



**Food and Agriculture
Organization of
the United Nations**



**World Health
Organization**

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REP12/NFSDU

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

*Thirty fifth Session
Rome, Italy, 2-7 July 2012*

REPORT OF THE THIRTY THIRD SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

*Bad Soden am Taunus, Germany
14 - 18 November 2011*



CX 5/20.2

**CL 2011/24-NFSDU
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TO: Codex Contact Points
Interested International Organizations

FROM: Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme

SUBJECT: **Distribution of the Report of the 33rd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (REP12/NFSDU)**

A. MATTERS FOR ADOPTION BY THE 35th SESSION OF THE COMMISSION:

Draft Guidelines Step 5/8 of the Procedure

1. Proposed Draft Nutrient Reference Values (NRVs) (para. 76, Appendix III).

Governments and interested international organizations wishing to comment on the above document, should do so in writing, in conformity with the *Procedure for the Elaboration of Codex Standards and Related Texts* (Procedural Manual of the Codex Alimentarius Commission), to the above address, before **15 March 2012**.

Draft Guidelines Step 5 of the Procedure

2. Proposed Draft Revision of the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 8-1991) (para. 126, Appendix IV).

Governments and interested international organizations wishing to comment on the above document, should do so in writing, in conformity with the *Procedure for the Elaboration of Codex Standards and Related Texts* (Procedural Manual of the Codex Alimentarius Commission), to the above address, before **15 March 2012**.

B. REQUEST FOR COMMENTS AND INFORMATION

Proposed Draft Guidelines at Step 3 of the Procedure

3. General Principles for Establishing Nutrient Reference Values for Nutrients Associated with Risk of Diet-Related Non-communicable Diseases for General Population (NRVs-NCD) (para. 66, Appendix V)

Governments and interested international organizations wishing to submit comments on the above document, should do so by writing preferably by email to Dr Barbara O. Schneeman, Director, Office of Nutrition Labeling and Dietary Supplements, Center for Food Safety & Applied Nutrition, U.S. Food and Drug Administration (HFS-800), 5100 Paint Branch Parkway, College Park, MD 20740, United States of America, E-Mail: barbara.schneeman@fda.hhs.gov, with a copy to the Secretariat at the address above before **1 February 2012**.

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SUMMARY AND CONCLUSIONS

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

Matters for consideration by the 35th Session of the Codex Alimentarius Commission

Draft Standards and Related Texts for adoption

The Committee:

- Advanced to Step 5/8 the Proposed Draft *Nutrient Reference Values for Nutrients Associated with Risk of Diet-Related Noncommunicable Diseases for General Population (NRVs-NCD)* (para. 76 and Appendix III).
- Advanced to Step 5 the Draft *Guidelines on Formulated Complementary Foods for Older Infants and Young Children* (para. 126 and Appendix IV)
- Forwarded the editorial amendment of the references in food hygiene provisions in the *Standard for Canned Baby Foods* (CODEX STAN 73-1981) and the *Standard for Cereal-Based Foods for Infants and Young Children* (CODEX STAN 74-1981) for adoption (para. 15)

Other matters for information

The Committee agreed:

- To return to Step 3 the Proposed Draft *General Principles for Establishing Nutrient Reference Values for Nutrients Associated with Risk of Diet-Related Non-communicable Diseases for General Population (NRVs-NCD)* for comment, redrafting and consideration at the next session (para. 66 and Appendix V)
- To return to Step 3 the Proposed Draft *Additional or Revised Nutrient Reference Values for Labelling Purposes in the Codex Guidelines on Nutrition Labelling* (para. 38), Proposed Draft *Revision of the Codex General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987) (para. 79) and Proposed Draft *Amendment of the Standard for Processed Cereal-Based Foods for Infants and Young Children* (CODEX STAN 74-1981) to include a New Part B for Underweight Children (para. 129) for redrafting, comments at Step 3 and consideration at the next session
- To consider the revision of the *Standard for Follow-up Formula* (CODEX STAN 156-1987) (para. 134) and the redrafted list of food additives (para. 8) at its next session

Matters referred to other Codex Committees

The Committee agreed:

- To forward to the Committee on Food Additives two food additives for endorsement (para. 6, Appendix II)
- To forward to the Committee on Food Labelling the comments on the draft definition of NRV (para. 12) and to agree that there was no need to revise the definition of trans-fatty acid (para. 13)
- To ask the Committee on Food Labelling to consider the question of whether to revise section 3.4.4 of the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) to insert a reference energy value in nutrition labelling (para. 58).

LIST OF ABBREVIATIONS

(Used in this Report)

AMDR	Acceptable Macronutrient Distribution Range
CCFA	Codex Committee on Food Additives
CCFL	Codex Committee on Food Labelling
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
CVD	Cardiovascular Disease
eLENA	electronic Library of Evidence for Nutrition Action
EU	European Union
eWG	electronic Working Group
FAO	Food and Agricultural Organization of the United Nations
IMAPP	Intake Monitoring Assessment Planning Programme
JEMNU	Joint FAO/WHO Expert Meetings on Nutrition
MAM	Moderate Acute Malnutrition
NCD	Noncommunicable Disease
NRV	Nutrition Reference Value
NUGAG	WHO Nutrition Guidance Expert Advisory Group
PUFA	Polyunsaturated Fatty Acid
pWG	physical Working Group
SAM	Severe Acute Malnutrition
SFA	Saturated Fatty Acid
UL	Upper Level of intake
UN	United Nations
WHA	World Health Assembly
WHO	World Health Organization

INTRODUCTION

1. The thirty-third Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held in Bad Soden am Taunus, Germany from 14 to 18 November 2011 at the kind invitation of the Government of Germany. The Session was chaired by Dr Pia Noble, Head of Division of Specific Foods, Food Supplements and Food Additives, Federal Ministry of Food, Agriculture and Consumer Protection. The Committee was attended by 269 delegates representing 68 Member Countries, one Member Organization and 33 International Organizations.

OPENING OF THE SESSION

2. Mr Peter Bleser, Parliamentary State Secretary to the Federal Minister of Food, Agriculture and Consumer Protection opened the Session and welcomed participants. He emphasized the importance of Codex work for improving food safety and protection of consumers' health as well as for fair practice in international trade of foods. He highlighted food security problems and stressed the need to support mothers and children to improve nutrition status. He also mentioned that international standards would contribute to solve problems such as malnutrition and obesity, which would affect not only personal quality of life but also increase of the cost of the national health system, and recalled the importance of nutrition labelling to allow consumers to make an informed choice.

Division of competence

3. Following Rule II.5 of the Rules of Procedure of the Codex Alimentarius Commission the Committee was informed about CRD 3 on the division of competence between the European Union (EU) and its Member States.

ADOPTION OF THE AGENDA (Agenda Item 1)¹

4. The Committee agreed to discuss Agenda Item 5 after Agenda item 6 and adopted the Provisional Agenda with the amendment as its Agenda for the Session.

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES (Agenda Item 2a)²

Committee on Food Additives

Food additives provisions in the Standard for Infant Formulas and Formula for Special Medical Purposes

5. The Committee noted the conclusions of the Committee on Food Additives in reply to its requests for clarification on the additives which had been considered for inclusion in the *Standard for Infant Formulas and Formula for Special Medical Purposes*. The CCFA had encouraged the CCNFSDU to give consideration to the grouping of substances proposed in paras 14-18 of CX/FA 11/43/15, where the requested additives had been grouped in accordance with their needs for different levels of assessment in the following categories: physiological body constituents, physiological metabolites and xenobiotics.

6. Taking into account the comments of the CCFA, the Committee agreed that the salts of citric and phosphoric acid, which may be considered as physiological body constituents, should be included in the list of additives. As Sodium citrates (331i and 331iii) and Potassium citrates (332i and 332ii) were already included in the additives section of the standard, the Committee agreed to forward for endorsement the levels for the acidity regulators Sodium phosphates (339i, ii and iii) and Potassium phosphates (340i, ii and iii) (see Appendix II).

¹ CX/NFSDU 11/33/1

² CX/NFSDU 11/33/2, CX/NFSDU 11/33/2-Add.1

7. The Delegation of Switzerland proposed to revise the list of substances initially proposed by the CCNFSDU, taking into account the comments made by the CCFA on the need for grouping the additives and the possible need for specific assessment and deleting as required the additives which may not be technologically justified. The Committee noted a comment on the need for clarification of the term “xenobiotics” which was not usually applied to additives and which could be better described as “other compounds”.

8. After some discussion, the Committee agreed that Switzerland would redraft the list of additives for circulation through a circular letter, and revise it in the light of the comments for consideration by the next session.

Carry-over of food additives into foods

9. In reply to the question of the Committee on Food Additives concerning the application of the carry-over of food additives in the foods included in food categories 13.1 and 13.2 of the General Standard for Food Additives (GSFA), the Committee confirmed that the carry-over was applied consistently with the Preamble of the GSFA, Section 4.3 : “*Carry-over of a food additive from a raw material or ingredient is unacceptable for foods belonging to the following food categories, unless a food additive provision in the specified category is listed in Tables 1 and 2 of this standard: a) 13.1- Infant formulae, follow-up formulae, and formulae for special medical purposes for infants; b) 13.2 - Complementary foods for infants and young children.*”

10. Some delegations pointed out that several additives which were included in the *Standard for Infant Formulas and Formula for Special Medical Purposes* and the *Standard for Cereal-Based Foods for Infants and Young Children*, and had been endorsed by the CCFA, were not included in Tables 1 and 2 of the GSFA and therefore asked the CCFA to consider their inclusion in the GSFA in order to ensure consistency between the additive provisions in specific standards and in the GSFA and in the application of the carry-over principle.

11. In order to ensure consistency in the additive provisions in the standards for foods for infants and young children, the Committee agreed to replace the current section on the carry-over principle in the Standard for Follow-up Formula and in the Standard for Canned Baby Foods by the following text at the beginning of the section on food additives:

Only the food additives listed in this section may be present in the foods covered by this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

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

Committee on Food Labelling

Definition of Nutrient Reference Values

12. The Committee noted that the draft definition (adopted at Step 5 by the Commission) had been referred to the CCNFSDU for comments. It was proposed to reconsider the definition after finalization of the principles for NRVs-NCDs which were under development and the possible need to include a reference to the General Principles but the Committee did not propose specific amendments at this stage.

Proposal for new work on the definition of trans-fatty acids

13. The Committee recalled that the Committee on Food Labelling, following the request of the delegation of Malaysia and further discussion, had invited the CCNFSDU to provide advice on the revision of the definition of trans-fatty acids. The Delegation of Malaysia informed the Committee that they wished to withdraw the request for the revision of the definition as the present definition was adequate. Other delegations expressed the view that there was not enough new scientific information to justify a revision of the definition. The Committee therefore agreed that there was no need to revise the definition at this stage.

14. The Delegation of Australia proposed that the definition of trans fatty acids should be reviewed to reconsider the exemption of conjugated fatty acids in view of new studies on the health effects of conjugated fatty acids. The Committee noted that this was a new issue and invited Australia to prepare a proposal for consideration of new work at the next session.

Food Hygiene Provisions

15. The Committee recalled that in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* and the *Standard for Follow-up Formula* (CODEX STAN 156-1987), reference was made to the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CAC/RCP 66-2008), which superseded the *Code of Hygienic Practice for Foods for Infants and Children* (CAC/RCP 21-1979) and considered how to update the reference to the superseded code in other texts. The Committee agreed to proceed as follows:

- *Standard for Cereal-Based Foods for Infants and Young Children* (CODEX STAN 74-1981): delete the reference to CAC/RCP 21-1979 and refer to the *General Principles of Food Hygiene*, which adequately cover the products concerned.
- *Standard for Canned Baby Foods* (CODEX STAN 73-1981): delete the reference to CAC/RCP 21-1979 and refer to the *Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods* (CAC/RCP 23-1979) and the *Code of Hygienic Practice for Aseptically Processed and Packaged Low-Acid Foods* (CAC/RCP 40-1993) as well as the *General Principles of Food Hygiene* (CAC/RCP 1-1969).
- *Guidelines for Formulated Supplementary Foods for Older Infants and Young Children* (CAC/GL 8-1991): revise the hygiene section while revising the Guidelines (see Agenda Item 6).

16. The Committee agreed to forward these amendments to the Commission for adoption as editorial and consequential amendments.

Committee on Methods of Analysis and Sampling

Endorsement of Methods of Analysis Provisions in Codex Standards

17. One delegation requested information on the work of the CCMAS on dietary fibre. It was noted that the CCNFSDU would be informed when the work on the selection of methods for dietary fibre was completed.

MATTERS OF INTEREST ARISING FROM FAO AND WHO (Agenda Item 2b)³

18. The Representative of FAO informed the committee about several current FAO activities such as a meeting on nutrition information, education and communication for 19 Latin American and Caribbean countries, to be held in El Salvador in December 2011 and an international conference on diet and activity assessment methods, to be held in Rome in May 2012. FAO is publishing a West African food composition table, a protein quality expert report, a book on milk and dairy products. With funds from the German Ministry of Food, Agriculture and Consumer Protection, FAO is developing a professional training programme for nutrition and communication. A new strategy for all nutrition work in FAO is being developed and should be finalized in 2012.

19. In reply to a question, the Representative indicated that updated data from countries on food composition could be provided to INFOODS or through FAO regional offices.

20. The Representative of WHO highlighted some of the activities which may be of relevance to the work of the Committee. WHO is currently developing a road map to implement the Political Declaration adopted at the High-level meeting of the UN General Assembly on the Prevention and Control of Non-communicable Diseases held in New York in September 2011 and its Action Plan. WHO is also developing a comprehensive implementation plan on maternal, infant and young child nutrition as requested by the World Health Assembly in May 2010. During 2011, five regional consultations on Scaling-up Nutrition were held to obtain inputs from Member States and other stakeholders for formulating a comprehensive implementation plan. A draft implementation plan will be reviewed at the Executive Board meeting in January 2012.

³ CX/NFSDU 11/33/3

21. WHO continues to work on implementing population salt reduction strategies, which include the development of monitoring and evaluation framework at the global level as well as various regional initiatives and intervention programmes. The Representative of WHO informed the committee of the launching of the WHO electronic Library of Evidence for Nutrition Action (eLENA) in August 2011, which provides a wide range of resources as detailed in the working document.

22. The Representative of WHO updated the Committee on the ongoing work of the WHO Nutrition Guidance Expert Advisory Group (NUGAG). The NUGAG Subgroup on Micronutrients finalized the guidelines on vitamin A supplementation for different population groups as well as the guidelines on the use of multiple micronutrient powders for home fortification of foods, iron supplementation, the safety of iron interventions for children and pregnant women living in areas of high malaria transmission, vitamin D and calcium supplementation. The Subgroup on Micronutrients is now reviewing various fortification guidelines. The NUGAG Subgroup on Diet and Health is planning to finalize the review of the scientific evidence and updating recommendations related to total fat, sugars, sodium and potassium at its next meeting in November 2011. In 2012 - 2013, this Subgroup is planning to review and update the recommendations on fats and fatty acids. The scope for the work will be finalized by NUGAG. The NUGAG subgroup on Diet and Health is developing guidance on severe acute malnutrition (SAM) and moderate acute malnutrition (MAM).

23. The Representative of WHO updated the Committee on the progress of the work on nutrient profiling, especially the field-testing of the guiding principles in several countries and, in reply to a question, indicated that stakeholders consultations had been held through the peer-reviewed process.

24. Some delegations pointed out that the work of WHO on marketing of foods to children, WHA resolutions and other WHO guidance on foods for infants and children were relevant to the work of the Committee and should be taken into account in Codex standards.

25. In reply to a question on the feasibility of joint FAO/WHO advice on nutrition, the Representative of WHO indicated that in view of the guideline review process in WHO, it was no longer possible to convene ad hoc expert consultations, and as regards the establishment of a joint FAO/WHO committee (JEMNU), consultations were ongoing with FAO.

PROPOSED DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES IN THE CODEX GUIDELINES ON NUTRITION LABELLING (Agenda Item 3)⁴

26. The Committee recalled that its last session had retained the Proposed Draft NRVs at Step 4 and had requested FAO and WHO to review the existing daily vitamin and mineral intake reference values for 28 vitamins and minerals, as well as information describing the basis for those values. In addition, the organizations were asked to give an estimate of the extent of the change in the scientific evidence base since 1998, the last time FAO/WHO held an expert meeting on vitamins and minerals.

27. The representatives of WHO/FAO presented the report on the Review of Existing Daily Vitamin and Mineral Intake Reference Values and indicated that FAO and WHO collaborated in collecting information for the review. Several methods were used to gather the information requested by the Committee. Data was retrieved from available databases, published documents, followed by examination of the original references for these values. National authorities were contacted through the WHO/FAO Regional and Country Offices, and a call for data was issued through the Codex Secretariat. They also completed a literature search of PubMed database for each nutrient to indicate the change in scientific literature since 1998.

28. Data were obtained from primary sources in developed and developing countries, countries with various national income levels, and from regions around the globe. Complexities identified in working in this area were lack of common terminology among the various countries; different terms are used for the same concept and the same term is used for different concepts depending on the country or organization. Additionally, detailed information was often difficult to acquire and more than 50% of countries for which data was compiled were from one region.

⁴ CX/NFSDU 11/33/4, CX/NFSDU 11/33/4-Add.1, CRD 4 (comments of Mali), CRD 10 (comments of Indonesia)

29. Data were obtained for 55 countries. The Representative of FAO reported that nearly all countries had values for a wide range of nutrients while fewer countries had values for other nutrients. To estimate the amount of scientific research about each nutrient during the past years, a literature search was conducted. There was a very wide range in the amount of scientific publications, with nearly 60 000 papers for calcium and less than 300 papers for pantothenate.

30. Examples of the graphs and tables were presented in the report for the nutrients calcium and biotin in order to reflect the structure of the report. The complete set of data for each country and nutrient was compiled in the spreadsheet that is available on the Codex ftp server (<ftp://ftp.fao.org/codex/Meetings/CCNFSDU/ccnfsdu33/NRVreport.xls>).

31. The Representative of WHO also presented an update on the progress towards the completion of the request made to WHO to consider the establishment of daily potassium intake values for the general population. The Committee was informed that a new WHO recommendation on potassium developed by the NUGAG group would be available in 2012.

32. Some delegations indicated that they had some corrections to make to the data presented in the report and it was agreed that information concerning necessary corrections of the WHO/FAO report to be submitted to NPUinfo@who.int by 30th November 2011.

33. The Committee expressed its thanks to FAO and WHO for this comprehensive report and considered how to proceed further, as it was recalled that the report had been requested to facilitate further consideration of NRVs for inclusion in the Guidelines on Nutrition Labelling.

34. One delegation indicated that in some cases consideration should be given to establishing two NRVs for different purposes (adequacy and risk of NCDs). The Committee agreed that at this stage its first task was to establish NRVs for the general population based on adequacy and that consideration could be given to other types of NRVs in the future.

35. The Committee discussed the need to prioritise the consideration of a limited number NRVs according to their importance for labelling purposes, as some delegations questioned the feasibility of reviewing all NRVs for consideration at the next session, and also whether sodium and potassium should be excluded.

36. The Delegation of Australia proposed to convene an electronic working group to review all proposed draft NRVs included in Appendix IV of the report of the 31st Session ALINORM 10/33/26.

37. After some discussion, the Committee agreed to proceed with the consideration of all NRVs, identified in Appendix IV to ALINORM 10/33/26, considered in previous sessions, taking into account the FAO/WHO report and established an electronic working group working in English with the following terms of reference:

- To consider the FAO/WHO Report *Review of existing daily vitamin and mineral intake reference values* summarized in CX/NFSDU 11/33/4 and given in full in the data compilation spreadsheet posted on the Codex website at <ftp://ftp.fao.org/codex/Meetings/CCNFSDU/ccnfsdu33/NRVreport.xls>.
- To recommend Nutrient Reference Values (values and footnotes) for vitamins and minerals for the general population older than 36 months.
- To formulate these recommendations based on the data of the FAO/WHO report “*Review of the existing daily vitamin and mineral intake reference values*” in accordance with the General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for the General Population.
- To identify and report any issues in the application of the General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals that may arise from this work.

Status of the Proposed Draft Additional or Revised NRVs

38. The Committee agreed to return the Proposed Draft NRVs for redrafting by the above-mentioned working group, circulation for comments at Step 3 and consideration at the next session.

PRINCIPLES FOR THE DEVELOPMENT AND REVIEW OF NRVS FOR LABELLING PURPOSES FOR NUTRIENTS ASSOCIATED WITH RISK OF DIET-RELATED NONCOMMUNICABLE DISEASES (Agenda Item 4)

General Principles for Establishing Nutrient Reference Values for Nutrients Associated with Risk of Diet-Related Noncommunicable Diseases for General Population (NRVs-NCD) (Agenda Item 4a)⁵

39. The Committee recalled that its last session had agreed to return the document to Step 3 and that it had established an eWG chaired by the United States of America and co-chaired by Chile and Thailand to prepare a revised document for its next session.

40. The Delegation of the United Kingdom informed the Committee that its comments in CX/NFSDU 11/33/6-Add.2 were not intended for consideration at the Committee and therefore the Committee noted that the comments were withdrawn.

41. The delegation of the United States of America, as the chair of the eWG, introduced the document CX/NFSDU 11/33/6 and informed that the eWG had considered all main aspects that had not been considered at the last session of CCNFSDU. The eWG also identified additional issues to be considered at the Committee including the potential for more than one NRV, NRV for protein, consolidation of annexes on NRV-NCD and vitamin and mineral NRV principles and presentation of information on NRVs in the Guidelines on Nutrition Labelling.

42. The Committee expressed its thanks to the United States of America, Chile and Thailand and to the working group for this comprehensive work and agreed to consider the revised document section by section in the following order: section 1, section 3, section 2 and additional issues. Besides editorial amendments, the Committee agreed with the following changes.

1. Preamble

43. In the third sentence, the Committee agreed to start with “governments are encouraged” for consistency with the Annex on vitamin and mineral NRV principles and to insert “diet-related” before “noncommunicable diseases” for consistency in the document.

44. The Committee noted that these principles would apply not only to the establishment of Nutrient Reference Values in national level, but also to the establishment of Codex Nutrient Reference Values for labelling purposes, as stated in the preamble.

3.1 Criteria for selection of nutrients

45. Regarding the first bullet point, some delegations supported to retain “probable” because “probable” scientific evidence, which is weaker than “convincing” evidence, was still strong according to the current definition in this document, more evidence should be used for establishing Codex NRVs, more NRVs would be established with “probable” evidence, and it would be the only way for developing countries to refer to the Codex NRVs.

46. Other delegations did not support the use of “probable” evidence to establish NRVs because Codex texts should be consistent with the provisions for the scientific substantiation of health claims, the definition of “probable” in this document would be applicable only to cancer, not to other non-communicable diseases, and had not been used in any FAO/WHO report. The establishment of NRVs was not overly restricted without using “probable” evidence, as several NRVs could be considered on the basis of convincing evidence.

47. The Representative of WHO indicated that new terms would replace the use of probable and convincing scientific evidence and the inclusion of “probable” scientific evidence was in line with the actual use of the term in the older report which was consistent with the definition being considered by the Committee and that the sentence included in the footnote may take care of concerns of health claims.

⁵ REP 11/NFSDU Appendix IV, CL 2010/53-NFSDU, CX/NFSDU 11/33/5 (Comments in reply to CL 2010/53-NFSDU of Argentina, Australia, Costa Rica, European Union, Malaysia, Mexico and United States of America), CX/NFSDU 11/33/6 (Report of electronic working group), CX/NFSDU 11/33/6-Add.1 (Comments of Brazil, Chile, China, Colombia, Egypt, Japan, Malaysia, Norway, Philippines, Thailand, United States of America, Uruguay, ICBA, IDF and NHF), CX/NFSDU 11/33/6-Add.2 (Comments of Canada, European Union, Mexico and Nicaragua), CRD 4 (Comments of Mali), CRD 6 (Comments of Australia, Nicaragua, Turkey and FoodDrinkEurope), CRD 10 (Comments of Indonesia), CRD 14 (Comments of Jamaica), CRD 17 (Comments of Malaysia)

48. After extensive discussion, the Committee agreed to delete “probable” from the first sentence and to consider text on the suitability of probable evidence.

49. Some delegations supported to include the text in square brackets “in addition, governments may consider the suitability of probable evidence...”; other delegations proposed to include the simplified text “the suitability of probable evidence may need to be considered”. After some discussion, the Committee agreed to put both texts in square brackets with the definition of “convincing” and “probable” and consider the matter at the next session.

50. The Committee agreed with the following amendment on the first sentence of the first bullet point: to put “relevant” at the beginning of the sentence, to delete “strength of” before “evidence”; to rephrase “the nutrient-noncommunicable disease risk relationship” as “the relationship between nutrient and noncommunicable disease risk”; and to include “including validated biomarkers for relevant disease risk”.

3.2 Selection of suitable data sources to establish NRVs-NCD

51. Regarding section 3.2.1, one delegation proposed that the sentence should begin with the first option rather than the second option for consistency with the vitamin and mineral NRV principles. The Committee however agreed with the second option because that improved the clarity of the text and the inconsistency should be considered when these two annexes would be consolidated. Section 3.2.2 was amended accordingly.

52. Some observers proposed that the last sentence in section 3.2.2 should be an independent paragraph as it would be applied to both section 3.2.1 and section 3.2.2. The Committee did not agree because the text was designated only for the recognized authoritative scientific bodies other than FAO/WHO.

53. One observer proposed to include “independent” before recognized authoritative scientific bodies in section 3.2.2 and section 3.3.2. The Committee noted that it had already stated that the review of the science should be independent and that the recognized authoritative scientific bodies was expected to be independent and therefore the Committee agreed not to amend the text.

54. One delegation proposed to remove “as appropriate” in the last sentence of section 3.2.2 and the Committee agreed.

55. In section 3.2.3, the Committee agreed to replace “these values” with “the daily intake reference values” for clarification and replace “healthy populations” with “the general population” for consistency.

3.3 Selection of appropriate basis for determining and expressing NRVs-NCD

56. In section 3.3.1, one delegation raised the question of how the principle applied in the case of NRVs for nutrients associated with diet-related noncommunicable diseases and indicated that for certain nutrients there might be evidence of a positive association between its intake and the risk of developing a disease or disorder but there is not necessarily a clearly identifiable threshold. The Committee agreed to make “a quantitative reference value” plural as more than one quantitative reference values for daily intake could be obtained from scientific evidence.

57. One delegation proposed to insert “FAO/WHO or other” before “recognized authoritative scientific bodies” in section 3.3.2 and section 3.4 for consistency and the Committee agreed with the proposal.

58. Regarding the last sentence of section 3.3.5, the Committee agreed to ask CCFL to consider the question of whether to revise section 3.4.4 of the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) to insert a reference energy value in nutrition labelling.

3.4 Consideration of daily intake values for upper levels

59. Some delegations proposed to delete the section as it was not clear how to apply the principle to diet-related noncommunicable disease and as the scientific data to establish the upper levels for many of the nutrients associated with NCDs were insufficient or inconclusive. Other delegations expressed the view that the section was necessary that Acceptable Macronutrient Distribution Range (AMDR) should be added as an example and that UL and AMDR has been recognized by authoritative scientific bodies. After some discussion, the Committee agreed to include the sentence with AMDR as an example and remove the square brackets from the section. The Delegation of Malaysia expressed a reservation on this decision.

2. Definitions

2.1 Nutrient Reference Values – Noncommunicable Disease (NRV-NCD)

60. One delegation proposed to move “including validated biomarkers for disease risk” from section 3.1 to this section. The Committee did not agree with the proposal as the biomarkers should appear in relation to scientific evidence and the definition should be consistent with the definition of NRVs developed by CCFL.

61. The Committee agreed to remove “chronic” for consistency and refer to “diet-related noncommunicable diseases”.

2.2 Daily Intake Reference Values

62. The Committee agreed to delete both texts in square brackets as definition should be generic. The Committee also agreed to move the last sentence of the section to the end of section 2.4 as it was more appropriate.

2.3 Upper Level of Intake, 2.4 Acceptable Macronutrient Distribution Range (AMDR)

63. The Committee agreed to include these two definitions as these terms appeared in section 3.4 and to replace “chronic” in section 2.4 with “diet-related noncommunicable” for consistency.

Other issues identified by eWG

64. Due to time constraints, the Committee agreed to consider the issues identified by the eWG at the next session.

Electronic Working Group

65. The Committee agreed to establish an eWG chaired by the United States of America and co-chaired by Thailand and Chile, to work in English and Spanish to prepare a revised document for the next session that would:

- 1) Focus on text left in brackets in the proposed draft Annex on general principles for NRVs-NCD.
- 2) Propose in a separate document for consideration a draft Annex to the Guidelines on Nutrition Labelling that consolidates the Annex on general principles for establishing vitamin and mineral NRVs and NRVs-NCD.
- 3) Further consider proposals for the need for one or more additional NRVs-NCD for other nutrients with a convincing level of scientific evidence;
- 4) Make proposals on additional issues for consideration in paragraphs 129 to 135 of CX/NFSDU 11/33/6 including
 - a) Whether more than one NRV could be set for certain nutrients
 - b) Proposed amendments to Section 3.4.4 of the Guidelines on Nutrition Labelling to refer to CCFL that relate to the listing of NRVs, and
 - c) Evaluate the interest in proposing new work to develop NRVs for total fat, available carbohydrate, and protein based on considerations other than diet-related NCDs such as energy balance.

Status of the Proposed Draft General Principles for Establishing Nutrient Reference Values for Nutrients Associated with Risk of Diet-Related Noncommunicable Diseases for General Population (NRVs-NCD)

66. The Committee agreed to return the Proposed Draft General Principles, as amended at the present session, to Step 3 for comments, redrafting by a working group as indicated above, further comments and consideration at the next session (see Appendix V).

Proposed Draft Nutrient Reference Values for Nutrients Associated with Risk of Diet-Related Noncommunicable Diseases for General Population (NRVs-NCD) (Agenda Item 4b)⁶

67. The Committee recalled that its last session agreed that in conjunction with the work on the Principles (Agenda Item 4a); the working group would also make proposals on NRVs for saturated fatty acid and sodium for consideration at the next session.

Saturated Fatty Acids

68. The Delegation of Thailand, as co-chair of the eWG, informed the Committee that the eWG had concluded that based on the draft principles two joint FAO/WHO expert consultation reports were proposed as primary data sources for the eWG to consider in proposing NRVs-NCD for these two nutrients: 1) for SFA—the report of the 2008 joint FAO/WHO expert consultation on fats and fatty acids in human nutrition (FNP 91), and 2) for sodium—the report of the 2002 joint FAO/WHO expert consultation on diet, nutrition and the prevention of chronic diseases (TR 916).

69. Many delegations agreed with the view of the eWG and supported the value 20 g as an NRV-NCD for saturated fatty acids. Some delegations also noted that 20 g was equivalent to 9% energy from saturated fatty acids in a reference daily intake 8370 kJ/ 2000 kcal.

70. The delegation of Malaysia and the observers of IDF and NHF did not support to establish an NRV-NCD for saturated fatty acids, because no convincing evidence had been provided to show any relationship between those amounts of saturated fatty acids and CVD; the ‘convincing’ evidence cited in the proposal related only to replacing saturated fatty acids with polyunsaturated fatty acids; NRV for SFAs based on replacement with polyunsaturated fatty acids was difficult for the general consumers to comprehend; the Joint FAO/WHO Expert Consultation Report on Fats and Fatty Acid recommended that the amount of polyunsaturated fatty acids should be considered; and saturated fatty acids were diverse groups of compounds with different physiological effects, including different effects on blood lipids. The replacement of saturated fatty acids could have adverse effects on health.

71. One delegation noted that there is convincing evidence relating saturated fat to CVD, and since the benefit for decreased CVD risk of lowering saturated fatty acid intake is realized when saturated fatty acid is replaced with polyunsaturated fatty acids (PUFAs), there may also be a need to include in the NRV only those saturated fatty acids linked to increased risk of CVD.

Sodium

72. The Delegation of Chile, as co-chair of the eWG, informed the Committee that the eWG had concluded that NRV-NCD on sodium should be established taking into consideration the draft principles considered under Agenda Item 4a and had proposed 2000 mg as a basis for a proposed NRV-NCD.

73. The Committee generally supported the outcome of the eWG and the level proposed. The Observer of EUSalt expressed the view that recent studies questioned the relationship between salt intake and cardiovascular diseases.

74. Regarding the FAO/WHO data sources, the Representative of WHO clarified that an additional reference should be made to the *Prevention of cardiovascular disease: Guidelines for assessment and management of cardiovascular risk. Geneva, World Health Organization, 2007* which were based on systematic reviews.

75. In reply to a question from one observer as to why the value was expressed in milligrams instead of grams, the Delegation of Chile explained that many delegations supported the use of milligrams in the eWG, that the sodium content was expressed in milligrams in most papers, that milligram was used for other minerals such as magnesium and iron, and that expressing in milligrams, resulting in higher numbers, was preferable for consumer information purposes.

⁶ CX/NFSDU 11/33/6 (Report of electronic working group), CX/NFSDU 11/33/6-Add.1 (Comments of Brazil, Chile, China, Colombia, Egypt, Japan, Malaysia, Norway, Philippines, Thailand, United States of America, Uruguay, ICBA, IDF and NHF), CX/NFSDU 11/33/6-Add.2 (Comments of Canada, European Union, Mexico and Nicaragua), CRD 4 (Comments of Mali), CRD 6 (Comments of Australia, Nicaragua, Turkey and FoodDrinkEurope), CRD 10 (Comments of Indonesia), CRD 14 (Comments of Jamaica), CRD 17 (Comments of Malaysia)

Status of the Proposed Draft Nutrient Reference Values

76. After some discussion, the Committee agreed to advance the proposed draft nutrient reference values, 20 g for saturated fatty acid and 2000 mg for sodium, to Step 5/8 for adoption by the 35th Session of the Codex Alimentarius Commission and inform them to CCFL (see Appendix III). The Delegation of Malaysia expressed its reservation on the NRV for saturated fatty acids.

PROPOSED DRAFT REVISION OF THE CODEX GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 9-1987) (Agenda Item 5)⁷

77. The Committee recalled that its last session had agreed to return the Proposed Draft Revised General Principles for redrafting by electronic and physical working groups chaired by Canada and co-chaired by Mexico and New Zealand, circulation for comments at Step 3, and consideration at the next session.

78. The delegation of Canada, as chair of the working group, introduced CRD 2, the report of the physical working group and informed the Committee that the pWG had considered the structure of the document, purposes of each section and individual principles and had not discussed in detail the wording of the principles. The working group had noted the following points for further discussion:

- Consider having separate general/overarching principles and guidance factors
- Principles specific to a particular type of addition could be considered as “additional” to the overarching/general principles
- Additional discussion is needed on the inclusion of purposes of addition in the introduction section
- Discussions are required on the inclusion of the different types of the addition in the General Principles/Guidelines

79. The Committee expressed its thanks to Canada, New Zealand and Mexico and to the working group. The Committee, noting that it could not consider the document due to time constraints agreed to return the proposed draft revision for redrafting by an eWG chaired by Canada and co-chaired by New Zealand and working in English, circulation for comments at Step 3, and consideration at the next session. The terms of reference were as follows:

- Obtain agreement on the structure (format) of the General Principles considering both headings and subheadings where these are required.
- Consider sections 3 to 7 of the General Principles (CAC/GL 9-1987) and obtain agreement on which principles are overarching or of general applicability, which principles are additional for specific types of additions, and which principles could be considered guidance factors rather than principles. This would include discussion of which principles are to be retained and which may not be needed.
- Consider whether the purposes of addition should be stated in the Introduction with principles for these included in the overarching or general principles section.
- Consider which definitions are required.
- Consider the level of demonstration of public health need required to support mandatory versus that required for voluntary addition of essential nutrients.

80. In reply to the comments that the eWG should work on the structure of the document first, the Delegation of Canada said that this could be done but they could be needed to revisit changes during the process to review each of principles. The Committee noted that the eWG should prioritize its work. The Delegation of EU noted that the question of the level of the demonstration of the public health need to justify the type of addition was not a priority at this stage.

⁷ REP 11/NFSDU, Appendix VII; CX/NFSDU 11/33/7; CX/NFSDU 11/33/7-Add.1 (Comments of Australia, Bolivia, China, Colombia, European Union, Malaysia, Norway, Peru, United States of America, IADSA, ICBA, IDF, ILSI, WSRO); CX/NFSDU 11/33/7-Add.2 (Comments of Argentina, Brazil, Chile, Mexico, Thailand); CRD 2 (Report of physical working group); CRD 4 (Comments of Mali); CRD 9 (Comments of Argentina, FoodDrinkEurope); CRD 10 (Comments of Indonesia); CRD 11b (Comments of Nicaragua); CRD 13 (Comments of Ghana); CRD 17 (Comments of Malaysia); CRD 19 (Comments of Paraguay)

PROPOSED DRAFT REVISION OF THE GUIDELINES ON FORMULATED SUPPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN (Agenda Item 6)⁸

81. The Committee recalled that its last session had agreed to return the Proposed Draft Guidelines for redrafting by an electronic working group chaired by Ghana and to establish a physical working group, chaired by Ghana and co-chaired by the United States of America which would meet immediately prior to the 33rd Session.

82. The Delegation of Ghana introduced the report and noted that the e-WG had taken into account two rounds of comments to prepare a revised version, which was subsequently considered by the physical working group and further revised as appears in CRD 1. The Delegation indicated that no conclusion had been reached on the inclusion of the Table in the Annex, and this would require further consideration.

83. The Committee expressed its thanks to Ghana, the United States and both working groups for their excellent work and considered the text section by section. The following amendments and comments were made in addition to editorial changes.

Title

84. The Chairperson recalled that the title had already been amended to replace the phrase “supplementary foods” with “complementary foods“, as defined by WHO.

2. Scope

85. Several delegations and observers proposed to refer to the WHO Global Strategy for Infant and Young Child Feeding and to one or more of the following World Health Assembly (WHA) Resolutions: WHA54.2 (2001), WHA 49.15(1996), WHA 55.25(2002) and WHA 63.23 (2010) in view of their relevance to the products under consideration. The Committee also noted a suggestion from one delegation to insert specific text from relevant WHA Resolutions in the standard for ease of reference.

86. Several delegations pointed out that WHA Resolutions were applicable to member countries and repeating them in a standard was not necessary, as the purpose of the scope was to define the products covered by the standard and therefore did not support the inclusion of any such reference. Some delegations also pointed out that WHA Resolutions were issued regularly and references to WHA Resolutions in the Guidelines could become rapidly outdated.

87. With reference to the status of the WHA resolutions, the Representative of WHO informed the Committee that a WHA resolution is not legally binding, but represents political commitment on the part of Member States and as such create a sense of accountability that Member States will implement in good faith the requests made to them by resolutions. The Representative indicated that WHA resolutions constitute international practice and consensus language that are also used in other international fora and in this context, including references to WHA resolutions or WHO Global Strategies in Codex guidelines should not pose any problem.

88. After some discussion, the Committee agreed to insert the wording used in the scope of the Standard for Cereal Based Foods, referring to the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001).

89. The Committee also noted a proposal to address inappropriate promotion of complementary foods and noted that such issues would be considered in the Labelling section.

3. Description

90. In section 3.1, some delegations indicated that the term “improved nutritional quality” was not clear and could be promotional and also could create confusion by implying that the family diet was not adequate. The Committee agreed that the paragraph was amended to refer to “appropriate nutritional quality” with additional text to explain the purpose of such formulation.

⁸ CX/NFSDU 11/33/8; CX/NFSDU 11/33/8-Add.1 (comments of Bolivia, Brazil, Chile, China, Colombia, Egypt, European Union, Malaysia, New Zealand, Peru, South Africa, United States of America, Uruguay, GAIN, IDF), CX/NFSDU 11/33/8-Add.2 (Comments of Australia, Mexico), CRD 1 (report of the physical working group), CRD 4 (Comments of Mali), CRD 8 (Comments of Botswana, Nicaragua), CRD 10 (Comments of Indonesia), CRD 11 (Comments of IBFAN), CRD 16 (Comments of Switzerland), CRD 17 (comments of Malaysia), CRD 18 (comments of ISDI)

91. With reference to the definition of complementary feeding period, the Representative of WHO indicated that for children 6 - 24 months the scientific evidence available indicates there is a demonstrated need for complementary foods with certain energy and nutrient density without which morbidity and mortality would be increased. Beyond the age of 24 months, the need for such foods has not been demonstrated. The WHO agreed that the following sentence could be included in 96bis as a committee agreement similar to the following text "The committee agreed to insert a footnote referring to the 2003 and 2005 WHO guiding principles documents in addition to the 2002 WHO report of a global consultation".

92. The Committee agreed that complementary foods can be used for older infants and young children 6 to 24 months and beyond. The Committee also agreed to insert in the footnote references to the 2003 and 2005 WHO guiding principles documents in addition to the 2002 WHO report of a global consultation.

4. Suitable raw materials and ingredients

93. In section 4.1.2.1 it was clarified that protein content is at least 20% on a dry weight basis.

94. In section 4.1.2.3 the text on phytoestrogens was amended for clarification purposes and to make it more general, as it did not apply only to soybean.

95. As regards section 4.1.3 Oil seed flours and oil seed protein products, some delegations expressed the view that some defatted oilseed flours and protein isolates were not fit for human consumption and should be deleted, especially defatted cottonseed flour, which is a by-product of the cotton industry and is commonly used as animal feed or fertiliser. It was however recalled that this product had been included in the list as it was used for human consumption in some countries. The text was amended to clarify that the products in section 4.1.3 could be used if produced and appropriately processed for human consumption.

96. The Committee asked the Representative of FAO to provide updated information at the next session on current references for producing and processing various seeds, legumes and pulses from FAO and other authoritative sources to update to the section

97. The Committee noted a proposal to place groundnuts in square brackets due to allergenic reactions, however it was recalled that groundnuts are an important ingredient of the local diet in several regions and they were retained in the list.

98. Following a proposal to add other oilseeds to the list, the text was amended to make it clear that the list provided only examples of commonly used oil seeds, and therefore countries could use other edible oilseeds available to them.

99. In reply to some questions on the safety of the raw materials and possible contamination, especially by mycotoxins, the Secretariat recalled that several codes of practice developed by the Committee on Contaminants in Foods can provide guidance to governments in this area, especially the *Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts* (CAC/RCP 55-2004) and the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003). It was agreed to insert these references in the relevant sections.

100. In section 4.1.4, it was agreed that "derived protein concentrates" from the animal source foods mentioned in the section could be used and the text was amended accordingly.

101. The Committee agreed with the proposal from some delegations to include a new section on fruit and vegetables as they can be good sources of micronutrients and their addition can be technologically feasible.

102. The Committee noted that one delegation proposed that vitamins and minerals should be included.

4.2 Other ingredients

103. The Committee agreed to add a reference to the additives used in the Standard for Canned Baby Foods and to align the section with text of the additives section in the Standard for Processed Cereal Based Foods in order to ensure consistency.

5. Technologies for and effects of processing

104. The Committee agreed with the proposal from an Observer to include a reference to the *Code of Practice for the Reduction of Acrylamide in Foods* (CAC/RCP 67-2009) in the relevant section.

105. In section 5.1, a reference to legumes was added for consistency with other sections. In section 5.3, the Committee discussed the appropriate term to be used concerning the effects of toasting: as heat resistant microorganisms might not be destroyed, the text was amended to reflect that microorganisms are reduced, as well as enzyme activity with heating.

106. The Committee noted a proposal to prohibit the use of ingredients treated by ionizing radiation, as in the Standard for Processed Cereal-Based Foods.

6. Nutritional composition and quality factors

107. The Committee agreed to change the title to “nutritional composition and quality factors” as it was more appropriate.

6.1 General Aspects

108. The second indent, “nutrient content of breast milk and breastmilk substitutes” was deleted and the third indent was amended to read “dietary habits and infant feeding practices” to make the text more general and cover all situations.

109. In section 6.1.1 the Committee agreed to replace “costs” with “quality” of raw materials and ingredients.

110. In section 6.1.3 some delegations expressed the view that 10g was a very small portion and could be considered as food for medical purposes, and in this case reference should be made to medical supervision. As an alternative, an observer suggested to use these foods subject to the advice from an independent health worker. It was also suggested that serving size should be addressed under the instructions for use. The Committee confirmed that in accordance with the definition, these foods are intended for the general population and not for medical purposes, and some amendments were made for clarification purposes.

111. In section 6.3.5 the Committee agreed to change the minimum protein content to 6% and the description of upper limit to “and typically should not exceed 15%” to allow for a broad range of products as proposed by ESPGHAN.

6.4 Fat

112. The Committee agreed to change the minimum fat content to 20% as proposed by ESPGHAN.

113. It was agreed to retain section 6.4.2 and the “alternative wording” as a new section 6.4.3 as it provided useful guidance on fatty acids.

6.5 Carbohydrates

114. Some delegations proposed to establish a maximum level of use for nutritive sweeteners, and noted that initially a maximum level of 10% was specified in the Guidelines. The Committee however could not come to a conclusion and retained the current text in square brackets for further consideration. The last sentence on dietary fibre was retained without square brackets as there was agreement on the maximum level.

6.6 Vitamins and Minerals

115. In section 6.6.1.2, the Representative of WHO indicated that for various reasons, the intake monitoring assessment planning programme (IMAPP), when completed, would not be a WHO product and therefore the reference was removed.

116. In section 6.6.2, the Committee agreed to remove the text in the square brackets and “cost”.

117. The term fortification was replaced with “nutrient addition” in the title of section 6.6.3 and some references were updated in the text.

New section 7

118. The Committee agreed to insert a section on Contaminants, using the text from the Standard for Processed Cereal-Based Foods.

8. Hygiene

119. The Section was updated to ensure consistency with other standards and references to the relevant codes of practice were inserted.

9.Packaging

120. An additional sentence on packaging material was inserted in section 9.2 to ensure consistency with the Standard for Processed Cereal-Based Foods.

10.Labelling

121. In response to some questions on general labelling requirements such as the language used and the expiry date, the Committee recalled that these provisions were covered in the General Standard for the Labelling of Prepackaged Foods, which applied to all foods.

122. In section 10.2.1.1 Name of the food, it was clarified that the true nature of the food should be reflected in the labelling and the rest of the paragraph was simplified by transferring some provisions to the instructions for use, which was also redrafted for clarification purposes as regards the age from which the product is recommended for use.

123. In section 10.2.4.6, it was agreed that foods not consumed during feeding should be discarded “unless consumed within the period recommended by the manufacturer under the instructions of use.”

124. The Committee noted the comments of an observer that description of the product should appear only in the list of ingredients in order to prevent inappropriate promotion of foods for infants and children and that family food should be consumed after one year of age.

Annex

125. Due to time constraints, it was not possible to consider the Annex at the session and it was agreed to consider it at the next session.

Status of the Proposed Draft Revised Guidelines for Formulated Complementary Foods for Older Infants and Young Children

126. The Committee agreed to advance the Proposed Draft Guidelines to Step 5 for adoption by the 35th Session of the Codex Alimentarius Commission (see Appendix IV)

PROPOSED DRAFT AMENDMENT OF THE STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN (CODEX STAN 74-1981) TO INCLUDE A NEW PART B FOR UNDERWEIGHT CHILDREN (Agenda Item 7)⁹

127. The Committee recalled that its last session had agreed to ask the 34th Session of the Commission to approve new work on the inclusion of a New Part B for Underweight Children in *the Standard for Processed Cereal-Based Foods for Infants and young Children* (CODEX STAN 74-1981) and to establish an electronic Working Group chaired by India to prepare a draft New Part B of the Standard for circulation at Step 3 and consideration by the next Session.

128. The Delegation of India, as chair of the eWG, introduced the document CX/NFSDU 11/33/9 and informed the Committee that the eWG had considered the proposed draft thoroughly, especially essential composition, cereal content, energy density and protein content.

129. The Committee expressed its thanks to India and to the working group. The Committee, noting that it could not consider the document due to time constraint agreed to return the proposed draft amendment for redrafting in the light of the written comments by an eWG chaired by India and working in English, circulation for comments at Step 3, and consideration at the next session.

PROPOSAL TO REVIEW THE CODEX STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987) (Agenda Item 8)¹⁰

130. The Committee recalled that at its last session the Delegation of New Zealand had proposed to prepare a discussion document for the Committee to consider the revision of part or all of the *Standard for Follow-up Formula* (CODEX STAN 156-1987) and that it had agreed with the proposal.

⁹ CX/NFSDU 11/33/9, CRD 7 (Comments of Botswana, European Union, Malaysia, IBFAN), CRD 10 (Comments of Indonesia), CRD 12 (Comments of South Africa), CRD 17 (Comments of Malaysia), CRD 19 (Comments of Paraguay)

¹⁰ CX/NFSDU 11/33/10, CRD 4 (Comments of Mali), CRD 5 (Comments of Egypt, Thailand), CRD 10 (Comments of Indonesia), CRD 15 (Comments of IBFAN, IACFO), CRD 19 (Comments of Paraguay), CRD 20 (Comments of Republic of Korea)

131. The Delegation of New Zealand, introducing the document CX/NFSDU 11/33/10, noted that the current standard was developed over 20 years ago and required updating to take into account technological developments and the diversification of follow-up formula in several countries. The Delegation therefore proposed to review the Standard and asked the Committee whether the Standard should be reviewed fully or partially.

132. According to the written comments, the Chair noted that there appeared to be support for the review the standard but the Committee should discuss whether it should be a partial or full review at the next session.

133. The Representative of WHO informed the Committee of the work underway in WHO concerning follow-up formula including the preparation of an information statement on follow-up formula in the context of the Code of Marketing of Breast-milk Substitutes which should be issues shortly.

134. The Committee expressed its thanks to New Zealand for the elaboration of the document. The Committee agreed to consider the matter at its next session as it did not have enough time to discuss it at the current session.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 9)

135. Neither other business nor future work was proposed at the session.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 10)

136. The Committee was informed that its 34th Session would take place in Germany, from 3 to 7 December 2012.

SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY:	DOCUMENT REFERENCE (REP12/NFSDU)
Proposed Draft Nutrient Reference Values (NRVs)	5/8	Governments 35 th CAC	para. 76 Appendix III
Proposed Draft Revision of the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 8-1991)	5	Governments 35 th CAC	para. 126 Appendix IV
General Principles for Establishing Nutrient Reference Values for Nutrients Associated with Risk of Diet-Related Non-communicable Diseases for General Population (NRVs-NCD)	2/3	Governments eWG led by United States and co-chaired by Thailand and Chile Governments 34 th CCNFSDU	para. 66 Appendix V
Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the Codex Guidelines on Nutrition Labelling	2/3	eWG led by Australia Governments 34 th CCNFSDU	para. 38
Proposed Draft Revision of the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987)	2/3	eWG led by Canada and co-chaired by New Zealand Governments 34 th CCNFSDU	para. 79
Proposed Draft Amendment of the Standard for Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981) to Include a New Part B for Underweight Children	2/3	eWG led by India Governments 34 th CCNFSDU	para. 129
Proposal to Review the Codex Standard for Follow-up Formula (CODEX STAN 156-1987)	-	34 th CCNFSDU	para. 134
proposed draft revision of the list of food additives	-	Switzerland 34 th CCNFSDU	para. 8

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proposed draft revision of the list of food additives	-	Switzerland 34 th CCNFSDU	para. 8

APPENDIX I

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APPENDIX II

FOOD ADDITIVES PROVISIONS FOR INFANT FORMULAE AND FORMULAS FOR SPECIAL MEDICAL PURPOSES

Additives considered as physiological body constituents		
INS	4.3 Acidity Regulators	
339i, ii and iii	Sodium phosphates	0.1 g expressed as P ₂ O ₅ singly or in combination and within the limits for sodium, potassium and phosphorus in section 3.1.3 (e) in all types of infant formula
340i, ii and iii	Potassium phosphates	0.1 g expressed as P ₂ O ₅ singly or in combination and within the limits for sodium, potassium and phosphorus in section 3.1.3 (e) in all types of infant formula

APPENDIX III

**PROPOSED DRAFT NUTRIENT REFERENCE VALUES FOR NUTRIENTS ASSOCIATED WITH RISK OF DIET-RELATED
NONCOMMUNICABLE DISEASES FOR GENERAL POPULATION (NRVS-NCD)**

(at Step 5/8 of the procedure)

For inclusion in the Guidelines on Nutrition Labelling

Nutrient	NRV-NCD
saturated fatty acids	20 g
sodium	2000 mg

APPENDIX IV

GUIDELINES ON FORMULATED COMPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN

(Step 5 of the procedure)

1. PURPOSE

To provide guidance on nutritional and technical aspects of the production of Formulated Complementary Foods for older infants and young children as defined in Section 3.1, including:

- i. Formulation of such foods, based on the nutritional requirements of older infants and young children;
- ii. Processing techniques;
- iii. Hygienic requirements;
- iv. Provisions for packaging;
- v. Provisions for labelling and instructions for use.

2. SCOPE

The provisions of these Guidelines apply to Formulated Complementary Foods for Older Infants and Young Children as defined in Section 3.1 below and include but are not limited to porridges containing cereals, ready-to-use products and food-based home fortificants. Micronutrient supplements, processed cereal based foods¹, and canned baby foods² are not covered by these Guidelines.

These Guidelines should be used in accordance with the Global Strategy for Infants and Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001).

3. DESCRIPTION

3.1 Formulated Complementary Foods for Older Infants and Young Children means foods that are suitable for use during the complementary feeding period. These foods are specifically formulated with appropriate nutritional quality to provide additional energy and nutrients to complement the family foods derived from the local diet by providing those nutrients which are either lacking or are present in insufficient quantities.

3.2 Older infants means persons from the age of 6 months and not more than 12 months of age.

3.3 Young children means persons from the age of more than 12 months up to the age of three years (36 months).

3.4 Complementary feeding period means the period when older infants and young children transition from exclusive feeding of breastmilk and/or breastmilk substitutes to eating the family diet³.

¹ Codex Standard for Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981, rev. 1-2006)

² Codex Standard for Canned Baby Foods (CODEX STAN 73-1981)

³ According to the WHO, 2002, Complementary Feeding, Report of the Global Consultation appropriate complementary feedings should start from the age of six months with continued breast feeding up to two years or beyond ; refer also to WHO 2003 Guiding Principles for Complementary feeding of the breastfed child, WHO 2005 Guiding principles for feeding non-breastfed children 6-24 months of age.

4. SUITABLE RAW MATERIALS AND INGREDIENTS

4.1 Basic Raw Materials and Ingredients

The following raw materials, most of which are locally available, are suitable ingredients for the production of Formulated Complementary Foods for older infants and young children under the specified conditions given below:

4.1.1 Cereals

4.1.1.1 All milled cereals suitable for human consumption may be used provided that they are processed in such a way as to reduce the fibre content, when necessary, and to decrease and, if possible, to eliminate anti-nutrients such as phytates, tannins or other phenolic materials, lectins, trypsin, and chymotrypsin inhibitors which can lower the protein quality and digestibility, amino acid bioavailability and mineral absorption. The use of appropriate enzymes may be considered to decrease fibre and anti-nutrients, if needed.

4.1.1.2 Besides carbohydrates (mainly consisting of starch) cereals contain a significant quantity of protein (8-12%) but are limiting in the amino acid lysine. Combining cereals with legumes and/or pulses, which are higher in lysine, can compensate for the limiting level in cereals.

4.1.2 Legumes and Pulses

4.1.2.1 Legumes and pulses, such as chick peas, lentils, peas, cowpeas, mungo beans, green gram, kidney beans and soya, containing at least 20% protein on a dry weight basis.

4.1.2.2 On the whole, legumes and pulses are deficient in L-methionine. Depending on the nature of the other ingredients in the formulation, the addition of L-methionine may be desirable in order to improve the nutritional value of the product.

4.1.2.3 Legumes and pulses must be appropriately processed to reduce, as much as possible, the anti-nutritional factors normally present, such as phytates, lectins (haemagglutinins), trypsin and chymotrypsin inhibitors. When phytoestrogen containing legumes and pulses such as soya are added as an ingredient, products with low levels of phytoestrogens should be used.

- Lectins can be reduced by moist heat treatment;
- Trypsin inhibitor activity may be reduced to acceptable levels by heating to high temperatures or by prolonged boiling.
- Phytate can be reduced enzymatically or by soaking or fermentation.
- Phytoestrogens can be reduced by fermentation.

4.1.2.4 Field beans or faba beans (*Vicia faba L.*) should not be used in the formulation of complementary food for older infants and young children because of the danger of favism. Heat treatment does not completely inactivate the toxic components (vicine and co-vicine).

4.1.3 Oil Seed Flours and Oil Seed Protein Products

4.1.3.1 Flours, protein concentrates and protein isolates of oil seeds are acceptable if manufactured to appropriate specifications^{4 5 6 7} which assure sufficient reduction of anti-nutritional factors and undesirable toxic substances such as trypsin and chymotrypsin inhibitors and gossypol. Such seeds may include

⁴ The following Guidelines were elaborated by the FAO/WHO/UNICEF Protein and Energy Advisory Group:

PAG Guidelines No 2: Preparation of Food Quality Ground Flour

PAG Guidelines No 4: Preparation of Edible Cotton Seed Protein Concentrates

PAG Guidelines No 5: Guideline for Heat Processed Soy Grits and Flours

⁵ Codex standard for Vegetable Protein Products (Codex STAN 174-1989)

⁶ Codex standard for Soy Protein Products (Codex STAN 175-1989)

⁷ Codex standard for Wheat Protein (Codex STAN 163-1987)

Soya beans: dehulled flour, (full fat and defatted) protein concentrate, protein isolate

Groundnuts: paste, protein isolate

Sesame seed: whole ground and defatted flour

Cottonseed: defatted flour

Sunflower seed: defatted flour, full fat

Low erucic acid rapeseed: full fat flour.

4.1.3.2 Defatted oil seed flours and protein isolates, if produced and appropriately processed for human consumption, can be good sources of protein (50-95%).

4.1.4 Animal Source Foods

Animal source foods such as meat, fish, poultry, eggs, milk and milk products are nutrient dense and good sources of high quality proteins and micronutrients and incorporation of these foods or their derived protein concentrates in Formulated Complementary Foods as technologically feasible is encouraged.

4.1.5 Fats and Oils

4.1.5.1 Fats and oils can be incorporated in adequate quantities as technologically feasible for the purpose of increasing the energy density of the product. Care must be taken to avoid oxidized fat which will adversely affect nutrition, flavour and shelf life. Such care is important for fat-containing ingredients (e.g., oil seed flours and oil seed protein products, fish meals, and fish protein concentrates) as well as fats and oils.

4.1.5.2 Partially hydrogenated fats (and oils) should not be used in Formulated Complementary Foods (Codex STAN 074-1981).

4.1.6 Fruits and Vegetables

Fruits and vegetables may be good sources of micronutrients and can be added to Formulated Complementary Foods, when technologically feasible.

4.2 Other Ingredients

Other ingredients, including those listed below, may be used to improve the nutritional quality and/or acceptability of the Formulated Complementary Foods provided that they are readily available and have been proven to be suitable and safe for their intended purpose.

4.2.1 Digestible carbohydrates

Energy density of Formulated Complementary Foods can be increased by the addition of digestible carbohydrates.

4.2.2 Food additives and flavours

Food additives and flavours listed in the Codex Standard for Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 074-1981, REV 1-2006) and the Codex Standard for Canned Baby Foods (CODEX STAN 73-1981) may be used in Formulated Complementary Foods to the maximum limits given in those Standards.

Only the food additives referred to in those Standards may be present in the foods covered by these Guidelines, as a result of carry-over from a raw material or other ingredients (including food additives) used to produce the food, subject to the following conditions:

- a) The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and
- b) The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw material or ingredients under good

manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CAC/STAN 192-1995).

5 TECHNOLOGIES FOR AND EFFECTS OF PROCESSING

5.1 Preliminary Treatment of Raw Materials

Cereals, legumes, pulses and oilseeds should first be treated to obtain wholesome and clean raw materials of good quality. Such treatments include, but are not limited to:

5.1.1 Cleaning or washing: to eliminate dirt, damaged grains, foreign grains and noxious seeds, insects and insect excreta and any adhering material.

5.1.2 Dehulling: when necessary, pulses, legumes, oilseeds and certain cereals such as oats, barley, sorghum, millet and teff should be dehulled as completely as is feasible to reduce the fibre content to acceptable levels and to decrease, and if possible, to eliminate phytates, tannins and other phenolic materials, trypsin and chymotrypsin inhibitors which can lower the protein digestibility and amino acid bioavailability and mineral absorption.

5.1.3 Degermination

5.1.3.1 Where necessary and appropriate, degermination of wheat, corn, soy and other crops should be considered in order to reduce the phytates content.

5.2 Milling

5.2.1 Milling or grinding of suitable raw materials should be carried out in such a way as to minimize the loss of nutritional value and to avoid undesirable changes in the technological properties of the ingredients.

5.2.2 Dry raw materials may be milled together, if technologically feasible, or mixed after milling or grinding.

5.2.3 Formulations containing milled cereals, legumes, pulses and/or oilseeds that have not been otherwise processed require prolonged boiling to gelatinize the starch portions and/or eliminate anti-nutritional factors present in legumes and pulses. Boiling improves the digestibility and absorption of nutrients.

5.2.4 The bulkiness of foods from food formulations containing dry ingredients obtained by milling of the raw materials can be reduced by adding, during the formulation, adequate amounts of enzymes such as alpha-amylase which, during the slow heating to boiling, predigest partially the starch and reduce the amount of water needed for the preparation of the food.

5.3 Toasting

5.3.1 Toasting (dry heating) enhances the flavour and the taste of the food through dextrinization of starch. It also improves digestibility and contributes to reducing the bulkiness of the formulated food. Moreover, it reduces micro-organisms and enzyme activity and destroys insects, thus improving keeping qualities.

5.3.2 Protein damage due to the Maillard reaction may occur in the presence of reducing carbohydrates. The toasting process should therefore be carefully controlled.

5.3.3 Pulses as well as oilseeds such as soya beans, groundnuts and sesame seeds can be toasted as whole grains directly or after soaking.

5.3.4 Toasted raw materials can be milled or ground for use as ingredients.

5.4 Sprouting, Malting and Fermentation

5.4.1 Cereals and pulses can be induced to germinate by soaking or humidifying. It is necessary, however, to ensure that growth of mycotoxin producing microorganisms does not occur. The action of natural amylases contained in the grains results in the predigestion of the starchy portion of the grain (dextrinization) thus reducing the bulk of the food when prepared for feeding and, ultimately,

increasing the nutrient density of the food. Sprouting, malting and fermentation can induce hydrolysis of phytates and decrease its inhibitory effect on mineral absorption, and may improve B vitamin content.

5.4.2 During the germination process, the seed coat of the grain splits and can be removed by washing. The malted raw material is milled or ground after drying.

5.5 Other Processing Technologies

5.5.1 Extrusion Cooking

5.5.1.1 The mix of milled or ground basic ingredients (cereals, pulses, oilseed flours) may be further processed by extrusion-cooking. Extrusion cooking may decrease available L-lysine, sulphur-containing amino acids, L-arginine, L-tryptophan and vitamins. The process should therefore be carefully controlled. The extruded product, after drying if necessary, is milled or ground to the desired particle size.

5.5.1.2 The effects of this technology are:

- gelatinization of the starchy portion of the mixture with minimal quantities of water;
- inactivation of lectins and reduction of trypsin inhibitor activity;
- a reduction in the quantities of water needed for preparation of the food;
- flavour development.

5.5.2 Enzymatic Predigestion

5.5.2.1 With this process the milled or ground basic ingredients (cereals, pulses, and oilseed flours) can be processed in the presence of water and appropriate enzymes under continuous stirring until the mixture acquires the desired fluidity. In the case of the use of amylase, starch molecules are split into dextrins and reducing sugars. After raising the temperature to inactivate the enzyme, the slurry is dried and comminuted to flour or to small flakes to allow for greater nutrient density.

5.5.2.2 The predigested product may have improved organoleptic characteristics, higher digestibility, good solubility, requires less water for the preparation of the food, and hence higher nutrient density.

6. NUTRITIONAL COMPOSITION AND QUALITY FACTORS

6.1 General Aspects

6.1.1 The selection of raw materials and ingredients for the formulation of Formulated Complementary Foods for Older Infants and Young Children should be made having regard to the provisions in Sections 4 and 5 and taking into account the following aspects:

- nutrient content of the local diet;
- dietary habits and infant feeding practices;
- other socio-economic aspects as determined by the national authorities dealing with nutrition;
- availability and quality of raw materials and ingredients.

6.1.2 All processing should be carried out in a manner that maintains protein quality and minimizes loss of micronutrients and maintains overall nutritive value.

6.1.3 Ten to fifty grammes of the product, when prepared according to the instructions, is considered a reasonable quantity which an older infant or young child during the complementary feeding period can ingest easily in one feeding and who may receive two or more feedings per day, depending on age. The range in amount per feeding allows for the various types of Formulated Complementary Foods. The lower part of the range applies to products with higher energy density (e.g., lipid-based products) whereas the upper part of the range would apply to products with lower energy density (e.g., porridges containing cereals).

6.2 Energy

6.2.1 The energy density of a mixture of milled cereals and pulses and defatted oilseed meals and flours on dry weight basis is relatively low.

6.2.2 The energy density of the food can be increased during manufacture by the addition of energy containing ingredients (i.e. fats and oils and/or digestible carbohydrates) and/or processing the basic raw materials and ingredients as indicated in Section 5.

6.2.3 The energy density of the Formulated Complementary Food should be at least 4 kcal per gram on dry weight basis.

6.3 Proteins

6.3.1 Mixtures of cereals, legumes, pulses and/or oilseed flours, can constitute an appropriate source of proteins, provided that the proteins in the Formulated Complementary Food satisfy the criteria below. Protein quality can also be improved by the inclusion of fish products, milk and milk products and/or other animal source foods.

6.3.2 The Protein Digestibility Corrected Amino Acid Score (PDCAAS)^{7,8,9} should not be less than 70 per cent of that of the WHO amino acid reference pattern for children from 2 – 5 years .

6.3.3 If, for technical reasons, the PDCAAS digestibility of a protein cannot be determined, the protein quality should be measured by biological assays. Alternatively, the protein quality may be calculated from published data on essential amino acid patterns of dietary proteins and their digestibility.

6.3.4 The addition of methionine, lysine, tryptophan or other limiting amino acids, solely in the L-form should be contemplated only when, for economic and technological reasons, no mixture of vegetable and/or animal proteins makes it possible to obtain an adequate protein quality (see 6.3.2).

6.3.5 Taking into account the preceding considerations, the energy from protein¹⁰ should not be less than 6 % of the total energy from the product and typically should not exceed 15%¹¹

6.4 Fat

6.4.1 Incorporation of fats and/or oils in Formulated Complementary Foods serves to increase the energy density and the amount of essential fatty acids as well as reduce total volume of the food consumed. At least 20 % of energy derived from fat¹⁰ is desirable.

6.4.2 The level of linoleic acid (in the form of glycerides) should not be less than 333 mg per 100 kcal or 1.6 g per 100 g of dry product **Error! Bookmark not defined.** and the fat or oil used in the production of Formulated Complementary Foods should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.

6.4.3 The use of edible oils containing polyunsaturated fatty acids, including omega-3 fatty acids and in particular docosahexaenoic acid, should be considered. The levels in the WHO/FAO recommendations (FAO/WHO Expert consultation on Fats and fatty acids in human nutrition, Geneva **Error! Bookmark not defined.**) may be considered.

6.5 Carbohydrates

6.5.1 Starch is likely to be a major constituent of many Formulated Complementary Foods. To ensure that its energy value is realized, this starch should be provided in a readily digestible form. Guidance on increasing the digestibility of starches is given in Section 5. [If nutritive sweeteners are used, they should be used sparingly.]

⁷ PDCAAS (%) = $\frac{\text{mg of limiting amino acid in 1 gram of test protein} \times \text{faecal true digestibility of test protein} \times 100}{\text{mg of limiting amino acid in 1 gram of reference protein}}$

⁸ The limiting amino acid is the essential amino present in the lowest proportion as compared with the quantity of this amino acid reference pattern

⁹ Sarwar, G., J. Nutr. 1997, 127:758-764.

¹⁰ Conversion factor based on Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985)

¹³ Michaelsen KF et al. 2009. Food and Nutr Bull 30:343-404

6.5.2 Dietary fibres and other non-absorbable carbohydrates are partially fermented by the intestinal flora to produce short-chain fatty acids, lactate and ethanol which may subsequently be absorbed and metabolized.

Increasing the intake of dietary fibres¹² increases stool bulk, may cause flatulence and decrease appetite. Fibre load also can reduce the energy density of Formulated Complementary Foods. They also may affect the efficiency of absorption of important nutrients from diets with marginal nutrient contents. The dietary fibre content of the Formulated Complementary Food should therefore be reduced to a level not exceeding 5 g per 100 g on a dry weight basis.

6.6 Vitamins and Minerals

6.6.1 Setting levels for the addition of vitamins and minerals

6.6.1.1 The decision to add vitamins and minerals to a Formulated Complementary Food should take into account local conditions including the nutrient contribution to the diet from local foods, vitamins and minerals provided by national programs, food processing technologies applied and the nutritional status of the target population as well as the requirements stipulated by national legislation and the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987).

6.6.1.2 If the dietary intake data for the target population are available, they can be used to determine appropriate levels for the addition of vitamins and/or minerals to ensure a low prevalence of either inadequate or excessive nutrient intakes using available assessment or monitoring tools.

6.6.1.3 If the dietary intake data for the target population is not available, the vitamins and minerals listed in the Table in the Annex to these Guidelines can be used as a reference for the selection of particular vitamins and minerals and their amounts for addition to a Formulated Complementary Food.

6.6.2 National authorities should ensure that the total micronutrient intake from the Formulated Complementary Foods, local diet (including breast milk and/or breast milk substitutes) and other sources do not regularly exceed recommended upper levels of micronutrient intake for older infants and young children.

6.6.3 Selecting vitamins and/or minerals for nutrient addition

6.6.3.1 When establishing the specifications for the premix of vitamin compounds and mineral salts, the vitamin and mineral content and presence of antinutritive substances in the other ingredients used in the formulation of the food should be taken into account.

6.6.3.2 Vitamins and/or minerals should be selected from the Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children (CAC/GL 10-1979) those authorised for cereal-based foods and canned baby foods.

6.6.3.3 The choice of a vitamin and/or mineral compound should take into account its relative bioavailability within the food vehicle, the effect on the sensory properties of the food vehicle and its stability in the packaged food vehicle under normal storage conditions. The General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987) provides specific guidelines in this area.

7. CONTAMINANTS

7.1 Pesticides Residues

The products should 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 ingredients do not remain, or, if technically unavoidable, are reduced to the maximum extent possible.

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

¹² Definition of Dietary fibre given in the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1885)

7.2. Other Contaminants

The product should 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.

8. HYGIENE

8.1 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 Principles of Hygiene (CAC/RCP 1-1969) 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).

8.2 The ingredients and final product should be prepared, packed and held under sanitary conditions and should comply with relevant Codex texts¹³.

9. PACKAGING

9.1 It is recommended that Formulated Complementary Foods for Older Infants and Young Children be packed in containers which will safeguard the hygienic and other qualities of the food.

9.2 The containers, including packaging material, shall be made only of materials 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 material, that standard shall apply.

10. LABELLING

10.1 It is recommended that the labelling of Formulated Complementary Foods for Older Infants and Young Children be in accordance with the Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985), the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) and the Guidelines on Nutrition Labelling (CAC/GL 2-1985).

10.2 The following mandatory provisions should apply:

10.2.1 The Name of the Food

10.2.1.1 The name of the food to be declared on the label shall indicate that the food is a Formulated Complementary Food for older infants and young children. The appropriate designation indicating the true nature of the food should be in accordance with national legislation. The major sources of protein and the age from which the product is recommended for use shall appear in close proximity to the name of the food.

10.2.2 List of Ingredients

The list of ingredients shall be declared in accordance with Section 4.2 of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985).

10.2.3 Declaration of Nutritive Value

The declaration of energy and nutrients on the label or in labelling shall contain the following information expressed per 100 grammes of the Formulated Complementary-Food as sold or otherwise distributed as well as per feeding of the food ready for consumption:

¹³ Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997); Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004); Code of Practice for the Reduction of Acrylamide in Foods (CAC/RCP 67-2009); Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts (CAC/RCP 55-2004); Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals, including annexes on Ochratoxin A, Zearalenone, Fumonisin and Tricothecenes (CAC/RCP 51-2003)

- (a) energy value, expressed in kilocalories and kilojoules;
- (b) the amounts of protein, carbohydrates and fat, expressed in grammes;
- (c) in addition to any other nutritional information required by national legislation, the total quantity *per feeding* of the *Formulated Complementary Food ready for consumption* of each vitamin and mineral added in accordance with Section 6.6, expressed in metric units.

10.2.4 Instruction for use

10.2.4.1 The label should 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 introduce formulated 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.

10.2.4.2 Directions as to the preparation and use of the food shall be given; preferably accompanied by graphical presentations.

10.2.4.3 The suggested number of feedings per day should be indicated.

10.2.4.4 In the case that addition of water is needed, the directions for the preparation shall include a precise statement that:

- (a) where the food contains non-heat-processed basic ingredients, the food must be adequately boiled in a prescribed amount of water;
- (b) where the food contains heat-processed basic ingredients:
 - (i) the food requires boiling, or
 - (ii) can be mixed with boiled water that has been cooled.

10.2.4.5 For Formulated Complementary Foods to which fats, sugars or other digestible carbohydrates should be added during preparation, the instructions for use shall identify appropriate sources and indicate the amounts of the ingredients to be added. In such situations, fats and oils with an appropriate essential fatty acid ratio should be recommended.

10.2.4.6 Directions for use shall include a statement that only an amount of food sufficient for one feeding occasion should be prepared at one time. Foods not consumed during the feeding occasion should be discarded, unless consumed within a period as recommended by the manufacturer under the instructions of use.

10.2.4.7 The label should also include a statement that Formulated Complementary Foods are to be consumed in addition to family foods and breast milk/breast milk substitutes.

ANNEX

TABLE

The reference INL₉₈ values listed in the Table provide a guide for selection and amounts of vitamins and minerals to be added to a Formulated Complementary Food. The suggested total quantity of each of these vitamins and/or minerals contained in a daily ration of the Formulated Complementary Food is at least 70% of INL₉₈.

VITAMINS AND MINERALS	REFERENCE ¹⁴ NUTRIENT INTAKE (RNI) or Individual Nutrient Levels ₉₈ (INL ₉₈)	ESTIMATED ¹⁵ AVERAGE REQUIREMENT (100% of the EAR)	70% of RNI ¹⁶
Vitamin A µg retinol equivalent	400	286	280
Vitamin D ¹⁷ µg	5	5	
Vitamin E mg (α-Tocopherol)	5	4	3.5
Vitamin C mg	30	25	21
Thiamine mg	0.5	0.4	0.35
Riboflavin mg	0.5	0.4	0.35
Niacin mg NE	6	5	4.2
Vitamin B ₆ mg	0.5	0.4	0.35
Folate µg DFE	150	120	105
Vitamin B ₁₂ µg	0.9	0.7	0.63
Calcium mg	500	417	350
Iron mg ¹⁸	11.6, 5.8, 3.9	11.6, 5.8, 3.9	8.1, 4.1, 3.4
Zinc mg ¹⁹	8.3, 4.1, 2.4	6.9, 3.4, 2.0	5.8
Iodine µg	90	64	63
Copper mg ²⁰	0.34	0.34	
Selenium µg	17	14	11.9
Vitamin K µg	15	15	10.5
Biotin µg ¹⁸	8	8	5.6
Pantothenic acid mg ¹⁸	2	2	
Magnesium mg ¹⁸	60	60	
Manganese mg ²¹	1.2	1.2	
Phosphorus mg ¹⁹	460	460	

¹⁴ RNI or INL₉₈ from FAO/WHO Vitamins and Mineral requirements in Human Nutrition. 2nd Edition. FAO/WHO 2004 (for all nutrients except copper, manganese and phosphorus)

¹⁵ Estimated Average Requirement (calculated values) based on FAO/WHO Recommended Nutrient Intakes. FAO/WHO Guidelines on Food Fortification with Micronutrients (WHO and FAO, 2006)

¹⁶ These values were calculated [by EWG Australia delegation], 70% of the RNI (INL₉₈)

¹⁷ Vitamin D should be added if there is inadequate exposure to sunlight

¹⁸ Because of skewed distribution of iron requirements for young children, the corresponding 100% RNI values are given for 5%, 10% and 15% respectively, dietary iron bioavailability

¹⁹ Zinc 100% EAR for low, medium and high; dietary zinc bioavailability

²⁰ Values are 100% Recommended Nutrient Intakes

²¹ Values are Dietary Reference Intakes. Institute of Medicine, 2002/2005 (Source for Copper, Manganese and Phosphorus).

APPENDIX V

**PROPOSED DRAFT ANNEX TO THE CODEX GUIDELINES ON NUTRITION
LABELLING:
GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR
NUTRIENTS ASSOCIATED WITH RISK OF DIET-RELATED NONCOMMUNICABLE
DISEASES FOR THE GENERAL POPULATION**

(At Step 3 of the Procedure)

1. PREAMBLE

These principles apply to the establishment of Codex Nutrient Reference Values for labelling purposes for nutrients associated with risk of diet-related noncommunicable diseases (NRVs-NCD) for the general population identified as individuals older than 36 months. These values may be used for helping consumers 1) estimate the relative contribution of individual products to overall healthful dietary intake, and 2) as one way to compare the nutrient content between products. Governments are encouraged to use the NRVs-NCD, or alternatively, consider the suitability of the general principles below and additional factors specific to a country or region in establishing their own reference values for labelling purposes, for nutrients associated with diet-related noncommunicable diseases.

For example, at the national level, population-weighted values for the general population may be established by weighting science-based reference values for daily intakes for age-sex groups using census data for a country and proportions of each age-sex group. Governments may also consider whether to establish separate food label reference values for specific segments of the general population.

2. DEFINITION(S)

2.1 Nutrient Reference Values - Noncommunicable Disease (NRVs-NCD) refer to Codex nutrient reference values for food labelling purposes for nutrients that are associated with risk of diet-related **noncommunicable** diseases not including nutrient deficiency diseases or disorders.

2.2 Daily Intake Reference Values as used in these principles refer to reference nutrient intake values provided by FAO/WHO or other recognized authoritative scientific bodies that may be considered in establishing an NRV-NCD based on the principles and criteria in Section 3. These values may be expressed in different ways (e.g., as a single value or a range), and are applicable to the total population or to a segment of the population (e.g., recommendations for a specified age range).

2.3 Upper Level of Intake (UL)²² is the maximum level of habitual intake from all sources of a nutrient or related substance judged to be unlikely to lead to adverse health effects in humans.

2.4 Acceptable Macronutrient Distribution Range (AMDR) is a range of intakes for a particular energy source that is associated with reduced risk of diet-related noncommunicable diseases while providing adequate intakes of essential nutrients. For macronutrients, they are generally expressed as a percentage of energy intake.

3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD**3.1 Criteria for Selection of Nutrients**

The following criteria should be considered in the selection of nutrients for the establishment of NRVs-NCD:

- Relevant convincing²³/ generally accepted²⁴ scientific evidence for the relationship between a nutrient and noncommunicable disease risk, including validated biomarkers for relevant disease risk.

²² Different countries may use other terms for this concept, for example, Tolerable Upper Nutrient Intake Level (UL) or upper end of safe intake range.

[In addition,

Option 1

governments may consider the suitability of probable evidence²⁵ in conjunction with other relevant bases in establishing their own food label reference value(s) .

OR

Option 2

the suitability of probable evidence⁴ may need to be considered.]

- Public health importance of the nutrient-noncommunicable disease risk relationship(s) among Codex member countries.

3.2 Selection of Suitable Data Sources to Establish NRVs-NCD

3.2.1 Relevant daily intake reference values provided by FAO/WHO that are based on a recent review of the science_ should be taken into consideration as primary sources in establishing NRVs-NCD.

3.2.2 Relevant daily intake reference values that reflect recent independent review of the science, from recognized authoritative scientific bodies other than FAO/WHO could also be taken into consideration. Higher priority should be given to values in which the evidence has been evaluated through a systematic review.

3.2.3 The daily intake reference values should reflect intake recommendations for the general population.

3.3. Selection of Appropriate Basis for Determining and Expressing NRVs-NCD

3.3.1 Relevant and peer-reviewed scientific evidence for quantitative reference values for daily intake should be available in order to determine an NRV-NCD that is applicable to the general population.

3.3.2 Daily intake reference values from FAO/WHO or other recognized authoritative scientific bodies that may be considered for NRVs-NCD include values expressed in absolute amounts or as a percentage of energy intake.

3.3.3 For practical application in nutrition labelling, a single NRV-NCD for the general population should be established for each nutrient that meets the principles and criteria in this Annex.

²³ [Convincing Evidence is evidence based on epidemiological studies showing consistent associations between exposure and disease, with little or no evidence to the contrary. The available evidence is based on a substantial number of studies including prospective observational studies and where relevant, randomized controlled trials of sufficient size, duration and quality showing consistent effects. The association should be biologically plausible. The definition of ‘convincing evidence’ was taken from the following FAO/WHO reports: 1) *Fats and Fatty Acids in Human Nutrition: Report of an Expert Consultation*. FAO Food and Nutrition Paper 91. Rome, FAO, 2010. and 2) *Diet, Nutrition and the Prevention of Chronic Diseases*. WHO Technical Report Series 916. WHO, 2003.]

²⁴ For these General Principles the terms convincing/generally accepted evidence are considered synonymous.

²⁵ [Probable Evidence is evidence strong enough to support a judgement of a probable causal relationship, which would generally justify goals and recommendations designed to reduce the incidence of cancer. All of the following are generally required:

- Evidence from at least two independent cohort studies, or at least five case control studies.
- No substantial unexplained heterogeneity between or within study types in the presence or absence of an association or direction of effect.
- Good quality studies to exclude with confidence the possibility that the observed association results from random or systematic error, including confounding, measurement error and selection bias.
- Evidence for biological plausibility.

The definition of ‘probable evidence’ is adapted from the World Cancer Research Fund/American Institute for Cancer Research (AICR) report: *Food, Nutrition, Physical Activity and the Prevention of Cancer: a Global Perspective*. Washington, DC: AICR, 2007, p. 60. The definition and application of “probable evidence” [is specific to consideration of an appropriate basis for food label reference values by governments], and is not applicable to Codex recommendations on scientific substantiation for health claims. The latter is provided in the Annex on Recommendations on the Scientific Substantiation of Health Claims in the Guidelines for Use of Nutrition and Health Claims (CAC-GL 23-1997).]

3.3.4 An NRV-NCD for the general population should be determined from the daily intake reference value for the general population or adults, or if given by sex, the mean of adult males and adult females.

3.3.5 Where a daily intake reference value is based on a percentage energy intake, the single NRV-NCD should be expressed in grams or milligrams based on a reference intake for the general population of 8370 kilojoules/2000 kilocalories.

Governments may use a Codex NRV-NCD based on the reference energy intake of 8370 kilojoules/2000 kilocalories, or may derive their own reference values for nutrition labelling based on another reference energy intake that considers factors specific to their country or region.

3.4 Consideration of Daily Intake Values for Upper Levels

The establishment of general population NRVs-NCDs should take into account daily intake reference values for upper levels established by FAO/WHO or other recognized scientific authoritative bodies where applicable (e.g., Upper Level of Intake, Acceptable Macronutrient Distribution Range).