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 06/29/26

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-ninth Session
Geneva, Switzerland, 3 - 8 July 2006

REPORT OF THE 27th SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Bonn, Germany
21 - 25 November 2005

Note: This document incorporates Circular Letter CL 2005/53-NFSDU

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CX 5/20.2 **CL 2005/53-NFSDU**
December 2005

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 27th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (ALINORM 06/29/26)**

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

1. Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children (ALINORM 06/29/26 para. 63 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 2006**.

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

1. Guidelines for the Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents (Part B) Provisions for Dietary Fibre (ALINORM 06/29/26 para. 28 and Appendix III).

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@bmvel.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 1 May 2006**;

2. Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Children (ALINORM 06/29/26 para. 110 and Section A of Appendix IV).

Governments and international organizations are invited to comment on the above text (except Section 3 Essential Composition and Quality Factors, for that see below) 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@bmvel.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 1 May 2006.**

Comments on Section 3 Essential Composition and Quality Factors should be sent to the Delegation of Germany preferably by an email to: Prof Dr. med. Hildegard **Przyrembel,** Direktorin und Professorin, Federal Institute for Risk Assessment (BfR), P.O. Box 33 00 13, 14191 Berlin, Germany, Tel.:+49 (1888) 4 12 - 32 21, Fax:+49 (1888) 4 12 - 37 15, E-Mail:h.przyrembel@bfr.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 15 February 2006.**

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

1. Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants: Section B (ALINORM 06/29/26 para. 129 and Section B of Appendix IV)

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 2006**;

D. REQUEST FOR COMMENTS AND INFORMATION AT STEP 3 OF THE PROCEDURE:

1. Advisory List of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for the use of Infants and Young Children (ALINORM 06/29/26 para.140 and Appendix V)

Governments and international organizations are invited to comment on the above text (for details see para. 140) 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@bmvel.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 2006.**

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 27th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses are as follows:

MATTERS FOR ADOPTION BY THE COMMISSION

The Committee:

- agreed to advance the Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children (para. 61, Appendix II) for final adoption and Section B of the Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (para 126, Appendix IV B) to Step 5 for adoption by the 29th Session of the Commission.

MATTERS OF INTEREST TO THE COMMISSION

The Committee:

- recognized that it was very important to provide their views to WHO/FAO so that they could draft a more focused document for implementing the Global Strategy on Diet, Physical Activity and Health within Codex. The Committee agreed to inform the Commission that due to time constraints no further discussion was possible (see paras 153-159).

MATTERS REFERRED TO OTHER COMMITTEES

Codex Committee on Milk and Milk Products (CCMMP)

The Committee agreed to inform all relevant committees of its decision to use a nitrogen conversion factor of 6.25 for the calculation of protein content for the purposes of the Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (see paras 80-82).

Codex Committee on Food Additives and Contaminants (CCFAC)

Following established Procedures between Commodity Committees and General Committees, the CCNFSDU refers the Section of Food Additives and Contaminants of the Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children for endorsement by the CCFAC (see paras 52-53).

Codex Committee on Food Labelling (CCFL)

Following established Procedures between Commodity Committees and General Committees, the CCNFSDU refers the Section of Food Labelling of the Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children for endorsement by the CCFL (see paras 55-62).

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INTRODUCTION

1. The Twenty-seventh Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held from 21 to 25 November 2005 in the Brückenforum, Bonn, by courtesy of the Government of Federal Republic of Germany. Dr Rolf Grossklaus, Director and Professor of the Federal Institute for Risk Assessment, Berlin, chaired the session. The Session was attended by 315 delegates, observers and advisors representing 68 member countries and one member organization and 33 international organizations.

OPENING OF THE SESSION

2. Mr Kühnle, Director General for Food Safety and Veterinary Affairs, speaking on behalf of the Federal Minister of Consumer Protection, Food and Agriculture, welcomed the participants and 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. He noted the very positive impact of the Codex Trust Fund on the increased participation of developing countries in the work of this session of the Committee and therefore in standard setting. Mr Kühnle emphasized the importance of Codex standards under the WTO and in improving food quality worldwide and drew the attention of the delegates to the fact that it was necessary to consider to which extent the Committee should work in the implementation of the WHO Global Strategy on Diet, Physical Activity and Health as currently more than 800 million people in developing countries were threatened by hunger while there were more than 1.5 billion obese people throughout the world. Mr Kühnle stressed that it was very important to arrive at consensus and to progress with the work in such important areas as foods for infants and young children and wished all success to the delegates in their important work.

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

3. 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.

4. The Delegation of UK, speaking on behalf of the EC Member Countries present at the current session, pointed out that it was necessary to consider how to proceed with the draft revised Standard for Gluten-Free Foods and drew the attention of the Committee to the fact that it was necessary to ensure that enough time should be left for consideration of the WHO Global Strategy under Agenda Item 10 “Other Business and Future Work”.

5. The Committee agreed to consider the paper on the Implementation of the WHO Global Strategy on Diet, Physical Activity and Health: Action that should be taken by Codex and the proposal of the delegation of Canada on the Proposal to amend the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987) under Agenda Item 10 “Other Business and Future Work” and adopted the Provisional Agenda as the Agenda for the Session.

6. The Committee accepted the proposal of the Delegation of Australia and agreed to establish an *Ad Hoc* Working Group, open to all interested parties, to prepare recommendations on how to clarify the scope and proceed with the consideration of the discussion paper on the Application of Risk Analysis for the Work of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU).

[1] CX/NFSDU 05/1; 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 18 (comments of India).

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

7. The Committee noted that a number of matters referred by the 28th 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 other matters as follows.

Gluten-Free Foods

8. The Committee recalled the decision of the 49th Session of the Executive Committee that the draft revised Standard for Gluten–Free Foods be held until such time as the scientific basis for the establishment of gluten levels and the method of determination were clarified.

9. The Committee noted that the Codex Committee on Methods of Analysis and Sampling (CCMAS)[3] had endorsed temporarily the R5 ELISA method for the determination of gluten as a Type I method.

10. The Observer from WGPAT informed the Committee that progress has been made on the analytical issue and proposed to ask the CCMAS to convert the R5 ELISA method from Type I temporarily endorsed to the endorsed status. The Observer informed the Committee that two studies had been published on the clinical issue. The study of Collin et al (2004) showed in 76 adult celiac patients that a gluten-free diet based on wheat starch with a gluten content from 20 to 200 mg/kg was safe. Catassi et al had finished a study on 36 adult patients challenged with gluten 0, 10 and 50 mg per day; however the final evaluation and the publication of this study were pending. Based on this new clinical material the Observer proposed to put the Gluten-Free Standard on the Agenda for the 28th Session of the Committee

11. The Observer from AOECS supported the proposal of the Observer from PWG requesting the CCMAS to convert the R5 ELISA method from temporarily endorsed to endorsed status and stressed the view that there was enough scientific evidence regarding thresholds and also daily consumption studies as documented in their comments provided in CRD 13 to start discussion and agree on levels of gluten in the draft revised Standard for Gluten–Free Foods.

12. The Committee agreed to discuss the Draft Standard for Gluten-Free Foods at its next session. It also agreed to further consider this matter under Agenda Item 10 “Other Business and Future Work” (see also para 159).

Food Additive Provisions in the Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children at Step 7

13. The Committee noted that the 37th Session of the Codex Committee on Food Additives and Contaminants (CCFAC) had returned to the CCNFSDU food additive provisions of the draft Revised Standard for Processed Cereal-Based Foods forwarded to the CCFAC for endorsement for clarification purposes. The Committee agreed to establish an *Ad Hoc* Working Group chaired by Switzerland and opened to all interested parties to prepare the necessary clarifications for the CCFAC (see also para 52).

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)[4]

14. The Committee recalled that its last session had discussed in detail the definition of dietary fibre and had agreed to circulate the Draft Table, including a revised definition, at Step 6 for further comments.

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[2] CX/NFSDU 05/2; CX/NFSDU 05/27/2-Add.1 (WHO paper on the Implementation of the WHO Global Strategy on Diet, Physical Activity and Health: Action that should be taken by Codex); CRD 9 (Matters from Other Codex Committees: Extract from the CCFAC report (ALINORM 05/28/12) on the Status of Endorsement of Food Additives Provisions in the Draft Revised Standard for Processed Cereal - Based Food for infants and Young Children); CRD 13 (comments of AOECS and ISDI); CRD 18 (comments of India).

[3] ALINORM 05/28/23, paras 66-72.

[4] ALINORM 05/28/26, Appendix III; CX/NFSDU 05/27/3 (comments of Argentina, Australia, Brazil, India, Mexico, New Zealand, United States of America, Venezuela, AAC, IADSA, ICGMA, ISDI); CRD 11 (comments of Chile); CRD 12 (comments of Canada, Costa Rica, Indonesia, South Africa,Thailand, ILSI), CRD 18 (comments of India)

Definitions

15. Several delegations supported a degree of polymerization (DP) of 3 and the Committee agreed to retain this value and to delete the reference to a value of 10. After some discussion, the Committee agreed that a DP not lower than 3 was intended to exclude mono- and disacharides and was not intended to reflect the average DP of the mixture, and amended the text accordingly.

16. The Committee discussed whether the reference to physiological properties should be included in the definition. Several delegations supported the inclusion of these properties as they were essential to characterize dietary fibre. The Delegation of the United States, supported by the Delegation of Japan, expressed its concern with the listing of physiological properties as such properties were not usually listed in the definition of nutrients and they might be interpreted as a justification for claims; and physiological effects should not be mentioned without appropriate methods to evaluate these effects. After some discussion, the Committee agreed to transfer the last paragraph of the "Recommendations" that addresses the need to demonstrate physiological effects, to the definition, and made some editorial amendments to the list of properties for clarification purposes.

17. The Delegation of Canada proposed to add provisions allowing for the use of material originating from plant or animal products that were not traditionally consumed as foods. The Committee however agreed that additional provisions were not necessary as the term "food raw material" covered all possible sources of dietary fibre.

18. The Committee discussed the footnote and in particular the reference to the AOAC method of analysis. Some delegations proposed to move the footnote to a section on methods of analysis while other delegations pointed out that the footnote did not make any specific recommendation as regards methods of analysis but clarified the nature of the compounds associated with dietary fibre extracted with polysaccharides by the AOAC method. The Committee could not come to a conclusion and retained the current footnote for further consideration.

19. The Representative of FAO informed the Committee that an FAO/WHO expert working group was currently reviewing scientific evidence on the physiology of carbohydrates and relevant definitions, and that its results would be available in mid 2006. This expert group would advise FAO and WHO about the appropriateness of convening an expert consultation in this area. The Committee agreed to consider the results of this expert group when it became available and in the meantime to proceed with the consideration of the conditions for claims.

20. The Committee noted that the AOAC method 991.43 had been endorsed by CCMAS in the past as applying to "special foods" and was listed in CODEX STAN 234[5]. The Secretariat recalled that methods of analysis should correspond to a specific provision in a standard, and that this issue should be clarified as currently no provisions existed in Codex standards or related texts for dietary fibre. Some delegations proposed to refer to the Englyst method and to forward it to the Committee on Methods of Analysis and Sampling for endorsement. Other delegations expressed the view that methods of analysis should not be discussed at this stage as additional data would be required, especially in order to compare existing methods.

21. The Committee agreed that methods of analysis would be considered at the next session using the list already compiled in CX/NFSDU 04/3-Add.1 and that all members would have an opportunity to put forward proposals for relevant methods as part of their comments on the Draft Table.

22. The Secretariat noted that the Table was part of the Guidelines for Use of Nutrition and Health Claims, intended for governments and therefore should not include Recommendations to Codex Committees; the provisions might be retained without reference to Codex Committees, or alternatively recommendations to Codex Committees might be included in the report as a position of the Committee.

Conditions for claims

23. The Delegation of the UK (speaking on behalf of EC Member Countries) expressed the view that figures relating to claims for fibre should be limited to solid foods as dietary fibre was provide mostly by solid foods and claims on liquid foods were therefore likely to mislead consumers. The Delegation of Japan pointed out that many liquid foods, such as fruit and vegetable juices or soups provided a source of dietary fibre and therefore supported the current conditions for claims for such products. This position was supported by several delegations, who

[5] Recommended Methods of Analysis and Sampling (1999)

pointed out that the consumption of liquid foods with a significant content of fibre contributed to the overall intake of fibre, and was therefore encouraged as part of national nutrition policies, in view of dietary habits in their countries. Some delegations also noted that claims for liquid foods would apply to new or non-traditional products that provided a source of dietary fibre.

24. Some delegations sought clarification on the conditions applicable to the claims "per serving" and whether the value of 1.5g per 100kcal was also applicable to servings. The Delegation of the United States stressed the importance of the expression "per serving" for the purposes of consumer information, and pointed out that in view of the highly variable size and energy density of servings for various foods, a specific value could not be specified per serving. The Delegation therefore proposed to retain a general expression "per serving" without a specific value, and noted that this would cover claims for liquid foods.

25. The Delegation of Australia proposed to refer to a percentage of the recommended intake per serving, both recommended intake and serving size to be determined at the national level. Several delegations expressed their concerns with the interpretation of provisions that were left to national authorities, especially for the purposes of international trade, and pointed out that further clarification was required in this respect.

26. The Committee could not come to a conclusion on the conditions for claims and agreed to retain in square brackets the original proposal for liquid foods: 1.5g per 100ml and the proposal referring to a percentage of the recommended intake per serving, for further consideration at the next session.

27. The Chairperson pointed out that substantial progress had been made and that comments should be sought on the sections in square brackets and on methods of analysis.

Status of the Draft Table of Conditions for Nutrient Contents (Part B Containing Provisions on Dietary Fibre (Guidelines for the Use of Nutrition Claims)

28. The Committee agreed to return the Draft Table of Conditions for Nutrient Contents (Dietary Fibre), as amended at the present session, to Step 6 for further comments and consideration by the next session (see Appendix III).

DISCUSSION PAPER ON THE PROPOSALS FOR ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES (AGENDA ITEM 4)[6]

29. 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: Principles for the establishment of NRVs, taking into account the guidelines developed by member countries in this area; NRVs for different population groups; and revision of the current list of nutrients.

30. The Delegation of South Africa introduced the revised paper, which, based on the comments received, covered criteria for the establishment of NRVs, proposals for NRVs for four different population groups and criteria for the selection of nutrients. The Delegation outlined the different means of establishing NRVs in several countries, including the USA, Australia/New Zealand, the EC and South Africa. The delegation drew the attention of the Committee to the importance of this work in view of the WHA Resolution 56.23 and indicated that optimum NRVs could be a measure to achieve the WHO's goal of better health for all.

General Comments

31. The Committee expressed its appreciation to South Africa for developing the document despite the challenges posed by the task.

32. The Chairperson drew the attention of the Committee to the fact that the purpose of NRVs as recommended by the Helsinki Consultation held in 1988, was to serve nutrient labelling purposes and not about finding optimum nutrition and that it should concentrate on developing general principles regarding the establishment of NRVs for vitamins and minerals so as to protect consumers against misleading information.

33. Several delegations drew the attention of the Committee that during the presentation of the paper the Delegation of South Africa provided much valuable data which was omitted from the discussion paper and

[6] CX/NFSDU 05/27/4; CRD 4 (comments of South Africa and USA); CRD 18 (comments of India)

proposed that the paper should be further developed with a focus on principles for the establishment of NRVs for nutrition labeling purposes.

34. The Delegation of the USA indicated that it had suggested several principles which could be used as a basis for further development of the document.

35. The Delegation of the European Community indicated its regret that the paper did not fully reflect its comments and that the revised paper should reflect different options for establishing NRVs and implications of these options.

36. The Observer from NHF pointed out that if the mandate of the Committee was to avoid misleading consumers then there was a need to discuss optimum nutrition levels.

37. The Observer from ILCA expressed concern with proposal for development of a set of NRVs for infants from 4 – 6 months to 1 year, as this age range did not reflect the age of introduction of complementary foods into the diet, which is 6 months.

38. The Representative of the FAO informed the Committee that the United Nations University will convene a technical workshop in collaboration with FAO and WHO to look at the process and concepts of harmonization of nutrient requirement recommendations. The report will be available next year.

39. The Committee agreed that the Electronic Working Group coordinated by the Delegation of South Africa and open to all members and observers, should continue development of the discussion paper with a focus on: principles for the establishment of NRVs for labeling purposes; and the need to establish NRVs for different population groups taking into account discussions and comments made at this Session.

40. The Committee urged Member Countries to assist South Africa in the development of the document.

DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN AT STEP 7 (Agenda Item 5)[7]

41. The Committee recalled that its last session had made substantial progress on the text and had returned the Draft Revised Standard to Step 6 as some sections required further consideration. The Committee discussed the text section by section and made the following amendments and comments.

Essential Composition

Carbohydrates

42. The Committee agreed to correct the error in the amount of added carbohydrates in section 3.4.2 to refer to 1.2g/100kJ (5g/100 kcal) and made some editorial corrections to ensure consistency throughout the text.

43. The Committee agreed to transfer the reference to L (+) lactic acid producing cultures from Section 3.Additives to Section 3.8 Optional Ingredients.

44. The Delegation of Norway, referring to the recommendations of the WHO Global Strategy for Diet Physical Activity and Health (DPAS), proposed to reduce the level of added sugars in the standard in order to reduce the risks of obesity and adverse health effects in infants and young children. The Delegation of Thailand, supported by other delegations, proposed to limit the levels of sugars added to half of the drafted level. Several delegations and observers supported the proposal to limit the intake of sugars in view of the risks involved and indicated that they implemented such policies at the national level. Some delegations pointed out that a high intake of sugars would also develop a taste for sweet foods in children, which should be prevented by limiting sugar intake in cereal-based foods.

[7] ALINORM 05/27/26, Appendix V, CX/NFSDU 05/27/5 (comments of Argentina, Australia, Brazil, China, India, Mexico, Turkey, United States, Venezuela, AAC, ENCA, IACFO, IBFAN, ISDI, IWGA), CRD 3 (comments of the EC), CRD 5 (comments of Bulgaria, Indonesia, Kuwait, Thailand, United States, AIDGUM, AOECS) CRD 9 (Provisions for Food Additives), CRD 18 (comments of India); CRD 21 (comments of IBFAN)

45. Other delegations pointed out that the WHO recommendations referred to the total diet and not to specific foods, and supported the current value, while noting that it could be revised when new scientific evidence became available.

46. The Representative of WHO informed the Committee that the recommendations of the 2002 WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases, 10% goal for the total energy provided, are the population nutrient intake goals for the prevention of diet related chronic diseases. These figures represent population averages that are judged to be consistent with maintenance of health in a population, as the distribution of intakes, characterized by the average per capita intake, not the intake of individuals. Using the figures of the population nutrient intake goals as a dietary guideline for individuals is not correct and using these figures to determine the nutritional quality of any specific food is not a straightforward process, as the contribution of the food to the total diet should be taken into account. Processed cereal-based foods have a major share in young children's diets in some countries, but the inter-country variation is large and should be taken into account. Moreover, these population intake goals are general dietary advice and guidance for both population groups and individuals for the prevention of diet-related chronic diseases. They were not developed for foods for infants and children who have specific requirements both for growth and maintenance of health.

47. The Representative pointed out that current work on the standard should be addressed separately from the implementation of the Global Strategy (DPAS) and noted that the current discussion reflected the need for active participation of member countries in the efforts of WHO and FAO to develop more focused actions in the framework of Codex to facilitate the implementation of the DPAS. The Representative therefore suggested to discuss these actions as a separate issue under Agenda Item 10.

48. The Observer from ESPHGAN expressed great support for WHO Global Strategy including its goals of moderating dietary intakes of fat, sugar and salt for populations as one important component of health promotion. However, the Observer pointed out that these recommendations were intended for populations at large and not specifically for infants, whose physiology is different from adults and older children. A direct and uncritical application of dietary goals to infant populations is not always appropriate, such as a high dietary intake of fibre and a low fat intake, which are desirable for adults and other children, might put infants at risk of inadequate nutrient intake. Similarly a limitation of the intake of dietary sugars to no more than 10% of dietary energy would appear inappropriate for infants. There is ample scientific evidence to show that infants and young children have a preference for sweet foods, which may represent a protective factor because marked bacterial overgrowth will quickly reduce sugar content in foods. While breast milk contains some 26% of energy as milk sugar (lactose), the recommendation of WHO Global Strategy on a moderation of dietary sugar intake is not intended to discourage breast feeding. Similarly, considerations on the composition of breast milk substitutes and complementary foods need to take into account the specific physiologic conditions of infancy. In this respect, ESPGHAN supported the proposal of limiting the content of added sugar in cereal-based foods to no more than 5g/100kcal (20% of energy content), which can contribute to a reduction of dietary sugar intake from the high level during breast feeding to a gradually lower level achieved in young children with the stepwise introduction of greater amounts of family foods.

49. The Observer of IBFAN stated that breast milk lactose provides specific nutritional and immunological functions in contrast to sugars added to cereal-based foods and supported the proposals by the Delegations of Norway and Thailand.

50. The Committee agreed to retain the current provisions for carbohydrates and to consider more specifically the implementation of the Global Strategy (DPAS) as separate issue under Agenda item 10. The Delegation of Thailand expressed its reservation with this decision.

Vitamins and minerals

51. The Delegation of Norway recalled its earlier position that levels of vitamins and minerals should be in conformity with the legislation of the country in which the product is sold, and that the maximum values for added Vitamins A and D were too high.

Food Additives

52. The Delegation of Switzerland presented the results of the working group that had convened during the session to address the issues raised by the Committee on Food Additives and Contaminants. The list of additives had been revised to retain only additives and exclude processing aids; clarification had been provided where required on technological justification, and two packing gases evaluated by JECFA had been included in the list. Flavouring agents in line with those in the Standard for Canned Baby Foods[8] were entered in the text as 3.9 "Optional Ingredients". The Committee expressed its appreciation to the Delegation of Switzerland and to the working group for their excellent work and agreed to insert the revised additives provisions in Section 3.

53. The Committee also agreed to change the wording of Section 4.10 on carry over to the wording proposed by CCFAC in CRD 9 and to move the section to the beginning of the Section on Food Additives.

Food Hygiene

54. On the proposal of ILCA, the Committee agreed to include a specific reference to the Code of Hygienic Practice for Foods for Infants and Children[9], in addition to the basic food hygiene texts in order to provide additional guidance to governments.

Food Labelling

Section 8.1.1

55. The Delegation of Botswana, supported by several delegations, expressed the view that nutrition claims should not be allowed in foods for infants and children, as they would mislead consumers, reduce the consumption of home made complementary foods and were inconsistent both with WHA Resolutions on Infants and Young Children Nutrition and with the Codex Guidelines on Use of Nutrition and Health Claims[10], whereby nutrition claims should be consistent with national nutrition policy and support that policy and are also prohibited unless allowed by national legislation. These delegations pointed out that their national regulations did not allow nutrition claims and expressed their concern with the statement that "nutrition claims shall be permitted", that could be understood as an obligation for governments to allow such claims.

56. Several delegations and observers supported the deletion of the text as nutrition claims were addressed from a horizontal point of view in the Guidelines for Use of Nutrition and Health Claims. Several other delegations and observers supported the current text allowing nutrition claims if their effects were demonstrated scientifically.

57. The Committee considered several alternative proposals for new text that would refer to paragraph 1.4 of the Guidelines for Use of Nutrition and Health Claims and indicate that nutrition claims "shall" or "may" be permitted under national legislation provided they have been demonstrated scientifically. Several delegations supported these proposals, with minor amendments during the discussion, in order to allow nutrition claims when permitted by national legislation under certain conditions.

58. The Delegations of Botswana, India, Kenya, Zimbabwe, South Africa and Tanzania and several Observers did not support these proposals and proposed to include the following text in section 8.1.1: "Nutrition claims shall not be permitted for cereal-based foods for infants and young children except where specifically provided for in national legislation", as it was in line with the spirit of section 1.4 of the Guidelines for Use of Nutrition and Health Claims.

59. Some delegations questioned the reference to the claims being "demonstrated in rigorous studies with adequate scientific standards" as it was not clear how the quality or relevance of these studies would be determined. Some delegations pointed out that this was left to national authorities, since nutrition claims would be regulated or addressed at the national level.

60. After an extensive discussion, the Committee agreed that nutrition claims "may be permitted under national legislation for the foods that are the subject of the standard provided they have been demonstrated in rigorous

[8] CODEX STAN 73 (1981)
[9] CAC/RCP 21-1979
[10] CAC/GL 23 – 1997 (revised 2001)

studies with adequate scientific standards". The Delegations of Botswana, India, Kenya, Zimbabwe, South Africa, and Tanzania expressed their reservations on this decision.

Section 8.6.1

61. The Delegation of Australia pointed out that the directions for use and storage instructions should always appear on the label affixed to the container in view of their importance for food safety purposes and therefore proposed to delete the reference to an accompanying leaflet. After some discussion, the Committee agreed that the information should always appear on the label and might also appear on an accompanying leaflet, and amended the text accordingly.

Section 8.6.3

62. The Committee agreed to delete the square brackets in the current text, and to specify that the label "may show the statement gluten free" when the product is composed of gluten free ingredients, and to insert a footnote referring to the Codex Standard for Gluten Free Foods[11].

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

63. The Committee agreed to forward the Draft Revised Standard to Step 8 for adoption by the 29th Session of the Codex Alimentarius Commission (see Appendix II)

DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS AT STEP 7 (AGENDA ITEM 6 (A))[12]

64. The Committee recalled that at its last session had agreed to return Section A of the Standard to Step 6 and Section B to Step 3 for further comments. The Committee also recalled that it had agreed to convene the Working Group before the current session to prepare proposals for consideration of provisions in Section 3.1 "Essential Composition and Quality Factors.

Section A

65. The Delegation of Germany, Chair of the Working Group on Section 3.1 Essential Composition and Quality Factors, informed the Committee that following decisions of the last Session of the Committee an Electronic Working Group prepared proposals for Section 3.1 and that ESPGHAN had convened an International Expert Group (IEG) consisting of paediatric nutrition research experts from 14 countries who provided scientific analysis on proposed nutrient levels, taking into account existing scientific reports on the subject. Their report was made available to the Working Group and to the Plenary. The Delegation highlighted the conclusions and proposals made by the Working Group and presented in CRD 1. The Delegation informed the Committee that the Working Group had made considerable progress in proposing a text and a format for Section 3.1 and indicated that the amounts of a range of nutrients were given in this section.

66. The Working Group proposed to split the table of Section 3.1 into two parts, namely essential nutrients and optional ingredients, and to split the table of essential nutrients into nutrient specific components with the relevant explanatory footnotes added. Subsequent to the agreement on Annex II which defined two kinds of upper values for nutrients, namely maximum values based on risk assessment and guidance upper levels based on nutritional safety and established history of apparently safe use, the Working Group proposed to indicate for each essential micronutrient the nature of the proposed upper value. It indicated that some Working Group participants have

[11] CODEX STAN 118 – 1981 (revised 1983)

[12] ALINORM 05/28/26, Appendix IV (A); CX/NFSDU 05/27/6 (comments of Argentina, Australia, Brazil, China, India, Malaysia, Mexico, New Zealand, Turkey, United States, Venezuela, CRN, ENCA, IACFO, IBFAN, ISDI); CX/NFSDU 05/27/6-Add.1 (Proposed List of Additives for the Codex Draft Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants, prepared by the Electronic Working Group); CX/NFSDU 05/27/6-Add.2 (comments of European Community, Iran, Kuwait, IDF); CRD 1 (Report of the Working Group on the Revision of Composition Requirements of the Draft Revised Standard for Infant Formula); CRD 6 (comments of Canada, Bulgaria, Indonesia, Kenya, United States of America, International Association for the Development of natural Gums (AIDGUM), CRN); CRD 11 (comments of Chile); CRD 18 (comments from India); CRD 20 (comments of IACFO); CRD 15 (comments of Mexico); CRD (comments of Argentina)

reserved their final opinions on a number of numerical values. Some reservations and comments were indicated in CRD 1 in appropriate places. The Delegation drew the attention of the Committee to the fact that no agreement had been reached on the upper value of total and/or added nucleotides.

67. The Delegation indicated that the text already agreed by the Committee and presented in Appendix IV (A) of ALINORM 05/28/26 was maintained in CRD 1 and that all amendments proposed by the Working Group were presented in bold for transparency purposes.

68. The Committee expressed its appreciation to the Working Group and to the International Expert Group convened by ESPHGAN for their excellent work and decided to start consideration of the document based on proposals prepared by the Working Group and presented in CRD 1. The Committee discussed the text and in addition to editorial amendments made the following changes and comments.

Annex II General Principles for Establishing Minimum and Maximum Values for the Essential Composition of Infant Formula

General Comments

69. To the question from the Observer of IACFO regarding why the declarations of interest by members of the International Expert Group were not made public, the Observer of ESPGHAN stated that all members of the expert group completed forms of the declarations of interest as required by scientific organizations and pointed out that these declarations were subsequently reviewed by two independent individuals and that no conflict of interests was found.

70. The Committee also noted that this was not an FAO/WHO expert consultation subject to FAO and WHO Rules, but an expert group convened by an international organisation with Observer Status and that these proposals were presented to the Committee under responsibility of ESPGHAN in accordance with Codex procedures.

71. To the proposal of the Delegation of Botswana to move the provision on fluoride to the Section on contaminants since there is no minimum level and the maximum level was addressing the presence of fluoride in water, it was clarified that the WHO regarded fluoride as essential element for dental health.

72. The Delegation of the Russian Federation pointed out that their country has been revising the legislation on infant feeding and that the current Codex document, based on latest scientific findings, was taken into account in the above revision.

Annex II General Principles

73. The Committee agreed with the amended Principles 3, 4, 5 and 7 proposed by the Working Group. In addition, the Committee agreed to amend the last sentence of Principle 4 and to include the reference to guidance upper values as this provision was already introduced in sections on Vitamins and Minerals.

74. To the question why the provision (ii) on energy density had been taken out of Principle 7, it was clarified that Section 3.1.2 provided for an energy density range, therefore this provision was redundant.

75. The Committee agreed that the amended General Principles for Establishing Minimum and Maximum Values for the Essential Composition of Infant Formula be inserted as an Annex to the draft Revised Standard for Infant Formula.

Section 3.1 Essential Composition

76. The Committee agreed to the proposal of the Delegation of the United States to introduce wording “Guidance Upper Levels” for Vitamins and Minerals where values were derived on the basis of established history of apparently safe use.

77. Different views were expressed regarding the proposal of the Working Group to add clarification in Section 3.1.1 regarding details of the demonstration of physiological, biochemical and functional outcomes in formula-fed infants in comparison to populations of healthy exclusively breast-fed infants. The Delegation of Indonesia, supported by some delegations, was of the opinion that the proposed wording did not add clarity to this Section and suggested to delete it while some other delegations and observers were of the view that this addition should be

maintained. After some discussion the Committee agreed to delete the proposed wording in order to keep this section short and more focused. The Observers from ILCA, IBFAN and IACFO did not agree with this decision.

78. The Committee noted that not only milk of cows or other animals but also mixtures of such origin could be used for the preparation of Infant Formula and therefore inserted wording to that effect for clarity in Section 3.1.1.

Section 3.1.3

79. The Committee agreed to insert a provision on guidance upper levels in Section 3.1.3 and to add a footnote clarifying this provision. The Delegation of Canada requested to have separate columns for maximum values and for guidance upper levels to ensure that these were clearly differentiated and for clarity and ease of use.

Protein

80. The wording "more specific" was changed to "different" in relation to conversion factor for a particular nitrogen source in footnote 1 of CRD 1 and the amended sentence was put in square brackets. The Committee added a sentence to this footnote to clarify that protein levels set in this standard were based on a nitrogen conversion factor of 6.25.

81. Some delegations expressed their concern regarding the nitrogen conversion factor of 6.25 used for calculation of protein content. The Delegation of Germany informed the Committee that this issue had been discussed at the Working Group at length. It was proposed to use the nitrogen conversion factor of 6.25 if scientific justification was provided. The Secretariat clarified that the calculation of nitrogen conversion factor was specific to the consideration for the Standard on Infant Formula and should not be regarded as recommendation to extend this type of calculation to other standards. The Delegation of New Zealand also requested that the relevant Codex Committees, in particular the CCMMP, be informed of the decision regarding the nitrogen conversion factor for the Standard on Infant Formula. The Observers of IDF and EDA indicated that there were a number of scientific publications recommending a protein conversion factor of 6.38 for total milk protein (i.e. FAO Food and Nutrition Paper 77/2003) and supported the inclusion of this factor.

82. The Committee noted the clarification by the Observer of ESPGHAN that different food proteins contain differing amounts of nitrogen however FAO/WHO used a factor of 6.25 for all their reports on protein requirements and quality. The Observer indicated that proteins derived from cows' milk used in current infant formula are usually modified with lower conversion factors than caseins and that variations of non-protein nitrogen contents in infant formula depending on the methods of production result in further marked changes of the nitrogen conversion factor, therefore, the use of nitrogen conversion factor of 6.38 for all milk derived protein sources in infant formula was not justified.

83. The Committee noted that wording proposed in footnote 3 required further consideration and put it into square brackets.

84. The word "intact" in front of cows' milk was deleted as proposed by the Working Group.

85. To the concerns expressed by Observers from IBFAN, ILCA, IACFO and ENCA regarding safety of soy and its isolates used for the preparation of infant formula, referring to their written comments in CX/NFSDU 05/26/6 and the request to give a full consideration to this matter, the Observer of ESPGHAN clarified that soy-based formulae were covered by the current standards as they were used in some cases for children who could not tolerate cows' milk.

Section 3.1.4

86. The Delegation of Egypt was of the view that Section 3.1.4 should not be limited to provisions of quantity of essential and semi-essential amino acids, proposed for reference purposes in Annex I, but consideration should be given to protein quality. Some delegations indicated that it was addressed by the ratio of some amino acids. Some delegations proposed to consider Annex I in more detail as it does not reflect variability of amino acids in human milk. The Committee agreed to address this matter at its next session and encouraged member Governments to submit their comments.

Lipids

87. The Committee discussed where in the document the specific prohibition on the use of commercially hydrogenated oils and fats should be placed. It was suggested to move this provision from Section 3.6 to footnote 5. The Delegation of Malaysia was of the view that it should remain under Section on specific prohibitions, however the Committee agreed to place it as a text in Section on total fat.

88. The Observer of IDF pointed out that, if the intention of the Committee was to allow the use of milk fats but not hydrogenated fat in infant formula, the value of 3% should be changed to 5%.

89. The Committee agreed to put the trans fatty acids value of 3% in square brackets for further consideration.

90. The Delegation of Egypt expressed its concern on the value proposed for erucic acid. The Delegation of the EC noted that proposals for specific prohibitions for the use of cotton seed and sesame oils were not addressed by the Working Group.

91. The Delegation of Mali voiced its concern as regard to the exclusion of the use of cotton-seed oil as it was of importance for African countries.

92. To the question why the denomination of lauric and myristic acids was changed from the percentage of total fat content to total fatty acids, the Delegation of Germany clarified that it was done for practical reasons because laboratories measured total fat content as fatty acids. The Committee noted that this change required further consideration and put the denomination of “total fatty acids” in square brackets throughout the document.

93. The Delegation of the United States pointed out that there are differences between the proposed maximum values and interim guidance upper levels for linoleic acid and some other nutrients in comparison to what is known to be established practice for the marketing of infant formulas in the United States for many years. The Delegation indicated that linoleic acid values in the United States were at the level of 1.4g per 100 kcal and suggested to add the maximum values, proposed by the Working Group, in square brackets.

94. Regarding the values proposed for linoleic acid, the Observer of ESPHAN indicated that this issue had been looked at by the IEG and it was felt that the value of 1.2 g per 100 kcal was too generous and higher levels might introduce imbalance in fats.

Carbohydrates

95. The Observer of the AOECS proposed to clarify that only precooked and/or gelatinized starches may be added to infant formula as proposed by ESPGHAN, and the Committee agreed to this proposal. Furthermore, the Observer of AOECS proposed that only naturally gluten-free starches should be used, however, this proposal was not accepted.

96. The Committee agreed to put the provisions for the addition of sucrose and fructose in square brackets as proposed by the Delegation of the EC.

Vitamins and other sections of essential composition and quality factors

97. The Delegation of Germany informed the Committee that the Working Group proposed to clarify the expression of retinol content in footnote 6 and pointed out that still there was a need to agree on how to express and publish maximum and guidance upper levels.

98. The Delegation of the United States pointed out that there are differences between the proposed maximum values and interim guidance upper levels for vitamin A and some nutrients and optional ingredients in comparison to what has been established practice for the marketing of infant formulas in the United States for many years. It is likely that other countries may find such discrepancies between established practice and the proposed guidance upper levels or maximum values.

99. The Delegation indicated that this variability occurs because the feasibility of achieving certain levels in infant formula is dependent on variability of endogenous nutrient levels in ingredients, the stability of the nutrient in the infant formula product over the shelf life of the product, variability associated with analytical methods, whether soy protein isolate or milk is the protein source, and/or whether the form is liquid or powdered formula. An additional complicating factor is that label values in some countries are regulated as absolute minimums at the

end of shelf life, but in other countries as average values. For appropriate risk management decisions on the recommendations put forward by the IEG, these technological issues need further consideration in setting appropriate maximum or guidance upper values.

100. The Delegation of the US therefore proposed to consider the following values:

Nutrient	Established practice for release of formula	Recommendation for a maximum value or guidance upper level (GUL)
Linoleic acid	1.4g	Max
Vitamin A	225 µg	Max
Thiamin	268-milk; 372-soy	GUL
Riboflavin	600 µg	GUL
Niacin	2330 µg milk; 3200 µg -soy	GUL
B12	1.86 µg	GUL
Pantothenic acid	1688 µg	GUL
Folic acid	74 µg	GUL
Biotin	12.8 µg -milk; 15.6 µg -soy	GUL
Vitamin C	100mg	GUL
Iron	3mg	Max or GUL
Copper	137 µg -milk; 200 µg -soy	Max or GUL
Manganese	21 µg -milk; 76 µg -soy	GUL
Potassium	162mg-milk; 190mg-soy	GUL
Optional Ingredients		
Nucleotides	16mg	Max

101. The Delegation indicated that for pantothenic acid, iron, and copper, there are questions about the minimum value as well as the maximum value or guidance upper level. For these nutrients, the history of apparently safe use must be considered before drastically reducing values to proposed maximums and minimums. The Delegation also noted that nucleotides refers to total nucleotides in cow's milk formulas as referred to in the table above and proposed to reconsider levels for individual nucleotides. Some delegations supported these proposals.

102. The Observer of ESPGHAN drew the attention of the Committee to the fact that maximum values were derived following principles explained in their written document and that IEG did not see reasons to add to infant formulas excessive amounts of any nutrient that does not serve any particular nutritional purpose or provide any other benefit.

103. The Delegation of the EC stressed the need to establish these values taking into account recent scientific opinion in order to protect public health.

104. The Delegation of Japan pointed out that it was necessary to clarify issues in relation to Section 3.2 on optional ingredients as their comments were not included in CRD 1 and suggested that the Electronic Working Group should also consider this section, including values and footnotes as well as Annex I.

105. The Observer from IBFAN, supported by the Observer from IACFO, pointed out that, if optional ingredients give particular benefits as demonstrated in breastfed populations, they should not be optional but available for all infants and therefore should be moved to the Section on Essential Composition.

106. The Committee noted that all these matters required further consideration, therefore agreed to keep the entire section in square brackets and asked the Electronic Working Group (EWG) under the chairmanship of Germany to look especially at the discrepancies between the proposed maximum values and the amounts of nutrients currently used in infant formula in member countries with the understanding that comments on this matter and other issues raised on Section 3 be sent to the Delegation of Germany by 15 February 2006. The Committee stressed the importance of providing justification for the values proposed in these comments. The Delegation would prepare a revised Section for consideration by the next session of the Committee. The Committee also asked ESPGHAN to provide an opinion on the discrepancies and noted the need for technical expertise in evaluating these discrepancies.

107. The Observer from ESPGHAN noted that when providing comments on vitamin and mineral levels in infant formula, as currently sold, the following data needed to be provided: information whether data provided are based on calculations or measurements; the time points of measured data (e.g., time of production, time of beginning of retail sale, random supplies from retail stores and time of end of shelf life); number of samples included; mean levels, standard deviations and ranges and data which might provide indications on safety of nutrient contents used. The Observer from ISDI proposed to submit global data for currently applied maximum values for infant formula.

108. Due to time constraints, the Committee was unable to discuss other sections in more detail and agreed to ask comments on other proposals suggested by the Working Group as presented in CRD 1.

Section 4 Food additives

109. The Committee recognized that it was not possible to consider this section at the present session due to lack of time, therefore it accepted the kind offer of the Delegation of Switzerland to prepare a revised list of additives taking into account proposals made by the CCFAC on this Section for the draft revised Standard for Cereal-Based Foods for Infants and Young Children and comments submitted to the current session. The revised list then will be circulated for consideration by the next session of the Committee.

Status of Section A of the Draft Revised Standard for Infant Formula and Formulas for Special medical Purposes Intended for Children

110. The Committee agreed to return Section A of the Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Children to Step 6 for comments and consideration at the next session (see Section A of Appendix IV).

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

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 4 (AGENDA ITEM 6b)[13]

112. The Committee recalled that it had agreed to return this section to Step 3 for further comments and that Section A was to serve as a model for this section. The Committee considered the document section by section and made the following changes and comments.

Section 1. Scope

113. The Committee noted that provision sections of the Scope of Section B should be in conformity with the relevant provisions of Section A and contain only modifications necessary for Formulas for Special Medical Purposes Intended for Infants.

114. The Committee deleted the square brackets in Section 1.1 and amended Section 1.2 to reflect that this Section refers specifically to this standard.

115. The Committee had a lengthy discussion on Section 1.3. A new Section 1.3 was added based on the relevant section of Section A and different wordings were proposed for this section. Several delegations and observers wished to insert the reference that formula could be used by infants during first 6 months of life to be in conformity with the WHA Resolution 55.25. Other delegations were of the view that the reference to 6 months was not appropriate. These delegations recalled that the products were to be administered under medical advice and pointed out that reference to Section 4.4.1 of CODEX STAN 180-1991[14] in Section 9.6.1 covered this issue. It was further pointed out that WHA resolutions were to be considered where relevant and should not be a hindrance to reaching a compromise as they were not "binding" for Codex work. In order to clarify the status of WHA resolutions in Codex, the Secretariat informed the Committee that it had considered this matter at the last Session and discussions were reflected in ALINORM 05/28/26, paras 56 and 57.

116. The Delegation of India proposed to insert a new sentence to the effect that these products should be used only under medical advice. The Committee, however, agreed that this requirement was already covered in Section 4.4 Additional Information of CODEX STAN 180-1991, whereby a statement "use under medical supervision" was required.

117. The Committee agreed to insert an amended Section 1.4 as proposed by the Delegation of the EC in CRD 3 and supported by several delegations. The Delegations of Tanzania, South Africa, Botswana, India and the Observers from ILCA and IBFAN, while supporting the inclusion of Section 1.4, strongly expressed their reservations to the amended text.

Section 2. Description

118. The Committee agreed to amend Section 2.1.1 to clarify that formula for special medical purposes intended for infants refers to a substitute for human milk and infant formula. An editorial amendment was made to Section 2.1.2 to correctly cross-reference it to Section A2.1.2.

Section 3. Essential Composition and Quality Factors

119. The Committee recalled that the relevant section in Section A of the standard was still under consideration and therefore agreed to place the entire section in square brackets until the relevant section in Section A was completed.

[13] ALINORM 05/28/26, Appendix IVB; CX/NFSDU 05/27/7 (comments of Argentina, Australia, China, India, Malaysia, Mexico, Turkey, USA, Venezuela, ENCA, IACFO, IBFAN, ISDI); CRD 3 (comments of the European Community); 7 (comments of Canada, Bulgaria, Indonesia, Kenya, Kuwait, USA, AIDGUM); 11 (comments from Chile); 18 (comments of India), 20 (comments of IACFO)

[14] Labelling of and Claims for Foods for Special Medical Purposes

3.1 Essential Composition

120. The Committee agreed to amend Section 3.1.1 to reflect that these products are based on ingredients from animal, plant and/or synthetic compounds and further agreed to replace "formulation" with "composition" in the first part of Section 3.1.2.

Optional Ingredients

121. The Committee agreed to retain Section 3.2.1 unchanged after extensive discussion was held on a proposal by the Observer from IACFO, supported by other observers that in Section 3.2.1, optional ingredients should be added only when demonstrated by independently funded research to be safe and essential for infant health when medically indicated that such ingredients should be mandatory. Many delegations pointed out that this concern was covered in the agreed upon principles in the Annex to the Standard. Concerns were raised by some delegations as to the status of an annex. The Secretariat clarified that all annexes were part of Codex standards and thus the principles as referred to were part of the standard.

122. It was agreed to remove the square brackets from Section 3.2.3 and to retain the text unchanged after considerable discussion on the importance of retaining the second part of the section as it covered very vulnerable populations.

Section 4. Food Additives

123. The Delegation of the EC expressed their concern that additional additives may need to be added to this section and further reiterated its concern with the inclusion of carrageenan. They proposed that a request be made to the Codex Committee on Food Additives and Contaminants to request JECFA to re-evaluate the safety of carrageenan.

124. The Committee agreed that the mandate of the Electronic Working Group coordinated by Switzerland and open to all Member Countries and Observers, would be extended and that this Working Group would look at all additives that may need to be included in Section B taking into account the discussions at this session.

Section 9. Labelling

125. After extensive discussion it was agreed to insert a Section 9.5 with a cross reference to Section A9.5 and agreed to delete Section 9.6.5 as this would be covered under Section 9.5 as it related to the provision on information for use.

126. The Committee noted that several delegations had made proposals to reorganize and amend the section in order to clarify the text and ensure consistency with Section A. However it was not possible to discuss these proposals in detail and the Committee agreed that the section would be considered further at the next session.

127. It was agreed to delete the square brackets from Section 9.6.4 concerning breastfeeding contraindications. Some observers raised their concern with this decision and proposed to amend the section by inserting the text from Section A9.6.4. The Observer from ILCA proposed to include "totally" before "contraindicated" to differentiate between metabolic diseases where partial breastfeeding was possible and permitted, however, the Committee did not agree to this proposal. The Delegation of Botswana and several Observers proposed to delete the reference to Section 4.5.3 and 4.5.5 of CODEX STAN 180 –1991 and to revise that text. The Committee also noted some additional proposals to amend the text. The Committee agreed to retain the current text. The Chairperson reiterated that this section together with all other sections would be open for further comments at Step 6 if adopted at Step 5 by the Commission.

128. To the question raised by the Delegation of South Africa with regard the provision of information on contamination by *Enterobacter sakazakii*, the Secretariat informed the Committee that *E. sakazakii* was one of several pathogens that may be present in infant formula and that this issue was under discussion in the Codex Committee on Food Hygiene who would be making recommendations on how this information should be presented.

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

129. The Committee noted that it was necessary to discuss this section of the standard concurrently with Section A and that it was desirable to have both sections of the standard at the same Step of development and the considerable progress made, agreed to advance Section B for adoption at Step 5 by the 29th Session of the Codex Alimentarius Commission (See Section B of Appendix IV).

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 7)[15]

130. The Committee recalled that it had requested the Delegation of Germany to revise the advisory list of nutrient compounds for use in foods for special dietary uses intended for the use by infants and young children.

131. The Delegation of Germany introduced the document and pointed out several changes made to the document based on discussions at the last session and in response to comments received. The Delegation informed the Committee that in accordance with criteria 2.2, all nutrient compounds for which no internationally or nationally recognized purity requirements exist, had been removed from the list and were reflected in a separate list in the document; that Lists A, B and C had been extended to foods for special medical purposes, that an additional column had been introduced under purity requirements identifying nutrient compounds for which Codex has established identity and purity specifications and that the list of additives for special vitamin forms had been reintroduced.

132. The Committee expressed its appreciation to the Delegation of Germany for the excellent work done and agreed to concentrate discussion only on those sections where no consensus could be reached at the last Session. The Committee made the following changes and recommendations on the following sections:

Preamble

133. To the concern raised by the Delegation of Indonesia that certain substances intended for use by infants and young children may not meet specific religious or dietary restrictions, the preamble was amended to reflect that the source of nutrient compounds may exclude the use of specific substances where religious or other dietary restrictions apply.

Section 2. Criteria for the inclusion and deletion of nutrient compounds from the advisory lists

134. Considerable discussion was held on the proposals under 2.1 (c). Several delegations expressed their concern that in the cases where no internationally recognized specifications of identity and purity were available, consideration should be given to national purity requirements and that it was uncertain as to what was used to determine purity requirements at the national level. The Committee agreed to include wording that national purity requirements evaluated by a process similar to a FAO/WHO process may be considered.

135. The Delegation of the United States proposed to delete section 2.1 (d) since the list was about the nutrient itself, and that the manufacturer had to guarantee the purity of the product. The Delegation of Germany cautioned against this deletion as this would leave the guarantee of purity entirely up to the manufacturer. After a brief discussion the Committee agreed to retain this section.

List of nutrient compounds that lack official purity requirements

136. The Committee held an extensive discussion on how to proceed with the list of nutrients that lack purity criteria. The Delegation of the United States raised its concern about the large number of nutrients listed which did not have purity criteria and proposed to remove them from the list. It was proposed that Member Countries be requested to come forward with their purity requirements so that those nutrients for which purity requirements were available could remain on the list. The Delegation of the EC, supported by other delegations was of the view that if nutrients without purity criteria were to be removed, that it was advisable to take this decision when the list

[15] CX/NFSDU 05/27/8; CX/NFSDU 05/27/8-Add.1 (comments of Argentina, Australia, Mexico, New Zealand, USA, ISDI); CRD 3 (comments of the European Community); CRD 8 (comments of Kenya, AIDGUM); CRD 11 (comments from Chile); CRD 18 (comments of India)

was finalized and proposed to urge Member Countries to provide purity requirements to the Delegation of Germany in order to complete the finalization of the Advisory List.

Section D Advisory List of Food Additives for Special Nutrient Forms

137. The Delegation of the EC, referring to its comments in CRD 3, proposed that the introductory paragraph on Section D should refer only to food additives and the Committee agreed to this proposal.

138. The Delegation of the United States pointed out that the Advisory List should not duplicate the listing of food additives that are already permitted for use for other technological functions and was of the view that only mannitol be retained in this section. The Delegation of the EC did not agree to this and suggested to retain all these substances for further discussion. No agreement could be reached on these proposals.

139. The Delegation of the United States indicated that there was confusion about the list in Section D and pointed out that last year the Committee agreed that in this section, only additives as nutrient carriers be retained in order to avoid duplication with the Section on Additives.

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

140. The Committee agreed to return the above list to Step 3 for further comments, especially requesting Member Countries to provide a list of their purity requirements by 30 March 2006 (see Appendix V). Countries should provide 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. The comments would be sent to the Delegation of Germany who will revise the list based on the information received. The revised list would be circulated for consideration at the next session of the Committee.

PROPOSED DRAFT RECOMMENDATIONS ON THE SCIENTIFIC BASIS OF HEALTH CLAIMS AT STEP 4 (Agenda Item 8)[16]

141. 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. Taking into account the comments received, the Delegation had presented in CRD 10 a summary of the main issues that required advice from the Committee in order to progress further in the elaboration of the document: the scope of the document; the relevance of safety concerns; and the nature of the scientific evidence required according to the type of health claims concerned, including the use of human studies or biomarkers.

142. As regards the scope of the document, the Committee noted that some written comments proposed to expand the scope to cover authorization procedures, but agreed that such procedures were the responsibility of national authorities. The Committee confirmed that the Proposed Draft Recommendations were intended to address the nature of the scientific evidence required to substantiate claims, in accordance with the mandate given by the Commission when new work had been approved.

143. The Committee noted a proposal to make the safety requirements mandatory, however several delegations and observers pointed out that all foods placed on the market should be safe and that food safety as such should not be addressed in the document. The Committee recalled that food safety was addressed in other Codex texts and confirmed that the purpose of the document was to address the issues related to the scientific substantiation of health claims, and only the safety issues directly related to the claims required specific consideration.

144. The Delegation of France recalled that three types of health claims were allowed and highlighted the issues relating to the type of scientific evidence required, which might differ according to the claim concerned. The Committee noted that the need for human studies and the use of biomarkers would need further consideration but could not discuss these issues in detail at this stage. The Delegation of the US indicated that risk assessments relating to health claims might be more appropriate than safety issues.

[16] CX/NFSDU 05/27/9, CX/NFSDU 05/27/9-Add.1 (comments of Argentina, Australia, Bolivia, Brazil, Mexico, New Zealand, Republic of Korea, United States, CIAA, IADSA, IFCGA, ILSI, ISDI), CRD 10 (comments of Canada, Denmark, France, Germany, Indonesia, Kenya, South Africa, United States, EFLA), CRD 19 (comments of ICGMA)

145. The Delegation of the United States drew the attention of the Committee to its written comments based on its experience at the national level with the regulation of health claims. The Delegation of the UK (speaking on behalf of EC Member Countries) informed the Committee that a draft regulation was under development and that it included disease reduction claims. The Observer from IADSA noted the relevance of the publication on the PASSCLAIM (Process for the Assessment of the Assessment of Scientific Support for Claims on Foods) project that was made available to delegates at the session. It was suggested that sufficient time be allowed for discussion of this agenda item at the next session.

146. The Committee could not discuss the document in detail due to time constraints and expressed its appreciation to the Delegation of France for its excellent work addressing complex issues in the revision of the document. It was agreed that a Circular Letter listing the questions to be addressed would be drafted on the basis of the summary on the main issues prepared by the Delegation of France and presented in CRD 10, would be sent for comments with a deadline of 31 March 2006, to be addressed to the Delegation of France

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

147. The Committee agreed to return the Proposed Draft Recommendations to Step 2/3 for redrafting by the Delegation of France in the light of the comments received, for further consideration at the next session.

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)[17]

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

149. The Delegation of Australia introduced the document and referred to progress made in the *ad hoc* Working Group and highlighted the work done in the Commission and other Committees in this area. The Delegation emphasized that following the spirit of the current draft Strategic Plan 2008 – 2013 much more work should be done in order to complete this activity by 2013.

150. Due to time constraints, the Committee did not have a substantive discussion on this matter. The Committee agreed to establish an Electronic Working Group open to all interested parties, in order to further develop the document for consideration at the next session of the Committee.

151. The Terms of Reference for the Electronic Working Group should be: to further consider issues raised in the agenda paper and to present recommendations; and to submit a proposal for new work to develop risk analysis principles and possibly guidelines for application to the work of the CCNFSDU.

152. The Committee expressed its appreciation to Australia and the Electronic Working Group for their excellent work in this complex area. The Chairperson expressed the view that this work should have a high priority in the work of the Committee.

OTHER BUSINESS AND FUTURE WORK (AGENDA ITEM 10)

Implementation of the WHO Global Strategy on Diet, Physical Activity and Health: Action that could be taken by Codex[18]

153. The Committee recalled that the 28th Session of the Commission in July 2005 had noted that the potential areas for action by Codex related to the implementation of the WHO Global Strategy on Diet, Physical Activity and Health (DPAS) were mainly relevant for the work of the Committee on Food Labelling and the Committee on Nutrition and Foods for Special Dietary Uses and that the WHO, in cooperation with FAO would produce a more focused document for consideration by these Committees, including specific proposals for new work.

154. The Representative of WHO introduced CRD 23 suggesting a way to address the request of the Commission and invited Members and Observers of the Committee to participate in an electronic forum to be established by WHO and FAO. This forum would serve to define, comment on and discuss possible areas for

[17] CX/NFSDU 05/27/10; CRD 17 (comments of CRN and NHF)
[18] CX/NFSDU 05/27/2 Add.1 and CRD 23 (Prepared by WHO in cooperation with FAO)

CCNFSDU to consider, which may include, among others: 1) Review of existing standards which may impede progress in achieving the objectives of the DPAS; 2) Proposals for the provision of scientific advice by FAO and WHO required for consideration on new or revised standards, guidelines and recommendations, relevant to the DPAS; 3) Consumer information covered under the Codex mandate, which could contribute to achieving to the objectives of the DPAS; and 4) Application of risk analysis to nutrition issues.

155. The Representative explained that WHO/FAO would provide an e-mail address to which the views can be sent. This e-mail address and details about the discussion period would be communicated to all Codex focal points by mid-December 2005 via the Codex list-serve, through the Codex Secretariat. The views received by WHO/FAO would be posted in a virtual share-point, to be housed on the WHO-internet, for others to access. The access code to this share-point, would be provided via the Codex list-serve as well. Comments would be accepted in English, Spanish and French and posted in the original language. Based on the forum discussions WHO/FAO would prepare a progress report to CAC in July 2006.

156. The Delegation of the UK underlined the importance of the Global Strategy and explained that the EC was taking forward a platform of action with the same title. It suggested that the CCNFSDU could make a positive contribution by setting up an electronic working group. Other delegations who spoke were positive about taking forward the global strategy in Codex. The Delegation of the UK further suggested that Codex Regional Coordinating Committees should also discuss the DPAS and its implications for Codex work within their regions.

157. The Delegations of Canada and The Netherlands offered their assistance to FAO and WHO to help develop the electronic forum and help define questions and nature of the scope to be addressed. The Delegation of Canada specifically offered to assist WHO/FAO to help summarize and clarify the comments made.

158. The Observer of CI welcomed the proposal of the WHO and FAO and called for the inclusion of food advertising as a part of consumer information.

159. The Committee recognized that it was very important to provide their views to WHO/FAO so that they could draft a more focused document for implementing the DPAS within Codex. The Committee agreed to inform the Commission that due to time constraints no further discussion was possible.

Draft Revised Standard for Gluten-Free Foods

160. Due to time constraints the Committee was unable to discuss this item. The Committee agreed to return the latest version of the Draft Revised Standard for Gluten-Free Food to Step 6 for comments and consideration at the next session of the Committee.

Proposal to Amend the Codex General Principles for the Addition of Essential Nutrients to Foods [19]

161. Due to time constraints the Committee was unable to discuss this item.

DATE AND PLACE OF THE NEXT SESSION (AGENDA ITEM 11)[20]

162. The Committee was informed that the 28th session would take place in Chiangmai, Thailand, scheduled from 30 October to 3 November 2006 at the kind invitation of the Government of Thailand.

[19] CX/NFSDU 05/27/11
[20] CRD 22 (Prepared by Thailand)

SUMMARY STATUS OF WORK

Subject Matter	Step	For Action by	Reference in ALINORM 06/29/26
Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children	8	29th CAC	para. 63 and Appendix II
Guidelines for Use of Nutrition Claims: Draft Table of Contents for Nutrient Contents (Part B, Dietary Fibre)	6	Governments; 28th CCNFSDU	para. 28 and Appendix III
Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Section A)	6	Governments; 28th CCNFSDU	para. 110 and Appendix IVA
Draft Revised Standard for Gluten-Free Foods	6	Governments; 28th CCNFSDU	para. 161 and ALINORM 04/27/26, Appendix II
Formulas for Special Medical Purposes Intended for Infants (Section B)	5	29th CAC	para. 129 and Appendix IVB
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	3	Governments, Germany; 28th CCNFSDU	para. 140 and Appendix V
Proposed Draft Recommendations on the Scientific Basis of Health Claims	2/3	France; Governments 28th CCNFSDU	para. 147
Discussion Paper on the Proposals for Additional or Revised Nutrient Reference Values (NRVs)	-	South Africa; 28th CCNFSDU	para. 39
Discussion Paper on the Application of Risk Analysis for the Work of the Codex Committee on Nutrition and Foods for Special Dietary Uses	-	Australia; 28th CCNFSDU	paras 148-152

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APPENDIX II

DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN

(At Step 8 of the Procedure)

1. SCOPE

This standard covers processed cereal-based foods intended for feeding infants as a complementary food generally from the age of 6 months onwards, taking into account infants' individual nutritional requirements, and for feeding young children as part of a progressively diversified diet, in accordance with the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution WHA 54.2 (2001).

2. DESCRIPTION

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

2.1. Product Definitions

Four categories are distinguished:

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

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

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

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

2.2 Other Definitions

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

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

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

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

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

3.2 Energy Density

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

3.3 Protein

3.3.1 The chemical index of the added protein shall be equal to at least 80% of that of the reference protein casein or the Protein Efficiency Ratio (PER) of the protein in the mixture shall be equal to at least 70% of that of the reference protein casein. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose. Only natural forms of L-amino acids should be used.

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

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

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

3.4 Carbohydrates

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

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

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

- the amount of added carbohydrates from these sources shall not exceed 1.2 g/100 kJ (5 g/100 kcal).
- the amount of added fructose shall not exceed 0.6 g/100 kJ (2.5 g/100 kcal).

3.5 Lipids

3.5.1 For products mentioned in point 2.1.2 the lipid content shall not exceed 1.1g/100 kJ (4.5 g/100 kcal) If the lipid content exceeds 0.8g/100kJ (3.3g/100kcal):

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

3.5.2 Product categories 2.1.1 and 2.1.4 shall not exceed a maximum lipid content of 0.8 g /100 kJ (3.3 g/100 kcal).

3.6 Minerals

3.6.1 The sodium content of the products described in Sections 2.1.1 to 2.1.4 of this Standard shall not exceed 24 mg/100 kJ (100 mg/100 kcal) of the ready-to-eat product.

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

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

3.7 Vitamins

3.7.1 The amount of vitamin B1 (thiamin) shall not be less than 12.5µg/100 kJ (50µg/100 kcal).

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

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

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

3.7.3 Reductions of the maximum amounts for vitamin A and Vitamin D referred to in 3.7.2 and the addition of vitamins and minerals for which specifications are not set above shall be in conformity with the legislation of the country in which the product is sold.

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

3.8 Optional Ingredients

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

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

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

3.9 Flavours

The following flavours may be used:

- Natural fruit extracts and vanilla extract GMP
- Ethyl vanillin and vanillin: 7 mg/100 g RTU

3.10 Quality Factors

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

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

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

3.11 Consistency and Particle Size

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

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

3.12 Specific Prohibition

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

The use of partially hydrogenated fats for these products is prohibited.

4. FOOD ADDITIVES

Only the food additives listed in this Section or in the Codex Advisory List of 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, Rev. 5 (2004)).

The following additives are permitted in the preparation of processed cereal-based foods for infants and young children, as described in Section 2.1 of this Standard (in 100 g of product, ready for consumption prepared following manufacturer's instructions unless otherwise indicated).

	INS no.			**Maximum level**	**Technological Justification**
4.1	**Emulsifiers**				
4.1.1	322	Lecithins		1.5 g	Retains homogeneity
4.1.2	471	Mono- and diglycerides		1.5 g	Retains homogeneity
4.1.3	472a	Acetic and fatty acid esters of glycerol		0.5 g singly or in combination	Retains homogeneity
4.1.4	472b	Lactic and fatty acid esters of glycerol			Retains homogeneity
4.1.5	472c	Citric and fatty acid esters of glycerol			Higher emulsifying power than lecithin and more hydrophylic capacities than mono- and diglycerides of fatty acids

4.2	**Acidity Regulators**				
4.2.1	500 ii	Sodium hydrogen carbonate		GMP, within the limits for sodium	pH-adjustment
4.2.2	501 ii	Potassium hydrogen carbonate		GMP	pH-adjustment
4.2.3	170 i	Calcium carbonate		GMP	pH-adjustment
4.2.4	270	L(+)-Lactic acid		GMP	pH-adjustment. Decrease risk of contamination from undesirable bacteria
4.2.5	330	Citric acid		GMP	pH-adjustment
4.2.6	260	Acetic acid		GMP	pH-adjustment
4.2.7	261	Potassium acetates			
4.2.9	262 i	Sodium acetate			
4.2.11	263	Calcium acetate			
4.2.12	296	Malic acid (DL) – L(+)-form only			pH-adjustment. Compensate for variable natural acidity of fruit
4.2.13	325	Sodium lactate (solution) – L(+)-form only			pH-adjustment
4.2.14	326	Potassium lactate (solution) – L(+)-form only			
4.2.15	327	Calcium lactate – L(+)-form only			
4.2.16	331 i	Monosodium citrate			pH-adjustment
4.2.17	331 ii	Trisodium citrate			
4.2.18	332 i	Monopotassium citrate			
4.2.19	332 ii	Tripotassium citrate			
4.2.20	333	Calcium citrate			
4.2.21	507	Hydrochloric acid			pH-adjustment

	INS no.			**Maximum level**	**Technological Justification**
4.2. 22	524	Sodium hydroxide		GMP	pH-adjustment
4.2.23	525	Potassium hydroxide			
4.2.24	526	Calcium hydroxide			
4.2.25	575	Glucono delta-lactone		0.5 g singly or in combination Tartrates as residue in biscuits and rusks	pH-adjustment Slow release acidifier Secondary raising agent
4.2.26	334	L(+)-Tartaric acid – L(+)form only			pH-adjustment In conjunction with 500 ii raising agent in biscuits and rusks
4.2.27	335 i	Monosodiumtartrate			
4.2.28	335 ii	Disodium tartrate			
4.2.29	336 i	Monopotassium tartrate – L(+)form only			
4.2.30	336 ii	Dipotassium tartrate – L(+)form only			
4.2.31	337	Potassium sodium L(+)tartrat L(+)form only			

	INS no.			Maximum level	Technological Justification
4.2.32	338	Orthophosphoric acid		Only for pH adjustment 0.1 g as P_2O_5, singly or in combination	pH-adjustment
4.2.33	339 i	Monosodium orthophosphate			
4.2.34	339 ii	Disodium orthophosphate			
4.2.35	339 iii	Trisodium orthophosphate			
4.2.36	340 i	Monopotassium orthophosphate			
4.2.37	340 ii	Dipotassium orthophosphate			
4.2.38	340 iii	Tripotassium orthophosphate			
4.2.39	341 i	Monocalcium orthophosphate			
4.2.40	341 ii	Dicalcium orthophosphate			
4.2.41	341 iii	Tricalcium orthophosphate			
4.3	**Antioxidants**				
4.3.1	306	Mixed tocopherols concentrate		300 mg/kg fat, singly or in combination	Protect from oxidation Synergistic effect with ascorbyl esters
4.3.2	307	Alpha-tocopherol			
4.3.3	304	L-Ascorbyl palmitate		200 mg/kg fat	Protect from oxidation Synergistic affect with tocopherols

	INS no.			Maximum level	Technological Justification
4.3.4	300	L-Ascorbic acid	}	50 mg, expressed as ascorbic acid and within the limits for sodium	Antioxidant in cereal bars Reduce discoloration in fruit preparations
4.3.5	301	Sodium ascorbate			
4.3.6	303	Potassium ascorbate			
4.3.7	302	Calcium ascorbate		20 mg, expressed as ascorbic acid	
4.6	**Raising Agents**				
4.6.1	503 i	Ammonium carbonate	}	Limited by GMP	Raising agent in rusks and biscuits
4.6.2	503 ii	Ammonium hydrogen carbonate			
4.6.3	500 i	Sodium carbonate			Raising agent in rusks and biscuits Sometimes used in combination with 503 i or 503 ii
4.6.4	500 ii	Sodium hydrogen carbonate			Raising agent in rusks and biscuits Sometimes used in combination with 503 i or 503 ii
4.7	**Thickeners**				
4.7.1	410	Carob bean gum	}	1 g singly or in combination 2 g in gluten-free cereal-based foods	Thickening agent and emulsion stabiliser
4.7.2	412	Guar gum			
4.7.3	414	Gum arabic			For fruit coating to prevent fruit from sticking together Also used as an ingredient of nutrient forms

	INS no.			**Maximum level**	**Technological Justification**
4.7.4	415	Xanthan gum			Thickener for semi-solid preparation Optimum viscosity achieved in combination with other thickeners
4.7.5	440	Pectins (Amidated and Non-Amidated)		1 g singly or in combination 2 g in gluten-free cereal-based foods	Gelling agent in place of gelatine Particularly efficient in presence of fruits and acidic preparations Optimum viscosity achieved in combination with other thickeners Used as binder in extruded cereals increasing cohesiveness of the cereal pieces after rehydration
4.7.6	1404	Oxidized starch		5 g singly or in combination	Physical properties that native starch tend to lose when processed
4.7.7	1410	Monostarch phosphate			
4.7.8	1412 1413 1414 1422	Distarch phosphate Phosphated distarch phosphate Acetylated distarch phosphate Acetylated distarch adipate			
4.7.9	1420	Starch acetate esterified with acetic anhydride			
4.7.10	1450	Starch sodium octenyl succinate			
4.7.11	1451	Acetylated oxidized starch			

	INS no.			Maximum level	Technological Justification
4.8	**Anticaking Agents**				
4.8.1	551	Silicon dioxide (amorphous)		0.2 g for dry cereals only	Most neutral anticaking agent, prevents clumping Ensures even distribution of nutrients
4.9	**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		GMP	

5. CONTAMINANTS

5.1. Pesticide Residues

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

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

5.2 Other Contaminants

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

6. HYGIENE

It is recommended that the products 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 Principle of Hygiene (CAC/RCP 1 1969, Rev. 3, 1997, Recommended International Codex of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979 (under revision)) and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

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

7. PACKAGING

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

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

8. LABELLING

8.1.1 The requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991), Codex Alimentarius Volume 1), the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985 (Rev. 1-1993) and the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997 (Rev. 2001) apply to this standard. With specific reference to section 7 of the Codex General Standard for the Labelling of Prepackaged Foods national jurisdictions may further restrict the use of pictorial devices.

Taking into account paragraph 1.4 of the Guidelines for Use of Nutrition and Health Claims, nutrition claims may be permitted under national legislation for the foods that are the subject of the standard provided that they have been demonstrated in rigorous studies with adequate scientific standards.

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

8.2 The Name of the Food

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

8.3 List of Ingredients

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

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

8.4 Declaration of Nutritive Value

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

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

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

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

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

8.5 Date Marking and Storage Instructions

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

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

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

8.6 Information for Utilization

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

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

8.6.3 When the product is composed of gluten-free ingredients and food additives, the label may show the statement “gluten-free”.[1]

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

8.7 Additional Requirements

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

9. METHODS OF ANALYSIS AND SAMPLING

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

In addition:

Detection of Irradiated Foods

Codex General Methods.

[1] Codex Standard for Gluten-Free Foods (118-1981 (under revision).

APPENDIX III

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

(At Step 6 of the Procedure)

COMPONENT	CLAIM	CONDITIONS
B.		**NOT LESS THAN**
Dietary Fibre	Source	3 g per 100 g or 1.5 g per 100 kcal or [10 % of recommended intake] per serving* [(liquid foods: 1.5 g per 100 ml)]
	High	6 g per 100 g or 3 g per 100 kcal or [20 % of recommended intake] per serving* [(liquid foods: 3 g per 100 ml)]

* Serving size [and recommended intake] to be determined at national level.

Definition and properties of dietary fibre:

Definition:

Dietary fibre means carbohydrate polymers[1] with a degree of polymerisation (DP) not lower than 3 [, which are neither digested nor absorbed in the small intestine. A degree of polymerisation not lower than 3 is intended to exclude mono- and disaccharides. It is not intended to reflect the average DP of a mixture. Dietary fibre consists of one or more of:

- Edible carbohydrate polymers naturally occurring in the food as consumed,
- carbohydrate polymers , which have been obtained from food raw material by physical, enzymatic or chemical means,.
- synthetic carbohydrate polymers.

Properties:

Dietary fibre generally has properties such as:

- Decrease intestinal transit time and increase stools bulk
- fermentable by colonic microflora

[1] When derived from a plant origin, dietary fibre may include fractions of lignin and/or other compounds when associated with polysaccharides in the plant cell walls and if these compounds are quantified by the AOAC gravimetric analytical method for dietary fibre analysis : Fractions of lignin and the other compounds (proteic fractions, phenolic compounds, waxes, saponins, phytates, cutin, phytosterols, etc.) intimately "associated" with plant polysaccharides are often extracted with the polysaccharides in the AOAC 991.43 method. These substances are included in the definition of fibre insofar as they are actually associated with the poly- or oligo-saccharidic fraction of fibre. However, when extracted or even re-introduced into a food containing non digestible polysaccharides, they cannot be defined as dietary fibre. When combined with polysaccharides, these associated substances may provide additional beneficial effects.

- Reduce blood total and/or LDL cholesterol levels
- Reduce post-prandial blood glucose and /or insulin levels.

With the exception of non-digestible edible carbohydrate polymers naturally occurring in foods as consumed where a declaration or claim is made with respect to dietary fibre, a physiological effect should be scientifically demonstrated by clinical studies and other studies as appropriate. The establishment of criteria to quantify physiological effects is left to national authorities.

RECOMMENDATIONS TO CODEX COMMITTEES USING THIS DEFINITION OF DIETARY FIBRES

Codex Committees, when making use of this definition, may wish to consider that:

- Food safety requirements should be met by the substances purporting to be presented as source of dietary fibres;
- The physiological effects listed in the definition may vary with the substances present in the foods and the justification for the use of the nutrition and health claims must accommodate this diversity;
- If the dietary fibre does not derive from plants, it may be appropriate to consider, when establishing labelling provisions, that consumers in many countries generally regard foods designated as sources of dietary fibre as having a plant origin.

Methods of Analysis for Dietary Fibre

APPENDIX IV (A)

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 6 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.

SECTION A: INFANT FORMULA

1. SCOPE

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

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

2.2 Other Definitions

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

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

[3.1 Essential Composition

3.1.1 Infant formula is a product based on milk of cows or other animals 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[1] levels, as appropriate. The general principles for establishing these levels are identified in Annex II of this standard.

a) Protein

Protein[2)] (g)

Per 100 kcal		Per 100 kJ	
Min	**Max**	**Min**	**Max**
1,8[3), 4)]	3.0	0.45[3), 4)]	0.7

2) [For the purpose of this standard, the calculation of the protein content 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 nitrogen source.] The protein levels set in this standard are based on a nitrogen conversion factor of 6.25.

3) [Infant formulae based on non-hydrolysed cows' 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.]

4) 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 (0.7 g/100 kJ) applies**.**

3.1.4 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 methionine and cysteine and of tyrosine and phenylalanine may be added together [unless the methionine to cysteine or the phenylalanine to tyrosine ratio are outside the range of 0.7-1.5 : 1].

3.1.5 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.

b) Lipids

Total fat[5)] (g)

Commercially hydrogenated oils and fats shall not be used in infant formula.

Per 100 kcal		Per 100 kJ	
Min	**Max**	**Min**	**Max**
4.4	6.0	1.05	1.4

5) Lauric and myristic acids are constituents of fats, but combined should not exceed 20% of [total fatty acids]. The content of trans fatty acids shall not be higher than [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 formulae. The erucic acid content shall be less than 1% of total fatty acids.

[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 safe use. They may be adjusted based on relevant scientific or technological progress.

Linoleic acid (g)

Per 100 kcal		Per 100 kJ	
Min	**Max**	**Min**	**Max**
0.3	1.2	0.07	0.3

α-Linolenic acid (mg)

Per 100 kcal		Per 100 kJ	
Min	**Max**	**Min**	**Max**
50	N.S.	12	N.S.

N.S. = not specified

Ratio linoleic/ α-linolenic acid

Min	**Max**	**Min**	**Max**
5:1	15:1	5:1	15:1

c) Carbohydrates

Total carbohydrates[6)]

Per 100 kcal		Per 100 kJ	
Min	**Max**	**Min**	**Max**
9.0	14.0	2.2	3.3

6) 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 may be added to Infant Formula up to 30% of total carbohydrates or up to 2 g/100 ml.

[Sucrose, unless needed, and the addition of fructose particularly should be avoided in infant formula, because of potential life-threatening symptoms in young infants with unrecognised hereditary fructose intolerance.]

d) Vitamins

Vitamin A (µg RE[7)])

Per 100 kcal		Per 100 kJ	
Min	**Max**	**Min**	**Max**
60	180	14	43

7) 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 (µg[8)])

Per 100 kcal	Per 100 kJ

Per 100 kcal		Per 100 kJ	
Min	**Max**	**Min**	**Max**
1	2.5	0.25	0.6

8) Calciferol. 1 µg calciferol = 40 IU vitamin D

Vitamin E (mg α TE[9])

Per 100 kcal		Per 100 kJ	
Min	**Guidance upper level**	**Min**	**Guidance upper level**
0.5[10]	**5**	**0.12[10]**	**1.2**

9) 1 mg α-TE (alpha-tocopherol equivalent) = 1 mg d-α-tocopherol

10) 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 α-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 (µg)

Per 100 kcal		Per 100 kJ	
Min	**Guidance upper level**	**Min**	**Guidance upper level**
4	**25**	1	**6**

Thiamin (µg)

Per 100 kcal		Per 100 kJ	
Min	**Guidance upper level**	**Min**	**Guidance upper level**
60	300	14	72

Riboflavin (µg)

Per 100 kcal		Per 100 kJ	
Min	**Guidance upper level**	**Min**	**Guidance upper level**
80	400	19	100

Niacin[11] (µg)

Per 100 kcal		Per 100 kJ	
Min	**Guidance upper level**	**Min**	**Guidance upper level**
300	1500	70	360

11) Niacin refers to preformed niacin

Vitamin B_6 (µg)

Per 100 kcal		Per 100 kJ	
Min	**Guidance upper level**	**Min**	**Guidance upper level**
35	175	8.5	45

Vitamin B_{12} (µg)

Per 100 kcal		Per 100 kJ	
Min	**Guidance upper level**	**Min**	**Guidance upper level**
0.1	0.5	0.025	0.12

Pantothenic acid (µg)

Per 100 kcal		Per 100 kJ	
Min	**Guidance upper level**	**Min**	**Guidance upper level**
60	300	15	75

Folic acid (µg)

Per 100 kcal		Per 100 kJ	
Min	**Guidance upper level**	**Min**	**Guidance upper level**
10	50	2.5	12

Vitamin C[12] (mg)

Per 100 kcal		Per100 kJ	
Min	**Max [*] [Guidance upper level]**	**Min**	**Max[*] [Guidance upper level]**
10	30	2.5	7

[12] expressed as ascorbic acid

Biotin (µg)

Per 100 kcal		Per 100 kJ	
Min	**Guidance upper level**	**Min**	**Guidance upper level**
1.5	7.5	0.4	1.5

e) Minerals and Trace Elements

Iron (formula based on cows' milk protein and protein hydrolysate) (mg)

Per 100 kcal		Per 100 kJ	
Min	**Max**	**Min**	**Max**
0.3[13]	1.3	0.07[13]	0.3

[13)] In populations where infants are at risk of iron deficiency, iron contents higher than the minimum level of 0.3 mg/100 kcal may be appropriate and recommended at a national level.

Iron (formula based on soy protein isolate) (mg)

Per 100 kcal		Per 100 kJ	
Min	**Max**	**Min**	**Max**
0.45	2.0	0.1	0.5

Calcium (mg)

Per 100 kcal		Per 100 kJ	
Min	**Max**	**Min**	**Max**
50	140	12	35

Phosphorus (formula based on cows' milk protein and protein hydrolysate) (mg)

Per 100 kcal		Per 100 kJ	
Min	**Guidance upper level]**	**Min**	**Guidance upper level**
25	90	25	90

Phosphorus (formula based on soy protein isolate) (mg)

Per 100 kcal		Per 100 kJ	
Min	**Guidance upper level ***	**Min**	**Guidance upper level**
30	100	7	25

Ratio calcium/ phosphorus

Per 100 kcal		Per 100 kJ	
Min	**Max**	**Min**	**Max**
1:1	2:1	1:1	2:1

Magnesium (mg)

Per 100 kcal		Per 100 kJ	
Min	**Guidance upper level**	**Min**	**Guidance upper level**
5	15	1.2	3.6

Sodium (mg)

Per 100 kcal		Per 100 kJ	
Min	**Guidance upper level**	**Min**	**Guidance upper level**
20	**60**	**5**	**14**

Chloride (mg)

Per 100 kcal		Per 100 kJ	
Min	**Guidance upper level**	**Min**	**Guidance upper level**
50	160	12	38

Potassium (mg)

Per 100 kcal		Per 100 kJ	
Min	**Guidance upper level**	**Min**	**Guidance upper level**
60	160	14	38

Manganese (µg)

Per 100 kcal		Per 100 J	
Min	**Guidance upper level**	**Min**	**Guidance upper level**
1	50	0.25	24

Iodine (µg)

Per 100 kcal		Per 100 kJ	
Min	**Guidance upper level**	**Min**	**Guidance upper level**
10	50	2.5	12

Selenium (µg)

Per 100 kcal		Per 100 kJ	
Min	**Guidance upper level**	**Min**	**Guidance upper level**
1	9	0.24	2.2

Copper (µg)[14)]

Per 100 kcal		Per 100 kJ	
Min	**Max**	**Min**	**Max**
35	80	8.5	19

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

Zinc (mg)

Per 100 kcal		Per 100 kJ	
Min	**Max**	**Min**	**Max**
0.5	1.5	0.12	0.36

f) Other Substances

Choline (mg)

Per 100 kcal		Per 100 kJ	
Min	**Max**	**Min**	**Max**
7	50	1.7	12

Myo-Inositol (mg)

Per 100 kcal		Per 100 kJ	
Min	**Max**	**Min**	**Max**
4	40	1	9.5

L-Carnitine (mg)

Per 100 kcal		Per 100 kJ	
Min	**Max**	**Min**	**Max**
1.2	N.S.	0.3	N.S.

3.2 Optional [or non-mandatory] 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 mg

Per 100 kcal	Per 100 kJ
12	3
Total [added] nucleotides mg Per 100 kcal	**Per 100 kJ**
5	1.2

Cytidine 5'-monophosphate (CMP) mg

Per 100 kcal	Per 100 kJ
2.5	0.6

Uridine 5'-monophosphate (UMP) mg

Per 100 kcal	Per 100 kJ
1.75	0.4

Adenosine 5'-monophosphate (AMP) mg

Per 100 kcal	Per 100 kJ
1.5	0.36

Guanosine 5'-monophosphate (GMP) mg

Per 100 kcal	Per 100 kJ
0.5	0.12

Inosine 5'-monophosphate (IMP) mg

Per 100 kcal	Per 100 kJ
1.0	0.24

Phospholipids mg

Per 100 kcal	Per 100 kJ
300 (or 2g/L)	72

Docosahexaenoic Acid[15)] (% of fatty acids)

Maximum	
0.5	

15) 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 is not a desirable constituent of infant formula but can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid.

Fluoride (µg)

Per 100 kcal	Per 100 kJ
60	14

]

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

3.3 Vitamin Compounds and Mineral Salts

Vitamins and minerals added in accordance with Section 3.1.3 (d and e) and 3.2.1 should be selected from the Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979).

3.4 Consistency and Particle Size

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

Purity Requirements

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

3.6 Specific Prohibitions

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

4. FOOD ADDITIVES

The following additives are permitted in the preparation of Infant Formula, as described in Section 1 of this Standard, and with the restrictions stated below:

WORKING GROUP'S PROPOSALS					
	INS NO.			**Maximum level in 100 mL of the ready-to-drink product**	**Technological Justification**
4.1	**Thickening Agents**				
4.1.1	412	Guar gum		0.1 g in all types of infant formula	Protects from physical separation
4.1.2	410	Carob bean gum (Locust bean gum)		0.1 g in all types of infant formula *REQUEST FOR 0.5 G*	Protects from physical separation Used in some anti-regurgitating formulas
4.1.3	1412	Distarch phosphate	}	0.5 g singly or in combination in soy-based infant formula only 2.5 g singly or in combination in hydrolyzed protein and/or amino acid-based infant formula only	Physical properties that native starch tends to lose when processed
4.1.4	1414	Acetylated distarch phosphate	}		
4.1.5	1413	Phosphated distarch phosphate	}		
4.1.6	1440	Hydroxypropyl starch	}		
4.1.7	407	Carrageenan		0.03 g in regular milk- and soy-based liquid infant formula only 0.1 g in hydrolyzed protein and/or amino acid-based liquid infant formula only	Thickening agent also used as an emulsifier; higher emulsifying power than lecithin and more hydrophylic capacities than mono- and diglycerides of fatty acids
4.2	**Emulsifiers**				
4.2.1	322 [1]	Lecithin [1]		0.5 g in all types of infant formula *	Natural stabiliser, retains homogeneity
4.2.2	471	Mono- and diglycerides		0.4 g in all types of infant formula *	Natural stabiliser, retains homogeneity of liquid

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

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

4.3	**pH-Adjusting Agents**				
4.3.1	524	Sodium hydroxide	}	Limited by GMP and within the limits for sodium and potassium in section 3.1.2(c) in all types of infant formula	Buffering capacity Improve in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying Selected depending on pH and composition of formula; also used as a buffering agent
4.3.2	500 ii	Sodium hydrogen carbonate	}		
4.3.3	500 i	Sodium carbonate	}		
4.3.4	525	Potassium hydroxide	}		
4.3.5	501 ii	Potassium hydrogen carbonate	}		
4.3.6	501 i	Potassium carbonate	}		
4.3.7	526	Calcium hydroxide	}		
4.3.8	331 i, iii	Sodium citrate(s)	}		
4.3.9	332 i, ii	Potassium citrate(s)	}		
4.3.10	270	L(+) Lactic acid [2]	}	Limited by GMP in all types of infant formula	Natural acid found in fermented milk products
4.3.11	330	Citric acid	}		Buffering and chelating capacity

4.3.12	338	Phosphoric acid (Ortho-)	}	Limited by GMP and within the limits for sodium and potassium in Section 3.1.2(c) in all types of infant formula	Stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying Selected depending on pH and composition of formula
4.3.13	*339 i, ii, iii*	*Sodium orthophosphates*	}		
4.3.14	*340 i, ii, iii*	*Potassium orthophosphates*	}		
4.4	**Antioxidants**				
4.4.1	306	Mixed tocopherols concentrate	}	1 mg in all types of infant formula singly or in combination	Protects from oxidation Synergistic effect with ascorbyl esters
4.4.2	307	Alpha-Tocopherol	}		
4.4.2	304	L-Ascorbyl palmitate		1 mg in all types of infant formula	Protects from oxidation Synergistic effect with tocopherols

4.5	**Packaging Gas (Propellants)**				
4.5.1	290	Carbon dioxide		GMP	Neutral gas used under modified packaging atmosphere in order to guarantee the quality of the product and to ensure shelf life; prevention of oxidation and rancidity
4.5.2	941	Nitrogen		GMP	
4.5.3	942	Nitrous oxide		GMP	
4.5.4	938	Argon		GMP	
4.5.5	939	Helium		GMP	
4.5.6	948	Oxygen		GMP	
4.5.7	949	Hydrogen		GMP	

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

4.6 Carry-over of Food Additives

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

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

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

5. CONTAMINANTS

5.1 Pesticide Residues

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

5.2 Other Contaminants

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

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

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

6. HYGIENE

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

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

7. PACKAGING

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

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

8. FILL OF CONTAINER

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

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

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

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

of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20^{o} C which the sealed container will hold completely filled.

9. LABELLING

In addition to the requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991), the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985 (Rev. 1-1993) and the Guidelines for Use of Nutrition and Health Claims 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 cow's milk is the only source of protein, the product may be labelled "Infant Formula Based on Cow's 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.

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

Or

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

9.2 List of Ingredients

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

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

9.3 Declaration of Nutritive Value

The declaration of nutrition information shall contain the following information 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 3.1.2 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**

[Products in liquid form may be used either directly or prepared with safe water and previously boiled water before feeding according to directions for use. Products in powder form also require safe and previously boiled water for preparation.

9.5.1 Adequate directions for the appropriate preparation 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 [or in the accompanying leaflet].

9.5.2 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label [or in the 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.]

9.6 Additional Labelling Requirements

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

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

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

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

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 supplemental foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.

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

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

10. METHODS OF ANALYSIS AND SAMPLING

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

[ANNEX 1]

Essential and semi-essential amino acids in breast milk

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

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

ANNEX II

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

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

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

3. The values to be established are based on an 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.

APPENDIX IV (B)

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 5 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 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 should be based on sound medical and nutritional principles. Their use should have been demonstrated by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of infants for whom they are 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 specially formulated, labelled and presented.

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 3.3

3.4 Consistency and Particle Size

see Section A 3.4

3.5 Purity Requirements

see Section A 3.5

3.6 Specific Prohibition

see Section A 3.6]

[4. FOOD ADDITIVES

see Section A 4.

The following additional food additives are permitted in the preparation of Formula for Special Medical Purposes Intended for Infants (to be filled in).]

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

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

9.1 The Name of the Food

9.1.1 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.

9.2 List of Ingredients

see Section A 9.2

9.3 Nutrition labelling

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

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

APPENDIX V

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

(At Step 3 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 use by 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 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 FAO/WHO process may be considered

(d) the stability of nutrient compound(s) in the food 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.

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

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC[1]	international and/or national bodies	IF[2]	FUF[3]	PCBF[4]	CBF[5]	FSMP[6]
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 pentahydrate), BP, DAB	√	√	√	√	√
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] CAC = Codex Alimentarius Commission
[2] IF = = infant formula
[3] FUF = follow-up formula
[4] PCBF = processed cereal based food
[5] CBF = canned baby food
[6] FSMP = food for special medical purposes

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC[1]	international and/or national bodies	IF[2]	FUF[3]	PCBF[4]	CBF[5]	FSMP[6]
1.11 Tricalcium diphosphate (Calcium phosphate, tribasic)		JECFA (1973), Ph Int, FCC, BP	√	√	√	√	√
Other calcium compounds proposed for inclusion:							
Malaysia: [1.12 Calcium pyrophosphate]	√ (2001)	JECFA (1982), FCC	?	?	?	?	?
New Zealand, Malaysia, ISDI: [1.13 Calcium sulphate]	√ (1979)	JECFA (1975), Ph Int, FCC, Ph Eur (dihydrate), DAB, MP	-	-	-	-	[√]
2. Source of Iron (Fe)							
2.1 Ferrous carbonate, stabilised with saccharose		DAB	-	-	√	√	√
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 Ferric orthophosphate		FCC	?	?	?	?	?

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC[1]	international and/or national bodies	IF[2]	FUF[3]	PCBF[4]	CBF[5]	FSMP[6]
Other iron compounds proposed for inclusion:							
EU, ISDI: [2.14 Sodium ferric diphosphate]		FCC	-	-	[√]	[√]	[√]
ISDI: [2.15 Ferrous citrate]		FCC	[√]	[√]	[√]	[√]	[√]
New Zealand: [2.16 Ferrous succinate]		MP, MI	?	?	?	?	?
South Africa: [2.17 Ferrous bisglycinate]		JECFA (2003)	?	?	?	?	?
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 glycerophosphate		Ph Eur, BPC	-	-	√	√	√
3.5 Magnesium hydroxide	√ (1979)	JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√
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	-	-	-	-	√

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC[1]	international and/or national bodies	IF[2]	FUF[3]	PCBF[4]	CBF[5]	FSMP[6]
3.12 Magnesium salts of citric acid		USP, DAC	√	√	√	√	√
Other magnesium compounds proposed for inclusion:							
3.13 Magensium carbonate		JECFA (1973), FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√
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)	√	√	-	-	√
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	√	√	-	-	√
Other sodium compounds proposed for inclusion:							
New Zealand: [4.11 Sodium chloride (iodised)]		USP, Ph Eur, BP, JP	?	?	?	?	?

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC[1]	international and/or national bodies	IF[2]	FUF[3]	PCBF[4]	CBF[5]	FSMP[6]
New Zealand: [4.12 Sodium sulphate]		JECFA (2000), Ph Int, FCC, USP, Ph Eur, BP, DAB	?	?	?	?	?
New Zealand: [4.13 Sodium tartrate]		JECFA (1963)	?	?	?	?	?
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	√	√	-	-	√
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 glycerophosphate		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)	√	√	-	-	√
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	√	√	√	√	√

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC[1]	international and/or national bodies	IF[2]	FUF[3]	PCBF[4]	CBF[5]	FSMP[6]
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	√	√	√	√	√
8. Source of Zinc (Zn)							
8.1 Zinc acetate		USP, Ph Eur (dihydrate)	√	√	√	√	√
8.2 Zinc chloride		USP, Ph Eur, JP, BP, DAB	√	√	√	√	√
8.3 Zinc gluconate		FCC, USP, DAC	√	√	√	√	√
8.4 Zinc oxide		Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√
8.5 Zinc sulphate		FCC, USP, Ph Eur, BP	√	√	√	√	√
Other zinc compounds proposed for inclusion:							
EU, ISDI: [8.6 Zinc carbonate]		BP (hydroxide carbonate)	-	-	-	-	[√]
9. Source of Manganese (Mn)							
9.1 Manganese(II) chloride		FCC	√	√	√	√	√
9.2 Manganese(II) citrate		FCC	√	√	√	√	√
9.3 Manganese(II) glycerophosphate		FCC	-	-	√	√	√
9.4 Manganese(II) sulphate		FCC, USP, Ph Eur (monohydrate)	√	√	√	√	√
9.5 Manganese(II) gluconate		FCC	√	√	√	√	√
10. Source of Selenium (Se)							
10.1 Sodium selenate		MI	√	√	NZ: [√]	-	√
10.2 Sodium selenite		DAC, MP, MI	√	√	NZ: [√]	-	√

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children				
	CAC[1]	international and/or national bodies	IF[2]	FUF[3]	PCBF[4]	CBF[5]	FSMP[6]
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	-	-	-	-	√
Other fluoride compounds proposed for inclusion:							
ISDI: [13.3 Calcium fluoride]		DAB	-	-	-	-	[√]

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

Nutrient Source	Purity Requirements determined by		Use in Food Categories for Infants and Young Children				
	CAC[1]	international and/or national bodies	IF[2]	FUF[3]	PCBF[4]	CBF[5]	FSMP[6]
1. Vitamin A							
1.1 all trans Retinol		FCC (vitamin A), USP, Ph Eur (vitamin A)	√	√	√	√	√

[1] CAC = Codex Alimentarius Commission
[2] IF = = infant formula
[3] FUF = follow-up formula
[4] PCBF = processed cereal based food
[5] CBF = canned baby food
[6] FSMP = food for special medical purposes

Nutrient Source	Purity Requirements determined by		Use in Food Categories for Infants and Young Children				
	CAC[1]	international and/or national bodies	IF[2]	FUF[3]	PCBF[4]	CBF[5]	FSMP[6]
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	√	√	√	√	√
Other provitamin A carotenoids proposed for inclusion:							
ISDI: [2.2 Provitamin A other than beta-carotene:							
[2.2.1 β-apo-8-carotenal]	√ (1991)	JECFA (1984), FCC	[√]	[√]	[√]	[√]	[√]
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	√	√	√	√	√
4. Vitamin E							
4.1 D-alpha-Tocopherol	√ (2001)	JECFA (2000), FCC, USP, Ph Eur	√	√	√	√	√
4.2 DL-alpha-Tocopherol	√ (1989)	JECFA (1986), FCC, USP, Ph Eur, Jap Food Stan	√	√	√	√	√
4.3 D-alpha-Tocopheryl acetate		FCC, USP, Ph Eur	√	√	√	√	√
4.4 DL-alpha-Tocopheryl acetate		FCC, USP, NF, Ph Eur, BP	√	√	√	√	√

Nutrient Source	Purity Requirements determined by		Use in Food Categories for Infants and Young Children				
	CAC[1]	international and/or national bodies	IF[2]	FUF[3]	PCBF[4]	CBF[5]	FSMP[6]
Other tocopheryl compounds proposed for inclusion:							
ISDI, EU, New Zealand: [4.5 D-alpha-Tocopheryl acid succinate]		FCC, NF	-	-	-	-	[√]
5. Vitamin C							
5.1 L-Ascorbic acid	√ (1981)	JECFA (1973), Ph Int, FCC, USP, Ph Eur, JP, Jap Food Stan, BP, DAB	√	√	√	√	√
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	√	√	√	√	√
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	√	√	√	√	√
7.2 Riboflavin-5'-phosphate sodium	√ (1991)	JECFA (1987), USP, Ph Eur, JP, Jap Food Stan, BP, DAB	√	√	√	√	√

Nutrient Source	Purity Requirements determined by		Use in Food Categories for Infants and Young Children				
	CAC[1]	international and/or national bodies	IF[2]	FUF[3]	PCBF[4]	CBF[5]	FSMP[6]
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	√	√	√	√	√
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	√	√	√	√	√
11.2 Sodium-D-pantothenate		Jap Food Stan, DAB	√	√	√	√	√
11.3 D-Panthenol/ DL-Panthenol		FCC, USP, Ph Eur	√	√	√	√	√
12. Vitamin B_{12}							
12.1 Cyanocobalamin		Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√	√	√
12.2 Hydroxocobalamin		Ph Int, USP, NF, Ph Eur (hydrochloride)	√	√	√	√	√
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							

Nutrient Source	Purity Requirements determined by		Use in Food Categories for Infants and Young Children				
	CAC[1]	international and/or national bodies	IF[2]	FUF[3]	PCBF[4]	CBF[5]	FSMP[6]
14.1 D-Biotin		FCC, USP, Ph Eur	√	√	√	√	√

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

Nutrient Source	Purity Requirements		Use in Food Categories for Infants and Young Children				
	CAC[1]	international and/or national	IF[2]	FUF[3]	PCBF[4]	CBF[5]	FSMP[7]
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)				√
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-Leucine		FCC, USP, Ph Eur, DAB					√
1.11 L-Lysine		USP	only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its				√
1.12 L-Lysine monohydrochloride		FCC, USP, Ph Eur, DAB					√

[1] CAC = Codex Alimentarius Commission
[2] IF = = infant formula
[3] FUF = follow-up formula
[4] PCBF = processed cereal based food
[5] CBF = canned baby food
[7] FSMP = food for special medical purposes
[8] ISDI proposed to add the following footnote: "As far as applicable, also the sodium, potassium calcium and magnesium salts of the amino acids as well as their hydrochlorides may be used."

Nutrient Source	Purity Requirements		Use in Food Categories for Infants and Young Children				
	CAC[1]	international and/or national	IF[2]	FUF[3]	PCBF[4]	CBF[5]	FSMP[7]
1.13 L-Methionine		Ph Int, FCC, USP, Ph Eur, DAB	intended use)				√
1.14 L-Phenylalanine		FCC, USP, Ph Eur					√
1.15 L-Threonine		FCC, USP, Ph Eur, DAB					√
1.16 L-Tryptophan		FCC, USP, Ph Eur, DAB					√
1.17 L-Tyrosine		FCC, USP, Ph Eur, DAB					√
1.18 L-Valine		FCC, USP, Ph Eur, DAB					√
Other amino acids and their derivatives proposed for inclusion:							
ISDI: 1.19 L-Alanine		FCC, USP, Ph Eur, DAB	-				√
1.20 L-Arginine L-aspartate		FP	-				√
1.21 L-Aspartic acid		FCC, USP, Ph Eur	-				√
1.22 L-Citrulline		USP, DAC	-				√
1.23 L- Glutamic acid		JECFA (1987), FCC, USP, Ph Eur	ISDI:[√]	ISDI:[√]			√
1.24 L-Glutamine		FCC, USP, DAB	ISDI:[√]	ISDI:[√]			√
1.25 Glycine		FCC, USP, Ph Eur	-				√
1.26 L-Proline		FCC, USP, Ph Eur, DAB	-				√
1.27 L-Serine		USP, Ph Eur, DAB	-				√
1.28 N-Acetyl-L-cysteine		USP, Ph Eur, DAB	-				√
1.29 N-Acetyl-L-methionine		FCC	-				√ except infants
2. Carnitine							
2.1 L-Carnitine		FCC, USP, Ph Eur	√	√	ISDI: [√]	ISDI: [√]	√

Nutrient Source	Purity Requirements		Use in Food Categories for Infants and Young Children				
	CAC[1]	international and/or national	IF[2]	FUF[3]	PCBF[4]	CBF[5]	FSMP[7]
Other carnitine compounds proposed for inclusion:							
ISDI: [2.2 L-Carnitine tartrate]		FCC, Ph Eur	-	-	-	-	√
3. Taurine							
3.1 Taurine		USP, JP	√	ISDI:[√]	-	-	√
4. Choline							
4.1 Choline chloride		FCC, DAC, DAB	√	√	√	√	√
4.2 Choline citrate		NF	√	√	√	√	√
4.3 Choline hydrogen tartrate		DAB	√	√	√	√	√
4.4 Choline bitartrate		FCC, NF, DAB	√	√	√	√	√
Other compounds proposed for inclusion:							
ISDI: 4.5 Lecithin		JECFA (1993), FCC	√	√	√	√	√
5. Myo-Inositol (=meso-Inositol)]		FCC, DAC	√	√	√	√	√
6. Nucleotides							
6.1 Guanosine 5-monophosphate (GMP)		JECFA (1985)	√	ISDI:[√]	-	-	√
6.2 Inosine 5-monophosphate (IMP)		JECFA (1974)	√	ISDI:[√]	-	-	√

LIST OF NUTRIENT COMPOUNDS THAT LACK OFFICIAL PURITY REQUIREMENTS

Nutrient Source	Purity Requirements determined by		Use in Food Categories for Infants and Young Children				
	CAC	international and/or national bodies	IF	FUF	PCBF	CBF	FSMP
LIST A:							
[Calcium citrate malate]	?	?	-	-	-	-	[√]
[Calcium enriched yeast]	?	?	-	-	-	-	[√]
[Calcium pyruvate monohydrate]	?	?	-	-	-	-	[√]

Nutrient Source	Purity Requirements determined by		Use in Food Categories for Infants and Young Children				
	CAC	international and/or national bodies	IF	FUF	PCBF	CBF	FSMP
[Cupric carbonate]	?	?	[√]	[√]	[√]	[√]	[√]
[Cupric citrate]	?	?	[√]	[√]	[√]	[√]	[√]
[Copper-lysine-complex]	?	?	[√]	[√]	[√]	[√]	[√]
[Sodium iodate]	?	?	-	-	[√]	[√]	[√]
[Zinc citrate]	?	?	[√]	[√]	[√]	[√]	[√]
[Zinc lactate]	?	?	[√]	[√]	[√]	[√]	[√]
[Manganese(II) carbonate]	?	?	[√]	[√]	[√]	[√]	[√]
[Sodium hydrogen selenite]	?	?	ISDI: [√]	ISDI: [√]	ISDI: [√]	ISDI: [√]	[√]
ISDI: [Selenium enriched yeast]	?	?	-	-	-	-	[√]
ISDI: [Chromium enriched yeast]	?	?	-	-	-	-	[√]
[Potassium fluoride]	?	?	-	-	-	-	[√]
LIST B:							
New Zealand: [Cholecalciferol cholesterol]	?	?	?	?	?	?	?
[DL-alpha-Tocopheryl acid succinate]	?	?	-	-	-	-	[√]
[DL-alpha-Tocopheryl polyethylene glycol 1000 succinate]	?	?	-	-	-	-	[√]
[Potassium-L-ascorbate]	?	?	[√]	[√]	[√]	[√]	[√]
[Pyridoxal 5-phosphate]	?	?	[√]	[√]	[√]	[√]	[√]
[Pyridoxal dipalmitate]	?	?	[√]	[√]	[√]	[√]	[√]
Malaysia: [Pyridoxamine]	?	?	?	?	?	?	?
LIST C:							
[L-Isoleucine hydrochloride]	?	?					[√]
[L-Leucine hydrochloride]	?	?					[√]
[L-Lysine acetate]	?	?	ISDI: [√]	ISDI: [√]	ISDI: [√]	ISDI: [√]	[√]
[L-Lysine L-Aspartate]	?	?	-				[√]
[L-Lysine L-Glutamate dihydrate]	?	?	-				[√]
[L-Ornithine]	?	?	-				[√]
[S-Adenosyl-L-methionine]	?	?	-				[√] except infants

Nutrient Source	Purity Requirements determined by		Use in Food Categories for Infants and Young Children				
	CAC	international and/or national bodies	IF	FUF	PCBF	CBF	FSMP
[L-Carnitine hydrochloride]	?	?	[√]	[√]	ISDI: [√]	ISDI: [√]	[√]
[Choline]	?	?	[√]	[√]	[√]	[√]	[√]
[Cytidine 5-monophosphate (CMP)]	?	?	[√]	ISDI: [√]	-	-	[√]
[Cytidine 5-monophosphate sodium salt]	?	?	[√]	ISDI: [√]	-	-	[√]
[Uridine 5-monophosphate (UMP)]	?	?	[√]	ISDI: [√]	-	-	[√]
[Uridine 5-monophosphate sodium salt]	?	?	[√]	ISDI: [√]	-	-	[√]
[Adenosine 5-monophosphate (AMP)]	?	?	[√]	ISDI: [√]	-	-	[√]
[Adenosine 5-monophosphate sodium salt]	?	?	[√]	ISDI: [√]	-	-	[√]
[Guanosine 5-monophosphate sodium salt]	?	?	[√]	ISDI: [√]	-	-	[√]
[Inosine 5-monophosphate sodium salt]	?	?	[√]	ISDI: [√]	-	-	[√]
ISDI: [Creatine monohydrate]	?	?					[√]

D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL VITAMIN FORMS

It has been proposed to replace "vitamin" by "nutrient" to read:

D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL NUTRIENT FORMS

For reasons of stability and safe handling, some vitamins have to be converted into suitable preparations, e.g. stabilised oily solutions, gelatine or gum arabic coated products, fat embedded preparations, dry rubbed preparations. For this purpose, the edible materials and the additives included in the respective Codex standard may be used.

ISDI and Switzerland have proposed that the introductory paragraph be amended to read:

➔ For reasons of stability and safe handling, some vitamins and nutrients have to be converted into suitable preparations, e.g. stabilised oily solutions, gelatine or gum arabic coated products, fat embedded preparations, dry rubbed preparations. For this purpose, the following substances permitted in the specific Codex standard respectively may be used:

	INS no.	Additive/ Carrier	Maximum Level in Ready-to-use Food [mg/kg]
(a)		Maltodextrins (in formulae with lactose as only carbohydrate)	500
(b)	414	Gum arabic (gum acacia)	100
(c)	551	Silicon dioxide	10
(d)	421	Mannit (B_{12} dry rubbing 0,1%)	10
(e)	331iii	Trisodium citrate (B_{12} acidic preparation 0,1%)	260
(f)	330	Citric acid (B_{12} acidic preparation 0,1%)	90
		Costa Rica:	
(g)		Fish gelatine	
(h)		Bovine gelatine	
(i)		Ethylcellulose	
(j)		Glycyl tristearate	
(k)		BHA/BHT	
(l)		Peanut oil	
(m)		Saccharose (in formulae with lactose as only carbohydrate)	10
	1400-1451	Modified starches (as included in the Supplementary List to section 5.1, Codex alimentarius Volume 1)	100
		Switzerland:	100
	1450	Starch sodium octenyl succinate	
		EC:	75
(p)	301	Sodium L-ascorbate (in coatings of nutrient preparations containing PUFAs)	

Proposal EC:

For reasons of stability and safe handling, some vitamins and nutrients have to be converted into suitable preparations, e.g. stabilised oily solutions, gelatine or gum arabic coated products, fat embedded preparations, 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:

	INS no.	Additive/ Carrier	Maximum Level in Ready-to-use Food [mg/kg]
(a)	414	Gum arabic (gum acacia)	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 coatings of nutrient preparations containing PUFAs)	75

Proposal USA:

	INS no.	Additive/ Carrier	Maximum Level in Ready-to-use Food [mg/kg]
(a)	421	Mannitol (B_{12} dry rubbing 0,1%)	10

Abbreviations:

BP = British Pharmacopoeia
BPC = British Pharmaceutical Codex
DAB = Deutsches Arzneibuch
DAC = Deutscher Arzneimittel-Codex
FCC = Food Chemicals Codex
FU = Farmacopoea Ufficiale della Republica Italiana
JP = The Pharmacopeia of Japan
Jap Food Stan = Japanese Food Standard
MI = Merck Index
MP = Martindale Pharmacopoeia
NF = The National Formulary (USA)
ÖAB = Österreichisches Arzneibuch
Ph Eur = Pharmacopoeia Europaea
Ph Franç = Pharmacopée Française
Ph Helv = Pharmacopoeia Helvetica
Ph Int = International Pharmacopoeia
USP = The United States Pharmacopoeia