



## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX ALIMENTARIUS COMMISSION

*Thirty sixth Session*  
*Rome, Italy, 1-5 July 2013*

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

*Bad Soden am Taunus, Germany*  
*3 – 7 December 2012*



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



**World Health  
Organization**

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**CL 2012/42-NFSDU  
December 2012**

**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 34<sup>th</sup> Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (REP13/NFSDU)**

The report of the 34<sup>th</sup> Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses will be considered by the 36<sup>th</sup> Session of the Codex Alimentarius Commission (Rome, Italy, 1-5 July 2013).

**MATTERS FOR ADOPTION BY THE 36<sup>th</sup> SESSION OF THE COMMISSION:**

**Draft and Proposed Draft Regional Standards at Step 8 and Steps 5/8 of the Procedure**

1. Draft Revision of the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 8-1991) (para. 41, Appendix II);
2. Draft Nutrient Reference Values (NRVs) (para. 65, Appendix V)
3. Proposed Draft General Principles for Establishing Nutrient Reference Values for Nutrients Associated with Risk of Diet-Related Non-Communicable Diseases for the General Population (NRVs-NCD) (para. 51, Appendix III); and consolidated version of the General Principles for Establishing Nutrient Reference Values (para. 59, Appendix IV)
4. Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the Codex Guidelines on Nutrition Labelling (para. 103, Appendix VII)

Governments and interested international organizations wishing to comment on the above documents should do so in writing, *preferably by e-mail*, to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (e-mail: [codex@fao.org](mailto:codex@fao.org); Fax +39 06 570 54593), before **31 March 2013**.

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## SUMMARY AND CONCLUSIONS

The 34<sup>th</sup> Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses reached the following conclusions:

### **Matters for adoption by the 36<sup>th</sup> Session of the Codex Alimentarius Commission**

The Committee:

- advanced to Step 8 and Step 5/8 the Draft Revision of the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (para. 41, Appendix II); the Draft Nutrient Reference Values (NRVs) (para. 65, Appendix V); the General Principles for Establishing Nutrient Reference Values for Nutrients Associated with Risk of Diet-Related Non-Communicable Diseases for General Population (NRVs-NCD) (para. 51, Appendix III); and the Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the Codex Guidelines on Nutrition Labelling (para. 103, Appendix VII).
- forwarded the Consolidation of the General Principles for Establishing NRVs of Vitamins and Minerals and General Principles for Establishing NRV-NCD for adoption (para. 59, Appendix IV)

### **Proposal for New Work**

The Committee agreed to submit to the Commission, through the Executive Committee a proposal for new work on:

- Proposal to Review the Codex Standard for Follow-up Formula (paras 147-148, Appendix VIII)

### **Other Matters of Interest to the Commission**

The Committee:

- agreed to return to Step 2/3 for redrafting, comments and further discussion at the next session the Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the Codex Guidelines on Nutrition Labelling (Other values than described above, including protein) (para. 103); the Proposed Draft Revision of the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987) (para. 125); and the Proposed Draft Amendment of the Standard for Processed Cereal-Based Foods for Infants and Young Children to Include a New Part B for Underweight Children (paras 133-135)

### **Matters of Interest to Other Committees and Task Forces**

#### **Committee on Food Labelling (CCFL)**

With regard to the question on Section 6.3 in the Guidelines on Nutrition and Health Claims, the Committee noted that there were different views on possible approaches and at this stage it was not possible to go into further detail but that CCFL should clarify the text (paras 5 – 9).

With regard to the request from the CCFL on the claim for “free” of trans fatty acids, the Committee agreed that it would consider the conditions after CCFL concludes to establish the claim after considering the global importance of trans fatty acids (paras 10 – 15).

#### **Committee on Methods of Analysis and Sampling (CCMAS)**

The Committee agreed to ask CCMAS to review the applicability of the methods of analysis for the trans fatty acid currently defined in the Guidelines on Nutrition Labelling (paras 16 – 19).

## INTRODUCTION

1. The thirty-fourth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held in Bad Soden am Taunus, Germany from 3 to 7 December 2012 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 274 delegates representing 62 Member Countries, one Member Organization and 31 International Organizations.

## OPENING OF THE SESSION

2. Mr Peter Bleser, Parliamentary State Secretary to the Federal Minister of Food, Agriculture and Consumer protection, Germany opened the Session and welcomed participants. He emphasized the importance of Codex work under SPS and TBT agreement in WTO and when fighting against hunger and malnutrition. He also highlighted the important role of scientists to ensure that Codex work was based on scientific evidence.

### Division of competence

3. Following Rule II.5 of the Rules of Procedure of the Codex Alimentarius Commission the Committee was informed about CRD 4 on the division of competence between the European Union (EU) and its Member States.

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

4. The Committee agreed to discuss biofortification through conventional breeding, proposed by IFPRI, under Agenda Item 11 “Other Business and Future Work” and noted that the questions regarding trans fatty acid referred from the Committee on Food Labelling (CCFL) should be considered under Agenda item 2a instead of Agenda Item 10. The Committee 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)<sup>2</sup>

### Comparative Claims

5. With regard to the request from CCFL about the condition for 10% of the NRV for comparative claims for micronutrients, the Committee clarified that 10% was the result of a pragmatic approach, rather than based on scientific evidence.

6. Some delegations were of the view that Section 6.3 in the Standard was confusing because the sentence included both macronutrients and micronutrients and suggested that the text should be made clearer.

7. Some delegations suggested that the increase in micronutrients should be based on the content of micronutrients between the compared foods as the requirement to base the comparison of increased micronutrients using the difference in NRV would complicate the implementation of this requirement and enforcement and for consistency with Section 6.3. Several delegations did not support the opinion as they used the current provisions for comparative claims for implementation purposes. Some delegations said that comparison should be based on substantial difference and that a 10% difference in micronutrient contents was too small.

8. One delegation considered that there was an inconsistency between the requirement for an absolute difference in nutrient content of 10% and the value for the claim for “source” of 15% of NRV per 100 g for vitamins and minerals. It was also suggested to use as the absolute minimum difference the value for “source” in the case of micronutrients as increased levels should be different versions of the same food or similar foods, which did not take into account fortification in the case of vitamins and minerals and proposed as an alternative solution to increase the relative difference to 25%.

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<sup>1</sup> CX/NFSDU 12/34/1; CRD 2 (Comments of Nigeria)

<sup>2</sup> CX/NFSDU 12/34/2; CRD 2 (Comments of Nigeria); CRD 9 (Comments of Malaysia)

9. The Committee noted that there were different views on possible approaches and at this stage it was not possible to go into further detail but that CCFL should clarify the text.

#### **Claim for “free” of trans fatty acids**

10. The Committee recalled that CCFL had asked the Committee to provide advice on the establishment of conditions for claims for “free” of trans fatty acids.

11. Some delegations supported the establishment of conditions for claims on free of trans fatty acids. One delegation proposed two different levels for fats and oils and fat emulsions and for ready-to-eat or other foods and did not support the claims for trans fatty acids associated with the levels of saturated fatty acids. Other delegations were of the view that the criteria associated with the levels of saturated fatty acids should be developed as in some products reducing trans fatty acid levels resulted in increasing saturated fatty acid levels.

12. Some delegations supported that the claims should be based on servings when serving size is regulated as this provides an important tool for consumers. Other delegations were of the view that the expression “per serving” was not appropriate because serving size might be misleading for consumers, especially in case the serving size was not regulated.

13. It was noted that the term “free” might be interpreted differently in each country.

14. One delegation expressed the view that trans fatty acids were of concern only in some countries, considering the previous discussion in CCFL and footnote in the Guidelines on Nutrition Labelling.

15. The Committee noted that CCFL had not concluded whether it would establish such a claim. The Committee therefore agreed that it would consider the conditions after CCFL concludes to establish the claim after considering the global importance of trans fatty acids.

#### **Methods of Analysis for trans fatty acids**

16. The CCFL had requested the Committee to consider requesting CCMAS to review method AOCS Ce 1H-05 for trans fatty acids in foods as it is only applicable to certain types of fats and oils and to consider method AOAC 996.06, currently a Type II method for the Guidelines on Nutrition Labelling for saturated fatty acids, as a Type II method for trans fatty acids for the purposes of the Guidelines on Nutrition Labelling and potentially for the Guidelines on Nutrition and Health Claims. One delegation indicated that AOAC 996.06 has not been validated for trans fatty acids.

17. One delegation proposed to establish a table for trans fatty acids in different types of foods as in the case of dietary fibre. Another delegation expressed the view that methods should be established only if a specific condition for claim was described. One delegation indicated that the Guidelines allows the declaration of trans fatty acids and that there should be a method for their determination.

18. The Secretariat recalled that AOCS Ce 1H-05 is listed only for trans fatty acids in infant formula as a specific level was defined in the corresponding standard, and that, a general approach, methods were selected when relevant provisions existed in Codex texts.

19. The Committee agreed to ask CCMAS to review the applicability of the methods of analysis for the trans fatty acid currently defined in the Guidelines on Nutrition Labelling.

#### **MATTERS OF INTEREST ARISING FROM FAO AND WHO (Agenda Item 2b)<sup>3</sup>**

20. The Representative of FAO explained that FAO has a new strategy aimed to support member countries to increase the effectiveness of food and agriculture systems in improving nutrition across the life cycle, working with partners at the national, regional and global levels. FAO would bring expertise on food based approaches to topics of complementary feeding and maternal nutrition in global efforts like the Zero Hunger Challenge. FAO would provide scientific advice on nutrition requirements, nutrition and dietary assessments, food consumption patterns and food composition.

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<sup>3</sup> CX/NFSDU 12/34/3

21. The Representative also said that FAO and WHO had worked together to finalize procedures to the Joint Expert Meetings on Nutrition (JEMNU), which would provide scientific advice to Codex and Member countries. JEMNU would not have a permanent secretariat and would be activated when scientific advice was requested, both organisations providing human resources for the temporary secretariat. Extra-budgetary funds would be required to carry out the work of the expert meetings. There would be a call for experts each time JEMNU is active. These experts would need to provide a declaration of interests and be approved by FAO and WHO. The report of JEMNU would be provided to Codex and members for their deliberation.

22. Referring to the document CX/NFSDU 12/34/3, the Representative of WHO highlighted some of the activities which may be of relevance to the on-going work of the Committee. These included the development of the comprehensive global monitoring framework for the prevention and control of noncommunicable diseases with indicators and a set of voluntary global targets including sodium target, the adoption of the Comprehensive Implementation Plan on maternal, infant and young child nutrition by the World Health Assembly (May 2012), the launching of the WHO Global Database on the Implementation of Nutrition Action (GINA), the publication of the technical note on supplementary foods for the management of moderate acute malnutrition in infants and children 6 – 59 months of age, as well as the work of the WHO Nutrition Guidance Expert Advisory Group (NUGAG), in particular its Subgroup on Diet and Health.

23. The Representative of WHO informed the Committee that the WHO Guidelines on Sodium and Potassium have been officially cleared by the Guideline Review Committee and will be published before the end of 2012 and the guidelines on total fat and sugars will soon be posted for public consultation before being submitted to the Guideline Review Committee in early 2013. Furthermore, the background systematic reviews on total fat intake in relation to weight gain will be published in the British Medical Journal (BMJ) in December 2012 and on sugars intake in relation to weight gain also in BMJ in January 2013.

24. The Representative of WHO also updated the Committee on the on-going work of the NUGAG Subgroup on Diet and Health on saturate fatty acids (SFA) and trans- fatty acids (TFA) for the prevention of NCDs. The required systematic reviews on SFA and TFA are currently being carried out and will be reviewed at the next meeting scheduled to be held in March 2013.

25. In response to the question raised by a delegate regarding the technical note on supplementary foods for the management of moderate acute malnutrition in infants and children 6 – 59 months of age, the Representative of WHO explained that it was the work of the NUGAG Subgroup on Lifecourse and Undernutrition, the on-going work of which was also presented to the Committee since 2010. The technical note provides summaries of the available evidence and presents some principles underlying the dietary management of moderate acute malnutrition in children with a proposed nutrient composition profile for supplementary foods relevant to situations in which their use may be warranted.

26. Some delegations expressed their appreciation to FAO and WHO for the establishment of JEMNU as it would provide the scientific basis for the work of the Committee and could be particularly relevant for some issues currently under consideration, especially NRVs for vitamins and minerals and NRV-NCDs. The Committee noted that a video Healthy Food, Healthy Child presenting an activity of the FAO EU Food Facility Project in Cambodia to improve dietary diversity and family feeding practices was available on the FAO website at <http://www.fao.org/ag/humannutrition/nutritioneducation/70106/en/>

#### **DRAFT REVISION OF THE GUIDELINES ON FORMULATED SUPPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN (CAC/GL 8-1991) (Agenda Item 3)<sup>4</sup>**

27. The Committee recalled that the Draft Revision had been adopted at Step 5 and forwarded to Step 6 by the 35<sup>th</sup> Session of the Commission.

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<sup>4</sup> REP12/NFSDU Appendix IV, CL 2012/19-NFSDU, CX/NFSDU 12/34/4 (comments of Brazil, Chile, Costa Rica, Ghana, Japan, New Zealand, Philippines, United States of America, GAIN, IBFAN and IACFO), CX/NFSDU 12/34/4-Add.1 (comments of Botswana, European Union, Malaysia, Mexico, Nigeria, Thailand, ISDI), CRD 8 (comments of Indonesia); CRD 18 (comments of ISDI); CRD 20 (comments of Republic of Korea)



28. The Committee agreed to focus on the sections which had not been completed at the last session and required further discussion: the text in square brackets in section 6.5, and the Annex which had not been considered due to time constraints. Some delegations and observers expressed the view that several other sections required further discussion to address all the written comments. Other delegations pointed out that the text had been discussed extensively in previous sessions and that it was important to finalise the revision of the Guidelines at the current session. After some discussion, the Committee agreed to consider the outstanding issues first and then consider other proposals which may be put forward.

29. The Committee considered the sections mentioned below and made the following amendments and comments, in addition to editorial amendments.

### **Section 6.5 Carbohydrates**

30. The Committee recalled that its last session had not been able to come to a conclusion on the provision for nutritive sweeteners in section 6.5.1 and the following text had been retained in square brackets: “If nutritive sweeteners are used, they should be used sparingly.”

31. The Committee had an extensive discussion and considered several alternative proposals to the term “nutritive sweeteners”. One delegation proposed to use the term “sugars as defined in the Codex Alimentarius and/or other carbohydrate sweeteners such as honey”, which had been used by the Committee on Processed Fruits and Vegetables to avoid confusion as “sweeteners” may include different types of products. Other delegations proposed to refer to “sugars” as defined in the Guidelines on Nutrition Labelling. The Representative of WHO proposed to use the term “free sugars”, in order to include all nutrients which could be used to sweeten formulated foods.

32. Several delegations supported the deletion of the text in square brackets as it did not provide any useful guidance since the term “sparingly” was not precise, and there was no evidence upon which to define a numerical value. Some delegations proposed alternative texts which referred to a numerical value of 10% of the energy requirements, or a recommendation for levels which should be “as low as practicable”. Other delegations supported the current text as it provided general guidance on the need to limit the use of sweeteners.

33. After some discussion, it was recalled that the rationale for this requirement was to limit the use of nutrients which gave a sweet taste to the product and it was also clarified that the section referred to carbohydrates and not to ingredients. It was therefore agreed that the text should read “any carbohydrate added for sweetness should be used sparingly”.

### **Annex**

34. The Committee agreed to retain the Annex in the Guidelines as it provided guidance regarding the selection and amount of vitamins and minerals. The list of Estimated Average Requirements was deleted and the Reference Nutrient Intakes (RNIs) defined in the *FAO/WHO Vitamins and Mineral Requirements in Human Nutrition* were retained. It was agreed that the suggested total quantity of each of these vitamins and minerals contained in a daily ration should be at least 50% of the RNIs or Individual Nutrient Level (INL<sub>98</sub>), instead of 70%, taking into account other sources of nutrients from breast milk and local diets and the columns was deleted. The footnotes were amended accordingly and clarified as regards Iron and Zinc values.

### **Other issues**

#### Section 4. Suitable raw materials and ingredients

35. In Section 4.1.3 Oil Seed Flours and Oil Seed products, one delegation expressed the view that defatted oil seed flours should not be allowed in formulated foods and reiterated the concerns expressed at the last session in this respect.

#### Section 5. Technologies for and effects of processing

36. In section 5.2.3 it was agreed that “adequate” rather than “prolonged” boiling was necessary to gelatinize starch portions as the boiling time may differ according to the ingredients.

37. The Committee noted a proposal to prohibit the use of ingredients treated by ionizing radiation to make the text consistent with the *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CODEX STAN 74-1981) but the current text was retained. Some delegations proposed to prohibit the use of genetically modified ingredients in view of possible adverse health effects. The Delegation of Ghana indicated that this question had been discussed in the working group, that there was no consensus and as no scientific evidence was available, it was not included in the Guidelines. It was also noted that Codex texts could always be revised if new scientific evidence became available.

#### Section 7. Contaminants

38. The Committee agreed to update the text of section 7.2 Other Contaminants for consistency with the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981).

#### Section 10. Labelling

39. Following a proposal on the labelling of allergens, the Committee recalled that the *General Standard for the Labelling of Prepackaged Foods* required the declaration of allergens for all foods.

40. Some delegations and observers proposed additional labelling provisions to ensure that presentation and marketing of formulated foods did not mislead consumers or create confusion with infant formula or discourage breastfeeding and that these products should not share the same branding as infant formula. After some discussion, the Committee agreed to add a new Section 11: “The products covered by these Guidelines are not breastmilk substitutes and shall not be presented as such” for consistency with the *Standard for Processed Cereal Based Foods for Infants and Young Children*.

#### **Draft Revision of the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children**

41. The Committee agreed to advance the Draft Revision to Step 8 for adoption by the 36<sup>th</sup> Session of the Codex Alimentarius Commission (see Appendix II).

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

#### **GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR NUTRIENTS ASSOCIATED WITH RISK OF DIET-RELATED NON-COMMUNICABLE DISEASES FOR GENERAL POPULATION (NRVS-NCD) (Agenda Item 4a)<sup>5</sup>**

42. The Committee recalled that at its last session it returned the Proposed Draft General Principles at Step 2 and established an eWG to redraft the Proposed Draft for consideration at the next session.

43. The Delegation of the United States, as chair of the eWG, introduced the working document and explained that the eWG had multiple tasks, including work on the unresolved text in the General Principles for Establishing NRVS-NCD, consolidation of the General Principles for Establishing NRVs of Vitamins and Minerals and for establishing NRVS-NCD and other matters related to NRVs. The Committee thanked the Delegations of United States, Thailand and Chile and the eWG for their excellent work.

44. The Committee considered the texts in Attachment B to CX/NFSDU 12/34/5 and made the following amendments and comments in addition to editorial changes.

#### **1. PREAMBLE**

45. The Committee agreed to remove the square brackets in the first paragraph, which allowed governments the flexibility to use other level of evidence than “convincing/ generally accepted scientific evidence” when they established NRVs in their countries. Consequentially, it was agreed to delete the last sentence in the first bullet point in Section 3.1. The Delegation of Malaysia proposed to delete the text in square brackets to increase the level of evidence required.

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<sup>5</sup> CX/NFSDU 12/34/5; CX/NFSDU 12/34/5-Add.1 (Comments of Canada, Republic of Korea, Norway, Philippines, South Africa, United States of America, ICBA); CX/NFSDU 12/34/5-Add.2 (Comments of Brazil, Costa Rica, European Union, Nigeria, Russian Federation, Uruguay); CRD 8 (Comments of Indonesia); CRD 12 (Comments of IDF); CRD 13 (Comments of NHF); CRD 15 (Comments of FoodDrinkEurope); CRD 17 (Comments of Thailand); CRD 20 (Comments of Republic of Korea)

### 3. GENERAL PRINCIPLES FOR ESTABLISHING NRVS-NCD

46. One delegation proposed that the first bullet point in Section 3.1 should read “Relevant convincing/ generally accepted scientific evidence or the comparable level of evidence under the GRADE classification ...” as WHO no longer used the term “convincing” and used GRADE evidence profile instead.

47. In response to the question raised on the methods for assessing the quality of evidence, the Representative of WHO explained that the categorization and criteria for “convincing, probably, possible or insufficient” evidence were used for the first time by the 2002 Joint WHO/FAO Expert Consultation<sup>1</sup> and were also used by the 2008 Joint FAO/WHO Expert Consultation<sup>2</sup>. However, starting the implementation of the new guideline development process in WHO in 2009, WHO uses the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) approach to assess the quality of a body of evidence. GRADE categorizes the quality of evidence as “high, moderate, low or very low”. These quality ratings are made to the body of evidence assessed for the PICO question which takes into consideration of factors such as risk of bias, inconsistency, indirectness, imprecision, reporting bias. The Representatives of WHO and FAO informed the Committee that JEMNU will also use GRADE methods for its work.

48. Several delegations were of the view that they needed time to study the proposal. Some delegations said that only convincing evidence should be considered. After some discussion, the Committee agreed with the text proposed. The Delegations of Brazil and Malaysia expressed their reservation because there was no time for consideration and consultation with national stakeholders.. (or place in the next para ? )

49. The Representative of WHO described the current approach to assessment that is found in the WHO handbook. The Committee agreed to remove square brackets in the first bullet point in Section 3.1. The Delegation of Brazil was of the view that the text should be retained in square brackets for further consideration. The Delegation of Malaysia did not agree with the second part of the text in para. 3.1 and proposed its deletion.

50. With regard to the footnote to “convincing”, the Committee agreed to delete the first of two references for the source of the definition, noting that the first report refers to the second one.

#### Status of the Proposed Draft General Principles

51. The Committee agreed to advance the Proposed Draft General Principles to Step 5/8 for adoption by the 36<sup>th</sup> Session of the Commission (Appendix III). The Delegation of Malaysia expressed their objection to the decision.

### CONSOLIDATION OF THE GENERAL PRINCIPLES FOR ESTABLISHING NRVS OF VITAMINS AND MINERALS AND GENERAL PRINCIPLES FOR ESTABLISHING NRV-NCD (Agenda Item 4b)<sup>6</sup>

52. The Committee recalled that at its last session it agreed to establish an eWG whose mandate included to 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.

53. The Committee agreed to consolidate these two Guidelines, subject to adoption of the Annex by the Commission. The Delegation of Malaysia expressed their objection to the decision.

54. It was clarified that the consolidated text would not be necessary to take the Step procedure as it was considered as editorial amendments. The Committee considered Attachment C to CX/NFSDU 12/34/5 and the following amendments and comments were made in addition to editorial changes and consequential changes made in Agenda Item 4a.

#### 1. PREAMBLE

55. The Committee agreed to delete the text in the square brackets in the second paragraph.

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<sup>6</sup> CX/NFSDU 12/34/5

## 2. DEFINITIONS

56. With regard to definitions of NRVs-R and NRVs-NCD, the Committee agreed to take Option 2, which was to propose to CCFL that the new definition of NRVs for inclusion in Section 2 of the Guidelines on Nutrition Labelling be revised, with replacement in the definition of Nutrient Reference Values of “include” with “comprise” to clarify that there are only two types of NRVs. (Appendix VI)

57. The Committee agreed to use the term “the daily intake reference value” in the definition of Individual Nutrient Level 98 (Section 2.4 in the original document) as the original term might be confusing with NRV.

## 3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs

58. In Section 3.2.1.2, the Committee agreed to remove the square brackets of “NRVs-R” and remove the alternative text.

### Status of the Draft Nutrient Reference Values

59. The Committee agreed to forward the consolidated text for consideration by the 41<sup>st</sup> Session of CCFL and to the 36<sup>th</sup> Session of the Commission for adoption (Appendix IV).

### DRAFT NUTRIENT REFERENCE VALUES (NRVS) (Agenda Item 4c)<sup>7</sup>

60. The Committee recalled that at its last session it had forwarded to the Commission at Step 5/8 the proposed draft NRVs on saturated fatty acids and sodium and that the Commission had adopted it at Step 5 for further consideration by the Committee in the light of the outcome of the WHO work on sodium and saturated fatty acids.

61. The Delegation of Philippines did not support the proposed NRV-NCD for saturated fat because of its different effects on blood lipids and individual saturated fatty acids exhibit different biological properties, physiological effects and metabolic properties among other reasons. The Delegation of Malaysia did not support to establish an NRV on saturated fatty acids because there was no consensus at the last session of the Committee; the effects of different SFA should be considered as not all SFAs would raise blood cholesterol; and some studies suggested that the intake of SFA was not significantly associated with NCDs. The Delegation also expressed the view that the Committee should respect the conclusion of the Commission and wait for the outcome of WHO work. This view was supported by Delegations of Pakistan and Philippines as well as the Observers of IDF and NHF.

62. Several delegations supported to advance the NRVs to Step 8 because: they were based on convincing scientific evidence, including the report of the Joint Expert Consultation Report on Fats and Fatty acids in Human Nutrition; the declaration of sodium and saturated fatty acids are mandatory in the Guidelines on Nutrition Labelling where nutrient declaration was applied; the work was important to implement the Global Strategy on Diet, Physical Activity and Health; and developing countries needed such guidance. One delegation noted that if an NRV on a specific saturated fatty acids were to be established, the value could be more restrictive; the guideline provided flexibility for governments to develop specific NRVs for particular populations; and in addition, WHO/FAO recommendations were for total SFA intake in the diet.

63. In response to the question raised about the on-going work of the NUGAG Subgroup on Diet and Health regarding the development of the updated guidelines on SFA and TFA, the Representative of WHO stated that WHO will continue to inform the Committee of the progress and outcomes of the work. However, based on the available evidence and recommendations to date including the joint FAO/WHO Expert Consultations and WHO’s guidelines, WHO would support the proposed 20 g of SFA as NRV-NCD. Regarding the proposed 2000 mg of sodium as NRV-NCD, the Representative noted that the new WHO guideline on sodium intake for adults and children (2012) also support the value and requested this new guidelines to be also referenced.

64. It was clarified that the Committee was able to advance the NRVs to Step 8 if it agreed, regardless of availability of the outcome of the Systematic Review.

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<sup>7</sup> REP12/NFSDU Appendix III; CL 2012/19-NFSDU; CX/NFSDU 12/34/7 (Comments of Brazil, Costa Rica, Japan, New Zealand, Philippines, United States of America); CX/NFSDU 12/34/7-Add.1 (Comments of Thailand); CRD 9 (Comments of Malaysia)

### Status of the Draft Nutrient Reference Values

65. The Committee agreed to advance the Draft Nutrient Reference Values, 20 g for saturated fatty acids and 2000 mg for sodium, to Step 8 for adoption by the 36<sup>th</sup> Session of the Commission (Appendix V). The Delegations of Malaysia and Philippines expressed their objection on the NRV for saturated fatty acids.

### OTHER RECOMMENDATIONS RELATED TO AGENDA ITEM 4

66. The Delegation of Thailand, as the co-chair of the eWG, explained the work of the eWG, including potential suitable data sources for assessing convincing evidence in addition to FAO/WHO data sources and new work on NRV for protein.

#### Section 3.4.4 of the Guidelines on Nutrition Labelling

67. The Committee considered the proposal of the eWG to amend Section 3.4.4 of the Guidelines that relate to the listing of NRVs. The Committee agreed with the following amendments in addition to editorial and consequential amendments.

68. The Committee agreed to replace “achieve overall healthful dietary intake” with “make choices that contribute to an overall...” in the third paragraph for consistency and remove square brackets in the fourth paragraph. The Committee also agreed to insert footnotes to saturated fatty acid and sodium with appropriate reference.

69. The Committee agreed to refer the amendment to CCFL for consideration. (Appendix VI)

#### NRV for Protein

70. The Committee considered the proposal of the eWG to review the NRV for protein. Several delegations questioned whether it was a high priority and highlighted the NRV, 50 g, was supported by the recent evaluation by EFSA.

71. Some delegations supported the work as the 2002 Joint WHO/FAO/UNU Expert Consultation and data from recognized authoritative scientific bodies provided a scientific basis.

72. It was clarified that the work for NRV for protein had already been covered in the scope of the Proposed Draft Additional or revised Nutrient Reference Values for Labelling Purposes in the Codex Guidelines on Nutrition Labelling and that new work proposal was not necessary. The Committee therefore agreed that the NRV for protein would be considered by the eWG that would work for NRVs for vitamins and minerals (See Agenda Item 5).

#### Other matters

73. The Delegation of the United States noted that they would prepare a discussion paper on a potential NRV for potassium in relation to the risk of NCD and consider suitable data sources from FAO/WHO and recognized authoritative scientific bodies.

### PROPOSED DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES IN THE CODEX GUIDELINES ON NUTRITION LABELLING (Agenda Item 5)<sup>8</sup>

74. The Committee recalled that its last session had considered the report presented by FAO and WHO on the *Review of the existing daily vitamin and mineral intake reference values* and had agreed that an electronic working group (eWG) chaired by Australia would, on the basis of the report and in accordance with the *General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for the General Population* consider all nutrient reference values (NRVs) for vitamins and minerals listed in Appendix IV, ALINORM 10/33/26, and formulate recommendations for NRVs for vitamins and minerals for the general population, for comments and consideration at the next session.

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<sup>8</sup> CX/NFSDU 12/34/8, CX/NFSDU 12/34/8-Add.1 (comments of Canada, Philippines, South Africa, United States of America, Uruguay, IADSA), CX/NFSDU 12/34/8-Add.2 (comments of Brazil, Chile, Costa Rica, European Union, New Zealand, ICGMA, IDF), CRD 8 (comments of Indonesia), CRD 10 (comments of Chile), CRD 12 (comments of IDF), CRD 13 (comments of NHF), CRD 15 (comments of FoodDrinkEurope)

75. The Delegation of Australia indicated that the *General Principles* had been applied in the process of selecting the NRVs, while recognising that several approaches could be taken, and that the data calculations and associated issues involved in deriving a comparator from the FAO/WHO spreadsheet were presented in Attachment 4. The eWG had considered potential NRVs derived from WHO/FAO Recommended Nutrient Intakes (RNIs) and those for which no RNI had been established, and which were based on the Institute of Medicine (IOM) Dietary Reference Intakes (DRI). The potential NRVs had been grouped into several categories according to their suitability.

76. The Committee thanked the Delegation of Australia and the working group for their comprehensive work on complex issues and discussed their recommendations as presented below.

### **Sodium and Potassium**

77. As regards the recommendation not to consider NRVs for sodium and potassium, it was recalled that the Committee had so far considered only an NRV-NCD for sodium, and that the current session had agreed under Agenda Item 4 to consider a discussion paper on potassium in relation to NCD at the next session. The Committee agreed that whether NRVs could be established according to both dietary adequacy and reduction of risk of NCD would require further discussion at a later stage.

### **Suitable NRVs derived from WHO/FAO RNIs**

78. The Committee considered the recommendations of the WG to establish revised or new NRVs for the following vitamins and minerals derived from WHO/FAO RNIs and considered suitable: Vitamin K, Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenate, and Biotin; Calcium and Iodine.

79. Some delegations expressed the view that the values for several vitamins and minerals were too low and should not be classed as suitable and that at the national level they had problems of micronutrient deficiencies. Other delegations supported the values proposed as they resulted from FAO/WHO recommendations based on science and would be applicable at the national level.

80. One Observer pointed out that the values proposed for the NRVs were too low and should be increased in order to ensure optimal health and to take into account current scientific studies, and also that the levels of calcium and magnesium should be balanced. This view was supported by one delegation.

81. One Observer supported the values in Table 1 with the exception of biotin, for which scientific evidence justified a higher level, and pointed out that there were no safety issues involved.

82. Another Observer expressed the view that the value for calcium was too high for the purposes of labelling, and may result in preventing nutrition claims for milk and milk products as a source of Calcium, and also proposed that Vitamin K should be presented as K1 and K2.

83. The Delegation of Australia clarified how the values had been derived, recalled that they were intended for a healthy population and that the Principles allowed governments to establish NRVs at the national level as required. As regards Vitamins K1 and K2, the Delegation pointed out that in most countries for which values were reported, the distinction between isomers was not made.

84. The Committee generally agreed that the above NRVs were suitable for inclusion in the Guidelines on Nutrition Labelling and noted some questions concerning the opportunity of adopting only a partial list of NRVs while further work was still required on other values. It was however agreed that this would allow progress on the update of the NRVs.

85. The Committee agreed to forward the values mentioned above to Step 5/8 for adoption by the 36<sup>th</sup> Session of the Commission (see Appendix VII, see also para. 103).

### **Other NRVs derived from WHO/FAO RNIs**

86. The Committee agreed with the conclusion of the working group that the following NRVs for vitamins and minerals derived from WHO/FAO RNIs were potentially unsuitable for use in Codex nutrition labelling: Vitamin A, Vitamin D, Vitamin E, Vitamin C, Magnesium, Selenium, and discussed how to proceed.

87. The Committee agreed that scientific advice could be sought from FAO/WHO, through JEMNU, on the suitability of these NRVs and that, for this purpose, specific questions should be formulated, possibly by an electronic WG, for consideration by the next session. The Representatives of FAO and WHO pointed out that requests should be prioritised, that the questions should be clearly formulated and that the time frame would depend on the nature of the requests and on the availability of resources.

88. The Committee noted the information on the process followed in the United States to develop NRVs and was informed that in the EU, EFSA was conducting a full review of vitamins and minerals which would be completed in 2015.

#### Iron and Zinc

89. The Committee noted that although the NRVs for Iron and Zinc are derived from WHO/FAO RNIs, they were considered separately because of their multiple values based on varying percentages of absorption from national diets and there was no agreement in the WG on the number of NRVs which should be established.

90. Some Observers supported a pragmatic approach with a single percentage at the international level, as in view of current data, it was not possible to establish different values. It was also noted that, at the national level, countries had the possibility to determine the NRV corresponding to the % absorption of Iron and Zinc in national diets. Another Observer expressed the view that different values should be established for males and females.

91. The Committee agreed that the issues related to NRVs for Iron and Zinc could not be addressed at this stage and would require further consideration.

#### **Other NRVs**

92. The Committee agreed that other potential NRVs for vitamins and minerals which were not derived from WHO/FAO RNIs and were based on the Institute of Medicine (IOM) Dietary Reference Intakes (DRI) would be set aside for further consideration at a later date: Phosphorus, Chloride, Copper, Fluoride, Manganese, Chromium, Molybdenum.

#### **Recognized, authoritative, scientific body**

93. The Committee generally agreed with the approach outlined in the process for further work and considered the working definition of “Recognized, authoritative, scientific body” proposed by the working group for the purpose of establishing NRVs. It was agreed to refer to “national and/or regional authorities” and clarification of appropriate term was requested to Codex Secretariat. In addition, some further amendments were made for clarification purposes. Following a proposal to refer to organisations supported by an UN agency, the Representative of WHO clarified that only FAO and WHO carried out normative work and could provide scientific advice. The text was modified accordingly and the Committee agreed on the following working definition:

##### Recognized, authoritative, scientific body (RASB)

For the purposes of establishing Codex Nutrient Reference Values, a recognized authoritative scientific body is an organization supported by a government(s) or competent national and/or regional authorities or FAO and/or WHO that provides independent and transparent\* authoritative scientific advice on daily intake reference values upon request, and for which such advice is recognised through its use in the development of policies in one or more countries.

\* In providing transparent scientific advice, the Committee would have access to what was considered by a RASB in establishing a daily intake reference value in order to understand the derivation of the value.

94. The Committee noted that this definition was for use in the process of selection of NRVs and was not intended for inclusion in the Guidelines on Nutrition Labelling.

#### **Conversion Factors**

95. The Committee discussed the conversion factors to be included after the list of NRVs in section 3.4.4. of the Guidelines.

96. The Committee agreed with the proposed conversion factor for niacin and discussed the conversion factor for Folate. Several delegations pointed out that it was premature to establish dietary equivalents for Folate and folic acid as they differed according to the mode of consumption: supplement taken separately, fortified food, or natural folate in food. It was noted that the values proposed were from the IOM report and referred to folic acid added to food or as a supplement consumed with food, and this is clarified in the Table.

97. After some discussion, it was also agreed to insert a note to the Table to reflect that conversion factors were intended to provide supporting information for national authorities but not to harmonise the conversions factors *per se*. One delegation noted the concern but did not agree that this text should be incorporated into the Guidelines on Nutrition Labelling.

98. The Committee agreed that the conversion factors for Vitamins A and E should be considered further at the next session.

### Footnotes

99. In section 3.4.4 of the Guidelines on Nutrition Labelling, the Committee agreed to delete:

- Footnote 7 regarding the review of the lists of nutrients, as it is always possible to update Codex texts in view of new developments.
- Footnote 9 on NRVs for Vitamin D, Niacin and iodine as the preamble of the General Principles mentions that governments can consider the suitability of the General Principles and additional factors in establishing their own NRVs (consistency: starting with capital or small letters)

100. It was agreed that the proposal to delete the second sentence of Footnote 9 on Iron and Zinc in CX/NFSDU 12/34/8 would require further consideration.

### Other matters

101. The Committee did not specifically discuss the other recommendations in the working document and agreed that they should be considered further by the electronic working group (see below), especially the replacement of 'bioavailability' with 'absorption' for Iron and Zinc and the inclusion of dietary descriptions corresponding to the established rates of absorption for Iron and Zinc.

### Further work

102. The Committee agreed to proceed with work on NRVs following and for this purpose, agreed to establish an electronic working group chaired by Australia and working in English, with the Terms of Reference:

- 1 Recommend draft additional or revised NRVs-R for Vitamins A, D, E, C, Magnesium, Selenium, Iron and Zinc and relevant conversion factors, developed according to the following process:
  - a) select one or more recognized authoritative scientific bodies (RASB) according to the Committee's working definition of RASB;
  - b) derive candidate NRVs-R from daily intake reference values that are reported by each selected RASB and WHO/FAO for the above vitamins and minerals in accordance with the relevant General Principles;
  - c) i) evaluate the characteristics of candidate NRVs-R for the purpose of international applicability and the relevant conversion factors and determine draft recommendations;and
  - ii) determine whether some or all of the evaluation in c-i) should be referred to FAO/WHO for scientific advice and if so, draft appropriate questions for FAO/WHO.
- 2 Review the NRV for protein in accordance with the relevant General Principles and as appropriate, recommend a draft revised NRV-R for protein.
- 3 Review the working definition of RASB, and as appropriate, recommend a final definition of RASB.



### **Status of the Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the Guidelines on Nutrition Labelling**

103. The Committee agreed to advance to Step 5/8 the Proposed Draft NRVs for Vitamin K, Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenate, Biotin, Calcium and Iodine with the conversion factors for Folate and Niacin and related footnotes (see Appendix VII). The other values were returned for further consideration in the working group as described above, comments at Step 3 and consideration at the next session.

### **PROPOSED DRAFT REVISION OF THE CODEX GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 9-1987) (Agenda Item 6)<sup>9</sup>**

104. The Committee recalled that its last session had considered the report of the physical working group that had met prior to the session and could not consider the document in detail due to time constraints. It had agreed to return the proposed draft revision for redrafting by an eWG chaired by Canada and co-chaired by New Zealand.

105. The Delegation of Canada indicated that the WG had agreed to continue with a structure including Scope; Definitions; Principles; and Principles for Specific Types of Nutrient Addition, with final decisions to be taken on the naming of the sections. The Delegation noted that there was disagreement mainly on the need for sub-sections on the specific types of addition, and proposed to first discuss the merits of having principles for restoration, nutritional equivalence of substitute foods and special purpose foods, as well as Section 4.1 as to whether this deals only with mandatory addition or more generally the addition of essential nutrients to address a demonstrated public health need, prior to proceeding through the document clause by clause.

106. The Committee thanked Canada, New Zealand and the working group for their excellent and comprehensive work on the revision

#### **General**

107. The Committee discussed whether it was necessary to include separate subsections for the specific types of addition of essential nutrients, such as restoration or nutritional equivalence, as it was specified that the addition of nutrients should be rational and safe. Some delegations supported retaining these sections that are in the original document in order to provide additional guidance to governments and the meaning of rational and safe addition, while several other delegations considered that they should be deleted as “rational and safe” already covered such requirements.

108. The Committee discussed whether foods for special dietary uses and/or special purpose foods should be included in the Principles as some delegations considered that they should be excluded.

109. One delegation suggested deleting the definition of “special purpose foods” in section 2.9 as the principle established in section 4.4 (Nutrient addition to Special Purpose Foods) is already covered by the fundamental principles. Other delegations proposed to refer to the current definition of Foods for Special Dietary Uses. Some modification to the scope, there seems to be agreement to delete section 4.4 but the other types of addition still need to be discussed.

110. Several delegations pointed out that there should be a clear separation between mandatory and voluntary addition of nutrients in certain sections, and that if section 4.1.1 applied to both types of addition there could be some confusion as to how to demonstrate a public health need to the authorities. Other delegations pointed out that public health need had to be demonstrated in both mandatory and voluntary addition. Some delegations pointed out that both voluntary and mandatory addition can address public health needs.

111. The Committee considered some of the sections highlighted below. As there was no conclusion on any of the proposals, which were put forward for further consideration in the redrafting of the text at a later stage, all proposals put forward were included in square brackets.

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<sup>9</sup> CX/NFSDU 12/34/9, CX/NFSDU 12/34/9-Add.1 (comments of Brazil, Philippines, IADSA, ICBA), CX/NFSDU 12/34/9-Add.2 (Canada, Chile, Costa Rica, European Union, New Zealand, Norway, Thailand, United States of America, ICGMA, IDF), CRD 8 (comments of Indonesia), CRD 9 (comments of Malaysia), CRD 11 (comments of Chile); CRD 16 (comments of Mexico)

## Introduction

112. Several delegations supported the use of “Principles” instead of the current title, “General Principles”. It was noted that the terminology would be reconsidered following further discussion of the entire document.

113. The Committee noted a proposal by the Delegation of Europea Union to reinsert the provisions on the purpose of the addition of essential nutrients to foods in the Introduction, rather than in section 3 on Principles. The Delegation of United States noted that at the 32<sup>nd</sup> session of the Committee it had agreed to move the text to section 3.

114. The Committee considered a proposal to add the following text at the end of the paragraph “(principles...) that prevent the indiscriminate addition of nutrients to foods”. Some delegations supported this addition to strengthen the provisions of the introduction as to “rational and safe” addition, while other delegations considered that it was not necessary, and no conclusion was reached at this stage. The Committee considered replacing “national “ with “official” authorities as it would include both regional and national and was used in other Codex texts.

## Section 1. Scope

115. The Committee had an extensive discussion on whether to exclude infant formula from the Scope. Several delegations did not support an exception only for infant formula, and pointed out that specific levels of vitamins and minerals were defined in other standards besides the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants*. Other delegations considered that infant formula should be excluded as it is the only food consumed by infants of a certain age group. The Committee could not come to a conclusion and agreed that it required further consideration.

## Section 2. Definitions

116. In section 2.6 on mandatory addition, some amendments were made for clarification purposes but there was no consensus on the proposal to insert “as part of a food standard”.

117. In section 2.7 on voluntary addition, Some delegations proposed to make it clear that even voluntary fortification should be clearly justified and under the control of the official authorities and several terms were proposed: official authorities permitting food manufacturer to add nutrients; manufacturers choosing to add essential nutrients” in conjunction” or “in conformity” with national legislation; or referring to the purpose of the Guidelines or to Codex Principles. The Committee could not come to a conclusion and retained all alternatives for further consideration.

## Section 3. Principles

118. The Committee considered proposals for referring to “general” or “overarching” principles in the title of the section in order to differentiate the principles in section 3 and 4, and to avoid confusion with the title of the entire document, if it was decided to refer only to “Principles”.

119. In section 3.1.1 and 3.1.3, it was proposed to refer to prevention, in addition to correction of a demonstrated deficiency. Several delegations and one Observer objected to this term as claims for the prevention and cure of diseases were not allowed in the framework of Codex. Other delegations considered that the section should reflect a logical sequence between correcting deficiencies, reducing risk: maintenance of health and nutritional status and ensuring nutritional quality of foods, and some reordering was also suggested. One delegation drew the attention to the possibility of misleading health claims on prevention of diseases. Another delegation noted that this was not related to prevention of diseases but preventing nutrient deficiency. Some observers supported the reference to prevention of deficiencies.

120. In section 3.1.3, there was some agreement to transfer the last sentence to section 4 as it was more related to the types of nutrient addition.

121. The first sentence of section 3.1.4 was deleted as it was not necessary and some editorial amendments were made for clarification purposes.

122. In section 3.1.4, the Committee noted a proposal to refer to “idealizing”, and the comments that this was covered the requirements not to deceive the consumer, and it was noted that this could be discussed in further consideration of the document.

## Conclusion

123. The Committee recognized that it was not possible to proceed further with the text as many critical issues remained to be addressed and insufficient time remaining, and agreed to establish an electronic working group chaired by Canada and co-chaired by New Zealand and working in English, to consider the comments made in writing and at the session, to prepare a revised draft for comments and consideration at the next session.

124. The Committee also agreed to convene a physical working group prior to the next session to consider the revised draft and the comments at Step 3.

## Status of the Draft Revision of the Proposed Draft Revision of the Codex General Principles for the Addition of Essential Nutrients to Foods

125. The Committee agreed to return the Proposed Draft Revision for redrafting by an electronic working group as mentioned above, comments at Step 3 and consideration at the next session.

## PROPOSED DRAFT AMENDMENT OF THE STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN TO INCLUDE A NEW PART B FOR UNDERWEIGHT CHILDREN (Agenda Item 7)<sup>10</sup>

126. The Committee recalled that the 34<sup>th</sup> Session of the Commission had approved 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), that at the last session of the Committee it had not been able to consider the proposed draft due to time constraint and that it had agreed to return the proposed draft amendment for redrafting in the light of the written comments by an eWG chaired by India, circulation for comments at Step 3, and consideration at the next session.

127. The Committee noted that an invitation letter to the eWG had not been distributed and that it had not requested comments at Step 3 due to late distribution of the document. The Delegation of India said that they had asked for comments to the members of the eWG established in 2011; however some contact persons had changed in some members in eWG and could not participate. The Delegation had also taken into account the comments informally received when redrafting.

128. The Committee considered the scope of the proposed draft. The Delegation of India explained that “young children” at the second line was unintentionally deleted and that the Standard would cover food intended for underweight young children.

129. Several delegations said that they needed time to study the document due to late arrival of the document. Several delegations pointed out that foods for children at risk of becoming underweight should be covered by Part A of the Standard. The Delegation of India clarified that Part A does not address the problem sufficiently.

130. The Representative of WHO stated the need for further clarification of the scope of the proposed standard for which these foods are intended. Underweight, whether it is to cover – 1 SD and above or -2 SD and above, is a combination of stunting and wasting and stunted and wasted children do not have the same dietary needs. In addition, the scope stated in CX/NFSDU 12/34/10 includes those at risk of becoming underweight which would include all children in a certain setting and that could be covered by the existing Standard. The Representative suggested that perhaps what the Delegation of India would like to address would be moderate acute malnutrition in children which is measured by weight-for-height between -3 and -2 Z-scores of the median of the WHO child growth standards.

131. One delegation pointed out that obesity of children is also a problem and expressed their concern that the term “risk of becoming underweight” might be used as a marketing tool for whole population. The Delegation of India said that the Standard was to increase cereal content to provide energy and protein to address underweight. The Delegation of India explained that stunting is a different situation which may not be corrected by such complementary foods but may require special medical or therapeutic foods. The Committee did not reach a consensus.

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<sup>10</sup> CX/NFSDU 12/34/10; CRD 7 (Comments of Thailand)

132. One delegation proposed to change the scope to “high energy, high protein food” to focus on the nature of food rather than target population. The Delegation of India did not agree with the proposal because the scope in Part A focuses on target population.

### **Status of the Proposed Draft Amendment of the Standard for Processed Cereal-Based Foods for Infants and Young Children to Include a New Part B for Underweight Children**

133. The Committee agreed to establish an eWG, chaired by India and co-chaired by Botswana and working in English, to revise the Proposed Draft, especially the Scope, taking into account the comments made during the session and WHO technical note “Food supplementation for children with moderate acute malnutrition”.

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

135. The Committee noted that the chair of the eWG should prepare an invitation letter and send it to Codex Secretariat for distribution to all Members and observers as soon as possible.

### **PROPOSAL TO REVIEW THE CODEX STANDARD FOR FOLLOW-UP FORMULA (Agenda Item 8)<sup>11</sup>**

136. The Committee recalled that at its 32<sup>nd</sup> Session it had agreed that New Zealand would prepare a discussion paper to consider the full or partial review of the *Standard for Follow-up Formula* (CODEX STAN 156-1987) and that at the last Session it had agreed to consider the matter at the next session as it had not had enough time to consider the discussion paper.

137. The Delegation of New Zealand explained that the 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. The Committee thanked New Zealand for the discussion paper.

138. The Committee agreed with full review of the Standard. Several delegations pointed out that the food covered by the Standard, which was intended for infants between 6 and 12 months old, would be covered by the Standard for Infant Formula and Formulas for Special Medical purposes Intended for Infants, which is for foods intended for infants up to 12 months old and that the scope is therefore overlapping with that standard.

139. In this regard, one delegation proposed to change the scope of the Standard for foods for young children between 12 months and 36 months old. Other delegations, supported by some observers, were of the view that a standard on foods for children older than 12 months was not necessary because family food and breast milk are sufficient for them. In addition, they did not support the extension of its scope to cover “growing-up milk”. Several delegations expressed their view that if there were no standard for these foods which were traded internationally, they would not be regulated appropriately. Some delegation said that the role of such products in diet should be scientifically considered. After some discussion, the Committee agreed that the review should include whether such a standard was still necessary in light of global infant and child feeding recommendation. Some delegations and observers pointed out that:

- The WHA resolutions (eg WHA 39.28) on infant and young child feeding state that specially formulated baby milks such as follow up and growing up milks are unnecessary and therefore there was no need for Codex international standards for such products.
- The challenge of having international standards for such products is that this might prevent governments from preventing such unnecessary baby food imports, on optimal infant and young child feeding or child health grounds.
- These products could be regulated at national levels if necessary.

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<sup>11</sup> CX/NFSDU 12/34/11; CRD 2 (Comments of Nigeria); CRD 5 (Comments of Costa Rica); CRD 6; CRD 8 (Comments of Indonesia); CRD 9 (Comments of Malaysia); CRD 19 (Comments of New Zealand); CRD 20 (Comments of Republic of Korea)

140. The representative of WHO stated that the World Health Assembly has clearly stated that specially formulated milks such as so called follow-up milks is not necessary (WHA 39.28). Therefore, if the Committee would proceed with a review of the existing *Standard for Follow-up Formula*, WHO would support a full review, provided that the review would also consider the question of whether follow-up formula is an appropriate part of the diets of older infants and young children as noted in the section 3.4 of the document CX/NFSDU 12/34/11, and requested this question to be included as part of the purpose and scope of the new work, and this was accepted.

141. The Committee considered the proposed project document and made following amendments and comments, in addition to editorial changes.

### **3. Main Aspects to be Covered**

142. The Committee clarified that products referred to in some countries as follow-on formula was covered under the review.

### **4. Assessment against the Criteria for the Establishment of Work Priorities**

143. The Committee noted that “growing-up milk” is a commercial term and agreed to include “so-called” before the term in the proposed project document. The Committee agreed that, in the context of the project document, reference to “so-called growing-up milk products” should be interpreted as covering all milk-based drinks and similar products intended for young children.

### **7. Identification of Any Requirement for and Availability of Expert Scientific Advice**

### **8. Identification of Any Need for technical Input to the Standard from External Bodies so that This Can Be Planned for**

144. The Committee noted that input from technical experts with respect to producing the products was necessary. One delegation was of the view that the Standard should be reviewed by experts on nutrition for infant and young children and food science and technology.

145. It was clarified that in general, Section 7 includes the scientific advice from FAO and WHO and Section 8 from other bodies and the Committee amended the project document accordingly, taking into account the Risk Analysis Principles. One observer proposed to include data from social science about use, marketing, prevalence and parental perception of those products.

146. Time line for the work was adjusted as in appendix.

### **Conclusion**

147. The Committee agreed to propose new work to review the *Standard for Follow-up Formula* (Appendix VIII). Subject to the approval of the Commission, the Committee further agreed to establish an eWG, chaired by New Zealand and co-chaired by France and Indonesia and working in English and French, with the following Terms of Reference:

- i. Develop a draft discussion document for the review of the *Standard for Follow-up Formula* (CODEX STAN 156-1987) with an initial focus on the essential composition of Follow-up Formula for older infants and young children aged 6-36 months
- ii. Consider if any differences are required in the essential composition for older infants (6-12 months) and young children (12-36 months)
- iii. Identify areas where additional technical guidance and expert advice will be required by the Committee
- iv. Collect data and information on Follow-up Formula and its role in the diet that will assist the Committee with the review of the Follow-up Formula standard
- v. Develop a draft revised standard for consideration by the CCNFSDU at Step 2

148. The Committee noted that the eWG would start working early next year due to its huge workload.

**PROPOSED DRAFT REVISION OF THE LIST OF FOOD ADDITIVES (Agenda Item 9)<sup>12</sup>**

149. The Committee recalled that at its last session it had 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. One delegation requested further information on the categorization of food additives as outlined in the paper from CCFA.

150. The Committee agreed to consider the matter at the next session because there was no time to look into the document due to late delivery. The Committee noted that Switzerland would prepare the document which would include information on whether each additive was necessary or not for the products.

**PROPOSAL TO REVIEW THE CODEX DEFINITION OF TRANS FATTY ACIDS (Agenda Item 10)<sup>13</sup>**

151. The Committee recalled that at its last session it had agreed that Australia would prepare a discussion paper on the definition of trans fatty acids to reconsider the exemption of conjugated fatty acids in view of new studies on the health effects for consideration at the next session.

152. In response to request from Australia, the representative of WHO stated that the on-going work of the NUGAG Subgroup on Diet and Health on SFA and TFA, conjugated linolenic acid is also included in the review in terms of the health effects on prioritized health outcomes such as coronary heart disease, blood lipids, total cholesterol/LDL and HDL cholesterol, all cause mortality, stroke, diabetes, cardiovascular disease as well as adverse effects, but not on health benefits *per se*.

153. The Committee agreed to defer the consideration of this agenda item until after the outcome of NUGAG is available.

**OTHER BUSINESS AND FUTURE WORK (Agenda Item 11)****Proposal to Develop a Discussion Paper on the Biofortification of Staple Food Crops with Essential Vitamins and Minerals by Conventional Breeding<sup>14</sup>**

154. The Observer of IFPRI made a presentation about biofortification of crops by conventional breeding and proposed that it would prepare a discussion paper for consideration at the next session.

155. Several delegations supported the development of a discussion paper. Several delegations questioned what the purpose of the discussion paper was and recalled that biofortification had been excluded from the revision of the General Principles for the Addition of Essential Nutrients to Foods. One Delegation asked if IFPRI considered whether the existing *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987) might be used for biofortification.

156. The Delegation of Canada proposed to collaborate with IFPRI to clarify the purpose of the discussion paper on the biofortification of the staple food crops with essential vitamins and mineral by conventional breeding and assist the development and how to direct, if appropriate. The Committee agreed with the proposal of Canada.

**DATE AND PLACE OF THE NEXT SESSION (Agenda Item 12)**

157. The Committee was informed that its 35<sup>th</sup> Session was scheduled to be held in Germany, from 4 to 8 November 2013, the final arrangements being subject to confirmation by the Host Country and the Codex Secretariat.

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<sup>12</sup> CX/NFSDU 12/34/12

<sup>13</sup> CX/NFSDU 12/34/13; CRD 3 (Comments of Costa Rica, Nigeria, Philippines); CRD 14 (Comments of IADSA); CRD 15 (Comments of FoodDrinkEurope)

<sup>14</sup> CRD 1

## SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY:	DOCUMENT REFERENCE (REP13/NFSDU)
Draft Revision of the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 8-1991)	8	Government 36 <sup>th</sup> CAC	para. 41 Appendix II
Draft Nutrient Reference Values (NRVs)	8	Government 36 <sup>th</sup> CAC	para. 65 Appendix V
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)	5/8	Government 36 <sup>th</sup> CAC	para. 51 Appendix III
Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the Codex Guidelines on Nutrition Labelling (Vitamin K, Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenate, Biotin, Calcium and Iodine and related footnotes)	5/8	Government 36 <sup>th</sup> CAC	para. 103 Appendix VII
Consolidation of the General Principles for Establishing NRVs of Vitamins and Minerals and General Principles for Establishing NRV-NCD	adoption	Government 36 <sup>th</sup> CAC	para. 59 Appendix IV
Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the Codex Guidelines on Nutrition Labelling (Other values than described above, including protein)	2/3	eWG chaired by Australia Government 35 <sup>th</sup> CCNFSDU	para. 103
Proposed Draft Revision of the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987)	2/3	eWG chaired by Canada and co- chaired by New Zealand Government 35 <sup>th</sup> CCNFSDU	para. 125
Proposed Draft Amendment of the Standard for Processed Cereal-Based Foods for Infants and Young Children to Include a New Part B for Underweight Children	2/3	eWG chaired by India and co- chaired by Botswana Government 35 <sup>th</sup> CCNFSDU	paras 133 - 135
Proposal to Review the Codex Standard for Follow-up Formula (CODEX STAN 156-1987)	1/2/3	eWG chaired by New Zealand co-chaired by France and Indonesia Government 35 <sup>th</sup> CCNFSDU	paras 147 – 148 Appendix VIII
Discussion Paper on a Potential NRV for Potassium in relation to the risk of NCD	discussion paper	United States	para. 73
Proposed Draft Revision of the List of Food Additives	discussion paper	Switzerland	para. 150
Discussion Paper on Biofortification	discussion paper	Canada, IFPRI	para. 156

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## APPENDIX II

**GUIDELINES ON FORMULATED COMPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN****(Step 8)****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 foods<sup>1</sup>, and canned baby foods<sup>2</sup> 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 diet<sup>3</sup>.

**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

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

<sup>2</sup> Codex Standard for Canned Baby Foods (CODEX STAN 73-1981)

<sup>3</sup> 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.

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 beans, 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 phytate, 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<sup>4,5,6,7</sup> which assure sufficient reduction of anti-nutritional factors and undesirable toxic substances such as trypsin and chymotrypsin inhibitors and gossypol. Such oil seeds may include

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.

<sup>4</sup> 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

<sup>5</sup> Codex Standard for Vegetable Protein Products (CODEX STAN 174-1989)

<sup>6</sup> Codex Standard for Soy Protein Products (CODEX STAN 175-1989)

<sup>7</sup> Codex Standard for Wheat Protein (CODEX STAN 163-1987)

### 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.

### 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 appropriate 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 (CODEX 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:** where necessary and appropriate, degermination of wheat, corn, soy and other crops should be considered in order to reduce the phytate 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 adequate 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 microorganisms 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 dextrans 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 Formulated Complementary Food, 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)<sup>8910</sup> 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 protein<sup>11</sup> should not be less than 6 % of the total energy from the product and typically should not exceed 15%<sup>12</sup>

<sup>8</sup> PDCAAS (%) =  $\frac{\text{mg of limiting amino acid in 1 gram of test protein} \times \text{true digestibility of test protein}}{\text{mg of limiting amino acid in 1 gram of reference protein}} \times 100$

<sup>9</sup> The limiting amino acid is the essential amino acid present in the lowest proportion as compared with the quantity of this amino acid reference pattern

<sup>10</sup> Sarwar, G., J. Nutr. 1997, 127:758-764.

<sup>11</sup> Conversion factor based on Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985)

<sup>12</sup> Michaelsen KF et al. 2009. Food and Nutr Bull 30:343-404

## 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 fat<sup>13</sup> 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 and the fat or oil when 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 FAO/WHO recommendations<sup>14</sup> 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. Any carbohydrate added for sweetness should be used sparingly.

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 fibres<sup>15</sup> 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 breastmilk and/or breastmilk 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.

<sup>13</sup> Conversion factor based on Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985)

<sup>14</sup> FAO/WHO Expert Consultation on Fats and Fatty Acids in Human Nutrition. Geneva 2008.

<sup>15</sup> Definition of Dietary Fibre given in the Codex Guidelines on Nutrition Labelling (CAC/GL 2- 1985).

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.

### **7.2. Other Contaminants**

The product should not contain contaminants or other undesirable substances (e.g. biologically active substances) in amounts which may represent a hazard to the health of older infants and young children. The product covered by the provisions of these Guidelines shall comply with those maximum residue limits and maximum levels established by the Codex Alimentarius Commission.

## **8. HYGIENE**

8.1 It is recommended that the products covered by the provisions of these Guidelines 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 texts<sup>16</sup>.

## **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**

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.

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<sup>16</sup> Examples of relevant Codex texts include 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)

### 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:

- (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 Instructions 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 for use.

10.2.4.7 The label should also include a statement that Formulated Complementary Foods are to be consumed to complement family foods and breastmilk/breastmilk substitutes.

## 11. Additional Requirements:

The products covered by these Guidelines are not breastmilk substitutes and shall not be presented as such.



## ANNEX

TABLE

The reference INL<sub>98</sub> 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 50% of INL<sub>98</sub>.

VITAMINS AND MINERALS	REFERENCE NUTRIENT INTAKE (RNI) or Individual Nutrient Levels <sub>98</sub> (INL <sub>98</sub> ) <sup>17</sup>
Vitamin A µg retinol equivalent	400
Vitamin D <sup>18</sup> µg	5
Vitamin E mg (α-Tocopherol)	5
Vitamin C mg	30
Thiamine mg	0.5
Riboflavin mg	0.5
Niacin mg NE	6
Vitamin B <sub>6</sub> mg	0.5
Folate µg DFE	150
Vitamin B <sub>12</sub> µg	0.9
Biotin µg	8
Pantothenic acid mg	2
Vitamin K µg	15
Calcium mg	500
Iron mg <sup>19</sup>	11.6, 5.8, 3.9
Zinc mg <sup>20</sup>	8.3, 4.1, 2.4
Iodine µg	90
Copper mg <sup>21</sup>	0.34
Selenium µg	17
Magnesium mg	60
Manganese mg <sup>21</sup>	1.2
Phosphorus mg <sup>21</sup>	460

<sup>17</sup> RNI or INL<sub>98</sub> from FAO/WHO Vitamins and Mineral requirements in Human Nutrition.2nd Edition. FAO/WHO 2004 (for all nutrients except copper, manganese and phosphorus)

<sup>18</sup> Vitamin D should be added if there is inadequate exposure to sunlight

<sup>19</sup> Iron values are given for 5%, 10 % and 15% dietary iron bioavailability

<sup>20</sup> Zinc values are given for low, medium and high dietary zinc bioavailability

<sup>21</sup> Values are Dietary Reference Intakes. Institute of Medicine, 1997/2001 (Source for Copper, Manganese and Phosphorus).

## APPENDIX III

**PROPOSED DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR NUTRIENTS ASSOCIATED WITH RISK OF DIET-RELATED NONCOMMUNICABLE DISEASES FOR THE GENERAL POPULATION**

(at Step 5/8)

**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 including the level of evidence required, 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)<sup>1</sup>** 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:

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<sup>1</sup> Different countries may use other terms for this concept, for example, Tolerable Upper Nutrient Intake Level (UL) or upper end of safe intake range.

- Relevant convincing<sup>2</sup>/generally accepted<sup>3</sup> scientific evidence or the comparable level of evidence under the GRADE classification<sup>4</sup> for the relationship between a nutrient and noncommunicable disease risk, including validated biomarkers for the disease risk, for at least one major segment of the population (e.g., adults).
- 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.

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 Reference 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).

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<sup>2</sup> At the time these guiding principles were drafted, the definition and criteria for “convincing evidence” from the following FAO/WHO report were used: *Diet, Nutrition and the Prevention of Chronic Diseases*. WHO Technical Report Series 916. WHO, 2003.

<sup>3</sup> For these General Principles the terms convincing/generally accepted evidence are considered synonymous.

<sup>4</sup> WHO’s Guidelines Review Committee. WHO Handbook for guideline development. Geneva, World Health Organization (WHO), 2012 ([http://apps.who.int/iris/bitstream/10665/75146/1/9789241548441\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/75146/1/9789241548441_eng.pdf)).

## APPENDIX IV

**PROPOSED DRAFT ANNEX TO THE CODEX GUIDELINES ON NUTRITION LABELLING – CONSOLIDATED VERSION:****GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR THE GENERAL POPULATION**

(for adoption)

**1. PREAMBLE**

These Principles apply to the establishment of Codex Nutrient Reference Values (NRVs) 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, or alternatively, consider the suitability of the general principles below including the level of evidence required, and additional factors specific to a country or region in establishing their own reference values for labelling purposes. 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. In addition, governments may establish reference values for food labelling that take into account country or region specific factors that affect nutrient absorption, utilization, or requirements. Governments may also consider whether to establish separate food label reference values for specific segments of the general population.

**2. DEFINITIONS**

**2.1 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 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 general population or to a segment of the population (e.g., recommendations for a specified age range).

**2.2 Individual Nutrient Level 98 (INL<sub>98</sub>)**<sup>1</sup> is the daily intake reference value that is estimated to meet the nutrient requirement of 98 percent of the apparently healthy individuals in a specific life stage and sex group.

**2.3 Upper Level of Intake (UL)**<sup>2</sup> 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****3.1 Selection of Suitable Data Sources to Establish NRVs**

**3.1.1** 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.

**3.1.2** 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.

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<sup>1</sup> Different countries may use other terms for this concept, for example, Recommended Dietary Allowance (RDA), Recommended Daily Allowance (RDA), Reference Nutrient Intake (RNI), or Population Reference Intake (PRI).

<sup>2</sup> Different countries may use other terms for this concept, for example, Tolerable Upper Nutrient Intake Level (UL) or upper end of safe intake range.

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

## **3.2 Selection of Nutrients and Appropriate Basis for NRVs**

### **3.2.1 Selection of Nutrients and Appropriate Basis for NRVs-R**

**3.2.1.1** The NRVs-R should be based on Individual Nutrient Level 98 (INL<sub>98</sub>). In cases where there is an absence of an established INL<sub>98</sub> for a nutrient for a specific sub-group(s), it may be appropriate to consider the use of other reference values or ranges that have been established by recognized authoritative scientific bodies. The derivation of these values should be reviewed on a case-by-case basis.

**3.2.1.2** The general population NRVs-R should be determined by calculating the mean values for a chosen reference population group older than 36 months. NRVs-R derived by the CCNFSDU are based on the widest applicable age range for each of adult males and females.

**3.2.1.3** For the purpose of establishing these NRVs-R, the values for pregnant and lactating women should be excluded.

### **3.2.2 Selection of Nutrients and Appropriate Basis for NRVs-NCD**

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

- Relevant convincing<sup>3</sup>/ generally accepted<sup>4</sup> scientific evidence or the comparable level of evidence under the GRADE classification<sup>5</sup> for the relationship between a nutrient and noncommunicable disease risk relationship, including validated biomarkers for the disease risk, for at least one major segment of the population (e.g., adults).
- Public health importance of the nutrient-noncommunicable disease risk relationship(s) among Codex member countries.

**3.2.2.2** 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.

**3.2.2.3** 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.

**3.2.2.4** 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.

**3.2.2.5** 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.

**3.2.2.6** 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.

## **3.3 Consideration of Daily Intake Reference Values for Upper Levels**

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

<sup>3</sup> At the time these guiding principles were drafted, the definition and criteria for “convincing evidence” from the following FAO/WHO report were used Diet, Nutrition and the Prevention of Chronic Diseases. WHO Technical Report Series 96. WHO, 2003.

<sup>4</sup> For these General Principles the terms convincing/generally accepted evidence are considered synonymous.

<sup>5</sup> WHO’s Guidelines Review Committee. WHO Handbook for guideline development. Geneva, World Health Organization (WHO), 2012 ([http://apps.who.int/iris/bitstream/10665/75146/1/9789241548441\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/75146/1/9789241548441_eng.pdf)).

## APPENDIX V

**PROPOSED DRAFT NUTRIENT REFERENCE VALUES FOR NUTRIENTS ASSOCIATED  
WITH RISK OF DIET-RELATED NONCOMMUNICABLE DISEASES FOR GENERAL  
POPULATION (NRVS-NCD)****(Step 8)***For inclusion in the Guidelines on Nutrition Labelling*

<b>Nutrient</b>	<b>NRV-NCD</b>
saturated fatty acids	20 g
sodium	2000 mg

## APPENDIX VI

**PROPOSED AMENDMENT TO THE GUIDELINES ON NUTRITION LABELLING  
(CAC/GL 2-1985)**

(for consideration by CCFL)

**2.6 Nutrient Reference Values (NRVs)\*** are a set of numerical values that are based on scientific data for purposes of nutrition labelling and relevant claims. They comprise the following two types of NRVs:

**Nutrient Reference Values- Requirements (NRVs-R)** refer to NRVs that are based on levels of nutrients associated with nutrient requirements.

**Nutrient Reference Values - Noncommunicable Disease (NRVs-NCD)** refer to NRVs that are based on levels of nutrients associated with the reduction in the risk of diet-related noncommunicable diseases not including nutrient deficiency diseases or disorders.

\* See also the Annex for the General Principles for the Establishment of Nutrient Reference Values.

### 3.4 Presentation of nutrient content

3.4.4 Numerical information on vitamins and minerals should be expressed in metric units and/or as a percentage of the NRV Nutrient Reference Value per 100 g or per 100 ml or per package if the package contains only a single portion. In addition, this information may be given per serving as quantified on the label or per portion provided that the number of portions contained in the package is stated.

In addition, information on protein and additional nutrients may also be expressed as percentages of the NRV Nutrient Reference Value.<sup>1</sup> where an NRV has been established.

The following NRVs Nutrient Reference Values are for the general population identified as individuals older than 36 months. They should be used for labelling purposes to help consumers make choices that contribute to an achieve overall healthful dietary intake. in the interests of international standardization and harmonization.

They include comprise two types of NRVs: Nutrient Reference Values-Requirements (NRVs-R) and Nutrient Reference Values – Noncommunicable Disease (NRVs-NCD).<sup>1</sup>

#### 3.4.4.1 NRVs-R

To be included later; see results agenda item 5

#### 3.4.4.2 NRVs-NCD

Saturated fatty acids	20 g <sup>2,3</sup>
Sodium	2000 mg <sup>3</sup>

<sup>1</sup> ~~In order to take into account future scientific developments, future FAO/WHO and other expert recommendations and other relevant information, the list of nutrients and the list of nutrient reference values should be kept under review.~~

<sup>1</sup> The general principles and related definitions used in establishing these NRVs are identified in ~~Identify the Annex or Annexes~~.

<sup>2</sup> This value is based on the reference energy intake of 8370 kilojoules/2000 kilocalories.

<sup>3</sup> The selection of these nutrients for the establishment of an NRV was based on “convincing evidence” for a relationship with NCD risk as defined in the report *Diet, Nutrition and the Prevention of Chronic Diseases*. WHO Technical Report Series 916. WHO, 2003.

APPENDIX VII

**PROPOSED DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES IN THE CODEX GUIDELINES ON NUTRITION LABELLING**

(Step 5/8)

**Proposed Draft NRVs**

<b>Vitamins and Minerals</b>	<b>NRVs -R</b>
<b>Vitamins</b>	
Vitamin K (µg)	60
Thiamin (mg)	1.2
Riboflavin (mg)	1.2
Niacin (mg NE)	15
Vitamin B6 (mg)	1.3
Folate (µg DFE)	400
Vitamin B12 (µg)	2.4
Pantothenate (mg)	5
Biotin (µg)	30
<b>Minerals</b>	
Calcium (mg)	1,000
Iodine (µg)	150

**Conversion factors for niacin and folate equivalents**

<b>Vitamin</b>	<b>Dietary equivalents</b>	
Niacin	1 mg niacin equivalents (NE) =	1 mg niacin 60 mg tryptophan
Folate	1 µg dietary folate equivalents (DFE) =	1 µg food folate 0.6 µg folic acid added to food or as supplement consumed with food 0.5 µg folic acid as supplement taken on an empty stomach

The conversion factors for vitamin equivalents in the Table provide supporting information for national authorities to enable national authorities to determine the application of NRVs at national level and they are not intended as a harmonisation of the conversion factors per se.



## APPENDIX VIII

**PROPOSAL TO REVIEW THE CODEX STANDARD FOR FOLLOW-UP FORMULA  
(CODEX STAN 156-1987)****PROJECT DOCUMENT****1 PURPOSE AND SCOPE OF THE NEW WORK**

The purpose of the proposed new work is a review of the Codex Standard for Follow-up Formula (CODEX STAN 156-1987, hereafter called ‘the Standard’). The Codex Standard for Follow-up Formula was issued in 1987. The category of food covered by the Standard has been subject to significant development over the 25 years since its development. There is a concern that the Standard may not provide adequate guidance to members in relation to the range of existing and potential follow-up formula products, and that it does not incorporate the key directions taken in the recent review of the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981(Rev.2007)). A review of the Standard would explore the lack of harmonisation in regulations for follow-up formula across member countries, and will include consideration of issues such as technological developments in follow-up formula production and composition over the past 25 years, the age range of the intended population, product definition, the role of such products in the diet and the need for such a Standard.

An interlinked set of social and technological developments over the past 20-30 years has prompted a growing interest from industry to provide consumers with a wider selection of infant formula products. ACNielsen reported a 12 per cent increase in global infant formula product sales from 2006 to 2007. According to Euromonitor International, the estimated global consumption of follow-up formula in 2010 was in the vicinity of 438,000 tonnes. This compares to the estimated global consumption of 309,000 tonnes in 2005. The growth in the follow-up formula market has been greatest in Asia, particularly China. Eastern Europe, and to a lesser extent the Middle East and Latin America are also experiencing growth in their infant formula products markets. It is expected that the global market for infant formula products will continue to grow rapidly due to factors such as rising disposable income levels and the growing number of working mothers.

**2 RELEVANCE AND TIMELINESS**

The current Standard is outdated. There is a marked diversification of national follow-up formula standards across members, and this is expected to continue in the absence of an up-to-date international reference point. Several countries have already modified their regulations for follow-up formula since the development of the Standard, while other countries either use the current Standard or have adopted regulations that closely follow it. In addition, a number of countries are currently working on, or have already developed, regulations for ‘growing-up milk’ products. In many cases, the age range for growing-up milk products in these regulations overlaps the age range used in the Standard. A similar situation is also evident between member countries in the overlap of age ranges for some follow-up formula and infant formula regulations. A revised Standard may be useful for promoting international harmonisation in the regulation of follow-up formula products.

**3 MAIN ASPECTS TO BE COVERED**

A full review of the Standard would look at the following aspects:

**Description**

There are discrepancies between member countries’ follow-up formula regulations, particularly with regard to the defined age-range for which follow-up formula products are intended. The current Standard states that follow-up formula is suitable for infants and young children aged between 6 and 36 months. There are broadly two approaches in country regulations to the age range for follow-up formula, whereby some country regulations are consistent with the age range (6 – 36 months) in the Standard, while others provide a narrower age range of 6-12 months.

The Standard contains the following definitions:

- **Follow-up formula** means ‘a food intended for use as a liquid part of the weaning diet for the infant from the 6<sup>th</sup> month on and for young children’.
- **Infants** are defined as ‘a person not more than 12 months of age’.
- **Young children** means ‘persons from the age of more than 12 months up to the age of three years (36 months)’.
- **Follow-up formula** is further defined as a ‘food prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin, which have proved to be suitable for infants from the 6<sup>th</sup> month on and for young children’.

#### Essential Composition and Quality Factors

There is a concern that scientific and technological developments and changes in consumption patterns since the introduction of the Standard mean that it may no longer provide adequate guidance to member countries. This is especially important as many countries rely on the Standard for domestic regulation, and the Standard is the default for inter-country trade in follow-up formula.

There has been considerable advancement in the science underpinning the nutritional needs of infants. This was considered in detail in the review of Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981(Rev.2007)). There is an argument that these advances should be considered as part of a review of the follow-up formula Standard. The main areas of concern include (but are not limited to):

- the minimum and maximum levels of protein in the current Standard;
- maximum or guiding upper limits for vitamins and minerals; and
- the provisions for optional ingredients.

#### Labelling

The use of health claims on food products for infants and young children continues to be a contentious issue. The current Codex Guideline for Use of Nutrition and Health Claims (CAC/GL 23 – 1997) states under section 1.4 that ‘Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation’. The Standard does not contain any explicit provisions for nutrition and health claims.

#### The International Code of Marketing of Breast-milk Substitutes

The 1981 WHO International Code of Marketing of Breast-milk Substitutes (the WHO Code) applies to marketing and related practices in relation to the following products:

- breast-milk substitutes, including infant formula;
- other milk products, foods and beverages, including bottle-fed complementary foods;
- feeding bottles, and teats.

There is a divergence in approaches between member countries as to whether follow-up formula is defined as a breast-milk substitute, and whether follow-up formula products fall within the scope of the WHO Code. The WHO urges all Member States to take action to give effect to the principles and aim of the WHO Code as appropriate to their social and legislative framework.

Additional Requirements of the Codex Standard (Section 9.6) states that ‘the products covered by this standard are not breast-milk substitutes and shall not be represented as such’. It is worth noting that the WHO briefing note on "Follow-Up Formula in the Context of the International Code of Marketing of Breast-milk Substitutes" is presently being considered for revision by the WHO pending review of new and emerging information on the subject.

#### Other Issues

Other sections of the Codex Standard would be assessed to ensure they reflect the latest Codex position including food additives, contaminants, packaging and hygiene.

## **4 ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES**

### **4.1 General criterion**

The proposed revision of the Standard is focused on establishing whether this standard provides for the adequate supply of nutrients through the provision of safe follow-up formula products which are scientifically demonstrated to support the nutritional requirements of the infants and young children for whom these products are intended, in order to promote normal growth and development.

Due to scientific and technical developments, there may be a need to ensure the Standard represents the optimal composition that might be achieved, while also considering safety and suitability.

The diversification of national regulation for follow-up formula products across member countries may present significant issues for the international trade of these products. For example, differences in the regulations applied to exports of follow-up formula may disadvantage countries seeking to ensure that follow-up formula product exports are safe and suitable for the intended consumer and equally may disadvantage consumers if the regulations are too liberal. International standards can provide guidance on the appropriate level of regulation to ensure safety and suitability while facilitating trade.

The new work can contribute to facilitating international trade by providing clear international guidance on provisions for follow-up formula products.

### **4.2 Criteria applicable to commodities**

*a) Volume of production and consumption in individual countries and volume and pattern of trade between countries.*

Follow-up formula is manufactured in many countries and has become a commodity of increasing trade significance with consistent growth in international trade over the past decade. According to Euromonitor International, the estimated global consumption of follow-up formula in 2010 was in the vicinity of 438,000 tonnes. This compares to the estimated global consumption of 309,000 tonnes in 2005. Much of the growth in sales and consumption has been in developing countries. China and Indonesia have the highest volume of consumption of follow-up formula of all the countries included in the Euromonitor survey with a reported market of 127,100 and 30,400 tonnes, respectively in 2010.

*b) Diversification of national legislation and apparent resultant or potential impediments to international trade.*

The Standard is 24 years old and has not been reviewed during this time. It is apparent from a review of national regulation for follow-up formula that differences exist between countries. Although we are not aware of any evidence of market failure in those markets that have adopted the Standard in its entirety or partially, it appears that some countries have since reviewed and updated their national legislation for this commodity due to developments in scientific research. The differences in national regulations may create barriers to the international trade in safe and suitable follow-up formula products.

An updated Standard would assist in providing an improved technical and scientific basis for establishing national regulations.

*c) International or regional market potential.*

Follow-up formula products are widely traded. A revised Standard should enhance opportunities for insuring global and regional trade.

*d) Amenability of the commodity to standardisation.*

While there is general support for the harmonisation of food regulations for follow-up formula to assist in eliminating any impediments to international trade, many industry representatives are keen to retain permissions for the addition of 'optional ingredients' to follow-up formula to allow for innovation and product development.

e) *Coverage of the main consumer protection and trade issues by existing or proposed general standards.*

Updating the Standard to ensure that it is based on robust and up-to-date science will facilitate an internationally harmonised approach to this commodity and thereby contribute to consumer protection whilst ensuring fair practices in trade.

f) *Number of commodities which would need separate standards indicating whether raw, semi-processed or processed.*

One of the critical issues to be addressed in the review of the Standard is the intended age range for follow-up formula. Depending on the age range determined, the CCNFSDU could also consider expanding the scope of the Standard to explicitly include or not so-called growing-up milk products as these are generally intended for young children in the age range of the Standard on follow-up formula.

g) *Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body (ies).*

A review of the Standard would require technical support and input from recognised international experts in the area of infant and young child nutrition, as well as from governments and relevant international organisations.

## **5 RELEVANCE TO CODEX STRATEGIC GOALS**

The proposed work is consistent with the Commission's strategic goals with particular reference to the following:

Goal 1: Promoting sound regulatory frameworks - Revision and update of the current Codex Standard will greatly assist in promoting sound regulatory frameworks for these products.

Goal 2: Promoting widest and consistent application of scientific principles and risk analysis- The revision of the current standard will draw on the latest scientific evidence and facilitate the development of a risk based standard for regulation of these products.

Goal 5: Promoting maximum and effective participation of members - The products covered by the proposed work is of significant global interest and the revision process will be carried out with the input and participation of as many members as possible.

## **6 INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING DOCUMENTS**

Codex has developed standards for other foods that cover this age range, including:

- Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981(Rev.2007))
- Standard for Processed Cereal-based foods for infants and young children (CODEX STAN 74-1981)
- Standard for Canned Baby Foods (CODEX STAN 73-1981)
- Guidelines on formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 09-1991)

## **7 IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE**

The Committee may seek expert scientific advice as needed from FAO and WHO in the area of infant and young child nutrition and suitable manufacturing of these foods.

## **8 IDENTIFICATION OF ANY NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES SO THAT THIS CAN BE PLANNED FOR**

A review of the Standard may require technical support and input, as needed by recognised international experts in the area of infant and young child nutrition and manufacturing of these products.

**9 PROPOSED TIMELINE FOR COMPLETION OF THE NEW WORK**

Subject to approval, the proposed time line for completion of the new work is as follows:

Endorsement of new work proposal by CCNFSDU and establishment of electronic working group to develop draft discussion document and draft revised standard

July 2013	Approval of new work by CAC
Between July and October 2013	Circulation for comments at Step 3
November 2013	Consideration of draft revised standard at Step 4 by CCNFSDU
November 2013 – November 2014	Consideration of draft standard and further work with technical experts and eWG and circulation for comments at Step 3
November 2015	Consideration of draft standard and advancement at Step 5
July 2016	CAC adoption of draft standard to Step 5
November 2016	Discussion of draft standard and advancement to Step 8
July 2017	Adoption of draft standard at Step 8

The revision and progression of work between sessions will be carried out through electronic/physical working groups to ensure timely development of the standard.