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 07/30/26-Rev.

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Thirtieth Session
Rome, Italy, 2 - 7 July 2007

REPORT OF THE 28th SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Chiang Mai, Thailand
30 October - 3 November 2006

Note: This document incorporates Circular Letter CL 2006/50-NFSDU

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CX 5/20.2 **CL 2006/50-NFSDU**
November 2006

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 28th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (ALINORM 07/30/26)**

A. REQUEST FOR COMMENTS AND INFORMATION AT STEP 8 OF THE PROCEDURE:

1. Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants, Sections A and B (ALINORM 07/30/26 para. 90 and Appendix II).

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, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org) **before 31 March 2007**.

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

Draft Revised Standard for Gluten-Free Foods (ALINORM 07/30/26, para 108 and Appendix IV)

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 5 29 – 49 65, e-mail: ccnfsdu@bmelv.bund.de with a copy to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org) **before 31 March 2007**;

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

Draft Revised Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for the Use by Infants and Young Children (ALINORM 07/30/26 para. 130 and Appendix V)

Governments and international organizations are invited to comment on the above text and should do so in writing, preferably by email to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 06 5705 4593, e-mail: codex@fao.org), **before 31 March 2007**;

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 28th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses are as follows:

MATTERS FOR ADOPTION BY THE COMMISSION AT STEP 8

The Committee:

Agreed to advanced the Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants: Section A: Draft Revised Standard for Infant Formula and Section B: Formulas for Special Medical Purposes Intended for Infants for final adoption by the 30th Session of the Commission (para 90, Appendix II).

MATTERS FOR ADOPTION BY THE COMMISSION AT STEP 5

The Committee:

Agreed to advanced the Draft Revised Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for the Use by Infants and Young Children for provisional adoption (para 130, Appendix V).

MATTERS FOR CONSIDERATION BY THE COMMISSION

The Committee:

Agreed to start new work on the establishment and application of risk analysis principles by the Committee on Nutrition and Foods for Special Dietary Uses. The Project Document, prepared by Australia and presented in CX/NFSDU 06/289 would be forwarded to the 30th Session of the Commission for consideration of new work proposals (para. 143).

MATTERS OF INTEREST TO THE COMMISSION

The Committee:

While considering the Implementation of the WHO/FAO Global Strategy on Diet, Physical Activity and Health, agreed to proceed with the consideration of the revision of the Nutrient Reference Values (NRVs) for vitamins and minerals and to ask the Committee on Food Labelling its advice concerning the revision and extension of the list of NRVs in the Guidelines for Nutrition Labelling to other nutrients associated with increased and decreased risk of non communicable diseases. The Committee agreed that if this reply was positive it would consider new work on the revision and extension of the list to relevant nutrients at its next session. The Committee concluded that there was no support to initiate work for claims for trans fatty acids and include restrictions on both saturated and trans fatty acids in the conditions for comparative claims. The Committee agreed to consider reviewing and re-establishing the Guidelines for the Use of Codex Committees on the Inclusion of Provisions on Nutritional Quality in Food Standards and Other Codex Texts at the next session of the Committee based on document which would provide more explanation on the development of such guidelines (see paras 144-156).

MATTERS REFERRED TO OTHER COMMITTEES

Codex Committee on Food Additives (CCFA)

Following the established Procedures between Commodity Committees and General Committees, the CCNFSDU refers the Section on Food Additives of the Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants for endorsement and advice by the CCFA and JECFA (for details see paras 56-68 and 83-85 and Appendix III).

Codex Committee on Food Contaminants (CCFC)

Following the established Procedures between Commodity Committees and General Committees, the CCNFSDU refers the Section on Food Contaminants of the Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants for endorsement and advice by the CCFC and JECFA (for details see paras 56-68 and 83-85 and Appendix II).

Codex Committee on Food Labelling (CCFL)

Following the established Procedures between Commodity Committees and General Committees, the CCNFSDU refers the Section of Food Labelling of the Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants for endorsement by the CCFL (see paras 71-77 and 86-89 and Appendix II).

MATTERS FOR INFORMATION TO OTHER COMMITTEES

Codex Committee on Milk and Milk Products (CCMMP)

The Committee recalled that the question of the nitrogen conversion factor had been substantially discussed at its earlier sessions, that the Committee on Milk and Milk Products had expressed the view that the conversion factor should be 6.38 as in the case of milk products and that the Commission had referred this question to the CCNFSDU for further consideration. The Committee agreed with the proposal of the working group to use a nitrogen conversion factor of 6.25 for infant formula “unless a scientific justification is provided for the use of a different conversion factor for a particular product”, and to indicate that a factor of 6.38 was used for other milk products, while the conversion factor in other soy products was 5.71. (for details see paras -29-33 and Appendix II).

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INTRODUCTION

1. The Twenty-eighth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held from 30 October to 3 November 2006 in Chiang Mai, Thailand by the kind invitation of the Government of Thailand. The Session was chaired by Dr Rolf Grossklaus, Director and Professor of the Federal Institute for Risk Assessment, Berlin, and co-chaired by Mr Somchai Charnnarongkul, Deputy Secretary-General, National Bureau of Agricultural Commodity and Food Standards, Thailand. The Session was attended by 244 delegates, observers and advisors representing 45 member countries, one member organization and 24 international organizations.

OPENING OF THE SESSION

2. Mr Somchai Charnnarongkul, Deputy Secretary-General, National Bureau of Agricultural Commodity and Food Standards on behalf of Ministry of Agriculture and Cooperatives of Thailand warmly welcomed the Committee and indicated that Thailand, as one of the major food producers and exporters has recognized the significance of nutrition as well as food safety for the wellbeing of the people. Mr Charnnarongkul indicated that Thailand has restructured the entire food chain process in order to comply with international and national food standards and therefore to ensure food safety for international and national consumers. While pointing out the importance of issues under consideration by the Nutrition Committee Mr Charnnarongkul invited the delegates familiarize with traditional heritage and unique culture of Chaing Mai and wished all success in the Committee's deliberations.

3. Mr Bernhard Kühnle, Director General for Food Safety and Veterinary Affairs, Federal Ministry of Food and Agriculture and Consumer Protection, Germany also welcomed the participants on behalf of the Federal Minister and expressed its sincere appreciation to the Government of Thailand for hosting the meeting in Thailand. He noted the importance of the work of the Committee in ensuring the highest standards worldwide to protect the health of infants and children while ensuring fair trade practices. While referring to the Provisional Agenda for this session of the Committee, Mr Kühnle noted the long work on the revision of the Draft Standard for Infant Formula and encouraged the delegates to finalize it as well as the Draft Revised Standard for Gluten Free Foods in order to ensure the protection of such vulnerable populations. Mr Kühnle indicated that it was very important to progress with the work on Substantiation of Health Claims in order to protect consumers from deceptive and misleading claims and to arrive at consensus with the other work of the Committee. In conclusion, Mr Kühnle wished all success to the delegates in their important work.

ADOPTION OF THE AGENDA (Agenda Item 1)[1]

4. The Delegation of the European Community (EC) presented CRD 2 on the division of competence between the European Community and its Member States according to Article 5, of Rule II of Procedure of the Codex Alimentarius Commission.

5. The Committee noted that FAO/WHO had prepared an information paper about their work on the scientific update on dietary fibre (CRD 19) and agreed to discuss Agenda Item 3 after Agenda Item 6 in order to allow more time for delegates to study the FAO/WHO paper in more detail.

6. In view of the importance of the issue, the Committee agreed to the proposal of the Delegation of Finland, speaking on behalf of the European Community Member States present at the current session, to consider the comments on the Implementation of the WHO Global Strategy on Diet, Physical Activity and Health after Agenda Item 6. The Committee also accepted the proposal of the Delegation of Thailand to consider the discussion paper on the revision of Section 3.4 "Carbohydrates" of the Codex Standard for Processed Cereal-Based Foods for Infants and Young Children in connection with the WHO Global Strategy. Further, the Committee agreed to consider the discussion paper submitted by the Delegation of India in Annex I of CRD15 regarding energy density in Processed Cereal-Based Foods for Infants and Young Children along with the WHO Global Strategy on Diet, Physical Activity and Health.

[1] CX/NFSDU 06/26/1; CRD 2 (Annotated Provisional Agenda on the Division of Competence between the European community and its Member States according to Rule II paragraph 5 of the Codex Alimentarius Commission; CRD 15 (comments of India).

7. With these modifications the Committee adopted the Provisional Agenda as the Agenda for the 28th Session of the Committee.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES (Agenda Item 2)[2]

8. The Committee noted that a number of matters referred by the 29th Session of the Codex Alimentarius Commission (CAC), by FAO/WHO and other Codex Committees were for information purposes or would be discussed in more detail under relevant Agenda Items. In addition the Committee noted matters referred as follows.

Time frame for items under long consideration

9. The Committee noted that the Commission endorsed the proposals of the 57th Session of the Executive Committee regarding the improving management of work and agreed to establish a time frame for completion of its items which were on the Codex Step Procedure.

GUIDELINES FOR THE USE OF NUTRITION CLAIMS: DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (PART B CONTAINING PROVISIONS ON DIETARY FIBRE) AT STEP 7 (Agenda Item 3)[3]

10. The Committee recalled that its last session had agreed to circulate the Draft Table, including a revised definition, at Step 6 for further comments.

11. The Representative of WHO informed the Committee of the work of the joint FAO/WHO scientific update on carbohydrates in human nutrition, following the information provided to the 27th Session of CCNFSDU. The Representative indicated that the last Joint FAO/WHO Expert Consultation on Carbohydrates in Human Nutrition was held in 1997 and since then, several expert consultations have taken place including the Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases, which highlighted a number of issues related to carbohydrates that required further review and assessment. FAO and WHO had strived to organize an expert consultation to update the recommendations made by the 1997 Expert Consultation, however, due to the financial difficulties holding of a formal expert consultation has not been possible. In order to address a number of urgent issues related to carbohydrates, FAO and WHO agreed to undertake a scientific update, pending a formal expert consultation when the necessary resources are identified. This process was viewed as an important step in preparing for the eventual Expert Consultation on Carbohydrates in Human Nutrition.

12. The Representative informed that the topics covered represented a wide range of topics on the role of carbohydrates in health and that papers prepared were thorough scientific update on those identified issues related to carbohydrates and the identification of topics for further discussion and consideration among experts.

13. A meeting of the authors together with several other expert peer-reviewers was held in July 2006 to review all the scientific papers and at this meeting, the experts undertook the review of the issues related to dietary fibre among various other issues and proposed a definition of dietary fibre.

14. The Representative highlighted the rationale employed by the experts for defining dietary fibre as "intrinsic plant cell wall polysaccharides". These include: 1) Existing epidemiological studies which established health benefits of "dietary fibre" are based on population studies with diets that contain fruits, vegetables and whole grain cereal food which have the characteristics of containing plant cell walls. Based on this scientific evidence, various national and international dietary guidelines which promote the intake of the plant foods defined as a natural food component, reference intake values and health claims have been developed; 2) Reference to non-digestibility in the human small intestine was not included as this does not provide a consistent indicator of plant rich diets. Non digestibility can be affected by food processing or synthetic or added sources may be added to food; 3) Similarly, the inclusion of "properties" of fibre, such as

[2] CX/NFSDU 06/26/2; CRD 3 (information from WHO); CRD 15 (comments of India).

[3] ALINORM 06/29/26, Appendix III; CX/NFSDU 06/28/3 (comments of Argentina, Australia, China, Costa Rica, India, Mexico, Peru, United States of America, IADSA, ICGMA, IDF, ISDI); CRD 4 (comments of Brazil, Canada, Chile, Indonesia, Malaysia, Philippines, Vietnam, Thailand, AAC, ILSI); CRD 15 (comments of India), CRD 16 (Proposal for a definition of and methods of analysis for dietary fibre content, prepared by drafting group led by France and Sweden, July 2004); CRD 19 (FAO/WHO Scientific update on carbohydrates in human nutrition).

"increases stool bulk" or "reduces blood total and/or LDL cholesterol" was considered inappropriate as part of a definition as this would be difficult to manage when it comes to defining a method of measurement. For example, many dietary components contribute to lowering blood cholesterol; 4) Polysaccharides are the best bio-marker of the presence of plant cell wall in foods; 5) It was agreed that the definition of dietary fibre needs to define chemical component to be measured. The need for chemical approach was also recommended by the 1997 FAO/WHO Expert Consultation on CHO in Human Nutrition.

15. When considering the definition of dietary fibre, the expert groups had reviewed and analyzed various existing definitions, including the currently proposed definition by this Committee, definition of the US National Academy of Sciences in 2003, among others. However, they encountered various discrepancies in applying those definitions. After considerable discussions, the expert group agreed to define that: "Dietary fibre consists of intrinsic plant cell wall polysaccharides", which was the original concept of "dietary fibre". When the attention was first drawn to fibre, plant cell wall was considered as a marker of whole foods, such as fruit, vegetables and whole grain cereals. There was never any intention that the multiple components of the plant cell wall were beneficial to health and they have never been shown to be. To this end, the Representative of WHO called the attention to the comments made by some Member States in CX/NFSDU 06/28/3 regarding the footnote 1 to the definition currently proposed by this Committee. Components such as phenolic compounds, waxes, saponins, phytates, cutin, phytosterols, etc. have never been shown to have health benefits and "possible beneficial effects of certain substances fall outside the scope of the definition".

16. The Committee noted that the proposed draft definition was about to be completed and that proposed FAO/WHO definition differed considerably from the one on which Committee worked for a number of years and considered how to progress on this matter.

17. A number of delegations expressed their wish to continue working on the proposed definition for dietary fibre as proposed by the Committee and presented in Appendix III of ALINORM 06/29/26. It was indicated that the current CCNFSDU definition was wider and covered issues that were relevant to the work of Codex Alimentarius. The Delegation of Benin was of the view that dietary fibres of animal origin could be considered for inclusion.

18. Several other Delegations and observers supported the work on definition of dietary fibre proposed by the expert group involved in the joint FAO/WHO Scientific Update on Carbohydrates in Human Nutrition as the definition expressed in CRD 19 was scientifically clearer and that the Codex mandate was to protect consumer health. The Delegation of Sweden referred to the current Codex definition of dietary fibre in the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985) and that this definition includes edible plant and animal material not hydrolised by the endogenous enzymes of the human digestive tract. The Observer of IACFO stressed the role of WHO as a parent organization of Codex.

19. Some delegations drew the attention of the Committee to the necessity to study methodological problems of the determination of dietary fibre in more detail. It was noted that validated methods for determination of specific components of dietary fibre were available but no single validated method existed that is consistent with the proposed definition by Codex, therefore it was not possible to combine these results in order to determine total dietary fibre.

20. To the concerns raised by some delegations regarding the status of this FAO/WHO scientific update and unavailability of names of experts and references to scientific publications, the Representative of WHO clarified that there were over 40 experts from different countries and that the references to scientific publications and the list of experts could be made available and that scientific papers would be published early next year.

21. The Committee noted that there was no agreement on how to progress with the work further, therefore accepted the proposal of the Chairperson to seek additional comments on the current draft definition and the proposed definition in CRD 19.

Status of the Draft Table of Conditions for Nutrient Contents: (Part B Containing Provisions on Dietary Fibre

22. The Committee agreed to return the Draft Table of Conditions for Nutrient Contents containing provisions on dietary fibre to Step 6. The Committee agreed to issue a Circular Letter asking comments and additional input on the definition and other provisions of dietary fibre. The Committee noted that a Circular Letter should contain the current Appendix III, the content of CRD 19 and also additional clarification provided by the WHO, if any including information on the publication of the scientific papers.

DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS: SECTION A DRAFT REVISED STANDARD FOR INFANT FORMULA (Agenda Item 4a)[4]

23. The Committee recalled that its last session had returned Section A of the Draft Revised Standard to Step 6 for further comments and consideration by two electronic working groups that would consider respectively the sections on essential composition and on food additives. It had also been agreed that a physical working group chaired by Germany would be held prior to the session to consider composition requirements.

24. The Committee considered the recommendations of the working groups on sections 3 and 4. As regards the other sections, the Chair recalled that agreement had been reached on several sections of the Draft Standard in earlier sessions and the Committee agreed to concentrate on the provisions that had been retained in square brackets for further discussion. The Committee considered the Draft Standard section by section and made the following amendments and comments.

25. The Committee agreed on an editorial amendment to section 2.1 and other relevant sections in order to refer to "the product" instead of "infant formula" as the final standard would apply also to Formulas for Special Medical Purposes (FSMP).

Section 3. Essential Composition and Quality Factors

Section 3.1 Essential Composition

26. The Delegation of Germany presented the report of the electronic working group that had been held prior to the session (CRD 1) and noted that although it had not been able to discuss the whole of Section 3, consensus had been reached on many subsections. It was noted that different delegations applied different interpretations of the General Principles for Establishing Minimum and Maximum/Guidance Upper Levels for the Essential Composition of Infant Formula and that this prevented agreement in particular on Guidance Upper Levels. The Working Group had therefore agreed to follow a three-step procedure 1) necessary revisions of the minimum levels for nutrients in the present Standard 2) necessary revision of the maximum levels for nutrients in the present Standard and introduction of additional maximum levels according to recent scientific data, and 3) definition of Guidance Upper Levels for other nutrients according to the General Principles and addition of text to indicate that the application of these levels would be left to national authorities. To resolve this question an informal working group was set up, chaired by the Delegation of Canada, The results of this working group were introduced by the Delegation of Canada and were presented in Annex 1 of CRD 1. These values were inserted in the Table in section 3 and discussed as follows. The agreed format has three separate columns for minimum, maximum and guidance upper values GULs).

27. In section 3.1.3, the Committee agreed to amend the text of Footnote 1 as proposed by the working group to clarify that GULs which met the nutritional requirements of infants and had an established history of safe use could be established in the absence of sufficient scientific information. The Committee therefore agreed that "maximum values" would be established when these values were based on a scientific risk assessment and would be replaced by GULs where appropriate throughout the section. It was also clarified how GULs should be interpreted and used at the national level.

28. With reference to the question of upper levels, the Observer from NHF supported the principle that "when children have already adapted well to the formula, there is no need to follow the upper limit" and proposed that it should be applied to food supplements for all age groups.

[4] ALINORM 06/29/4, Appendix IVA, CX/NFSDU 06/28/4 (comments of Argentina, Australia, Bolivia, China, Costa Rica, India, Norway, Peru, United States, AIDGUM, ENCA, IDF, ILCA, ISDI), CX/NFSDU 06/28/4-Add. 2 (Proposals of the Working Group for the Sections on Food Additives), CX/NFSDU 06/28/4-Add. 3 and CRD/CX/NFSDU 06/28/4-Add. 3 (Proposals of the electronic Working Group on Section 3), CX/NFSDU 06/28/4-Add. 4 (comments on the additives section: Argentina, Guatemala, Kenya, United States, Vietnam, ISDI), CRD 1 (report of the Working Group on Section 3 held on 28 November 2006), CRD 5 (comments of Canada, Chile, European Community, Indonesia, Malaysia, Philippines, South Africa, Thailand, IACFO), CRD 6 (Brazil, Canada, European Community, Indonesia, Japan, Norway, Thailand), CRD 8 (Canada, Thailand, USA), CRD 15 (India), CRD 27 (Botswana), CRD 28 (IBFAN), , CRD 30 (Proposed Tables for Food Additives resulting from the discussion).

a) Protein

29. The Committee agreed on a minimum value of 1.8 g/100 kcal and a maximum value of 3g/100 kcal for milk based formula. The Committee recalled that the question of the nitrogen conversion factor had been substantially discussed at its earlier sessions, that the Committee on Milk and Milk Products had expressed the view that the conversion factor should be 6.38 as in the case of milk products and that the Commission had referred this question to the CCNFSDU for further consideration.

30. The Committee agreed with the proposal of the working group to use a nitrogen conversion factor of 6.25 for infant formula "unless a scientific justification is provided for the use of a different conversion factor for a particular product", and to indicate that a factor of 6.38 was used for other milk products, while the conversion factor in other soy products was 5.71. The Observer of IDF noted that although the factor of 6.25 relates to the final product, the specific conversion factor of 6.38 for milk protein and 5.71 for soy protein relate to the ingredients used in the manufacture of infant formulae and to products that are outside the scope of the standard. This should ensure consistency among various Codex standards regarding conversion of nitrogen into proteins.

31. The Delegation of India expressed its reservation on this decision as it supported a conversion factor of 6.38 for infant formula deriving protein exclusively from milks and 5.71 for infant formula deriving protein exclusively from soy. The Delegation of Japan drew the attention of the Committee of conversion factor 6.38 used in quoting of para. 17 of ALINORM 06/29/11 and para. 179 of ALINORM 06/29/41.

32. The Committee agreed to rearrange the footnotes for clarification purposes and to retain the text of Footnote 6 concerning infant formula containing lower protein values without square brackets and to refer to milk instead of "cow's milk" to ensure consistency throughout the standard.

33. The Committee noted that there had been no support in the working group for a proposal from some observers to consider adverse effects of soy protein isolates. It noted that an evaluation of the use of these products was underway in several scientific organizations, and that ESPGHAN would seek cooperation with these organisations and to provide information on the result of these evaluations following their completion to the Committee.

b) Lipids

34. The Committee agreed to retain the current minimum value of linoleic acid (300 mg/100 kcal) and to establish a GUL of 1400 mg.

35. The Committee agreed with the proposal of the Delegation of Canada to delete phospholipids from section 3.2.3 and to specify in Footnote 8 that the total content of phospholipids should not exceed 300 mg/100 kcal. The maximum percentage of trans fatty acids was retained without square brackets and some editorial amendments were made for clarification purposes.

c) Carbohydrates

36. The Committee agreed to clarify in Footnote 9 that precooked or gelatinized starches should be gluten-free by nature.

37. Some delegations proposed to delete the reference to sucrose, or to separate sucrose from fructose in the second paragraph of Footnote 6, pointing out that adverse effects were mostly associated with fructose. The Committee however agreed to refer to fructose as an ingredient and to retain the rest of the text unchanged, taking into account that sucrose could be used to improve taste.

d) Vitamins

38. The values proposed in Annex 1 of CRD 1 were agreed by the Committee.

39. The Committee agreed with the proposal of the Delegation of New Zealand to amend the guidance upper level of Vitamin B_{12} to 1.5 in order to take into account natural variations in milk levels.

40. As regards Vitamin C, the Delegation of Australia proposed to specify a guidance upper level of 30 mg for powdered infant formula. The Delegation of the United States pointed out that higher levels were necessary when water at a high temperature was used to reconstitute formula, due to significant losses. The Committee agreed on a guidance upper level of 70 mg with a footnote clarifying that this level took into account possible high losses over shelf life in liquid formula, and that for powdered products lower upper levels should be aimed at.

e) Minerals and Trace Elements

Iron

41. The Committee recalled that the level of iron had been already discussed extensively and that no consensus had been reached due to the wide differences between the levels allowed in various countries. The Committee agreed to retain a single level of iron for all types of formula instead of two and to establish a minimum level of 0.45 mg. As there was no agreement on the upper level, some delegations proposed to refer to a range (1.3 to 2.4 mg), while other delegations proposed that no specific values should be mentioned.

42. The Observer from ESPGHAN pointed out that considerable evidence on adverse effects of excessive intake of iron was available from clinical studies in infants and that it had already presented scientific arguments supporting a maximum level of 1.3 mg/100 kcal. Setting of maximum levels for iron content per 100 ml was recommended by recent independent scientific reviews in the United States (1.65mg), the EU (1.3mg) and the IEG (1.3), and that the adverse effects of excessive iron intake included enhanced growth and gut colonization of pathogenic bacteria, a higher prevalence of diarrhea, and limited bioavailability of copper and zinc. The Observer therefore recommended that if guidance upper levels were to be set by national authorities, they should not exceed the range of 1.3 to 2.4 mg/100 kcal.

43. After some discussion, the Committee agreed that the establishment of upper levels should be left to national authorities and inserted a footnote to this effect.

44. The Committee agreed that the minimum ratio calcium/phosphorus should be 1:1 and the maximum 2:1, amended the maximum level for potassium to 180 mg, and the GUL for copper to 120 mkg.

Section 3.2 Optional ingredients

Total Nucleotides

45. The Delegation of Mexico, supported by other delegations, stressed the positive health effects of nucleotides and proposed to establish a maximum level of 16 mg/100 kcal, based on the concentration in human milk. Other delegations proposed to leave the establishment of specific levels to national authorities. After some discussion, the Committee agreed that levels may need to be determined at the national level.

Docosahexaenoic Acid

46. The Delegation of Japan, supported by other delegations, proposed to increase the proposed maximum level (0.5 % of fatty acids) to 1%, since studies carried out in Japan and other Asian countries demonstrated that the average level found in human milk was from 0.5 to 1%. The Delegation did not support the conditions of use of docosahexaenoic acid (DHA) specifying that if it was added to infant formula, arachidonic acid (AA) should reach at least the same content as DHA because there is least scientific evidence to justify this decisive expression, and because according to extensive surveys with many cases of breast milk, especially with Asian, rather less AA to DHA ratio are presented. The Delegation proposed as a compromise to use the text included in the written comments of ISDI, referring to addition of arachidonic acid in a range of 0 to 2%.

47. Other delegations supported the current level of 0.5% as it was based on current scientific evidence regarding the safety of human milk. The Observer from ESPGHAN noted that human milk content of DHA and DHA/AA ratio vary with dietary intakes of breastfeeding women, particularly fish consumption. However human milk always contains AA with mean levels near 0.4 % of fatty acids and published studies on the safety of DHA have been mostly performed with formula containing at least as much AA as DHA, whereas there is little evidence to demonstrate health benefits of adding DHA alone. ESPGHAN therefore supported the inclusion of a requirement to add AA along with DHA and the current proposal on the ratio between DHA and AA.

48. After an extensive discussion, the Committee agreed to retain the current proposals as a guidance upper level and to specify in the footnote that “national authorities may deviate from these conditions”, in order to recognize that different data existed in some countries. The Delegation of Japan reserved its position on this decision.

Fluoride

49. The Delegation of South Africa drew the attention of the Committee to new scientific data published by the United States National Research Council on the adverse effects of fluoride in drinking water and to the recent revision of the WHO Guidelines for Drinking Water Quality, that included maximum limits for fluoride, and therefore proposed to delete fluoride from the list of optional ingredients.

50. The Delegation of the United States clarified the status of the recommendations from the NRC in relation to the scientific studies discussed in the report, and pointed out that this was a report on maximum levels of fluoride in drinking water, and also noted that an adequate intake level had also been established in the Dietary Reference Intake Report. The quoted studies may have been a part of discussions in the NRC report, but were not part of recommendations of the report.

51. The Observer from ESPHGAN noted that available scientific evidence pointed to dose dependent adverse effects of fluoride, such as fluorosis, while there was no indication that complete avoidance of fluoride exposure would result in health benefits, as numerous studies lead to the conclusion that an appropriate level of fluoride exposure contributes to the reduction of dental caries risk. However, it was important to avoid excessive fluoride exposure and ESPGHAN supported a maximum level of 100 µg/100 kcal.

52. The Committee generally agreed that fluoride should not be added to infant formula and should be deleted from the list of optional ingredients, and discussed the maximum level to be allowed, as several values were put forward. The Committee noted several proposals to insert the fluoride provisions in the specific prohibitions, or as a separate section, or in the essential composition requirements. After some discussion, it was agreed to add a new section 3.3 to the effect that fluoride should not be added and that its level should not exceed 100 µg/100 kcal.

Annex 1

53. The Delegation of Germany indicated that the working group had agreed that Annex 1 should be revised with regard to the inclusion of the variability of the stated mean amino acid content of breast milk and with regard to the origin of the data

54. The Delegation of the United States expressed the view that the use of average values in the Table was not acceptable as there was a variety of values and the Table should be based on the IEG report , while Table 5 presented the source of these values. After some discussion, the Committee agreed that the Delegation of Germany would replace the values in Annex 1 by inserting values of the IEG Report. The Table should indicate that all the values can be used by national authorities.

55. The Committee expressed its appreciation to the Delegation of Germany and to the Working Group for their excellent work at the present session and throughout the revision of the standard, which had greatly facilitated the revision of the section on the basis of updated scientific evidence.

Section 4. Food Additives

56. The Delegation of Switzerland presented the report of the electronic working group that had worked between the sessions in order to redraft the Section on additives at the request of the last session of the Committee and pointed out that the approaches to the use of additives in infant formula varied widely between delegations.

General considerations

57. The Delegation of Switzerland, while presenting the report of the working group, recalled the background of consideration by JECFA of additives for use in infant foods, as follows. The Committee noted that the *Principles for the Safety Assessment of Food Additives and Contaminants* (WHO EHC 70, 1987) confirmed the principles that had been developed by the FAO/WHO Meeting on Additives in Baby Foods (1971), establishing a distinction between baby foods suitable for infants up to 12 weeks and older infants, due to physiological reasons, and concluded that “it is prudent that foods intended for infants under 12 weeks should contain no additives at all”. However the *Principles* recognized “that in practice there may be certain exceptions on technological grounds”, which were further specified. It was also noted that some additives had been evaluated by JECFA specifically for use in infant foods (for infants below 12 weeks) while others had been evaluated for the general population but not for this group of population.

58. The Committee noted that the basis of the advice provided by JECFA on additives in foods for young infants had been established in 1971 and agreed that further advice on the inclusion of additives in infant

formula was necessary. The Committee agreed to ask the CCFA to put forward the following question to JECFA: to what extent an ADI established by JECFA, whether numerical or not specified, applied to young infants below 12 weeks; what scientific principles should apply to the evaluation of additives intended for this group of population; and whether the establishment of an ADI in itself was sufficient or whether other issues had to be addressed.

59. The Committee discussed whether the establishment of specific principles for use of additives in infant formula should be developed, as proposed by some delegations, and agreed that it would be preferable to defer consideration of this matter pending advice from JECFA.

60. Some delegations recalled that the revised Standard for Processed Cereal Based Foods for Infants and Young Children referred to the carry over of additives, and proposed to include a similar wording in the standard. The Chair recalled that the products were not the same and that carry over of additives was not allowed in the current Standard for Infant Formula. After some discussion, the Committee agreed to insert the text used for cereal based foods as an introduction to the list of additives and to ask the advice of the CCFA on the applicability of the language for carry over to infant formula.

Additives for inclusion in the Draft Standard

61. In view of the above considerations, the Committee considered the options put forward by the working group on how to proceed with the current section on additives:

1) Proceed with all food additives already listed in the current standard; defer discussion of other additives after JECFA has provided its opinion

2) Proceed with non controversial additives cleared by JECFA specifically for infants

3) Defer consideration of Section 4 until JECFA has provided its opinion

62. The EC explained that in their view the use of food additives in foods intended for infants and young children should be limited to those where there is a clear technological need and where that function can not be fulfilled by an additive on the list and expressed preference for option 2.

63. The Committee agreed to proceed with the first option and to establish a working group chaired by Switzerland during the session to identify the additives that could be included in the current Draft Standard and those that would require further consideration. The Committee considered three lists of additives that were proposed by the working group: Table 1: additives that are considered suitable for use in infant formula and formula for special medical purposes (FSMP) intended for infants use (sections A and B); Table 2 including additives for which suitability for use in sections A and B should be determined; and Table 3 including additives intended only for FSMP (section B).

64. As regards Table 1, the Delegation of the United States expressed the view that the list of additives in the current standard should be retained in view of their long history of use, with the understanding that it could be amended when new scientific advice became available.

65. The Delegation of the EC proposed to delete carrageenan from the current list in view of its adverse effects to health of young infants, until the JECFA reevaluation scheduled for 2007 became available. After some discussion, the Committee agreed to insert a footnote to the effect that national authorities may restrict the use of carrageenan until the evaluation by JECFA had been completed.

66. The Committee agreed that Table 1 would include all those additives and levels of use that were considered suitable for in infant formula and formula for special medical purposes and would be forwarded to the CCFA for endorsement and to the Commission as section 4 of the Draft Standard.

67. The Committee agreed to forward the additives in Table 2 to the CCFA for advice on their suitability in the products covered by sections A and B and evaluation by JECFA if required, in the light of the advice that would be provided on the general questions mentioned above. The Committee agreed to forward the additives in Table 3 to CCFA for advice on their suitability in the products covered by section B and evaluation by JECFA if required. Tables 2 and 3 are presented in Appendix III.

68. The Committee expressed its appreciation to the Delegation of Switzerland and to the working group for their comprehensive work in order to facilitate the update of the additives section.

Section 6. Food Hygiene

69. It was proposed to amend the text of section 6.1 to specify that the product "shall be prepared" in accordance with the provisions of the section. However the Committee noted that this was the standard section on food hygiene endorsed by the Committee on Food Hygiene and included in the Procedural Manual, and that any change would require further consideration by the Committee on Food Hygiene with specific justification.

70. Observers from IBFAN, ILCA and IACFO proposed to include additional labeling provisions to warn parents and caregives regarding intrinsic contamination of powdered infant formula with pathogenic microorganisms. However several delegations recalled that this issue had already been discussed, that hygiene provisions were addressed in detail in the relevant Code of Hygienic Practice, currently under revision in the Committee on Food Hygiene, and that no labeling provisions should be introduced in the section on food hygiene. The Committee agreed to retain the current section.

Section 9. Labelling

71. The Committee agreed to reword the first paragraph to repeat the provisions in the Guidelines on Nutrition and Health Claims as regards claims for foods for infants and children, and to introduce some editorial changes. Section 9.6.6 on nutrition an health claims was therefore deleted.

72. The Committee agreed to delete section 9.1.6 on labelling related to iron content in view of its earlier decision to establish a minimum level for iron of 0.45 mg/100 kcal.

73. The Committee had an extensive discussion on the use of boiled water for reconstitution of infant formula. Several delegations expressed the view that the use of previously boiled water did not ensure the safety of the products as contamination might occur after boiling, while drinking water did not require boiling to be safe, and therefore proposed to refer to "safe" water as this covered all possible cases in order to prevent contamination. Other delegations and observers supported a specific reference to boiled water in order to provide clear guidance to consumers regarding the intrinsic contamination of powdered infant formula. Some delegations pointed out that the provisions of the standard were not intended to provide information directly to consumers, but to provide guidance to governments on how to provide adequate information to consumers. Following discussion of several proposals, the Committee agreed that the paragraph would refer to "water that is safe or has been rendered safe by previous boiling before feeding according to directions for use" and clarified the provisions for each type of formula (powdered or liquid).

74. Following some exchange of views on how to address issues of contamination of infant formula, the Secretariat informed the Committee that the Proposed Draft Code of Hygienic Practice for powdered Formulae for Infants and Young Children addressing all issues related to contamination with pathogenic microorganisms, in particular *Enterobacter sakazakii* and *Salmonella*, and including relevant labelling aspects , would be considered by the next session of the Committee on Food Hygiene, on the basis of the scientific advice provided by FAO/WHO Expert Consultation and Technical Meeting. Several delegations and the Observer from IDF pointed out that advice on the safety of the product were addressed in the Code of Hygienic Practice and that work on the revision of the standard should not duplicate the work on the revision of the Code.

75. The Representative of WHO informed the Committee that the FAO/WHO Technical Meeting on *Enterobacter sakazakii* and *Salmonella* in Powdered Infant Formula had considered a risk assessment model and the impact of different control measures on the reduction of risk, such as different temperatures of the water used for reconstitution of formula. Recommendations had also been made to member states and in particular to review labels in order to provide information on the health hazards of inappropriate preparation.

76. The Committee noted the proposals of the observers of IAFCO, IFBAN and ILCA for additional warning in the label concerning intrinsic pathogenic microorganisms. However several delegations pointed out that this was adequately covered by section 9.5.4, referring to "a warning about to the health hazards of inappropriate preparation", in order to provide guidance to governments in accordance with the recommendations of the FAO/WHO Technical Meeting. The section was amended to add "storage and use" of the product so as to cover health hazards at all stages. The Delegation of South Africa expressed its reservation on this section as it did not consider that the information provided was sufficient.

77. The Committee discussed whether the reference to an accompanying leaflet should be retained, as several delegations stressed the need to include all relevant information on the label of the product itself and not on a leaflet. The Committee agreed that the use of the leaflet could be allowed in addition to the labelling of the product and amended the text accordingly.

Section 10. Methods of Analysis and Sampling

78. The Delegation of the United States pointed out that methods of analysis for infant formula had not been revised for a long time and included several obsolete methods, and therefore proposed a revised list with updated methods. The Committee agreed to insert this list in section 10 and to forward it to CCMAS for endorsement.

DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS: SECTION B: FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS AT STEP 7 (Agenda Item 4 b)[5]

79. The Committee recalled that it had agreed to forward this section to Step 5 for adoption by the Commission and that after adoption at Step 5 comments were requested at Step 6 of the Procedure. It also recalled that Section A was to serve as a model for this section and that cross-references were used to relevant Sections of Section A. The Committee considered the document section by section and in addition to editorial corrections made the following comments and changes.

Section 1. Scope

80. The Committee noted some proposals to delete specific wording or to add additional references to WHA Resolutions, or to clarify the Scope by characterizing it into distinct categories, however it felt that the wording of this Section should be consistent with the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and that characterization of the Scope into distinct categories might exclude some products necessary for correction of some carbohydrate or amino acid metabolic disorders.

Section 3.1 Essential composition

Section 3.1.2

81. Since the products covered by this Section were intended to be sole sources of nutrition, the Committee agreed to amend it in order to emphasize that their nutritional safety and adequacy in supporting the growth and development shall be scientifically demonstrated and be beneficial in the dietary management of the infants for whom it was intended.

82. The Committee noted that in some cases there might be a need to use products containing chromium and molybdenum, therefore inserted new Section 3.1.4 setting requirements for these elements.

Section 4 Food Additives

83. The Observer from ISDI informed the Committee that more additives had been used in the products covered by this section as compared to infant formula for technological reasons due to their composition.

84. The Committee discussed whether to continue work on additional list of additives at this stage or after final adoption of the Draft Standard and concluded that it would not continue work on additives at this stage.

85. The Committee noted that additional additives may be needed for Formula for Special Medical Purposes, therefore inserted a sentence to clarify that such uses may be determined by national authorities.

Section 9 Labelling

86. The Committee noted several proposals to introduce new provisions to emphasize the importance of breastfeeding or to include entire sub-sections from Section A, or to transfer some sections from one to the other, however did not agree with these proposals.

Section 9.1 The name of the product

87. The Committee agreed to add a cross-reference to Section A 9.1.1 and clarified how to label formula if cow's milk was the only source of protein. The Section was renumbered accordingly. The Observer from

[5] ALINORM 06/29/26, Appendix IVB; CX/NFSDU 06/28/4-Add.1 (comments of Argentina, Bolivia, Brazil, Canada, Costa Rica, Guatemala 1 and 2, Israel, Mexico 1 and 2, Philippines, USA, Vietnam, ISDI); 7 (comments of Chile, European Community, India, Malaysia, Mexico, Philippines, Vietnam, IACFO); 15 (comments of India), CRD 25 (comments of ILCA); CRD 27 (comments of Botswana); CRD 28 (comments from IBFAN); CRD 25 (comments of ILCA), CRD 29 (comments of ILCA).

IACFO requested that the name of the product should not imply a health advantage. The label should have no pictures or text which idealise the product in line with Section A 9.6.2.

88. To the question on how to understand the cross-references in Section B, for example to Section A 9.5, it was clarified that in this case all provisions of Section A 9.5 apply to Section B.

89. The Committee inserted the heading for Section 9.5 and introduced Section 10 on methods of analysis and sampling which was omitted previously.

Status of the Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants

90. The Committee recognized that excellent progress had been made on the revision of the Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants and agreed to advance Sections A containing provisions for infant formula and Section B containing provisions for formulas for special medical purposes intended for infants to Step 8 for final adoption by the 30th Session of the Codex Alimentarius Commission (Appendix II).

DRAFT REVISED STANDARD FOR GLUTEN-FREE FOODS AT STEP 7 (Agenda Item 5)[6]

91. The Committee recalled that at its last session it had agreed to return the latest version of the Draft Revised Standard for Gluten-Free Food to Step 6 for comments and consideration by the current session of the Committee.

92. The Observer from the Prolamin Working Group recalled that the Codex Committee on Methods of Analysis and Sampling at its last session had endorsed the R5 Mendez (ELISA) Method as Type I method and informed that new scientific and clinical data were available on how much gluten might be tolerated by celiac patients. The Observer proposed to use the level of 20 mg/kg for naturally gluten free foods and 100 mg/kg for foods rendered gluten-free in Section 2.1 Definition.

93. The Committee considered the document section by section and in addition to editorial corrections made the following comments and changes.

Title

94. The Committee agreed to the proposal of the Delegation of Germany that the title could better describe the content of the Standard and proposed an alternative title for the Standard in square brackets for further comments and consideration "Standard for foods for special dietary uses intended for people with celiac disease".

Scope

95. The Committee agreed to amend the Section 1.1 to clarify that this standard applied for foodstuffs and ingredients that were naturally free of gluten and those which have been specifically prepared to meet the dietary needs of persons intolerant to gluten.

Section 2.1 Definition

96. The Committee agreed to the proposal to refer to the total level of gluten in foods ready for consumption instead of dry weight in sections a), b) and c) of definition and in Section 3.1 of Essential Composition on Gluten-free. It was agreed that levels of gluten should be expressed as mg/kg.

97. The Committee agreed to clarify the introductory sentence of the definition to read: "The products covered by this standard are described as follows" and rearranged the order in sections a) and b) for clarity.

98. The Committee discussed whether oats should be allowed in gluten-free foods. The Observer from PWG indicated that recent scientific data showed that oats can be tolerated by the majority but not all celiac patients and in order to overcome this problem proposed to remove square brackets from the outs in Section 2 a) and to add a footnote with a clarification to that effect. The Observer from AOECS drew the attention of the Committee to the fact that 5% of celiac patients were sensitive to oats and therefore the footnote

[6] CL 2006/5-NFSDU; CX/NFSDU 06/28/5 (comments of Argentina, Brazil, Canada, Costa Rica, European Community, Mexico, Peru, Philippines, United States of America, AAF, AOECS, ISDI, IWGA, WGPAT); CRD 9 (comments of Chile, Indonesia, Philippines, South Africa); CRD 15 (comments of India); CRD 17 (comments of ISDI).

should contain that any consumption of uncontaminated oats should be done under medical control of gastroenterologists.

99. The Committee noted that this was an international standard and it was up to national authorities to decide on the definition of gluten-free foods for dietary management of celiac patients, therefore after some discussion agreed to add the following footnote to the oats:

> "Outs can be tolerated by most but not all people with celiac disease. Therefore, the use of oats not contaminated with gluten permitted in gluten-free foods for dietary management of celiac disease may be determined at national level".

100. The Delegations of Mexico and Observer of AOECS expressed their reservation on leaving this matter for the decision of national authorities, as they pointed out that the inclusion of foods containing oats in the diet has to decided by the treating physician.

101. The Committee considered how to address the description of gluten levels in "gluten free" foods definition. Some delegations proposed to use two thresholds: 20 mg/kg for products naturally free from gluten listed in section 2.1 a), 100 mg/kg for products rendered gluten-free and 100 mg/kg for the mixture of the categories of products.

102. Some delegations indicated that two levels of gluten for "gluten-free" foods might be misleading for consumers and were of the view that only one level of 20 mg/kg should be set for all types of products. The Observer of AOCS recalled that the products described in 2.1 b) and c) are wheat starch based products and consequently when wheat starch based is below 100 mg/kg, the final product as consumed contains considerable lower gluten traces, therefore the AOECS internal standard, which is 20 mg/kg for the term "gluten-free", allows also these few wheat starch based products to be called gluten-free; and national authorities can see in the ingredient list, whether or not gluten-free rendered wheat starch is used.

103. The Committee noted the proposal of the Delegation of Finland, speaking on behalf of the member states present at the current session, that the matter of one or two levels of gluten and how to use the names of products described in Section 2.1 Description could be addressed in the Labelling Section therefore included two sentences in Section 4.1 to that effect. Some delegations did not agree with this proposal. Some delegations indicated that the definition should make a clear distinction between products, therefore additional sentences to the Section on Labeling alone could not solve the problem. After some debate, the Committee agreed to add new sentences in square brackets for further comments and consideration. The Delegation of the United States requested clarification on the appropriate use of terms "gluten" and "prolamins" in this standard.

104. The Committee agreed that the issue of levels required further consideration and agreed to put the value of 20 mg/kg for section 2.1 a) and value for 100 mg/kg for sections b) and c) in square brackets.

105. In Section 3.2 the Committee agreed to refer to "products covered by this standard" rather than "gluten-free" foods for clarification purposes.

106. The Committee recognized that consensus could not be reached at the present session and considered how to proceed with the further revision of the Standard.

107. Some delegations were of the view that despite time constraints the Committee made a good progress and that few unresolved issues remained and urged the Committee to work further in order to try to finalize the Standard. Some other delegations indicated that this standard had not been considered for long time and that substantive work was needed to ensure that new developments were incorporated in the standard. After some discussion, the Committee noted that further additional work was necessary in all sections and decided not to pursue the consideration of the Standard at the current session. It was suggested to ask additional comments and set up an electronic working group to prepare a revised version for comments and consideration by the next session of the Committee. The Secretariat drew the attention of the Committee to the difficulties faced by some electronic working groups and that in case of late comments it was not always possible for such working groups to prepare documents in time.

Status of the draft revision of the Standard for Gluten-Free Foods

108. The Committee agreed to return the Draft Revised Standard for Gluten-Free Foods to Step 6 for further comments (see Appendix IV). The Committee also agreed to convene a physical working group Chaired by Sweden and co-chaired by Canada before the next Session of the Committee to review the comments

received and to prepare proposals in order to assist the Plenary in finalizing the Standard at the next Session of the Committee.

PROPOSED DRAFT REVISION OF THE ADVISORY LIST OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR THE USE BY INFANTS AND YOUNG CHILDREN AT STEP 4 (Agenda Item 6)[7]

109. The Committee recalled that at its last session it agreed to return the above list to Step 3 for comments, especially requesting Member Countries to provide a list of their purity requirements and information that addresses how the nutrient compound satisfies or does not satisfy the criteria in Section 2.1 for inclusion or deletion in the list; and that it had requested the Delegation of Germany to revise the advisory list in view of these comments.

110. The Delegation of Germany introduced the document and described changes made to the document based on discussions at the last session and in response to numerous comments received. The Delegation pointed out that in order to progress with further elaboration of the document it was necessary to agree how to deal with nutrient compounds for which no internationally or nationally recognized purity requirements existed which had been introduced to the list, that it was necessary to decide on the final structure of the list from the three options presented in the document and on introduced list of amino acids and advisory list of food additives for use as nutrient carriers which were reflected in separate lists of the document. The Delegation indicated that sections and provisions for which decisions should be taken were presented in grey and in square brackets for easier reference.

111. The Committee expressed its appreciation to the Delegation of Germany for the excellent work done and agreed to concentrate discussion only on those sections comments were received and square brackets existed. In addition to editorial and formatting corrections the Committee made the following changes and recommendations on the following sections.

Title

112. The Committee clarified the title to read: "Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children".

Section 2.2

113. The Committee agreed to add a sentence at the end of the paragraph to clarify that a country proposing to add or delete a nutrient compound to the list was responsible for submitting information on how proposed compound met criteria in Section 2.1.

114. The Committee decided to use the format presented as the third option in the document and amended the heading of the last column and first column of Infant Formula to include Section A and B and to clarify that it applied for foods for special medical purposes intended for infants and young children.

Section A Mineral Salts and Trace Elements

Section 1. Source of calcium

115. The Committee noted that there were no specific uses proposed for calcium pyrophosphate listed in Section 1.12 therefore decided to delete it from the list and clarified the use of calcium sulfate.

116. The Committee clarified uses for ferrous succinate (Section 2.15), ferrous bisglycinate(Section 2.16) and ferric orthophosphate (Section 2.17).

117. The Committee noted that it was not clear which elements were used for iodization of sodium chloride therefore deleted it from the list and clarified the uses of sodium sulphate and sodium tartarate.

Substances without purity criteria

118. It was noted that copper-lysine complex did not have international or national purity criteria, therefore the Committee considered how to proceed with substances for which there were no specific purity

[7] CX/NFSDU 06/28/6-Revised; CX/NFSDU 05/26/6-Add.1 (comments of Brazil, United States of America, Vietnam, AIDGUM, ISDI); CRD 10 (comments of the European Community, Thailand); CRD 15 (comments of India); CRD 18 (comments of Peru).

requirements established at international or national level and decided to retain these provisions in square brackets and to encourage countries to submit criteria until the next session of the Committee.

119. The Committee clarified uses for sodium selenite and selenate compounds. It was noted that there were purity criteria for these substances in Denmark.

120. The Delegation of South Africa indicated that fluoride was not an essential element and suggested to take it out from the list, however the Committee noted that there might be particular conditions for their use in some products, therefore retained on the list for the use in Section B of infant formula and foods for special medical purposes intended for infants and young children. The Delegation of South Africa expressed its reservation to this decision.

121. The Committee noted that only L-amino acids might be used and accepted the proposal of the Delegation of United States to clarify footnote 7 regarding the applicability of some compounds in the list for FSMP and clarified the uses for some amino acids.

122. The Committee clarified uses for lecithin and some nucleotide compounds and deleted purity references for some nucleotides.

Section C Amino Acids and Other Nutrients

Section 8 Antioxidants and Section 9 Other Compounds

123. It was noted US GRAS was not an appropriate reference for purity criteria. The category of antioxidants contained in Section 8 and Other Compounds in Section 9 were deleted from the list.

124. The Committee deleted in List B cholecalciferol cholesterol and pyridoxamine because of the lack of official purity criteria.

125. The Committee decided to leave S-Adenosyl-L-methionine in FSMP in square brackets.

Section D Advisory List of Food Additives for Special Nutrient Forms

126. The Committee clarified the title of Section D to refer to "nutrient" compounds rather than to "vitamin".

127. The Committee agreed to clarify uses of nutrients and food additives in introductory paragraph of Section D, and that the additives in the list may be used as nutrient carriers as proposed by the Delegation of the European Community.

128. It was proposed to increase the level of uses for Gum Arabic (gum acacia) from 10 mg/kg to 100 mg/kg due to technological reasons and reflect the level in the current standard. However, no agreement was reached on this proposal, therefore the Committee decided to put both figures in square brackets.

129. The Committee agreed to send the Section D for endorsement to CCFA as these additives were in addition to those allowed in the respective standards.

Status of the revision of the advisory list of nutrient compounds for use in foods for special dietary uses intended for the use by infants and young children

130. The Committee noted significant progress made on the revision of the list and agreed to advance the list to the 30th Session of the Commission for adoption at Step 5 (see Appendix V). The Committee was of the view that the work on the revision of the Lists could be completed during two subsequent sessions of the Committee.

PROPOSED DRAFT RECOMMENDATIONS ON THE SCIENTIFIC BASIS OF HEALTH CLAIMS AT STEP 4 (Agenda Item 7)[8]

131. The Delegation of France introduced the Proposed Draft Recommendations that had been redrafted with the assistance of a drafting group and circulated for comments, following the decision of the last session of the Committee. The Delegation presented a summary of the work done on the basis of comments received and sought advice from the Committee in order to progress further in the elaboration of the document: whether the health claims should be applicable to a food/food component or all diet; and how to assess the

[8] CX/NFSDU 06/28/7, CX/NFSDU 06/28/7-Add.1 (comments of Argentina 1 and 2, Australia, Bolivia, Brazil, Guatemala, Kenya, New Zealand, United States of America, CIAA, IADSA, ISDI, WSRO), CRD 11 (comments of Chile, Malaysia, Mexico, Thailand, United States of America), CRD 15 (comments of India).

strength of evidence required to justify health claims, and how to proceed with reevaluation of health claims. In view of time constraints, the Delegation suggested that the proposed draft Recommendations should be added to as Appendix to the current Guidelines for the Use of Nutrition and Health Claims. and that the document be retained at Step 4.

132. The Committee noted comments from some delegations that health claims were intended for foods or food constituents but not for whole diets and that provisions related to healthy diets were presented in Section 8 of the Guidelines for Use and Nutrition and Health Claims. In addition, these Codex guidelines provided for a total diet contained health claims language. Therefore, the Committee agreed to limit the scope for health claims to foods/food constituents.

133. As regards the strength of evidence to justify health claims, it was pointed out that this Annex should focus on procedures for the review of scientific evidence for substantiation of health claims.

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

134. The Committee agreed to retain the Proposed Draft Recommendations at Step 4 for further consideration at the next session.

DISCUSSION PAPER ON THE PROPOSALS FOR ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES (Agenda Item 8)[9]

135. The Committee recalled that an electronic working group coordinated by the Delegation of South Africa was requested to revise the discussion paper on Nutrient Reference Values (NRVs) for labelling purposes by addressing the following issues: to set up principles for the establishment of NRVs, and the need to establish NRVs for different population groups.

136. The Delegation of South Africa introduced the revised document, which overviewed the existing situation and current practices in member countries; criteria for establishing NRVs for food labeling purposes and use of NRVs by national authorities and the basis for NRVs in different countries. The Delegation drew the attention of the Committee to the importance of agreeing on criteria identified in the paper and on the number of NRV populations groups as well as on how the protein NRV should be updated. The Delegation indicated that it had no capacity or resources to continue working on this document.

137. The Committee thanked the Delegation of South Africa for their excellent work and, in view of time constraints, considered how to progress this work.

138. The Committee noted the proposal of the Delegation of the European Community that the revision of NRVs was very important work and should be continued in order to establish NRVs for adult population and infants from 6 to 36 month and that the work should focus on establishing NRVs for vitamins and minerals.

139. The Committee accepted the kind offer of the Delegation of Republic of Korea to lead further work on this matter with the understanding that a revised paper would be considered at the next session of the Committee.

DISCUSSION PAPER ON THE APPLICATION OF RISK ANALYSIS FOR THE WORK OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (Agenda Item 9)[10]

140. The Committee recalled that the last session had agreed that the Electronic Working Group led by Australia would further develop the Discussion Paper on the Application of Risk Analysis for the Work of the Committee.

141. The Chairperson of the Committee expressed appreciation to Australia for very high quality of paper and in view of time constraints suggested to have a very brief discussion.

142. The Delegation of Australia proposed that the Committee, accepts in principle, the 15 recommendations in the discussion paper; agree to forward the proposal for new work given in Attachment II to the 30th Session of the Commission in 2007 and agree to continue the work of the Electronic Working Group, led by

[9] CX/NFSDU 06/28/8; CRD 12 (Summary of inputs received from Working Group members on the revision and addition of NRVs for food labeling purposes during 2004 to 2005, with special focus on the criteria for establishing NRVs); CRD 13 (comments of the United States of America, Thailand); CRD 15 (comments of India).
[10] CX/NFSDU 06/28/9; CRD 14 (comments of Chile).

Australia, with new Terms of Reference to develop and present draft principles for application of risk analysis to the work of the CCNFSDU.

143. After a short discussion the Committee agreed to start new work on the establishment and application of risk analysis principles by the Committee on Nutrition and Food for Special Dietary Uses. The Project Document, prepared by Australia and presented in CX/NFSDU 06/28/9 would be forwarded to the 30th Session of the Commission for consideration of new work proposals.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 10):

IMPLEMENTATION OF THE WHO GLOBAL STRATEGY ON DIET, PHYSICAL ACTIVITY AND HEALTH[11]

144. The Committee recalled that the 29th Session of the Commission in July 2006 had considered this matter and that CAC agreed that WHO and FAO would complete a document containing concrete proposals for possible actions by Codex and that it would be circulated for comments to all Codex Contact Points. The comments received together with the document itself, would be considered by the next sessions of the CCNFSDU and CCFL. The views and recommendations of these Committees would then be forwarded to the 30th Session of the Commission for further guidance.

145. The Representative of WHO, while presenting the document, recalled that the contributions received in the electronic forum convened in early 2006 had been useful to update and focus the proposals for action in the framework of Codex, especially as regards nutrition and labelling, and thanked members and observers for their active participation and support in the process. The Representative drew the attention of delegates to the recommendations which were more relevant to the Committee and highlighted the importance of scientific advice and information to Codex work in the area of nutrition.

146. The Committee agreed with the proposal of the Chair to concentrate its discussions on the recommendations put forward in section B of CL 2006/44-CAC.

147. In reply to some questions and suggestions on how to coordinate Codex work in the implementation of the Global Strategy, set work priorities, and ensure coordination between Committees, the Chair and the Secretariat recalled that the CCNFSDU and CCFL would report to the Commission on their conclusions, including proposals for new work and that the Commission exercised overall coordination and provided general orientation throughout Codex work. As regards priorities for new work, the Criteria for the establishment of Work Priorities applied to Codex Committees and the Executive Committee considered all items of new work prior to the Commission as part of the Critical Review. As regards direct interaction between committees, this was achieved through the standing item on "matters referred" that allowed each committee to put forward questions or requests for specific action to another committee, as required.

Nutrition Labelling

148. The Committee considered the recommendation on nutrient labelling "Develop NRVs for nutrients that are associated with both increased and decreased risk of non communicable diseases"

149. Several delegations supported continued work on the NRVs, that was also under consideration at the present session. Some delegations were of the view that work on the NRVs should be extended to cover nutrients associated with increased and decreased risk of non communicable diseases, and that principles for the establishment of NRVs should be developed. Other delegations proposed to initiate work on NRVs with the revision of the values for vitamins and minerals and to consider the addition of new nutrients at a later stage. The Committee discussed the use that would be made of updated and additional nutrient values, in view of the current basis for nutrient declaration in the Guidelines on Nutrition Labelling. The Committee also noted that footnote to section 3.4.4 of the Guidelines on Nutrition Labelling specified that the list of nutrient reference values should be kept under review in order to take into account scientific developments.

150. The Committee agreed to proceed with the consideration of the revision of the NRVs for vitamins and minerals and to ask the Committee on Food Labelling its advice concerning the revision and extension of the list of NRVs in the Guidelines for Nutrition Labelling to other nutrients associated with increased and

[11] CL 2006/44-CAC; CRD 3 (comments of South Africa); CRD 22 (comments of Malaysia), CRD 24 (comments of ICGMA), CRD 26 (comments of Bolivia, Canada, Japan, Mexico, New Zealand, United States, IACFO, IADSA, ICBA, IDF), CX/NFSDU 06/28/10, CX/NFSDU 06/28/11,CRD 21 (Proposal of Thailand), CRD 15 (Proposal of India).

decreased risk of non communicable diseases. The Committee agreed that if this reply was positive it would consider new work on the revision and extension of the list to relevant nutrients at its next session.

Nutrition Claims (trans fatty acids)

151. The Committee considered whether to develop condition for claims for trans fatty acids and include restrictions on both saturated and trans fatty acids in the conditions for comparative claims for these nutrients.

152. The Delegation of Denmark informed the Committee that Denmark has introduced a national regulation setting a maximum limit for the content of trans fatty acids in oils and fats.

153. The Delegation of the United States expressed the view that the issue of nutrition claims that included criteria for trans fatty acids was already addressed to a certain extend in the Guidelines for Use of Nutrition and Health Claims in the Table of Conditions for Claims, in the footnote to the condition for saturated fat and cholesterol . The Observer of IACFO supported the establishment of maximum limits for trans fatty acids. The Observer from IDF pointed out that there was insufficient scientific justification to classify all trans fatty acids as having negative effects on health and that not all saturated fats caused adverse effects and that nutrition claims should be based on science.

154. The Committee concluded that there was no support from members to initiate work in this area.

Production and Processing Standards Regarding the Nutritional Quality and Safety of Foods

155. The Delegation of Canada expressed its support for proposed action 5.1 and in this regard supported the FAO/WHO recommendation to consider reviewing and re-establishing the Guidelines for the Use of Codex Committees on the Inclusion of Provisions on Nutritional Quality in Food Standards and Other Codex Texts, included in the Procedural Manual until their revocation by the Commission in 1997. The Committee noted that this text had been deleted from the Procedural Manual was reviewed to convert specific instructions to Committees into guideline for governments.

156. The Delegation of the EC questioned the approach that would be taken in such Guidelines as compared with the current horizontal approach to food law in many countries, and noted that the exact purpose and use of the Guidelines should be clarified. Other delegations also expressed the view that some clarification was necessary on the nature and scope of this proposal, and their relationship with national nutrition policies should be discussed in more detail. The Committee therefore agreed that the delegation of Canada would prepare a document providing more explanations on the development of such guidelines, for consideration at the next session.

PROPOSALS FOR NEW WORK

Revision of the Standard for Processed Cereal-Based Foods (Section 3.4)

157. The Delegation of Thailand recalled that it had expressed its reservation when the 29th Session of the Commission adopted the Standard for Cereal based Foods for Infants and Young Children, as it did not support the amount of sugars allowed under current section 3.4 of the Standard, and that the Commission had agreed to request the CCNFSDU to evaluate the need to revise section 3.4 of the adopted standard in the light of the recommendation of the Global Strategy. The Delegation pointed out that high sugar contents in foods for infants and young children was a risk factor mentioned specifically in paragraph 22 of the Global Strategy and also enhanced sweet taste preference and the risk of dental caries in children, and therefore proposed to revise and reduce the current level of sugars in section 3.4. This proposal was supported by the delegations of Norway and South Africa and some observers.

158. The Delegation of the European Community, supported by the Delegation of the United States, recalled that the revision of the Standard for Cereal Based Foods had been finalized after many years of extensive discussions and it did not appear necessary to undertake its revision immediately. The Delegation recalled that the recommendation of the goal of 10% sugars of the total energy sugars was an intake population goal and should not be interpreted as a nutrient level in specific food, and pointed out that cereal based foods was part of a diversified diet, which had been taken into account when establishing nutrient provisions.

159. The Committee agreed not to undertake new work on the revision of the Standard for Cereal Based Foods at this stage, and noted that this question maybe reconsidered when more experience had been gained with the application of the standard.

Revision of the Standard for Processed Cereal-Based Foods (Sections 3.2, 3.3, and 3.4)

160. The Delegation of India recalled that it had expressed its reservation when the 29th Session of the Commission adopted the Standard for Processed Cereal-Based Foods for Infants and Young Children, as it did not support the minimum cereal content, energy density and minimum protein content in the Standard. The Commission had agreed to request the CCNFSDU to evaluate the need to revise sections 3.2, 3.3 and 3.4 of the adopted standard. The Delegation stressed the need to bear in mind the objective of reducing malnutrition while considering nutrient contents in the relevant standards, and therefore made the following proposals: to increase the cereal content to 50% instead of 25% to ensure adequate nutrient intake; to increase the energy density to 4-5 kcal/g on a dry weight basis; and to increase the protein content to 15%. This proposal was supported by the Delegation of Norway.

161. The Observer of ESGHAN proposed to form an Ad Hoc Working Group to review the scientific basis and health effects of the nutrient composition of complimentary food products. The delegations of Norway and Thailand supported this proposal.

162. The Delegation of the European Community expressed the view that the nutrient content of cereal based foods had been extensively discussed, including the issues raised by India, and that the standard was intended for the general population, in which case an increased level of protein could result in excessive protein intake.

163. The Committee recognized that there was no support to undertake new work on the revision of the standard.

Proposal for new work to amend the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987)[12]

164. The Delegation of Canada indicated that the General Principles were adopted in 1987 and since then there were changed approaches or philosophies related to controlling the addition of vitamin and minerals for foods, changes in technologies employed for achieving addition or enhancement of vitamin and mineral levels in foods and an increased interest in the addition to foods of non-nutrient bioactive substances. The Delegation pointed out that all these suggest that a review of the General Principles may be timely to ensure that these principles continue to be relevant and useful.

165. The Delegation proposed new work that would address three separate issues within the Principles: non-traditional addition of vitamins and minerals to foods; discretionary addition of vitamins and minerals to food to provide consumers with a greater variety of foods with added vitamin and mineral nutrients and addition of bioactive substances that are essential constituents to foods. The Delegation indicated that the document contains details necessary for project document and work would be in line with the terms of reference and Strategic Objectives of the Commission.

166. The Committee accepted the offer of the Delegation of Canada to prepare a discussion paper which would address these issues for consideration by the next session of the Committee.

AVE ATQUE VALE

167. The Committee noted the forthcoming retirement of Prof Hildegard Przyrembel (Germany), long standing Chairperson of the Working Group on the Infant Formula after long years of contribution to the work of the Codex Committee on Nutrition and Foods for Special Dietary Uses. The Committee expressed its sincere appreciation for her long and devoted work to the goals of the Committee and wished her good health and long life in the years to come.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 11)

168. The Committee was informed that the 29th session would take place in Bad Neuenahr, Germany, scheduled from 12 to 16 November 2007, subject to confirmation by the host government and the Codex Secretariat.

[12] CX/NFSDU 06/28/11

SUMMARY STATUS OF WORK

Subject Matter	Step	For Action by	Reference in ALINORM 07/30/26
Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants Section A: Draft Revised Standard for Infant Formula	8	Governments, 30th CAC	para. 90 and Appendix II
Formulas for Special Medical Purposes Intended for Infants Section B: Formulas for Special Medical Purposes Intended for Infants	8	Governments, 30th CAC	para. 90 and Appendix II
Guidelines for Use of Nutrition Claims: Draft Table of Contents for Nutrient Contents (Part B Containing Provisions on Dietary Fibre)	6	Governments; 29th CCNFSDU	para. 22
Draft Revised Standard for Gluten-Free Foods	6	Governments; 29th CCNFSDU	para. 108 and Appendix IV
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	5	30th CAC; Governments; 29th CCNFSDU	para. 130 and Appendix V
Proposed Draft Recommendations on the Scientific Basis of Health Claims	4	29th CCNFSDU	para. 134
Discussion Paper on the Proposals for Additional or Revised Nutrient Reference Values (NRVs)	-	Republic of Korea; 29th CCNFSDU	paras 135-139
Discussion paper on the Proposal for New Work to Amend the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987)	-	Canada; 29th CCNFSDU	paras 164-166
New work			
Establishment and Application of Risk Analysis Principles by the Codex Committee on Nutrition and Foods for Special Dietary Uses. Project document is available in Annex of CX/NFSDU 06/28/8.	-	30th CAC; Australia; Governments; 29th CCNFSDU	paras 140-143

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APPENDIX II

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

SECTION A: DRAFT REVISED STANDARD FOR INFANT FORMULA

(At Step 8 of the Procedure)

PREAMBLE:

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.

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

1.3 Only products that comply with the criteria laid down in the provisions of this section 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.

1.4 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).

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 product 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 or a mixture thereof and/or other ingredients which have been proven to be suitable for infant feeding. The nutritional safety and

adequacy of infant formula shall be scientifically demonstrated to support growth and development of infants. All ingredients and food additives 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 kcal (295 kJ) of energy.

3.1.3 Infant formula prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GUL)[1], as appropriate. The general principles for establishing these levels are identified in Annex II of this standard.

a) Protein[2), 3), 4)]

Unit	Minimum	Maximum	GUL
g/100 kcal	1.8 [5), 6)]	3.0	-
g/100 kJ	0.45 [5), 6)]	0.7	-

[2)] For the purpose of this standard, the calculation of the protein content of the final product prepared ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. The value of 6.38 is generally established as a specific factor appropriate for conversion of nitrogen to protein in other milk products, and the value of 5.71 as a specific factor for conversion of nitrogen to protein in other soy products.

[3)] 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 I); nevertheless for calculation purposes, the concentrations of tyrosine and phenylalanine may be added together. The concentrations of methionine and cysteine may be added together if the ratio is less than 2:1; in the case that the ratio is between 2:1 and 3:1 the suitability of the formula has to be demonstrated by clinical testing.

[4)] 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.

[5)] The minimum value applies to cows' milk protein. For infant formula based on non-cows' milk protein other minimum values may need to be applied. For infant formula based on soy protein isolate, a minimum value of 2.25 g/100 kcal (0.5 g/100 kJ) applies.

[6)] Infant formula based on non-hydrolysed milk protein containing less than 2 g protein/ 100 kcal and infant formula based on hydrolysed protein containing less than 2.25 g protein/ 100 kcal should be clinically evaluated.

b) Lipids

Total fat [7, 8)]

Unit	Minimum	Maximum	GUL
g/100 kcal	4.4	6.0	-
g/100 kJ	1.05	1.4	-

[7)] Commercially hydrogenated oils and fats shall not be used in infant formula.

[8)] Lauric and myristic acids are constituents of fats, but combined shall not exceed 20% of total fatty acids. The content of trans fatty acids shall not exceed 3 % of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in infant

[1] Guidance upper levels are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in infant formulas should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs.

formulae. The erucic acid content shall not exceed 1% of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).

Linoleic acid

Unit	Minimum	Maximum	GUL
mg/100 kcal	300	-	1400
mg/100 kJ	70	-	330

α-Linolenic acid

Unit	Minimum	Maximum	GUL
mg/100 kcal	50	N.S.	-
mg/100 kJ	12	N.S.	-

N.S. = not specified

Ratio linoleic/ α-linolenic acid

Min	Max
5:1	15:1

c) Carbohydrates

Total carbohydrates[9)]

Unit	Minimum	Maximum	GUL
g/100 kcal	9.0	14.0	-
g/100 kJ	2.2	3.3	-

[9)] Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by nature may be added to Infant Formula up to 30% of total carbohydrates and up to 2 g/100 ml.
Sucrose, unless needed, and the addition of fructose as an ingredient should be avoided in infant formula, because of potential life-threatening symptoms in young infants with unrecognised hereditary fructose intolerance.

d) Vitamins

Vitamin A

Unit	Minimum	Maximum	GUL
µg RE[10)]/100 kcal	60	180	-
µg RE[10)]/100 kJ	14	43	-

[10)] expressed as retinol equivalents (RE).
1 µg RE = 3.33 IU Vitamin A = 1 µg all-trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

Vitamin D_3

Unit	Minimum	Maximum	GUL
µg[11)]/100 kcal	1	2.5	-
µg[11)]/100 kJ	0.25	0.6	-

[11)] Calciferol. 1 µg calciferol = 40 IU vitamin D

Vitamin E

Unit	Minimum	Maximum	GUL
mg α-TE[12)]/100 kcal	0.5[13)]	-	5
mg α-TE[12)]/100 kJ	0.12[13)]	-	1.2

[12)] 1 mg α-TE (alpha-tocopherol equivalent) = 1 mg d-α-tocopherol

[13)] Vitamin E content shall be at least 0.5 mg α-TE per g PUFA, using the following factors of equivalence to adapt the minimal vitamin E content to the number of fatty acid double bonds in the formula: 0.5 mg -TE/g linoleic acid (18:2 n-6); 0.75 α-TE/g α-linolenic acid (18:3 n-3); 1.0 mg α-TE/g arachidonic acid (20:4 n-6); 1.25 mg α-TE/g eicosapentaenoic acid (20:5 n-3); 1.5 mg α-TE/g docosahexaenoic acid (22:6 n-3).

Vitamin K

Unit	Minimum	Maximum	GUL
µg/100 kcal	4	-	27
µg/100 kJ	1	-	6.5

Thiamin

Unit	Minimum	Maximum	GUL
µg/100 kcal	60	-	300
µg/100 kJ	14	-	72

Riboflavin

Unit	Minimum	Maximum	GUL
µg/100 kcal	80	-	500
µg/100 kJ	19	-	119

Niacin[14)]

Unit	Minimum	Maximum	GUL
µg/100 kcal	300	-	1500
µg/100 kJ	70	-	360

[14)] Niacin refers to preformed niacin.

Vitamin B_6

Unit	Minimum	Maximum	GUL
µg/100 kcal	35	-	175
µg/100 kJ	8.5	-	45

Vitamin B_{12}

Unit	Minimum	Maximum	GUL
µg/100 kcal	0.1	-	1.5
µg/100 kJ	0.025	-	0.36

Pantothenic acid

Unit	Minimum	Maximum	GUL
µg/100 kcal	400	-	2000
µg/100 kJ	96	-	478

Folic acid

Unit	Minimum	Maximum	GUL
µg/100 kcal	10	-	50
µg/100 kJ	2.5	-	12

Vitamin C[15)]

Unit	Minimum	Maximum	GUL
mg/100 kcal	10	-	70[16)]
mg/100 kJ	2.5	-	17[16)]

[15)] expressed as ascorbic acid

[16)] This GUL has been set to account for possible high losses over shelf-life in liquid formulas; for powdered products lower upper levels should be aimed for.

Biotin

Unit	Minimum	Maximum	GUL
µg/100 kcal	1.5	-	10
µg/100 kJ	0.4	-	2.4

e) Minerals and Trace Elements

Iron

Unit	Minimum	Maximum	GUL[17)]
mg/100 kcal	0.45	-	-
mg/100 kJ	0.1	-	-

[17)]Levels may need to be determined by national authorities.

Calcium

Unit	Minimum	Maximum	GUL
mg/100 kcal	50	-	140
mg/100 kJ	12	-	35

Phosphorus

Unit	Minimum	Maximum	GUL
mg/100 kcal	25	-	100[18)]
mg/100 kJ	6	-	24[18)]

[18)] This GUL should accommodate higher needs with soy formula.

Ratio calcium/ phosphorus

Min	Max
1:1	2:1

Magnesium

Unit	Minimum	Maximum	GUL
mg/100 kcal	5	-	15
mg/100 kJ	1.2	-	3.6

Sodium

Unit	Minimum	Maximum	GUL
mg/100 kcal	20	60	-
mg/100 kJ	5	14	-

Chloride

Unit	Minimum	Maximum	GUL
mg/100 kcal	50	160	-
mg/100 kJ	12	38	-

Potassium

Unit	Minimum	Maximum	GUL
mg/100 kcal	60	180	-
mg/100 kJ	14	43	-

Manganese

Unit	Minimum	Maximum	GUL
µg/100 kcal	1	-	100
µg/100 kJ	0.25	-	24

Iodine

Unit	Minimum	Maximum	GUL
µg/100 kcal	10	-	60
µg/100 kJ	2.5	-	14

Selenium

Unit	Minimum	Maximum	GUL
µg/100 kcal	1	-	9
µg/100 kJ	0.24	-	2.2

Copper [19)]

Unit	Minimum	Maximum	GUL
µg/100 kcal	35	-	120
µg/100 kJ	8.5	-	29

[19)] Adjustment may be needed in these levels for infant formula made in regions with a high content of copper in the water supply.

Zinc

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.5	-	1.5
mg/100 kJ	0.12	-	0.36

f) Other Substances

Choline

Unit	Minimum	Maximum	GUL
mg/100 kcal	7	-	50
mg/100 kJ	1.7	-	12

Myo-Inositol

Unit	Minimum	Maximum	GUL
mg/100 kcal	4	-	40
mg/100 kJ	1	-	9.5

L-Carnitine

Unit	Minimum	Maximum	GUL
mg/100 kcal	1.2	N.S.	-
mg/100 kJ	0.3	N.S.	-

3.2 Optional ingredients

3.2.1 In addition to the compositional requirements listed under 3.1.3, 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 or to provide other benefits that are similar to outcomes of populations of breastfed babies.

3.2.2 The suitability for the particular nutritional uses of infants and the 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 The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100 kJ) in the Infant Formula ready for consumption shall not exceed:

Taurine

Unit	Minimum	Maximum	GUL
mg/100 kcal	-	12	-
mg/100 kJ	-	3	-

Total nucleotides
Levels may need to be determined by national authorities.

Docosahexaenoic Acid [20)]

Unit	Minimum	Maximum	GUL
% of fatty acids	-	-	0.5

[20)] If docosahexaenoic acid (22:6 n-3) is added to infant formula, arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. National authorities may deviate from the above conditions, as appropriate for the nutritional needs.

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

3.3 Fluoride

Fluoride should not be added to infant formula. In any case its level should not exceed 100 µg /100 kcal (24µg/100 kJ) in infant formula prepared ready for consumption as recommended by the manufacturer.

3.4 Vitamin Compounds and Mineral Salts

Vitamins and minerals added in accordance with Section 3.1.3 (d and e) and other nutrients added in accordance with 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).

3.5 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.

3.6 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.

3.7 Specific Prohibitions

The product and its component shall not have been treated by ionizing irradiation.

4. FOOD ADDITIVES

Only the food additives listed in this Section or in the Codex Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979) may be present in the foods described in section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

a) The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and

b) The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CAC/STAN 192-1995).

The following food additives are acceptable for use in the preparation of infant formula, as described in Section 2.1 of this Standard (in 100 ml of product, ready for consumption prepared following manufacturer's instructions, unless otherwise indicated):

	INS no.	Additive	Maximum level in 100 ml of the product ready for consumption	Technological Justification
4.1 Thickeners				
4.1.1	412	Guar gum	0.1 g in liquid formulas containing hydrolysed protein	Retains homogeneity
4.1.2	410	Carob bean gum (Locust bean gum)	0.1 g in all types of infant formula	Retains homogeneity
4.1.3	1412	Distarch phosphate	0.5 g singly or in combination in soy-based infant formula only	Retains homogeneity
4.1.4	1414	Acetylated distarch phosphate		Retains homogeneity
4.1.5	1413	Phosphated distarch phosphate	2.5 g singly or in combination in hydrolyzed protein- and/or amino acid based infant formula only	Retains homogeneity
4.1.6	1440	Hydroxypropyl starch		Retains homogeneity
4.1.7	407	Carrageenan[21)]	0.03 g in regular milk- and soy-based liquid infant formula only 0.1 g in hydrolysed protein- and/or amino acid based liquid infant formula only	Retains homogeneity
4.2 Emulsifiers				
4.2.1	322	Lecithins	0.5 g in all types of infant formula[22)]	Retains homogeneity
4.2.2	471	Mono- and diglycerides	0.4 g in all types of infant formula[22)]	Retains homogeneity
4.3 Acidity Regulators				
4.3.1	524	Sodium hydroxide	0.2 g singly or in combination and within the limits for sodium, potassium and calcium in section 3.1.3 (e) in all types of infant formula	pH adjustment
	INS no.	**Additive**	**Maximum level in 100 ml of the product ready for consumption**	**Technological Justification**
4.3.2	500ii	Sodium hydrogen carbonate		pH adjustment

[21)] Evaluation by JECFA is pending. National authorities may restrict its use until JECFA evaluation has been completed.
[22)] If more than one of the substances INS 322, 471 are added the maximum level for each of those substances is lowered with the relative part as present of the other substances

	INS no.	Additive	Maximum level in 100 ml of the product ready for consumption	Technological Justification
4.3.3	500i	Sodium carbonate	0.2 g singly or in combination and within the limits for sodium, potassium and calcium in section 3.1.3 (e) in all types of infant formula	pH adjustment
4.3.4	525	Potassium hydroxide		pH adjustment
4.3.5	501ii	Potassium hydrogen carbonate		pH adjustment
4.3.6	501i	Potassium carbonate		pH adjustment
4.3.7	526	Calcium hydroxide		pH adjustment
4.3.12	270	L(+) lactic acid	Limited by GMP in all types of infant formula	pH adjustment
4.3.13	330	Citric acid	Limited by GMP in all types of infant formula	pH adjustment
	331	Sodium citrate	Limited by GMP in all types of infant formula	pH adjustment
	332	Potassium citrate	Limited by GMP in all types of infant formula	pH adjustment
4.4 Antioxidants				
4.4.2	307b	Mixed tocopherol concentrate	1 mg in all types of infant formula singly or in combination	Protects from oxidation
4.4.3	304i	L-Ascorbyl palmitate	1 mg in all types of infant formula singly or in combination	Protects from oxidation
4.9 Packing Gases				
4.9.1	290	Carbon dioxide	GMP	Used to pack under inert atmosphere Protect nutrient quality and guarantee product shelf life
4.9.2	941	Nitrogen		

5. CONTAMINANTS

5.1 Pesticide Residues

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

5.2 Other Contaminants

The product shall 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), 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

The requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985), the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985) and the Guidelines for Use of Nutrition and Health Claims apply to infant formula and formula for special medical purposes for infants. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation. In addition to these requirements the following specific provisions apply:

9.1 The Name of the Food

9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

9.1.2 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.

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

9.1.4 If cows' milk is the only source of protein, the product may be labelled "Infant Formula Based on Cows' Milk".

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

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 minerals, these ingredients may be arranged as separate groups for vitamins and minerals. 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 which should be 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 or per 100 milliliters of the food as sold as well as per 100 milliliters 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 3.1.3 and any other ingredient as listed in paragraph 3.2 of this Standard per 100 grammes or per 100 milliliters of the food as sold as well as per 100 milliliters 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 Products in liquid form may be used either directly or in the case of concentrated liquid products, must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that formula remaining after feeding should be discarded, shall appear on the label and in any accompanying leaflet.

9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.

9.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.

9.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label and in any accompanying leaflet.

9.6 Additional Labelling Requirements

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

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

b) the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk;

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.

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.

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 complementary 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.

10. METHODS OF ANALYSIS AND SAMPLING

Analyte	Method
Dietary fibre, total	AOAC 991.43
Iodine (milk-based formula)	AOAC 992.24
Pantothenic acid	AOAC 992.07
Vitamin A (retinol)	AOAC 992.04
Vitamin A (retinol)	AOAC 992.06
Vitamin K	AOAC 992.27
Vitamin D (D_3, milk based infant formula)	AOAC 992.26
Vitamin E - milk-based formula	AOAC 992.03
Vitamin B12	AOAC 986.23
Vitamin B6	AOAC 985.32
Vitamin C	AOAC 985.33
Determination of Choline	AOAC 999.14
Determination of Vitamin K	AOAC 999.15
Detection of Irradiated foods	Codex general methods
Determination of Lead	Codex general methods
Calcium	AOAC 984.27
Chloride	AOAC986.26
Carbohydrates	method described in CAC/VOL IX Ed 1, Part III
Crude protein	Method described in CAC/VOL IX Ed 1, Part III
Fat	CAC/RM 55-1976
Fatty Acids	AOAC 996.06
Fill of containers	CAC/RM 46-1972
Folic acid	AOAC 992.05.
Linoleic acid	AOAC 992.25
Niacin and nicotinamide	AOAC 985.34
Phosphorus	AOAC 986.24
Protein efficiency ratio (PER)	AOAC 960.48
Riboflavin	AOAC 985.31
Selenium	AOAC 968.15
Sodium and potassium	ISO 8070 IDF 119A
Sodium and potassium	AOAC 984.27
Thiamine	AOAC 986.27
Total dietary fibre	AOAC 985.29

Annex I

Essential and semi-essential amino acids in breast milk*

For the purpose of this Standard the essential and semi-essential amino acids in human milk from published studies which report measurements of the total nitrogen content and/or the calculation method of the protein content, expressed as mg per g of nitrogen and as mg per 100 kcal are listed.

The average level of an amino acid (mg per g of nitrogen) from each study was used to calculate the corresponding amino acid content per 100 kcal of an infant formula with the minimum protein content of 1.8 g/ 100 kcal accepted in this Standard (mg amino acid/g nitrogen in breast-milk divided by the nitrogen conversion factor of 6.25 and multiplied by 1.8).

The mean of the sums of the average amino acid levels from all studies was converted in the same manner to the average amounts of an amino acid per g of protein (total nitrogen x 6.25) and per 100 kcal of energy (columns 19 and 20 of the table).

National authorities may use all of the listed values.

** Adapted from Koletzko B, Baker S, Cleghorn G, et al, Global standard for the composition of infant formula: Recommendations of ESPGHAN coordinated international expert group. J Pediatr Gastroenterol Nutr. 2005;41:584-599.*

	Lönnerdal &Forsum (1985)		**Darragh & Moughan (1998)**		**Bindels & Harzer (1985)**		**Janas et al. (1987)**		**Villalpando et al. (1998)**				**Räihä et al. (2002) mod Nayman et al. (1979)**		**Yonekubo et al. (1991)**		**Mean of all amino acids contents**		
	Pooled banked milk at 4-16 weeks		**Pooled over 20 days at 10-14 weeks (n=20)**		**24 hours, pooled at 5 weeks (n=10)**		**24 hours, pooled at 8 weeks (n=10)**		**24 hours, pooled at 4-6 months**				**Pooled banked milk at >1 month**		**Milk at 21 days –2 months**				
									Mexico (n=40)		**Houston (n=40)**								
mg amino acid per	**g N**	**100 kcal**	**g N**	**100 kcal**	**g N**	**100 kcal**	**g N**	**100 kcal**	**g N**	**100 kcal**	**g N**	**100 kcal**	**g N**	**100 kcal**	**g N**	**100 kcal**	**g nitro-gen**	**g pro-tein**	**100 kcal**
Arginine	157	*36*	200	*58*	281	*81*	184	*53*	168	*48*	184	*53*	172	*50*	223	*64*	**196**	**31**	*56*
Cysteine	111	*32*	173	*50*	108	*31*	101	*29*	167	*48*	134	*39*	133	*38*	118	*34*	**131**	**21**	*38*
Histidine	111	*32*	156	*45*	255	*73*	112	*32*	112	*32*	108	*31*	122	*35*	150	*43*	**141**	**23**	*41*
Isoleucine	242	70	333	96	376	108	306	88	292	84	331	95	300	86	374	108	**319**	**51**	92
Leucine	457	*132*	598	*172*	713	*205*	611	*176*	528	*152*	541	*156*	572	*165*	667	*192*	**586**	**94**	*169*
Lysine	314	*90*	406	*117*	522	*150*	365	*105*	366	*105*	408	*118*	361	*104*	421	*121*	**395**	**63**	*114*

	Lönnerdal &Forsum (1985)		Darragh & Moughan (1998)		Bindels & Harzer (1985)		Janas et al. (1987)		Villalpando et al. (1998)				Räihä et al. (2002) mod Nayman et al. (1979)		Yonekubo et al. (1991)		Mean of all amino acids contents		
	Pooled banked milk at 4-16 weeks		Pooled over 20 days at 10-14 weeks (n=20)		24 hours, pooled at 5 weeks (n=10)		24 hours, pooled at 8 weeks (n=10)		24 hours, pooled at 4-6 months				Pooled banked milk at >1 month		Milk at 21 days –2 months				
									Mexico (n=40)		Houston (n=40)								
mg amino acid per	**g N**	**100 kcal**	**g N**	**100 kcal**	**g N**	**100 kcal**	**g N**	**100 kcal**	**g N**	**100 kcal**	**g N**	**100 kcal**	**g N**	**100 kcal**	**g N**	**100 kcal**	**g nitro-gen**	**g pro-tein**	**100 kcal**
Methionine	78	*22*	90	*26*	89	*26*	73	*21*	99	*29*	76	*22*	83	*24*	92	*26*	**85**	**14**	*24*
Phenyl-alanine	153	*44*	243	*70*	344	*99*	183	*53*	440	*127*	439	*126*	217	*62*	240	*69*	**282**	**45**	*81*
Threonine	217	*62*	316	*91*	344	*99*	251	*72*	248	*71*	242	*70*	256	*74*	269	*77*	**268**	**43**	*77*
Tryptophan	NA		NA		172	*50*	79	*23*	112	*32*	89	*26*	111	*32*	122	*35*	**114**	**18**	*33*
Tyrosine	201	*58*	241	*69*	369	*106*	191	*55*	292	*84*	299	*86*	233	*67*	249	*72*	**259**	**42**	*75*
Valine	253	*73*	327	*94*	376	*108*	267	*77*	286	*82*	331	*95*	317	*91*	364	*105*	**315**	**50**	*90*

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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 independent 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 the safety of such values.

For nutrients with a documented risk of adverse health effects the upper levels to be taken into account will be determined using a science-based risk assessment approach. Where scientific data are not sufficient for a science-based risk assessment, consideration should be given to an established history of apparently safe use of the nutrient in infants, as appropriate. Values derived on the basis of meeting the nutritional requirements of infants and an established history of apparently safe use should be considered as interim guidance upper levels. The approach to setting maximum and upper guidance values shall be made transparent and comprehensible.

5. When establishing minimum and maximum amounts, the following should also 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 considered:

a) The mean intake of prepared formula for infants from birth to six months of age is 750 ml per day, and

b) a representative body weight for an infant over this period is 5 kg,

and

c) a representative caloric intake of an infant over this period is 500 kcal per day (or 100 kcal/kg/day).

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.

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

SECTION B: FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS

(At Step 8 of the Procedure)

1. SCOPE

1.1 This section of the standard applies to Formula for Special Medical Purposes Intended for Infants in liquid or powdered form intended for use, where necessary, as a substitute for human milk or infant formula in meeting the special nutritional requirements arising from the disorder, disease or medical condition for whose dietary management the product has been formulated.

1.2 This section of the standard contains compositional, quality, labelling and safety requirements for Formula for Special Medical Purposes Intended for Infants.

1.3 Only products that comply with the criteria laid down in the provisions of this section of this standard would be accepted for marketing as formula for special medical purposes intended for infants.

1.4 The application of this section of the standard should take into account, as appropriate for the products to which the section applies and the special needs of the infants for whom they are intended, 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).

2. DESCRIPTION

2.1 Product definition

2.1.1 Formula for Special Medical Purposes Intended for Infants means a substitute for human milk or infant formula that complies with Section 2, Description, of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding.

2.1.2

See Section A 2.1.2

2.2 Other Definitions

See Section A 2.2

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

3.1.1. Formula for Special Medical Purposes intended for Infants is a product based on ingredients based of animal, plant and/or synthetic origin suitable for human consumption. All ingredients and food additives shall be gluten-free.

3.1.2 The composition of Formula for Special Medical Purposes Intended for Infants shall be based on sound medical and nutritional principles. The nutritional safety and adequacy of the formula shall be

scientifically demonstrated to support growth and development in the infants for whom it is intended, as appropriate for the specific products and indications. Their use shall be demonstrated by scientific evidence to be beneficial in the dietary management of the infants for whom it is intended.

3.1.3 The energy content and nutrient composition of Formula for Special Medical Purposes intended for infants shall be based on the requirements for infant formula as given in sections A 3.1.2 and A 3.1.3, except for the compositional provisions which must be modified to meet the special nutritional requirements arising from the disease(s), disorder(s) or medical condition(s) for whose dietary management the product is specifically formulated, labelled and presented.

3.1.4 In addition to the requirements in 3.1.3 the following requirements shall also be taken into account, where appropriate:

Chromium

Unit	Minimum	Maximum	GUL
µg/100 kcal	1.5	-	10
µg/100 kJ	0.4	-	2.4

Molybdenum

Unit	Minimum	Maximum	GUL
µg/100 kcal	1.5	-	10
µg/100 kJ	0.4	-	2.4

3.2 Optional ingredients

3.2.1 In addition to the compositional requirements listed under 3.1.3, other ingredients may be added in order to provide substances ordinarily found in human milk or required to ensure that the formulation is suitable as the sole source of nutrition for the infant and for the dietary management of his/her disease, disorder or medical condition.

3.2.2 The suitability for the intended special medical purpose, the suitability for the particular nutritional use of infants and the safety of these substances shall be scientifically demonstrated. The formula shall contain sufficient amounts of these substances to achieve the intended effect.

3.2.3 Only L(+)lactic acid producing cultures may be used in Formulas for Special Medical Purposes for infants if shown to be safe and appropriate for use in these vulnerable populations.

3.3 Vitamin Compounds and Mineral Salts

See Section A 3.4

3.4 Consistency and Particle Size

See Section A 3.5

3.5 Purity Requirements

See Section A 3.6

3.6 Specific Prohibitions

See Section A 3.7

4. FOOD ADDITIVES

See Section A 4

Additional food additives may be needed for Formula for Special Medical Purposes Intended for Infants. Such use may be determined by national authorities.

5. CONTAMINANTS

See Section A 5.

6. HYGIENE

See Section A 6.

7. PACKAGING

See Section A 7.

8. FILL OF CONTAINER

See Section A 8.

9. LABELLING

See introductory paragraph of Section A 9.

9.1 The Name of the Food

9.1.1 See Section A 9.1.1

9.1.2 The name of the product shall be "Formula for Special Medical Purposes Intended for Infants" or any appropriate designation indicating the true nature of the product, in accordance with national usage.

9.1.3 If cows' milk is the only source of protein, the product may be labelled "Formula for Special Medical Purposes Intended for Infants Based on Cows' Milk".

9.2 List of Ingredients

See Section A 9.2

9.3 Declaration of Nutritive Value

Formula for Special Medical Purposes Intended for Infants shall be labelled with complete nutrition labelling according to Section 4.2 of Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991).

9.4 Date Marking and Storage Instructions

See Section A 9.4

9.5 Information for Use

See Section A 9.5

9.6 Additional Labelling Requirements

9.6.1 Formula for Special Medical Purposes Intended for Infants shall be labelled with the additional information as specified in Sections 4.4.1, 4.4.3, 4.4.4, 4.5.1 and 4.5.5 of CODEX STAN 180-1991.

9.6.2 A prominent statement indicating that the product is intended as the sole source of nutrition shall appear on the label.

9.6.3 In addition, the information specified in Sections 4.5.2, 4.5.3 and 4.5.6 of CODEX STAN 180-1991 shall be included on the label or be provided separately from the package.

9.6.4 Labels and information provided separately from the package should not discourage breastfeeding, unless breastfeeding is contraindicated on medical grounds for the disease(s), disorder(s) or medical condition(s) for which the product is intended.

9.6.5

See Section A 9.6.5

10. Methods of Analysis

See Section A 10.

APPENDIX III

CODEX DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS – SECTION 4. FOOD ADDITIVES

TABLE 1

SEE SECTION 4. FOOD ADDITIVES IN APPENDIX II

TABLE 2

SECTION A OF THE DRAFT REVISED STANDARD - REQUEST FOR ADDITIONAL FOOD ADDITIVES

	INS no.	Additive	Maximum level in 100 ml of the product ready for consumption	Technological Justification
4.1 Thickeners				
4.1.8	415	Xanthan gum	GMP	Retains homogeneity
4.7.3	414	Gum arabic (acacia)	GMP	Retains homogeneity
4.2 Emulsifiers				
4.2.3	472c	Citric and fatty acid esters of glycerol	0.75 g in powder formula[1)] 0.9 g in liquid formula containing hydrolysed protein or amino acids[1)]	Retains homogeneity
4.2.4	473	Sucrose esters of fatty acids	12 mg in formula containing hydrolysed protein or amino acids[1)]	Retains homogeneity
4.2.5	472e	Tartaric and fatty acid esters of glycerol	0.5 mg	Retains homogeneity
4.2.6	472a	Acetic and fatty acid esters of glycerols	GMP	Retains homogeneity

[1)] If more than one of the substances INS 472c, 473 are added the maximum level for each of those substances is lowered with the relative part as present of the other substances

	INS no.	Additive	Maximum level in 100 ml of the product ready for consumption	Technological Justification
4.3 Acidity Regulators				
4.3.8	331i	Sodium dihydrogen citrate	0.2 g singly or in combination and within the limits for sodium, potassium and calcium in section 3.1.3 (e) in all types of infant formula	pH adjustment
4.3.9	331iii	Trisodium citrate		pH adjustment
4.3.10	332i	Potassium dihydrogen citrate		pH adjustment
4.3.11	332ii	Tripotassium citrate		pH adjustment
4.3.14	338	Phosphoric acid	0.1 g expressed as P_20_5 singly or in combination and within the limits for sodium, potassium and phosphorus in section 3.1.3(e) in all types of infant formula	pH adjustment
4.3.15	339i	Monosodium dihydrogen monophosphate		pH adjustment
4.3.16	339ii	Disodium hydrogen monophosphate		pH adjustment
4.3.17	339iii	Trisodium monophosphate		pH adjustment
4.3.18	340i	Monopotassium dihydrogen monophosphate		pH adjustment
4.3.19	340ii	Dipotassium hydrogen monophosphate		pH adjustment
4.3.20	340iii	Tripotassium monophosphate		pH adjustment
4.4 Antioxidants				
4.4.1	306	Vitamin E concentrate	1 mg in all types of infant formula singly or in combination	Protects from oxidation
4.4.4	309	Gamma-tocopherol		Protects from oxidation
4.4.5	308	Delta-tocopherol		Protects from oxidation

TABLE 3

SECTION B OF THE DRAFT REVISED STANDARD REQUEST FOR ADDITIONAL FOOD ADDITIVES

	INS no.	Additive	Maximum level in 100 ml of the product ready for consumption	Technological Justification
4.1 Thickeners				
	401	Sodium alginate	100 mg	Retains homogeneity
	405	Propane 1,2-diolalginate	20 mg	Retains homogeneity
	410	Carob bean gum (Locust bean gum) [1)]	0.5 g	Retains homogeneity
	412	Guar gum[1)]	1 g	Retains homogeneity
	415	Xanthan gum	0.12 g	Retains homogeneity
	440	Pectins	1 g	Retains homogeneity
	466	Sodium carboxymethyl cellulose	1 g	Retains homogeneity
	1450	Starch sodium octenyl succinate	2 g	Retains homogeneity
	414	Gum arabic (acacia)	GMP	Retains homogeneity
4.2 Emulsifiers[2)]				
	471	Mono- and diglycerides[1)]	0.5 g	Retains homogeneity
	472c	Citric and fatty acid esters of glycerol	0.75 g in powder formula 0.9 g in liquid formula containing partially hydrolysed protein, peptides or amino acids	Retains homogeneity

[1)] These additives are in the present Codex standard 72-1981 for Infant Formula at different levels.

[2)] If emulsifiers are used in combination, the combined levels should be within the levels listed and be proportionately reduced, and with the minimum amount necessary to achieve the intended technical effect.

	INS no.	Additive	Maximum level in 100 ml of the product ready for consumption	Technological Justification
	472e	Diacetyltartaric and fatty acid esters of glycerol	0.5 g	Retains homogeneity
	473	Sucrose esters of fatty acids	12 mg in formula containing hydrolysed protein, peptides or amino acids	Retains homogeneity

APPENDIX IV

DRAFT REVISED STANDARD FOR GLUTEN-FREE FOODS (CODEX STAN 118-1981, AMENDED 1983)

or

[STANDARD FOR FOODS FOR SPECIAL DIETARY USES INTENDED FOR PEOPLE WITH COELIAC DISEASE]

(At Step 6 of the Procedure)

1. SCOPE

1.1 This standard applies to those foodstuffs and ingredients that are naturally free of gluten and those which have been specially 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

The products covered by this standard are described as follows:

a) consisting of or made only from ingredients which do not contain any prolamins from wheat, durum wheat, rye, barley, oats[1] or any *Triticum* species such as spelt (*Triticum spelta* L.), kamut (*Triticum polonicum* L.) or their crossbred varieties with a gluten level not exceeding 20 mg/kg in total based on the foods ready for consumption.;

or

b) consisting of ingredients from wheat, rye, barley, oats or any *Triticum* species such as spelt (*Triticum spelta* L.), kamut (*Triticum polonicum* L.) or their crossbred varieties, which have been rendered "gluten-free"; with a gluten level not exceeding [100 mg/kg] in total based on the foods ready for consumption.;

or

c) any mixture of the two ingredients as in a) and b) with a gluten level not exceeding [100 mg/kg] in total based on the foods ready for consumption.

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.

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[1] Oats can be tolerated by most but not all people with coeliac disease. Therefore, the use of oats not contaminated with gluten permitted in gluten-free foods for the dietary management of coeliac disease may be determined at national level.

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 gluten sensitivity. 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 mg/kg, that the total content of gluten from wheat, rye, barley, oats or crossbred varieties of these does not exceed [100 mg/kg] in these foodstuffs or ingredients defined in 2.1 b) and c) on the basis of foods ready for consumption. The prolamin content of liquid food products is in the same way expressed in mg/kg of the original product.

3.2 Products covered by this standard, substituting important basic foodstuffs, should supply approximately the same amount of vitamins and minerals as the original foodstuffs they replace.

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

4. LABELLING

In addition to the general labelling provisions contained in the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985), and any specific labelling provisions set out in a Codex standard applying to the particular food concerned, the following provisions for the labelling of “gluten-free foods” shall apply:

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

[Foods naturally gluten-free

Where food is by its nature free of gluten, as described in paragraph 2.1 a), the term describing the level of gluten should not precede the name of the food, but should be in the form “(the name of the food), gluten-free food”.]

[The labelling term used to describe products defined in sections 2.1 b) and 2.1.c) of the standard should be distinguishable from the labelling used to describe products defined in section 2.1 a). The product at 2.1.a) shall be labelled as naturally gluten-free or gluten-free. The labelling terms in 2.1.b) and 2.1.c) shall be determined at national level.]

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 V

ADVISORY LISTS OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

(At Step 5 of the Procedure)

1. PREAMBLE

These lists include nutrient compounds, which may be used for nutritional purposes in foods for special dietary uses intended for infants and young children in accordance with 1) the criteria and conditions of use identified below and 2) other criteria for their use stipulated in the respective standards. In addition, the sources from which the nutrient compound is produced may exclude the use of specific substances where religious or other specific dietary restrictions apply. As noted in the respective standards, their use may either be essential or optional.

2. CRITERIA FOR THE INCLUSION AND DELETION OF NUTRIENT COMPOUNDS FROM THE ADVISORY LISTS

2.1 Nutrient compounds that are to be added for nutritional purposes to foods for infants and young children may be included in the Lists only if:

(a) they are shown to be safe and appropriate for the intended use as nutrient sources for infants and young children

(b) it is demonstrated by appropriate studies in animals and/or humans that the nutrients are biologically available

(c) the purity requirements of the nutrient compounds conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission, or in the absence of such specifications, with another internationally recognised specification. If there is no internationally recognised specification, national purity requirements that have been evaluated according to or similar to a FAO/WHO process may be considered

(d) the stability of nutrient compound(s) in the food(s) in which it is (they are) to be used can be demonstrated

(e) the fulfilment of the above criteria shall be demonstrated by generally accepted scientific criteria.

2.2 Nutrient compounds may be added to the Lists based on the criteria above. Nutrient compounds shall be deleted from the Lists if they are found no longer to meet the above criteria. If a country proposes to add or delete a nutrient compound to/from a list, the country should provide information that addresses how the nutrient compound satisfies/does not satisfy the criteria in Section 2.1.

A: ADVISORY LIST OF MINERAL SALTS AND TRACE ELEMENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
1. Source of Calcium (Ca)								
1.1 Calcium carbonate	√ (1981)	JECFA (1973), Ph Int, FCC, USP, NF, Ph Eur, BP, DAB	√	√	√	√	√	√
1.2 Calcium chloride	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, JP, BP, DAB	√	√	√	√	√	√
1.3 Tricalcium dicitrate (Calcium citrate)	√ (1979)	JECFA (1975), FCC, USP, DAC	√	√	√	√	√	√
1.4 Calcium gluconate	√ (1999)	JECFA (1998), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√
1.5 Calcium glycerophosphate		FCC, Ph Eur, Ph Franc	√	√	√	√	√	√
1.6 Calcium L-lactate	√ (1978)	JECFA (1974), FCC, USP, Ph Eur (tri- and penta-hydrate), BP, DAB	√	√	√	√	√	√

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[3] IF Sect. B = Formula for Special Medical Purposes Intended for Infants
[4] FUF = Follow-up Formula
[5] PCBP = Processed Cereal Based Food
[6] CBF = Canned Baby Food
[7] FSMP = Food for Special Medical Purposes

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
1.7 Calcium hydroxide	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, BP	√	√	√	√	√	√
1.8 Calcium oxide	√ (1979)	JECFA (1975), FCC, DAC	-	√	-	√	√	√
1.9 Calcium dihydrogen phosphate (Calcium phosphate, monobasic)	√ (1997)	JECFA (1996), Ph Int, FCC	√	√	√	√	√	√
1.10 Calcium hydrogen phosphate (Calcium phosphate, dibasic)	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√
1.11 Tricalcium diphosphate (Calcium phosphate, tribasic)		JECFA (1973), Ph Int, FCC, BP	√	√	√	√	√	√
1.12 Calcium sulphate	√ (1979)	JECFA (1975), Ph Int, FCC, Ph Eur (dihydrate), DAB	-	√		-	-	√
2. Source of Iron (Fe)								
2.1 Ferrous carbonate, stabilised with saccharose		DAB	-	√	-	√	√	√

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Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
2.2 Ferrous fumarate		Ph Int, FCC, USP, Ph Eur, BP	√	√	√	√	√	√
2.3 Ferrous gluconate	√ (2001)	JECFA (1999), FCC, USP, Ph Eur, DAB, BP	√	√	√	√	√	√
2.4 Ferrous lactate	√ (1991)	JECFA (1989), FCC, NF	√	√	√	√	√	√
2.5 Ferrous sulphate	√ (2001)	JECFA (1999), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√
2.6 Ferric ammonium citrate	√ (1987)	JECFA (1984), FCC, DAC	√	√	√	√	√	√
2.7 Ferric citrate		FCC	√	√	√	√	√	√
2.8 Ferric diphosphate (pyrophosphate)		FCC	√	√	√	√	√	√
2.9 Hydrogen reduced iron		FCC, DAB	-	√	-	√	√	√
2.10 Electrolytic iron		FCC	-	√	-	√	√	√
2.11 Carbonyl iron		FCC	-	√	-	√	√	√
2.12 Ferric saccharate		Ph Helv, DAB, ÖAB	-	√	-	√	√	√
2.13 Sodium ferric diphosphate		FCC	-	√	-	√	√	√

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Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
2.14 Ferrous citrate		FCC, FSANZ	√	√	√	√	√	√
2.15 Ferrous succinate		MP, MI, FSANZ	√	√	√	√	√	√
2.16 Ferrous bisglycinate		JECFA (2003)	√	√	√	√	√	√
2.17 Ferric orthophosphate		FCC	-	-	-	√	-	-
3. Source of Magnesium (Mg)								
3.1 Magnesium hydroxide carbonate		JECFA (1979), USP, BP, DAB	√	√	√	√	√	√
3.2 Magnesium chloride	√ (1979)	JECFA (1979), FCC, USP, Ph Eur (-4,5-hydrate), BP, DAB	√	√	√	√	√	√
3.3 Magnesium gluconate	√ (2001)	JECFA (1998), FCC, DAC	√	√	√	√	√	√
3.4 Magnesium glycero-phosphate		Ph Eur, BPC	-	√	-	√	√	√
3.5 Magnesium hydroxide	√ (1979)	JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√

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	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
3.6 Magnesium lactate	√ (1987)	JECFA (1983) (Mg-DL-Lactate, Mg-L-Lactate)	-	√	-	√	√	√
3.7 Magnesium oxide		JECFA (1973), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√
3.8 Magnesium hydrogen phosphate Magnesium phosphate, dibasic)	√ (1985)	JECFA (1982), FCC, DAB	√	√	√	√	√	√
3.9 Trimagnesium phosphate (Magnesium phosphate, tribasic)	√ (1981)	JECFA (1982), FCC	√	√	√	√	√	√
3.10 Magnesium sulphate		Ph Eur (heptahydrate), FCC, USP, JP, BP, DAB, DAC	√	√	√	√	√	√
3.11 Magnesium acetate		Ph Eur, DAC	-	√	-	-	-	√
3.12 Magnesium salts of citric acid		USP, DAC	√	√	√	√	√	√
3.13 Magnesium carbonate		JECFA (1973), FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√

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			Sec. A[2]	Sec. B[3]				
4. Source of Sodium (Na)								
4.1 Sodium carbonate	√ (1979)	JECFA (1975), FCC, USP, NF, Ph Eur, BP, DAB	√	√	√	-	-	√
4.2 Sodium hydrogen carbonate (Sodium bicarbonate)	√ (1979)	JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	-	-	√
4.3 Sodium chloride		Ph Int, FCC, USP, Ph Eur, JP, BP, DAB	√	√	√	-	-	√
4.4 Trisodium citrate (Sodium citrate)		JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	-	-	√
4.5 Sodium gluconate	√ (1999)	JECFA (1998), FCC, USP, DAC	√	√	√	-	-	√
4.6 Sodium L-lactate	√ (1978)	JECFA (1974), FCC, USP, Ph Eur, BP, DAB	√	√	√	-	-	√
4.7 Sodium dihydrogen phosphate (Sodium phosphate, monobasic)	√ (1995)	JECFA (1963), FCC, USP, Ph Eur (dihydrate)	√	√	√	-	-	√

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4.8 Disodium hydrogen phosphate (Sodium phosphate, dibasic)		JECFA (1975), Ph Int, FCC, USP, BP	√	√	√	-	-	√
4.9 Trisodium phosphate (Sodium phosphate, tribasic)		JECFA (1975), FCC, DAC	√	√	√	-	-	√
4.10 Sodium hydroxide	√ (1979)	JECFA (1975), Ph Int, FCC, USP, NF, Ph Eur, JP, BP, DAB	√	√	√	-	-	√
4.11 Sodium sulphate		JECFA (2000), Ph Int, FCC, USP, Ph Eur, BP, DAB, FSANZ	√	√	√	√	√	√
4.12 Sodium tartrate		JECFA (1963), FSANZ	√	√	√	√	√	√
5. Source of Potassium (K)								
5.1 Potassium carbonate	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, DAC	√	√	√	-	-	√
5.2 Potassium hydrogen carbonate (Potassium bicarbonate)	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, BP, DAB	√	√	√	-	-	√

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	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
5.3 Potassium chloride	√ (1983)	JECFA (1979), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√
5.4 Tripotassium citrate (Potassium citrate)		JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√
5.5 Potassium gluconate	√ (1999)	JECFA (1998), FCC, USP, DAC	√	√	√	√	√	√
5.6 Potassium glycero-phosphate		FCC	-	√	-	√	√	√
5.7 Potassium L-lactate	√ (1978)	JECFA (1974), FCC, DAB	√	√	√	√	√	√
5.8 Potassium dihydrogen phosphate (Potassium phosphate, monobasic)	√ (1979)	JECFA (1982), FCC, NF, Ph Eur, BP, DAB	√	√	√	-	-	√
5.9 Dipotassium hydrogen phosphate (Potassium phosphate, dibasic)	√ (1979)	JECFA (1982), FCC, BP	√	√	√	-	-	√
5.10 Potassium phosphate, tribasic	√ (1979)	JECFA (1982)	√	√	√	-	-	√

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	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
5.11 Potassium hydroxide	√ (1979)	JECFA (1975), FCC, NF, Ph Eur, JP, BP, DAC	√	√	√	-	-	√
6. Source of Copper (Cu)								
6.1 Cupric gluconate (Copper gluconate)		FCC, USP	√	√	√	√	√	√
6.2 Cupric sulphate (Copper sulphate)	√ (1981)	JECFA (1973), FCC, USP, Ph Eur, DAB	√	√	√	√	√	√
6.3 Cupric carbonate		MI	√	√	√	√	√	√
6.4 Cupric citrate		FCC, USP	√	√	√	√	√	√
7. Source of Iodine (I)								
7.1 Potassium iodide		Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√
7.2 Sodium iodide		Ph Eur, USP, BP, DAB	√	√	√	√	√	√
7.3 Potassium iodate	√ (1991)	JECFA (1988), FCC	√	√	√	√	√	√
7.4 Sodium iodate		FCC	-	√	-	√	√	√
8. Source of Zinc (Zn)								
8.1 Zinc acetate		USP, Ph Eur (dihydrate)	√	√	√	√	√	√
8.2 Zinc chloride		USP, Ph Eur, JP, BP, DAB	√	√	√	√	√	√

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	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
8.3 Zinc gluconate		FCC, USP, DAC	√	√	√	√	√	√
8.4 Zinc lactate		FCC	√	√	√	√	√	√
8.5 Zinc oxide		Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√
8.6 Zinc sulphate		FCC, USP, Ph Eur, BP	√	√	√	√	√	√
8.7 Zinc carbonate		USP, BP (hydroxide carbonate)	-	√	-	-	-	√
9. Source of Manganese (Mn)								
9.1 Manganese(II) chloride		FCC	√	√	√	√	√	√
9.2 Manganese(II) citrate		FCC	√	√	√	√	√	√
9.3 Manganese(II) glycero-phosphate		FCC	-	√	-	√	√	√
9.4 Manganese(II) sulphate		FCC, USP, Ph Eur (monohydrate)	√	√	√	√	√	√
9.5 Manganese(II) gluconate		FCC	√	√	√	√	√	√
9.6 Manganese(II) carbonate		MI	√	√	√	√	√	√
10. Source of Selenium (Se)								
10.1 Sodium selenate		MI	√	√	√	√	-	√
10.2 Sodium selenite		DAC, MP, MI	√	√	√	√	-	√

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Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
10.3 Sodium hydrogen selenite		DVFA	-	√	-	-	-	√
11. Chromium (Cr III)								
11.1 Chromium (III) sulphate		USP, MI	-	√	-	-	-	√
11.2 Chromium (III) chloride		USP, MI	-	√	-	-	-	√
12. Molybdenum (Mo VI)								
12.1 Sodium molybdate		Ph Eur (dihydrate), BP, DAB	-	√	-	-	-	√
12.2 Ammonium molybdate		FCC, USP	-	√	-	-	-	√
13. Fluoride (F)								
13.1 Sodium fluoride		FCC, USP, Ph Eur, BP, DAB	-	√	-	-	-	√
13.2 Potassium fluoride		FCC, DAB	-	√	-	-	-	√
13.3 Calcium fluoride		DAB	-	√	-	-	-	√

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B: ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
1. Vitamin A								
1.1 all trans Retinol		FCC (vitamin A), USP, Ph Eur (vitamin A)	√	√	√	√	√	√
1.2 Retinyl acetate		FCC (vitamin A), USP, Ph Eur (vitamin A), Jap Food Stan	√	√	√	√	√	√
1.3 Retinyl palmitate		FCC (vitamin A), USP, Ph Eur (vitamin A), Jap Food Stan	√	√	√	√	√	√
2. Provitamin A								
2.1 Beta-Carotene	√ (1991)	JECFA (1987), FCC, USP, Ph Eur, Jap Food Stan	√	√	√	√	√	√
3. Vitamin D								
3.1 Vitamin D_2 = Ergocalciferol		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	√	√	√	√	√	√
3.2 Vitamin D_3 = Cholecalciferol		Ph Int, FCC, USP, Jap Food Stan, BP, DAB	√	√	√	√	√	√

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Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
4. Vitamin E								
4.1 D-alpha-Tocopherol	√ (2001)	JECFA (2000), FCC, USP, NF, Ph Eur	√	√	√	√	√	√
4.2 DL-alpha-Tocopherol	√ (1989)	JECFA (1986), FCC, USP, NF, Ph Eur, Jap Food Stan	√	√	√	√	√	√
4.3 D-alpha-Tocopheryl acetate		FCC, USP, NF, Ph Eur	√	√	√	√	√	√
4.4 DL-alpha-Tocopheryl acetate		FCC, USP, NF, Ph Eur, BP	√	√	√	√	√	√
4.5 D-alpha-Tocopheryl acid succinate		FCC, USP, Ph Eur	-	√	-	-	-	√
4.6 DL-alpha-Tocopheryl acid succinate		NF, MP, MI, USP, Ph Eur	-	√	-	-	-	√
4.7 DL-alpha-Tocopheryl polyethylene glycol 1000 succinate		FCC	-	√	-	-	-	√
5. Vitamin C								
5.1 L-Ascorbic acid	√ (1981)	JECFA (1973), Ph Int, FCC, USP, Ph Eur, JP, Jap Food Stan, BP, DAB	√	√	√	√	√	√

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Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
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5.2 Calcium-L-ascorbate	√ (1983)	JECFA (1981), FCC, USP, Ph Eur	√	√	√	√	√	√
5.3 6-Palmitoyl-L-ascorbic acid (Ascorbyl palmitate)		JECFA (1973), FCC, USP, NF, Ph Eur, Jap Food Stan, BP, DAB	√	√	√	√	√	√
5.4 Sodium-L-ascorbate		JECFA (1973), FCC, USP, Ph Eur, Ph Franc, Jap Food Stan, DAC	√	√	√	√	√	√
5.5 Potassium-L-ascorbate		FCC	√	√	√	√	√	√
6. Vitamin B_1								
6.1 Thiaminchloride hydrochloride		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	√	√	√	√	√	√
6.2 Thiamin mononitrate		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	√	√	√	√	√	√
7. Vitamin B_2								
7.1 Riboflavin	√ (1991)	JECFA (1987), Ph Int, FCC, USP, Ph Eur, JP, Jap Food Stan, BP, DAB	√	√	√	√	√	√

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Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
7.2 Riboflavin-5'-phosphate sodium	√ (1991)	JECFA (1987), USP, Ph Eur, JP, Jap Food Stan, BP, DAB	√	√	√	√	√	√
8. Niacin								
8.1 Nicotinic acid amide (Nicotinamide)		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, BP, DAB	√	√	√	√	√	√
8.2 Nicotinic acid		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, BP, DAB	√	√	√	√	√	√
9. Vitamin B_6								
9.1 Pyridoxine hydrochloride		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	√	√	√	√	√	√
9.2 Pyridoxal 5-phosphate		MI, FCC, USP	√	√	√	√	√	√
10. Folic acid								
10.1 N-Pteroyl-L-glutamic acid		Ph Int, FCC, USP, Ph Eur, Jap Food Stan	√	√	√	√	√	√
11. Pantothenic acid								
11.1 Calcium-D-pantothenate		FCC, USP, Ph Eur, Jap Food Stan, DAB	√	√	√	√	√	√

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Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
11.2 Sodium-D-pantothenate		Jap Food Stan, DAB	√	√	√	√	√	√
11.3 D-Panthenol/		FCC, USP, Ph Eur	√	√	√	√	√	√
11.4 DL-Panthenol		FCC, USP, Ph Eur	√	√	√	√	√	√
12. Vitamin B_{12}								
12.1 Cyanocobalamin		Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√	√
12.2 Hydroxo-cobalamin		Ph Int, USP, NF, Ph Eur (hydro-chloride)	√	√	√	√	√	√
13. Vitamin K_1								
13.1 Phytomenadione (2-Methyl-3-phytyl-1,4-naphthoquinone/ Phylloquinone/ Phytonadione)		Ph Int, FCC (vitamin K), USP, Ph Eur, BP	√	√	√	√	√	√
14. Biotin								
14.1 D-Biotin		FCC, USP, Ph Eur	√	√	√	√	√	√

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C: ADVISORY LIST OF AMINO ACIDS AND OTHER NUTRIENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
1. Amino acids[8]								
1.1 L-Arginine		FCC, USP, Ph Eur, BP, DAB	only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use)	√	only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use)			√
1.2 L-Arginine hydrochloride		FCC, USP, Ph Eur, BP, DAB		√				√
1.3 L-Cystine		FCC, USP, Ph Eur		√				√
1.4 L-Cystine dihydrochloride		MI		√				√
1.5 L-Cysteine		DAB		√				√
1.6 L-Cysteine hydrochloride		FCC, Ph Eur		√				√
1.7 L- Histidine		FCC, USP, Ph Eur, DAB		√				√
1.8 L- Histidine hydrochloride		FCC, Ph Eur, DAB		√				√
1.9 L-Isoleucine		FCC, USP, Ph Eur, DAB		√				√
1.10 L-Isoleucine hydrochloride		FCC, USP		√				√
1.11 L-Leucine		FCC, USP, Ph Eur, DAB		√				√
1.12 L-Leucine hydrochloride		MI, FCC, USP		√				√

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[8] As far as applicable, also the free, hydrated and anhydrous forms of amino acids, and the hydrochloride, sodium, and potassium salts of amino acids may be used for FSMP.

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
1.13 L-Lysine		USP	only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use)	√	only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use)			√
1.14 L-Lysine monohydrochloride		FCC, USP, Ph Eur, DAB		√				√
1.15 L-Methionine		Ph Int, FCC, USP, Ph Eur, DAB		√				√
1.16 L-Phenylalanine		FCC, USP, Ph Eur		√				√
1.17 L-Threonine		FCC, USP, Ph Eur, DAB		√				√
1.18 L-Tryptophan		FCC, USP, Ph Eur, DAB		√				√
1.19 L-Tyrosine		FCC, USP, Ph Eur, DAB		√				√
1.20 L-Valine		FCC, USP, Ph Eur, DAB		√				√
1.21 L-Alanine		FCC, USP, Ph Eur, DAB	-	√	-	-	-	√
1.22 L-Arginine L-aspartate		FP	-	√	-	-	-	√
1.23 L-Aspartic acid		FCC, USP, Ph Eur	-	√	-	-	-	√
1.24 L-Citrulline		USP, DAC	-	√	-	-	-	√
1.25 L- Glutamic acid		JECFA (1987), FCC, USP, Ph Eur	-	√	-	-	-	√

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Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
1.26 L-Glutamine		FCC, USP, DAB	-	√	-	-	-	√
1.27 Glycine		FCC, USP, Ph Eur	-	√	-	-	-	√
1.28 L-Ornithine		MI, FCC	-	√	-	-	-	√
1.29 L-Ornithine monohydrochloride		DAB	-	√	-	-	-	√
1.30 L-Proline		FCC, USP, Ph Eur, DAB	-	√	-	-	-	√
1.31 L-Serine		USP, Ph Eur, DAB	-	√	-	-	-	√
1.32 N-Acetyl-L-cysteine		USP, Ph Eur, DAB	-	√	-	-	-	√
1.33 N-Acetyl-L-methionine		FCC	-	-	-	-	-	√ not for infants
1.34 L-Lysine acetate		FCC, USP, MP; Ph Eur	-	√	-	-	-	√
1.35 L-Lysine L-Aspartate		Jap Food Stan	-	√	-	-		√
1.36 L-Lysine L-glutamate dihydrate		Jap Food Stan	-	√	-	-	-	√
1.37 Magnesium L-aspartate		Ph Eur	-	√	-	-	-	√
1.38 Calcium L-glutamate	√ (1991)	JECFA, FCC, FSANZ, Jap Food Stan	-	√	-	-	-	√

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	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
1.39 Potassium L-glutamate		JECFA, FCC, FSANZ, Jap Food Stan	-	√	-	-	-	√
2. Carnitine								
2.1 L-Carnitine		FCC, USP, Ph Eur	√	√	√	√	√	√
2.2 L-Carnitine hydrochloride		FCC	√	√	√	√	√	√
2.3 L-Carnitine tartrate		FCC, Ph Eur	√	√	√	-	-	√
3. Taurine								
3.1 Taurine		USP, JP	√	√	√	-	-	√
4. Choline								
4.1 Choline		FCC, USP	√	√	√	√	√	√
4.2 Choline chloride		FCC, DAC, DAB	√	√	√	√	√	√
4.3 Choline citrate		NF	√	√	√	√	√	√
4.4 Choline hydrogen tartrate		DAB	√	√	√	√	√	√
4.5 Choline bitartrate		FCC, NF, DAB	√	√	√	√	√	√
4.6 Lecithin	√ (1995)	JECFA (1993), FCC	√	√	√	√	√	√
5. Inositols								
5.1 Myo-Inositol (=meso-Inositol)]		FCC, DAC	√	√	√	√	√	√

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			Sec. A[2]	Sec. B[3]				
6. Nucleotides								
6.1 Adenosine 5-mono-phosphate (AMP)		FSANZ	√	√	√	-	-	√
6.2 Cytidine 5-mono-phosphate (CMP)		FSANZ, Jap Food Stan	√	√	√	-	-	√
6.3 Guanosine 5-mono-phosphate (GMP)		JECFA (1985)	√	√	√	-	-	√
6.4 Inosine 5-monophos-phate (IMP)		JECFA (1974)	√	√	√	-	-	√
[6.5 Disodium Uridine 5-monophosphate salt		FSANZ, Jap Food Stan	[√]	[√]	[√]	-	-	[√]
[6.6 Disodium Guanosine 5-monophosphate salt		FCC, JECFA, FSANZ, Jap Food Stan	[√]	[√]	[√]	-	-	[√]
[6.7 Disodium Inosine 5-monophosphate salt		FCC, JECFA, FSANZ, Jap Food Stan	[√]	[√]	[√]	-	-	[√]

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LIST OF NUTRIENT COMPOUNDS THAT LACK OFFICIAL PURITY REQUIREMENTS

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children					
	CAC[1]	international and/or national bodies	IF		FUF[4]	PCBF[5]	CBF[6]	FSMP[7] for infants and young children
			Sec. A[2]	Sec. B[3]				
LIST A:								
[Copper-lysine-complex]	?	?	[√]	[√]	[√]	[√]	[√]	[√]
[Zinc citrate]	?	?	[√]	[√]	[√]	[√]	[√]	[√]
LIST B:								
[Pyridoxal dipalmitate]	?	?	-	[√]	-	[√]	[√]	[√]
LIST C:								
ISDI: [Calcium-L-methylfolate]	?	?	[√]	[√]	-	-	-	[√]
LIST D:								
[Uridine 5-monophosphate sodium salt]	?	?	[√]	[√]	[√]	-	-	[√]
[Guanosine 5-mono-phosphate sodium salt]	?	?	[√]	[√]	[√]	-	-	[√]
[Inosine 5-monophosphate sodium salt]	?	?	[√]	[√]	[√]	-	-	[√]
[Cytidin 5-monophosphate sodium salt]	?	?	[√]	[√]	[√]	-	-	[√]
[Uridine 5-monophosphate (UMP)]	?	?	[√]	[√]	[√]	-	-	[√]
[Adenosine 5-monophosphate sodium salt]	?	?	[√]	[√]	[√]	-	-	[√]
[S-Adenosyl-L-methionine]	?	?	-	-	-	-	-	[√] except infants
[Creatine monohydrate]	?	?	-	[√]	-	-	-	[√]

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D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL NUTRIENT FORMS

For reasons of stability and safe handling, some vitamins and other nutrients have to be converted into suitable preparations, e.g. gum arabic coated products, dry rubbed preparations. For this purpose, the food additives included in the respective specific Codex standard may be used. In addition, the following food additives may be used as nutrient carriers:

	INS no.	Additive/ Carrier	Maximum Level in Ready-to-use Food [mg/kg]
(a)	414	Gum arabic (gum acacia)	[10] or [100]
(b)	551	Silicon dioxide	10
(c)	421	Mannitol (B_{12} dry rubbing 0,1%)	10
(d)	1450	Starch sodium octenyl succinate	100
(e)	301	Sodium L-ascorbate (in coating of nutrient preparations containing PUFAs)	75

Abbreviations:

BP	=	British Pharmacopoeia
BPC	=	British Pharmaceutical Codex
DAB	=	Deutsches Arzneibuch
DAC	=	Deutscher Arzneimittel-Codex
DVFA	=	Danish Veterinary and Food Administration
FCC	=	Food Chemicals Codex
FSANZ	=	Food Standards Australia New Zealand
FU	=	Farmacopoea Ufficiale della Republica Italiana
JP	=	The Pharmacopeia of Japan
Jap Food Stan	=	Japanese Food Standard
MI	=	Merck Index
MP	=	Martindale Pharmacopoeia
ÖAB	=	Österreichisches Arzneibuch
Ph Eur	=	Pharmacopoeia Europaea
Ph Franç	=	Pharmacopée Française
Ph Helv	=	Pharmacopoeia Helvetica
Ph Int	=	International Pharmacopoeia
USP	=	The United States Pharmacopoeia