invited to comment on the above text and should do so in writing, preferably by email to: Dr Rolf Grossklaus, Director and Professor, Federal Institute for Risk Assessment, P.O. Box 33 00 13, 14191 Berlin, Germany, Fax: +49 1888 412 - 37 15, e-mail: rgrossklaus@bfr.bund.de with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org), **before 1 June 2004**.

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 25th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses are as follows:

MATTERS FOR ADOPTION BY THE COMMISSION

The Committee:

- agreed to advance the Proposed Draft Guidelines on Vitamin and Mineral Supplements (para. 26, Appendix IV), the Proposed Draft Revised Standard for Infant Formula (para. 61, Appendix V) and the Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infant and Young Children (para. 130, Appendix VI) to Step 5 for adoption by the 27th Session of the Commission.

MATTERS OF INTEREST TO THE COMMISSION

The Committee:

- agreed to retain the Draft Revised Standard for Gluten-Free Foods at Step 7 until more data on tolerance levels of gluten are available (paras 27-35);

MATTERS REFERED TO OTHER COMMITTEES

Codex Committee on Methods of Analysis and Sampling

The Committee agreed to forward the R5-Mendez ELISA method (for gliadin/gluten detection) to the CCMAS for endorsement (para. 37)

Codex Committee on Food Additives and Contaminants

The Committee agreed to ask the CCFAC whether the establishment of functional classes that were not covered currently was required, especially enzymes and propelling gas. The Committee also noted that there were some inconsistencies between the names of functional classes of additives used in different Codex texts and recalled that this question was under consideration in Codex and JECFA (para 91).

The Committee also noted that ADI does not apply to infants under 12 weeks of age because toxicity tests used to derive ADIs do not cover that phase of life, and agreed to request that the CCFAC refer the use of ADIs for food additives used in foods for infants under than 12 weeks of age to JECFA for re-examination, as proposed by the Delegation of Canada (para 92).

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INTRODUCTION

1. The Twenty-fifth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held from 3 to 7 November 2003 in the Bruckenforum, Bonn, by courtesy of the Government of Federal Republic of Germany. Dr Rolf Grossklaus, Director and Professor of the Federal Institute for Risk Assessment, Berlin, chaired the session. The Session was attended by 225 delegates, observers and advisors representing 48 Member countries and 29 International Organizations.

OPENING OF THE SESSION

2. Dr Walter Toepner, speaking on behalf of the Federal Ministry of Consumer Protection, Food and Agriculture, welcomed the participants and noted the importance of the work of the Committee to ensure the highest standards worldwide to protect the health of consumers and to ensure fair trade practices. He also noted the positive impact of Codex standards in improving food quality and their important role under the Agreements of the WTO and drew the attention of the delegates to the fact that this session would be the 25th after the foundation of the Committee. Dr Toepner emphasized the substantively increased participation at the CCNFSDU meetings during these years and that it was very important to base all deliberations on state of the art of science, especially in such areas as foods for infant and young children. Finally Dr Toepner wished all success to the meeting and to the delegates in their important work.

ADOPTION OF THE AGENDA (AGENDA ITEM 1)

3. The Committee accepted the proposal of the Delegation of Australia and agreed to consider Agenda Item 10 "Application of Risk Analysis to the Work of the CCNFSDU" following item 4 due to its relevance and possible impact on agenda items 5, 6 and 7. The Committee also agreed to consider the issue of trans-fatty acids as a separate item under Agenda item 11 "Other Business and Future Work". With these modifications the Committee adopted the Provisional Agenda as the Agenda for the Session.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES (AGENDA ITEM 2)[1]

Matters arising from the 26th Session of the Codex Alimentarius Commission (CAC)

4. The Committee noted matters related to the decisions of the 26th Session of the Codex Alimentarius Commission. In addition the Committee noted other matters as follows.

Matters arising from FAO and WHO

FAO Technical Workshop on Energy Conversion Factors

5. The Committee noted that the final report of the above Workshop has not been distributed to Member countries before the meeting and that there might be implications for the work of the Committee in relation to harmonization of energy content in foods. The Committee asked the Secretariat to prepare a short paper summarizing the conclusions of the Workshop and describing which possible actions might be necessary for the CCNFSDU in the future.

WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic diseases

6. The Representative of WHO informed the Committee of the report of the Joint WHO/FAO Expert Consultation on diet, nutrition and the prevention of chronic diseases (Geneva, 28th January - 1st February 2002) which was organized in response to the increasing global public health problem of diet-related chronic

[1] CX/NFSDU 03/2; CRD 5 (Joint FAO/WHO Statement on the Diet, Nutrition and the Prevention of Chronic Diseases); CRD 10 (comments from ICGMA).

diseases in both developed and developing countries. The WHO Representative referred to the joint FAO/WHO statement which was included in CRD 5 (pp 22-23), including the updated population nutrient intake goals. These recommendations play a major role in placing diets and nutrition at the forefront of not only public health, but also development programmes and policies. Codex guidelines on both nutrition labelling and nutrition and health claims will be important means for implementing these global recommendations, in addition to assisting consumers make health choices that are both easy and understandable. Decisions on nutrition guidelines, nutrition labelling, and nutrition and health claims thus need to be seen not in isolation, but rather in the context of broader efforts to develop effective public health strategies and policies.

7. The WHO Representative further stated the report of the joint WHO Expert Consultation serves as part of the scientific basis for developing a WHO global strategy on diet, physical activity and health to be submitted to WHO's governing bodies in 2004. FAO is also in the process of discussing with Member Nations on the findings of the Expert Consultation and is exploring the possible implications for agricultural policies and practices.

8. The Observer of IUFOST drew the attention of the Committee to the fact that the International Conference on Nutrition and the World Food Summit both made it clear that greater efforts were needed to assure that every infant, child and adult had access to adequate amount of good quality and safe food every day. The Observer stated that the FAO/WHO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases was not based on sound science and that the report did not take into account a large set of data from recent controlled clinical trials that were applicable to evolution of the nutrition and health effects of different food groups and food ingredients. The Observer stated that the major focus of the FAO/WHO report was on obesity and related chronic diseases and that the report contained many unjustified recommendations for reduction or elimination of consumption of meats, meat and animal products, most fats and oils, salt, fruit juices and carbohydrates included in bread, pasta, rice, potatoes and root crops. The Observer pointed out that the March 2003 FAO Committee on Agriculture did not accept the recommendations of the FAO/WHO report and called for a specific meeting of FAO Member Countries in early 2004 to thoroughly review the report and its adverse implications for agriculture and food supplies.

Upper Levels for Vitamins and Minerals

9. The Committee noted that the FAO/WHO Expert Consultation on upper levels for vitamins and minerals was part of the FAO future Programme of work, subject to the availability of funding.

Functional Foods

10. The Committee noted that the request for scientific advice on functional foods requested by the FAO/WHO Regional Coordinating Committee for Asia would be considered by the Executive Committee with the other requests for scientific advice in order to establish priorities.

11. Some delegations noted that functional foods should not be considered as a separate category of foods and that this issue could be addressed in the framework of health claims. It was noted that scientific advice was more urgent in the area of establishment of safe upper limits for vitamins and minerals.

12. The Committee was of the view that the issue of functional foods could be also addressed while considering item 9 on the Scientific Basis for Health Claims.

Committee on Food Labelling

Significant amount and declaration of vitamins and minerals

13. An Ad Hoc Working Group[2] was convened to facilitate discussions in the Plenary in order to clarify the questions referred to this Committee by the Committee on Food Labelling: 1) what was meant by "a significant amount" from the nutritional point of view, and in particular what percentage of the NRV for vitamins and minerals should be required to allow nutrient declaration of vitamins and minerals and 2) whether the declaration should be made per serving or per 100g or 100 ml or both.

14. Regarding the first question, the Working Group noted the recent amendment to the Guidelines on Nutrition Labelling presented in ALINORM 03/22A (Appendix III). Section 3.2.6.2. of these Guidelines, in their amended version, set a threshold for the declaration of vitamins and minerals of at least "5 per cent of the Nutrient Reference Value or of the officially recognized guidelines of the national authority having jurisdiction per 100 g or 100 ml or per serving as quantified on the label". The Working Group concluded that there was no argument from the nutritional point of view to change this value.

15. Regarding the second question, the Working Group confirmed that the solution proposed by the same provision of the Guidelines (point 3.2.6.2.), as amended, was appropriate, namely the declaration of vitamins and minerals "per 100 g or 100 ml or per serving as quantified on the label".

16. The Committee endorsed these proposals and agreed to forward them to the Committee on Food Labelling.

Trans - fatty acids

17. See para 150.

GUIDELINES FOR THE USE OF NUTRITION CLAIMS: DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (PART B CONTAINING PROVISIONS ON DIETARY FIBRE AT STEP 7)

DISCUSSION PAPER INCLUDING PROPOSALS FOR A DEFINITION, METHOD OF ANALYSIS AND CONDITIONS FOR DIETARY FIBRE CONTENT (AGENDA ITEM 3)[3]

18. The Committee recalled that its last session had agreed that the Delegation of France with assistance of the drafting group would prepare a discussion paper including proposals for a definition, method of analysis and conditions for fibre content, in the light of recent scientific updates.

19. The Delegation of France introduced the paper, highlighting the revised definition that included only plant material in order to ensure the consistency of the nutritional message and described the properties of dietary fibre. Several methods of analysis were also proposed to determine different types of compounds in dietary fibre, on the basis of AOAC methods. The Delegation also indicated that Annex 1 included a list of carbohydrate polymers, some of which were proposed for inclusion while the others required further scientific advice. The Committee expressed its appreciation to the Delegation of France for its comprehensive work on these complex issues.

20. Some delegations and observers expressed the view that the definition proposed was too restrictive and in particular that fibre of animal origin should be included, as the definition should focus on the properties of dietary fibre and it was not current practice to refer to the origin of nutrients in existing definitions. It was also noted that the definition proposed would create some practical difficulties as regards enforcement.

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[2] Italy (Chair), Canada, France, Germany, Hungary, the Netherlands, Slovenia, New Zealand, the USA, the European Commission, ICGMA, IFT, IDF and ISDC.

[3] ALINORM 01/26, Appendix III; CX/NFSDU 03/3; CRD 5 (comments of Philippines); CRD 15 (comment of Indonesia)

21. Some delegations and observers also questioned the restriction to carbohydrate polymers with a degree of polymerisation superior to three, as this would exclude some substances that were normally classified as dietary fibre. Some delegations questioned the need for an Annex, as it would need to be regularly updated and might create confusion on the substances that were covered by the definition.

22. The Committee discussed whether the definition should include references to the physiological properties of dietary fibre, or whether this should be avoided in order to prevent their use as claims, but could not come to a conclusion and agreed that this issue required further consideration.

23. The Delegation of Japan pointed out that the intake for liquids was higher and that therefore the values for sources and high should be lower, and the Committee agreed to include specific provisions for liquid foods in the Table. The Delegation also proposed to replace the methods proposed with AOAC Method 2001.03 that could determine all types of dietary fibre. The Committee however did not consider the methods in detail at this stage.

24. The Delegation of Sweden, supported by other delegations, pointed out that the values in the Table were too high and would not allow a claim for source for ordinary foods, but mostly for foods with added dietary fibre and the Committee agreed that this should be further discussed.

25. The Committee could not come to a conclusion on the definition of fibre and agreed that further consideration should be given to this issue. It was therefore agreed that an electronic working group coordinated by the Delegation of France and Sweden and open to all interested delegations and observers should review the definition to make it more inclusive and consider the related methods.

Status of the Draft Table of Conditions for Nutrient Contents (Provisions on Dietary Fibre)

26. The Committee agreed to circulate the Draft Provisions in the Table, as amended at the present session for comments at Step 6 for further consideration at the next session (see Appendix II).

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

27. The Committee recalled that the Standard had been retained at Step 7 pending resolution of the issues on the method of determination of gluten and the thresholds of gluten tolerance in celiac patients.

28. The Chairman of the Working Group on Prolamin Analysis and Toxicity (WGPAT) Prof. Stern introduced the progress report and informed the Committee that analytical work made considerable progress and that a reliable enzyme-linked immunoassay R5-Mendez (ELISA) method supported by 9 of 10 WGPAT panel members was published. Prof Stern indicated that this method was able to detect 1.5 mg/kg gliadin and that it was collaboratively tested by 20 laboratories. He also drew the attention to the delegates to the fact that a European Gliadine Reference material was available from the Institute for Reference Materials and Measurements (IRMM) and that final certification of this material was expected by mid 2004.

29. The Delegation of Sweden referring to its written comments suggested forwarding both the AOAC 991.19[5] and the proposed R5-Mendez ELISA methods to the CCMAS for their technical advice and possibly temporary endorsement as without an appropriate method it was not possible to protect consumer against fraud and proceed with reliable research data on gluten tolerance. The Delegation also suggested deleting "old" references in Section 6 of General Outline of the Method of Analysis and Sampling of the Draft Revised Standard and to replace it with the text of Section 6.2 Determination of Gluten in Foodstuffs and

[4] CX/NFSDU 00/4; CX/NFSDU 03/4 (Report of the Working Group on Prolamin Analysis and Toxicity); CX/NFSDU 03/4-Add.1 (comments from Sweden, incomplete comments from Finland, AOECS, IWGA); CRD 5 (complete comments from Finland); I. Valdes et all. Innovative Approach to Low-Level Gluten Determination in Foods Using a Novel Sandwich Enzyme-Linked Immunosorbent Assay Protocol, (printed with the permission of publishers).

[5] AOAC Official Methods of Ana;ysis; Supplement March 1995; Chapter 32.13.32.1.24. AOAC Official Method 991.19 Gliadin as measure of gluten in foods. Colorimetric monoclonal antibody enzyme immunoassay method.

Ingredients presented in their comments in the document CX/NFSDU 03/4-Add.1. Some delegations and observers supported these proposals.

30. The Observer from AOECS thanked the WGPAT for their work in particular regarding the results of the international collaborative trials and proposed to the Committee to recommend the R5-Mendez ELISA method to the CCMAS for endorsement for gliadin/gluten detection as this method was the most reliable for the time being.

31. The Committee noted that the clinical trials in order to identify a tolerable threshold level of gluten intake for celiac patients were underway and that this work would be accomplished in one year, therefore it was not possible to agree on provisions of levels of gluten in the Draft Revised Standard. The Committee also noted that the data presented by the Government of Finland (CRD 5) showed that oats were tolerated by celiac patients however no decision on this matter was taken at this stage.

32. The Committee agreed to forward the R5-Mendez ELISA method to the CCMAS for endorsement and recognized that it was not possible to take any decision on tolerable levels of gluten at this stage.

33. The Committee also agreed to substitute the wording in Section 6 in the draft revised Standard as proposed by the Delegation of Sweden.

34. The Committee expressed its appreciation to WGPAT and Prof. Stern for their valuable work on method of analysis and expressed the hope that the work in this area would not be terminated.

Status of the Draft Revised Standard for Gluten-Free Foods

35. The Committee decided to send the R5-Mendez method to the CCMAS and retain the current draft standard at Step 7 until more data on tolerance levels of gluten are available (see Appendix III).

PROPOSED DRAFT GUIDELINES FOR VITAMINS AND MINERAL SUPPLEMENTS (AGENDA ITEM 5)[6]

36. The Committee recalled that the last session had returned the Proposed Draft Guidelines to Step 3 for further comments as a number of substantial issues remained to be discussed. The Committee considered the text section by section and made the following amendments and comments.

Title

37. Some delegations proposed to delete the reference to "food" in the title (food supplements) as it was not necessary as the Scope made it clear only foods were covered by the Guidelines. The Committee also noted a proposal to refer to supplements "regulated as foods". After an exchange of views it was however agreed to retain the current title and to refer to "food supplements" where necessary throughout the text.

Preamble

38. The Committee noted the proposal of the Delegation of South Africa to amend the Preamble to highlight the role of vitamins and minerals in the prevention of chronic disease. The Committee however noted that claims related to the prevention of disease were prohibited according to the General Guidelines on Claims. After some discussion, the Committee agreed to retain the current text as it resulted from considerable discussion and consensus at the last session.

Scope

[6] ALINORM 01/26A, Appendix IV; CX/NFSDU 03/5 (comments of Australia, Brazil, Germany, Malaysia, New Zealand, South Africa, Spain, CRN, IADSA), CX/NFSDU 03/5-Add. 1 (comments of United States, CRN, EC), CRD 5 (comments of the Philippines), CRD 7 (comments of Vietnam), CRD 9 (comments of India), CRD 15 (comments of Indonesia).

39. Some delegations indicated that there should be no reference to national authorities concerning regulation of vitamins and mineral supplements as drugs or foods, as this might create barriers to trade and the Guidelines applied to products in international trade, and therefore proposed to delete the first sentence. It was also pointed out that the second sentence made it clear that the Guidelines applied only to foods. The delegations of Malaysia and India expressed the view that the sentence should be retained. After some discussion the Committee agreed to delete the first sentence of section 1.2 and to amend the second sentence to clarify that the Guidelines applied to foods.

40. The Committee agreed to add provisions to the effect that food supplements containing vitamins and minerals and other ingredients were also subject to these Guidelines as far as their vitamin and mineral content was concerned, as proposed by the Observer from the EC. The Delegation of Norway did not support this inclusion as other ingredients than vitamins and minerals should not be covered by these Guidelines.

Definitions

41. The Committee deleted the reference to "dose" as it might create confusion with drugs and the reference to a significant amount of energy as it was not clearly defined. The Committee agreed to delete the last sentence concerning the rationale for supplementation of the diet because it was already covered by the Preamble, although some delegations proposed to retain it. It was also specified that the purpose of these products is to supplement the intake of vitamins and/or minerals from the normal diet.

42. The Committee discussed whether a specific reference should be made to small unit quantities. Some delegations pointed out that this was necessary to reflect that vitamins and minerals were provided in dose form and should be taken in small unit quantities, to reflect the difference with ordinary foods. Other delegations expressed the view that this was not necessary as the text already indicated that these products were not in a conventional food form and the type of product concerned was illustrated by the examples. The Committee agreed to retain the reference to small units in square brackets for further consideration.

Section 3. 1 Selection of Vitamins and Minerals

43. In section 3.1.2, the Committee discussed the inclusion of both natural or synthetic sources of vitamins and minerals but could not come to a conclusion and retained the text in square brackets for further discussion. The Committee agreed to delete section 3.1.3 concerning the limitation of supplements for reasons of health protection as the safety of the products was addressed in the section concerning risk assessment.

Section 3.2 Contents of Vitamins and Minerals

44. In Section 3.2.1 on minimum amount, some delegations proposed to establish a minimum level to 33% of the recommended daily intake as vitamins and minerals should be presented in a concentrated form. Other delegations proposed to retain the value of 15% as it corresponded to the value for "source" in the Guidelines for Use of Nutrition Claims and a higher value might create practical difficulties for certain nutrients. The Committee agreed with this latter proposal after some discussion.

45. The Committee noted that further clarification would be needed concerning the reference to recommended daily intakes or to NRV for labelling purposes in this section and throughout the text.

46. In section 3.2.2 on maximum amounts, the Delegations of Brazil, Norway, Malaysia and Thailand supported the first option specifying a maximum level of vitamin and/or mineral in order to prevent excessive intake and as no adequate risk assessment methodology for nutrients had been established as yet.

47. Several other delegations supported the second option referring to the establishment of safe upper limits on the basis of scientific risk assessment and the Committee agreed to retain this option.

48. The Committee discussed the need to take into account the reference intake values of vitamins and minerals for the population as several delegations and observers pointed out that this requirement was covered by the rest of the section. Some other delegations proposed to retain this provision to ensure the

scientific basis of the process and the Committee agreed to retain the last sentence of section 3.2.2 in square brackets for further discussion.

49. The Committee agreed to delete section 3.2.3.

Section 4. Packaging

50. After some discussion the Committee agree to delete section 4.3 on the requirement for child-resistant packages and to replace it with an additional paragraph in the labelling section specifying that the product should be stored out of reach of young children (new section 5.9).

Section 5. Labelling

51. The Committee deleted the square brackets in section 5.2, agreed that the name of the product should be "food supplements" for consistency with the rest of the text, and reworded the sentence for clarification purposes. The Committee noted some other proposals to amend the section but recalled that the "name of the food" was part of the mandatory labelling requirements specified in the General Standard for the Labelling of Prepackaged Foods.

52. In section 5.3 the Committee deleted the square brackets and agreed to use the term "should" rather than "shall" as the text was not a standard. The Committee however noted that further discussion would be needed concerning these terms throughout the section in order to ensure consistency, and taking into account the provisions of the General Standard. The Committee also agreed that the units used should be consistent with the Guidelines on Nutrition Labelling.

53. In section 5.4 the Committee discussed whether the declaration of vitamin or minerals should be the amount per portion of the product recommended for daily consumption, or the amount per single use, in order to provide clear information to the consumer. The Committee could not come to a conclusion and retained the reference to amounts per single use in square brackets for further discussion.

54. While considering section 5.5, the Chairman recalled that there was a need to update the NRV that had been established following the Helsinki Consultation (1988). Some delegations pointed out that the current list of NRV was incomplete and required additions and updates. It was noted that the establishment of recommended daily intakes would require an expert consultation in order to consider available scientific evidence. However, the Committee could consider the update of NRV for labelling purposes as it would be the responsibility of regulators to establish such values.

55. The Committee agreed that a Circular Letter would be sent to ask for proposals for additional or revised NRVs for labelling purposes, that might be established for the general population or for specific population groups. These proposals would be reviewed by an electronic working group coordinated by the Delegation of South Africa and open to all interested delegations and observers, in order to develop a document with proposals for revised NRVs for consideration by the next session.

56. The Committee made some editorial changes to section 5.5 for consistency with the other sections.

57. In section 5.7 the Committee agreed to replace the reference to a "warning statement" with "advice to the consumer not to exceed the maximum one-day amount" as this allowed for more flexibility while protecting consumer health.

58. The Committee amended section 5.8 to reflect that "the label should not state or imply that supplements can be used for the replacement of meals or a varied diet" and deleted the square brackets.

59. The Committee agreed to delete section 5.9 indicating that the supplement should be taken on the advice of a nutritionist, a dietician or a medical doctor. The Delegations of Malaysia and the Philippines did not support the deletion of this section as they considered that such advice was necessary.

60. A new section 5.9 was added as agreed following the decision taken under section 4.3 (see para..)

Status of the Proposed Draft Guidelines for Vitamins and Mineral Food Supplements

61. The Committee, recognizing that considerable progress had been made on the text, agreed to advance the Proposed Draft Guidelines for adoption at Step 5 by the 27th Session of the Codex Alimentarius Commission (see Appendix IV).

PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA (AGENDA ITEM 6)[7]

62. The Committee recalled that the Proposed Draft revised Standard for Infant Formula was returned to Step 3 for further comments especially on the Scope, sections on compositional requirements and food additives.

63. The Delegation of Germany, Chair of the electronic Working Group on the Scope, introduced documents and informed the Committee that document CX/NFSDU 03/6-Add.1 contained proposals for possible ways for further elaboration of standard(s) for healthy/sick infants and contained description of advantages and disadvantages of each . The Delegation indicated that the following options were provided: 1) a draft proposal for infant formula (Draft Standard A) which was based on the proposed Draft Revised Standard for Infant Formula (ALINORM 03/26A, Appendix II) and the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1990) and contained provisions for healthy and sick infants and children; 2) Draft Standard B which covered only such formula for special medical purposes which could provide the sole source of nutrition during the first month of life to substitute for either breast-milk or infant formula and 3) Part C which outlined the advantages and disadvantages of the draft standards A and B. A third draft Standard D was also included in CX/NFSDU 03/Add.1 consisting of a revision of Codex Standard 180-1991 suitably amended to take into account formula for special medical purposes intended for infants.

64. The Committee had a very long and extensive debate regarding the way of further revision of the Proposed Draft Revised Standard for Infant Formula.

65. Several delegations and observers indicated that they preferred a single standard covering provisions for all infants. They were of the view that a separate standard for foods for special medical purposes intended for sick infants was not justified as only a few amendments were necessary to the current standard under revision and that the elaboration of two separate standards might create confusion among consumers, legislators and might lead to discouraging breastfeeding.

66. Many other delegations and observers were of the view that two separate standards were necessary for regulatory purposes as the standard for special medical purposes should have had different compositional requirements, different section on food additives and specific labeling requirements. They indicated that two separate standards might be easier understood and it was easier to enforce and that it might reduce the possibility of confusion.

67. The Representative of WHO drew the attention of delegates to the fact that irrespective of the way the Committee proceeds with the development of one or two standards both Infant Formula and Formula for

[7] ALINORM 03/26A, Appendix II; CX/NFSDU 03/6 (comments from Australia, Brazil, Malaysia, Mexico, New Zealand, Spain, United States, CRN, ISDI,WHO); CX/NFSDU 03/6-Add.1 (Discussion paper of the Electronic Drafting Group on the Scope and the Text of the Proposed Draft Revised Standard for Infant Formula); CX/NFSDU 03/6-Add.2 (Working Group on the Essential Composition of Infant Formula); CX/NFSDU 03/6-Add.3 (Comments from Japan, European Community, IBFAN, ENCA); IACFO comments, CRD 1(Report of the Working Group on the Essential Composition of Infant Formula); CRD 2 (comments from Australia, Czech Republic, Denmark, Germany, New Zealand, Norway, Poland, Spain, CRN, ENCA submitted on Section 3.1 Essential Composition); CRD 3 (Working Group's Proposals for Food Additives in the Proposed Draft Revised Standard for Infant Formula and the Proposed Draft Standard for Processed Cereal-Based Foods for Infants and Children); CRD 5 (comments from Bulgaria, Canada, ENCA, Philippines); CRD 6 (comments from IBFAN); CRD 9 (comments from India); CRD 11 (comments from Botswana); CRD 12 (comments from CRN); CRD 13 (comments from ENCA); CRD 14 (comments from China); CRD 15 (comments from Indonesia).

Special Medical Purposes were covered by the provisions of the International Code of Marketing of Breast Milk Substitutes and subsequent WHA Resolutions.

68. After a lengthy debate the Committee decided as a compromise to elaborate one Standard having a preamble and two different Sections: one section A which would cover formula for healthy infants and another (Section B) for formula for special medical purposes for infants. It was agreed that the necessary cross-references would be made in both sections while revising the Standard. It was also agreed that the decision how to incorporate the Standard into their national law and to have one standard with sections or two separate standards would be left to national authorities. The Committee noted that the work on the revision of the Section for formula for Infant Formula was more advanced and therefore decided to proceed with the revision of section A first.

Title

69. The Committee agreed to amend the title to incorporate the development of both options and put the second part related to formula for special medical purposes in square brackets for further comments on the name of the product.

Preamble

70. As a consequence of its earlier decision (see para 68 above), the Committee decided that a Preamble should cover both sections and put the wording in square brackets.

Scope

71. Some delegations were of the view that the Scope of the Standard should be common and should cover both options, however some other delegations indicated that since Sections A and B would cover different formulas they have to be separated and it should be made very clear what would be covered by each of them. After some discussion the Committee agreed that the Scope of Section A should cover formulas in liquid or powdered forms intended for normal nutritional requirements of infants and Scope for Section B would cover formulas for special medical purposes. The Committee decided to use the wording as proposed in Annex 1 of CX/NFSDU 03/6-Add.1 for the Scope in both Sections.

Section A Infant Formula

72. The Committee clarified the wording in Section 1.2 by moving the last sentence from Section 2.1.1 of Description that only products which comply with provisions in this standard could be marketed as infant formula and inserted an additional wording preventing the marketing of products other that infant formula to be suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life.

73. The Committee amended the wording regarding the application of the standard in Section 1.3 in order to take into account the WHO Global Strategy for Infants and Young Child Feeding and put the reference to WHA Resolution 55.25 (2002) in square brackets as it was necessary to study in more detail what further implication this reference might have.

Section 2 Description

74. The Committee deleted the reference to “normal” as it was superfluous and already covered by provisions of Section 1.1.

75. The Committee noted that the safety and nutritional adequacy of infant formula required demonstration of scientific justification and substituted the text of Section 2.1.2 by the wording proposed by Canada in CRD 5 and put it in square brackets for further comments. The Committee deleted the reference to “boiling” water and moved this sentence to Section 9.5 Information for Use”. The Observer of ENCA objected to the proposal of deletion of “boiled” water.

Section 3.1 Essential Composition

76. The Delegation of Germany presented CRD 1 prepared by the Working Group which met before the session and informed the Committee that on the basis of the comments submitted and the outcome of consideration in the Working Group the General Principles for Establishing Minimum and Maximum Values for the Essential Composition of Infant Formula were revised and presented in Annex I. The Delegation indicated that minimum and maximum amounts of nutrients were also revised and presented in Annex II of CRD 1 together with amendments.

77. The Committee thanked the Delegation of Germany and the Working Group for their excellent work and generally accepted the proposals of the Working Group presented in CRD 1. The Committee decided to use it as the basis for further revision of the Section of Essential Composition and made the following amendments.

78. The Committee noted that the addition to Principle 4 regarding maximum values for nutrients with or without documented adverse health effects required further consideration therefore agreed to keep this addition in square brackets.

79. The Committee agreed to put Section "ii" regarding energy content in prepared formulas in square brackets for further comments and consideration.

80. The Committee decided to attach the General Principles for Establishing Minimum and Maximum Values for the Essential Composition of Infant Formula as an Annex to the Revised Standard in order to ensure transparency and document the basis of decisions of the Committee on this matter.

81. In Section 3.1.1 the Committee deleted the reference to edible constituents of different origin and substituted it to "ingredients" for clarification purposes and agreed with the proposal of AOECS to add an additional sentence to emphasize that all ingredients and food additives should be gluten-free in square brackets.

82. The Committee revised the wording in Section 3.1.2 which clarified provisions of minimum and maximum amounts of nutrients in the "old" table as it was no longer relevant and superfluous.

Section 3.2 Optional Ingredients

83. In Section 3.2.1, the Committee clarified that the right technical reference to compositional requirements listed in Section 3.1 related to "ingredients" rather than "nutrients" in order to provide "substances" rather than "nutrients" which were ordinarily found in human milk to ensure the sole source of nutrients for infants. Subsequent changes for clarification purposes were made in Section 3.2.2.

84. The Committee deleted the first part of sentence in Section 3.2.3 and moved the rest of sentence related the intended effect of substances taking into account their levels in human milk.

Section 3.6 Specific prohibition

85. The Delegation of Malaysia drew the attention of the Committee to the fact that the wording on page 3, 3rd paragraph of CRD 1 was not accurate and suggested to replace it by the following text: "Malaysia proposed to prohibit the use of commercially hydrogenated oils and fats, which would have the desired effect of restricting the trans-fatty acid content. To facilitate monitoring and regulatory work, Malaysia will support the establishment of an appropriate, evidence-based upper limit for trans fatty acid content of infant formula".

86. The Committee agreed to include the wording regarding prohibition of the use of commercially hydrogenated oils and fats, as proposed by the Delegation of Malaysia, and put it in square brackets.

87. The Delegation of Brazil supported by Observers from ENCA and IACFO proposed to prohibit the use of ingredients derived from genetic modification, however the Committee noted that the recently concluded

Task Force on Foods derived from Biotechnology provided Principles for risk analysis and Guidelines for Safety Assessment of Foods Derived from Recombined DNA plants and microorganisms subsequently adopted by the Commission, and that the Task Force did not propose any prohibition of the use of foods derived from these materials.

Section 4. Food Additives

88. The Delegation of Switzerland introduced the report of the Working Group that had reviewed the additive provisions, according to criteria based on the Preamble of the General Standard for Food Additives (GSFA), and providing technical justification for all proposals. The Committee expressed its thanks to the Delegation of Switzerland and to the Working Group for their constructive work.

89. The Observer from the EC expressed the view that the use of carrageenan was not suitable for infants below three months and should not be included in the list.

90. Some delegations questioned the exception to the carry-over principle for infant formula as it was not consistent with the General Standard for Food Additives and the Committee agreed to ask the Committee on food Additives and Contaminants (CCFAC) whether the carry-over principle should apply to additives in infant formula.

91. The Committee agreed to ask the CCFAC whether the establishment of functional classes that were not covered currently was required, especially enzymes and propelling gas. The Committee also noted that there were some inconsistencies between the names of functional classes of additives used in different Codex texts and recalled that this question was under consideration in Codex and JECFA.

92. The Committee also noted that ADI does not apply to infants under 12 weeks of age because toxicity tests used to derive ADIs do not cover that phase of life, and agreed to request that the CCFAC refer the use of ADIs for food additives used in foods for infants under than 12 weeks of age to JECFA for re-examination, as proposed by the Delegation of Canada.

93. The Committee therefore agreed to retain the whole section in square brackets pending clarification of the above issues and to circulate it for comments and consideration at the next session.

Section 9. Labelling

Section 9.1 Name of the Food

94. As a result of its earlier decision concerning the scope of the standard, the Committee deleted the text referring to foods for special medical purposes in section 9.1.5 and retained the sentence on health claims in square brackets for further discussion as a new section 9.66 as some delegations noted that it should rather be included in a specific section rather than in the “name of the food”. Some observers expressed the view that the name of the food could constitute a health claim and that this problem should be addressed. The Committee agreed to add a reference to nutrition claims, as proposed by the Delegation of Uruguay and for consistency with the Draft Guidelines for Use of Nutrition and Health Claims.

95. The Observer from the EC expressed the view that that if any text regarding prohibition or restriction of health claims was retained it should reflect the text included in the Draft Guidelines for Use of Nutrition and Health Claims at Step 6, especially the fact that such claims may be permitted by relevant national legislation.

96. The Chair recalled that the question of health claims was still under consideration in the Committee on Food Labelling and the Committee agreed to consider this question at the next session in view of further developments in that Committee.

Section 9.6 Additional Labelling Requirements

97. In section 9.6.1, the Committee had an extensive discussion on the statement concerning breastfeeding and agreed to delete the first option including an example and to retain the sentence referring to the statement " breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk. Some delegations and observers favoured first option to be retained.

98. The Observer from ENCA proposed to add a specific prohibition of claims on optional ingredients. The Committee however noted that the general provisions on health claims would apply to all ingredients. Some observers proposed to add a warning to address a problem in relation to Enterobacter because the product was not sterile.

99. Some delegations proposed to delete section 9.6.5 as there was no risk of confusion between infant formula and follow-on formula and foods for special medical purposes. Several other delegations pointed out that such a risk existed in practice and the Committee agreed to retain the sentence without square brackets.

Status of the Proposed Draft Revised Standard for Infant Formula

100. The Committee noted that significant progress was made in the revision of the Standard and agreed to forward Section A containing provisions for infant formula to the 27th Session of the Commission for adoption at Step 5 (see Appendix V).

101. The Committee asked the Delegation of Germany to prepare Section B containing formula for special medical purposes for circulation for comments at Step 3.

102. The Committee also agreed that a Working Group would be convened before the next session of the Committee to review the comments and proposals for compositional requirements in order to facilitate discussions at the Plenary.

PROPOSED DRAFT REVISED STANDARD FOR PROCESSED CEREAL BASED FOODS FOR INFANTS AND YOUNG CHILDREN (AGENDA ITEM 7)[8]

103. The Committee recalled that its last session had returned the Proposed Draft Standard to Step 3 for further comments as several substantial issues remained to be resolved. The Committee considered the text section by section, concentrating on the issues that had not been addressed and made the following amendments.

Scope

104. The Committee agreed to add a reference to the WHO Global Strategy for Infant and Young Child Feeding and to WHA Resolution WHA 55.25 (2002), as proposed in the comments of WHO and put it in square brackets for further comments.

3.1 Essential Composition

105. After an exchange of views, the Committee agreed to retain the current section 3.1.1 with an editorial amendment as it was consistent with the Description that clearly specified that the product contained at least 25% cereals.

106. The Delegation of India expressed the view that starchy roots should not be used in cereal-based foods as their nutritional value was not adequate for infants and young children. The Observer from ISDI supported India in the use of legumes and pulses as primary ingredients because of their nutritional value. The

[8] ALINORM 03/26A, Appendix III; CX/NFSDU 03/7 (comments of Australia, Brazil, Spain, AAC, ISDI, IWGA, WHO) , CX/NFSDU 03/7-Add.1 (New Zealand, AOECS, EC, Japan), CX/NFSDU 03/7-Add. 2 (comments of ISDI), CRD 3 (Report of the Working Group on Food Additives) CRD 5 (comments of the Philippines), CRD 6 (comments of IBFAN), CRD 7 (comments of Vietnam), CRD 8 (comments of Norway), CRD 10 (comments of ICGMA), CRD 15 (comments of Indonesia)

Committee however noted that these roots were mentioned in the standard as they provided locally available raw materials for the preparation of complementary foods in a number of developing countries and that Codex standards should be as inclusive as possible to apply on a world-wide basis. The Committee retained the current text that resulted from extensive discussions and consensus in the last session.

Section 3.3 Protein

107. The Committee noted some proposals to amend the reference to the Protein Efficiency Ratio; to define the reference protein (casein); to introduce another indicator; and to harmonize it with the index used in the Standard for Infant Formula. However the Committee did not consider this question in detail and member countries were invited to provide specific comments for consideration at the next session.

Section 3.5 Lipids

108. The Committee deleted all square brackets in the section and corrected the references to product categories. It also corrected a maximum lipid content. The Committee also transferred the sentence concerning the prohibition of partially hydrogenated fats (without square brackets) to section 3.11 Specific Prohibition.

109. The Representative of WHO noted that this section did not address the issue of trans-fatty acids, and pointed out that the Joint FAO/WHO Expert Consultation on Diet, Nutrition and the prevention of Chronic Diseases had set the population daily nutrient intake goal for trans-fatty acids at <1% of total energy intake[9]. The health risk of exceeding this level was classified as "convincing". The content of trans-fatty acids of complementary foods destined to infants and young children should not differ from the recommended content of the overall diet. The Representative of WHO therefore suggested that an upper level of trans fatty acids equivalent to < 1% of the energy content be applied in the case of such complementary foods.

110. The Committee agreed that any discussion on trans-fatty acid levels should await discussion of the definition of trans-fatty acids to be discussed on Agenda Item 11 (see para 150).

Section 3.6 Minerals

111. The Committee clarified the expression of sodium per kilojoules in section 3.6.1 and the type of products covered by section 3.6.3. Some delegations proposed to keep the level of sodium as low as possible or to delete the higher level allowed for children over one year. The Representative of WHO indicated that the population intake goal was 2g/day. Some observers pointed out that for children over one year, the ingredients used in complementary foods, especially milk, had a high content in sodium and that the current value would not result in an intake exceeding the recommendations of WHO. The Committee could not come to a conclusion and retained the current values in square brackets for further discussion.

Section 3.7 Vitamins

112. The Committee discussed the need for a minimum amount of vitamin B1 and the values proposed but could not come to a conclusion and agreed to retain the value in square brackets for further consideration. The Committee noted that minimum value could not be reached without enrichment.

113. The Committee also agreed to replace a reference to derogations with "reduction" to the maximum amounts proposed for Vitamins A and D.

Section 3.8 Optional Ingredients

114. Some delegations questioned the basis for the inclusion of section 3.8.3 concerning the use of cocoa only after nine months of age and the Committee noted that this provision had been retained from the earlier standard. However, there did not appear to be a scientific justification for its inclusion.

[9] WHO Technical Report Series No. 916, p. 56, Table 6

115. Some delegations and observers proposed to retain the section and to extend the period of nine months to 12 or 24 months as cocoa might cause allergic reactions. The Committee however recalled that the list of foods and ingredients that can cause hypersensitivity and should always be declared in the label did not include cocoa. The Delegation of Uruguay pointed out that this provision should be retained to protect consumers. The Committee recalled the position taken by the Commission "when there is evidence that a risk to human health exists but scientific data are insufficient or incomplete"[10].

116. The Committee agreed to delete the provision concerning cocoa and noted the position of the delegations of India, Norway, Uruguay, Peru, Bolivia, Brazil and the Observers of ENCA and IACFO that it should be retained. The Committee also noted that the provisions in the standard could be reconsidered if relevant scientific evidence was put forward.

Section 4 . Food Additives

117. The Delegation of Switzerland introduced the proposals of the Working Group that had reviewed the additive provisions, according to criteria based on the Preamble of the General Standard for Food Additives (GSFA). The Committee expressed its thanks to the Delegation of Switzerland and to the Working Group for their constructive work.

118. The Committee confirmed that the additives levels should be expressed on the basis of 100g of the ready-to-eat product although the current values were expressed on dry weight basis.

119. The Committee noted that citric acid and lactic acid as acidity regulators were listed with a specific level of use although they had an ADI not specified and were included in Table 3 of the GSFA that listed additives permitted in accordance with GMP.

120. The Delegation of India questioned the fact that no flavourings except ethyl vanillin were mentioned in the list. The Observer from ENCA expressed the view that no synthetic flavours should be allowed in these products. The Committee noted that flavours were evaluated by JECFA but had no INS number and were not classified as additives, and that this was a general issue that would need to be addressed in the Committee on Food Additives and Contaminants. The Committee also noted that the list proposed in CRD 3 was a result of the proposals put forward in the Working Group that only ethyl vanillin had been proposed as a flavouring agent. The Delegation of France asked that carry over should not be allowed for cereal based foods.

121. The Committee agreed to replace the current additives section with the section presented in CRD 3.

Section 8. Labelling

122. In section 8.1.1, the Committee considered the two alternative proposals discussed at the last session concerning the use of pictures in the label.

123. The Delegation of Nigeria, supported by other delegations, pointed out that the use of pictures was necessary in countries where the rate of illiteracy was high in order to identify and provide instructions for use. Other delegations with the same situation of illiteracy expressed the view that the use of pictures create confusion by idealizing the use of the product, and should not be allowed in any case.

124. Several delegations supported the first option that referred to the section 7.1 of the General Standard for the Labelling of Prepackaged Foods and gave the possibility to national authorities to restrict further the use of pictorial devices. The Delegations of Uruguay, Peru, Bolivia, Indonesia and the observers from ENCA, IBFAN, IACFO supported the second option that specifically referred to the prohibition of text or pictures which idealize or suggest an inappropriate age of introduction. After an extensive discussion, the Committee agreed to retain the first option as section 8.1.1.

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[10] Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius (Procedural Manual, 13th Edition)

125. The Observer from the EC expressed the view that that if any text regarding prohibition or restriction of health claims was retained it should reflect the text included in the Draft Guidelines for Use of Nutrition and Health Claims at Step 6, especially the fact that such claims may be permitted by relevant national legislation.

126. The Chair recalled that the question of health claims was still under consideration in the Committee on Food Labelling and the Committee agreed to consider this question at the next session in view of further developments in that Committee. The current text on nutrition and health claims was retained in square brackets for further discussion.

Section 8.6 Information for Utilization

127. The Committee agreed to delete the square brackets in section 8.6.4 and to reword the text for clarification purposes. The Delegations of Peru and Kenya and the observers from ENCA, IBFAN and IACFO proposed to refer to "independent" health workers, or to specify that they should be free from commercial interest or conflict of interest. The Committee recalled that a WHO definition of "health worker" existed while other terms were not defined and noted that in several countries "independent" was understood as independent from government and would therefore create confusion. The Committee therefore agreed to retain the current reference to "health worker".

128. The Observer from IWGA proposed that Section 8.6.3 should be in conformity with requirements for the labelling of allergens in the Codex General Standard for the Labelling of Prepacked Foods, i.e. that the presence of main substances known to cause hypersensitivity always has to be indicated. The Committee however clarified that the labelling standard referred only to cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these.

129. The Committee deleted the last sentence concerning conformity with provisions of the paragraph as it was superfluous.

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

130. The Committee, noting that substantial progress had been made on the revision of the text, agreed to advance the Proposed Draft Revised Standard for adoption at Step 5 by the 27th Session of the Codex Alimentarius Commission (see Appendix VI).

PROPOSED DRAFT ADVISORY LIST(S) OF MINERAL SALTS AND VITAMIN COMPOUNDS FOR THE USE IN FOODS FOR INFANTS AND CHILDREN (CAC/GL 10-1979) (AGENDA ITEM 8)[11]

131. The Committee recalled that the proposed draft Advisory List(s) had been revised by the Delegation of Germany and circulated for comments at Step 3.

132. The Delegation of Germany introduced the document and informed the delegates of the structure and changes of the document. The Delegation drew the attention of the Committee to the fact that for several compounds it was not possible to find appropriate references for purity requirements and it was not clear enough whether several compounds such as ferric phosphates presented in 2.13 and 2.16 were identical or not.

133. Several delegations noted the usefulness of the document however drew the attention of the Committee to the fact that due to recent availability of the document before the session it was not possible to discuss it with the relevant stakeholders inside countries and it was not clear enough which references should be used for purity in the absence of JECFA evaluation and which international body would be responsible for the selection, evaluation and updating of the list.

[11] CX/NFSDU 03/8; CX/NFSDU 03/8-Add.1 (comments of European Community); CRD 5 (comments of Malaysia).

134. The Observer of the EC noted that in drafting of the document prepared by Germany some omissions had occurred and suggested that all the sources of copper, zinc and manganese listed in the document should be permitted for use in processed cereal based foods and canned baby foods. The Observer also suggested considering which substances would be suitable as nutrient sources for formula for special medical purposes.

135. The Committee noted that it had no mandate to elaborate the proposed advisory list of food additives for special vitamin forms and therefore decided to take it out from the document, however it was indicated that in the case of deletion there was a necessity to ensure that additives necessary for production of proposed compounds would be considered in the general standard for food additives. The Committee therefore agreed with the proposal of the Delegation of the United States to ask the CCFAC to consider the establishment of a new class of additives for "nutrient carriers".

136. The Delegation of Canada proposed that these additives may need to be retained in the list as there was no carry-over allowed.

Status of the Proposed Draft Revised Advisory List(s) of Mineral salts and Vitamin Compounds for the Use in Foods for Infants and Young Children

137. The Committee requested the Delegation of Germany to revise the list on the basis of written comments and comments at the current session. The revised list would then be circulated at Step 3 for comments and consideration at the next session of the Committee.

PROPOSED DRAFT RECOMMENDATIONS ON THE SCIENTIFIC BASIS OF HEALTH CLAIMS (AGENDA ITEM 9)[12]

138. The delegation of France introduced the document and recalled that the 22nd Session of the Committee had considered the document on the Scientific Basis of Health Claims. During its last 24th session, the Committee considered the request of the Codex Committee on Food Labelling on resuming the work on the establishment of scientific criteria relevant for the justification of health claims and it was agreed to proceed with the elaboration of the document on the proposed draft recommendation on the scientific basis for claims.

139. The Delegation of the United Kingdom referring to its national experience on the regulation of health claims drew the attention of the delegates to the fact that recommendations in the document did not provide sufficient guidance for the preparation of dossiers on scientific evaluation and proposed to assist France in this regard.

140. The Observer of IACFO indicated that the statement in the first sentence in Section 3.1 regarding the quality of scientific justification was quite vague and suggested to refer to "peer reviewed independent scientific evidence". The Observer proposed to add a third bullet in Section 4 to read "there should be a general agreement within the scientific community that claims are valid" and to include an additional bullet at the end of Section 5 to read "corrective action should be mandated, if required".

141. The Observer of ICGMA suggested that under the Preamble the 2nd bullet point was not necessary as the first bullet point already covered it and under 2.1 the 3rd bullet point the reference to validation of analytical methods was a regulatory issue and included in the Draft Guidelines for the Use of Nutrition and Health Claims (Section 7.3) be deleted. Under Section 5 the 1st bullet point health claims should be reevaluated only if significant new findings have been published.

142. Some delegations and observers indicated that there were some valuable written comments and that these comments should be taken into account in further elaboration of the document.

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[12] CX/NFSDU 03/9; CX/NFSDU 03/9-Add.1 (comments of Malaysia, New Zealand and IDF); CRD 4 (comments of Germany and ILSI); CRD 5 (comments of Philippines); CRD 7 (comments of Vietnam); CRD 10 (comments of ICGMA); CRD 12 (comments of CRN).

143. The Committee expressed its appreciation to the Delegation of France and their partners for this valuable document.

Status of the Proposed Draft Recommendations on the Scientific Basis of Health Claims

144. The Committee requested the Delegation of France together with all interested parties to revise the document on the basis of its consideration at the current session and written comments submitted. The Committee agreed that the revised document would be circulated for comments at Step 3 for consideration at the next session of the Committee.

APPLICATION OF RISK ANALYSIS TO THE WORK OF THE CCNFSDU (AGENDA ITEM 10)[13]

145. The Delegation of Australia introduced the document and recalled that the CCNFSDU first considered the matter of dietary modelling to inform a risk-based approach for its decision making at its 20th session in 1996. After discussion of the potential to incorporate nutrient intake (dietary exposure) assessments within a risk-based approach at its 22nd Session in 2000, it was agreed that CCNFSDU would proceed with the development of a methodology for the application of risk assessment to relevant Codex standards and related texts. It also noted that while adopting the Working Principles for Risk Analysis, the Commission requested that relevant Codex committees develop or complete specific guidelines on risk analysis in their respective areas, consistent with the overarching Working Principles for inclusion in the Procedural Manual, as recommended in the Action Plan.

146. The Delegation highlighted ramifications of these developments to the work of the CCNFSDU and presented two recommendations in relation to the future work of the Committee in this area:

- to acknowledge that Working Principles for Risk Analysis are highly relevant to the Committee' s work and
- to elaborate specific principles and guidelines for Risk Analysis relevant to the work of the Committee.

147. The Delegation of the United States supported these proposals and indicated that risk analysis principles should acknowledge the unique characteristics of nutrients.

148. Some other delegations and observers also supported the above recommendations. It was noted that scientific process should be part of risk management decisions and that some guiding principles and guidelines were necessary especially for the establishment of safe upper levels of nutrients.

149. The Committee agreed that the Delegation of Australia[14] would lead an electronic working group and invited Member Countries to submit their proposals to the Delegation of Australia with the understanding that an outline of specific guidelines prepared on the basis of Working Principles for Risk Analysis adopted by the Commission would aim to be prepared for consideration at the next session of the Committee.

OTHER BUSINESS AND FUTURE WORK (AGENDA ITEM 11)

Trans-fatty acids

150. The Committee noted that discussions on the definition of trans-fatty acids required more time and preparation, therefore accepted the kind offer of the Delegation of Malaysia in cooperation with Denmark and other interested parties working electronically to prepare a discussion paper for consideration at the next session of the Committee.

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[13] CX/NFSDU 03/10.

[14] All interested parties should communicate their willingness to participate directly to Australia.

DATE AND PLACE OF THE NEXT SESSION (AGENDA ITEM 12)

151. The Committee was informed that the 26th session would take place in Bonn, Germany tentatively scheduled for the first week of November 2004 and further details would be determined by the host Government and the Codex Secretariat.

SUMMARY STATUS OF WORK

Subject Matter	Step	For Action by	Reference in ALINORM 04/27/26A
Draft Revised Standard for Gluten-Free Foods	7	25th CCNFSDU CCMAS	para. 35 and Appendix III
Guidelines for the Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents (Part B) Dietary Fibre)	6	Governments; 26th CCNFSDU*	para. 26 and Appendix II
Proposed Draft Guidelines for Vitamin and Mineral Supplements	5	27th CAC, 26th CCNFSDU	para. 61 and Appendix IV
Proposed Draft Revised Standard for Infant Formula	5	27th CAC 26th CCNFSDU	para. 100 and Appendix V
Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children	5	27th CAC, 25th CCNFSDU	para. 130 and Appendix VI
Proposed Draft Revision of the Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for use by Infants and Young Children	2	Germany, Governments, 26th CCNFSDU	para 137
Proposed Draft Recommendations on the Scientific Basis of Health Claims	2	France, Governments', 26th CCNFSDU	para. 144
Guidelines on the Application of Risk Analysis to the Work of the CCNFSDU	1/2/3	Australia Governments 26th CCNFSDU	para. 149
Discussion Paper on the FAO Technical Workshop on Energy Conversion Factors	-	Codex Secretariat	para.5

* Consideration at Step 7 in the light of scientific evidence available at the time of the 25th Session

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Appendix II

GUIDELINES FOR THE USE OF NUTRITION CLAIMS: DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (PART B)[1] DIETARY FIBRE

(At Step 6 of the Procedure)

COMPONENT	CLAIM	CONDITIONS
B.		**NOT LESS THAN**
[Dietary Fibre]	Source	3 g per 100 g or 1.5 g per 100 kcal or per serving [(liquid foods: 1,5 g per 100 ml)]
	High	6 g per 100 g or 3 g per 100 kcal or per serving [(liquid foods: 3 g per 100 ml)]

[1] Serving size to be determined at national level

Appendix III

DRAFT REVISED STANDARD FOR GLUTEN-FREE FOODS [15]

1. SCOPE

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

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

2. DESCRIPTION

2.1 Definition

"Gluten-free" foods are foodstuffs so described:

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

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

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

2.2 Subsidiary Definitions

2.2.1 Gluten

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

2.2.2 Prolamins

Prolamins are defined as the fraction from gluten that can be extracted by 40 - 70% of ethanol. The prolamin from wheat is gliadin, from rye is secalin, from barley hordein and from oats avenin.

It is however an established custom to speak of glutensensitivity. The prolamin content of gluten is generally taken as 50%.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Gluten-free

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

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

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

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[15] This text was previously published as CX/NFSDU 98/4.

4. LABELLING

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

5. CLAIMS

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

6. GENERAL OUTLINE OF THE METHOD OF ANALYSIS AND SAMPLING

6.1 Determination of gluten

Enzyme-Linked Immunoassay R5 Mendez (ELISA) Method

6.2 Determination of gluten in foodstuffs and ingredients

Methods used for determination should be traceable and calibrated against an internationally accepted standard, if available.

The detection limit has to be appropriate according to the state of the art and the technical standard.

The quantitative determination of gluten in foodstuffs and ingredients shall be based on an immunologic method.

The antibody to be used should react with the cereals that are toxic for persons sensitive to gluten and should not cross-react with the other cereals or other constituents of the foodstuffs and ingredients.

The qualitative analysis as indicating presence of protein shall be based on DNA-methods or other relevant methods.

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

APPENDIX IV

PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL FOOD SUPPLEMENTS

(At Step 5 of the Procedure)

PREAMBLE

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

1. SCOPE

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

Food supplements containing vitamins and/or minerals as well as other ingredients should also be in conformity with the specific rules on vitamins and minerals laid down in these Guidelines.

1.2 . These Guidelines do apply in those jurisdictions where products defined in 2.1 are regulated as foods.

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

2. DEFINITIONS

2.1 Vitamin and mineral food supplements for the purpose of these guidelines derive their nutritional relevance primarily from the minerals and/or vitamins they contain. Vitamin and mineral supplements are sources in concentrated forms of those nutrients alone or in combinations, marketed in forms such as capsules, tablets, powders, solutions etc., not in a conventional food form and whose purpose is to supplement the intake of vitamins and/or minerals from the normal diet

[They are designed to be taken as measured small unit quantities].

3. COMPOSITION

3.1 Selection of vitamins and minerals

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

3.1.2 The sources of vitamins and minerals may be from either [natural or synthetic sources] and should be based on consideration such as safety and bioavailability. In addition, purity criteria should take into account FAO/WHO standards, or if FAO/WHO standards are not available, international Pharmacopoeias or recognized international standards. In the absence of criteria from these sources, and national legislation may be used.

3.1.3 Vitamin and mineral supplements may contain all vitamins and minerals that comply with the criteria in 3.1.1, a single vitamin and/or mineral or an appropriate combination of vitamins and/or minerals.

3.2 Contents of vitamins and minerals

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

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

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

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

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

4. PACKAGING

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

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

5. LABELLING

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

The name of the product shall be "food supplement" with an indication of the category(ies) of nutrients or of the individual vitamin(s) and/or mineral(s) contained in the product as the case may be.

5.3 The amount of the vitamins and minerals present in the product should be declared in the labelling in numerical form. The units to be used should be units of weight consistent with the Codex Guidelines on Nutrition Labelling.

5.4 The amounts of the vitamin and minerals declared should be those per portion of the product as recommended for daily consumption on the labelling [and if different, the amount per single use].

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

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

5.7 The label shall contain advice to the consumer not to exceed the maximum one-day amount

5.8 The label should not state or imply that supplements can be used for the replacement of meals or a varied diet.

5.9 The label shall contain a statement that the product should be stored out of reach of young children.

APPENDIX V

PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA [AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS]

(At Step 5 of the Procedure)

REAMBLE:

[This standard is divided into two sections. Section A refers to Infant Formula, and Section B deals with Formulas for special medical purposes intended for Infants.]

Section A: Infant Formula

1. SCOPE

1.1 This section of the standard applies to infant formula in liquid or powdered form intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants.

1.2 The section of the standard contains compositional, quality and safety requirements for Infant Formula.

Only products that comply with the criteria laid down in the provisions of this standard would be accepted for marketing as infant formula. No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life.

1.3 The application of this section of the Standard should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001) and [WHA55.25 (2002)].

2. DESCRIPTION

2.1 Product Definition

2.1.1 Infant formula means a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding.

2.1.2 [The safety and nutritional adequacy of infant formula shall be scientifically demonstrated in meeting the nutritional requirements of the infants for whom they are intended.]

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

2.2 Other Definitions

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

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

[3.1 Essential Composition

3.1.1 Infant formula is a product based on milk of cows or other animals and/or other ingredients, which have been proven to be suitable for infant feeding. [All ingredients and food additives used shall be gluten-free.]

3.1.2 Infant formula prepared ready for consumption in accordance with instructions of the manufacturer shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than [70 or 75] kcal ([295 or 315] kJ) of energy.

3.1.3 Infant formula prepared ready for consumption shall contain per 100 kcal [100 kJ] the following nutrients within the following minimum and maximum levels. The general principles for establishing these levels are identified in Annex II of this standard.

a) Protein
(i) Protein content = nitrogen content x [6.25 or 6.38].

(ii) For an equal energy value the formula must contain an available quantity of 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 [**unless the methionine to cystine ratio exceeds 2.0**].

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

Nutrients (per 100 kcal, unless otherwise stated)		
a) Protein [1] [g]	***Minimum***	***Maximum***
Cow's milk protein	1.8 [2]	3
Soy protein	[1.8 or 2.25]	3
Protein hydrolysates		
L-carnitine [mg]	[≥ 1.2]	N.S. [3]
Addition of taurine [mg]	[0]	[12]
Nucleotides, if added [4] mg]	[0]	[5]
b) Fat and fatty acids		
Total fat [g]	4.4	[6.0 or 6.5]
[Phospholipids]	N.S.	[≤ 1 g/L]
[Inositol] [mg]	[4]	[40]

[1] Calculation of protein content: N x [6.25 or 6.38]; [non-protein nitrogen (formulae made from intact protein) <15% of total nitrogen]

[2] Infant formulae containing 1.8 g/100 kcal should be clinically evaluated

[3] N.S. = not specified

[4] Maximum content per nucleotide as specified in the text. (see end of table).

[Lauric and myristic acids]		[Together ≤ 20% of total fatty acids]
Linoleic acid [g]	[0.3 or 0.5]	1.2
[Formulae without added LCPUFA]		
α-linolenic acid [mg]	[≥50 or 100]	N.S.
Linoleic/α-linolenic ratio	5	15
[Formulae with added LCPUFA]		
[α-linolenic acid [mg] [5]	[≥ 50 mg]	
[Linoleic/α-linolenic ratio [5]	[5-20]	
[n-6 LCPUFA]	[≤ 2% of total fatty acids]	
[Arachidonic acid]	[≤ 1% of total fatty acids]	
[n-3 LCPUFA]	[≤ 1% of total fatty acids]	
[Ratio EPA/DHA (wt/wt)]	[<1]	
[Cottonseed/sesame oils	No use of these type of oils]	
[Conjugated linoleic acid (CLA)	No intentional addition]	
[Trans fatty acids	≤ 3 or 4% of total fatty acids]	
Erucic acid		≤ 1% of total fatty acids
c) Carbohydrates		
Total carbohydrates [g]	9	14
[Lactose in cows' milk protein- and protein hydrolysates formulae [g]	≥ 4.5]	
[Lactose in soy protein formulae	No requirement]	
[Saccharose	None in cows' milk protein and soy protein formulae ≤ 20% of total carbohydrates in protein hydrolysates formulae]	
[Fructose	None]	
[Glucose	No intentional addition to formulae based on intact proteins, ≤ 2 g in formulae based on protein hydrolysates]	
[Maltose, maltodextrins	Unrestricted]	

[5] If DHA content >0.2% of total fatty acids.

5 " "

[Starches	≤ 30% of total carbohydrates (≤ 2 g/100 mL) as precooked or gelatinised naturally gluten-free starches No starches modified by enzymatic cross-linking or stabilisation]	
d) Vitamins		
Vitamin A [µg RE] [6]	60	180
Vitamin D [µg] [7]	1	2.5
Vitamin E [mg αTE] [8]	≥ 0.5 mg αTE/g PUFA [(corrected for double bond, see footnote [9])], but in no case less than 0.5/100 kcal	[5]
Vitamin K [µg]	4	[20]
Thiamin [µg]	[40 or 60]	[300]
Riboflavin [µg]	[60 or 80]	[400]
Niacin [µg]	[300 or 800]	[1200]
Vitamin B_6 [µg]	35	[165]
Vitamin B_{12} [µg]	0.1	[0.5]
Pantothenic acid [µg]	[300 or 400]	[2000]
Folic acid [µg]	[4 or 10]	[30]
Vitamin C [mg] [10]	[8 or 10]	[30]
Biotin [µg]	1.5	[7.5]
e) Minerals and Trace Elements		
Iron [mg]		
Cow's milk protein and protein hydrolysate formulae	[0.3 or 0.5]	[1.3 or 1.5]
Soy protein formulae	[0.45 or 1.0]	[1.9 or 2.0]
Calcium [mg]	50	[140]
Calcium/Phosphorus-Ratio	1.0	[2.0 or 2.2]
Phosphorus [mg]	Cows' milk protein- and protein hydrolysate formulae: 25 Soy protein formulae: [30] [Bioavailable phosphorus, if	90 [100]

[6] expressed as retinol equivalent (RE). 1 µg RE = 3.33 IU Vitamin A

[7] Calciferol. 1 µg calciferol = 40 IU Vitamin D

[8] Alpha-Tocopherol-Equivalent (TE)

[9] [0.5 mg α-TE/1 g linoleic acid (18:2n-6); 0.75 mg α-TE/1 g γ-linolenic acid (18:3n-3); 1.0 mg α-TE/1 g arachidonic acid (20:4n-6); 1.25 mg α-TE/1 g eicosapentaenoic acid (20:5n-3); 1.5 mg α-TE/1 g docosahexaenoic acid (22:6n-3)] or [per g of polyunsaturated fatty acids, expressed as linoleic acid].

[10] expressed as ascorbic acid

	measured: 20-70 mg]	
Magnesium [mg]	5	15
Sodium [mg]	20	60
Chloride [mg]	50	[125 or 160]
Potassium [mg]	60	[145 or 160]
Chromium [µg]	No recommended minimum and maximum levels	
Manganese [µg]	[1 or 5]	[100]
Molybdenum [µg]	No recommended minimum and maximum levels	
Fluoride [µg]	N.S.	[100]
Iodine [µg]	[5 or 10]	[50]
Selenium [µg]	[N.S. or 3]	[9]
Copper [µg] [11]	[20 or 35]	[80 or 100]
Zinc [mg]		
Cow's milk protein and protein hydrolysate formulae	0.5	[1.5]
Soy protein formulae	0.75	2.40
f) Choline [mg]	7	[30 or 50]

[Nucleotide [mg]]		
Cytidine 5'-monophosphate (CMP)	N.S.	2.50
Uridine 5'-monophosphate (UMP)	N.S.	1.75
Adenosine 5'-monophosphate (AMP)	N.S.	1.50
Guanosine 5'-monophosphate (GMP)	N.S.	0.50
Inosine 5'-monophosphate (IMP)	N.S.	1.00

3.2 Optional Ingredients

[11] [Adjustments may be needed in these levels for infant formula made in regions with a high content of copper in the water supply]

3.2.1 In addition to the compositional requirements listed under 3.1, other ingredients may be added in order to provide substances ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrition for the infant.

3.2.2 The suitability

for the particular nutritional uses of infants and safety of these substances shall be scientifically demonstrated. The formula shall contain sufficient amounts of these substances to achieve the intended effect, taking into account levels in human milk.

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

3.3 Vitamin Compounds and Mineral Salts

Vitamins and minerals added in accordance with Section 3.1.2 (a,b,c,d) and 3.2.1 should be selected from the Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979).

3.4 Consistency and Particle Size

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

3.5 Purity Requirements

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

3.6 Specific Prohibition

The product and its components shall not [contain commercially hydrogenated oils and fats and 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:

WORKING GROUP'S PROPOSALS					
	INS NO.			**Maximum level in 100 mL of the ready-to-drink product**	**Technological Justification**
4.1	**Thickening Agents**				
4.1.1	412	Guar gum		0.1 g in all types of infant formula	Protects from physical separation
4.1.2	410	Carob bean gum (Locust bean gum)		0.1 g in all types of infant formula ***REQUEST** FOR 0.5 G*	Protects from physical separation Used in some anti-regurgitating formulas
4.1.3	1412	Distarch phosphate	}	0.5 g singly or in combination in soy-based infant formula only 2.5 g singly or in combination in hydrolyzed protein and/or amino acid-based infant formula only	Physical properties that native starch tends to lose when processed
4.1.4	1414	Acetylated distarch phosphate	}		
4.1.5	1413	Phosphated distarch phosphate	}		
4.1.6	1440	Hydroxypropyl starch	}		
4.1.7	407	Carrageenan		0.03 g in regular milk- and soy-based liquid infant formula only 0.1 g in hydrolyzed protein and/or amino acid-based liquid infant formula only	Thickening agent also used as an emulsifier; higher emulsifying power than lecithin and more hydrophylic capacities than mono- and diglycerides of fatty acids
4.2	**Emulsifiers**				
4.2.1	322 [1]	Lecithin [1]		0.5 g in all types of infant formula *	Natural stabiliser, retains homogeneity

4.2.2	471	Mono- and diglycerides		0.4 g in all types of infant formula *	Natural stabiliser, retains homogeneity of liquid products and liquid reconstituted powders
4.2.3	*472c*	*Citric and fatty acid esters of glycerol*		*0.75 g in powder formula ** *0.9 g in liquid formula containing partially hydrolyzed protein, peptides or amino acids **	Higher emulsifying power than lecithin and more hydrophylic capacities than mono- and diglycerides of fatty acids, especially in formulas not containing whole protein
4.2.4	*473*	*Sucrose esters of fatty acids*		*12 mg in formula containing hydrolyzed protein, peptides or amino acids **	Higher emulsifying power than lecithin and more hydrophylic capacities than mono- and diglycerides of fatty acids, especially in formulas not containing whole protein
				*** If more than one of the substances INS nos. 322, 471, 472c and 473 are added, the maximum level for each of those substances is lowered with the relative part as present of the other substances*	

[1] INS no. 322 refers to both Lecithin and Partially hydrolyzed lecithin.

4.3	**pH-Adjusting Agents**				
4.3.1	524	Sodium hydroxide	}	Limited by GMP and within the limits for sodium and potassium in section 3.1.2(c) in all types of infant formula	Buffering capacity Improve in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying Selected depending on pH and composition of formula; also used as a buffering agent
4.3.2	500 ii	Sodium hydrogen carbonate	}		
4.3.3	500 i	Sodium carbonate	}		
4.3.4	525	Potassium hydroxide	}		
4.3.5	501 ii	Potassium hydrogen carbonate	}		
4.3.6	501 i	Potassium carbonate	}		
4.3.7	526	Calcium hydroxide	}		
4.3.8	331 i, iii	Sodium citrate(s)	}		

4.3.9	332 i, ii	Potassium citrate(s)	}		
4.3.10	270	L(+) Lactic acid [2]	}	Limited by GMP in all types of infant formula	Natural acid found in fermented milk products
4.3.11	330	Citric acid	}		Buffering and chelating capacity Stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying Selected depending on pH and composition of formula
4.3.12	*338*	*Phosphoric acid (Ortho-)*	}	*Limited by GMP and within the limits for sodium and potassium in Section 3.1.2(c) in all types of infant formula*	
4.3.13	*339 i, ii, iii*	*Sodium orthophosphates*	}		
4.3.14	*340 i, ii, iii*	Potassium orthophosphates	}		
4.4	**Antioxidants**				
4.4.1	306	Mixed tocopherols concentrate	}	*1 mg in all types of infant formula singly or in combination*	Protects from oxidation Synergistic effect with ascorbyl esters
4.4.2	*307*	*Alpha-Tocopherol*	}		
4.4.2	304	L-Ascorbyl palmitate		1 mg in all types of infant formula	Protects from oxidation Synergistic effect with tocopherols
4.5	***Packaging Gas (Propellants)***				
4.5.1	*290*	*Carbon dioxide*		*GMP*	Neutral gas used under modified packaging atmosphere in order to guarantee the quality of the product and to ensure shelf life; prevention of oxidation and rancidity
4.5.2	*941*	*Nitrogen*		*GMP*	
4.5.3	*942*	*Nitrous oxide*		*GMP*	
4.5.4	*938*	*Argon*		*GMP*	
4.5.5	*939*	*Helium*		*GMP*	
4.5.6	*948*	*Oxygen*		*GMP*	
4.5.7	*949*	*Hydrogen*		*GMP*	

[2] JECFA evaluated lactic acid for use as a food additive at its 9th and 17th Meetings. Lactic acid was assigned an ADI of "not specified" but it was determined that only the L+ form was safe for infants. An electronic search of the JECFA electronic data base for INS no 270 results in "No matches were found"; however, searching for Lactic Acid results in "Lactic acid No. 930 : Not Limited (No safety concern at current levels of intake when used as a flavouring substance); Functional class: Acid; Acidifier; Flavouring agent".

[4.5 Carry-over of Food Additives

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

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

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

5. CONTAMINANTS

5.1 Pesticide Residues

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

5.2 Other Contaminants

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

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

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

6. HYGIENE

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

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

7. PACKAGING

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

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

8. FILL OF CONTAINER

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

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

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

(iii) not less than 90% v/v for products weighing more than 250 g (8 oz.)

of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20° C which the sealed container will hold completely filled.

9. LABELLING

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

9.1 The Name of the Food

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

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

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

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

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

9.1.5 [No health claims shall be made regarding the dietary properties of the product.]

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

Or

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

9.2 List of Ingredients

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

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

9.3 Declaration of Nutritive Value

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

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

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

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

9.4 Date Marking and Storage Instructions

9.4.1 The date of minimum durability (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer.

In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

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

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

9.5 Information for Use

9.5.1 Directions as to the preparation and use of the food, and its storage and keeping after the container has been opened shall appear on the label or on the accompanying leaflet. When in liquid form, infant formula may be used either directly or prepared with safe water before feeding according to directions for use. In powdered form infant formula also requires safe, and previously boiled water for preparation.

9.6 Additional Labelling Requirements

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

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

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

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

d) instructions for appropriate preparation;

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

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

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

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

9.6.5 The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula, and formula for special medical purposes.

9.6.6 [No [nutrition and] health claims shall be made regarding the dietary properties of the product.]

10. METHODS OF ANALYSIS AND SAMPLING

Dietary fibre, total	AOAC 991.43
Iodine (milk based formula)	AOAC 992.24
Pantothenic acid	AOAC 992.07
Pantothe-nic acid	*The Analyst* 89 (1964)(1) 3-6, 232 US Dept Agr., *Agr. Handbook* 97 (1965)
Vitamin A	AOAC 974.29
Vitamin A (retinol isomers)	AOAC 992.04
Vitamin A (retinol)	AOAC 992.06
Vitamin A in foods in which carotenes have been added as a source of vitamin A	AOAC 942.15
Vitamin K_1	AOAC 992.27
Vitamin D (D_3, milk based infant formula)	AOAC 992.26
Vitamin E	AOAC 971.30
Vitamin E (milk based infant formula)	AOAC 992.03
Vitamin B12	AOAC 952.20
Vitamin B6	AOAC 961.15
Vitamin C	AOAC 967.22; AOAC 967.21
Determi-nation of choline	AOAC 999.14 (Enzymatic method)
Determi-nation of Vitamin K	AOAC 999.15 (LC method)
Detection of Irradiated Foods	Codex General Methods
Determination of Lead	Codex General Methods
Calcium	AOAC 984.27
Chloride	
Carbohy-drates	Method described in CAC/VOL IX-Ed.1, Part III
Crude protein	Method described in CAC/VOL IX-Ed.1, Part III
Fat	CAC/RM 55-1976
Fill of containers	CAC/RM 46-1972
Folic acid	AOAC 944.12
Linoleate (in the form of glycerides)	AOAC 922.06; 969.33; 963.22; 979.19
Loss of drying	AOAC 934.01; AOAC 925.23
Nicotin-amide for foods not based on milk	AOAC 961.14
Nicotin-amide for milk- based foods	AOAC 944.13
Phospho-rus	AOAC 986.24
Protein efficiency ratio (PER)	AOAC 960.48
Riboflavin	AOAC 970.65
Sodium and potassium	AOAC 984.27
Sodium and potassium	ISO 8070:1987 IDF 119A/1987
Thiamine	AOAC 942.23
Total dietary fibre	AOAC 985.29

[ANNEX 1]

Essential and semi-essential amino acids in breast milk

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

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

Annex II

GENERAL PRINCIPLES FOR ESTABLISHING MINIMUM AND MAXIMUM VALUES FOR THE ESSENTIAL COMPOSITION OF INFANT FORMULA

1. The goal of establishing minimum and maximum values is to provide safe and nutritionally adequate infant formula products that meet the normal nutritional requirements of infants**.**

2. A nutritionally adequate infant formula will promote growth and development consistent with science based standards and meet the nutritional requirements of infants when fed as a sole source of nutrition during the first months of life up to the introduction of appropriate complementary feeding.

3. The values to be established are based on an evaluation, in particular of the scientific evidence of the amounts needed to meet the nutritional requirements of infants, considering relevant human infant studies and the composition of breast-milk.

4. In addition to the principles set out in No. 3, when setting minimum and maximum values, consideration will also be given to evidence of adverse health effects.
[Maximum values for nutrients with a documented risk of adverse health effects will be determined using a science-based risk assessment approach.
Maximum values for those nutrients without evidence of adverse effects serve as guidance levels for manufacturers. The approach to setting maximum levels for guidance purposes shall be made transparent and comprehensible.]

5. When establishing minimum and maximum amounts, the following should be taken into account:

a) bioavailability, processing losses and shelf-life stability from the ingredients and formula matrix,

b) total levels of a nutrient in infant formula, taking into account both naturally occurring nutrients in the ingredients and added nutrients,

c) the inherent variability of nutrients in ingredients and in water that may be added to the infant formula during manufacture.

6. Overages for individual nutrients, as appropriate, to ensure that the required minimum levels are met throughout the shelf-life of the formula, will be included in the maximum value.

7. In establishing minimum or maximum amounts of nutrients per 100 kcal (or per 100 kJ) of infant formula based on consideration of reference values for the nutrients expressed as units per daily intake or per kilogram of body weight, the following assumptions will be used:

a) The mean intake of prepared formula for infants from birth to six months of age is 750 ml per day. This is based on the following assumptions:

i) a representative body weight for an infant over this period would be 5 kg and a representative caloric intake would be 500 kcal per day (or 100 kcal/kg/day) over the first six months; and

[ii) prepared formulas provide about 67 kcal/100 ml].

Modifications of the approach may be needed when there is justification for deviating from one or more of these assumptions with regard to the specific formula product or specific infant population group.

APPENDIX VI

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 complementary food generally from the age of 6 months onwards, taking into account infants' individual nutritional requirements, and for feeding young children as part of a progressively diversified diet, in accordance with the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001) and [WHA55.25 (2002)].

2. DESCRIPTION

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

2.1. Product Definitions

Four categories are distinguished:

2.1.1 Products consisting of cereals which are or have to be prepared for consumption with milk or other appropriate nutritious liquids;

2.1.2 Cereals with an added high protein food which are or have to be prepared for consumption with water or other appropriate 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

3.1.1 *The four categories listed in 2.1.1 to 2.1.4* are prepared primarily from one or more milled cereal products, such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat. They may also contain legumes (pulses), starchy roots (such as arrow root, yam or cassava) or starchy stems or oil seeds in smaller proportions.

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

3.2 Energy Density

The energy density of cereal-based foods should not be less than 0.8 kcal/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 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 casein. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose. Only natural forms of L-amino acids should be used.

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

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

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

3.4 Carbohydrates

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

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

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

- the amount of added carbohydrates from these sources shall not exceed 2g/100 kJ (8.4 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 point 2.1.2 the lipid content shall not exceed 1.1g/100 kJ (4.5 g/100 kcal) If the lipid content exceeds 0.8g/100kJ (3.3g/100kcal):

- the amount of linoleic acid (in the form of triglycerides=linoleates) shall not be less than 70 mg/100 kJ (300 mg/100 kcal) and shall not exceed 285 mg/100 kJ (1200 mg/100 kcal).
- *the amount of lauric acid shall not exceed 15% of the total lipid content*
- *the amount of myristic acid shall not exceed 15% of the total lipid content"*

3.5.2 Product categories 2.11 and 2.1.4 shall not exceed a maximum lipid content of 3.3 g/100 kcal (0.8 g /100 kJ)

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][(24 mg/100 kJ)] 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] [(48 mg/100 kJ)].

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

3.6.3 The calcium content shall not be less than 12 mg/100 kJ (50 mg/100 kcal) for products mentioned in point 2.1.4 manufactured with the addition of milk and presented as such.

3.7 Vitamins

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

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

	µg/100kcal	µg/100kJ
vitamin A (µg retinol equivalents)	60 – 180	14-43
vitamin D	1 – 3	0.25-0.75

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

3.7.3 Reductions of the maximum amounts for vitamin A and Vitamin D 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 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.

3.9 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.

The use of partially hydrogenated fats for these products is prohibited

4. FOOD ADDITIVES

4. Food Additives

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

	INS no.			**Maximum level in 100 g of the product**	**Technological Justification**
4.1	**Emulsifiers**				
4.1.1	322 [1]	Lecithin [1]		1.5 g	Natural stabiliser, retains homogeneity
4.1.2	471	Mono- and diglycerides		1.5 g	Retains homogeneity
4.1.3	*472a*	*Acetic and fatty acid esters of glycerol*	*}*	*0.5 g singly or in combination*	Retains homogeneity
4.1.4	*472b*	*Lactic and fatty acid esters of glycerol*	*}*		Retains homogeneity
4.1.5	*472c*	*Citric and fatty acid esters of glycerol*	*}*		Higher emulsifying power than lecithin and more hydrophyilic capacities than mono- and diglycerides of fatty acids
4.2	**pH-Adjusting Agents**				
4.2.1	500 ii	Sodium hydrogen carbonate		GMP, within the limits for sodium	Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying; Buffering capacity
4.2.2	501 ii	Potassium hydrogen carbonate	}	GMP	
4.2.3	170 i	Calcium carbonate	}		pH-adjusting agent
4.2.4	270 [2]	L(+) Lactic acid		1.5 g ***Request*** *for L(+)-lactic acid producing cultures at GMP* [3]	Natural acid found in fermented milk Natural way to reduce pH Decreases risk of contamination from undesirable bacteria; adds taste; long use as an acidifier

4.2.5	330	Citric acid		2.5 g	Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying; Buffering and chelating capacity Citric acid and citrates are natural compounds

[1] INS no. 322 refers to both Lecithin and Partially hydrolyzed lecithin.

[2] JECFA evaluated lactic acid for use as a food additive at its 9th and 17th Meetings. Lactic acid was assigned an ADI of "not specified" but it was determined that only the L+ form was safe for infants. An electronic search of the JECFA electronic data base for INS no 270 results in "No matches were found"; however, searching for Lactic Acid results in "Lactic acid No. 930 : Not Limited (No safety concern at current levels of intake when used as a flavouring substance); Functional class: Acid; Acidifier; Flavouring agent".

[3] Cultures are not considered as food additives; CODEX STAN 72-1981 (Infant Formula) permits "4.3.11 L(+) Lactic acid producing cultures Limited by GMP in all types of infant formulae"

4.2.6	*260*	*Acetic acid (Acetic, glacial)*	}	*Only for pH adjustment* *GMP*	Improve in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying Acetic acid and acetates are natural compounds Selected depending on the pH and composition of the formula
4.2.7	*261*	*Potassium acetates*	}		
4.2.8	*262 i, ii*	*Sodium acetates*	}		
4.2.9	*263*	*Calcium acetate*	}		
4.2.10	*296*	*Malic acid (DL) – L(+)-form only*	}		pH-adjustment to compensate for variable natural acidity of fruit
4.2.11	*325*	*Sodium lactate (solution) – L(+)-form only*	}		Improve in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying Selected depending pH and composition of formula Lactic acid and lactates are natural compounds
4.2.12	*326*	*Potassium lactate (solution) – L(+)-form only*	}		
4.2.13	*327*	*Calcium lactate – L(+)-form only*	}		
4.2.14	*331 i, iii*	*Sodium citrate*			Improves in-processing handling, stabilising

4.2.15	*332 i, ii*	*Potassium citrate*	*}*		effect during industrial preparation such as pasteurisation, sterilisation, drying; Buffering and chelating capacity Citrates are natural compounds
4.2.16	*333*	*Calcium citrate*	*}*		
4.2.17	*507*	*Hydrochloric acid*	*}*		Acidifier, pH-adjustment
4.2.18	*524*	*Sodium hydroxide*	*}}*		Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying
4.2.19	*525*	*Potassium hydroxide*			
4.2.20	*526*	*Calcium hydroxide*			
4.2.21	*575*	*Glucono delta-lactone*	*}*	*0.5 g singly or in combination* Tartrates as residue in biscuits and rusks	Slow release acidifier Secondary leavening agent
4.2.22	*334*	*L(+)-Tartaric acid - L(+)form only*	*}*		In conjunction with 500 ii leavening/raising agent in biscuits and rusks
4.2.23	*335 i, ii*	*Sodium L(+)-Tartrates - L(+)forms only*	*}*		
4.2.24	*336*	*Potassium L(+)-Tartrate - L(+)form only*	*}*		
4.2.25	*337*	*Potassium Sodium L(+)-Tartrate - L(+)form only*	*}*		
4.2.26	*338*	*Orthophosphoric acid*	*}*	Only for pH adjustment *0.1 g as P_2O_5*	Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying; Buffering and chelating capacity
4.2.27	*339 i, ii, iii*	*Sodium orthophosphates*	*}*		
4.2.28	*340 i, ii, iii*	*Potassium orthophosphates*	*}*		
4.2.29	*341 i, ii, iii*	*Calcium orthophosphates*	*}*		
4.3	**Antioxidants**				
4.3.1	306	Mixed tocopherols concentrate	}	300 mg/kg fat, singly or in combination	Protect from oxidation Synergistic effect with ascorbyl esters
4.3.2	307	Alpha-tocopherol	}		
4.3.3	304	L-Ascorbyl palmitate		200 mg/kg fat	Protects from oxidation Synergistic affect with tocopherols

4.3.4	300, 301, 303 [4]	L-Ascorbic acid and its sodium and potassium salts	} }	50 mg, expressed as ascorbic acid and within the limits for sodium	Antioxidant in cereal bars Reduce discoloration in fruit preparations
4.3.5	*302*	*Calcium ascorbate*		*20 mg, expressed as ascorbic acid*	
4.4	**Flavours**				
4.4.1		Vanilla extract		GMP	Component of chocolate and part of the characterising flavour Other flavours may be needed, further discussion is necessary
4.4.2		Ethyl vanillin	}	7 mg on an "as consumed basis"	
4.4.3		Vanillin	}		
4.5	**Enzymes**				
4.5.1		Malt carbohydrases		GMP	Should be listed separately in a separate list of processing aids and therefore should not be listed as food additives.
4.6	**Leavening Agents**				
4.6.1	503 i	Ammonium carbonate	}	Limited by GMP	Raising agent in rusks and biscuits Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying
4.6.2	503 ii	Ammonium hydrogen carbonate	}		
4.6.3	*500 i, ii*	*Sodium carbonates*		*Limited by GMP*	Raising agent in rusks and biscuits Sometimes used in combination with 503 i or 503 ii Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying
4.6.4	*501 i, ii*	*Potassium carbonates*		*Limited by GMP*	Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying

[4] INS no. 303 Potassium ascorbate: Specifications not indicated by JECFA.

4.7	**Thickening agents**				
4.7.1	*410*	*Carob bean gum*	}	*Singly or in combination:* *1 g in weaning food* *2 g in gluten-free cereal-based foods*	Thickening agent and emulsion stabiliser
4.7.2	*412*	*Guar gum*	}		
4.7.3	*414*	*Gum arabic*	}		For fruit coating to prevent fruit from sticking together Also used as an ingredient of nutrient forms
4.7.4	*415*	*Xanthan gum*	}	*Singly or in combination:* *1 g in weaning food* *2 g in gluten-free cereal-based foods*	Thickener for semi-solid preparation Optimum viscosity achieved in combination with other thickeners
4.7.5	*440*	*Pectins (Amidated and Non-Amidated)*	}		Gelling agent in place of gelatine Particularly efficient in presence of fruits and acidic preparations Optimum viscosity achieved in combination with other thickeners Used as binder in extruded cereals increasing cohesiveness of the cereal pieces after rehydration
4.7.6	*1404*	*Oxidized starch*	}	*5 g singly or in combination*	*Physical properties that native starch tend to lose when processed*
4.7.7	*1410*	*Monostarch phosphate*	}		
4.7.8	*1412, 1413, 1414, 1422*	*Modified starches*	}		
4.7.9	*1420*	*Starch acetate esterified with acetic anhydride*	}		
4.7.10	*1450*	*Starch sodium octenyl succinate*	}		
4.7.11	*1451*	*Acetylated oxidized starch*	}		

4.8	**Anti-caking Agent**				
4.8.1	*551*	*Silicon dioxide (amorphous)*		*0.2 g for dry cereals only*	Most neutral Anticaking agent, prevents clumping Ensures even distribution of nutrients
4.9	**Packaging Gas (Propellants)**				
4.9.1	*290*	*Carbon dioxide*		*GMP*	Neutral gas used under modified packaging atmosphere to protect quality and guarantee shelf life
4.9.2	*941*	*Nitrogen*		*GMP*	
4.9.3	*942*	*Nitrous oxide*		*GMP*	
4.9.4	*938*	*Argon*		*GMP*	
4.9.5	*939*	*Helium*		*GMP*	
4.9.6	*948*	*Oxygen*		*GMP*	
4.9.7	*949*	*Hydrogen*		*GMP*	

5. CONTAMINANTS

5.1 Pesticide Residues

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

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

5.2 Other Contaminants

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

6. HYGIENE

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

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

7. PACKAGING

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

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

8. LABELLING

8.1.1 The requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991), Codex Alimentarius Volume 1) apply to this standard. With specific reference to section 7 of that Standard national jurisdictions may further restrict the use of pictorial devices.

or

[No nutrition and health claims shall be made regarding the dietary properties of the products covered by the provisions of this standard.]

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

8.2 The Name of the Food

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

8.3 List of Ingredients

8.3.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these shall be arranged as separate groups for vitamins and

minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

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

8.4 Declaration of Nutritive Value

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

(a) The energy value, expressed in kilocalories (kcal) and kilojoules (kJ), and the amount of protein, carbohydrate and fat expressed in grammes (g) per 100 g or 100 ml of the food as sold, and where appropriate, as per specified quantity of the food as suggested for consumption;

(b) The average amount of each vitamin and mineral for which specific levels are defined in section 3.6 and 3.7 expressed in numerical form per 100g or 100 ml of the food as sold and, where appropriate, as per specified quantity of the food as suggested for consumption;

(c) Any other nutritional information required by national legislation.

8.4.2 The labelling may bear the average amount of the vitamins and minerals when their declaration is not covered by the provisions of section 8.4.1 (b) expressed in numerical form per 100g or 100 ml of the product as sold and, where appropriate, per specified quantity of the food as suggested for consumption.

8.5 Date Marking and Storage Instructions

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

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

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

8.6 Information for Utilization

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

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

8.6.3 The presence or absence of gluten should be indicated on the label.

8.6.4 The label shall indicate clearly from which age the product is recommended for use. This age shall not be less than six months for any product.. In addition, the label shall include a statement indicating that the decision when precisely to begin complementary feeding, including any exception to six months of age, should be made in consultation with a health worker, based on the individual infant’s specific growth and development needs. Additional requirements in this respect may be made in accordance with the legislation of the country in which the product is sold.

8.7 Additional Requirements

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

9. METHODS OF ANALYSIS AND SAMPLING

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

In addition:

Detection of Irradiated Foods

Codex General Methods.