

# CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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**REP17/NFSDU**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX ALIMENTARIUS COMMISSION**

*Fortieth Session*

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**REPORT OF THE THIRTY-EIGHTH SESSION OF THE  
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**

**Hamburg, Germany**

**5 – 9 December 2016**

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## SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step	Para.
Members CCEXEC73 CAC40	Adoption	Proposed amendments to Section 6, paragraph 33 of the nutritional risk analysis principles (Procedural Manual)	-	-	12(i)
Codex Secretariat CAC40	Adoption	Editorial amendments to the <i>Guidelines on Nutrition Labelling</i>	CAC/GL 2-1985	-	12(ii)
CAC40	Adoption	Editorial amendments to various CCNFSDU standards: flavourings	CODEX STAN 73-1981 CODEX STAN 74-1981 CODEX STAN 156-1987 CAC/GL 8-1991	-	16
Members CCEXEC73 CAC40	Adoption	NRV-R for vitamins D and E and the conversion factors for vitamin E equivalents	CAC/GL 2-1985	5/8 and 8	26 and 28, 36
CCNFSDU39	Discussion	NRV-R for older infants and young children	CAC/GL 2-1985	-	40
CCNFSDU40	Discussion	Proposed draft essential composition and quality factors (section A: follow up formula for older infants); and certain essential composition and quality factors (section B: young children)	CODEX STAN 156-1987	4	125
Members EWG (New Zealand, France and Indonesia) CCNFSDU39	Redrafting	Review of the <i>Standard for Follow-up formula</i> (other sections)	CODEX STAN 156-1987	2/3	122 - 123
EWG (Zimbabwe, South Africa) CCNFSDU39	Redrafting	Proposed draft definition for biofortification	-	2/3	146
EWG Russia, Chile CCNFSDU39	Redrafting	Proposed draft NRV-NCD for EPA and DHA long chain omega-3 fatty acids	CAC/GL 2-1985	2/3	154
EWG (South Africa, Senegal, Uganda) CCNFSDU39	Redrafting	Proposed draft guideline for ready-to-use therapeutic foods (RUTF)	-	2/3	166
CCNFSDU39	Discussion	Claim for "free" of trans fatty acids	-	-	170
EWG (European Union, Russia) CCNFSDU39	Discussion	Mechanism / framework for considering technological justification / consider or confirm technological justification for certain food additives	-	-	178

CCMAS38 CAC40	Advice or endorsement / Adoption	Methods of analysis for provisions in the <i>Standard for infant formula and formulas for special medical purposes intended for infants</i>	CODEX STAN 72- 1981	-	180 - 190
FAO	Request	Consideration of possible Guidance on DIAAS for protein quality assessment	-	-	83, 165

### LIST OF ABBREVIATIONS

AI	Adequate intake
CAC	Codex Alimentarius Commission
CCCF	Codex Committee on Contaminants in Foods
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCFA	Codex Committee on Food Additives
CCFH	Codex Committee on Food Hygiene
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
CCMAS	Codex Committee on Methods of Analysis and Sampling
CRD	Conference Room Document
DHA	Docosahexaenoic acid
DIAAS	Digestibility indispensable amino acid score
EFSA	European Food Safety Authority
ELISA	Enzyme-linked Immunosorbent assay
EPA	Eicosapentaenoic acid
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
GUL	Guidance upper level
IDF	International Dairy Federation
INS	International numbering system
IOM	Institute of Medicine (renamed Health and Medicine Division)
ISDI	International Special Dietary Foods Industries
ISO	International Organization for Standardization
JECFA	Joint Expert Committee on Food Additives
JEMNU	FAO/WHO Joint Expert Meetings on Nutrition
LC-PUFA	Long chain-polyunsaturated fatty acids
NUGAG	WHO Nutrition Guidance Expert Advisory Group
NRV-R	Nutrient reference values - requirements
NRV-NCD	Nutrient reference values – non-communicable diseases
PDCAAS	Protein digestibility corrected amino acid score
PER	Protein efficiency ratio
PWG	Physical Working Group
RASB	Recognized authoritative scientific body
RUTF	Ready-to-use therapeutic food
SAM	Severe acute malnutrition
TFA	Trans fatty acid
UN	United Nations
UNICEF	United Nations Children's Fund
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHA	World Health Assembly
WHO	World Health Organization

## INTRODUCTION

1. The thirty-eighth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held in Hamburg, Germany, from 5 to 9 December 2016 at the kind invitation of the Federal Government of Germany. The Session was chaired by Dr Pia Noble, Former Head of Division of Specific Foods, Food Supplements and Food Additives, Federal Ministry of Food and Agriculture of Germany. The Committee was attended by 56 member countries, one member organisation and 38 observer organisations. A list of participants is given in Appendix I.

## OPENING OF THE SESSION

2. Dr. Klaus Heider, Director-General for Food Policy, Product Safety and Innovation, Federal Ministry of Food and Agriculture of Germany, speaking on behalf of Mr Christian Schmidt Federal Minister for Food and Agriculture, welcomed delegates. Dr Heider reviewed the history of the Committee and recalled the outstanding achievements of CCNFSDU over the previous 50 years. Mr Tom Heilandt, Secretary of the Codex Alimentarius Commission also addressed the meeting.
3. To mark the 50<sup>th</sup> anniversary of the Committee, delegates welcomed three former chairs to the meeting: Dr. Horst Drews, Prof. Dr. Arpad Somogyi and Dr. Rolf Großklaus.

### Division of competence<sup>1</sup>

4. The Committee noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Rules of Procedure of the Codex Alimentarius Commission as presented in CRD1.

### **ADOPTION OF THE AGENDA (Agenda Item 1)**<sup>2</sup>

5. The Committee adopted the Provisional Agenda as its Agenda for the Session and agreed that item 4b would be discussed before item 4a. The Committee also agreed to discuss document CX/NFSDU 16/38/12 (Methods of analysis in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981)), prepared by the United States of America, under item 11, Other Business and Future Work.

### **Matters Referred to the Committee by the Codex Alimentarius Commission and/or Other Subsidiary Bodies (Agenda Item 2)**<sup>3</sup>

6. The Committee noted that some matters were only for information, that several matters would be considered under other relevant agenda items and took the following decisions:

#### **Consistency of the Risk analysis Texts across relevant Committee**

7. The Committee considered the draft proposal prepared by the Secretariat on the amendment to Section 6 "Selection of risk assessor by CCNFSDU", paragraph 33 of the nutritional risk analysis principles to include JEMNU as a primary source of scientific advice and noted the following comments made by members:
  - Support for the addition of JEMNU to the text as well as various sources for provision of scientific advice;
  - Importance to ensure that the language used in the text is consistent with other related texts on the provision of scientific advice used by other Committees like CCFH, CCCF, CCFA;
  - JEMNU should be the primary source of information and therefore FAO, WHO as well as the second sentence to paragraph 33 should be deleted from the text;
  - The second sentence should be retained to enable consideration of scientific advice from other sources as this would provide flexibility to the Committee;
  - Scientific advice should be protected from conflict of interest and undue influence.
8. The Codex Secretariat clarified that the text was consistent with other risk analysis principles e.g. food hygiene and contaminants in food and feed, and that FAO and WHO would be the first call for scientific advice. She further explained that the second sentence of paragraph 33 provided flexibility. If FAO and WHO were not in a position to provide timely scientific advice then the Committee could consider other sources.
9. The Representative of FAO informed the Committee that FAO and WHO have in place sound and robust

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<sup>1</sup> CRD1

<sup>2</sup> CX/NFSDU 16/38/1

<sup>3</sup> CX/NFSDU 16/38/2, CRD4 (Comments from European Union, Kenya, African Union, IDF and ISDI); CRD14 (Comments from Benin)

policies and procedures that ensure independence as well as addressing the concerns related to undue influence at all stages of delivery of scientific advice to Codex including: call for experts; before and during meetings and impartiality of experts.

10. The Chair underscored the importance of drawing information from other scientific bodies (i.e. RASBs) apart from FAO, WHO and JEMNU that would provide flexibility to the Committee. She also noted the need to have consistent language across the different risk analysis texts and as a result of this some of the proposed amendments were typographical in nature and were intended to provide the required consistency.

#### Other

11. The Committee also noted the existing inconsistencies in sections 3.1 and 3.2 in the *Guidelines on Nutrition Labelling* (CAC/GL 2 -1985) arising out of further amendments to the definition of RASB in section 2.5 during CAC39.

#### **Conclusion**

12. The Committee agreed:
  - i. To forward the proposed amendments to Section 6, Paragraph 33 to the Commission for adoption (Appendix II);
  - ii. That the Codex Secretariat would compile the proposed amendments to section 3.1 and 3.2 of *Guidelines on Nutrition Labelling* (CAC/GL 2 -1985) and forward them to CAC40 for adoption.

#### **Methods of Analysis**

13. The Committee agreed to establish an In-Session Working Group, chaired by the United States of America, to examine: the questions raised by CCMAS on different methods for provisions in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEXSTAN 72-1981); as well as the proposals in document CX/NFSDU 16/38/12.
14. The Committee further agreed not to include the ELISA G12 method in the *Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten* (CODEX STAN 118-1979) noting that there were no comparability results with R5; and it would be considered at a future date when the results from the ongoing comparability studies by the international Working Group on Prolamin Analysis and Toxicity become available.

#### **Editorial amendment to texts on flavourings**

15. The Committee agreed to the proposals from CCFA on the editorial amendments related to the appropriate use of the term flavourings in the following standards: *Standard for Canned Baby Foods* (CODEX STAN 73-1981); *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CODEX STAN 74-1981); *Standard for Follow-up Formula* (CODEX STAN 156-1987); *Guidelines on Formulated Complementary Foods for Older Infants and Young Children* (CAC/GL 8-1991). The amendments are as indicated in Appendix II.

#### **Conclusion**

16. The Committee agreed to forward the amended texts to CAC40 for adoption.

#### **FAO and WHO policies/strategies/guidelines<sup>4, 5</sup>**

17. The Representative of WHO called the attention of the Committee to the discussions of CCEXEC71 and CAC39 on the relations between FAO and WHO policies/strategies/guidelines and the work of Codex, and noted the increasing reference and request to Codex by the World Health Assembly (WHA) to strengthen its work and call to Member States to use Codex standards/guidelines to protect and promote the health of the population. But in recent years, the reference to Codex and the use of its standards/guidelines had been challenged in the discussions at WHA because Codex standards/guidelines were not always developed ensuring WHO policies and recommendations nor are they in line with WHO guidelines. The Representative noted that CAC39 had proposed that this matter be further discussed at CCEXEC79 in 2017 and finally highlighted the importance of Member Countries and observers of CCNFSDU to give full consideration to this.
18. The Representative of FAO noted that FAO and WHO were making a wide variety of resources available to the Codex Alimentarius Commission and its subsidiary bodies, including its own policy initiatives, scientific advice as well other resources and tools, and encouraged the Committee to make best use of these various resources. He further reminded the Committee that the Commission is an independent organization with a mandate to develop standards that ensure both food safety as well as enabling fair trade practices for all food items. He encouraged the Committee to leverage all resources to ensure their fullest use to fulfil the mandate of Codex for ensuring food safety and fair trade practices for all food items of relevance to the Committee.

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<sup>4</sup> REP16/EXEC, para 113 – 122

<sup>5</sup> REP16/CAC, para 137 – 145

**MATTERS OF INTEREST ARISING FROM FAO AND WHO (Agenda Item 3)<sup>6</sup>**

19. The Representative of FAO drew the attention of the committee to various activities of FAO of interest to CCNFSDU: (1) The International Nutrition Symposium on Sustainable Food Systems for Healthy Diets and Improved Nutrition, that was held in Rome on 1-2 December 2016. (2) The recent declaration by the UN General Assembly of the UN Decade of Action on Nutrition for the years 2016 to 2025, which committed Member States to ten years of sustained and coherent nutrition action. (3) The joint FAO and WHO technical consultation on “Staple crops biofortified with increased micronutrient content for improving vitamin and mineral status in populations” that was convened in April 2016. (4) The recent publication of an FAO Handbook on Food Labelling, which explains the general principles and good practices for food labelling, including international standards for labelling<sup>7</sup>.
20. In response to a request for information on the status of work concerning the definition of biofortification (in order to avoid duplication of work), the Representative of FAO informed the Committee that the technical consultation was ongoing and that FAO/WHO were waiting for CCNFSDU to provide a definition.
21. Referring to the document CX/NFSDU/16/38/3, the Representative of WHO highlighted some of the activities which may be of relevance to the on-going work of the Committee. In particular, she called the attention of the Committee to the resolution ([WHA69.9](#)) on the WHO guidance on ending the inappropriate promotion of foods for infants and young children<sup>8</sup> which clarifies that, in order to protect, promote and support breastfeeding, the marketing of “follow-up formula” and “growing-up milks” - targeted for consumption by infants and young children aged 6 months to 3 years - should be regulated in the same manner as infant formula for 0 to 6-month-olds. She also highlighted: 1) Technical meeting on nutrition labelling for promoting healthy diets held in December 2015, outcomes and evidence reviews of which will contribute to the new work being carried out by CCFL; 2) on-going work of the WHO Nutrition Guidance Expert Advisory Group (NUGAG) Subgroup on Diet and Health on polyunsaturated fatty acids (PUFA), non-sugar sweeteners, carbohydrates (fibre and starch) and dietary patterns; 3) development of nutrient profile models for regulating marketing of food and non-alcoholic beverages to children which will also be adapted for possible use for other applications, such as sales and promotion of foods and beverages in and around schools, taxation and front-of-pack labelling; and 4) on-going work on the development of risk assessment, disclosure and management tools to safeguard against possible conflicts of interest in policy development and implementation of nutrition programmes.
22. The Representative of WHO also informed the Committee of WHO’s initiative on removing sugar-sweetened beverages from sales and services in WHO Headquarters and in some of the Regional Offices, which was launched in October 2016 and also in UNAIDS in November 2016, as part of the “Walk the Talk” initiative through implementing WHO’s policies and guidelines.

**DRAFT NRV-R FOR VITAMIN E (Agenda item 4a)<sup>9</sup>****PROPOSED DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES IN THE GUIDELINES ON NUTRITION LABELLING (VITAMIN D AND THE DIETARY EQUIVALENTS AND CONVERSION FACTOR FOR VITAMIN E) (Agenda Item 4b)<sup>10</sup>***Dietary equivalents and conversion factor for Vitamin E*

23. Australia, as chair of the electronic working group (eWG2015), reminded the Committee of the proposal for D- $\alpha$ -tocopherol as the only isomer with vitamin E activity and further drew the attention of the Committee to their comments in CX/NFSDU 16/38/4 which provided an updated review of all available information in RASB reports to identify the units of vitamin E in food used to derive the dietary intakes on which the adequate intakes (AIs) were based. Australia indicated it was worth noting that the equivalency equation had minor impact on estimates of vitamin E intake.
24. Those delegations supporting inclusion of all isomers for vitamin E activity as listed in the FAO/WHO (2004) publication, noted that these isomers, such as tocotrienols, also exhibited vitamin E activity and that these should be given due recognition and not be ignored. An observer was of the view that vitamin E was a complex

<sup>6</sup> CX/NFSDU 16/38/3

<sup>7</sup> Link to download publication: <http://www.fao.org/documents/card/en/c/fc5f4bc2-650a-4704-9162-9eb9b3a1fdd0/>  
<sup>8</sup> [http://apps.who.int/gb/ebwha/pdf\\_files/WHA69/A69\\_7Add1-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_7Add1-en.pdf)

<sup>9</sup> CL 2016/19-NFSDU, CX/NFSDU 16.38/4 (comments from Australia, Canada, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, European Union, Ghana, New Zealand, Paraguay, Philippines, Unites of States of America, CEFIC, CRN, ELC, IFT, IADSA and ISDI); CRD 5 (comments from India, Malaysia, Mexico, Peru and African Union), CRD 14 (comments from Benin); CRD16 (comments from Republic of Korea).

<sup>10</sup> REP16/NFSDU, Appendix II, Part III; CX/NFSDU 16/38/5 (comments from Argentina, Brazil, Canada, Costa Rica, Cuba, United States of America, ELC and ISDI); CRD 6 (comments from India, Indonesia, Malaysia, African Union and NHF); CRD 14 (comments from Benin); CRD 16 (comments from Republic of Korea).



of at least eight isomers and if only  $\alpha$ -tocopherol were recognized as vitamin E, Codex would not be in line with nutrition science on vitamin E.

25. Those in support of the identification of  $\alpha$ -tocopherol as vitamin E noted that other isomers, such as tocotrienols, while having vitamin E activity, were at levels of activity which did not meet the principles for establishing NRVs-R.

#### **Conclusion**

26. The Committee agreed to submit 1 mg  $\alpha$ -tocopherol (1mg RRR- $\alpha$ -tocopherol) as the dietary equivalent for vitamin E to CAC40 for adoption at Step 5/8 (Appendix III), noting the reservations of Malaysia and Indonesia to this decision.

#### **NRV-R for Vitamin E**

27. The Committee noted the general support for the NRV-R for vitamin E of 9 mg/day as all recommendations were Adequate Intakes (AIs) and a global value should be established, while those in favour of higher values indicated that the higher value was more in line with the needs of their particular populations, was more scientifically correct, and in line with the European Food Safety Authority (EFSA) opinion.

#### **Conclusion**

28. The Committee agreed to forward the NRV-R for vitamin E of 9 mg/day to CAC40 for adoption at Step 8 (Appendix III), noting the reservation of China to this decision.

#### *NRV-R for Vitamin D*

29. The Committee recalled the interim decision of CCNFSDU37 to retain the NRV-R for vitamin D of 5  $\mu$ g/day and to add a footnote on vitamin D to indicate that competent national or regional authorities should determine an appropriate NRV-R that accounts for population sunlight exposure and other relevant factors.

30. The Committee considered the proposal to revise upward the NRV-R for vitamin D from 5  $\mu$ g/day to either 10 or 15  $\mu$ g/day and a revised footnote to indicate the basis for the NRV-R.

31. The Committee noted the following views expressed on each of the levels:

32. Those in support of 15  $\mu$ g/day noted that it was in line with EFSA and Institute of Medicine (IOM) opinion; that this level was necessary to take into account latitude, cultural practices and use of sun block which limited endogenous, cutaneous vitamin D synthesis in spite of high sunlight exposure; that in some countries, there were vitamin D deficiencies and that levels even higher than 15  $\mu$ g/day were needed.

33. Those in support of 10  $\mu$ g/day in line with the Nordic Nutrition Recommendations 2012 reminded the Committee that the NRV-R was for labelling purposes and not for treatment of deficiencies; and was more appropriate. In addition to labelling values, NRVs can also be used as a guide for setting fortification levels.

34. Those delegations supporting retention of the current NRV-R of 5  $\mu$ g/day, indicated that due to the high exposure to sunlight in their countries, such an increase was not necessary. The footnote as agreed at CCNFSDU37 would still enable countries to set their own NRVs-R depending on their national or regional situation.

35. The Committee, noting a lack of consensus, then considered a proposal for a range from 5 – 15  $\mu$ g/day, while retaining a revised footnote: *the value of 15  $\mu$ g is based on minimal sunlight exposure throughout the year. Competent national and/or regional authorities should determine an appropriate NRV-R that best accounts for population sunlight exposure and other relevant factors.*

#### **Conclusion**

36. The Committee agreed to submit the NRV-R for vitamin D for a range from 5 – 15  $\mu$ g/day with the footnote as mentioned above for adoption by CAC40 at Step 5/8 (Appendix III).

#### **NRV-R FOR OLDER INFANTS AND YOUNG CHILDREN (Agenda item 4c)<sup>11</sup>**

37. The chair introduced the item and recalled the decision of the last session of the Committee as outlined in REP16/NFSDU, para. 51.

38. The Committee considered the following options:

- continue work through an eWG with the terms of reference as agreed at CCNFSDU37;
- postpone discussion; or

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<sup>11</sup> REP16/NFSDU, para.51

- discontinue work.

39. While there was interest to continue work through an eWG, it was not possible to find co-chairs to assist those countries who expressed interest in leading this extensive work.

### Conclusion

40. The Committee agreed to postpone discussion until the next session of the Committee.

### REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987) (Agenda Item 5)<sup>12</sup>

41. The Chair of the electronic working group (eWG) New Zealand, speaking on behalf of the co-Chairs France and Indonesia, introduced the item and briefly outlined the work undertaken.

#### Essential Composition of Follow-up Formula (FUF) for older infants (6-12 months)

42. The Chair of the eWG recalled that the essential compositional requirements for follow-up formula for older infants aged 6-12 month still to be finalised included: protein, vitamin K, vitamin C, zinc, DHA and L(+) lactic acid producing cultures.

43. The Committee considered the recommendations of the eWG and made the following decisions and comments.

#### Protein

44. The Committee agreed a maximum value of 3.0 g/100 kcal although China expressed a preference for a level of 3.5 g/100 kcal;

45. The EU agreed to accept a value of 3.0 g/100 kcal, taking into account the limited evidence upon which to clearly determine a maximum level.

46. The Committee agreed to postpone the decision on a minimum level until the next session, also mindful that an EFSA opinion was expected by April 2017 assessing a level of 1.61 g/100 kcal.

#### Footnote 2 – nitrogen conversion factor for soy products

47. The Chair of the eWG informed the Committee that CCMAS had been unable to provide guidance on this matter.

48. The Representative of FAO reminded the Committee that all methods that relied on the total nitrogen determination for an estimate of the protein concentration were approximations in nature. The determination of the true protein content and/or the protein content with a view on relevance to human nutrition was not possible through a simple conversion from nitrogen to protein.

49. He added that given the importance of protein for human nutrition and for the valuation of food sources, a change of the established conversion factor was likely to have major impact on the evaluation of agricultural products as well as on product formulation, product labelling and potentially dietary recommendations regarding all products containing the protein source for which the conversion factor was modified.

50. In conclusion, he mentioned that if such an undertaking were to be considered for soybeans, the Committee should consider whether a similar argument might be true for other food categories and trigger the need to review all conversion factors (dairy, meat, fish (already ongoing at FAO fisheries), other vegetables such as beans and pulses, etc.).

51. An observer referring to CRD 4, called for an expert panel and requested to leave the footnote 2 as is until advice from this expert panel is received.

52. The Committee:

- agreed on the wording for footnote 2 as amended;
- agreed on the wording of footnotes 3, 4 and 5;
- agreed to further discuss the wording of footnote 6 for clinical evaluation of formula based on non-hydrolysed milk protein at protein levels of 1.6 – 1.8 g/100 kcal and the need for clinical evaluation of formula based on hydrolysed protein as there was currently no consensus.

#### Vitamin K: minimum requirements

<sup>12</sup> CX/NFSDU 16/38/6; CX/NFSDU 16/38/6 Add.1 (comments from Argentina, Brazil, Canada, Colombia, Costa Rica, Nepal, New Zealand, Norway, Philippines, United States of America, AOCS, CEFS, ELC, ENSA, ENSA/EUVEPRO, HKI, IBFAN, IDF and ISDI) and Add.2 (comments from Ecuador, European Union, Malaysia, Thailand, Vietnam and IFT); CRD 2, 13 and 17 – Report of the Physical Working Group, CRD 3 (comments from India, Indonesia, Kenya, Nigeria, African Union); (CRD14 (comments from Benin); CRD15 (comments from Chile, Mexico, ESPHGAN).

53. The Committee agreed to a value of 4µg/100 kcal.

**Vitamin C: minimum requirements**

54. The Committee agreed to a value of 10mg/100 kcal.
55. The EU and Norway indicated that they could accept the levels agreed by the Committee for both vitamins K and C in the spirit of compromise, and taking into account the global nature of Codex standards, despite their preference for a value of 1 µg/100 kcal (vitamin K) and 4 mg/100 kcal (vitamin C) – as recommended by EFSA based on infants' requirements.

**Zinc: guidance upper level (GUL)**

56. The Committee agreed on a GUL of 1.5 mg/100 kcal and to delete the maximum value from footnote 20.
57. The EU and Brazil indicated that they could accept the levels agreed by the Committee for zinc, in the spirit of compromise, despite a preference for 1.0 mg/100 kcal. The EU and Norway stated that a GUL of 1.5 mg/100 kcal could lead to an excessive intake of zinc and so constituted a safety risk.

**Docosahexanoic acid (DHA)**

58. The Committee agreed:
- i. to set a minimum content in a footnote if DHA is added as an optional ingredient;
  - ii. to further consider the levels for DHA based on total energy density instead of as a percentage of total fat.

**Optional addition: L (+) lactic acid producing cultures**

59. It was outlined that lactic acid producing cultures should not be added unless the safety and suitability is demonstrated in order to avoid any health risk.
60. Norway was of the view that the safety and suitability of the use of probiotics in formula had not to date been fully demonstrated..
61. Concerns were also expressed that a number of issues had not yet been addressed including risks to those who were immuno-compromised; possible metabolic syndromes that could appear; possible excessive stimulation of the immune system, and the transfer of resistant bacteria.
62. Other risks including inadequate practices for preparing the product and lack of knowledge on how the products may be marketed were also mentioned.
63. In terms of the technological use of L (+) lactic acid producing cultures for the purpose of producing acidified follow-up formula, it was noted that the final formula should not contain significant amounts of viable L (+) lactic acid producing cultures. The safety and suitability of the addition of L (+) lactic acid producing cultures for particular beneficial physiological effects must be demonstrated by clinical evaluation and generally accepted scientific evidence for the particular strain used. The text was redrafted to reflect these issues.

**Framework for the essential composition of follow-up formula<sup>13</sup> for young children (12-36 months)**

64. The Chair of the physical working group (pWG) New Zealand, introduced the item and highlighted the conclusions of the pWG as presented in CRD2.

**Section 4: Framework for the Essential Composition of follow-up formula for Young Children**

65. The Chair of the pWG recalled the previous decision of the Committee to review the compositional requirements for follow-up formula with a point of differentiation at 12 months. Section A of the proposed framework referred to the essential composition and labelling of follow-up formula for older infants, whilst Section B dealt with the essential composition and labelling of the product for young children.
66. In the general discussion, the following views were expressed:
- Section A (older infants) could be incorporated into the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* and the current separation in Section A and Section B could be revised once the definitions of the products had been agreed.
  - The product for 12-36 months should not be called "follow-up formula". The current composition under discussion potentially makes the product unsuitable for feeding children less than 12 months and having the same name may cause confusion. This term can create confusion as it combines infants and young children under a single heading. Section A and Section B could become two separate standards.

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<sup>13</sup> Note: the name of the product has not yet been decided and will be further discussed in the EWG.

- There is concern with the multiplicity of standards and consideration should be given to have instead a single standard.
- Policy coherence with appropriate reference to WHA resolutions and WHO guidelines should be taken into consideration.

67. In response to concerns that agreement had already been reached on the future form of the standard, the Codex Secretariat noted that it was possible to keep the matter open on the final structure of the standard. Options could include one standard in two parts, two separate standards, or merged with other standards.

68. The Committee supported this position and recognised that it would be possible to see levels of commonality between product ranges as progress was made on the detail of the standard. Continuing to work on an A/B format for the moment would assist the Committee in gaining an understanding of what work could be completed the following year.

69. The Committee agreed on the proposed framework.

#### **Principles for mandatory addition**

70. The Chair of the eWG outlined the approach as to what would be captured in the mandatory composition and how to structure and implement the essential composition (section 3.1.4 of the draft standard). The approach taken to determine the mandatory requirements for the essential composition of follow-up formula for young children was based on the agreements in 2015 and in previous eWGs that a standard for a product for 12-36 months of age needed to be:

- flexible in the composition to address key nutrients of concern which may vary regionally;
- less prescriptive, as follow-up formula for young children does not need to contain the full range of nutrients that are mandated for addition to follow-up formula for older infants;
- however, consistent with compositional parameters for follow-up formula for older infants (where possible); contain the key nutrients of global concern in the diets of young children, as well as the key nutrients in cows' milk; and maintain nutritional integrity.

71. This approach was elaborated in the eWG to develop principles to underpin the selection of nutrients for the mandatory essential composition of follow up formula for young children. It was noted that these were working principles only and would not appear in the standard but would be captured in the report of the current meeting.

#### **Principles for selecting which nutrients must be mandatory**

72. The Committee considered the amended principles as follows:

Evidence to support:

1. contribution to the nutritional needs of young children where the consumption of the nutrient is widely inadequate; and/or
2. contribution of adequate amounts of key nutrients from milk, and if appropriate breast milk, where such nutrients are key contributors to the diet of young children; and/or
3. the nutritional quality and integrity of product to ensure nutritional safety.

73. It was noted that breastmilk, formulas for infants and milk were all suitable for this age group. Therefore any levels specified in this standard would need to accommodate these foods.

74. In discussing and amending the text, delegates made the following observations:

- The Committee had initially agreed to a limited list of mandatory components, however that list was increasing. It may therefore be more appropriate to modify the text, to take into account those parts of the world where there is no concern, or high concern for a particular component.
- The initial intention was a small core composition. That core has subsequently been added to with almost every nutrient. The list can be revisited to see if all are core components or if some can be optional.
- If the Committee leaves all decisions to national authorities, then it will never reach the Codex goal of an international reference standard.
- There is concern that not all countries will be able to set levels for nutrients at the national level. Codex should set minimum/maximum levels so that countries have a guide.
- The text should stress the importance of breastfeeding.

- There is a risk of expanding trade to developing countries that do not want the product. If core mandatory components are reduced, then unsuitable nutrients might be added for which claims might be made.
- Key principles of Codex to ensure protecting the health of consumers and fair practices in food trade should be followed.
- The Committee should work on a harmonised product with core common agreements and not lose sight of the goal of achieving a product similar to breast milk.

75. The Committee agreed to the principles as amended (para. 72).

#### **Framework for Optional Addition**

76. The Committee discussed a revised proposed wording for section 3.2 of the draft standard.

77. Senegal with support from Togo raised concerns that it was not possible to quantify optional compositional requirements when exact levels for these substances had not been indicated.

78. A preference was expressed for a principle-based approach rather than inclusion of any nutrients in a list. It was further stated that additions should be chosen from the essential composition of follow-up formula for older infants. This view was based on the recommendations by EFSA that formula consumed during the first year can continue to be used by young children. It was noted that this option would provide more guidance, and, to a greater extent, ensure that follow-up formula for young children were safe.

79. The Committee agreed on the proposed text for section 3.2.3 as amended.

#### **Energy density**

80. The Committee agreed on the proposed text for section 3.1.2.

#### **Energy contribution from macronutrients**

81. The Committee:

- i. agreed to set maximum levels for available carbohydrate and minimum levels for protein and fat;
- ii. agreed to set a minimum level for protein of 1.8 g/100 kcal;
- iii. noted that levels for available carbohydrate that were considered included values of 12, 12.5 and 14 g/100 kcal;
- iv. noted that levels for fat that were considered included 3.5, 4.0 and 4.4 g/100 kcal;
- v. agreed that no minimum level would be set for carbohydrate and no maximum levels for protein and fat;
- vi. noted that the information in CRD17 could serve as a guide for further discussions on these levels to further consider specific levels for maximum carbohydrate and minimum fat at the next session.

#### **Protein quality**

82. There was widespread support to establish protein quality requirements. In discussing the need to include minimum protein quality requirements the following views were expressed:

- It was stated that there was no need for a level of protein quality if the definition included reference to suitable ingredients (as referenced in 3.1.1 of section B).
- If the Committee wished to set a value of not less than 85% of casein, then questions arose if it applied only to the Protein Efficiency Ratio (PER) method and/or the Protein Digestibility Corrected Amino Acid Score (PDCAAS).
- Reference to a certain quality level of protein should be maintained.
- There would be a concern that other plant base proteins may not be of appropriate quality to support growth if this requirement were removed.

83. In response to a question on the use of DIAAS (Digestible Indispensable Amino Acid Score), the Representative of FAO clarified that the DIAAS method for protein quality assessment was not yet ready. He advised that for an interim period the PDCAAS method should be used. FAO would consider convening an expert consultation to provide guidelines.

84. The Committee agreed that the quality of protein shall not be less than 85% of that of casein and agreed to the proposed text on methods to determine protein quality.

#### **Quality of Dietary Fat**

85. The Committee agreed to include a mandatory requirement for  $\alpha$ -linolenic acid as proposed by the pWG

(50 mg/100 kcal) and the mandatory requirement for linoleic acid at 300 mg/100 kcal.

86. The EU stated that they were not aware of any deficiency of linoleic acid in the EU. However as this is a health concern in other regions they agreed to include and accept the proposed level on the understanding that the statement in section 3.1.4. applies.

#### **Commercially Hydrogenated oils**

87. The Committee agreed that partially hydrogenated oils and fats should not be used due to health concerns regarding trans-fatty acids.

#### **Types of carbohydrates**

88. The Chair of the pWG explained that the issue related to a footnote to specify suitable carbohydrates to be used in product for young children.
89. The Committee agreed that lactose should be the preferred type of carbohydrate and that the reference to gluten-free precooked and/or gelatinised starches could be removed due to diversity of the young child's diet.
90. The Committee agreed to continue discussing the limits on sugars as it was not yet possible to reach consensus on the maximum level for sugars as a percentage of available carbohydrates until a decision has been taken on the maximum level for carbohydrates (see para 81) and on a wording regarding limiting carbohydrates that contribute to the sweet taste.

#### **Iron and vitamin C levels**

91. The Committee agreed to the recommendation of the pWG.
92. The EU agreed to accept the proposed levels (due to possible health concerns in other regions) on the understanding that the statement in section 3.1.4. applies.

#### **Calcium, riboflavin and vitamin B12 levels**

93. Some Members supported including a calcium to phosphorus ratio for nutritional integrity and to retain a nutritionally balanced product.
94. The Committee agreed to the recommendation of the pWG for the minimum, maximum and GUL values for calcium, riboflavin and vitamin B12 and to discuss further the calcium: phosphorous ratio.
95. The EU agreed to accept the proposed levels (due to possible health concerns in other regions) on the understanding that the statement in section 3.1.4. applies.

#### **Zinc**

96. The Chair of the pWG reported widespread support that zinc should be included as a mandatory nutrient as it met the amended principle 1 and was widely inadequate in the diets of young children. This view was not supported by the EU as it was not deemed to meet any of the principles for mandatory addition. It was stated that zinc inadequacy was not an issue in Europe, and therefore not a global issue; nor was cows' milk a significant contributor of zinc in the diet.
97. The Committee agreed to a Guidance Upper Level (GUL) of 1.5 mg /100 kcal.

#### **Vitamin A**

98. The Chair of the pWG reported widespread support that vitamin A should be included as a mandatory nutrient as it met the amended principle 1 and was widely inadequate in the diets of young children.
99. In discussion, the following views were expressed:
- There was originally agreement to establish a smaller number of core nutrients and then consider additional ones. There is a problem with mandatory addition.
  - Milk is a significant source of vitamin A. Taking min/max values of 48-75 µg RE/100 kcal would be safer.
  - The maximum level proposed is that of CODEX STAN 72-1981 and it is therefore appropriate to keep the maximum level at 180 µg RE/100 kcal.
  - Codex standards are used by countries to develop their health systems and programmes. These countries do require levels as they may not have the resources to determine their own levels as this would require data collection.
  - Fortification would have to be supported by a rationale of the targeted audience and reduce the concern of over consumption.
  - There are no toxicological problems that are applicable to this age group.

100. Norway expressed their concern that the value of 180 µg RE/100 kcal was too high and that those in the 12-36 months age range received vitamin A from a progressively diversified diet. They proposed a value of 120 µg RE/100 kcal (an average taken from full fat milk and 180 µg RE/100 kcal from infant formula) which was also in line with EFSA advice and higher than the breast milk level of 85 µg RE/100 kcal. The EU also shared this concern.
101. The Committee agreed to the text and the values for vitamin A as proposed by the pWG.
102. The EU and Norway expressed their reservation to this decision.

#### **Vitamin D**

103. The Committee agreed to continue discussing these values.

#### **Sodium**

104. The Committee agreed not to set any values but to state that “*Sodium chloride should not be added to [name of the product] for young children*”.

#### **Scope**

105. There was widespread support to differentiate the two products in the scope and labelling sections (and throughout the document) between *older infants* and then *younger children*, adopting the same approach as that for compositional requirements.
106. There was also very broad support to include references to the *International Code of Marketing of Breast-milk Substitutes* (1981), the *Global Strategy for Infant and Young Child Feeding* and all relevant World Health Assembly resolutions and WHO guidelines in the scope of the draft Standard. These included WHA 39.28, WHA 63.23 and WHA 69.9.
107. Members and Observer organizations also underlined the importance of aligning the scope of this draft standard with that of the *Standard for Infant Formula and formulas for Special Medical Purposes Intended for Infants*.
108. The Committee discussed the alternatives and relative advantages of including relevant WHO guidelines and WHA resolutions in the scope of the standard or either as a preamble or introduction.
109. The Codex Secretariat, in response to the question of the status of the preamble or introduction, clarified that from a legal point of view everything that was written in the standard was an integral part of the standard. She reminded the Committee that it should also consider the requirements of the *Format for Codex Commodity Standards* (Procedural Manual) when developing this text and that the scope should contain a clear and concise statement.
110. The Representative of WHO supported the proposal to use the contents of the scope from the *Standard for Infant Formula and formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981) which include references to the *International Code of the Marketing of Breast-milk Substitutes* and relevant WHA resolutions, but the reference to WHA resolutions should be expanded to include recent relevant WHA resolutions, including 69.9.
111. In response to the question raised regarding whether FUF for young children is considered as a breast milk substitute, the Representative of WHO stated that in accordance with the new WHO Guidance on ending the inappropriate promotion of foods for infants and young children from 6 to 36 months of age (which had been accepted by Member States through adoption of resolution WHA69.9), both products for older infants (6 to 12 months) and young children (12 to 36 months) are considered as breast-milk substitutes and therefore, they will be covered by the *International Code of Marketing of Breast-milk Substitutes*.
112. This statement was supported by India and other delegations and observers.
113. The Committee agreed that:
- i. the scope from the *Standard for Infant Formula and formulas for Special Medical Purposes Intended for Infants* should be the starting point for this standard;
  - ii. the reference to relevant WHO guidelines and WHA resolutions could either be included in a preamble to the standard or in the scope;
  - iii. all remaining matters could be considered in the eWG.

#### **Labelling**

114. The Chair of the eWG noted that the section of the standard regarding older infants could be aligned with the infant formula standard but raised the question of labelling in the standard for young children.
115. There was widespread support for differentiating between the two age groups with appropriate labelling for

each. It was also noted the importance of differentiating between products that are nutritionally appropriate and those products that are not substitutes for breast-milk.

116. It was noted that the issue of whether the products should be considered breast-milk substitutes or not would be considered by the eWG.
117. In response to the concern raised about the current language contained in section 9.6, stating that the products covered by the standard are not a breast milk substitute, the Representative of WHO stated that as the products currently under consideration for inclusion in the standard are considered as breast milk substitutes in the new WHO Guidance, they are therefore covered by the *International Code of Marketing of Breast-milk Substitutes* and their labelling requirements and promotion must be informed by relevant Code provisions and resolutions, and by relevant Guidance recommendations. Language to this effect should be added to the section on labelling. This would ensure consistency with the proposed statements under the scope (or preamble) of the standard referencing the Code and relevant resolutions.
118. It was requested that the eWG also examine the promotional aspect as well as misleading claims, especially misleading health claims.
119. Observer organisations noted the need to clearly state that the products should not be used for younger infants as there was a risk of inadequate nutritional input. They also stated there should be a statement that the products were not necessary and a positive message about continued breast feeding.
120. In response to a question as to whether Codex standards also extended to promotional practices, the Secretariat clarified, that while Codex could deal with issues of advertising it did not have specific guidelines for marketing. Any labelling conditions would be referred to CCFL and a possible solution could be to refer to the WHO guidelines and WHA resolutions in the preamble to the standard.
121. India requested the Committee to include the WHA resolutions 54.2 and 69.9 in the labelling of the draft standard on follow-up formula for older infants and young children.

### Conclusion

122. The Committee agreed to establish an eWG, hosted by New Zealand and co-hosted by France and Indonesia, working in English with the following terms of reference:
  - i. Finalise the minimum protein requirements and levels for the optional addition of DHA on the Essential Composition of Follow-up Formula for older infants (6-12 months) (Sub-section 3 of Section A);
  - ii. Finalise the outstanding requirements for the Essential Composition of product for young children (12-36 months) (Sub-section 3 of Section B);
  - iii. Finalise the product definitions contained within Definition 2.1 including the name of product for 12-36 months;
  - iv. Review the Scope and Labelling Sections with a point of differentiation at 12 months, for Section A and Section B of the draft Standard based on the discussions at CCNFSDU38, and propose draft text.
123. The points for further discussion and consideration as indicated in Appendix IV will be circulated for comments at Step 3 and forwarded to the eWG as a starting point for their discussion.
124. The eWG will consider working via the online platform currently being used for eWGs and will report back to the Committee at its next session.
125. All other requirements on which agreement has been reached will be held at Step 4 (Appendix IV).
126. Subject to the outcome of the eWG, consideration will be given to convening a pWG chaired by New Zealand and co-chaired by France and Indonesia prior to the next session.
127. The proposed timeline for the development of the draft standard would be: adoption at Step 5 in 2018 with a view to adoption by CAC in July 2019. The CCEXEC would be informed accordingly.

### PROPOSED DRAFT DEFINITION FOR BIOFORTIFICATION (Agenda Item 6)<sup>14</sup>

128. Zimbabwe, as the co-Chair of the eWG, introduced document CX NFSDU 16/38/8 and noted that the eWG had revised the nine criteria to 6 (six); and based on these, a draft definition had been developed. Accordingly the eWG made five recommendations for consideration by CCNFSDU.

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<sup>14</sup> CX/NFSDU 16/38/7; CX/NFSDU 16/38/7 Add.1 (comments from Australia, Brazil, Canada, Costa Rica, Cuba, El Salvador, Guatemala, New Zealand, Nicaragua, Panama, Paraguay, Philippines, ICBA, ICGMA, IFPRI and IFT); CX/NFSDU 16/38/7 Add.2 (comments from Ghana, Malaysia, Mexico, United States of America, FoodDrinkEurope and IBFAN); CRD 7 (comments from Ecuador, European Union, India, Nigeria, Peru, Thailand and African Union); CRD 14 (comments from Benin).



129. The Chairperson proposed to the Committee to first discuss recommendation 1 (Criteria) and recommendation 2 (the definition for biofortification) before considering other recommendations.

### General Comments

130. The Committee noted the following general comments made by delegations:
- The scope of the draft definition was too large; covered many different processes, including modern biotechnology (GMOs); and there was no clarity on what exactly it would cover; and the use of such a definition as a claim was of great concern, due to the potential risk of its misuse and misleading consumers.
  - Issues related to biofortification could be better addressed through use of existing Codex Standards instead of by establishing a definition. The definition of biofortification was considered to be an important concept for the academic world rather than for Codex.
  - The definition should focus on the meaning of biofortification and exclude its purpose.
  - The definition should be broad; cover pre-processing aspects of food production; and should ensure that safe food is secured for the population.
  - The background paper on biofortification by FAO and the Cochrane review by WHO should be taken into account.
  - Concern was expressed about a single nutrient approach rather than promotion of diversified diets.
  - In several countries the term biofortification would be difficult to use because of its close connotation with organic agriculture.
131. An observer informed the Committee about some aspects of their genetic selection programme which starts with the Svalbard Global Seed Vault. This selection is then followed by conventional breeding for high micronutrient content in staple food crops.
132. The Representative of FAO clarified that the FAO background paper on “Biofortification: A food-based approach for improving micronutrient intake” would provide information on the biofortification process, as part of a broader portfolio of food-based approaches to prevent micronutrient deficiencies. However, and as indicated in para. 20, the report expects CCNFSDU to provide a definition.
133. The Chairperson clarified that CCNFSDU<sup>15</sup> had decided that the definition would be broad enough to cover the various organisms and methods of biofortification and sufficiently detailed to distinguish between them.

### Recommendation 1 (Criteria)

134. The Committee considered all the six criteria in general, proposed changes and made the following specific comments:

#### Criterion 1

135. Animal feed and fertilisers should be excluded from this criterion as well as methods of production as they are considered under criterion 6.

#### Criterion 2

136. This criterion should not only cover essential nutrients but all nutrients (micro and macro) as defined in the *Guidelines on Nutrition Labelling (CAC/GL 2-1985)*.

#### Criterion 3

137. This criterion is directly linked to nutrient bioavailability rather than level of nutrient absorption – a term that is already covered in the *Nutritional Risk Analysis Principles and Guidelines for Application to the Work of CCNFSDU*. Increased absorption would be difficult to measure and enforce.

#### Criterion 4

138. The general purpose should be the goal of improved nutritional quality for human health.

#### Criteria 5

139. There should be a significant increase in nutrient levels beyond the normal variation.
140. It was noted that it would not always be possible to have consistent nutrient levels because of natural variation.
141. Measurable levels of nutrients were directly linked to nutritional quality of food. The improvement could be made by either increasing the nutrient (e.g. zinc) or decreasing the anti-nutrient (e.g. phytate). Thus

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<sup>15</sup> REP15/NFSDU para 163

measurement of suitable change may require measure in food or in the consumer (i.e. bioavailability).

142. The increased levels of nutrients in biofortified food should be significant (or higher) than the natural variation when compared to non-biofortified food. The criterion should be clarified further to indicate that the increase in nutrient levels was in the food.

#### Criterion 6

143. There is need to further discuss this criterion especially: coverage (prior to processing); methods of production which should be carefully defined and harmonised; the role of Competent Authorities, and how to avoid potential trade restrictions that could arise from production methods.
144. Food processing, and addition of essential nutrients to food during normal processing should be excluded from this criterion as this type of addition is covered by *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987).

#### Other proposals

145. One Observer noted the need to establish a new criterion that would ensure that food was not produced using unsafe technologies and that such a criterion would require an independent and rigorous evaluation of such food.

#### **Conclusion**

146. The Committee noted that there was need for further discussion on some of the criteria especially criterion 6 (Methods of production and its corresponding footnote) and agreed to:
- i. re-establish an eWG hosted by Zimbabwe, and co-hosted by South Africa and working in English only to revise the criteria on the basis of the discussion at the session and the written comments submitted to the session, and to further develop the definition on biofortification for consideration its next session;
  - ii. revise the timelines for completion of the work to 2018 by CCNFSDU and adoption by the Commission in 2019, and accordingly inform CCEXEC.
147. The Committee agreed to consider recommendations 3-5 at the next session.

#### **PROPOSED DRAFT NRV-NCD for EPA and DHA LONG CHAIN OMEGA-3 FATTY ACIDS (Agenda item 7)<sup>16</sup>**

148. The Russian Federation, as co-chair of the eWG speaking on behalf of the co-chair, Chile, introduced the item and presented the results of the eWG.
149. The co-Chair reported that:
- in the eWG discussion, a number of member countries continued to question if EPA and DHA were the right nutrients for an NRV-NCD considering that the relation with cardiovascular health was not well characterized.
  - at the request of some member countries, the co-chairs had reviewed the strength of evidence presented in 13 recent systematic reviews and meta-analyses relevant to the PICO question, formulated in line with WHO methodology, under the GRADE classification; and
  - 22 scientific and expert organisations were proposed by members and shortlisted as listed in CX/NFSDU 16/38/8. In selecting RASBs, the eWG expressed different views on the RASB selection, which originated from different interpretations of 3.1.2 of the General Principles for Establishing Nutrient Reference Values for General Population (Annex to the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985).
150. Based on all the evidence a proposal for an NRV-NCD of 250 mg/day was proposed.
151. The Representative of WHO informed the Committee of the status of the systematic reviews being carried out on polyunsaturated fatty acids (PUFA) as part of the guideline development by the NUGAG Subgroup on Diet and Health. The critical and important health outcomes identified for PUFA reviews for adults include cardiovascular mortality, cardiovascular events, coronary heart disease (including lipids), stroke, all-cause mortality, neuro-cognition (including dementia), type 2 diabetes, depression, breast cancer, atrial fibrillation, inflammatory bowel disease and measures of adiposity. The NUGAG meeting held three weeks ago reviewed the preliminary outcomes of the systematic reviews and the analysis of RCTs on n-3 LC-PUFA in adults, suggested no effects on cardiovascular events and mortality. Regarding other critical and important health

<sup>16</sup> CX/NFSDU 16/38/8; CX/NFSDU 16/38/8 Add.1 (comments from Canada, Colombia, Cuba, Ghana, Mexico, New Zealand, Paraguay, Philippines, CRN, ELC, GOED, IADSA, ICGMA and ISDI); CX/NFSDU 16/38/8 Add.2 (comments from Brazil, Costa Rica, Japan and the United States of America); CRD 8 (comments from Ecuador, European Union, Peru, Thailand and African Union); CRD14 (comments from Benin).

outcomes, the systematic reviews seemed to indicate no effect on any outcomes other than a small non-significant increase in HDL and decrease in triglycerides. An initial analysis of some cohort studies which reviewed fish oil and food sources with n-3 LC-PUFA as exposure seemed to suggest a non-significant decrease in all-cause mortality. The systematic reviews of both RCTs and cohort studies are currently being finalised and planned for completion in April 2017.

152. The representative further offered to present the final outcomes of the systematic reviews and analysis of NUGAG in a side-event at CCFNSDU39.

### **Conclusion**

153. In view of the decision of CCFNSDU37 for the need to take into account the work of NUGAG, the Committee agreed to defer discussion until the next session. In addition it was agreed that a discussion would be held at the next session on the interpretation of 3.1.2 of the *General Principles for Establishing Nutrient Reference Values for General Population*.
154. The Committee agreed to re-establish the eWG, hosted by Russia and Chile, working in English to take into account the final report of NUGAG and to make recommendations for an NRV-NCD for consideration by CCFNSDU at the next session.
155. The Committee agreed to a new timeline for completion of the work by 2018 and to inform the CCEXEC accordingly.

### **PROPOSED DRAFT GUIDELINE FOR READY-TO-USE THERAPEUTIC FOODS (Agenda item 8)<sup>17</sup>**

156. South Africa as chair of the eWG, speaking on behalf of the co-Chairs Senegal and Uganda, introduced the item. He reviewed the process followed by the eWG and presented the Committee with a series of recommendations for their consideration.

#### **Recommendation 1 - Purpose**

157. The Committee agreed on the wording and outline structure of the purpose of the guideline.

#### **Recommendation 2 – Scope**

158. Discussion focussed primarily on the targeted age range for the guideline of 6-59 months. Members and Observers noted that while it was true that ready-to-use therapeutic foods (RUTF) were given to other age groups, the primary focus for treating severe acute malnutrition (SAM) was on the stated range of 6-59 months and this should remain the priority. Developing a guideline with a more open age range would make it more difficult to set a definition of SAM or the compositional and nutritional requirements.
159. Regarding the question on the age limitation of 6–59 months, the Representative of WHO stated that WHO guidelines and other related documents use the age range of 6–59 months, but the definition of RUTF in the 2007 Joint Statement states “children from the age of six months”, as noted by an observer. The Representative confirmed this was not a contradiction as RUTF were also used by older children (or even by adults who are severely malnourished) and as mentioned by UNICEF, the dose of RUTF is adjusted according to the body weight of the child under treatment.
160. It was noted that a preamble or introduction to the guideline could be another option for the eWG when working on the development of the text relating to appropriate use.
161. Other suggestions included use of a preamble to state the importance of integration of RUTF into sustainable local family based solutions and breastfeeding from 6 months. A reference to the *Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions* (CAC/RCP 20-1979) could be made.
162. The Secretariat noted that an introduction or preamble could set the scene for the guideline and the eWG should try and expand on this aspect and then reference how the guideline should be used.
163. The Committee agreed to the recommendation for scope and to task the eWG with elaborating an introduction or preamble for discussion at the next meeting.

#### **Recommendation 4 - food additives and 12b - contaminants**

164. The Committee agreed that the eWG should discuss raw materials and ingredients before deciding which other Codex committees may have to be consulted.

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<sup>17</sup> CX/NFSDU 16/38/9; CX/NFSDU 16/38/9 Add 1 (comments from Brazil, Canada, Colombia, Cuba, Ecuador, El Salvador, Paraguay, Philippines, ELC, HKI, IACFO, IBFAN, IDF, ISDI and UNICEF); CX/NFSDU 16/38/9 Add.2 (comments from Ghana, Japan and United States of America); CRD 9 (Comments from Ecuador, El Salvador, European Union, India, Kenya, Mexico, Nigeria, Thailand, African Union and FEDIOL); CRD 14 (comments from Benin).

**Recommendation 11 - quality of protein**

165. The Representative of FAO confirmed that in the interim the PDCAAS method should be used as DIAAS was not yet completed. The RUTF would be added to the terms of reference of the guidelines in using PDCAAS methods as referenced in para 83 so that a guideline could be produced in the shortest possible time.

**Conclusion**

166. The Committee agreed to establish an eWG, hosted by South Africa and co-hosted by Senegal and Uganda and working in English and French to continue to develop the proposed guideline for circulation for comments at Step 3 and consideration at the next session.

**DISCUSSION PAPER ON CLAIM FOR “FREE” OF TRANS FATTY ACIDS (Agenda Item 9)<sup>18</sup>**

167. Canada introduced document CX/NFSDU 16/38/10, and informed the Committee that CCNFSDU36 had agreed to wait for the outcome of the NUGAG report and also to take into account the reply from CCMAS before the claim from free of Trans Fatty Acids (TFA) could be further considered. Based on advice from CCMAS and the latest scientific information from WHO, the discussion paper had been revised and a new proposal made. A value of 1 g of TFA per 100 g of fat was proposed. Canada also stated that according to the two WHO systematic reviews, trans fatty acids and saturated fatty acids were both reported to have an effect on the blood lipid profile and, therefore, the conditions for the claim of free of saturated fats should be kept as part of a claim on free of TFA.
168. On the methods of analysis for TFA, Canada noted that comments made at CCNFSDU36 and CCMAS36 that “the methods of analysis for determining TFAs should be practical and internationally accepted as well as being reliable and consistently reproducible” were valid. Based on these comments, three options were now available for recommendation to CCMAS depending on the food matrix.
169. One delegation while supporting the three options, expressed a concern that the determination of TFA using the proposed methods was rather complex and some countries did not have the required resources. Many developing countries, especially in the Near East and South East Asia where TFA consumption is high, required support in the development in capacity of trans fat analysis.

**Conclusion**

170. Noting the importance of methods of analysis to the question of TFA, the Committee agreed to first request CCMAS to review if the three methods were applicable to determine TFA as defined in both the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) and the WHO definition – at least one double bond in the trans configuration - at the level of 1 g per 100 g of fat. Based on the reply from CCMAS, the Committee would consider the proposed level for the claim.

**ALIGNMENT OF FOOD ADDITIVE PROVISIONS IN STANDARDS DEVELOPED BY CCNFSDU (Agenda Item 10)<sup>19</sup>**

171. The Codex Secretariat introduced document CX/NFSDU 16/38/11 and recalled the decision of CCNFSDU37 to start work on alignment of food additives in the commodity standards under its mandate in line with the recommendation of CCFA. The Secretariat further noted that the document also proposed to establish an eWG to explore the alignment of food additive provisions and develop a framework on how to address the question on technological justification of substances prior to being proposed for evaluation by JECFA for their potential use as additives in commodity standards developed by CCNFSDU.

**General consideration**

172. The Committee reaffirmed that the use of food additives in food intended for babies should be kept to a minimum and recalled the basic principle on the use of additives in baby foods as set out by JECFA and adopted by CAC i.e. “*Baby foods should be prepared without food additives whenever possible. Where the use of a food additive becomes necessary in baby foods, great caution should be exercised regarding both the choice of additive and its level of use.*” (JECFA, 1971, Annex 3 of TRS 488).
173. The Committee further noted that, CCFA was currently developing guidelines to be used by commodity committees to undertake work on alignment; and that it would be important to take into account such guidance when undertaking the work of alignment of food additives by CCNFSDU.

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<sup>18</sup> CX/NFSDU 16/38/10; CRD 10 (comments from India, Indonesia, Kenya, Malaysia, Nigeria, United States of America, African Union, IDF and IFMA); CRD 14 (comments from Benin); CRD 16 (Comments from Republic of Korea).

<sup>19</sup> CX/NFSDU 16/38/11; CRD 11 (comments from Nigeria, Thailand, African Union, IFMA and ISDI); CRD 14 (comments from Benin).

### Technological justification

#### *Xanthan gum (INS 415) and Pectin (INS 440)*

174. The observer from ISDI informed the Committee that CCNFSDU36 had recommended the evaluation of Xanthan gum (INS 415) and Pectin (INS 440), by JECFA, for use as a thickener in the *Standard for Infant Formula and Formulas for Special Medical Purposes intended for Infants* (CODEX STAN 72-1981), Section B. The Committee's attention was also drawn to the recent evaluation by JECFA82 (June 2016) that had recommended the two additives were safe for use in this product at the specified levels. ISDI, supported by several observers, requested CCNFSDU to consider including these two additives in CODEX STAN 72-1981.
175. The Chairperson noted that members had not had sufficient time to study the information on technological justification provided on the two additives (CRD11), and proposed to refer the substances to the eWG for consideration and to discuss the outcome at the next session.

#### *Gellan gum (INS 418)*

176. Regarding the technological justification on the use of gellan gum (INS 418) in infant formula, formulas for special medical purposes intended for infants, and follow-up formula, the Committee noted that in the European Union, these products were being produced without the use of gellan gum and in the EU's view, gellan gum was not necessary and not technologically justified for use in these foods. This view was supported by other delegations.
177. Noting that confirmation of the technological need was required to support JECFA evaluation of gellan gum (INS 418), the Committee agreed to refer the matter to the eWG for consideration and agreed to inform CCFA that reply would be provided at a future date.

### Conclusion

178. In light of the above discussion the Committee agreed to:
- i. Defer the alignment of food additives, until the guidance document on alignment of additives is finalized by CCFA;
  - ii. Establish an eWG, hosted by the European Union, and co-hosted by the Russian Federation working in English with the following terms of reference:
    - a) Propose a mechanism or framework for considering the technological justification for substances intended for inclusion on the priority list of substances for JECFA evaluation;
    - b) To consider and confirm the technological justification of gellan gum; and
    - c) To propose how to handle new substances that have already been evaluated by JECFA, but for which technological justification has not yet been confirmed by CCNFSDU (i.e. xanthan gum, pectin).

### OTHER BUSINESS AND FUTURE WORK (Agenda item 11)<sup>20</sup>

#### **Methods of analysis for provisions in the *Standard for infant formula and formulas for special medical purposes intended for infants* (CODEX STAN 72-1981)**

179. The Committee considered the report of the in-session working group and took the following decisions:

#### Chromium, selenium and molybdenum: review of criteria

180. The Committee agreed:
- i. to inform CCMAS that it did not support using the criteria approach because:
    - a) a general or single conversion factor to convert  $\mu\text{g}/100\text{kCAL}$  to  $\mu\text{g}/\text{g}$  should not be used, as the energy density of infant formula varies across products; and
    - b) none of the current methods in CODEX STAN 234-1999, nor the newer methods AOAC 2011.19 | ISO 20649 | IDF 235 meet the criteria (REP16/MAS, para. 31).
  - ii. to request that CCMAS reconsider the method for chromium, selenium and molybdenum, AOAC 2011.19 | ISO 20649 | IDF 235 as Type II in light of published validation data measuring the minimum level for chromium, selenium and molybdenum in CODEX STAN 72-1981, and
  - iii. to inform CCMAS that the other methods for chromium, selenium and molybdenum other than the AOAC method were still fit for purpose and to reconsider their classification, if necessary.

<sup>20</sup> CX/NFSDU 16/38/2; CX/NFSDU 16/38/12; CRD 12 (comments of Mexico, Nigeria, Thailand, African Union and ISDI); CRD 14 (comments from Benin); CRD 18 (Report of the in-session working group on methods of analysis).

181. In response to the concerns expressed with regard to the inclusion of methods requiring expensive instrumentation and the typing of these methods as Type II, it was clarified that the method was for dispute settlement purposes and that for routine analysis, other methods were available and could be used.

#### Vitamin B12

182. The Committee confirmed that the existing method, AOAC 986.23, is fit for purpose.
183. The Committee noted that the method AOAC 2011.10 | ISO 20634 had already been endorsed by CCMAS and should be sent to CAC for adoption (Appendix V).

#### Total fatty acid profile

184. The Committee agreed to inform CCMAS that the current method, AOAC 996.06, is fit for purpose and agreed with its classification as Type III. Method AOAC 2012.13 endorsed by CCMAS should be sent to CAC for adoption (Appendix V).
185. The Committee requested that the provision be retained as “total fatty acid” profile to maintain consistency with the term used in CODEX STAN 72-1981.

#### Myo-inositol and Vitamin E

186. The Committee confirmed that the definition and scope of the methods harmonize and should be sent to CAC for adoption (Appendix V).
187. A delegation noted that CODEX STAN 72-1981 recognizes forms of vitamin E as  $\alpha$ -tocopherol, while the *Advisory List Of Nutrient Compounds For Use In Foods For Special Dietary Uses Intended For Infants And Young Children* (CAC/GL 10-1979) lists DL- $\alpha$ -tocopherol forms which have half of activity of D form and could lead to a slight over-estimation depending on use of DL- $\alpha$ -tocopherol nutrient forms. The observer from AOAC confirmed that the method can measure either form, but cannot separate DL forms from L forms, and that at present there were no other validated methods, but that studies were ongoing.

#### Formula for the conversion of units

188. The Committee agreed to inform CCMAS that it did not recommend an explanatory text on conversion of units in CODEX STAN 72-1981.

#### Vitamin C

189. The Committee agreed to submit the method, AOAC 2012 | ISO/DIS 20635 for review, classification as Type II, endorsement and inclusion in CODEX STAN 234-1999 in Part A, section “foods for special dietary uses: with the description “infant formula”.
190. The Committee also agreed to request CCMAS to remove or reclassify methods that are not validated for infant formula in CODEX STAN 234-1999 that might be replaced by the abovementioned method.

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

191. The Committee was informed that the 39<sup>th</sup> Session was scheduled to be held in Berlin, Germany from 4 to 8 December 2017, the final arrangements being subject to confirmation by the host government in consultation with the Codex Secretariat.

## APPENDIX I

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## APPENDIX II

**AMENDMENT TO PROCEDURAL MANUAL: THE NUTRITIONAL RISK ANALYSIS PRINCIPLES AND GUIDELINES FOR APPLICATION TO THE WORK OF THE COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (SECTION 6 – SELECTION OF RISK ASSESSOR BY CCNFSDU)****(for adoption)****(Note: amendments in bold and underlined)**

33. Consistent with their important role in providing scientific advice to the Codex Alimentarius Commission and its subsidiary bodies, FAO and/or WHO, including the FAO/WHO Joint Expert Meetings on Nutrition (JEMNU), are acknowledged as the primary source of nutritional risk assessment advice to Codex Alimentarius. This acknowledgement however, does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies, as approved by the Commission.

**AMENDMENTS TO NUTRITION STANDARDS (RELATED TO FLAVOURINGS)****(for adoption)****STANDARD FOR CANNED BABY FOODS****CODEX STAN 73-1981****4.5 Flavourings**

4.5.1 Vanilla extract Limited by good manufacturing practice

4.5.2 Ethyl vanillin 7 mg

4.5.3 Vanillin 7 mg

**STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN****CODEX STAN 74-1981****3.9 Flavourings**The following **flavourings** may be used:

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

**STANDARD FOR FOLLOW-UP FORMULA****CODEX STAN 156-1987****4.5 Flavourings**

4.5.1 Natural Fruit Extracts GMP

4.5.2 Vanilla extract GMP

4.5.3 Ethyl vanillin 5 mg

4.5.4 Vanillin 5 mg

## GUIDELINES ON FORMULATED COMPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN

CAC/GL 8-1991

### 4.2.2 Food additives and flavourings

Food additives and flavourings listed in the *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CODEX STAN 74-1981) and the *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).

## APPENDIX III

**PROPOSED DRAFT AND DRAFT REVISED NUTRIENT REFERENCE VALUES AND  
CONVERSION FACTORS FOR LABELLING PURPOSES IN THE *GUIDELINES ON NUTRITION  
LABELLING (CAC/GL 2-1985)***

(for adoption at Step 8 and Step 5/8)

**3.4.4.1 NRVs-R**

<b>Vitamins</b>	
Vitamin D <sup>1</sup> (µg)	5 – 15*
Vitamin E <sup>2</sup> (mg)	9

\* The value of 15 µg is based on minimal sunlight exposure throughout the year. Competent national and/or regional authorities should determine an appropriate NRV-R that best accounts for population sunlight exposure and other relevant factors

**Conversion factors for vitamin equivalents (for adoption at Step 5/8)**

<b>Vitamin</b>	<b>Dietary equivalents</b>	
Vitamin E	1 mg α-tocopherol	1 mg RRR- α-tocopherol (d- α-tocopherol)

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<sup>1</sup> For adoption at Step 5/8

<sup>2</sup> For adoption at Step 8

**PROPOSED DRAFT REVISED STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987)****(Section A: All text held at Step 4, except for those sections in square brackets, which are at Step 3)<sup>1</sup>****SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS****3. ESSENTIAL COMPOSITION AND QUALITY FACTORS****3.1 Essential composition**

3.1.1 **Follow-up formula for older infants** is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of older infants.

The nutritional safety and adequacy of follow-up formula for older infants shall be scientifically demonstrated to support growth and development of older infants.

3.1.2 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than 70 kcal (293 kJ) of energy

3.1.3 Follow-up Formula prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GUL), as appropriate.

**a) Protein<sup>2), 3), 4)</sup>**

Unit	Minimum	Maximum	GUL
g/100 kcal	[1.8] <sup>5),6)</sup>	3.0	-
g/100 kJ	[0.43] <sup>5),6)</sup>	0.72	-

<sup>2)</sup> For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.

<sup>3)</sup> For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981)); nevertheless for calculation purposes the concentrations of tyrosine and phenylalanine may be added together and the concentrations of methionine and cysteine may be added together.

<sup>4)</sup> Isolated amino acids may be added to follow-up formula only to improve its nutritional value for infants. Essential and semi-essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L-forms of amino acids shall be used.

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

<sup>6)</sup> Follow-up formula based on non-hydrolysed milk protein containing [1.61 – 1.8 g] protein/100 kcal should be clinically evaluated by a competent national and/or regional authority. Follow-up formula based on hydrolysed protein containing less than [2.25 g protein/100 kcal] should be clinically evaluated].

<sup>1</sup> Parts in square brackets (at Step 3) for comments and discussion in EWG.



**b) Lipids****Total Fat** <sup>7),8)</sup>

Unit	Minimum	Maximum	GUL
g/100 kcal	4.4	6.0	-
g/100 kJ	1.1	1.4	-

<sup>7)</sup> Partially hydrogenated oils and fats shall not be used in follow-up formula for older infants.

<sup>8)</sup> Lauric acid and myristic acids are constituents of fats, but combined shall not exceed 20% of total fatty acids. The content of trans fatty acids shall not exceed 3% of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in infant formulae. The erucic acid content shall not exceed 1% of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).

**Linoleic acid**

Unit	Minimum	Maximum	GUL
mg/100 kcal	300	-	1400
mg/100 kJ	72	-	335

**α-Linolenic acid**

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

\*N.S. = not specified

**Ratio linoleic acid/ α-Linolenic acid**

Min	Max
5:1	15:1

**c) Carbohydrates****Available carbohydrates**<sup>9)</sup>

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

<sup>9)</sup> Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20% of available carbohydrate.

**d) Vitamins****Vitamin A**

Unit	Minimum	Maximum	GUL
µg RE <sup>10)</sup> /100 kcal	75	180	-
µg RE <sup>10)</sup> /100 kJ	18	43	-

<sup>10)</sup> expressed as retinol equivalents (RE)

1 µg RE = 3.33 IU Vitamin A = 1 µg trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

#### Vitamin D

Unit	Minimum	Maximum	GUL
µg <sup>11)</sup> /100 kcal	1.0	3.0	-
µg <sup>11)</sup> /100 kJ	0.24	0.72	-

<sup>11)</sup> Calciferol. 1 µg calciferol = 40 IU vitamin D.

#### Vitamin E

Unit	Minimum	Maximum	GUL
mg α-TE <sup>12)</sup> /100 kcal	0.5 <sup>13)</sup>	-	5
mg α-TE <sup>12)</sup> /100 kJ	0.12 <sup>13)</sup>	-	1.2

<sup>12)</sup> 1 mg α-TE (alpha-tocopherol equivalents) = 1 mg d-α-tocopherol

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

#### Vitamin K

Unit	Minimum	Maximum	GUL
µg /100 kcal	4	-	27
µg /100 kJ	1.0	-	6.5

#### Thiamin

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

#### Riboflavin

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

#### Niacin <sup>14)</sup>

Unit	Minimum	Maximum	GUL
µg /100 kcal	300	-	1500
µg /100 kJ	72	-	360

<sup>14)</sup> Niacin refers to preformed niacin

#### Vitamin B<sub>6</sub>

Unit	Minimum	Maximum	GUL
µg /100 kcal	35	-	175
µg /100 kJ	8.4	-	41.8

**Vitamin B<sub>12</sub>**

Unit	Minimum	Maximum	GUL
µg /100 kcal	0.1	-	1.5
µg /100 kJ	0.024	-	0.36

**Pantothenic acid**

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

**Folic acid**

Unit	Minimum	Maximum	GUL
µg /100 kcal	10	-	50
µg /100 kJ	2.4	-	12

**Vitamin C<sup>15)</sup>**

Unit	Minimum	Maximum	GUL
mg /100 kcal	10	-	70 <sup>16)</sup>
mg /100 kJ	2.4	-	17 <sup>16)</sup>

<sup>15)</sup> expressed as L-ascorbic acid

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

**Biotin**

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

**e) Minerals and Trace Elements****Iron<sup>[17]</sup>**

Unit	Minimum	Maximum	GUL
mg /100 kcal	1.0	2.0	-
mg /100 kJ	0.24	0.48	-

<sup>[17]</sup> For Follow-up formula based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36/100 kJ) and maximum of 2.5 mg/100 kcal (0.6 mg/100 kJ) applies

**Calcium**

Unit	Minimum	Maximum	GUL
mg /100 kcal	50	-	180
mg /100 kJ	12	-	43

**Phosphorous**

Unit	Minimum	Maximum	GUL
mg /100 kcal	25	-	100 <sup>18)</sup>
mg /100 kJ	6	-	24 <sup>18)</sup>

<sup>18)</sup> This GUL should accommodate higher needs with soy formula.

**Ratio calcium/phosphorous**

Min	Max
1:1	2:1

**Magnesium**

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

**Sodium**

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

**Chloride**

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

**Potassium**

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

**Manganese**

Unit	Minimum	Maximum	GUL
µg /100 kcal	1.0	-	100
µg /100 kJ	0.24	-	24

**Iodine**

<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
µg /100 kcal	10	-	60
µg /100 kJ	2.4	-	14.3

**Selenium**

<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
µg /100 kcal	2	-	9
µg /100 kJ	0.48	-	2.2

**Copper<sup>19)</sup>**

<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
µg /100 kcal	35	-	120
µg /100 kJ	8.4	-	2

<sup>19)</sup> Adjustment may be needed in these levels for follow-up formula made in regions with a high content of copper in the water supply

**Zinc<sup>20)</sup>**

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

<sup>20)</sup> For Follow-up formula based on soy protein isolate a minimum value of 0.75 mg/100 kcal (0.18 mg/100 kJ).

**3.3.2 Optional Ingredients**

3.3.2.1 In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients or substances may be added to follow-up formula for older infants where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.

3.3.2.2 When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect, taking into account levels in human milk.

3.3.2.3 The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100kJ) in the Follow-up Formula ready for consumption shall not exceed the levels listed below. This is not intended to be an exhaustive list, but provides a guide for competent national and/or regional authorities as to appropriate levels when these substances are added.

**Taurine**

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

**Total nucleotides**

Levels may need to be determined by national authorities.

**Docosahexaenoic acid<sup>21)</sup>**

<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 kcal	-	-	<b>[to be fixed after the fat content has agreed upon]</b>

<sup>21)</sup> If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, a minimum level of [20 mg/100kcal] should be reached, and arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs.

**Choline**

<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg /100 kcal	-	-	50
mg /100 kJ	-	-	12

**Myo-inositol**

<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg /100 kcal	-	-	40
mg /100 kJ	-	-	9.6

**L-Carnitine**

Levels may need to be determined by national authorities.

3.3.2.4 Only L (+) lactic producing cultures may be used for the purpose of producing acidified follow-up formula for older infants. The acidified final formula product should not contain significant amounts of viable L (+) lactic acid-producing cultures, and residual amounts should not represent any health risk.

3.3.2.5 The safety and suitability of the addition of specific strains of L(+) lactic acid producing cultures for particular beneficial physiological effects, at the level of use, must be demonstrated by clinical evaluation and generally accepted scientific evidence. When added for this purpose, the final product ready for consumption shall contain sufficient amounts of viable cultures to achieve the intended effect.

**Section B (All text held at Step 4, except for those sections in square brackets which are at Step 3)**

**SECTION B: [NAME OF PRODUCT] FOR YOUNG CHILDREN**

**3. ESSENTIAL COMPOSITION AND QUALITY FACTORS**

**3.1 Essential composition**

3.1.1 **[Name of product] for young children** is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of young children.

The nutritional safety and adequacy of [Name of Product] for young children shall be scientifically demonstrated to support growth and development of young children.

3.1.2 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than 70 kcal (293 kJ) of energy. National and/or regional authorities can deviate from the minimum energy content in line with national/regional dietary guidelines taking into account the nutritional needs of the local population.

3.1.3 (Name of product) for young children prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GUL), as appropriate.

**a) Protein<sup>\*)</sup>, <sup>\*\*)</sup>**

Unit	Minimum	Maximum	GUL
g/100 kcal	1.8	-	-
g/100 kJ	0.43	-	-

<sup>\*)</sup> For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.

<sup>\*\*)</sup> The quality of protein shall not be less than 85% of that of casein.

The protein quality shall be determined provisionally using the PER or PDCAAS and other methods that come available in the future.

**b) Lipids<sup>\*\*)</sup>**

**Total fat**

Unit	Minimum	Maximum	GUL
g/100 kcal	[3.5] or [4.0] or [4.4]	-	-
g/100 kJ	[0.84] or [0.96] or [1.1]	-	-

**α-linolenic acid**

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

**Linoleic acid**

Unit	Minimum	Maximum	GUL
mg/100 kcal	300	-	-
mg/100 kJ	72	-	-

\*\*\*) Partially hydrogenated oils and fats shall not be used in [name of product] for young children.

**c) Carbohydrates**

**Available carbohydrates<sup>4)</sup>**

Unit	Minimum	Maximum	GUL
g/100 kcal	-	[12.0] or [12.5]	-
g/100 kJ	-	[2.9] or [3.0]	-

<sup>4)</sup> Lactose should be the preferred carbohydrates in [name of product] based on milk protein. Sugars, other than lactose [or other carbohydrates contributing to the sweet taste of [name of product]] should not exceed [10%] or [20%] of available carbohydrate. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source.

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

Unit	Minimum	Maximum	GUL
mg/100 kcal	1.0	3.0	-
mg/100 kJ	0.25	0.7	-

<sup>5)</sup> For [name of product] based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36 mg/100 kJ) applies.

**Vitamin C<sup>6)</sup>**

Unit	Minimum	Maximum	GUL
mg/100 kcal	10	-	70
mg/100 kJ	2.4	-	17

<sup>6)</sup> expressed as L-ascorbic acid

**Calcium**

Unit	Minimum	Maximum	GUL
mg/100 kcal	90	-	280
mg/100 kJ	22	-	67

[Ratio calcium/phosphorous]

Min	Max
[1:1]	[2:1]

**Riboflavin**

Unit	Minimum	Maximum	GUL
µg/100 kcal	80	-	650
µg/100 kJ	19	-	155

**Vitamin B12**

Unit	Minimum	Maximum	GUL
µg/100 kcal	0.1	-	2.0
µg/100 kJ	0.024	-	0.48



**Zinc**

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

**Vitamin A**

Unit	Minimum	Maximum	GUL
µg RE <sup>8)</sup> /100 kcal	60	180	-
µg RE <sup>8)</sup> /100 kJ	14	43	-

<sup>8)</sup> expressed as retinol equivalents (RE)

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

**[Vitamin D]**

Unit	Minimum	Maximum	[GUL]
µg <sup>9)</sup> /100 kcal	[1.5] or [1.0]	[4.5] or [3.0]	-
µg <sup>9)</sup> /100 kJ	[0.36 ] or [0.24]	[1.08] or [0.72]	-

<sup>9)</sup> Calciferol. 1 µg calciferol = 40 IU vitamin D.

**Sodium chloride** should not be added to [name of the product] for young children.

3.1.4 National and/or regional authorities may add mandatory requirements for essential nutrients listed under 3.1.3, Section B. Any additional mandatory nutrients should be chosen from the essential composition of follow-up formula for older infants under 3.1.3 Section A. If additional mandatory nutrients are added, the nutrient levels must be based on the nutrient composition of follow-up formula for older infants (3.1.3 Section A) which is informed by the composition of breast milk, and take into account the inherent levels of nutrients in cows' milk.

All nutrient levels may be amended if the nutritional needs of the local population and scientific justification warrants such deviation.

**3.2 Optional Ingredients**

3.2.1 In addition to the essential compositional requirements listed under 3.1.3 Section B, other ingredients, substances or nutrients may be added to [name of the product] for young children where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated by national and/or regional authorities and demonstrated by generally accepted scientific evidence. Optional ingredients listed in 3.1.3 Section A are also permitted.

3.2.2 When any of these ingredients, substances or nutrients is added the formula shall contain sufficient amounts to achieve the intended effect.

3.2.3 Additional nutrients may also be added to [name of the product] for young children provided these nutrients are chosen from the essential composition of follow-up formula for older infants and levels are as per the minimum, maximum, GULs stipulated for follow-up formula for older infants (3.1.3 Section A) and take into account the inherent levels of nutrients in cows' milk; or amended by national and/or regional authorities if the nutritional needs of the local population and scientific justification warrants such deviation.

APPENDIX V

**METHODS OF ANALYSIS FOR PROVISIONS IN CODEX STAN 72-1981  
PART A: For information to CCMAS and adoption by CAC**

Commodity	Provision	Method	Principle	Type
Infant formula	Vitamin B12	AOAC 2011.10   ISO 20634	HPLC	II
		AOAC 986.23 Total B12 as cyanocobalamin	Turbidmetric	III
Infant formula	Myo-inositol	AOAC 2011.18   ISO 20637	LC-pulsed amperometry	II
Infant formula	Vitamin E	AOAC 2012.10   ISO 20633	HPLC	II
Infant formula	Total fatty acid	AOAC 2012.13   ISO 16958   IDF 231	Gas chromatography	II

**PART B: For endorsement by CCMAS**

Commodity	Provision	Method	Principle	Type
Infant formula	Vitamin C	AOAC 2012.22   ISO/DIS 20635	HPLC	II
Infant formula	Chromium, Selenium, molybdenum	AOAC 2011.19   ISO 20649   IDF 235	ICP-MS	II <sup>1</sup>

**DETERMINATION OF TFA:  
PART C: for review by CCMAS (suitability for determination of TFA)**

Product	Method		
	ISO 16958/IDF 231/ AOAC 2012.13	AOCS Ce 1h-05 and AOAC 996.06	AOCS Ce 1j-07 and Ce 2b-11/Ce 2c-11
Dairy and ruminant products/fats	✓		✓
Adult nutritionals	✓		
Infant Formula	✓	✓	Ce 2b-11 only
Samples containing vegetable oils		✓	
Samples containing marine oils or other oils with long chain polyunsaturated fatty acids			✓ (Ce 1i-07 is recommended instead of 1j-07)
Samples with unknown fat sources			✓

<sup>1</sup> Submitted to CCMAS to reconsider the classification of the method as Type II