



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



**World Health  
Organization**

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**REP16/NFSDU**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX ALIMENTARIUS COMMISSION**

*Thirty-ninth Session*

*Rome, Italy*

*27 June – 01 July 2016*

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

**Bad Soden am Taunus, Germany**

**23 - 27 November 2015**

**NOTE:** This report includes Circular Letter CL 2015/33-NFSDU.



**To:** Codex Contact Points  
Interested International Organisations

**From:** Secretariat,  
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**Subject: DISTRIBUTION OF THE REPORT OF THE 37<sup>TH</sup> SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (REP16/NFSDU)**

The Report of the 37<sup>th</sup> Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses will be considered by the 39<sup>th</sup> Session of the Codex Alimentarius Commission (Rome, Italy, 27 June - 1 July 2016).

**PART A - MATTERS FOR ADOPTION BY THE 39<sup>TH</sup> SESSION OF THE CODEX ALIMENTARIUS COMMISSION**

**DRAFT STANDARDS AND RELATED TEXTS AT STEP 5/8 OF THE PROCEDURE**

- 1. Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the *Guidelines on Nutrition Labelling: NRV-R for Copper, Iron (dietary description and footnote), Magnesium, Phosphorus, Vitamin E and Vitamin A (dietary equivalents and conversion factors)*, at Step 5/8 (para. 52a), Appendix II, Part I).**

**OTHER ITEMS FOR ADOPTION**

- 2. Amendments to the Annex of the *Guidelines on Nutrition Labelling (CAC/GL2-1985)* (para. 52a), Appendix II, Part II);**
- 3. Amendments to Section 10, Methods of analysis in *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)* to refer to *Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999)* (para. 96, Appendix V, Part II).**

Governments and international organisations wishing to submit comments on the above texts should do so in writing, in conformity with the *Procedure for the Elaboration of Codex Standards and Related Texts* (Part 3 – Uniform Procedure for the Elaboration of Codex Standards and Related Texts, Procedural Manual of the Codex Alimentarius Commission), **by e-mail ([codex@fao.org](mailto:codex@fao.org)) before 31 May 2016.**

**PART B – REQUEST FOR COMMENTS AT STEP 3**

- 4. The NRV-R for Vitamin D and the dietary equivalents and conversion factor for Vitamin E (para. 52b) and Appendix II, Part III).**

Governments and international organisations wishing to submit comments on the above matter (Part B) should do so in writing, to the Secretariat, Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) email: [ccnfsdu@bmel.bund.de](mailto:ccnfsdu@bmel.bund.de) with copy to Codex Alimentarius Commission, by email: [codex@fao.org](mailto:codex@fao.org) **by 15 October 2016.**

## SUMMARY AND CONCLUSIONS

The Thirty-seventh Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU37) reached the following conclusions:

### Matters for action by CAC39

*Draft Standards for adoption at Step 5/8 of the Procedure*

- Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in *the Guidelines on Nutrition Labelling* (CAC/GL 2-1985): NRV-R for Copper, Iron (dietary description and footnote), Magnesium, Phosphorus, Vitamin E and Vitamin A (dietary equivalents and conversion factors), at Step 5/8 (para. 52a) and Appendix II, Part I).

*Other texts for adoption*

- Amendments to the Annex to CAC/GL 2-1985 (para. 52a and Appendix II, Part II).
- Amendments to Section 10, Methods of analysis in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981) (para. 96 and Appendix V, Part II).

*Approval for New work*

- Guideline for Ready to Use Therapeutic Food” (RUTF) (paras 87-88 and Appendix IV).

### Other matters of Interest to CAC39

The Committee:

- Removed the ML for lead in the section on contaminants of CODEX STAN 72-1981 and aligned the section with a reference to the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) (para. 8).
- Agreed to make available the recorded details of all NRVs-R as an information document (para. 45 and Appendix VI);
- Returned the draft NRV-R for Vitamin D; and the dietary equivalents and conversion factor for Vitamin E to Step 3 (para. 52 b and Appendix II, Part III);
- Agreed to continue work on the revision of the *Standard for Follow-up formula* (CODEX STAN 156-1987), retaining the definitions in section 2.1.2 and 2.2 and the essential composition and optional ingredients at Step 4, while returning the remainder of the text to Steps 2/3 (para. 61 and Appendix III, Parts I and II);
- Returned the Proposed Draft Definition for Biofortification to Step 2/3 (para. 71);
- Returned the proposed draft NRV-NCD for EPA and DHA long chain omega-3 fatty acids to Step 2/3 (para. 80); and
- Agreed to defer discussion on claims for “Free” of Trans Fatty Acids to the next session (paras 9 and 89).

### Matters referred to other Committees

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

The Committee:

- requested confirmation from CCMAS on whether the results of the two methods (R5 and G12) are fully comparable for all products covered by CODEX STAN 118-1979 (para. 10);
- requested advice on the accuracy and appropriateness of 5.71 as the nitrogen factor for soy protein isolates used in formula for infants and young children (para. 57b); and
- submitted the methods for nutrients in infant formula for technical review, typing, endorsement and inclusion in CODEX STAN 234-1999 (para. 96 and Appendix V, Part I).

#### **Committee on Food Additives**

The Committee provided information to CCFA on the technological need for the use of gum Arabic (Acacia gum) (INS 414) in food category 13.1 and carrageenan (INS 407) in food category 13.2. (paras 89 - 90).

The Committee agreed to discontinue the “wish list” of food additives and to consider alignment of the food additives provisions in the different standards under its responsibility with the GSFA (paras 91-92).

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## INTRODUCTION

1. The thirty-seventh Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held in Bad Soden am Taunus, Germany, from 23 to 27 November 2015 at the kind invitation of the Federal Government of Germany. The Session was chaired by Dr Pia Noble, Head of Division of Specific Foods, Food Supplements and Food Additives, Federal Ministry of Food and Agriculture of Germany. The Committee was attended by 66 member countries, one member organisation and 36 observer organisations. A list of participants is given in Appendix I.

## OPENING OF THE SESSION

2. Dr. Bettina Hartwig, Head of the Directorate for Food Policy at the Federal Ministry of Food and Agriculture of Germany, speaking on behalf of Dr Robert Kloos State Secretary, Federal Ministry of Food and Agriculture, welcomed delegates and thanked the government of Indonesia for their hospitality and the excellent cooperation for the last session of the Committee held in Bali.
3. Dr Hartwig underlined the importance the Federal Government attached to Codex and its contribution to raising awareness of food safety. She stressed that working on the basis of sound scientific principles was the very asset of Codex. Looking forward to the valuable work the Committee would be carrying out during the session, Dr Hartwig expressed her desire that the Committee would work in a spirit of compromise in order to complete the tasks before it.

### 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 noting that the discussion on Agenda Item 9 would be deferred until the next session of the Committee, as the outcome of the 6<sup>th</sup> meeting of the WHO Nutrition Guidance Expert Advisory Group (NUGAG) was not available.

## MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES (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.

### Monitoring of Standards Development

7. The Committee recalled its response on the monitoring of the strategic plan from its last session (REP 15/NFSDU Appendix II), that there was no need to develop a new approach for management of its work.

### ML for lead in infant formula

8. The Committee agreed to remove the ML for lead from the section on contaminants in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981) and instead to make reference to the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995).

### Lowest level of trans fatty acids (TFAs)

9. The Committee decided that the Delegation of Canada should take into account the reply of CCMAS when preparing the discussion paper on Claim for “Free” of Trans Fatty Acids for the next session.

### Examination of “ELISA G12” as a potential additional method for inclusion in Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CODEX STAN 118-1979)

10. The Committee noted the reply from CCMAS in particular with respect to validation of the R5 and G12 methods, based on the two matrices, maize and rice, but questioned: which method to adopt for mixed matrices; the comparability of the two methods (if different results emerge) and the implications for “gluten-free” labelling. The Committee decided to seek further clarification from CCMAS with the following request as outlined below.

- Taking into account that the thresholds in CODEX STAN 118-1979 were established on the basis

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<sup>1</sup> CRD1

<sup>2</sup> CX/NFSDU 15/37/1

<sup>3</sup> CX/NFSDU 15/37/2; CRD3 (Comments of Ecuador, European Union, Kenya, Mali, African Union and ISDI)

of the results given by the ELISA R5 Method, can CCMAS confirm that the results of the two methods (R5 and G12) are fully comparable for all products covered by the standard, in particular:

- products manufactured from ingredients naturally free of gluten (e.g. buckwheat, millet, amaranth, quinoa, etc.);
- products manufactured from gluten-containing ingredients (e.g. partially hydrolysed wheat protein, wheat starch, malt extract, glucose syrups, etc.);
- products based on oats; and
- liquid matrices.

#### **MATTERS OF INTEREST ARISING FROM FAO AND WHO (Agenda Item 3)<sup>4</sup>**

11. The Representative of FAO explained that FAO had recently developed a new dietary diversity indicator, Minimum Dietary Diversity-Women (MDD-W), used for assessing the diversity of women's diets at the individual level<sup>5</sup>. MDD-W is a proxy indicator for global use in assessing the micronutrient adequacy of diets of women at a reproductive age. The new indicator reflects that women consuming foods from five or more food groups have a greater likelihood of meeting their micronutrient needs than women consuming foods from fewer food groups. The new indicator provides a new tool for assessment, target setting, and advocacy. An operational manual to guide the data collection for this indicator will be released in December 2015. The UN Standing Committee on Nutrition (UNSCN) and the Global Nutrition Report 2015 have also endorsed MDD-W as a priority nutrition indicator for tracking the progress of the SDGs, especially SDG-2. FAO will continue to support countries in developing capacity to implement this indicator for tracking the progress of nutrition.
12. FAO and WHO are developing the pilot version of a tool called FAO/WHO GIFT (FAO/WHO Global Individual Food consumption data Tool) to estimate nutrient intake and to identify key sources of nutrients in the diet at the individual level. This comprehensive database will collate micro data for the production of indicators in the field of nutrition, dietary exposure and environmental impact. The pilot version is under development based on four datasets from low-income countries. More information is available on the FAO website<sup>6</sup>.
13. FAO re-launched a website on Food-Based Dietary Guidelines (FBDGs) in November 2014. This serves as a platform for a worldwide information exchange on nutritional guidelines. The website currently features national food based dietary guidelines from 78 countries, and will be continuously updated as new guidelines are created or revised. FAO continues to provide direct technical assistance to countries in developing national FBDGs. Furthermore, a review is being developed in relation to "The developments in healthy and sustainable eating and dietary guidelines and related policies: a state of play assessment." The report will be published in December 2015.
14. The Representative of WHO highlighted some of the activities of relevance to the on-going work of the Committee. These included; 1) the new WHO guideline on sugars intake for adults and children which was published in March 2015; 2) WHO Technical Meeting on Fiscal Policies on Diet held in May 2015; 3) WHO Technical meeting on Nutrition Labelling for Promoting Healthy Diets scheduled to be held in December 2015; 4) on-going work of the NUGAG Subgroup on Diet and Health, including the completing of the draft guidelines on saturated fatty acids (SFA), trans-fatty acids (TFA) and total fat, updating of recommendations on carbohydrates intake, reviewing health effects of non-sugar sweeteners, different dietary patterns as well as polyunsaturated fatty acids (PUFA); 5) systematic reviews on the effectiveness of lipid-based nutrient supplements for the treatment and prevention of under-nutrition in pregnant women and children 6–59 months of age; 6) WHO/FAO meeting on "Staple crops biofortified with increased vitamins and minerals: considerations for a public health strategy" scheduled to be held in April 2016 and preparation of their background systematic reviews; 7) recommendations to prevent inappropriate marketing of complementary food; 8) development of nutrient profile models for regulating marketing of food and non-alcoholic beverages to children as well as for other applications, such as school food procurement, implementation of fiscal policies and developing front-of-pack labelling systems.
15. The Representative of WHO further informed the Committee of the Pacific workshop on nutrition, non-communicable diseases (NCD) and the role of Codex, organized jointly by the WHO Regional Office for the Western Pacific and the FAO Sub-regional Office for the Pacific in Fiji in April 2015. The workshop brought together national Codex contact points and nutrition focal points from Member States in the Pacific and explored possible ways to ensure that the work of the Codex takes into consideration the need to address

<sup>4</sup> CX/NFSDU 15/37/3

<sup>5</sup> <http://www.fao.org/documents/card/en/c/678ab9d4-e7a8-4388-9f9f-1c709ea47752/>

<sup>6</sup> <http://www.fao.org/food/nutrition-assessment/foodconsumptiondatabase/en/>

the burden of obesity and diet-related NCD, learning from the work which CCNFSDU and CCFL have been implementing since 2005 to address NCD concerns.

**PROPOSED DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES IN THE *GUIDELINES ON NUTRITION LABELLING (VITAMIN A, D, E, MAGNESIUM, PHOSPHOROUS, CHROMIUM, COPPER, CHLORIDE AND IRON) AT STEP 4 (Agenda Item 4)*<sup>7</sup>**

16. The Delegation of Australia, as Chair of the eWG, introduced document [CX/NFSDU 15/37/4](#), reviewed the work of the eWG and briefly outlined the 19 recommendations.

17. The Committee considered recommendations 1-19 of the eWG and made the following decisions and comments:

**Recommendation 1 – NRV-R for Vitamin A**

18. The Committee agreed to retain the NRV-R for Vitamin A at 800 µg which was now derived from the IOM and noted that this level had contributed to management of Vitamin A deficiency and complemented interventions on Vitamin A deficiency currently being undertaken in different countries.

**Recommendation 2 and 3 – NRV-R for Vitamin D**

19. The Committee considered the proposal of the eWG to revise upward the NRV-R value for Vitamin D from 5 µg to either 10 µg or 15 µg, and noted the following views expressed on each of the proposed levels:

- Delegations in favour of retaining the NRV-R value at 5 µg observed that in some countries populations were exposed to adequate sunlight and thus a low value was needed in such countries. They proposed that a footnote could be introduced allowing authorities to increase these levels depending on the local situation.
- Delegations supporting the increase of the NRV-R value to 10 µg or 15 µg pointed out that higher values were for populations with minimal exposure to sunlight. An observer was of the opinion that to achieve optimal health a level of 15 µg or more was more appropriate.
- The need to wait for an EFSA opinion, which was expected to take into account the most recent scientific findings.

20. The Committee agreed:

- a) to postpone consideration of the NRV-R for Vitamin D to its next session in order to take into account: the EFSA outcome in February 2016 and the most recent scientific findings;
- b) as an interim measure, to retain the current value of 5 µg and to add a footnote on Vitamin D, under section 3.4.4.1, NRVs-R (CAC/GL 2-1985) to read as follows "*Competent National and/or regional authorities should determine an appropriate NRV-R that best accounts for population sunlight exposure and other relevant factors*".

**Recommendation 4 – NRV-R for Vitamin E**

21. The Committee considered the recommendation and noted proposals by some delegations to increase the draft NRV-R value to either 12 mg or 15 mg based on a preference for INL<sub>98</sub>.

22. The Committee agreed to adopt an NRV-R for Vitamin E of 9 mg noting the reservation of Malaysia, South Africa, and Indonesia.

**Recommendation 5, 6 and 7 – NRV-R for Iron, description and footnote**

23. The Committee agreed to establish two values for iron based on the FAO/WHO 2004 report. The Representative of FAO explained that the FAO/WHO figures for iron, i.e. 14 mg (15% dietary absorption) and 22 mg (10% dietary absorption) took into account dietary absorption of iron across the globe in both plant-based diets (mainly from the developing countries), which are associated with a lower iron absorption, and mixed-diets (consumed in the developed countries) which have a higher iron absorption. He proposed that in future, when revising the NRVs, CCNFSDU should consider the FAO/WHO Joint Expert Meetings on Nutrition (JEMNU) as the primary source of scientific advice, as JEMNU would consider NRVs at the global level.

24. The Committee also noted the concern raised by an observer organization on the need for two levels for iron, i.e. one for men and another for women of child bearing age; and that a man of 50 years has 2-3 times

<sup>7</sup> [CX/NFSDU 15/37/4](#); [CX/NFSDU 15/37/4 Add.1](#) (Comments of Brazil, Canada, Chile, Costa Rica, Ghana, New Zealand, United States of America, African Union, ELC, IADSA and ISDI); [CX/NFSDU 15/37/4 Add.2](#) (Comments of Egypt, Malaysia, Mali and FoodDrinkEurope); CRD4 (Comments of Colombia, European Union, India, Indonesia, Kenya, Philippines and IFMA); [CRD13](#) (Comments of El Salvador); [CRD14](#) (Comments of NHF)

stored iron in his body as compared to a woman of the same age. Therefore, in their view, this value cannot be averaged.

25. The Committee agreed to:
- modify the NRV-R to refer to % dietary absorption; and
  - to revise the NRV-R from 14 mg to 14mg (15% dietary absorption) and 22 mg (10% dietary absorption).
26. The Committee agreed to:
- the dietary description related to the NRV-R for iron as recommended by the eWG.
  - attach to iron the same footnote previously attached to zinc, as recommended by the eWG.

#### **Recommendation 8 – NRV-R for Magnesium**

27. The Committee noted that the derivation of the value for NRV-R for magnesium established in 1988 was not sufficiently clear and that the proposed new value was now based on average calculations obtained from balance studies from RASBs.
28. One observer noted that since the Committee already set the NRV-R for calcium at 1 000 mg, the minimum value for magnesium should be set at 400 – 500 mg.
29. The Committee agreed to the revised NRV-R value for magnesium of 310 mg noting the reservation of South Africa.

#### **Recommendation 9 – NRV-R for Phosphorus**

30. The Committee noted that the proposed value for NRV-R for phosphorus of 700 mg was based on the IOM  $INL_{98}$  value, which was similar to the value proposed in the EFSA preliminary scientific opinion and that the EFSA revised final figure was now 550 mg.
31. The Committee noted the following issues:
- EFSA had modified the value to 550 mg based on evidence that the ratio between phosphorus and calcium in the whole body (that could ensure bone health) was between 1.4 to 1.9 and the lower ratio of 1.4 was used in calculations because there was higher phosphorus intake in the western diet; and
  - The NRV-R for phosphorus of 550 mg was preferred by some delegations as absorption of dietary phosphorus is linked with calcium in a ratio of 2:1.
32. The Committee agreed to adopt the recommendation for the NRV-R for phosphorus at 700 mg noting the reservations of Mali, Senegal and Togo as they preferred the NRV-R of 550 mg stating that more scientific evidence was necessary regarding the calcium phosphorus ratio.

#### **Recommendation 10 – NRV-R for Copper**

33. The Committee noted that:
- the EFSA value of 1.5 mg was an adequate intake (average population intake as well as balance studies). Recent balance studies for men indicated that an intake of 900 µg per day may not be sufficient to achieve zero balance for this element in the body; and therefore an NRV-R of 900 µg was considered to be not high enough;
  - Codex texts were voluntary in nature;
  - given the above EFSA opinion and the General Principles of the Codex Alimentarius, competent national and/or regional authorities may set a higher NRV-R for copper; and
  - the recommendation from the eWG of 900 µg was based on the  $INL_{98}$  of IOM.
34. The Committee agreed to adopt the recommendation for the NRV-R for copper of 900 µg based on the  $INL_{98}$  of IOM in the spirit of compromise.

#### **Recommendation 11 – NRV-R for Chromium**

35. The Committee discussed the need to establish an NRV-R for chromium and noted:
- the limited evidence that chromium was an essential nutrient; the limited indicators of the beneficial effects on health; and
  - the gaps around the data source and concerns regarding the methodology used to derive an NRV-R value of 30 µg;
  - An observer was of the opinion that chromium was essential to health and that a value should be set in

the range of 50 – 200 µg.

36. The Committee agreed not to establish an NRV-R for chromium at present, due to the limited scientific information on the essentiality of this mineral. It could be considered at a future date.

#### **Recommendation 12 – NRV-R for Chloride**

37. The Committee considered the proposal on whether to establish an NRV-R for the chloride nutrient and noted the following issues:

- The value of 3 000 mg as being equimolar with NRV-NCD for sodium, but as such not justified for establishing an NRV-R;
- The NRV-R for chloride was not necessary as chloride was not considered an essential nutrient and was also not linked to NCD;
- No clinical deficiency situation for chloride had ever been reported and moreover chloride was always available in the diet; and
- It would be better to wait for solid scientific information and then establish a value in the future.

38. The Committee agreed not to establish an NRV-R for chloride at present. It could be considered at a future date, as at present, it was considered not necessary.

#### **Recommendation 13 – Vitamin A Dietary Equivalents and Conversion Factors**

39. The Committee considered the dietary equivalents and conversion factors of Vitamin A, i.e. Retinol Equivalent (RE) and Retinol Activity Equivalent (RAE), and agreed to delete reference to chemical forms of Vitamin A added to food as it was not necessary to include molecular calculations.

40. The Committee was not able to agree on a single conversion factor noting the different conversion factors used globally.

41. The Committee agreed to adopt the recommendation with the above amendment to the second table to section 3.4.4.1 in the *Guidelines on Nutrition Labelling*, renamed as proposed (recommendation 15).

#### **Recommendation 14 – Vitamin E Dietary Equivalents and Conversion Factors**

42. In considering this recommendation, the Committee noted that there were divergent views on  $\alpha$ -tocopherol as the only isomer with Vitamin E activity:

- Delegations supporting identification of all forms of Vitamin E isomers as the active forms of Vitamin E, called for the inclusion of all Vitamin E isomers listed by the FAO/WHO (2004) publication, as these isomers also exhibited Vitamin E activity in addition to other important biological activities, and that Vitamin E was thus described as a complex.
- Delegations in support of the identification of only  $\alpha$ -tocopherol as Vitamin E mentioned that  $\alpha$ -tocopherol was the only compound that exhibited Vitamin E activity and thus contributed to the direct essentiality of this Vitamin; and that other isomers were antioxidants.
- The Representative of WHO mentioned that the 2006 FAO/WHO publication identified  $\alpha$ -tocopherol as the only isomer with Vitamin E activity.

43. Noting the lack of consensus, the Committee agreed to postpone the decision on this recommendation to its next session. However, it was agreed to delete reference to different forms of Vitamin E added to food.

#### **Recommendation 16 – RASB Definition in Guidelines on Nutrition Labelling**

44. The Committee agreed with the recommendation to insert the definition of RASB in the Annex to the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985).

#### **Recommendation 17 – Record of NRV-R Decisions**

45. The Committee agreed that the recorded details of all the NRVs-R from the current revision would be made available as an information document on the Codex website (Appendix VI).

#### **Approach to establish NRVs-R for Older Infants and Young Children**

46. The Committee discussed the need for the NRV-R for Older Infants and Young Children and noted the following opinions as expressed by delegations:

- The work could be beneficial to countries that had national legislation; and that it would be important to investigate the extent to which such legislation existed in different countries with a view to supporting harmonisation.

- Nutrient requirements may differ as children grow and this area may benefit from the work of FAO and WHO. The workload would be considerable for the Committee and therefore JEMNU could assist in this task.
  - This work would help in scientific work for areas such as feeding and child health; and that such work should be neither for labelling nor claim purposes.
  - One observer noted the separation between young infants and older infants could be a potential area for promotional claims; and the work would have detrimental effects to older infants and young children as it would impact on breastfeeding and consumption of family foods; there was a question about how to ensure that the outcome of the work did not end up as promotional claims.
  - Such work should not be put on high priority.
47. The Chairperson explained that JEMNU had been established to provide scientific advice to CCFSDU and that it was time for the Committee to consider requesting such advice in this area.
48. On the proposal of Scientific advice from JEMNU the Committee exchanged views and noted the following:
- The JEMNU process would help the Committee move forward on an informed basis;
  - RASBs have the nutrient values, and the type of scientific advice needed by CCFSDU was already available;
  - Nutrient declaration in standards as used in products was not available and this could benefit from the work of JEMNU;
  - Countries could benefit in setting their national legislation;
  - Establishing NRV-R for older infants and young children would help the labelling of complementary foods enriched with vitamins; and
  - The recommendations of RASBs were used in absence of recent FAO/WHO scientific advice; and it was more logical to seek expert advice for this work from JEMNU as this would provide a harmonised approach.
49. The Representative of FAO recalled that JEMNU had been established for the purpose of providing scientific advice to CCFSDU and noted the support expressed by different delegations on this matter. He advised the Committee to establish a priority list of needs for scientific advice to enable planning for JEMNU work.
50. In response to the discussion on the possibility for requesting JEMNU to undertake the work, the Representative of WHO reminded the Committee of the Terms of Reference and Rules of Procedures of JEMNU, in particular Step 1 which states the need for the Codex body or Member Countries requesting information or scientific advice from JEMNU to formulate the PICO<sup>8</sup> questions necessary for JEMNU to respond to specific requests.

### Conclusion

51. In light of the above discussion, the Committee agreed as follows:
1. To establish an eWG with the following terms of reference:
    - A. Assess the need and value for the establishment of NRV-R for older infants and young children in Codex texts in relation to:
      - i. the purpose of such NRVs-R in the *Guidelines for Nutrition Labelling* (CAC/GL 2-1985) and Codex texts for special dietary use for older infants and young children; and
      - ii. the specific population groups to which these NRV-R may apply.
    - B. Where a need is established under TOR1 above, and taking account of the discussion in sections 7 and 8 of CX/NFSDU15/37/4, recommend parameters for NRV-R with respect to the:
      - i. essential nutrients;
      - ii. appropriate population groups; and
      - iii. scope of application of NRV-R to Codex tests in TOR1 (i).
    - C. Where a need is established under TOR1 above, assess the need for scientific advice provided by JEMNU.

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<sup>8</sup> The PICO acronym stands for P - patient, problem or population; I – intervention; C - comparison, control or comparator; O - outcomes

- D. Review the operation of nutrition labelling provisions in Codex texts under TOR1 (i) and where appropriate develop a request to CCFL to provide advice on the potential for amendments to provide further clarity.

In absence of a member ready to lead the eWG, the Committee appealed to members to come forward and that the matter would be reconsidered at its next session.

2. Recommendations 2 and 14, whose final discussions had been postponed to its next Session would be circulated for comments at Step 3.
3. To discontinue consideration of recommendation 18 and 19 as it was explained that these two recommendations were related to possible work of the above mentioned eWG.

**Status of the proposed draft additional or revised nutrient reference values for labelling purposes in the *Guidelines on Nutrition Labelling* (vitamin A, D, E, magnesium, phosphorous, chromium, copper, chloride and iron)**

52. The Committee agreed:

- a) to forward the new and revised NRVs-R for Copper, Iron (dietary description and footnote), Magnesium, Phosphorus, Vitamin E and Vitamin A (dietary equivalents and conversion factors) at Steps 5/8 (with the omission of Steps 6 and 7), and the amendments to the *Annex to the General Principles for Establishing Nutrient Reference Values for the General Population (para 2.5)* for adoption by CAC39 (Appendix II, Part I and Part II); and
- b) to return the NRV-R for Vitamin D and the dietary equivalents and conversion factor for Vitamin E to Step 3 for comments (Appendix II, Part III).

**REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987) AT STEP 4 (Agenda Item 5)<sup>9</sup>**

53. The Delegation of New Zealand as Chair of the eWG and pWG, introduced the item and highlighted the conclusions of the PWG as presented in CRD2.

General discussion

54. The Committee noted that:

- a) Work would be done in phases and present consideration was on the definitions (section 2) and essential composition (section 3) for the products designated for older infants (from age 6 months and not more than 12 months of age).
- b) Scope and labelling would be considered at a later stage and this could include referencing the relevant WHA resolutions on optimal infant and young child feeding, and on the lack of the need of the products. The Delegation of India reiterated its position on the need to address Follow up Formula (FUF) as per WHA resolution 39.28 and that if the Standard for Follow-up Formula was to be developed then it supported the standard only beyond 12 months to 36 months of age. If special consideration with regard to requirements for older infants was to be given, then the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981) should be opened as the current proposal was to realign the *Standard for Follow-up Formula* with the existing CODEX STAN 72-1981.
- c) The renaming of the product categories could be considered at later stage.

Specific discussion

Description and Definitions (section 2)

55. The Committee:

- a) Agreed to refer to “product” rather than “food” (section 2.1.1) for consistency with *Standard for Infant Formula and Formulas for Specific Medical Purposes Intended for Infants* (CODEX STAN 72–1981) and the Procedural Manual; and to make consequential changes as necessary throughout the text;
- b) Did not agree to the request from WHO, supported by some delegations and observers, to amend section 2.1.1 to include the statement that “The use of this product must not replace breastmilk and lead

<sup>9</sup> CX/NFSDU 15/37/5; CX/NFSDU 15/37/5 Add.1 (Comments of Argentina, Brazil, Canada, Chile, Costa Rica, Ghana, Morocco, New Zealand, Norway, Philippines, United States of America, African Union, ELC, ENSA, EUVEPRO, GOED, IDF, IFT and ISDI); CX/NFSDU 15/37/5 Add. 2 (Comments of Egypt, Malaysia and Mali); CRD5 (Comments of Colombia, Ecuador, European Union, India, Kenya, Malaysia, Mexico, Vietnam and IBFAN); CRD11 (Comments of ISDI); CRD15 (Comments of Thailand, ELC and IFT)

to cessation of continued breastfeeding”, as this concept could be better addressed under ‘scope’ or elsewhere in the Standard;

- c) Noted that the definitions could be revisited as the work on the review progressed.

Essential Composition and Quality Factors (for older infants 6-12 months) (Section 3)

56. The Committee:

- a) Agreed with the essential composition for energy, total fat, carbohydrates,  $\alpha$ -linolenic acid, linoleic acid, Vitamins D, E, riboflavin, niacin, Vitamin B<sub>6</sub>, Vitamin B<sub>12</sub>, pantothenic acid, biotin, folic acid, thiamin, calcium, phosphorus, magnesium, sodium, chloride, potassium, manganese, selenium, and copper.

- b) Amended the title of total carbohydrate to refer to available carbohydrate, to take into account that the levels indicated referred to digested and absorbed carbohydrates and not to oligosaccharides.

- c) Clarified that sucrose and fructose should not be added unless needed as a source of carbohydrates.

- Noted the reservations of the Delegations of India and South Africa to the inclusion of glucose polymers, supported by observer organisations. The Delegation of India reserved its position on addition of glucose polymers and for keeping the phrase “Sucrose and/or fructose should not be added, unless needed, and provided the sum of these does not exceed 20% of total carbohydrate.” in the draft standard. One observer expressed concern that glucose polymers should only be used where needed in soya formulas and that hydrolysed proteins are not needed in Follow up Formulas because they are not foods for special medical purposes.

- Noted the strong concerns of the Representative of WHO with keeping the statement on adding sucrose and/or fructose, if needed, in the footnotes for the title of carbohydrates, as this was in contradiction to the WHO guideline on sugars intake in adults and children issued in March 2015. This was supported by some delegations and observers.

- d) Agreed with minimum and GUL for iodine.

- Noted the preference of the Delegations of the European Union and Norway for a lower GUL for iodine, because assuming an intake of 500kcal per day, would lead to an excess of what these delegations consider to be the tolerable Upper intake Level (UL) for iodine for young children, and thus there was a need to avoid such a safety risk. Noted that these delegations could accept the proposal of 60  $\mu$ g as a compromise.

- e) Agreed with the minimum and maximum for Vitamin A.

- Noted that the Delegations of the European Union, Norway and Brazil could accept the level of 180  $\mu$ g/100 kcal as a compromise despite their preference for a lower level of 114  $\mu$ g/100 kcal for reasons as expressed for iodine.

- f) Agreed with the proposed minimum and maximum for iron.

- Noted the preference of the Delegation of Canada for a precautionary approach and thus a preference for a maximum level of 1.5 mg/100 kcal, because of concerns related to over consumption; or in view of the large variation in iron status around the globe, adding a footnote to the GUL column that levels may be determined by National Authorities similar to the note in CODEX STAN 72-1981.

57. The Committee agreed to continue the discussion of Vitamin C, Vitamin K, zinc and protein and potential interactions among certain vitamins and minerals as no agreement could be reached and noted the discussions on these issues as follows:

(a) Protein minimum and maximum levels – The Committee considered proposals to lower the level to either 1.65 or 1.8. While noting that there had been an over-emphasis on protein intake in the past and that now reduction was promoted, the Committee considered that the evidence was still not sufficient to support a lower level at this time. The Committee agreed to retain both minimum levels for further consideration. Noting that there was a connection between the minimum and the maximum levels, the maximum level proposals would also be retained for further consideration.

(b) Footnotes for protein - The Committee supported footnotes 2, 3, 4 and 5 and re-inserted footnote 6 in square brackets to indicate the need for clinical evaluation of follow-up formula based on non-hydrolysed milk protein but noted that the actual values would need further discussion. One delegation and one observer pointed out that there was no reason to use hydrolysed protein in follow-up formula intended for healthy older infants. The values in footnotes 5 and 6 were dependent on the finalisation of the minimum and maximum levels. Regarding the conversion factor of 5.71 in footnote 2, the Committee agreed to request CCMAS to provide advice on the accuracy and appropriateness of 5.71 as the nitrogen factor for soy protein

isolates used in formula for infants and young children and to take into account the amino acid profile of the isolate.

(c) Vitamin K – There was no agreement on the two minimum levels proposed for Vitamin K. Arguments for retention of a higher level were based on the history of safe use, the alignment with the value for infant formula and the importance of Vitamin K for overcoming haemorrhagic problems. Arguments to lower level were based on the dietary requirements set by EFSA and FAO/WHO. Both minimum levels were retained for further consideration.

(d) Vitamin C – There was no agreement on the two minimum levels proposed for this vitamin. Arguments for a lower level were based on the requirements needed for this age group and the fact that the need for Vitamin C could be fulfilled through complementary feeding. Arguments for the retention of the higher level were that it would be in line with requirements for infant formula and that complementary foods did not always provide sufficient levels of Vitamin C.

#### Optional ingredients (Section 3.3.2)

58. The Committee noted or took the following decisions:

- a) With reference to the term “generally accepted scientific evidence” used in section 3.3.2.1, the Representative of WHO noted that the criteria and level of evidence described in the *Guideline on Nutrition Labelling* (CAC/GL 2-1985) is “Relevant convincing / generally accepted scientific evidence or the comparable level of evidence under the GRADE classification” and she, therefore, suggested to use this phrase in order to harmonize the criteria and level of the evidence used in the Codex texts
- b) agreed to the second option proposed for section 3.3.2.2; to refer to “effect” for consistency with the infant formula standard, and to amend section 3.3.2.3 to refer also to regional competent authorities;
- c) Agreed to retain taurine, nucleotides, docosahexaenoic acid (DHA), myo-inositol, choline and L-carnitine in the list as proposed and clarified that the list was not exhaustive;
- d) Agreed that DHA should be optional, but the minimum level should be further discussed and in view of this decision agreed to the minimum, maximum and the ratios for linoleic and  $\alpha$ -linolenic acid;
  - Noted that the Delegation of the European Union considered it prudent to require the mandatory addition of DHA to follow-up formulas in amounts similar to those in breastmilk. This consideration is based on DHA's structural role in the nervous tissue and the retina, its involvement in normal brain and visual development, the need for the developing brain to accumulate large amounts of DHA in the first two years of life and the fact that the intake of pre-formed DHA generally results in a DHA status more closely resembling that of a breastfed infant (than the one achieved with ALA alone);
- e) Noted that the inclusion of only L+ lactic acid producing cultures should be further considered as the long term effects of these cultures were not yet fully scientifically demonstrated in this age group.

#### Essential Composition of Follow-Up Formula for Young Children (12-36 Months)

59. The Committee agreed to the approach and key themes for the Essential Composition of Follow-Up Formula for Young Children (12-36 Months) as outlined in CX/NFSDU 15/37/5 (section 8).

#### **Conclusion**

60. The Committee agreed to establish:

- a) an eWG chaired by New Zealand, co-chaired by France and Indonesia and working in English only with the following terms of reference:
  - Finalise Section 3 on the Essential Composition of Follow-up Formula for older infants (6-12 months);
  - Review the compositional requirements of Follow-up Formula for young children (12-36 months) based on the discussions at CCFSDU37 and the approach outlined in CX/NFSDU 15/37/5;
  - Refine Definition 2.1.1 based on the outcomes of the review of the compositional requirements for 6-36 months with a point of differentiation at 12 months;
  - Explore issues for further consideration by CCFSDU38 on Section 9 (Labelling) to inform the revision of the Sections of the Standard on Scope and Labelling.
- b) A pWG, to meet immediately prior to the next session, chaired by New Zealand, co-Chaired by France and Indonesia and working in English, French and Spanish to consider the recommendations of the eWG, especially the compositional requirements of the 12-36 months age group, and taking into account comments submitted at Step 3, prepare further recommendations for consideration by

CCNFSDU38.

**Status of the Review of the *Standard for Follow-Up Formula (CODEX STAN 156-1987)***

61. The Committee agreed to:
- Retain the definitions in section 2.1.2 and 2.2, and the agreed essential composition, and optional ingredients at Step 4 (Appendix III Part I) until the revision of the other sections were agreed.
  - Return the definition in section 2.1.1 and remaining essential composition requirements (Appendix III, Part II) to Step 2/3, and consideration by the next Session of the Committee.

**PROPOSED DRAFT DEFINITION FOR BIOFORTIFICATION AT STEP 4 (Agenda Item 6)<sup>10</sup>**

62. The Chairperson recalled the prior discussion in the Committee and noted the request from CAC38 on how the definition would be used and where it would be best placed.
63. The Delegations of Zimbabwe and South Africa, as co-Chairs of the eWG, introduced the paper and summarised the nine criteria identified as the source of the proposed definition and presented four options for a definition.

**Discussion**

64. The Committee agreed not to discuss the proposed definitions at this time and considered whether the criteria contained in the working document were suitable in general to guide the further work of the eWG.
65. The Committee agreed that, in line with the project document, the definition should be as broad as possible to include all possible types of agricultural processes and organisms which would improve the nutritional quality of the product. The Committee noted that the term biofortification did not always translate easily, as “bio” had different meanings in different regions of the world and so the working group could also explore defining a better term.
66. The Committee discussed, inconclusively, whether foods enhanced through recombinant-DNA technology should be included in the definition. The Committee noted that for the safety of such foods relevant Codex texts existed (CAC/GL 45-2003, Annex 2).
67. The Committee, however, noted that should recombinant DNA technology be included in criteria 1, then consideration could be given to some explanatory text that “competent national and/or regional authorities may decide which agricultural practices they would consider”. The Delegation of India reserved its position on inclusion of modified food/organisms in the proposed text for the draft definition of bio-fortification.
68. The Committee considered that the definition should be further developed before entering into considerations of labelling and claims of health benefits. The Committee agreed that the effects of the enhancement should be measurable against objective criteria such as nutrient reference values and not just as an increase as compared to non-fortified products.
69. The Committee noted questions with regards to the bioavailability of the enhanced nutrients and how it could be measured. The Committee agreed that anti-nutrients should be further discussed, as decreasing anti-nutrients could increase the availability of nutrients. One observer noted that some substances cited as anti-nutrients (e.g. phytates) had positive health effects thus their reduction might be counter-productive.

70. **Conclusion**

The Committee agreed to establish an eWG co-chaired by Zimbabwe and South Africa and working in English to:

- consider the replies to the request for comments at Step 3 on the proposed draft definition and the comments made at the session;
- consider the request from CAC38 on how the definition would be used and where it would be best placed; and
- propose a draft definition for further consideration by the next session of the Committee.

**Status of the proposed draft definition for biofortification**

71. The Committee agreed to return the Proposed Draft Definition for Biofortification to Step 2/3, for consideration at the next session of the Committee.

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<sup>10</sup> [CX/NFSDU 15/37/6](#); [CX/NFSDU 15/37/6 Add.1](#) (Comments of Brazil, Canada, Chile, Mali, New Zealand, Paraguay, Philippines, Rwanda, United States of America, African Union, IBFAN, ICBA, ICGMA, IDF and IFPRI); [CRD6](#) (Comments of Colombia, India, Kenya, Malaysia and Thailand)

**PROPOSED DRAFT NRV-NCD FOR EPA AND DHA LONG CHAIN OMEGA-3 FATTY ACIDS AT STEP 4**  
(Agenda Item 7)<sup>11</sup>

72. The Delegation of Russia, as co-Chair of the eWG, introduced the report and the proposal for an NRV-NCD of 250 mg/day based on information and data from three WHO and/or FAO/WHO consultation reports; three RASBs (which had met the definition of an RASB), and a review of meta-analyses published since 2012.
73. The Committee considered the recommendations as presented in [CX/NFSDU 15/37/7](#) and noted that there were divergent views on the proposal.
74. Those delegations and observers who supported the recommendation of 250 mg/day pointed out that there was sufficient evidence to support the link between the NRV-NCD and reduction in risk of coronary heart disease mortality. In response to questions on whether it was necessary to consider the ratio of DHA to EPA, it was clarified that this had been considered and that a majority in the eWG had agreed not to establish a ratio as there was no evidence that the ratio would influence the health impact.
75. Those delegations of the opinion that it was premature to establish an NRV-NCD of 250 mg/day expressed the following views:
- The relationship between DHA and EPA and mortality from coronary heart disease (CHD) had not been sufficiently characterised to establish an NRV-NCD;
  - The evidence was largely based on the consumption of fish and it was not clear whether it was possible to extrapolate this to individual DHA and EPA;
  - Not all criteria as per the GP 3.2.2.1 had been met, in particular with regard to the GRADE classification; and
  - Not all RASBs had been considered.
76. The Committee therefore considered the need to obtain additional scientific advice through JEMNU or NUGAG.
77. The Representative of WHO informed the committee that NUGAG was in the process of initiating work on review of polyunsaturated fatty acids (PUFAs) and that a request could be taken up in this work rather than duplicating work through JEMNU. The Representative also explained that the JEMNU process could only be initiated if there was a clear request and if resources to allow this process to proceed were forthcoming as per steps 1 and 2 of the terms of reference and rules of procedure of JEMNU which describe the way in which the specific scope of the work should be formed and how funds are to be sourced (<http://www.fao.org/ag/humannutrition/68531/en>).
78. There was significant support for initiating a request to JEMNU and for FAO and WHO to work together to provide scientific advice to CCNFSDU. It was noted that this was in line with the Nutritional Risk Analysis Principles for the Committee which acknowledge FAO and WHO as the primary source of scientific advice. However, it was agreed that since NUGAG was already in the process of scoping a review, (and that a preliminary report would be available before the next session of the Committee), the Committee could evaluate the NUGAG work as it became available, continue work on the NRV and consider whether any additional scientific advice would be needed in the future. The major health outcome should remain reducing the risk of coronary heart disease mortality.

**Conclusion**

79. The Committee agreed to re-establish the eWG, led by Russia and Chile, working in English and Spanish, to further develop the NRV-NCD for EPA and DHA long chain omega-3 fatty acids in accordance with the General Principles for Establishing Nutrient Reference Values for the General Population (Annex to the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985), taking into account also the work of NUGAG as was done when establishing the NRV-NCD for sodium and potassium.

**Status of the proposed draft NRV-NCD for EPA and DHA long chain omega-3 fatty acids**

80. The Committee agreed to return the proposed draft NRV-NCD for EPA and DHA long chain omega-3 fatty acids to Step 2/3 for consideration by the next session.

**DISCUSSION PAPER ON A STANDARD FOR READY-TO-USE FOODS (Agenda Item 8)<sup>12</sup>**

81. The representative of UNICEF presented a summary of the revised discussion paper and noted that the

<sup>11</sup> [CX/NFSDU 15/37/7](#); [CX/NFSDU 15/37/7 Add.1](#) (Comments of Brazil, Canada, Egypt, Japan, New Zealand, Paraguay, Philippines, United States of America, ELC, FoodDrinkEurope, GOED, IADSA, ICGMA, IDF); [CX/NFSDU15/37/7 Add.2](#) (Comments of Ecuador and the European Union); CRD7 (Comments of Colombia, Thailand and IFMA)

<sup>12</sup> [CX/NFSDU 15/37/8](#); [CRD8](#) (Comments of Colombia, India, Kenya, Philippines, Thailand, African Union and IBFAN)

revision had taken into account the comments made during CCFDU36. The purpose of the work was now to establish a guideline (and not a standard) for a single product known as “Ready to Use Therapeutic Food” (RUTF) used in the management of severe acute malnutrition (SAM).

82. The Committee expressed general support for the new work. Some members and observers noted that RUTF should be considered as one of the interventions within the broader strategy for combating malnutrition and that the guideline should consider other relevant Codex texts and take into account the use of local products, and local food consumption patterns. It was also noted that aspects related to marketing were outside the scope of Codex.
83. One observer noted that as these products were not intended for sale to the public there was an urgent need to ensure that they are not marketed and promoted except through purely scientific and factual information to health professionals, Governments and NGOs.
84. Another observer was of the opinion that the Committee should wait for conclusive evidence including the WHO review findings on the effectiveness of RUTF in treating SAM.
85. The Representative of WHO informed the Committee that the on-going systematic reviews, by WHO, related to lipid-based nutrition supplements, which were being undertaken as part of the process to develop recommendations on formulated foods for the treatment and prevention of under nutrition in pregnant women and children 6-59 months of age, would not develop guidance on the nutrient composition of RUTF. The Representative also stated that WHO had been concerned about the proposal when it was initially presented by UNICEF as it had included Ready to Use Supplementary Foods (RUSF), but was now more comfortable with the proposal put forward to the Committee at this Session as it no longer included this product.
86. The Delegation of India did not support the current proposal due to lack of sufficient scientific data in favour of using Ready to Use Therapeutic Food (RUTF) in the management of severe acute malnutrition (SAM). In the report of CCFDU36 (2014), REP15/NFSDU, paragraph 182 stated “The Chairperson suggested that the decision be postponed until the next session of the committee when the review from WHO would be available and there would be a better basis for a decision” which is still awaited. India strongly supported the use of local food in accordance with national policy. India also objected to RUTF being promoted audio-visually in the meeting of the CCFDU when the draft discussion paper was only under consideration.
87. The Committee reviewed the project document, noted comments and made subsequent editorial amendments (Appendix IV).

### **Conclusion**

88. The Committee agreed to establish an eWG, led by South Africa and co-Chaired by Senegal and Uganda and working in English and French, and that, subject to the approval of new work by CAC39, would develop the proposed guideline for consideration at the next session.

### **DISCUSSION PAPER ON CLAIM FOR “FREE” OF TRANS FATTY ACIDS (Agenda Item 9)<sup>13</sup>**

89. The Committee agreed to defer this matter to the next session and that the Delegation of Canada would continue to develop the discussion paper taking into account the outcome of the 6<sup>th</sup> meeting of the WHO Nutrition Guidance Expert Advisory Group (NUGAG) and the reply from CCMAS (REP15/MAS, paras 34-36).

### **FOOD ADDITIVES IN THE STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (CODEX STAN 72-1981) (Agenda Item 10)<sup>14</sup>**

90. The Chairperson recalled that CCFDU36 had agreed to keep amending the working list of additives (wish-list) up to the current session, when decisions would be made on its future status. The Chairperson also reminded the Committee of the request by CCFA to clarify the use of gum arabic (Acacia gum) (INS 414) in food category 13.1 “Infant formula, follow-up formula and formula for special medical purpose for Infants”, and the use of carrageenan (INS 407) in food category 13.2 “Complementary foods for infants and young children and products conforming to the corresponding commodity standards”.

### *Replies to CCFA*

91. On the use of gum arabic (Acacia gum) (INS 414) in food categories 13.1 and the corresponding Commodity standards the Committee agreed to inform CCFA that there was no technological need for the use of gum arabic (Acacia gum) (INS 414) in food category 13.1 “Infant formula, follow-up formula and formula for special medical purpose for Infants” and products conforming to the corresponding commodity standards, however it was used as a nutrient carrier. The Delegations of Sudan and Nigeria expressed their reservation to this decision.

<sup>13</sup> CX/NFSDU 15/37/9 (Not issued)

<sup>14</sup> REP15/NFSDU, Appendix VI; CRD9 (Comments of Colombia, Indonesia, Philippines and Thailand)

92. On the use of carrageenan (INS 407) in food category 13.2 and the corresponding commodity standards the Committee noted that in some countries it was used and approved as a stabilizer and emulsifier in canned baby foods, while in others it was not permitted because in those countries the technological need was not demonstrated.

*Working list of food additives (wish-list)*

93. The Committee agreed to no longer use the “wish list”, noting that:
- carrageenan had been endorsed by CCFA in food categories 13.1.1 and 13.1.3 of the GSFA and adopted by CAC;
  - the following substances were already on the priority list of substances proposed for evaluation by JECFA: Carob bean gum (INS 410); Pectin (INS 440) and Xanthan gum (INS 415); and
  - in accordance with the decision of CCNFSDU36, all other food additives not on the JECFA priority list would be removed.
94. The Codex Secretariat informed the Committee of the procedures for entry of new substances and/or revision of adopted food additives provisions in the GSFA; and for establishing a priority list of substances for evaluation by JECFA. It was also confirmed that there was still time to respond to circular letters CL 2015/11-FA and CL 2015/12-FA for new additives or changes to existing additives in CODEX STAN 72-1981 for alignment in the GSFA.
95. The Committee encouraged members to reply to circular letters CL 2015/11-FA and CL 2015/12-FA and agreed to consider alignment of the food additives provisions in the different standards under its jurisdiction with the GSFA at its next session.

**OTHER BUSINESS AND FUTURE WORK (Agenda Item 11)<sup>15</sup>**

**Methods of analysis in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)***

96. The Committee agreed to submit the eight methods for nutrients in infant formula (vitamin B12, myo-inositol, chromium, selenium, molybdenum, nucleotides, vitamins A and E, fatty acid profile, iodine and pantothenic acid) as presented in CX/NFSDU 15/37/10 (Rev) to CCMAS for technical review, typing, endorsement and inclusion in the *Recommended Methods of Analysis and Sampling* (CODEX STAN 234-1999) as these methods reflected the most recent scientific methods of analysis for nutrients in infant formula and were fully validated for these products (Appendix V, Part I). The Committee also agreed to amend Section 10, Methods of analysis in CODEX STAN 72-1981 to refer to CODEX STAN 234-1999 (Appendix V, Part II).
97. In response to concerns with regard to the typing of some methods, and the inclusion of extremely costly methods, (i.e. those based on inductively coupled plasma-mass spectrometry) as opposed to less expensive atomic absorption spectrometry methods, it was clarified that the methods were for purposes of dispute settlement and that for routine analysis, other methods were available and could be used. It was suggested that the proposed new methods based on the principle ICP-MS were considered as type III, given that some countries may not be able to use these methods in cases of dispute settlement. CCMAS would also be able to further consider the correct typing of the methods.

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

98. The Committee was informed that the 38<sup>th</sup> Session was scheduled to be held in Germany from 5 to 9 December 2016, the final arrangements being subject to confirmation by the Host Government in consultation with the Codex Secretariat.

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<sup>15</sup> CX/NFSDU 15/37/10 Rev; CRD10 (Comments of Brazil, Colombia, Ecuador, European Union, Indonesia, Mali, Mexico, Morocco and African Union); CRD18 (Comments of Thailand)

## SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY	DOCUMENT REFERENCE (REP16/NFSDU)
Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the <i>Guidelines on Nutrition Labelling</i> (CAC/GL 2-1985)	5/8	Governments CAC39	Para. 52a Appendix II Part I
Draft amendment to the Annex of the <i>Guidelines on Nutrition Labelling</i> (CAC/GL 2-1985) to add a definition for RASBs	Adoption	Governments CAC39	Para. 50a Appendix II Part II
Draft amendment to Section 10, Methods of analysis in <i>Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants</i> (CODEX STAN 72-1981)	Adoption	Governments CAC38	Para. 94 Appendix V Part I
Proposed Draft NRV-R for Vitamin D and the dietary equivalents and conversion factor for Vitamin E)	3	CCNFSDU38	Para. 52b Appendix II Part III
Review of the <i>Standard for Follow-Up Formula</i> (CODEX STAN 156-1987) (Section 2.1.1 and 2.2 and essential composition and optional ingredients) (6-12 months)	4	CCFNSDU38	Para. 61a and Appendix III, Part I
Review of the <i>Standard for Follow-Up Formula</i> (CODEX STAN 156-1987)	2/3	EWG/ PWG (New Zealand, France and Indonesia) CCNFSDU38	Para. 61b Appendix III, Part II
Proposed Draft Definition for Biofortification	2/3	EWG (Zimbabwe, South Africa) CCNFSDU38	Para. 71
Proposed Draft NRV-NCD for EPA and DHA long chain omega-3 fatty acids	2/3	EWG (Chile, Russian Federation) CCNFSDU38	Para. 80
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APPENDIX II

**PART I. PROPOSED DRAFT NEW OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES IN THE *GUIDELINES ON NUTRITION LABELLING (CAC/GL 2-1985)***

(for adoption at Step 5/8)

**3.4.4.1 NRVs-R**

<b>Vitamins</b>	
Vitamin A (µg RAE or RE)	800
Vitamin D (µg)	5*
Vitamin E (mg)	9
<b>Minerals</b>	
Magnesium (mg)	310
Iron (mg)**	14 (15% dietary absorption; Diversified diets, rich in meat fish, poultry, and/or rich in fruit and vegetables) 22 (10% dietary absorption; Diets rich in cereals, roots or tubers, with some meat, fish, poultry and/or containing some fruit and vegetables)
Copper (µg)	900
Phosphorus (mg)	700

\* Competent national and/or regional authorities should determine an appropriate NRV-R that best accounts for population sunlight exposure and other relevant factors.

\*\* Competent national and/or regional authorities should determine an appropriate NRV-R that best represents the dietary absorption from relevant diets.

Note: New text is presented in **bold and underlined font**; deletion in ~~strikethrough font~~

**Conversion factors for ~~niacin and folate~~ vitamin equivalents**

<b>Vitamin</b>	<b>Dietary equivalents</b>	
Niacin	1 mg niacin equivalents (NE) =	1 mg niacin 60 mg tryptophan
Folate	1 µg dietary folate equivalents (DFE) =	1 µg food folate 0.6 µg folic acid added to food or as supplement consumed with food 0.5 µg folic acid as supplement taken on an empty stomach
<b><u>Vitamin A</u></b>	<b><u>1 µg retinol activity equivalents (RAE) =</u></b>	<b><u>1 µg retinol</u></b> <b><u>12 µg β-carotene</u></b> <b><u>24 µg other provitamin A carotenoids</u></b>
	<b><u>OR</u></b> <b><u>1 µg retinol equivalents (RE) =</u></b>	<b><u>1 µg retinol</u></b> <b><u>6 µg β-carotene</u></b> <b><u>12 µg other provitamin A carotenoids</u></b>

The conversion factors for vitamin equivalents in the Table provide supporting information for ~~national authorities~~ to enable **competent** national **and/or** **regional** authorities to determine the **appropriate** application of NRVs-R ~~at national level.~~

**PART II. PROPOSED DRAFT AMENDMENTS TO THE ANNEX OF THE *GUIDELINES ON NUTRITION LABELLING*  
(CAC/GL 2-1985)**

(for adoption)

New paragraph 2.5

2.5 Recognized Authoritative Scientific Body (RASB) as used in these Principles refers to FAO and/or WHO (FAO/WHO), or an organization supported by a competent national and/or regional authority(ies) that provides independent, transparent\*, scientific and authoritative advice on daily intake reference values through primary evaluation\*\* of the scientific evidence upon request and for which such advice is recognized through its use in the development of policies in one or more countries.

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

\*\* Primary evaluation involves a review and interpretation of the scientific evidence to develop daily intake reference values, rather than the adoption of advice from another RASB.

B: Amendments to footnotes 13 and 15

<sup>13</sup> At the time these guiding principles were drafted, the definition and criteria for “convincing evidence” from the following FAO/WHO report were used Diet, Nutrition and the Prevention of Chronic Diseases. WHO Technical Report Series ~~916~~ 96. WHO, 2003.

<sup>15</sup> WHO’s Guidelines Review Committee. WHO Handbook for guideline development. Geneva, World Health Organization (WHO) , ~~2014~~ 2012 ([http://www.who.int/kms/handbook\\_2nd\\_ed.pdf](http://www.who.int/kms/handbook_2nd_ed.pdf) [http://apps.who.int/iris/bitstream/10665/75146/1/9789241548441\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/75146/1/9789241548441_eng.pdf)).

C. Amendments to Section 3.4.4.1 NRVs-R

<b>Vitamins</b>	
Niacin (mg NE)	15**
Iodine (µg)	150**

~~\*\* Competent national and/or regional authorities should determine an appropriate NRV-R that best represents the dietary absorption from relevant diets.~~

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

(at Step 3)

**NRVs-R**

Vitamin D ( $\mu\text{g}$ )	[10 $\mu\text{g}$ or 15 $\mu\text{g}$ ]
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**Conversion factors**

<b>Vitamin</b>	<b>Dietary equivalents</b>	
Vitamin E	1 mg $\alpha$ -tocopherol =	1 mg RRR- $\alpha$ -tocopherol (d- $\alpha$ -tocopherol)

**PROPOSED DRAFT REVISED STANDARD FOR FOLLOW-UP FORMULA  
(CODEX STAN 156-1987)**

**(PART I. at Step 4)**

**1. [SCOPE]**

**2. DESCRIPTION**

**2.1 Product Definition**

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

**2.2 Other Definitions**

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

2.2.2 The term **older infant** means a person from the age of 6 months and not more than 12 months of age.

2.2.3 The term **young child** means a person from the age of more than 12 months up to the age of three years (36 months).

**3. ESSENTIAL COMPOSITION AND QUALITY FACTORS** (*for older infants 6-12 months*)

**3.1 Essential composition**

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

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

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.

**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> Commercially hydrogenated oils and fats shall not be used in follow-up formula

<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

**$\alpha$ -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 /  $\alpha$ -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
$\mu$ g RE <sup>10)</sup> /100 kcal	75	180	-
$\mu$ g RE <sup>10)</sup> /100 kJ	18	43	-

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

1  $\mu$ g RE = 3.33 IU Vitamin A = 1  $\mu$ g 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
$\mu$ g <sup>11)</sup> /100 kcal	1.0	3.0	-
$\mu$ g <sup>11)</sup> /100 kJ	0.24	0.72	-

<sup>11)</sup> Calciferol. 1  $\mu$ g calciferol = 40 IU vitamin D.

**Vitamin E**

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

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

<sup>13)</sup> Vitamin E shall be at least 0.5 mg  $\alpha$ -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  $\alpha$ -TE /g linoleic acid (18:2 n-6); 0.75  $\alpha$ -TE/g  $\alpha$ -linolenic acid (18:3 n-3); 1.0 mg  $\alpha$ -TE/g arachidonic acid (20:4 n-6); 1.25 mg  $\alpha$ -TE/g eicosapentanoic acid (20:5 n-3); 1.5 mg  $\alpha$ -TE/g docosahexaenoic acid (22:6 n-3).

**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

**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 (0.36mg/100 kJ) a maximum of 2.5 mg/100 kcal (0.6/100 kJ) applies.

**Calcium**

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

**Phosphorus**

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/phosphorus**

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	-	100
µg /100 kJ	0.24	-	24

**Iodine**

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

**Selenium**

Unit	Minimum	Maximum	GUL
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	-	29

<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.

**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 competent national and/or regional authorities.

**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 competent national and/or regional authorities.

**PART II. Review of the *Standard for Follow-up Formula (CODEX STAN 156-1987)*  
Sections for further consideration by EWG**

2.1.1 **Follow-up formula** means a product intended for use as

- (a) a liquid part of the diet for older infants when complementary feeding is introduced; and  
b) a liquid part of the progressively diversified diet of young children.]

**3. ESSENTIAL COMPOSITION AND QUALITY FACTORS (for older infants 6 – 12 months)**

**3.1 Essential composition**

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

<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
g/100 kcal	[1.8] or [1.65] <sup>5)6)</sup>	[3.5] or [3.0] or [2.5]	-
g/100 kJ	[0.43] or [0.39] <sup>5)6)</sup>	[0.84] or [0.72] or [0.60]	-

<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. The value of 6.38 is generally established as a specific factor appropriate for conversion of nitrogen to protein in other milk products, and the value of [5.71] as a specific factor for conversion of nitrogen to protein in other soy 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); 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 or non-goats' 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 (0.54 g/100 kJ)] applies.

<sup>6)</sup> Follow-up formula based on non-hydrolysed milk protein containing less than [2 g protein/100 kcal] and] infant [formula based on hydrolysed protein containing less than [2.25 g protein/100 kcal] should be clinically evaluated].

**Vitamin K**

<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
µg /100 kcal	[1] or [4]	-	27
µg /100 kJ	[0.24] or [1]	-	6.5

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

<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg /100 kcal	[4] or [10]	-	70 <sup>16)</sup>
mg /100 kJ	[1] or [2.4]	-	17 <sup>16)</sup>

<sup>15)</sup> expressed as 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.

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

<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg /100 kcal	0.5	-	[1.0] or [1.5]
mg /100 kJ	0.12	-	[0.24] or [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) and maximum of [1.25 mg/100 kcal (0.3/100 kJ)] applies.

## 3.3.2 Optional ingredients

**Docosahexaenoic acid**<sup>20)</sup>

<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
% of fatty acids	[0.3]	-	0.5

<sup>20)</sup> If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which 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.

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

## PROJECT DOCUMENT

### For a Guideline for Ready to Use Therapeutic Foods (RUTF)

#### 1. Purpose and Scope of the Guideline

The scope of the work is to clearly define RUTF in terms of its composition and safety aspects related to suitable ingredients, incorporation of the nutritional composition as outlined in the 2007 Joint Statement by WHO, WFP, UNSCN and UNICEF<sup>1</sup>, appropriate criteria and limits for relevant microbiological hazards and chemical contaminants (e.g. heavy metals, mycotoxins and pesticides) and labelling requirements respectively in order to provide protection to vulnerable consumers of RUTF.

#### 2. Relevance and Timeliness

Currently RUTF products are produced in 19 and consumed in approximately 60 countries, mostly developing nations, and are traded extensively across borders. Most countries where RUTF are consumed have incorporated the use of RUTF into their national guidelines for outpatient, or community management of SAM. As the ability to reach malnourished children increases, there will be a greater demand for RUTF products produced in more appropriate sites, closer to the recipients. A codex guideline for RUTF will provide a reference for industry, consumers and government regulatory authorities to follow and provide the needed framework for the supply of consistently safe and nutritionally appropriate emergency food aid products across national borders.

#### 3. The main aspects to be covered

Guidance on

- i. minimum requirements for appropriate ingredients to be included in RUTF taking into consideration the effects of anti-nutritive factors that can affect macro and micro nutrient absorption. Consideration of inclusion of a protein quality score such as PDCAAS or DIAAS within the nutritional composition requirements.
- ii. composition based on the adoption of the nutritional composition as specified in existing WHO documents for RUTF and their future modification.
- iii. hygienic practice for production, handling, processing, storage and distribution and associated microbiological criteria for RUTF with reference to the General Principles of Food Hygiene and other relevant Codex texts.
- iv. chemical contaminants/criteria with reference to the *General Standard for Contaminants and Toxins in Food and Feed*.
- v. labelling of RUTF in accordance with the *General Standard for the Labelling of Pre-packaged Foods* and other relevant Codex texts.
- vi. Reference Methods of Analysis and Sampling
- vii. nutrient compounds used for the RUTF.

All work will be coordinated with the applicable general subject Codex Committee to ensure the appropriate application of Codex expertise and resources.

#### 4. General criteria

The Codex Alimentarius Commission has a mandate of protecting consumer's health and ensuring fair practices in food trade. The proposed guideline will meet this criterion by promoting consumer protection from the point of view of health, food safety and ensuring fair practices in the food trade and in particular:

- i. The nutritional composition will protect the consumer's health by providing a scientifically-based composition to facilitate recovery from malnutrition. The definition of the nutritional and food safety aspects for RUTF will enable harmonized specifications and regulation of these food products at a national level for the protection of the consumers, especially vulnerable children;
- ii. Appropriate labelling of RUTF in accordance with the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes*. (CODEX STAN 180-1991) will protect consumer health by clearly communicating the appropriate use, purpose and target group for RUTF thereby protecting intended and unintended consumers.

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<sup>1</sup> Joint Statement on Community-Based Management of Severe Acute Malnutrition by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children's Fund, 2007

## **5. Criteria applicable to general subjects**

### **(a) Diversification of national legislations and potential impediments to international trade**

National legislations for RUTF are not harmonised and this impedes trade of this commodity due to the lack of a clear international normative definition of this food.

### **(b) Scope of work and priorities between safety of RUTF, microbial and chemical contaminants**

The scope of work in developing a guideline for RUTF includes areas of work where the CCNFSDU, CCFH, CCCF and CCFL will need to be engaged. In terms of work priorities those areas related to the safety of these products need to be addressed at the outset given the lack of global science-based specifications for microbial and chemical contaminants.

### **(c) Work already conducted by FAO and WHO in this field**

The development of the guideline by the CCNFSDU would involve the assessment of the work already conducted by FAO and WHO in relation to their consultation with the international partner organisations.

In relation to nutritional aspects, the scientific basis for standards have already been developed for the existing nutritional composition of RUTF by the 2007 Joint Statement by WHO, WFP, UNSCN and UNICEF<sup>1</sup>, this can be assessed by CCNFSDU for inclusion into the RUTF guideline.

In reference to the microbiological hazards, UNICEF and WFP have already solicited scientific advice from FAO and WHO and an additional expert meeting was convened in this area in December 2014, so an adequate scientific basis to address microbiological food safety issues has been established.

An assessment of the work that has been undertaken to address microbiological safety both by the CCFH, and also the meeting of experts in December 2014 is also important as this will serve to address the most pressing issue of protecting large numbers of consumers from a food safety perspective.

### **(d) Amenability of the subject to standardization**

Taking into account the existing global guidance from WHO on these products standardisation in this area is attainable through defining: energy levels; protein content; lipids contents; moisture content; micronutrients; allowed minerals; raw material requirements etc.

### **(e) Global magnitude of the problem**

- i. RUTF are traded in 60 different countries, through several borders and have wide distribution, so food quality issues have considerable impact globally.
- ii. Globally, in 2013, 51 million children under five were wasted and 17 million were severely wasted. In 2013 approximately two thirds of all wasted children lived in Asia and almost one third in Africa, with similar proportions for severely wasted children.<sup>2</sup> Children with severe wasting or SAM have a risk of death eleven times higher than that of children without SAM.<sup>3</sup>
- iii. RUTF is provided to aid organisations and governments who have programs established to manage cases of SAM. The United Nations International Children's Fund (UNICEF), United States Agency for International Development (USAID), Doctors without Borders, Action against Hunger, and the International Red Cross in addition to many other aid agencies procure RUTF to manage cases of SAM. Many governments procure RUTF for use in community programs and hospitals.
- iv. For example, in 2014 UNICEF procured more than 30,440 Metric Ton (MT) of RUTF worth \$112 million USD, which reached approximately 2.6 million children with SAM. The product was mostly distributed to the regions of West and Central Africa (14 MTs) including Nigeria, Niger, Burkino Faso, Mali, Chad, Democratic Republic of Congo and Cameroon; followed by the region of East Africa (9 MTs) including Ethiopia, South Sudan, Sudan, Somalia and Kenya; the region of the Middle east (4 MTs) including Afghanistan and Yemen and Asia (2 MTs) including Pakistan.

### **(f) Relevance to the Codex strategic objectives;**

The proposed work will contribute to advancing the following Codex Strategic Goals in the Codex Strategic Plan 2014-2019:

- i. Strategic Goal 1: Establish international food safety guidelines that address current and emerging food issues

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<sup>2</sup> International Food Policy Research Institute. 2014. Global Nutrition Report 2014: Actions and Accountability to Accelerate the World's Progress on Nutrition. Washington, DC.

<sup>3</sup> Santini A, Novellino E, Armini V, and Ritieni A. State of the art of Ready-to-Use Therapeutic Food: a tool for nutraceuticals addition to foodstuff. Food Chemistry. 2013; Oct 15; vol 140(4):843-9

The provision of a guideline for RUTF will address a gap in food safety of a processed food that is traded globally.

- ii. Goal 2: Ensure the application of risk analysis principles in the development of Codex Standards

## **6. Information on the relation between the proposal and other existing Codex documents**

The proposed work will make reference to relevant standards and related texts in particular of the following:

- *Guidelines on Formulated Complementary Foods for Older Infants and Young Children* (CAC/GL 8-1991)
- *Standard for Infant formula and Formulas for Special medical purposes intended for infants* (CODEX STAN 72 -1981)
- *Advisory lists of mineral salts and vitamin compounds for use in Foods for Infants and Children* (CAC/GL 10-1979)
- *General Principles for Establishing Minimum and Maximum Values for the Essential Composition of Infant Formula* (Annex II, CODEX STAN 72-1981)
- *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CAC/GL 21-1997)
- *Code of Hygienic Practice for Low Moisture Foods* (CAC/RCP 75-2015), *Code of Hygienic practice for Powdered Infant Formulae for Infants and young children* (CAC/RCP 66-2008) and its annexes.
- *General Principles of Food Hygiene* (CAC/RCP1-1969)
- *Code of Hygienic Practice for Groundnuts (Peanuts)* (CAC/RCP 22-1979)
- *General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985) and *General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses* (CODEX STAN 146-1985)
- As the products composition can be made of ingredients such as peanuts, milk powders, sugar, oil, legumes, cereal and vitamin and mineral premix, the relevant standards for these commodity raw materials should be taken into consideration.

## **7. Identification of any requirement for and availability of expert scientific advice**

The development of the Guideline will be consistent with the use of scientific advice and risk analysis principles in the articulation of the nutritional ingredient composition and safety aspects.

## **8. Identification of any requirement for technical input to the guideline from external bodies so that this can be planned for**

No need for technical input from external bodies.

## **9. Proposed timeline**

Subject to approval by the Commission in 2016, the development of the Guideline will be submitted for consideration by CCNFSDU in 2016 and expected to take four session of CCNFSDU or less depending upon the relevant inputs and agreement from members. Final adoption by the Commission is foreseen for 2020.

**PART I. METHODS OF ANALYSIS IN THE STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (CODEX STAN 72-1981)**

(for endorsement by CCMAS)

AOAC Official Methods validated in Infant Formula with ISO/IDF References

<b>Commodity</b>	<b>Provision</b>	<b>Method</b>	<b>Principle</b>	<b>Proposed Type</b>
Infant Formula	Vitamin B12	AOAC 2011.10 ISO 20634	High Performance Liquid Chromatography (HPLC)	II
Infant Formula	Myo-Inositol	AOAC 2011.18 ISO 20637	Liquid Chromatography (LC)-pulsed amperometry	II
Infant Formula	Chromium	AOAC 2011.19 ISO 20649   IDF 235	Inductive Coupled Plasma-Mass Spectrometry (ICP-MS)	II
Infant Formula	Selenium	AOAC 2011.19 ISO 20649   IDF 235	ICP-MS	II
Infant Formula	Molybdenum	AOAC 2011.19 ISO 20649   IDF 235	ICP-MS	II
Infant Formula	5'-Mononucleotides	AOAC 2011.20 ISO 20638	LC	II
Infant Formula	Vitamin A Palmitate (Retinyl Palmitate), Vitamin A Acetate (Retinyl Acetate), Total Vitamin E (dl- $\alpha$ -Tocopherol and dl- $\alpha$ -Tocopherol Acetate)	AOAC 2012.10 ISO 20633	HPLC	II
Infant Formula	Total Fatty Acid Profile	AOAC 2012.13 ISO 16958   IDF 231	Gas Chromatography	II
Infant Formula	Iodine	AOAC 2012.15 ISO 20647   IDF 234	ICP-MS	II
Infant Formula	Pantothenic Acid	AOAC 2012.16 ISO 20639	Ultra HPLC-MS/MS	II

**PART II. AMENDMENT TO THE STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL  
MEDICAL PURPOSES INTENDED FOR INFANTS (CODEX STAN 72-1981)**

(for adoption)

Note: New text is presented in **bold and underlined font**; deletion in ~~striketrough~~ font

**10. METHODS OF ANALYSIS AND SAMPLING<sup>4</sup>**

**See the *Recommended Methods of Analysis and Sampling* (CODEX STAN 234-1999).**

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<sup>4</sup>~~To be finalized.~~

**APPENDIX VI**

**INFORMATION DOCUMENT ON DERIVATION OF NUTRIENT REFERENCE VALUES-  
REQUIREMENTS (NRVs-R) FOR LABELLING PURPOSES IN THE GUIDELINES ON NUTRITION  
LABELLING (CAC/GL 2-1985)**

<b>Nutrient</b>	<b>NRV-R</b>	<b>INL<sub>98</sub>, AI, or both</b>	<b>RASB source documents for derivation of NRVs-R</b>	<b>CCNFSDU Report</b>
<b>Vitamins</b>				
Vitamin A	800 µg (RAE or RE)	INL <sub>98</sub>	IOM (2001)	REP 16/NFSDU, 2015
Vitamin D				
Vitamin C	100 mg	INL <sub>98</sub>	Average EFSA (2013), NIHN (2013)	REP 15/NFSDU, 2014
Vitamin E	9 mg (TBD)	AI	Nordic Council (2013), and average of EFSA (2015), NHRMC/MOH (2006), NIHN (2013), WHO/FAO (2004)	REP 16/NFSDU, 2015
Vitamin K	60 µg	INL <sub>98</sub>	WHO/FAO (2004)	REP 13/NFSDU, 2012
Thiamin	1.2 mg	INL <sub>98</sub>	WHO/FAO (2004)	REP 13/NFSDU, 2012
Riboflavin	1.2 mg	INL <sub>98</sub>	WHO/FAO (2004)	REP 13/NFSDU, 2012
Niacin	15 mg NE	INL <sub>98</sub>	WHO/FAO (2004)	REP 13/NFSDU, 2012
Vitamin B <sub>6</sub>	1.3 mg	INL <sub>98</sub>	WHO/FAO (2004)	REP 13/NFSDU, 2012
Folate	400 µg DFE	INL <sub>98</sub>	WHO/FAO (2004)	REP 13/NFSDU, 2012
Vitamin B <sub>12</sub>	2.4 µg	INL <sub>98</sub>	WHO/FAO (2004)	REP 13/NFSDU, 2012
Pantothenate	5 mg	INL <sub>98</sub>	WHO/FAO (2004)	REP 13/NFSDU, 2012
Biotin	30 µg	INL <sub>98</sub>	WHO/FAO (2004)	REP 13/NFSDU, 2012
<b>Minerals</b>				
Calcium	1,000 mg	INL <sub>98</sub>	WHO/FAO (2004)	REP 13/NFSDU, 2012
Magnesium	310 mg	INL <sub>98</sub>	Average IOM (1997), NIHN (2013), WHO/FAO (2004), Nordic Council (2013)	REP 16/NFSDU, 2015
Iron	14 mg, 22 mg	INL <sub>98</sub>	WHO/FAO (2004)	REP 16/NFSDU, 2015
Zinc	11 mg, 14 mg	INL <sub>98</sub>	iZiNCG (2004)	REP 15/NFSDU, 2014 <sup>1</sup>
Iodine	150 µg	INL <sub>98</sub>	WHO/FAO (2004)	REP 13/NFSDU, 2012
Copper	900 µg	INL <sub>98</sub>	IOM (2001)	REP 16/NFSDU, 2015
Selenium	60 µg	INL <sub>98</sub> and AI	Average IOM (2000), NHMRC/MOH (2006), EFSA (2014), NIHN (2013), Nordic Council (2013)	REP 15/NFSDU, 2014
Manganese	3 mg	AI	Average EFSA (2013), IOM (2001)	REP 15/NFSDU, 2014
Molybdenum	45 µg	INL <sub>98</sub>	IOM (2001)	REP 15/NFSDU, 2014
Phosphorus	700 mg	INL <sub>98</sub>	IOM (1997)	REP 16/NFSDU, 2015
<b>Other</b>				
Protein	50 g	INL <sub>98</sub>	WHO/FAO (2007)	REP 14/NFSDU, 2013
Fluoride			Not established	REP 15/NFSDU, 2014
Chromium			Not established	REP 16/NFSDU, 2015
Chloride			Not established	REP 16/NFSDU, 2015

<sup>1</sup> Also footnote and dietary description

#### ABBREVIATIONS

NRV-R: Nutrient Reference Values – Requirements

INL<sub>98</sub>: Individual Nutrient Level 98

AI: Adequate Intake

RASB: Recognized Authoritative Scientific Body