

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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ALINORM 05/28/26

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX ALIMENTARIUS COMMISSION

Twenty-eighth Session  
Rome, Italy, 4 - 9 July 2005

### REPORT OF THE 26<sup>th</sup> SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Bonn, Germany  
1 – 5 November 2004

**Note:** This document incorporates Circular Letter CL 2004/53-NFSDU

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CX 5/20.2

CL 2004/53-NFSDU  
November 2004

**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 26<sup>th</sup> Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (ALINORM 05/28/26)

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

**1. Draft Guidelines for Vitamin and Mineral Food Supplements (ALINORM 05/28/26 para. 35 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](mailto:codex@fao.org)) **before 31 March 2005**.

**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 05/28/26 para 22 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](mailto: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](mailto:codex@fao.org)) **before 1 May 2005**;

**2. Draft Revised Standard for Infant Formula (ALINORM 05/28/26 para 99 and Appendix IV (Section A))**

Governments and international organizations are invited to comment on the above text (except Section 3 Essential Composition and Quality Factors, for that see para. 51) 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](mailto: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](mailto:codex@fao.org)) **before 1 May 2005**;

**3. Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children, (ALINORM 05/28/26 para.119 and Appendix V)**

Governments and international organizations are invited to comment on the above text and should do so in writing, preferably by email to: 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](mailto: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](mailto:codex@fao.org)), **before 1 May 2005**;

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

**1. Proposed Draft Formulas for Special Medical Purposes Intended for Infants (ALINORM 05/28/26 para 100 and Appendix IV (Section B)).**

Governments and international organizations are invited to comment on the above text (except Section 3 Essential Composition and Quality Factors, for that see para.89) 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](mailto: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](mailto:codex@fao.org)), **before 1 May 2005**;

## SUMMARY AND CONCLUSIONS

The summary and conclusions of the 26<sup>th</sup> Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses are as follows:

### **MATTERS FOR ADOPTION BY THE COMMISSION**

The Committee:

- agreed to advance the Proposed Draft Guidelines on Vitamin and Mineral Supplements (para. 35, Appendix II) for final adoption by the 28<sup>th</sup> Session of the Commission.

### **MATTERS OF INTEREST TO THE COMMISSION**

The Committee:

- welcomed the offer of FAO and WHO to address the establishment of Nutrient Reference Values (NRVs) in the framework of the expert consultations that would be convened in the future, including for carbohydrates and fats and oils (para. 40).

### **MATTERS REFERRED TO OTHER COMMITTEES**

#### **Codex Committee on Methods of Analysis and Sampling**

The Committee clarified the request from the CCMAS regarding the R5-Mendez ELISA method (for gliadin/gluten detection) (paras 6-7 and 148).

#### **Codex Committee on Food Additives and Contaminants**

The Committee agreed to forward the section on Food Additives of the Draft Revised Standard for Cereal-Based Foods for Infants and Children including provisions on carry over (paras 107-111).

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## INTRODUCTION

1. The Twenty-sixth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held from 1 to 5 November 2004 in the Bruckenforum, Bonn, by courtesy of the Government of Federal Republic of Germany. Dr Rolf Grossklaus, Director and Professor of the Federal Institute for Risk Assessment, Berlin, chaired the session. The Session was attended by 265 delegates, observers and advisors representing 61 member countries and 28 international organizations.

## OPENING OF THE SESSION

2. Dr Walter Toepner, 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 also noted the positive impact of the Codex Trust Fund on the participation of developing countries in the standard setting and the importance of Codex standards in improving food quality worldwide. Dr Toepner drew the attention of the delegates to the fact that it was very important to arrive to the consensus in such important areas as foods for infant and young children and wished all success to the meeting and to the delegates in their important work.

## ADOPTION OF THE AGENDA (AGENDA ITEM 1)<sup>1</sup>

3. The Delegation of the European Community 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 Committee accepted the proposal of the delegation of Australia and agreed to discuss Agenda Item 9 on the Application of Risk Analysis to the Work of the Committee after Agenda Item 3 in view of its importance to subsequent Agenda items. With this amendment it adopted the Provisional Agenda as the Agenda for the Session.

## MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES (AGENDA ITEM 2)<sup>2</sup>

5. The Committee noted that a number of matters referred by the 27<sup>th</sup> 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*

6. The Committee recalled that the Codex Committee on methods of Analysis and Sampling (CCMAS)<sup>3</sup> while temporarily endorsing the Enzyme-Linked Immunoassay R5 Mendez (ELISA) as Type IV method, had requested the CCNFSDU to clarify what should be measured since section 6.2 of the draft revised Standard for Gluten-Free Foods referred to a detection limit of 10 ppm without specifying whether this apply to gluten or gliadins and how it related to the provision of “gluten free”.

7. The Committee was informed that Enzyme-Linked Immunoassay R5 method measured gliadins and that it was necessary to use a conversion factor of 2 to convert levels of gliadins to gluten. Therefore the Committee agreed to amend the last line in Section 6.2 of the Standard<sup>4</sup> and insert “gluten” after “ppm”. The Committee also agreed to discuss the Draft Standard for Gluten-Free Foods at its next session and decided to consider this matter on Agenda Item 11 “Other Business and Future Work” in more detail, if necessary and to inform the CCMAS about these deliberations.

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<sup>1</sup> CX/NFSDU 04/1; 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.

<sup>2</sup> CX/NFSDU 04/2; CRD 3 (Matters from WHO and Other Codex Committees); CRD 15 (FAO/WHO web address for Development of a Scientific Collaboration to Create a Framework for Risk Assessment of Nutrients and related Substances, prepared by WHO); CRD 16 (Additional Matters from Other Codex Committees).

<sup>3</sup> ALINORM 04/27/23, paras 92-101.

<sup>4</sup> ALINORM 04/27, Appendix III.

**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)<sup>5</sup>**

8. The Committee recalled that its last session had not come to a conclusion on the definition of fibre and had agreed that an electronic working group coordinated by the Delegations of France and Sweden would review the definition to make it more inclusive and consider the related methods.
9. The Delegation of France indicated that the document had been redrafted in the light of the written comments received in order to propose a revised definition, methods of analysis and other recommendations
10. The Committee generally agreed that the definition of fibre should include the physiological properties of the substance in addition to chemical characteristics, and considered how the definition could be clarified to reflect these properties.
11. The Committee had a discussion on the degree of polymerisation that should characterise dietary fibre, as the document proposed a degree of polymerisation (DP) not lower than 3. The Delegation of the United States expressed the view that a DP of 10 should be used as some substances with a lower DP had a sweetening effect and their physiological effects were not those associated with fibre. Several other delegations supported a DP of 3 as this was consistent with current scientific evidence on the physiological effects of various types of fibre.
12. The Committee agreed to redraft the first sentence of the definition for clarification purposes and agreed to include a DP of 10 in square brackets for further consideration, as an alternative to the proposed DP of 3.
13. The Delegation of Thailand proposed to amend the text to reflect that some types of fibre were derived from non-food material, such as bark, and if the Committee agreed to limit to only plant source, this refer to “raw material from plant”, but if the Committee agreed to include also the animal source, it will refer to “raw material from plant and animal”. Some delegations also proposed to limit the definition of fibre to substances of plant origin. The Committee however retained the current understanding that fibre was obtained “from food raw material”.
14. The Committee agreed to rearrange the text of the second part of the definition for clarification purpose, to delete the reference to “laxative properties” as this could be understood as a medicinal claim and to replace it with “decreased transit time”.
15. The Delegation of the United States expressed concern with the listing of physiological properties that might be interpreted as a justification for health claims related to these properties. The Delegation of the United States expressed its concern that with the definition of dietary fibre as proposed, it implied that justification should be provided even for foods that naturally contained fibre, whereas such justification should normally apply only to foods containing added fibre. The Delegation of the European Community pointed out that physiological properties should be mentioned in the definition as a further qualifying criterion, irrespective of the claims that might be made.
16. The Delegation of Canada proposed to include a sentence to the effect that scientific justification should be provided when declaration or claims were made. The Committee agreed to retain an additional sentence and to specify that an exception should be made for “non-digestible edible carbohydrate polymers naturally occurring in foods”, and to leave the establishment of criteria to quantify physiological effects to national authorities.
17. The Committee agreed to retain the additional “Recommendations” proposed in the working paper for further consideration, but did not come to a conclusion on where they should be placed in the Guidelines.
18. The Secretariat recalled that health claims were already addressed in the Guidelines for Use of Nutrition and Health Claims, that the criteria for scientific basis were under consideration in the Committee, and that the current mandate of the CCNFSDU was only to establish conditions for nutrition claims for dietary fibre as

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<sup>5</sup> ALINORM 04/27/26, Appendix II. CX/NFSDU 04/3 (comments of Argentina, Australia, Costa Rica, Malaysia, Mexico, IADSA), CRD 4 (comments of Australia, Brazil, South Africa, AAC, ICGMA), CX/NFSDU 04/3-Add.1, CRD 5 (comments of Brazil, Canada), CRD6 (comments of the EC)

proposed in the Table, and that additional amendments to the Guidelines as regards health claims would require approval as new work.

19. The Committee agreed that the Table should refer to “dietary fibre” and the square brackets on that term were deleted. The Committee decided not to discuss the values in the Table as the issues related to the definition had not been solved and required further consideration.

### **Methods of Analysis**

20. The Committee noted the request for clarification on the status of the AOAC methods, especially whether they had been approved for final action. Some delegations proposed to include the Englyst method in the list of methods as it was used in several countries. Other delegations supported the view expressed in the working paper, and noted that the Englyst method was not used world-wide and was not suitable as a routine method. Some delegations stated that the Englyst method was an appropriate analytical method for some foods and should be included in the table.

21. The Committee noted that no decision could be taken on methods of analysis at this stage since the conditions for claims had not yet been finalized, and agreed that they would be require further consideration. The Committee noted that upon finalization the methods would forwarded for endorsement to the Committee on Methods of Analysis and Sampling, on the basis of the criteria for the selection of Codex methods of analysis.

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

22. The Committee agreed to return the Draft Part B Containing Provisions on Dietary Fibre, as amended at the present session, to Step 6 for further comments and consideration at the next session (see Appendix III).

### **DRAFT GUIDELINES FOR VITAMINS AND MINERAL FOOD SUPPLEMENTS (AGENDA ITEM 4)<sup>6</sup>**

23. The Committee recalled that the last 27<sup>th</sup> session of the Codex Alimentarius Commission adopted the Proposed Draft Guidelines at Step 5 and advanced it to Step 6 for further comments and consideration by the Committee. The Committee decided to consider the text of the Guidelines focusing its discussions on sections containing square brackets and made the following amendments and comments.

#### **General comments**

24. The Committee noted that at its last session it was agreed to refer to vitamins and mineral “food” supplements not only in the title but also in relevant parts and therefore made editorial amendments where necessary throughout the text.

#### **Definitions**

25. The Committee discussed how to address the wording in relation to reference to small unit quantities in Section 2.1. Some delegations were of the view that this last sentence was necessary to reflect that vitamins and minerals were provided in dose form and should be taken in small unit quantities, to reflect the difference with ordinary foods. Other delegations expressed the view that this was not necessary as the text already indicated that these products were not in a conventional food form and the type of product concerned was illustrated by the examples therefore this text should be deleted. The Committee agreed to amend the second sentence clarifying that vitamins and mineral supplement sources are designed to be taken in measured small-unit quantities and added a footnote to clarify that the small-unit quantities referred to physical forms of vitamin and mineral supplements and to their potency of supplements.

#### **Section 3.1 Selection of vitamins and minerals**

26. The Committee agreed to amend the first sentence in Section 3.1.2 to clarify that not only sources of vitamins and minerals may be natural or synthetic but also their selection should be based on considerations of safety and bioavailability.

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<sup>6</sup> ALINORM 04/27/26, Appendix IV; CX/NFSDU 04/4 (comments of Argentina, Australia, China, Iran, Malaysia, Mexico, New Zealand, Poland, United States, IADSA, NHF), CRD 6 (comments of the EC), CRD 7 (comments of Brazil and South Africa), CRD 13 (comments of India, Philippines).



27. The Committee also clarified the last sentence of this paragraph to emphasize that in the absence of international purity criteria, national legislation may be used.

28. It was proposed to include provitamin and vitamin-like substances in the guidelines, however the Committee recalled that it had agreed earlier to limit guidelines to vitamins and minerals for which the Recommended Daily Intake was established by FAO/WHO. The Delegation of South Africa pointed out that provitamins were already included in Section 3.1.1.

### **Section 3.2 Contents of vitamins and minerals**

29. The Committee had quite a lengthy discussion regarding the last paragraph containing additional explanation of conditions when maximum levels of vitamins and minerals are set.

30. Some delegations proposed to convert this paragraph into criterion “c” since it clarified requirements for setting maximum levels, while other delegations were of the view that this provision was already covered by criterion “a” dealing with establishment of upper safe levels of vitamins and minerals based on scientific risk assessment it should be deleted from the document.

31. The Committee agreed to add an additional sentence to this paragraph to clarify that maximum levels should not be solely based on recommended nutrient intakes.

### **Section 5. Labelling**

32. The Committee amended the first sentence of section 5.1 as recommended by the Codex Committee on Food Labelling in order to be consistent with general labelling requirements.

33. In section 5.4 the Committee inserted an additional wording at the end of sentence to clarify that in addition to the amounts of the vitamins and minerals declared per portion of the product as recommended for daily consumption, the amount per unit for single use may also be given.

34. The Committee made some editorial changes to section 5.6 for simplification and clarification purposes.

### **Status of the Draft Guidelines for Vitamins and Mineral Food Supplements**

35. The Committee, recognizing that considerable progress had been made on the text, agreed to advance the Draft Guidelines for adoption at Step 8 by the 28<sup>th</sup> Session of the Codex Alimentarius Commission (see Appendix II).

### **REPORT ON THE PROPOSALS FOR ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES<sup>7</sup>**

36. The Committee recalled that at its last session it had agreed that a Circular Letter would be sent to ask for proposals for additional or revised NRVs for labelling purposes, and that the proposals would be reviewed by an electronic working group coordinated by the Delegation of South Africa, in order to develop proposals for revised NRVs. The Delegation of South Africa introduced the document that took into account the written comments received and made some proposals for further consideration of this issue.

37. The Committee agreed that the purpose of the revision of NRVs was to establish reference values for the purpose of labelling that would apply to all foods. The Committee discussed the possibility of asking for scientific advice from FAO and WHO in the revision of the current NRVs, that had been established on the basis of the recommendation of the Helsinki Consultation held in 1988. Several delegations pointed out that considerable scientific evidence had been put forward since that date and that international references were necessary in order to facilitate harmonisation of nutrition labelling provisions among member countries.

38. The Representative of FAO informed the Committee that the FAO/WHO expert consultations on nutritional requirements held since the Helsinki Consultation had not considered the establishment of NRVs, and that expert consultations on the following subject were scheduled in the FAO programme of work: nutrient risk assessment (2005); carbohydrates in human nutrition (2006); and fats and oils in human nutrition (date to be determined).

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<sup>7</sup> ALINORM 04/27/26, Appendix II. CX/NFSDU 04/3 (comments of Argentina, Australia, Costa Rica, Malaysia, Mexico, IADSA), CRD 4 (comments of Australia, Brazil, South Africa, AAC, ICGMA), CX/NFSDU 04/3-Add.1

39. The Representative of WHO recalled that when Codex Committee put forward requests for scientific advice, the questions addressed to expert consultations should be very clear, and drew the attention of the Committee to the need for additional resources when such requests were made.

40. The Committee noted that it did not appear feasible to convene a specific expert consultation on the revision of NRVs in the near future, and welcomed the offer of FAO and WHO to address the establishment of NRVs in the framework of the expert consultations that would be convened in the future, including for carbohydrates and fats and oils.

41. The Committee had an exchange of views on the substances that should be included in the list of NRVs. The Delegation of the EC expressed the view that the list should focus on vitamins and minerals and should not include other substances such as long chain fatty acids, lutein, choline and lycopene. Some delegations indicated that the current list of vitamins was incomplete and should be revised in the light of current scientific evidence. Some delegations pointed out that NRVs were also needed for macronutrients and noted that the current list included a NRV for protein.

42. The Delegation of the United States pointed out that a set of principles should be developed for the establishment of NRVs taking into account the experience of member countries in the establishment of reference values for the purpose of labelling.

43. The Committee recalled that currently there was only one set of NRV for the general population and discussed whether several sets of NRVs should be established for different population groups. Several delegations proposed to distinguish between infants and young children and adults; other delegations proposed to define more subgroups on the basis of age and gender. The Committee agreed that this question would require further consideration and that the electronic working group could prepare proposals on how to address this issue.

44. The Committee agreed that the electronic Working Group coordinated by the Delegation of South Africa would revise the discussion paper that should address the following questions: the development of principles for the establishment of NRVs, taking into account the guidelines developed by member countries in this area; the need to establish NRVs for different population groups; and the revision of the current list of nutrients.

45. The Committee expressed its appreciation to the Delegation of South Africa and to the Working Group for their constructive work on the complex issues related to NRVs.

46. The Delegation of South Africa drew attention of the delegates to the fact that they had no possibility to translate comments, therefore asked member governments to submit their comments in English only.

#### **DRAFT REVISED STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (AGENDA ITEM 5)<sup>8</sup>**

47. The Committee recalled that at its last session it had agreed to have one standard containing two Sections: Section A for Infant Formula and Section B for formulas for special medical purposes intended for infants. Section A on (Draft Revised Standard for Infant Formula) had been adopted by the Commission at Step 5 and advanced to Step 6 for comments and further consideration by the Committee and Section B containing formulas for special medical purposes had been distributed for comments at Step 3.

#### **Section A**

48. The Delegation of Germany, Chair of the Working Group on Section 3.1 Essential Composition informed the Committee that document CRD 1 described the issues discussed and the proposals made to the Plenary by the WG. The Delegation indicated that it did not finish its work due to time constraints and that it was able to consider only Sections 3.1.1, 3.1.2 and 3.1.3 a) and b). The Delegation indicated that the Working Group was

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<sup>8</sup> ALINORM 04/27/26, Appendix V; CX/NFSDU 04/5 (comments of Argentina, Australia, China, Czech Republic, Iran, Japan, Malaysia, Mexico, New Zealand, Poland, United States, CRN, ENCA, IBFAN, IDF, ISDI); CX/NFSDU 03/6 (comments of Australia, Brazil, Cuba, Iran, Japan Malaysia, Mexico, United States, ENCA, IACFO, IBFAN, ISDI on Section B of the Standard); CRD 1 (Working Group's Proposals for Section 3.1); CRD 6 (comments of the EC); CRD 7 (comments of Brazil and South Africa); CRD 8 (comments of Bulgaria, AOECs); CRD 9 (comments of Norway); CRD 13 (comments of China, Chile, India, Philippines, ENCA, IACFO).

not able to make decisions when presented with scientific evidence to support different values for nutrients and requested the guidance from the Committee on how to organize its work more effectively in the future.

### **General considerations**

49. The Delegation of the EC drew the attention of the Committee to the fact that the Working Group made some valuable proposals such as the rearrangement of the format for this section, in which order to separate essential composition and optional constituents, therefore the mandate to WG should be extended to rearrange it. The delegation also pointed out that very strict deadlines for comments should be followed.

50. In this regard, the Committee agreed to ask the Observer of ESPGHAN, who is the member of the Working Group, to provide a paper containing scientific analysis for the proposals on nutrient levels taking into account existing scientific reports on the subject, in consultation with the international scientific community, with the understanding that this paper would facilitate the process of decision taking at the next session of the Committee.

51. The Committee agreed that an electronic Working Group led by Germany<sup>9</sup> would prepare proposals on the basis of CRD 1 and comments submitted to this session until the end of 2004. These proposals then would be forwarded to ESPGHAN who will prepare the paper containing scientific analysis of these proposals by June 2005. The Committee also clarified that the Annex on amino acids should be included for revision and that the Electronic Working Group should take into account Annex II on General principles for Establishing Minimum and Maximum Values for the Essential Composition of Infant Formula.

52. The Committee decided to concentrate discussions on sections of Section A containing square brackets and in addition to editorial changes agreed to the following amendments.

### **Title**

53. The Committee agreed to take out the square brackets from the Title and Preamble.

### **Section 1. Scope**

54. The Committee had an extensive debate regarding Section 1.3 containing references to the International Code of Marketing of Breast - Milk Substitutes, the WHO Global Strategy for Infant and Young Children Feeding and World Health Assembly Resolutions. Some delegations proposed to retain the reference to WHA Resolution 55.25 while other delegations indicated that the Resolution 55.25 contained the reference to future WHA resolutions and that it was difficult to commit to these future documents without knowing their content.

55. The Secretariat drew the attention of the Committee to the fact that this matter was considered at the Executive Committee at its 48<sup>th</sup> Session (ALINORM 01/4, paras 38-39) and the last Session of the Codex Alimentarius Commission (ALINORM 04/41, para. 83) and the CCNFSDU was requested to take into account the Global Strategy and related WHA Resolution 55.25 on infant and young child nutrition.

56. The WHO Representative informed the Committee that the general policies adopted by the WHA regarding infant and young children nutrition are currently the policies laid down in the Global Strategy for Infant and Young Child Feeding and the International Code of Marketing of Breast-Milk Substitutes. As WHA resolutions may amend these specific policies or otherwise may contain elements relevant for the work of this Committee, WHO would refer to it relevant WHA resolutions for its information and consideration.

57. The Committee agreed to consider the relevance of such resolutions for its work.

58. The Committee agreed to delete the reference to WHA Resolution 55.25 as its provisions were already covered by the WHO Global Strategy for Infant and Young Child Feeding.

### **Section 2. Description**

59. The Committee had discussion on the wording contained in Section 2.1.2 regarding scientific demonstration of safety and nutritional adequacy of infant formula. Some delegations felt that this section was very important therefore square brackets should be taken out as it was essential that infant formula undergo appropriate clinical

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<sup>9</sup> Brazil, Canada, China, Costa Rica, Denmark, France, EC, India, Japan, Kenya, Korea, Malaysia, Mexico, New Zealand, Norway, Romania, Russian Federation, Switzerland, United States, CRN, ESPGHAN, IACFO, IBFAN, IDF, ISDI, ENCA.

testing in order to ensure that it is nutritionally adequate for those infants to whom they are destined. Other delegations indicated that the wording in this section was not clear as products by definition should satisfy safety and nutritional adequacy requirements and that these provisions were already covered in other sections. Different wordings were proposed to amend this section; however after some debate the Committee decided to clarify that safety related to nutritional aspects of infant formula and that nutritional safety and adequacy shall be scientifically demonstrated to support growth and development of infants and transferred this section to Section 3.1.1 for consistency.

60. The Observer from IACFO expressed its view that scientific review should be assured by independent body in order to avoid any conflict of interests.

### **Section 3. Essential Composition and Quality Requirements**

61. The Committee accepted the recommendation of the WG and deleted the square brackets from the last sentence on gluten-free ingredients and food additives.

62. The Committee deleted the reference to sections a) and b) in Section 3.3 in relation to the addition of vitamins and minerals for clarification purposes.

63. The Delegation of India supported by Tanzania proposed to exclude ingredients obtained by genetic modification as a precautionary measure to protect infants and children. The Delegation of Brazil suggested that the safety of genetically modified ingredients should be scientifically assessed on a case-by-case basis and in accordance with national legislation. The Committee recalled that the Codex Alimentarius Commission had adopted a set of principles and guidelines on how to address the safety of foods derived from modern biotechnology therefore it was not possible to forbid foods which have been approved as safe following the risk assessment.

64. The Delegation of Australia referred to its written comments and suggested if Section A does not establish levels for trace elements such as chromium and molybdenum, that levels should be included in section B.

65. In section on Specific prohibitions it was proposed to separate the issues of ionizing radiation and to elaborate a list of prohibitions with the use of commercially partially hydrogenated oils and fats; and to move the prohibitions currently proposed in Section 3.1.3 to this section. The Delegation of the United States expressed their concern that the elaboration of such a list might be understood as all inconclusive and this could lead to some confusion. The Committee noted that there was no consensus on this matter and decided to leave this section unchanged. The delegation of New Zealand drew the Committee's attention to the fact that CCMMP highlighted the need for a consistent application of the milk protein nitrogen conversion factor of 6.38.

### **Section 4. Additives**

66. The Committee supported the view of the Delegation of the United States that the selection of food additives should follow the principles expressed in the General Principles for the Use of Food Additives and the Preamble of the General Standard of Food Additives, and noted that this was also specified in the Procedural Manual.

67. The Delegation of the EC expressed concern with the use of Carageenan (INS 497) in view of the advice of the Scientific Committee for Foods of the EU concerning the absorption of carageenan in the immature gut in the very young infant. The Delegation also indicated that the use of Carob Bean Gum (INS 410) should not be allowed in infant formula but restricted to formulas for special medical purposes. Some delegations and the Observer from ISDI indicated that carob bean gum and other thickeners were needed for technological reasons in infant formula. The Delegation of the United States proposed to add Xanthan Gum (INS 145) with a level of GMP as its ADI is "not specified". The Committee noted the view of the Observer from ENCA that thickeners should not be used and the view of the Observer from ESPGHAN that their use in infant formula should be strictly restricted.

68. The Delegation of India expressed the view that the use of phosphates should be restricted as they could affect the calcium/phosphorus ratio, which might cause adverse effects on bone metabolism. The Committee noted that this issue should be addressed generally for all additives that may affect the nutritional properties of the product. The Delegation of the United States proposed to include provisions to this effect at the beginning of the section on additives.

69. The Committee recognized that it would not be possible to consider the entire section on additives at the present session due to lack of time and the substantial comments on this section. The Committee therefore agreed that the Delegation of Switzerland would coordinate an Electronic Working Group open to all interested delegations to prepare a revised list of additives taking into account all written comments received and the discussion at the present session, for consideration by the next session of the Committee.

#### **Section 4.5 Carry-over of Food Additives**

70. The Committee agreed to retain square brackets only on paragraph b) on carrier substances, pending resolution of the issues related to carriers in the Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children, that was also under consideration at the present session (see also Agenda item 7).

#### **Section 9. Labelling**

71. The Committee recalled that the Committee on Food Labelling had referred back sections 9.1.3, 9.1.6, 9.2.1, 9.3 and 9.6.6 to the CCNFSDU for further consideration and had endorsed all other sections.

72. The Committee amended section 9 to include references to other relevant general labelling texts, in addition to the General Standard for the Labelling of Prepackaged Foods. In section 9.1 a reference to the “appropriate language(s)” in the plural was included as this was necessary in multilingual countries.

73. The Committee agreed to delete section 9.1.5 concerning the prohibition of health claims as this was covered by the Guidelines for Use of Nutrition and Health Claims, whereby nutrition and health claims were prohibited in the absence of specific provisions in Codex standards or national legislation. The Delegations of Brazil, India, Malaysia, Thailand, Zimbabwe and the Observers from ENCA, IBFAN and IACFO expressed their objection to the deletion of section 9.1.5.

74. The Committee noted some proposals to amend the section on iron declaration (9.1.6) but agreed to defer discussion of this section until composition requirements had been finalized.

75. In section 9.2.1, the Committee agreed that the possibility to arrange vitamins and minerals as separate groups should remain optional and amended the text accordingly. The Committee amended section 9.3 to the effect that the mandatory nutrition information “should be” in a specific order and noted that the rest of the section was consistent with the Guidelines on Nutrition Labelling. The Committee amended paragraph a) and b) to insert the declaration of nutrient per 100 millilitres, as this was necessary when formula was sold in liquid form.

76. To concerns expressed by the Observer from ENCA, the Representative of WHO informed the Committee that the FAO/WHO Workshop on *Enterobacter sakazakii* and other microorganisms in powdered infant formula had provided recommendations for risk reduction strategies at all stages from production to consumption, including the use of the product by the final consumer. The recommendations of the Workshop would be used in the revision of the Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979), that was currently underway in the Committee on Food Hygiene. The Committee expressed its appreciation to FAO and WHO for convening a consultation on this important public health issue and agreed that it would consider this issue further at its next session, taking into account the progress made by the Committee on Food Hygiene on the revision of the Code.

77. Some Observers proposed to include a warning on the label to the effect that the product was not sterile. The Committee however agreed that all issues related to contamination would be discussed at the next session, including information for consumers.

78. The Secretariat indicated that the *General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses* (CODEX STAN 146-1985) (Section 4.8.1 Storage of Opened Foods) included relevant provisions that might be used by member countries, and in particular that “a warning should be included in the label if the food is not capable of being stored...”.

79. The Committee agreed to reorder section 9.5 Information for Use and 9.6 Additional Labelling Requirements for clarification purposes, on the basis of the proposal from the Delegation of Canada in CRD 9.

80. The Committee discussed whether instructions for use could appear on the label or in accompanying leaflet. Some delegations expressed the views that these instructions were very important and should always be on the label, since an accompanying leaflet might be lost. The Committee agreed to put the reference to the accompanying leaflet in (new) sections 9.5.1 and 9.5.2 in square brackets for further consideration.

81. The Delegation of Switzerland proposed to insert a new a paragraph in section 9.6 to allow the use of nutrition claims supported by appropriate scientific evidence: “Nutrition claims shall be permitted for infants and young children when they have been demonstrated in rigorous studies with adequate scientific standards”. The Delegation of Tanzania pointed out that nutrition claims on infant formula would mislead consumers and objected to this inclusion or proposed that it should be put in square brackets. The Committee did not discuss this question further due to time constraints and retained the current Section 9.6.6 in square brackets.

## **SECTION B: FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS<sup>10</sup>**

82. The Delegation of Germany introduced the document and recalled that at the request of the last session of the CCNFSDU it had prepared Section B containing provisions for formulas for special medical purposes for infants that was circulated for comments at Step 3. The Delegation indicated that were necessary cross-references were made with Section B and Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991).

83. The Committee agreed to consider the document section by section and in addition to editorials changes made the following amendments.

### **Section 1      Scope**

84. Taking into account that different views were expressed by member countries, the Committee agreed to insert the additional wording “or infant formula” in Section 1.1 to clarify that it also meets the special nutritional requirements arising from disorders or medical conditions for whose dietary management the product was formulated and put it in square brackets.

85. The Committee clarified that section B in addition to quality and safety also contains labelling requirements therefore amended wording in Section 1.2 to this effect.

### **Section 2      Description**

86. Some delegations proposed to delete the wording “by itself” in second paragraph of section 2.1.1 as some formulas for special medical purposes for infants may not, by themselves, satisfy nutritional requirements like in the case for phenylketonuria. Other delegations stated that the Committee had agreed at its last session that Section B would apply only to formulas for special medical purposes intended for infants that were sole sources of nutrition. After some discussion the Committee agreed to leave this section unchanged.

87. The Committee agreed to substitute “patients” for which there was no clear definition by clarifying that it related to infants “with specific disorders, diseases or medical conditions” in Section 2.1.1.

88. Some delegations indicated that it would be very useful to elaborate a catalogue of diseases and conditions for which such infant formulas are to be used, however the Committee recalled that these conditions were already defined in the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes.

### **Section 3      Essential composition and quality factors**

89. The Committee noted that this part of the document is closely related to Section A that this would be further elaborated by the Electronic Working Group (see also para 51).

90. The Committee agreed to delete the square brackets from the last sentence in Section 3.1.1, following earlier decision concerning section A (para. 3.1.1).

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<sup>10</sup> CL 2004/20-NFSDU; CX/NFSDU 04/6 (Comments of Australia, Brazil, Cuba, Iran, Japan, Malaysia, Mexico, United States, ENCA, IACFO, IBFAN, ISDI); CX/NFSDU 04/6-Add.1 (comments of New Zealand); CRD 6 (comments of the EC); CRD 9 (comments of Brazil, Bulgaria, Canada, Norway).

91. The Committee noted that the correct reference in Section 3.2.1 in relation compositional requirements should be 3.1.3.

92. The Committee noted that this section covered very vulnerable populations, therefore agreed to the proposal of the Delegation of the United States to add the wording specifying conditions for the use of L(+) lactic acid producing cultures and put it in square brackets for further comments and consideration.

#### **Section 4 Additives**

93. Due to time constraints and similar issues pending resolution in section A, the Committee requested the Delegation of Switzerland to develop proposals for this section for consideration by the Committee at its next session.

#### **Section 9. Labelling**

94. The Delegation of the EC pointed out that the current text included some repetitions and that it would be preferable to include cross-references to Section A of the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991). The Committee agreed to use the revised text proposed by the EC in CRD 6 as a basis for discussion.

95. Some delegations and observers indicated that the inclusion of several references to another standard created confusion, and expressed the view that it was not entirely clear whether all labelling provisions of the Standard 180-1991 applied to infant formula. Several delegations supported the use of these references and the Committee agreed to include them in the labelling section under discussion.

96. Under section 9.6 Additional Labelling Requirements, the reference to the relevant sections of CODEX STAN 180-1991 was introduced in sections 9.6.1 and 9.6.3, and some additional changes were made for clarification purposes.

97. The Observer from ENCA proposed to include paragraphs 9.6.1, 9.6.2 and 9.6.3 of section A into section B in order to complete paragraph 9.6.4.

98. In section 9.6.4, some delegations proposed to delete the reference to contraindication for breastfeeding on medical grounds. The Committee however retained these provisions without change.

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

99. The Committee noted that despite progress made in the revision of the Standard, the section on compositional requirements required fundamental reconsideration therefore agreed to return Section A of the Standard to Step 6 for further comments (see Section A of Appendix IV).

100. The Committee also agreed to return Section B containing provisions for formulas for special medical purposes intended for children to Step 3 for further comments (see Section B of Appendix IV).

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

#### **DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN AT STEP 7 (AGENDA ITEM 6)<sup>11</sup>**

102. The Committee recalled that the 27<sup>th</sup> Session of the Commission had adopted the Proposed Draft Standard at Step 5 and that it had been circulated for comments at Step 6 by Circular Letter CL 2004/21-NFSDU.

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<sup>11</sup> ALINORM 04/27/26, Appendix VI, CX/NFSDU 04/7 (comments of Argentina, China, Czech Republic, Iran, Malaysia, Mexico, New Zealand, Poland, United States of America, AAC, CI, IBFAN, ISDI, IGWA), CRD 6 (comments of the EC), CRD 10 (comments of Brazil, Bulgaria, IWGA), CRD 13 (comments of China, India, Philippines, ENCA), CRD 19 (comments of ENCA)

103. The Chair proposed to concentrate on the sections that remained in square brackets and the issues to be resolved. The Committee considered the Draft Standard section by section and made the following amendments.

### **Scope**

104. Following its earlier decision concerning the reference to WHA Resolutions in the Draft Standard for Infant Formula, the Committee agreed to delete the reference to the WHA Resolution WHA 55.25 (2002) (see paras 53-58).

### **Section 3.6 Minerals**

105. The Committee agreed to retain the provisions in the first part of the section related the sodium to apply to all products covered by the standard and to delete the exception for children over one year of age.

### **Section 3.7 Vitamins**

106. Some delegations and observers proposed to reduce the proposed value of 60 µg/100kcal for vitamin B1 (thiamin) as the level proposed could not be met with foods that were not fortified. The Delegation of the EC proposed to increase the current value in order to enhance the nutritional contribution of the products to the overall diet of infant and young children. After some further discussion, the Committee agreed on a value of 12.5 µg/100 kJ (50 µg/100 kcal).

### **Section 4. Food Additives**

107. The Committee agreed that the additive levels should be expressed on the basis of 100g of the product ready for consumption and amended the text accordingly.

108. The Committee recalled its discussion on flavours at the last session and noted that flavours are evaluated by JECFA but are not classified as additives. In reply to a question the Secretariat indicated that some standards included a general statement allowing the use of natural flavours and their synthetic equivalent, and that levels for vanillin and ethyl vanillin were specified in the Standard for Chocolate and Chocolate Products. The Delegation of the United States indicated that the Committee on Food Additives and Contaminants has endorsed the definition on flavours. After an exchange of views, the Committee agreed to delete the provisions for vanilla extract, vanillin, and ethyl vanillin.

109. The Delegation of the United States questioned the use of propellant gases for cereal based foods but noted that there may be a technological need for additives that function as packaging gases and suggested the Committee consider the need for these additive functions.

110. The Committee agreed to replace the levels of use for 270 L(+)Lactic Acid and 330 Citric Acid with GMP since the ADI for both additives is “not limited”. The Delegation of France, supported by the Delegation of the EC, proposed to specify that no food additives should be present as a result of carry over from raw materials and other ingredients, with specified exceptions. The Committee agreed to insert a new section 4.10 on carry over, that was similar to the section on carry over for infant formula.

111. The Committee agreed that the additives section would be forwarded to the CCFAC for endorsement, including the provisions on carry over.

### **Section 8. Labelling**

112. The Committee recalled that the Committee on Food Labelling had referred back section the second paragraph of section 8.1.1, sections 8.3.1, 8.4 and 8.6.3 for further consideration and had endorsed all other sections.

113. The Committee amended section 8.1.1 to include references to other general labelling texts, in addition to the General Standard for the Labelling of Prepackaged Foods.

114. The Committee agreed to delete the second paragraph of section 8.1.1 concerning the prohibition of nutrition and health claims as this was covered by the Guidelines for Use of Nutrition and Health Claims.

115. The Committee agreed with the proposal of several delegations to include provisions allowing the use of nutrition claims. The Delegation of Tanzania, supported by some observers, objected to the inclusion of



nutrition claims as this would mislead the consumer, and proposed to apply the general provisions of the Guidelines for Use of Nutrition and Health Claims to cereal-based foods.

116. The Committee amended sections 8.3.1 on the list of ingredients and 8.4.1 on the declaration of nutrition information, following its earlier decision on the corresponding sections of the sections of the standard for infant formula (see paras 71-74).

117. The Committee discussed section 8.6.3 requiring the declaration of the absence or presence of gluten. The Observer from IWGA expressed the view that the general provisions of the General Standard for the Labelling for Prepackaged Foods adequately addressed the declaration of gluten, and that there was no need for specific provisions for cereal-based foods. The Observer of AO ECS recalled the high importance for glutenintolerant infants to have the statement “gluten-free” on the label of these kind of products, when they are composed of gluten-free ingredients and food additives, and suggested an alternative sentence. The Committee noted that the Standard for Gluten Free Foods included specific labelling provisions, and it was proposed to refer to this standard. After some discussion, the Committee agreed to delete the current text and to include new text on the declaration of “gluten free” products in square brackets.

118. The Observer from ENCA proposed to reintroduce the provisions limiting the use of cocoa in cereal based foods, but the Committee noted that this had been presented in CRD 19 at the current session and that there was no time to consider this question. The Observer from ENCA also proposed to address the risks of contamination by *Enterobacter sakazakii* with the inclusion of specific labelling provisions. The Committee recalled that this question could be considered at the next session in the light of the recommendations of the Committee on Food Hygiene (see para. 76).

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

119. The Chairperson noted that significant progress had been made on the revision of the standard, however some sections required further consideration. The Committee therefore agreed to return the Draft Standard, as amended at the present session, to Step 6 for further comments and consideration at the next session (see Appendix V).

### **PROPOSED DRAFT ADVISORY LIST(S) OF MINERAL SALTS AND VITAMIN COMPOUNDS FOR THE USE IN FOODS FOR INFANTS AND CHILDREN (CAC/GL 10-1979) (AGENDA ITEM 7)<sup>12</sup>**

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

121. The Delegation of Germany introduced the document and informed the delegates of the structure and changes of the document. The Delegation drew the attention of the Committee to the fact that for further revision of the document it was necessary to get guidance from the Committee on three major areas:

- Whether in absence of purity criteria elaborated by JECFA other references for purity criteria should be accepted;
- Whether the use of nutrient compounds should also be indicated for the category of “foods for special medical purposes”; and
- Whether food additives for nutrient carriers be included again.

122. Due to time constrains the Committee was unable to consider this document section by section therefore decided to concentrate on the request of the Delegation of Germany.

123. The Committee agreed that in the absence of purity criteria elaborated by JECFA and/or other recognized international organizations also national requirements could be used. The Delegation of the United States suggested that the identity and purity specifications for food additives accepted by the Commission should be considered.

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<sup>12</sup> CL 2004/21-NFSDU; CX/NFSDU 04/8 (comments of Cuba, South Africa, Switzerland, United States, ISDI); CX/NFSDU 03/8-Add.1 (comments of New Zealand); CRD 6 (comments of the EC); CRD 11 (comments of Norway).

124. The Committee agreed to allow the use of these substances for foods for special medical purposes, therefore decided to delete the square brackets around the column containing FSMP.
125. The Committee had some discussion regarding the nutrient carriers. It was proposed to reintroduce advisory list of additives for special vitamin forms that had been deleted at the last session.
126. The Committee recognized that it could not take a final decision on this question until it had received the advice from the CCFAC on how to address carriers.
127. The Delegation of the United States proposed to support establishment by the CCFAC, which is considering this matter, of an additive functional class for nutrient carriers.
128. The Committee agreed to reintroduce the table containing additives used for special vitamin form carriers and to keep it only for the purpose of nutrient carriers.
129. The Committee also accepted the proposal of the Chairperson and agreed to change the title to read: "Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for use by Infants and Young Children".
130. To the question of the Delegation of South Africa regarding their proposal to consider the introduction of Ferrous bisglycinate into the list, the Committee clarified that this proposal should be assessed by the Delegation of South Africa in line with appropriate criteria for consideration by the Committee.

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

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

#### **PROPOSED DRAFT RECOMMENDATIONS ON THE SCIENTIFIC BASIS OF HEALTH CLAIMS (AGENDA ITEM 8)<sup>13</sup>**

132. The Committee recalled that its last session had discussed the Proposed Draft Recommendations and had agreed that the Delegation of France, with the assistance of interested delegations, would redraft the paper in the light of the comments received.
133. The Delegation of France highlighted the main changes that had been made to the earlier version: the scientific requirements about the claimed effect had been generally clarified; section 2.2 on the safety of the products included food safety as usually defined and nutritional safety; more emphasis was put on the need for studies in humans and clinical studies; and some changes had been made to the presentation of the text.
134. The Delegation also indicated that the Preamble would require further amendment to ensure consistency with the Preamble of the recently adopted Guidelines for Use of Nutrition and Health Claims.
135. The Committee expressed its appreciation to the Delegation of France for its comprehensive work on this important document. Due to time constraints, the Committee was unable to discuss the document section by section and agreed that it should be redrafted in the light of the comments received, for consideration in detail at the next session.

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

136. The Committee agreed to return the Proposed Draft Recommendations to Step 2/3 for redrafting by the Delegation of France, with the assistance of interested delegations and observers, for consideration at the next session.

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<sup>13</sup> CX/NFSDU 04/9; CX/NFSDU 04/9-Add.1 (CRD 12) (comments of Brazil, EFLA); CX/NFSDU 04/9-Add.2 (comments of New Zealand); CRD 13 (comments of Philippines).

**DISCUSSION PAPER ON THE APPLICATION OF RISK ANALYSIS TO THE WORK OF THE CCNFSDU (AGENDA ITEM 9)<sup>14</sup>**

137. The Committee recalled that it had requested the Delegation of Australia, working electronically with other interested parties, to prepare an outline of specific guidelines on the basis of Working Principles for Risk Analysis adopted by the Commission<sup>15</sup>.

138. The Delegation of Australia introduced the paper and drew the attention of the Committee to the fact that this paper has been developed as the result of the Commission's request that "relevant Codex Committees should develop or complete specific guidelines in their respective areas for the following inclusion in the Procedural Manual" as recommended in the Action Plan. The Delegation indicated that the Electronic Working Group (EWG) agreed that this work required a stepwise procedure i.e. to develop risk analysis principles applicable to the area of nutrition and only after that development of the outline of specific guidelines. The Delegation informed the Committee that the work of other Codex Committees in the area of risk analysis was noted that draft working principles for application to the work of Nutrition Committee has been prepared and presented in the Annex.

139. The Delegation was of the view that the additional work was necessary to reply to questions raised during the development of the document.

**General comments**

140. Many delegations complimented Australia on the development of this important document and supported further work in this area. It was indicated that this work should lead to some practical examples and that the Committee should stick to the development of methodological aspects for over dosage of nutrients. Some delegations pointed out that it was necessary to place more emphasis on nutrition aspects, to refine and better define principles in relation to the work of the Committee and to clarify the role of FAO/WHO in this respect. It was indicated that the document had been distributed in September and there was not enough time to study it with all interested parties in more detail.

141. The Secretariat drew the attention of the Committee to the fact that FAO/WHO were in the process of developing scientific principles on nutrient risk assessment and that this work should be taken into account in further development of this document.

142. The Committee agreed that the Electronic Working Group led by Australia and open to all interested parties should develop the discussion paper further taking into account comments at this session and with the understanding that the following areas would be covered in order to shape future considerations:

- Description of the Scope of nutritional risk analysis and interpretation of Codex risk analysis terminology in relation to nutrition;
- Description of the role of the risk assessor and risk manager and place of risk communication as they apply to the Committee and the FAO/WHO; and
- Examination of risk analysis models that are developed or being developed by other Codex Committees or *Ad Hoc* Task Forces to assist consideration of the most appropriate format and level of detail for principles and guidelines that will best serve the Committee's purposes.

**DISCUSSION PAPER ON THE DEFINITION OF TRANS FATTY ACIDS (AGENDA ITEM 10)<sup>16</sup>**

143. The Committee recalled that at its last session it had requested the Delegation of Malaysia in cooperation with Denmark and other interested parties to prepare a discussion paper for consideration at the next session of the Committee.

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<sup>14</sup> CX/NFSDU 04/10; CRD 6 (comments from the European Community); CRD 17 (comments from Council for Responsible Nutrition).

<sup>15</sup> ALINORM 04/27/26, para149.

<sup>16</sup> CX/NFSDU 04/11; CRD 6 (comments of the EC); CRD 14 (comments of Canada, South Africa, FEDIOL, ICGMA); CRD 18 (comments of IFMA).

144. The Delegation of Malaysia informed the Committee that the definition of trans-fatty acids was based on their chemical structure and the AOCS method of determination.

145. The Committee agreed that the definition of trans fatty acids should read:

*For the purpose of the Codex Guidelines on Nutrition Labelling and other related Codex Standards and Guidelines, trans fatty acids are defined as all the geometrical isomers of monounsaturated and polyunsaturated fatty acids having non-conjugated interrupted by at least one methylene group (-CH<sub>2</sub>-CH<sub>2</sub>-) carbon-carbon double bonds in the trans configuration.*

146. The Committee also agreed to send this definition to the Codex Committee on Food Labeling for use in the Codex Guidelines on Nutrition Labelling and other related Codex Standards and Guidelines.

147. The Observer of the IDF expressed its reservation regarding the deletion of the hydrogenation process as part of the definition.

#### **OTHER BUSINESS AND FUTURE WORK (AGENDA ITEM 11)**

##### **Gluten-Free Foods**

148. The Observer from the Prolamin Working Group informed the Committee that in addition to information provided on Agenda Item 2 (see paras 6 - 7) method R5 Mendez (ELISA) was independently validated and that additional information regarding particulars of this method would be submitted to the CCMAS.

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

149. The Committee was informed that the 27<sup>th</sup> session would take place in Bonn, Germany tentatively scheduled for the 21-25 of November 2005 and further details would be determined by the host Government and the Codex Secretariat.

## SUMMARY STATUS OF WORK

<b>Subject Matter</b>	<b>Step</b>	<b>For Action by</b>	<b>Reference in ALINORM 05/28/26</b>
Draft Guidelines for Vitamin and Mineral Supplements	8	28 <sup>th</sup> CAC	para. 35 and Appendix II
Draft Revised Standard for Gluten-Free Foods	7	27 <sup>th</sup> CCNFSDU	para. 7; ALINORM 04/27/26, Appendix II
Guidelines for the Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents (Part B) Dietary Fibre)	6	Governments; 27 <sup>th</sup> CCNFSDU	para. 22 and Appendix III
Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Section A)	6	Governments; 27 <sup>th</sup> CCNFSDU	para. 99 and Appendix IV, Section A
Formulas for Special Medical Purposes Intended for Infants (Section B)	3	Governments; 27 <sup>th</sup> CCNFSDU	para. 100 and Appendix IV, Section B
Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children	6	Governments, 27 <sup>th</sup> CCNFSDU	para. 119 and Appendix V
Proposed Draft Revision of the Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for use by Infants and Young Children	2/3	Germany, Governments, 27 <sup>th</sup> CCNFSDU	para. 131
Proposed Draft Recommendations on the Scientific Basis of Health Claims	2/3	France, Governments', 27 <sup>th</sup> CCNFSDU	para. 136
Discussion Paper on the Application of Risk Analysis to the Work of the CCNFSDU	-	Australia, 27 <sup>th</sup> CCNFSDU	para. 142
Discussion Paper on the Proposals for Additional or Revised Nutrient Reference Values (NRVs)	-	South Africa, 27 <sup>th</sup> CCNFSDU	para. 44

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**Appendix II****DRAFT GUIDELINES FOR VITAMIN AND MINERAL FOOD SUPPLEMENTS****(At Step 8 of the Procedure)****PREAMBLE**

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

**1. SCOPE**

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

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

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

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

**2. DEFINITIONS**

2.1 Vitamin and mineral food supplements for the purpose of these guidelines derive their nutritional relevance primarily from the minerals and/or vitamins they contain. Vitamin and mineral food supplements are sources in concentrated forms of those nutrients alone or in combinations, marketed in forms such as capsules, tablets, powders, solutions etc., that are designed to be taken in measured small-unit quantities<sup>1</sup> but are not in a conventional food form and whose purpose is to supplement the intake of vitamins and/or minerals from the normal diet.

**3. COMPOSITION****3.1 Selection of vitamins and minerals**

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

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

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

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<sup>1</sup> This refers to the physical forms of the vitamin and mineral food supplements not to the potency of the supplements.

### **3.2 Contents of vitamins and minerals**

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

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

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

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

When the maximum levels are set, due account may be taken of the reference intake values of vitamins and minerals for the population. This provision should not lead to setting of maximum levels that are solely based on recommended nutrient intakes (e. g. Population Reference Intake or Recommended Daily Allowance values).

## **4. PACKAGING**

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

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

## **5. LABELLING**

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

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

5.3 The amount of the vitamins and minerals present in the product should be declared in the labelling in numerical form. The units to be used should be units of weight consistent with the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985 (Rev.1 – 1993).

5.4 The amounts of the vitamins and minerals declared should be those per portion of the product as recommended for daily consumption and if different, the amount per unit for single use may also be given.

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

5.6 The label should indicate how the product should be used (quantity, frequency, special conditions).

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

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

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



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

\* Serving size to be determined at national level.

### Definition of dietary fibre

Dietary fibre means carbohydrate polymers<sup>1</sup> with a degree of polymerisation (DP) not lower than 3 [or 10], which are neither digested nor absorbed in the small intestine. 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, or of synthetic carbohydrate polymers .

Dietary fibre generally has properties such as:

- Decrease transit time and increase stools bulk
- Stimulate colonic fermentation
- Reduce blood total and/or LDL cholesterol levels
- Reduce post-prandial blood glucose and /or insulin levels.

*Material considered as dietary fibre should have at least one of these properties.*

### 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;

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<sup>1</sup> 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.

- 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.
- 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, the physiological effect must be scientifically demonstrated by clinical studies and other studies as appropriate. The establishment of criteria to quantify physiological effects is left to national authorities.

**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 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 used shall be gluten-free.

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

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

a) Protein

(i) [Protein content = nitrogen content x 6.25]

[Protein content = nitrogen content x 6.38 for cows' milk protein]

[Protein content = nitrogen content x 6.25 for soy or vegetable protein]

[Protein content = nitrogen content x 6.38 for hydrolysates of cows' milk protein]

[Protein content = nitrogen content x 6.25 for hydrolysates of cows' milk protein and of soy or vegetable proteins].

(ii) For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex 1); nevertheless, for calculation purposes, the concentration of methionine and cystine [and of tyrosine and phenylalanine] may be added together [unless the methionine to cystine and the tyrosine to phenylalanine] ratio exceeds 2.0].

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

<i>Nutrients (per 100 kcal, unless otherwise stated)</i>		
<i>a) Protein <sup>1</sup> [g]</i>	<i>Minimum</i>	<i>Maximum</i>
[Cow's] milk protein	1.8 <sup>2</sup>	3
Soy protein	2.25	3
Partial hydrolysates of milk protein	1.8 <sup>3</sup>	
L-carnitine [mg]	1.2	N.S. <sup>4</sup>
Taurine [mg]	N.S.	12
Nucleotides <sup>5</sup> [mg]	N.S.	[5]
Cytidine 5'-monophosphate (CMP)	N.S.	2.50
Uridine 5'-monophosphate (UMP)	N.S.	1.75
Adenosine 5'-monophosphate (AMP)	N.S.	1.50

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

<sup>2</sup> [Infant formulae containing 1.8 g/100 kcal should be clinically evaluated.]

<sup>3</sup> [Infant formulae containing less than 2.25g protein from hydrolysed protein per 100 kcal should be clinically evaluated]

<sup>4</sup> N.S. = not specified

<sup>5</sup> Maximum content per nucleotide as specified.

Guanosine 5'-monophosphate (GMP)	N.S.	0.50
Inosine 5'-monophosphate	N.S.	1.00
<b>b) Fat and fatty acids</b>		
Total fat [g]	4.4	6.0
[Phospholipids]	N.S.	[ 2 g/L]
Inositol[mg]	[4]	40
Lauric and myristic acids		Together ≤ 20% of total fatty acids
Linoleic acid [g]	[0.3]	[1.2]
<i>[Formulae without added LCPUFA]</i>		
α-linolenic acid [mg]	[50 or 100]	N.S.
Linoleic/α-linolenic ratio	5	15
<i>[Formulae with added LCPUFA]</i>		
[α-linolenic acid [mg] <sup>6</sup>	[≥ 50 mg]	
[Linoleic/α-linolenic ratio <sup>6</sup>	5	15
n-6 LCPUFA	N.S.	[2% of total fatty acids]
Arachidonic acid	N.S.	[1% of total fatty acids]
[n-3 LCPUFA]	N.S.	[2% of total fatty acids]
[DHA]		[0.5 of total fatty acids]
[Ratio EPA/DHA (wt/wt)]	[<1]	
[Cottonseed/sesame oils	No use of these type of oils]	
[Conjugated linoleic acid (CLA)	No intentional addition]	
<i>[Trans fatty acids</i>	≤ 3 or 4% of total fatty acids]	
Erucic acid		≤ 1% of total fatty acids
<b>c) Carbohydrates</b>		
Total carbohydrates [g]	9	14

<sup>6</sup> If DHA content >0,2 of total fatty acids

[Lactose in cows' milk protein- and protein hydrolysates formulae [g]	≥ 4.5]	
[Lactose in soy protein formulae	No requirement]	
[Saccharose	None in cows' milk protein and soy protein formulae ≤ 20% of total carbohydrates in protein hydrolysates formulae]	
[Fructose	None]	
[Glucose	No intentional addition to formulae based on intact proteins, ≤ 2 g in formulae based on protein hydrolysates]	
[Maltose, maltodextrins	Unrestricted]	
[Starches	≤ 30% of total carbohydrates (≤ 2 g/100 mL) as precooked or gelatinised naturally gluten-free starches No starches modified by enzymatic cross-linking or stabilisation]	
<b>d) Vitamins</b>		
Vitamin A [µg RE] <sup>7</sup>	60	180
Vitamin D [µg] <sup>8</sup>	1	2.5
Vitamin E [mg αTE] <sup>9</sup>	≥ 0.5 mg αTE/g PUFA [(corrected for double bond, see footnote <sup>10</sup> ), but in no case less than 0.5/100 kcal	[5]
Vitamin K [µg]	4	[20]
Thiamin [µg]	[40 or 60]	[300]
Riboflavin [µg]	[60 or 80]	[400]
Niacin [µg]	[300 or 800]	[1200]
Vitamin B <sub>6</sub> [µg]	35	[165]
Vitamin B <sub>12</sub> [µg]	0.1	[0.5]
Pantothenic acid [µg]	[300 or 400]	[2000]
Folic acid [µg]	[4 or 10]	[30]

<sup>7</sup> expressed as retinol equivalent (RE). 1µg RE = 3.33 IU Vitamin A

<sup>8</sup> Calciferil. 1µg calciferol = 40 IU Vitamin D

<sup>9</sup> Alpha-Tocopherol-Equivalent (TE)

<sup>10</sup> [0.5 mg α-TE/1 g linoleic acid (18:2n-6); 0,75 mg α-TE/1 g γ-linolenic (18:3n-3); 1.0 mg α-TE/1 g arachidonic acid (20:4n-6); 1.25 mg α-TE/1 g eicosapentaenoic acid (20:5n-3); 1,5 mg α-TE/1 g docosahexaenoic acid (22:6n-3)] or [per g of polyunsaturated fatty acids, expressed as linoleic acid]

Vitamin C [mg] <sup>11</sup>	[8 or 10]	[30]
Biotin [ $\mu$ g]	1.5	[7.5]
<b>e) Minerals and Trace Elements</b>		
Iron [mg]		
Cow's milk protein and protein hydrolysate formulae	[0.3 or 0.5]	[1.3 or 1.5]
Soy protein formulae	[0.45 or 1.0]	[1.9 or 2.0]
Calcium [mg]	50	[140]
Calcium/Phosphorus-Ratio	1.0	[2.0 or 2.2]
Phosphorus [mg]	Cows' milk protein- and protein hydrolysate formulae: 25 Soy protein formulae: [30] [Bioavailable phosphorus, if measured: 20-70 mg]	90 [100]
Magnesium [mg]	5	15
Sodium [mg]	20	60
Chloride [mg]	50	[125 or 160]
Potassium [mg]	60	[145 or 160]
Chromium [ $\mu$ g]	No recommended minimum and maximum levels	
Manganese [ $\mu$ g]	[1 or 5]	[100]
Molybdenum [ $\mu$ g]	No recommended minimum and maximum levels	
Fluoride [ $\mu$ g]	N.S.	[100]
Iodine [ $\mu$ g]	[5 or 10]	[50]
Selenium [ $\mu$ g]	[N.S. or 3]	[9]
Copper [ $\mu$ g] <sup>12</sup>	[20 or 35]	[80 or 100]
Zinc [mg]		
Cow's milk protein and protein hydrolysate formulae	0.5	[1.5]
Soy protein formulae	0.75	2.40
f) Choline [mg]	7	[30 or 50]

<sup>11</sup> expressed as ascorbic acid

<sup>12</sup> [Adjustment may be needed in these levels for infant formula made in regions with a high content of copper in the water supply]

### **3.2 Optional Ingredients**

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

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

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

### **3.3 Vitamin Compounds and Mineral Salts**

Vitamins and minerals added in accordance with Section 3.1.3 (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.

### **3.5 Purity Requirements**

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

### **3.6 Specific Prohibition**

The product and its components shall not [contain commercially hydrogenated oils and fats and shall not] have been treated by ionizing radiation.

## **4. FOOD ADDITIVES**

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



WORKING GROUP'S PROPOSALS					
	INS NO.			Maximum level in 100 mL of the ready-to-drink product	Technological Justification
<b>4.1</b>	<b>Thickening Agents</b>				
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 <i>REQUEST FOR 0.5 G</i>	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
<b>4.2</b>	<b>Emulsifiers</b>				
4.2.1	322 <sup>1</sup>	Lecithin <sup>1</sup>		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	Higher emulsifying power than lecithin and more hydrophylic capacities than mono- and

				protein, peptides or amino acids *	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	

<sup>1</sup> INS no. 322 refers to both Lecithin and Partially hydrolyzed lecithin.

<b>4.3</b>	<b>pH-Adjusting Agents</b>				
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 <sup>2</sup>	}	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	}		
<b>4.4</b>	<b>Antioxidants</b>				
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
<b>4.5</b>	<b>Packaging Gas (Propellants)</b>				
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	

<sup>2</sup> JECFA evaluated lactic acid for use as a food additive at its 9<sup>th</sup> and 17<sup>th</sup> 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° 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 requires 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 an 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	Vitamin B6	AOAC 961.15
Iodine (milk based formula)	AOAC 992.24	Vitamin C	AOAC 967.22; AOAC 967.21
Pantothenic acid	AOAC 992.07	Determination of choline	AOAC 999.14 (Enzymatic method)
Pantothenic acid	<i>The Analyst</i> 89 (1964)(1) 3-6, 232 US Dept Agr., <i>Agr. Handbook</i> 97 (1965)	Determination of Vitamin K	AOAC 999.15 (LC method)
Vitamin A	AOAC 974.29	Detection of Irradiated Foods	Codex General Methods
Vitamin A (retinol isomers)	AOAC 992.04	Determination of Lead	Codex General Methods
Vitamin A (retinol)	AOAC 992.06	Calcium	AOAC 984.27
Vitamin A in foods in which carotenes have been added as a source of vitamin A	AOAC 942.15	Chloride	
Vitamin K <sub>1</sub>	AOAC 992.27	Carbohydrates	Method described in CAC/VOL IX-Ed.1, Part III
Vitamin D (D <sub>3</sub> , milk based infant formula)	AOAC 992.26	Crude protein	Method described in CAC/VOL IX-Ed.1, Part III
Vitamin E	AOAC 971.30	Fat	CAC/RM 55-1976
Vitamin E (milk based infant formula)	AOAC 992.03	Fill of containers	CAC/RM 46-1972
Vitamin B12	AOAC 952.20	Folic acid	AOAC 944.12
		Linoleate (in the form of glycerides)	AOAC 922.06; 969.33; 963.22; 979.19

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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

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**[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:

	<b>per 100 kJ</b>	<b>per 100 kcal</b>
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

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

1. The goal of establishing minimum and maximum values is to provide safe and nutritionally adequate infant formula products that meet the normal nutritional requirements of infants.
2. A nutritionally adequate infant formula will promote growth and development consistent with science based standards and meet the nutritional requirements of infants when fed as a sole source of nutrition during the first months of life up to the introduction of appropriate complementary feeding.
3. The values to be established are based on an evaluation, in particular of the scientific evidence of the amounts needed to meet the nutritional requirements of infants, considering relevant human infant studies and the composition of breast-milk.
4. In addition to the principles set out in No. 3, when setting minimum and maximum values, consideration will also be given to evidence of adverse health effects. [Maximum values for nutrients with a documented risk of adverse health effects will be determined using a science-based risk assessment approach. Maximum values for those nutrients without evidence of adverse effects serve as guidance levels for manufacturers. The approach to setting maximum levels for guidance purposes shall be made transparent and comprehensible.]
5. When establishing minimum and maximum amounts, the following should be taken into account:
  - a) bioavailability, processing losses and shelf-life stability from the ingredients and formula matrix,
  - b) total levels of a nutrient in infant formula, taking into account both naturally occurring nutrients in the ingredients and added nutrients,
  - c) the inherent variability of nutrients in ingredients and in water that may be added to the infant formula during manufacture.
6. Overages for individual nutrients, as appropriate, to ensure that the required minimum levels are met throughout the shelf-life of the formula, will be included in the maximum value.
7. In establishing minimum or maximum amounts of nutrients per 100 kcal (or per 100 kJ) of infant formula based on consideration of reference values for the nutrients expressed as units per daily intake or per kilogram of body weight, the following assumptions will be used:

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

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

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

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

**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 3 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 contains compositional, quality, labelling and safety requirements for Formula for Special Medical Purposes Intended for Infants.

**1.3**

see Section A 1.3

**2. DESCRIPTION**

**2.1 Product definition**

2.1.1 Formula for Special Medical Purposes Intended for Infants means a breast-milk substitute 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 2.1.3

**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 and/or plant origin or on synthetic compounds suitable for human consumption. All ingredients and food additives shall be gluten-free.

3.1.2 The formulation 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 special medical purpose intended 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(+) producing lactic acid 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

## **9.6 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 The product shall be labelled in such a way as to avoid any confusion between formula for special medical purposes intended for infants, infant formula and follow-up formula.]

**APPENDIX V****DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN****(At Step 6 of the Procedure)****1. SCOPE**

This standard covers processed cereal-based foods intended for feeding infants as a complementary food generally from the age of 6 months onwards, taking into account infants' individual nutritional requirements, and for feeding young children as part of a progressively diversified diet, in accordance with the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001).

**2. DESCRIPTION**

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

**2.1. Product Definitions**

Four categories are distinguished:

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

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

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

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

**2.2 Other Definitions**

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

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

**3. ESSENTIAL COMPOSITION AND QUALITY FACTORS****3.1 Essential Composition**

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

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

**3.2 Energy Density**

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

**3.3 Protein**

3.3.1 The chemical index of the added protein shall be equal to at least 80% of that of the reference protein casein or the Protein Efficiency Ratio (PER) of the protein in the mixture shall be equal to at least 70% of that of the reference protein casein. In all cases, the addition of amino acids is permitted solely for the

purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose. Only natural forms of L-amino acids should be used.

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

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

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

### 3.4 Carbohydrates

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

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

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

- the amount of added carbohydrates from these sources shall not exceed 2g/100 kJ (8.4 g/100 kcal).
- the amount of added fructose shall not exceed 0.6 g/100 kJ (2.5 g/100 kcal).

### 3.5 Lipids

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

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

3.5.2 Product categories 2.1.1 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 100 mg/100 kcal(24 mg/100 kJ) of the ready-to-eat product. 3.6.2The 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 expressed in µg/100 kcal shall be within the following limits:

	µg/100kcal	µg/100kJ
vitamin A	60 – 180	14-43



(µg retinol equivalents)		
vitamin D	1 – 3	0.25-0.75

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

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

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

### 3.8 Optional Ingredients

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

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

### 3.9 Quality Factors

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

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

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

### 3.10 Consistency and Particle Size

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

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

### 3.11 Specific Prohibition

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

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

#### 4. FOOD ADDITIVES

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 in 100 g of the product	Technological Justification
4.1	Emulsifiers				
4.1.1	322 <sup>1</sup>	Lecithin <sup>1</sup>		1.5 g	Natural stabiliser, retains homogeneity
4.1.2	471	Mono- and diglycerides		1.5 g	Retains homogeneity
4.1.3	472a	Acetic and fatty acid esters of glycerol	}	0.5 g singly or in combination	Retains homogeneity
4.1.4	472b	Lactic and fatty acid esters of glycerol			Retains homogeneity
4.1.5	472c	Citric and fatty acid esters of glycerol			Higher emulsifying power than lecithin and more hydrophylic capacities than mono- and diglycerides of fatty acids
4.2	pH-Adjusting Agents				
4.2.1	500 ii	Sodium hydrogen carbonate		GMP, within the limits for sodium	Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying; Buffering capacity
4.2.2	501 ii	Potassium hydrogen carbonate	}	GMP	
4.2.3	170 i	Calcium carbonate			}}
4.2.4	270 <sup>2</sup>	L(+) Lactic acid		GMP Request for L(+)-lactic acid producing cultures at GMP <sup>3</sup>	Natural acid found in fermented milk Natural way to reduce pH Decreases risk of contamination from undesirable bacteria; adds taste; long use as an acidifier

4.2.5	330	Citric acid		GMP	Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying; Buffering and chelating capacity  Citric acid and citrates are natural compounds
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<sup>1</sup> INS no. 322 refers to both Lecithin and Partially hydrolyzed lecithin.

<sup>2</sup> JECFA evaluated lactic acid for use as a food additive at its 9<sup>th</sup> and 17<sup>th</sup> 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”.

<sup>3</sup> Cultures are not considered as food additives; CODEX STAN 72-1981 (Infant Formula) permits “4.3.11 L(+) Lactic acid producing cultures Limited by GMP in all types of infant formulae”

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

4.2.15	332 i, ii	Potassium citrate	}		effect during industrial preparation such as pasteurisation, sterilisation, drying; Buffering and chelating capacity  Citrates are natural compounds	
4.2.16	333	Calcium citrate	}			
4.2.17	507	Hydrochloric acid	}			Acidifier, pH-adjustment
4.2.18	524	Sodium hydroxide	}}			Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying
4.2.19	525	Potassium hydroxide	}			
4.2.20	526	Calcium hydroxide	}			
4.2.21	575	Glucono delta-lactone	}	0.5 g singly or in combination  Tartrates as residue in biscuits and rusks	Slow release acidifier  Secondary leavening agent	
4.2.22	334	L(+)-Tartaric acid - L(+)form only	}			
4.2.23	335 i, ii	Sodium L(+)-Tartrates - L(+)forms only	}			
4.2.24	336	Potassium L(+)-Tartrate - L(+)form only	}			
4.2.25	337	Potassium Sodium L(+)-Tartrate - L(+)form only	}			
4.2.26	338	Orthophosphoric acid	}		Only for pH adjustment  0.1 g as P <sub>2</sub> O <sub>5</sub>	Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying; Buffering and chelating capacity
4.2.27	339 i, ii, iii	Sodium orthophosphates	}			
4.2.28	340 i, ii, iii	Potassium orthophosphates	}			
4.2.29	341 i, ii, iii	Calcium orthophosphates	}			
4.3	Antioxidants					
4.3.1	306	Mixed tocopherols concentrate	}	300 mg/kg fat, singly or in combination	Protect from oxidation  Synergistic effect with ascorbyl esters	
4.3.2	307	Alpha-tocopherol	}			
4.3.3	304	L-Ascorbyl palmitate		200 mg/kg fat	Protects from oxidation  Synergistic affect with tocopherols	

4.3.4	300, 301, 303 <sup>4</sup>	L-Ascorbic acid and its sodium and potassium salts	}	50 mg, expressed as ascorbic acid and within the limits for sodium	Antioxidant in cereal bars Reduce discoloration in fruit preparations
4.3.5	302	Calcium ascorbate	}	20 mg, expressed as ascorbic acid	
-			}		
-			}		
4.5	Enzymes				
4.5.1		Malt carbohydrases		GMP	Should be listed separately in a separate list of processing aids and therefore should not be listed as food additives.
4.6	Leavening Agents				
4.6.1	503 i	Ammonium carbonate	}	Limited by GMP	Raising agent in rusks and biscuits
4.6.2	503 ii	Ammonium hydrogen carbonate	}		Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying
4.6.3	500 i, ii	Sodium carbonates		Limited by GMP	Raising agent in rusks and biscuits Sometimes used in combination with 503 i or 503 ii Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying
4.6.4	501 i, ii	Potassium carbonates		Limited by GMP	Improves in-processing handling, stabilising effect during industrial preparation such as pasteurisation, sterilisation, drying

<sup>4</sup> INS no. 303 Potassium ascorbate: Specifications not indicated by JECFA.

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

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

]

#### **4.10 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 4.9 of this standard within the limits of the maximum levels stipulated in this standard; and
- (c) [of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979) 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.

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), 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 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.

Nutrition Claims shall be permitted for foods for infants and young children where 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 or on the accompanying leaflet.

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

8.6.3 [When the product is composed of gluten-free ingredients and food additives, the label should show the statement "gluten-free".]

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.