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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,
    Codex Alimentarius Commission,
    Joint FAO/WHO Food Standards Programme,
    E-mail: codex@fao.org,
    Viale delle Terme di Caracalla,
    00153 Rome, Italy

Subject: DISTRIBUTION OF THE REPORT OF THE 37TH SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (REP16/NFSDU)

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

PART A - MATTERS FOR ADOPTION BY THE 39TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

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


2. Amendments to the Annex of the Guidelines on Nutrition Labelling (CAC/GL2-1985) (para. 52a), Appendix II, 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) 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: cnfsdu@bmel.bund.de with copy to Codex Alimentarius Commission, by email: 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

Other texts for adoption
- Amendments to the Annex to CAC/GL 2-1985 (para. 52a and Appendix II, 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. 52b 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).
# TABLE OF CONTENTS

Summary and Conclusions ...................................................................................................................... page ii  

Report of the Thirty Seventh Session of the Committee  
on Nutrition and Foods for Special Dietary Uses .................................................................................... page 1  

Summary Status of Work ...................................................................................................................... page 14  

**Paragraphs**  

Introduction ........................................................................................................................................................ 1  

Opening of the Session ............................................................................................................................... 2 - 3  

Adoption of the Agenda (Agenda Item 1) ........................................................................................................ 5  

Matters Referred to the Committee by the Codex Alimentarius Commission and/or Other Codex Committees (Agenda Item 2) ........................................................................................................ 6 - 10  

Matters of Interest Arising from FAO and WHO (Agenda Item 3) ...................................................................... 11 - 15  

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) ........................................................................................................ 16 - 52  

Review of the *Standard for Follow-up Formula* (CODEX STAN 156-1987) at Step 4 (Agenda Item 5) ................................................................................................................................. 53 - 61  

Proposed Draft Definition for Biofortification at Step 4 (Agenda Item 6) .................................................. 62 - 71  

Proposed Draft NRV-NCD for EPA and DHA Long Chain Omega-3 Fatty Acids at Step 4 (Agenda Item 7) ................................................................................................................................. 72 - 80  

Discussion Paper on a Standard for Ready-to-Use Foods (Agenda Item 8) .............................................. 81 - 88  

Discussion Paper on Claim for “Free” of Trans Fatty Acids (Agenda Item 9) ....................................................... 89  

Food Additives in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981) (Agenda Item 10) ...................................................................................... 90 - 95  

Other Business and Future Work (Agenda Item 11) ..................................................................................... 96 - 97  

Date and Place of Next Session (Agenda Item 12) ......................................................................................... 98  

**Appendices**  

Appendix I  

List of Participants ................................................................................................................................. page 15  

Appendix II  


Appendix III  


Part II. Review Of The *Standard for Follow-Up Formula* (CODEX STAN 156-1987) sections for further consideration by the EWG ........................................................................................................ page 44  

Appendix IV Project Document for a Guideline for Ready to Use Therapeutic Foods (RUTF) ................................................................................................................................. page 46
Appendix V

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) .......................................................... page 49

Part II. Amendment to the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981) (for adoption) ................................................................. page 50

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) ................................................................. page 51
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

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)

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 6th 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)

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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1 CRD1  
2 CX/NFSDU 15/37/1  
3 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)4

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 level5. 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 website6.

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

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4 CX/NFSDU 15/37/3
5 http://www.fao.org/documents/card/en/c/678ab9d4-e7a8-4388-9f9f-1c709ea47752/
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)

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 INL98.

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...
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:
   a) modify the NRV-R to refer to % dietary absorption; and
   b) to revise the NRV-R from 14 mg to 14mg (15% dietary absorption) and 22 mg (10% dietary absorption).

26. The Committee agreed to:
   a) the dietary description related to the NRV-R for iron as recommended by the eWG.
   b) 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 INL98 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 INL98 of IOM.

34. The Committee agreed to adopt the recommendation for the NRV-R for copper of 900 µg based on the INL98 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 α-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 α-tocopherol as Vitamin E mentioned that α-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 α-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 CCNFSDU 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 CCNFSDU 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 CCNFSDU 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\(^8\) 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.

\(^8\) 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)

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

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9 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, α -linolenic acid, linoleic acid, Vitamins D, E, riboflavin, niacin, Vitamin B₆, Vitamin B₁₂, 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 µg 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 µg/100 kcal as a compromise despite their preference for a lower level of 114 µg/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 α-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.

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 CCNFSDU37 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 CCNFSDU38 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
Status of the Review of the Standard for Follow-Up Formula (CODEX STAN 156-1987)

61. The Committee agreed to:
   a) 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.
   b) 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)¹⁰

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.

¹⁰ 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)
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.

The Committee considered the recommendations as presented in CX/NFSDU 15/37/7 and noted that there were divergent views on the proposal.

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.

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.

The Committee therefore considered the need to obtain additional scientific advice through JEMNU or NUGAG.

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/68351/en).

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

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

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)

The representative of UNICEF presented a summary of the revised discussion paper and noted that the
revision had taken into account the comments made during CCNFSDU36. 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 CCNFSDU36 (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 CCNFSDU 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)\textsuperscript{13}

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\textsuperscript{th} 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)**\textsuperscript{14}

90. The Chairperson recalled that CCNFSDU36 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 medial 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 medial 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.

\textsuperscript{13} CX/NFSDU 15/37/9 (Not issued)

\textsuperscript{14} REP15/NFSDU, Appendix VI; CRD9 (Comments of Colombia, Indonesia, Philippines and Thailand)
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)

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 CCNFSU36, all other food additives not on the JECFA priority list would be removed.

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.

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)


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/NFSU 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).

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)

The Committee was informed that the 38th 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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15 CX/NFSU 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

<table>
<thead>
<tr>
<th>SUBJECT MATTER</th>
<th>STEP</th>
<th>ACTION BY</th>
<th>DOCUMENT REFERENCE (REP16/NFSDU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft amendment to the Annex of the <em>Guidelines on Nutrition Labelling</em> (CAC/GL 2-1985) to add a definition for RASBs</td>
<td>Adoption</td>
<td>Governments CAC39</td>
<td>Para. 50a Appendix II Part II</td>
</tr>
<tr>
<td>Draft amendment to Section 10, Methods of analysis in <em>Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants</em> (CODEX STAN 72-1981)</td>
<td>Adoption</td>
<td>Governments CAC38</td>
<td>Para. 94 Appendix V Part I</td>
</tr>
<tr>
<td>Proposed Draft NRV-R for Vitamin D and the dietary equivalents and conversion factor for Vitamin E</td>
<td>3</td>
<td>CCNFSDU38</td>
<td>Para. 52b Appendix II Part III</td>
</tr>
<tr>
<td>Review of the <em>Standard for Follow-Up Formula</em> (CODEX STAN 156-1987) (Section 2.1.1 and 2.2 and essential composition and optional ingredients) (6-12 months)</td>
<td>4</td>
<td>CCFNSDU38</td>
<td>Para. 61a and Appendix III, Part I</td>
</tr>
<tr>
<td>Review of the <em>Standard for Follow-Up Formula</em> (CODEX STAN 156-1987)</td>
<td>2/3</td>
<td>EWG/ PWG (New Zealand, France and Indonesia) CCFNSDU38</td>
<td>Para. 61b Appendix III, Part II</td>
</tr>
<tr>
<td>Proposed Draft Definition for Biofortification</td>
<td>2/3</td>
<td>EWG (Zimbabwe, South Africa) CCNFSDU38</td>
<td>Para. 71</td>
</tr>
<tr>
<td>Proposed Draft NRV-NCD for EPA and DHA long chain omega-3 fatty acids</td>
<td>2/3</td>
<td>EWG (Chile, Russian Federation) CCNFSDU38</td>
<td>Para. 80</td>
</tr>
<tr>
<td>Proposed guideline for Ready-to-Use Foods (RUF)</td>
<td>1,2,3</td>
<td>EWG (South Africa, Senegal, and Uganda) CCNFSDU38</td>
<td>Para. 88 Appendix IV</td>
</tr>
<tr>
<td>Discussion Paper on Claim for “Free” of Trans Fatty Acids</td>
<td>-</td>
<td>Canada CCNFSDU38</td>
<td>Paras 9 and 87</td>
</tr>
<tr>
<td>Alignment of food additive provisions in standards developed by CCNFSDU</td>
<td>-</td>
<td>CCNFSDU38</td>
<td>Para. 94</td>
</tr>
</tbody>
</table>
APPENDIX I

LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES

CHAIRPERSON - PRÉSIDENT - PRESIDENTE

Dr Pia Noble
Federal Ministry of Food and Agriculture
Rochusstrasse 1
Bonn
Germany
Tel: +49 228 99 529 4665
Email: ccnfsdu@bmel.bund.de

ASSISTANT TO THE CHAIRPERSON - ASSISTANT AU PRÉSIDENT - ASISTENTE AL PRESIDENTE

Mrs Katharina Adler
Federal Ministry of Food and Agriculture
Rochusstrasse 1
Bonn
Germany
Tel: +49 228 99 529 4647
Email: ccnfsdu@bmel.bund.de

MEMBER COUNTRIES - PAYS MEMBRES - PAÍSES MIEMBROS

ALGERIA - ALGÉRIE - ARGELIA

Mr Yassine Tidjini
Ministère du Commerce
Cité Zerhouni Mokhtar, El Mohammadia Bab Ezzouar
Alger
Algeria
Tel: +213 21 89 07 61
Email: mire10yacine@hotmail.fr

AUSTRALIA - AUSTRALIE

Ms Janine Lewis
Food Standards Australia New Zealand
PO Box 7186
CANBERRA ACT
Australia
Tel: +61 62 6271 2245
Email: janine.lewis@foodstandards.gov.au

Ms Victoria Landells
Fonterra
327 Ferntree Gully Roas
MT WAPERLEY, VIC
Australia
Tel: +61 409 215 487
Email: Victoria.landells@fonterra.com

Ms Melissa Toh
Nestle Australia Ltd
Level 2, Building D, 1 Homebush Bay Drive
RHODES NSW
Australia
Tel: +61 2 9736 0416
Email: melissa.toh@au.nestle.com

BANGLADESH

Dr Swapan Kumar Roy
Bangladesh Breastfeeding Foundation (BBF)
Institute of Public Health (IPH) Room#197-200 (GF)
Mohakhali
Dhaka
Bangladesh
Tel: +8801943220587
Email: skroy1950@gmail.com

Mr Mohammad Molla
Infant and Young Child Nutrition Association of Bangladesh
Khan Mansoin (5th Floor) 107 Motijheel C/A, Dhaka-1000 Bangladesh.
DHAKA
Bangladesh
Tel: +8801713095976
Email: naharul.islam@bd.nestle.com

Mr Iftaker Rashid
Infant and Young Child Nutrition Association of Bangladesh
Khan Mansion (5th Floor) 107 Motijheel C/A, Dhaka-1000 Bangladesh.
DHAKA
Bangladesh
Tel: +8801714101229
Email: iftaker@lalmai.com

BELARUS - BÉLARUS - BELARÚS

Mrs Natalia Tsemborevitch
Scientific-Practical Centre of Hygiene
Ministry of Health
Belarus
Email: tse.natasha@yandex.ru
BELGIUM - BELGIQUE - BÉLGICA
Ms Isabelle Laquière
FPS public health.
Eurostation - Place victor horta, 40 bte 10
Brussels Belgium
Tel: +32 2 524 73 64
Email: isabelle.laquiere@health.belgium.be

BRAZIL - BRÉSIL - BRASIL
Ms Elisabete Gonçalves Dutra
National Health Surveillance Agency - Anvisa
SIA, Trecho 5, área especial 57
Brasilia-DF Brazil
Tel: +55 61 3462-5333
Email: elisabete.goncalves@anvisa.gov.br

Ms Ana Claudia Marquim Firmo De Araújo
National Health Surveillance Agency - Anvisa
SIA, Trecho 5, área especial 57
Brasilia-DF Brazil
Tel: 55 61 3462 5332
Email: ana.firmo@anvisa.gov.br

Ms Fernanda Oliveira
Brazilian Society of Pediatrics/UNIFESP
Rua Loefgreen 1647, Vila Clementino
Zip Code 04040-032
São Paulo Brazil
Tel: +55 11 50844538/+55 11 9815867
Email: fernandalco@gmail.com

Ms Thelma R. T. Lahóz Moya
ABIA – Brazilian Association of Food Industries
Av. Brigadeiro Faria Lima, 1478
11º andar São Paulo
Brazil
Tel: 55 11 30301394 / 55 11 9927580
Email: thelma.moya@abbott.com

Mr Helio Vannucchi
School of Medicine of Riberao Preto
University of Sao Paulo
Riberao Preto Brazil
Tel: 55-16-991114142
Email: hvannucc@fmrp.usp.br

CAMBODIA - CAMBODGE - CAMBOYA
Mr Oun Phan
Ministry of Commerce
Kdey Takoy Village, Sangkat Viel Sbov, Khan Chba Ampeuv
Phnom Penh Cambodia
Tel: +855-12568356
Email: oon.phan@yahoo.com

Mr Theng Dim
Ministry of Commerce
Kdey Takoy Village, Sangkat Viel Sbov, Khan Chba Ampeuv
Phnom Penh Cambodia
Tel: +855-12526660
Email: dimtheng@gmail.com

CANADA - CANADÁ
Dr William Yan
Health Canada
251 Sir Frederick Banting Driveway, A.L. 2203B,
Room B331
Ottawa Canada
Tel: 613-948-8478
Email: william.yan@hc-sc.gc.ca

Ms Melody Harwood
Neptune Technologies & Bioressources Inc.
Neptune Technologies and Bioressources Inc. 545 Promenade du Centropolis, Suite 100
Laval Canada
Tel: 424-384-7872
Email: M.Harwood@neptunebiotech.com

Ms Maya Villeneuve
Health Canada
251 Sir Frederick Banting Driveway, A.L. 2203B, room B333
Ottawa Canada
Tel: 613 - 960-4740
Email: maya.villeneuve@hc-sc.gc.ca

CHILE - CHILI
Mr Cristian Cofre
Ministerio de Salud
Mac Iver 459, piso 8
Santiago Chile
Tel: +56 2 25740610
Email: cristian.cofre@minsal.cl

Ms Ana Cristina Canales
Ministerio de Relaciones Exteriores
Teatino 180, piso 11
Santiago Chile
Tel: +56 2 28275237
Email: acanales@direcon.gob.cl
Mrs Karla Carmona  
Ministerio de Agricultura  
Nueva York 17, piso 4  
Santiago  
Chile  
Tel: +56 2 27979900  
Email: karla.carmona@achipia.gob.cl

Ms Taotao Deng  
China National Center for Food Safety Risk Assessment  
2-202, NO 37. Guangqu Road, Chaoyang District  
1000022 Beijing  
China  
Tel: 86-10-52165431  
Email: dengtaotao@cfsa.net.cn

Prof Junhua Han  
China National Center for Food Safety Risk Assessment  
2-209, NO 37. Guangqu Road, Chaoyang District,  
1000022 Beijing  
China  
Tel: 86-10-52165426  
Email: Hanjhua@cfsa.net.cn

Ms Dong Liang  
China National Center for Food Safety Risk Assessment  
2-202, 37 Guangqu Road, Building 2, Chaoyang  
1000022 Beijing  
China  
Tel: 86-10-52165430  
Email: liangdong@cfsa.net.cn

Ms Jing Shen  
Hangzhou entry-exit Inspection and Quarantine Bureau  
1716 Room No.2 Wensan Road, Xihu District,  
Hangzhou City, Zhejiang Province, China  
Hangzhou  
China  
Tel: +86-571-56663139  
Email: Shenj@ziq.gov.cn

Ms Lan Wu  
Shanghai entry-exit inspection & quarantine bureau of China  
66 Huacheng Avenue, Zhujiang New City, Tianhe District,  
Guangzhou  
China  
Tel: 86-20-38297960  
Email: wul@gdciq.gov.cn

Ms Yijing Zhao  
Shanghai entry-exit inspection & quarantine bureau of China  
Division for supervision on food safety, Section 3  
Rm.1215, No.1208 Minsheng Road, Pudong, Shanghai  
China  
Tel: 86-21-38620978  
Email: zhaoyj@shciq.gov.cn

Mr Dayue Bao  
China Food Information Center  
Room 2604,Tower B, Riyuetianl Building,No.17, Fangchengyuan  
Fengtai District  
Beijing  
China  
Tel: 86-10-58076603  
Email: baodayue@126.com

Mr Rui Chen  
The Center for Inspection and Supervision  
Nation Health and family planning Commission  
No32,Beisantiao Jiaodaokou, Dongcheng District  
Beijing  
China  
Tel: 86-10-840001019  
Email: chenhui@nhfpc.gov.cn

Ms Xinrui Dong  
Standard and Regulation Research Center, AQSIQ  
Room 909, Sanyuan Mansion, No.18 Xibahe Dongli  
Chaoyang District  
Beijing  
China  
Tel: 86-10-84603875  
Email: dongxx@aqsiq.gov.cn

Mr Guoqiang Gong  
National Health and Family Planning Commission  
No.1,Nan Road, Xizhimenwai, Xicheng Deistrict,  
Beijing  
China  
Tel: 86-10-68792985  
Email: gonggq@nhfpc.gov.cn

Mr Weixuan Lin  
Liaoning Entry- exit Inspection and Quarantine Bureau of The Peoples Republicof China  
NO.60 Changjiang East Load, Zhongshan District, Dalian  
Dalian  
Colombia  
Tel: 86-411-82583672  
Email: diciqlxw@sina.com

Ms Yanjun Liu  
China National Center for Food Safety Risk Assessment  
Building 2, No. 37 Guangqu Lu, Chaoyang  
Beijing  
China  
Tel: 86-10-52165516  
Email: Liuyanjun@cfsa.net.cn

Mr Chang Su  
National Institute for Nutrition and Health  
Chinese Center for Disease Control and Prevention  
29 Nanwei Road, Xicheng District  
Beijing  
China  
Tel: 86-10-83132503  
Email: suchanglon@126.com
Ms Sau King Carole Tam  
Centre for Food Safety, Food and Environmental Hygiene Department  
43/F, Queensway Government Offices,66 Queensway  
Hong Kong  
China  
Tel: (852) 28675526  
Email: csktam@fehd.gov.hk

Mr Mingfeng Wei  
China Food Information Center  
Room 2604,Tower B,Riyuetiandi Building,No.17,Fangchengyuan,Fengtai District,  
Beijing  
China  
Tel: 86-10-58076603  
Email: wmf@chinafic.org

Mr Weixing Yan  
China National Center for Food Safety Risk Assessment  
Building 2, no 37. Guangqu road, Chaoyang District  
Beijing  
China  
Tel: 86-10-52165426  
Email: yanweixin@cfsa.net.cn

Mr Chaoqun Yang  
Inner Mongolia Yili Industrial Group Co.,Ltd  
NO.55 Huaweixili,Chaoyang District,100021  
Beijing  
China  
Tel: 86 10 58640640  
Email: ytnyangchaogun@yili.com

COLOMBIA - COLOMBIE

Mrs Laura Otalora  
ANDI  
Carrera 83 No. 71 - 81 piso 3  
Bogotá  
Colombia  
Tel: 57316702781  
Email: lauraotalora52@hotmail.com

Ing Julio Cesar Vanegas Rios  
Instituto Nacional de Vigilancia de Medicamentos y Alimentos - INVIMA  
Carrera 68 No. 17 - 11  
Bogotá  
Colombia  
Tel: 057 1 2947800  
Email: jvanegasr@invima.gov.co

CUBA

Dr Yarisa Dominguez Ayllón  
National Institute of Hygiene, Epidemiology and Microbiology  
Infanta 1158  
La Habanna  
Cuba  
Tel: 53-78785919  
Email: yarisa65@yahoo.com

CÔTE D'IVOIRE

Mr Brou ComoÉ Marius Rodriguese  
Fédération des Associations de Consommateurs Actifs de Côte d'Ivoire (FACACI)  
Immeuble CERISON (Abidjan-Plateau), 3ème étage 10 BP 1534  
Abidjan  
Côte d'Ivoire  
Tel: 20210909  
Email: micopci@yahoo.fr

DENMARK - DANEMARK - DINAMARCA

Mrs Dagny Løvoll Warming  
Danish Veterinary and Food Administration  
Stationsparken 31  
Glostrup  
Denmark  
Tel: +45 7227 6900  
Email: dlw@fvst.dk

Mrs Marianne Larsen  
Danish Veterinary and Food Administration  
Stationsparken 31  
Glostrup  
Denmark  
Tel: +45 7227 6900  
Email: maola@fvst.dk

Mrs Laila Lundby  
Danish Agriculture and Food Council  
Axeltorv 3  
Copenhagen  
Denmark  
Tel: +45 3339 4476  
Email: llu@if.dk

DJIBOUTI

Mr Mouharam Fouad Abdallah  
Ministère du commerce cité Ministérielle,Djibouti ville  
Djibouti  
Djibouti  
Tel: 00253 77 82 11 94  
Email: marahuom@hotmail.com
ECUADOR - ÉQUATEUR

Mrs Maria Isabel Salazar Cobo
Ministerio de Salud Pública del Ecuador
Quito
Ecuador
Tel: 593-2 381-4400
Email: mariai.salazar@msp.gob.ec

EGYPT - ÉGYPTE - EGIPTO

Mr Mohamed Abd Elhamid Naser
Organization: Egyptian Organization for Standardization and Quality (EOS)
16 tadreeb el motderbeen
Cairo
Egypt
Tel: 0201281337667
Email: atch_toto3@yahoo.com

Dr Shaimaa Sarhan
Summit 44- ElShamaly 90 St., AlTagamoaaa ElKhames
New Cairo
Egypt
Tel: 01281130888
Email: shaimaa.sarhan@eg.nestle.com

Mr Yasser Shazly
Chamber of food industries
1195 Comish EL Nil, P.O Box
Cairo
Egypt
Tel: +20225748627
Email: yasser@egycfi.org.eg

EQUATORIAL GUINEA - GUINÉE ÉQUATORIALE - GUINEA ECUATORIAL

Mr Antonio Bonifatio Mba Ndong
Ministerio de Agricultura & Bosques
Avenida Hassan II
Malabo
Equatorial Guinea
Email: ambandong@yahoo.es

Mr Benito Obama Nve Mirue
Ministerio de Agricultura & Bosques
Avenida Hassan II
Malabo
Equatorial Guinea
Email: silvestreabaga@yahoo.es

EUROPEAN UNION - UNION EUROPÉENNE - UNIÓN EUROPEA

Mr Alexander Rogge
General Secretariat of the Council, Luxembourg
Presidency
Email: alexander.rogge@consilium.europa.eu

Ms Ella Strickland
European Commission
Rue Froissart 101
Brussels
Belgium
Tel: +32 229-93030
Email: ella.strickland@ec.europa.eu

Ms Stephanie Bodenbach
European Commission
Rue Belliard 232
Brussels
Belgium
Tel: +32 229-80938
Email: Stephanie.BODENBACH@ec.europa.eu

Ms Anja Brönstrup
European Food Safety Authority
Via Carlo Magno 1A
Parma
Italy
Tel: +39 0521 036 928
Email: Anja.BRONSTRUP@efsa.europa.eu

Mr Marco Castellina
European Commission
Rue Belliard 232 - 02/009
Brussels
Belgium
Tel: +32 229-97987
Email: Marco.CASTELLINA@ec.europa.eu

Ms Christophe Didion
European Commission
Rue Froissart 101 2/54
Brussels
Belgium
Tel: +32 229-95427
Email: Christophe.DIDION@ec.europa.eu

Mr Matteo Mascolo
European Union
Rue Breydel 4
Brussels
Belgium
Email: mrmascolo@gmail.com

FINLAND - FINLANDE - FINLANDIA

Ms Anna Lemström
Ministry of Agriculture and Forestry
P.O. Box 30 00023 *Government
Helsinki
Finland
Tel: +358 295 162145
Email: anna.lemstrom@mmm.fi
FRANCE - FRANCIA
Ms Alice Stengel
Ministère de l'économie, de l'industrie et du numérique
59, bd Vincent Auriol
Paris
France
Tel: 00 33 1 44 97 33 25
Email: Alice.STENGEL@dgccrf.finances.gouv.fr

Mrs Mathilde Bridier
Nutriset
Hameau du Bois Ricard
Malaunay
France
Email: mbridier@nutriset.fr

Mr Thomas Couaillet
Nutriset
Hameau du Bois Ricard
Malaunay
France
Tel: +33 2 32 93 82 82
Email: tcouaillet@nutriset.fr

Mr Anders Liljegren
Roquette S.A.
1 rue de la Haute Loge
Lestrem
France
Email: anders.liljegren@roquette.com

Mr Thibault Martenot
nutriset
Hameau du Bois Ricard
Malaunay
France
Email: tmartenot@nutriset.fr

GERMANY - ALLEMAGNE - ALEMANIA
Dr Hartmut Waldner
Federal Ministry of Food and Agriculture
Rochusstrasse 1
Bonn
Germany
Tel: +49 228 99 529 4961
Email: ccnfsdu@bmi.bund.de

Ms Claudia Callies-klüpfel
BASF SE
ENS/HR - F31
Lampertheim
Germany
Tel: +49 621 60 58377
Email: claudia.callies-kluepfel@basf.com

Dr Gert Krabichler
Merck Consumer Health
Frankfurter Straße 250
Darmstadt
Germany
Tel: +49 6151 856 3264
Email: gert.krabichler@merckgroup.com

Ms Inken Stark
Federation of German Dietetic Foods
Godesberger Allee 142 - 145
Bonn
Germany
Tel: +49 228 3085111
Email: stark@diaetverband.de

Ms Angelika Mrohs
German Federation of Food Law and Food Science
Claire-Waldoff-Str. 7
Berlin
Germany
Tel: +49 30 206143 133
Email: amrohs@bll.de

Ms Antje Preußker
German Federation for Food Law and Food Science
Claire-Waldoff-Str. 7
Berlin
Germany
Tel: +49 30 206143 146
Email: apreussker@bll.de

Ms Sabine Sulzer
Nestlé Deutschland AG
Lyoner Straße 23
Frankfurt am Main
Germany
Tel: +49 69 6671 2276
Email: sabine.sulzer@de.nestle.com

Dr Anke Weißenborn
Federal Institute for Risk Assessment
Max-Dohrn-Str. 8-10
Berlin
Germany
Tel: +49 30 18412 3812
Email: anke.weissenborn@bfr.bund.de

GHANA
Ms Maria Aba Lovelace-Johnson
Food and Drugs Authority
P. O. Box Ct 2783 Cantonments
Accra
Ghana
Tel: +233 233 208115619
Email: marieluv2004@hotmail.com

Ms Gloria Anowa Brown
Food and Drugs Authority
P. O. Box Ct 2783 Cantonments
Accra
Ghana
Tel: +233 244 884133
Email: anowaackon@gmail.com
Ms Joyce Okoree  
Ghana Standards Authority  
P. O. Box Mb 245  
Accra  
Ghana  
Tel: +233 244 381351  
Email: jooko88@yahoo.com

**HUNGARY - HONGRIE - HUNGRÍA**

Dr Éva Barna  
National Institute of Pharmacy and Nutrition  
Albert Flórián út 3/a  
Budapest  
Hungary  
Tel: +36 1 476 6450  
Email: Barna.Eva@ogyei.gov.hu

**INDIA - INDE**

Dr Sandhya Kabra  
Food Safety And Standards Authority of India (FDA)  
Bhawan, Near Bai Bhavan, Kotla Road,  
New Delhi - 110002  
India  
Tel: +91-11- 23237418  
Email: sandhyakabra@gmail.com

Dr K.v. Radha Krishna  
National Institute of Nutrition (NIN)  
India  
Tel: +91-40-27197254  
Email: vijrkk@yahoo.com

Ms Sukhmani Singh  
Food Safety And Standards Authority of India (FDA)  
Bhawan, Kotla Road, 110002  
New Delhi  
India  
Email: sukhmax@googlemail.com

**INDONESIA - INDONÉSIE**

Mrs Yusra Egayanti  
National Agency of Drug and Food Control  
Jl. Percetakan Negara 23  
Jakarta  
Indonesia  
Tel: +62 21 42875584  
Email: yusra.egayanti@pom.go.id

Mr Victor Basuki  
DuPont Nutrition & Health  
Jalan Ampera Raya No.9-10, South Jakarta  
Jakarta  
Indonesia  
Tel: +628111630280  
Email: victor.basuki@dupont.com

Prof Purwiyatno Hariyadi  
Southeast Asian Food & Agricultural Science & Technology (SEAFAST) Center  
Bogor Agricultural University, Bogor  
Indonesia  
Tel: (62) 251 8629903  
Email: phariyadi@ipb.ac.id

Mr Aslam Hasan  
Ministry of Industry  
Jl.Jenderal Gatot Subroto Kav.52-53, 17th Floor Jakarta Selatan  
JAKARTA  
Indonesia  
Tel: (62-21) 6252236  
Email: aslamhas@yahoo.com

Mrs Nani Hidayani  
APPNIA  
Souvereign Plaza 1st floor Jk. Tb Simatupang Kav 36  
Jakarta  
Indonesia  
Tel: +6221 29400268  
Email: nani.hidayani@mjn.com

Dr Prima Sehanputri  
APPNIA  
Sovereign Plaza Blok 1d, 1st Fl Jl. Tb Simatupang Kav 36  
Jakarta  
Indonesia  
Tel: +62 21 29400268  
Email: prima.sehanputri@gmail.com

Mrs Roch Ratri Wandansari  
The Indonesian Food and Beverages Association (GAPMMI)  
Annex Building 2nd floor (PPM Management complex)  
Jl. Menteng Raya No 9-19  
Jakarta  
Indonesia  
Tel: +62811886009  
Email: rwandansari@yahoo.com

**IRAN (ISLAMIC REPUBLIC OF) – IRAN (RÉPUBLIQUE ISLAMIQUE D’) – IRÁN (REPÚBLICA ISLÁMICA DEL)**

Mrs Atefeh Fooladi Moghadam  
Ministry of Health and Medical Education  
Iran  
Tel: +989125263015  
Email: Atefeh.fooladi@gmail.com

**IRELAND - IRLANDE - IRLANDA**

Dr Mary Flynn  
Food Safety Authority of Ireland  
Abbey Court Lower Abbey Street Dublin 1  
Dublin  
Ireland  
Tel: +353 1 8171315  
Email: award@fsai.ie
ITALY - ITALIE - ITALIA
Mr Ciro Impagnatiello
Ministry of Agricultural Food and Forestry Policies
Via XX Settembre, 20
Rome
Italy
Tel: +39 06 46654058
Email: c.impagnatiello@politicheagricole.it

Ms Silvia Nicoli
Ministry of agricultural, Food and Forestry Policies
Via XX Settembre, 20
Rome
Italy
Tel: +39 06 46654130
Email: s.nicoli@politicheagricole.it

JAPAN - JAPON - JAPÓN
Dr Toshitaka Masuda
Consumer Affairs Agency
5th Floor Sanno Park Tower, 2-11-1 Nagata-cho, Chiyoda-ku, Tokyo
Japan
Tel: +81-3-3507-8800
Email: g.codex-j@caa.go.jp

Ms Mami Endo
Consumer Affairs Agency
5th Floor Sanno Park Tower, 2-11-1 Nagata-cho, Chiyoda-ku, Tokyo
Japan
Tel: +81-3-3507-8800
Email: g.codex-j@caa.go.jp

Prof Hiroaki Hamano
International Life Sciences Institute Japan
Nishikawa Bldg 5F, 3-5-19 Kojimachi, Chiyoda-ku, Tokyo
Japan
Tel: +81-3-5215-3535
Email: hhamano@ilsijapan.org

Dr Yoshiko Ishimi
National Institute of Health and Nutrition
National Institutes of Biomedical Innovation
Health and Nutrition
1-23-1 Toyama, Shinjuku-ku
Tokyo
Japan
Tel: +81 3 3203 8063
Email: ishimi@nih.go.jp

Prof Satoshi Ishizuka
Hokkaido University
Kita 9, Nishi 9, Kita-ku, Sapporo
Sapporo
Japan
Tel: +81-11-706-2811
Email: g.codexj@caa.go.jp

Mr Kenji Kuroiwa
Ministry of Health, Labour and Welfare, Japan
1-2-2 Kasumigaseki, Chiyoda-ku
Tokyo
Japan
Tel: +81-3-5253-1111 (ext. 2408)
Email: codexj@mhlw.go.jp

Ms Aya Orto-Nozawa
Ministry of Agriculture, Forestry and Fisheries
1-2-1, Kasumigaseki, Chiyoda-ku
Tokyo
Japan
Tel: +81-3-3502-8732
Email: aya_orito460@maff.go.jp

KENYA
Mr James Ojambo
NESTL’E FOOD KENYA LTD
BOX 30265
NAIROBI
Kenya
Tel: +254206532291
Email: james.ojambo@ke.nestle.com

Mr Mutua Peter
KENYA BUREAU OF STANDARDS
54974
NAIROBI
Kenya
Tel: +254-20 6948000
Email: mutuap@kebs.org

KUWAIT - KOWEIT
Mrs Hashmeyah Alenezi
Public Authority for Industry
Safat
Kuwait
Tel: 0096525302672
Email: h.alanzei@pai.gov.kw

Mrs Zeinab Al Kandari
Ministry of Health
Email: zainb.alkandari@hotmail.com

LATVIA - LETTONIE - LETONIA
Mrs Inara Cine
Ministry of Agriculture of Latvia
Republikas laukums 2
Riga
Latvia
Tel: + 371 67027164
Email: Inara.Cine@zm.gov.lv

LUXEMBOURG - LUXEMBURGO
Ms Sarah Haunert
Ministry of Health
3, rue des Primeurs
Strassen
Luxembourg
Tel: (+352) 247 75634
Email: sarah.haunert@ms.etat.lu
MALAYSIA - MALAISIE - MALASIA

Mrs Norrani Eksan
Ministry of Health Malaysia
Level 4, Menara Prisma, No 26, Jalan Persiaran Perdana, Presint 3
Putrajaya
Malaysia
Tel: 603-88850794
Email: norrani@moh.gov.my

Ms Rokiah Don
Ministry of Health Malaysia
Level 1, Block E3, Complex E, Percint 1
Federal Government Administrative Office
Putrajaya
Malaysia
Tel: 603-88924556
Email: rokiah@moh.gov.my

Ms Rohaya Mamat
Federation of Malaysian Manufacturers
Wisma Fmm, No.3, Persiaran Dagang, Pju 9
Bandar Sri Damansara
Kuala Lumpur
Malaysia
Tel: 603-78825108
Email: rohaya.mamat@mjp.gov.my

Dr Kanga Rani Selvaduray
Malaysian Palm Oil Board
No 6, Persiaran Institut, Bandar Baru Bangi
Kajang, Selangor
Malaysia
Tel: 603-87694606
Email: krrani@mpob.gov.my

MALI - MALÍ

Dr Salimata Kone
Agence Nationale de la Sécurité Sanitaire des Aliments
Centre Commercial Rue 305 Quartier du Fleuve BPE : 2362
Bamako
Mali
Tel: +223 66724028/ +223 20 22 07 5
Email: coulibaly@salimata@gmail.com

Mr Bah Konipo
Ambassade du Mali en Italie
Rome
Italy
Email: bahkonipo@gmail.com

MEXICO - MEXIQUE - MÉXICO

Ms Pamela Suárez Brito
Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS)
Monterrey #33 PH, Col. Roma Delegación Cuauhtémoc
Mexico Distrito Federal
Mexico
Tel: 525550805213
Email: psuarez@cofepris.gob.mx

Mr Carlos Almanza
ILSI DE MÉXICO, A.C.
Prolongación Paseo de la Reforma No. 880, Lomas De Santa Fe
D.F.
Mexico
Tel: +52-55 5950 - 4000 Ext. 4620
Email: carlos.almanza@ilsi-mexico.org

Ms Jessica Gutierrez Zavala
Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS)
Monterrey #33 Col. Roma Delegación Cuauhtémoc
Mexico Distrito Federal
Mexico
Tel: 525550805215
Email: jiguieres@cofepris.gob.mx

Ms Xochitl Morales
Cámara Nacional de Industriales de la Leche, CANILEC
Benjamín Franklin 134 Col. Escandón
Mexico Distrito Federal
Mexico
Tel: 52-55-11039604 / 52-55-5516551
Email: xochitl.morales@mjp.com

Mr Aldo Heladio Verver Y Vargas Duarte
Comisión Federal Para La Protección Contra Riesgos Sanitarios
Oklahoma 14, Col. Napoles, Benito Juarez
Distrito Federal
Mexico
Tel: +52 55 50805200
Email: aververyvargas@cofepris.gob.mx

MOROCCO - MAROC - MARRUECOS

Mr Mohamed Tannaoui
Laboratoire Officiel d'Analyses et de Recherches Chimiques
25, Rue Nichakra (ex rue de Tours)
Casablanca
Morocco
Tel: +212 522 302007
Email: tannaoui1@yahoo.fr

Mrs Nawal Bentahila
Association Marocaine De Nutrition Infantile
Casablanca
Morocco
Tel: +212661868220
Email: nawal.bentahila@gmail.com

Mrs Ihssane Beqqali
Office National de Sécurité Sanitaire des produits Alimentaires
Avenue Ahmed Cherkaoui Agdal Rabat
Rabat
Morocco
Tel: +212673997817
Email: ihssanebeqqali@gmail.com
Mrs Nezha Mouane  
Moroccan Society of Paediatric Gastroenterology and Nutrition  
Rabat  
Morocco  
Tel: +212661229013  
Email: nezhamouane@hotmail.com

Dr Matina Joshi  
Department of Food Technology and Quality Control  
Babar Mahal, Kathmandu  
Kathmandu  
Nepal  
Tel: 9774262430  
Email: matina_joshi@yahoo.com

Mr Purna Chandra Wasti  
Department of Food Technology and Quality Control  
Babar Mahal  
Kathmandu  
Nepal  
Tel: 97714262741  
Email: pcwasti@gmail.com

Ms Erika Smale  
Ministry of Health, Welfare and Sports  
PO Box 20350  
The Hague  
Netherlands  
Tel: +31 (0)6 11370803  
Email: bh.smale@minvws.nl

Ms Jenny Reid  
Ministry for Primary Industries  
25 The Terrace  
Wellington  
New Zealand  
Email: jenny.reid@mpi.govt.nz

Ms Jane Broughton  
Nestle New Zealand Ltd  
Auckland  
New Zealand  
Email: jane.broughton@nz.nestle.com

Ms Jenny Campbell  
Fonterra Co-operative Group  
9 Princes Street  
Auckland  
New Zealand  
Email: Jenny.Campbell@fonterra.com

Ms Michelle Gibbs  
Ministry for Primary Industries  
25 The Terrace  
Wellington  
New Zealand  
Email: michelle.gibbs@mpi.govt.nz
PHILIPPINES

Ms Helena Alcaraz
Department of Health
Civic Drive Alabang Corporate City, Alabang
Muntinlupa City
Philippines
Tel: 857-1921
Email: hsalcaraz@fda.gov.ph

Ms Strawberry Francia
Nutrition Policy and Planning Division
Roces Avenue Extension, Taguig City
Taguig
Philippines
Tel: 028431337
Email: berry_francia@yahoo.com

POLAND

Dr Katarzyna Stos
National Food and Nutrition Institute
Powsinska Street 61/63
Warsaw
Poland
Email: kstos@izz.waw.pl

Mrs Anna Janasik
Agricultural and Food Quality Inspection
30, Wspolna St.
Warsaw
Poland
Tel: +48 22 623 29 03
Email: ajanasik@ijhars.gov.pl

REPUBLIC OF KOREA

Mrs Hye-young Lee
Ministry of Food and Drug Safety
Osong Health Technology Administration Complex 187, Osongsaengmyeong2-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do 363-700, Korea
Cheongju-si
Republic of Korea
Tel: +82-43-719-2259
Email: leehy96@korea.kr

Ms Sun-young Park
Ministry of Food and Drug Safety
Osong Health Technology Administration Complex, 187, Osongsaengmyeong2-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 363-700, Korea
Cheongju-si
Republic of Korea
Tel: +82-43-719-2271
Email: naverpsy@naver.com

Ms Elena Smirnova
Russian Institute of Nutrition
Ustyinskiy proezd 2/14
Moscow
Russian Federation
Tel: +7 495 698 53 89
Email: smirnova@ion.ru

RUSSIAN FEDERATION

Ms Elena Smirnova
Russian Institute of Nutrition
Ustyinskiy proezd 2/14
Moscow
Russian Federation
Tel: +7 495 698 53 89
Email: smirnova@ion.ru

Ms Julia Kalinova
The Coca-Cola Export Corporation, Moscow
Representation office
8 Ivana Franko str.
Moscow
Russian Federation
Tel: +74956516900
Email: jkalinova@coca-cola.com

Ms Sun-young Park
Ministry of Food and Drug Safety
Osong Health Technology Administration Complex, 187, Osongsaengmyeong2-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 363-700, Korea
Cheongju-si
Republic of Korea
Tel: +82-43-719-2259
Email: naverpsy@naver.com

Mr Jin Hyok Son
Ministry of Food and Drug Safety
Osong Health Technology Administration Complex, 187 Osongsaengmyeong2(i)-ro, Osong-eup, heungdeok-gu, cheongju-si, Chungcheongbuk-do, 363-700, korea
Cheongju-si
Republic of Korea
Tel: +82-43-719-3858
Email: sontoly33@korea.kr

Mr Anatoly Kutyshenko
Russian Union of Industrialists and Entrepreneurs (RUIE)
Kotelnicheskaya nab., 17
Moscow
Russian Federation
Tel: +7 916 2014060
Email: Anotol-k@rambler.ru

Mr Dmitriy Miklin
DNELN
Panfilova str., 19, BC
Khimki
Russian Federation
Tel: +7 916 2014060
Email: dmitriy.miklin@danone.com

Mr Alexey Petrenko
Russian Union of Industrialists and Entrepreneurs (RUIE)
Kotelnicheskaya nab., 17
Moscow
Russian Federation
Email: alexeypetrenko@eas-strategies.com
Mrs Veronika Vysotskaya  
Abbott Laboratories  
Leningradskoe highway., 16A, bld.1  
Moscow  
Russian Federation  
Tel: +7 495 258 42 80  
Email: veronika.vysotskaya@abbott.com

SAUDI ARABIA - ARABIE SAOUDITE - ARABIA SAUDITA

Mr Fahad Albadr  
Saudia Food and Drug Authority  
Saudia Food and Drug Authority (3292) North Ring Road - Al Nafal Unit (1)  
Riyadh  
Saudia Arabia  
Tel: +966112038222  
Email: codex.cp@sfda.gov.sa

SENEGAL - SÉNÉGAL

Prof Mohamadou Guelaye Sall  
UCAD  
BP 6251 DAKAR SENEGA  
DAKAR  
Senegal  
Email: mgsall@gmail.com

SINGAPORE - SINGAPOUR - SINGAPUR

Ms Yi Ling Tan  
Agri-Food and Veterinary Authority of Singapore  
52, Jurong Gateway Road, #14-01 Singapore 608550  
Singapore  
Tel: +65 6805 2915  
Email: tan_yi_ling@ava.gov.sg

SLOVAKIA - SLOVAQUIE - ESLOVAQUIA

Dr Iveta Trusková  
Public Health Authority of the Slovak Republic  
Trnávská 52  
Bratislava  
Slovakia  
Tel: +421 2 492 84 392  
Email: iveta.truskova@uvzsr.sk

Mrs Katarína Kromerová  
Public Health Authority of the Slovak Republic  
Trnávská 52  
Bratislava  
Slovakia  
Tel: +421249284327  
Email: katarina.kromerova@uvzsr.sk

SOUTH AFRICA - AFRIQUE DU SUD - SUDAFRICA

Mrs Andiswa Ngqaka  
DEPARTMENT OF HEALTH  
Private Bag X828  
PRETORIA  
South Africa  
Tel: +27 12 3958511  
Email: NgqakaA@health.gov.za

Mrs Antoinette Booyzen  
Department of Health  
Private Bag X828  
PRETORIA  
South Africa  
Tel: +27 12 395 8792  
Email: BooyzA@health.gov.za

SPAIN - ESPAGNE - ESPAÑA

Mrs Irene Gadea Cazalilla  
Spanish Agency for Consumer Affairs, Food Safety and Nutrition  
C Alcalá, 56  
Madrid  
Spain  
Email: igadea@msssi.es

SUDAN - SOUDAN - SUDÁN

Mrs Thoria Akasha Ali Ebeid  
Sudanese Standards and Metrology Organisation  
Khartoum / Sudan Soba  
Khartoum  
Sudan  
Tel: +249912468700  
Email: elnagaka@hotmail.com

SWEDEN - SUÈDE - SUECIA

Mrs Kristina Lagestrand Sjölin  
Principal Regulatory Officer / Ämneskoordinator International Affairs Department / Internationella avdelningen  
National Food Agency / Livsmedelsverket  
Box 622  
SE-751 26 UPPSALA  
SWEDEN  
Telephone +46 18 17 55 00 (switchboard/växel)  
Direct telephone +46 18 17 56 07  
E-mail: krsj@slv.se

SWITZERLAND - SUISSE - SUIZA

Mrs Elisabeth Nellen-regli  
Federal Food Safety and Veterinary Office FSVO  
Bern  
Switzerland  
Tel: +41 58 462 95 60  
Email: elisabeth.nellen@blv.admin.ch
Dr Dirk Cremer  
DSM Nutritional Products Europe Ltd.,  
Human Nutrition and Health  
P.O. Box 2676 Bldg. 242/2nd floor  
Basel  
Switzerland  
Tel: +41 61 815 79 65  
Email: dirk.cremer@dsm.com

Mrs Awilo Ochieng Pernet  
Federal Food Safety and Veterinary Office FSVO  
Bern  
Switzerland  
Email: awilo.ochieng@blv.admin.ch

Mrs Marie-france Pagerey  
Nestec SA  
Avenue Nestlé 55 Post Box  
Vevey  
Switzerland  
Email: MarieFrance.Pagerey@nestle.com

Mrs Ursula Trüeb  
Swiss Consumer Organizations  
Bölzli 1  
Magden  
Switzerland  
Tel: +41 61 841 12 56  
Email: ursula.trueb@vtxmail.ch

Mr Paul Zwiker  
Swiss Consumer Organizations  
Post Box 45  
Bischofzell  
Switzerland  
Tel: +41 71 420 06 44  
Email: zwiker@bluewin.ch

THAILAND - THAÏLANDE - TAILANDIA

Prof Kraisid Tontisirin  
National Bureau of Agricultural Commodity and Food Standards, Ministry of Agriculture and Cooperatives  
50 Phaholyothin Road, Lad Yao, Chatuchak  
Bangkok  
Thailand  
Tel: +66 (2) 561 2277  
Email: kraisid.tontisirin@gmail.com

Ms Mayuree Ditmyeyharoj  
Food and Drug Administration, Ministry of Public Health  
Tiwonond Road  
Nonthaburi  
Thailand  
Tel: +66 (2) 590 7185  
Email: bankvindy@yahoo.com

Mrs Junererat Hokiarti  
Food and Drug Administration, Ministry of Public Health  
Tiwonond Road  
Nonthaburi  
Thailand  
Tel: +66 (2) 590 7249  
Email: jrhk249@hotmail.co.th

Dr Pichet Itkor

Food Processing Industry Club  
The Federation of Thai Industries  
Queen Sirikit National Convention Center, Zone C 4th Floor, 60 New Rachadapisek Rd., Klongtoey  
Bangkok  
Thailand  
Tel: +66 (2) 345 1167  
Email: Pichet.itkor@mjn.com

Ms Pitchaya Kajonwaharth  
The Federation of Thai Industries  
Queen Sirikit National Convention Center, Zone C 4th Floor, 60 New Rachadapisek Rd., Klongtoey  
Bangkok  
Thailand  
Tel: +66 (2) 345 1167  
Email: pitchaya.kajonwaharth@abbott.com

Ms Sanida Khoonpanich  
National Bureau of Agricultural Commodity and Food Standards, Ministry of Agriculture and Cooperatives  
50 Phaholyothin Road, Lad Yao, Chatuchak  
Bangkok  
Thailand  
Tel: +66 (2) 561 2277 ext. 1445  
Email: sanida.sk@gmail.com

Dr Hataya Kongchuntuk Rodbumrung  
The Federation of Thai Industries  
Queen Sirikit National Convention Center, Zone C 4th Floor, 60 New Rachadapisek Rd., Klongtoey  
Bangkok  
Thailand  
Tel: +6684 751 4826  
Email: KHATAYA@AMWAY.COM

Ms Nongsuda Mongkolsmai  
The Federation of Thai Industries  
Queen Sirikit National Convention Center, Zone C 4th Floor, 60 New Rachadapisek Rd., Klongtoey  
Bangkok  
Thailand  
Tel: +66 (2) 345 1167  
Email: Nongsuda.mongkolsmai@danone.com

TOGO

Dr Tchala Kazia  
Ministry of Agriculture  
1, rue de l’Espérance LOME/TOGO  
LOME  
Togo  
Tel: +22890023325  
Email: kaziatchala@yahoo.fr

TURKEY - TURQUIE - TURQUÍA

Mr Dursun Kodaz  
Ministry of Food Agriculture and Livestock  
Eskisehir Yolu 9.Km, Lodumlu  
Ankara  
Turkey  
Tel: 00903122587755  
Email: dursun.kodaz@tarim.gov.tr
UGANDA - OUGANDA

Ms Irene Wanyenya
National Drug Authority
Plot 46-48 Lumumba Avenue P.O. Box 23096, Kampala
Uganda
Tel: +256 712 478333
Email: irene_w2k@yahoo.com

Mrs Agnes Chandia Baku
Ministry of Health
Plot 6 Lourdel Road, Wandegeya, P.O. Box 7272
Kampala
Uganda
Email: bakuchandia@ymail.com

Dr Jeanne Muhindo Bukeka
National Drug Authority
Plot 46-48 Lumumba Avenue P.O. Box 23096
Kampala
Uganda
Tel: +256 774 154333
Email: mjeannebukeka@gmail.com

UNITED STATES OF AMERICA - ÉTATS-UNIS D'AMÉRIQUE - ESTADOSUNIDOS DE AMÉRICA

Dr Leila Beker
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland
United States of America
Tel: 12404021851
Email: leila.beker@fda.hhs.gov

Ms Camille Brewer
Department of Health and Human Services
5100 Paint Branch Parkway, HFS-550
College Park, MD
United States of America
Tel: +1 240-402-1723
Email: Camille.brewer@fda.hhs.gov

Mrs Doreen Chen-moulec
U.S. Department of Agriculture
1400 Independence Ave
Washington, DC
United States of America
Tel: 202-720-4063
Email: Doreen.Chen-Moulec@fsis.usda.gov

Dr Carolyn Chung
U.S. Food and Drug Administration
5100 Paint Branch Parkway, HPS-830
College Park, MD
United States of America
Tel: 202 402 3068
Email: carolyn.chung@fda.hhs.gov

Ms Allison Cooke
Infant Nutrition Council of America
750 National Press Building 529 14th Street NW
Washington DC
United States of America
Tel: 202 207 1130
Email: accoke@kellencompany.com

Dr Cheryl Issa
Office of Food Safety and Applied Nutrition, U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland
United States of America
Tel: 124041441
Email: cheryl.issa@fda.hhs.gov

Ms Amy Mackey
Abbott Nutrition
3300 Stelzer Road RP3-2/Dept 104070
Columbus OH
United States of America
Tel: 614 624 4492
Email: amy.mackey@abbott.com

Ms Mardi Mountford
International Formula Council
1100 Johnson Ferry Road, Suite 300
Atlanta, GA
United States of America
Tel: 1404 252 3663
Email: mmountford@kellencompany.com

Dr Pamela Pehrsson
ARS-Nutrient Data Laboratory
10300 Baltimore Avenue Bldg. 005, Room 105
Beltsville
United States of America
Tel: 3015040635
Email: pamela.pehrsson@ars.usda.gov

URUGUAY

Mrs Nora Villalba
Ministerio de Salud
18 de Julio 1892
Montevideo
Uruguay
Email: noravillalba@gmail.com

VIET NAM

Mrs Thi Vinh Thuy Tran
Quality Assurance and Testing Center 3
49 Pasteur, District 1
Ho Chi Minh city
Viet Nam
Tel: 0909822906
Email: ttt-thuy@quatest3.com.vn

Dr Danh Tuyen Le
National Institute of Nutrition
48B Tang Bat Ho, street
Ha Noi
Viet Nam
Email: ledanhtuyen@gmail.com
ZIMBABWE
Mrs Ancikaria Chigumira
Ministry of Health and Child Care
P.O BOX CY1122 Causeway
Harare
Zimbabwe
Email: ancikaria53@gmail.com

Mr Fredy Chinyavanhu
Ministry of Health and Child Care

INTER-AMERICAN INSTITUTE FOR COOPERATION ON AGRICULTURE
Dr Horrys Friaça
IICA
1889 F Street, N.W., Suite 360, Washington, D.C.
20006
Washington
United States of America
Email: horrys.friaca@iica.int

ASSOCIATION INTERNATIONALE POUR LE DÉVELOPPEMENT DES GOMMES NATURELLES
Mr Olivier Bove
AIDGUM
Email: o.bove@aidgum.com

ASSOCIATION FOR INTERNATIONAL PROMOTION OF GUMS
Mr Thevenet Francis
Association for International Promotion of Gums AIPG
Sonninstrasse 28
Hamburg
Germany
Email: francis.thevenet@orange.fr

AOAC INTERNATIONAL
Mr Darryl Sullivan
AOAC INTERNATIONAL
2275 Research Boulevard
Rockville
United States of America
Email: darryl.sullivan@covance.com

ASSOCIATION OF EUROPEAN COELIAC SOCIETIES
Mrs Hertha Deutsch
AOECS, Association Of European Coeliac Societies
Anton Baumgartner Strasse 44/C5/2302
Vienna
Austria
Tel: +431667188
Email: hertha.deutsch@chello.at

P.O.Box CY 231, Causeway
Harare
Zimbabwe
Email: nepfoodsafty_zw@gmail.com

ORGANIZATIONS
ORGANISATIONS OBSERVEURS
ORGANIZACIONES OBSERVADORAS

CALORIE CONTROL COUNCIL
Ms Victoria Betteridge
Calorie Control Council
Tate & Lyle Plc 1 Kingsway
London
United Kingdom
Email: victoria.betteridge@tateandlyle.com

Mr Wim Caers
Calorie Control Council
Tate & Lyle Plc 1 Kingsway
London
United Kingdom
Email: wim.caers@tateandlyle.com

COMITÉ EUROPÉEN DES FABRICANTS DE SUCRE
Mrs Emilie Leibovitch Majster
CEFS (Comité européen des fabricants de sucre)
182 avenue de Tervuren
Brussels
Belgium
Email: emilie.majster@cefs.org

Dr Michael Packert
CEFS (Comité européen des fabricants de sucre)
182 avenue de Tervuren
Brussels
Belgium
Email: Michael.Packert@suedzucker.de

COUNCIL FOR RESPONSIBLE NUTRITION
Dr James Griffiths
CRN
1828 L St., NW Ste. 510
Washington
United States of America
Tel: 202-204-7662
Email: jgriffiths@crnusa.org
Ms Andrea Ferrenz  
CRN - Innophos, Inc.  
Innophos, Inc. 259 Prospect Plains Road  
Cranbury  
United States of America  
Tel: 301-651-6434  
Email: Andrea.Ferrenz@InnoPhos.com

Mr Harvey Kamil  
CRN - NBTY, Inc.  
NBTY, Inc. 2100 Smithtown Avenue  
Ronkonkoma  
United States of America  
Tel: 631-200-2020  
Email: hkamil@nbty.com

Mr Mark Ledoux  
CRN - NAI, Inc.  
Natural Alternatives International, Inc. 1185 Linda Vista Dr.  
San Marcos  
United States of America  
Tel: 760-736-7742  
Email: mledoux@nai-online.com

Dr Daniel Marsman  
CRN - Procter & Gamble  
P&G 8700 Mason-Montgomery Road  
Mason  
United States of America  
Tel: 513-698-6088  
Email: marsman.ds@pg.com

FEDERATION OF EUROPEAN SPECIALTY FOOD INGREDIENTS INDUSTRIES

Prof Stewart Forsyth  
ELC, Federation of European Specialty Food Ingredients Industries  
Email: elc@ecco-eu.com

Dr Thomas Sebastian Janssen  
ELC, Federation of European Specialty Food Ingredients Industries  
Email: thomas.janssen@budenheim.com

Ms Catherine Mignot  
ELC, Federation of European Specialty Food Ingredients Industries  
Email: catherine.mignot@dsm.com

Dr Rob Winwood  
ELC, Federation of European Specialty Food Ingredients Industries  
Email: rob.winwood@dsm.com

EARLY NUTRITION ACADEMY

Prof Berthold Koletzko  
Early Nutrition Academy (ENA)  
c/o Ludwig-Maximilians-Universität  
Dr von Hauner Children’s Hospital University of Munich  
Medical Center Lindwurmstr. 4  
München  
Germany  
Tel: + 49 89 44005 2826

Email: office.koletzko@med.uni-muenchen.de

EUROPEAN NETWORK OF CHILDBIRTH ASSOCIATIONS

Dr Helen Crawley  
ENCA  
Email: helen@firststepsnutrition.org

Mrs Isabelle Henschen  
ENCA  
Email: isabelle.henschen@afooda.lu

Mr Joseph Voss  
ENCA  
Email: aape@pt.lu

EUROPEAN SOCIETY FOR PAEDIATRIC GASTROENTEROLOGY HEPATOLOGY AND NUTRITION

Prof Walter Mihatsch  
MunichMunicipal Hospital Harlaching  
Sanatoriumsplatz 2  
München  
Germany  
Email: walter.mihatsch@gmx.de

EUROPEAN VEGETABLE PROTEIN FEDERATION

Mrs Susanne Meyer  
EUVEPRO  
Avenue Jules Bordet 142  
Brussels  
Belgium  
Email: euvepro@agep.eu

FOODDRINKEUROPE

Ms Mariska Dotsch  
FoodDrinkEurope  
Avenue des Nerviens 9-31  
Bruxelles  
Belgium  
Email: mariska.dotsch@unilever.com

Mr Dirk Jacobs  
FoodDrinkEurope  
9-31 Av. des Nerviens  
Brussels  
Belgium  
Email: d.jacobs@fooddrinkeurope.eu

Mrs Annie Loch  
FoodDrinkEurope  
Avenue des Nerviens 9-31  
Bruxelles  
Belgium  
Email: annie.loch@danone.com
Mrs Sabine Seggelke
FoodDrinkEurope
Avenue des Nerviens 9-31
Bruxelles
Belgium
Email: sabine.seggelke@dsm.com

GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S
Dr Harry Rice
Global Organization for EPA and DHA Omega-3s
Email: harry@goedomega3.com

HELEN KELLER INTERNATIONAL
Ms Jane Badham
Helen Keller International
P.O.Box 67396 Bryanston 2021
Johannesburg
South Africa
Email: jane@jbconsultancy.co.za

INTERNATIONAL ASSOCIATION OF CONSUMER FOOD ORGANIZATIONS
Ms Patti Rundall
IACFO
c/o Baby Milk Action 34 Trumpington Street
Cambridge
United Kingdom
Tel: +44 1223 464420
Email: prundall@babymilkaction.org

INTERNATIONAL ALLIANCE OF DIETARY/FOOD SUPPLEMENT ASSOCIATIONS
Ms Arevik Aivazova
IADSA
50 Rue de l'Associations
Brussels
Belgium
Email: secretariat@iadsa.org

Mr Harunobu Amagase
IADSA
50 Rue de l'Associations
Brussels
Belgium
Tel: +32 2 209 11 55
Email: secretariat@iadsa.org

Dr Tomoji Igarashi
IADSA
50 Rue de l'Associations
Brussels
Belgium
Tel: +32 2 209 11 55
Email: secretariat@iadsa.org

Mr Xavier Lavigne
IADSA
50 Rue de l'Association
Brussels
Belgium
Tel: +32 2 209 11 55
Email: secretariat@iadsa.org

Dr Nico Raczek
IADSA
50 Rue de l'Association
Brussels
Belgium
Tel: +32 2 209 11 55
Email: secretariat@iadsa.org

Prof David Richardson
IADSA
50 Rue de l'Association
Brussels
Belgium
Tel: +32 2 209 11 55
Email: secretariat@iadsa.org

Ms Cynthia Rousselot
IADSA
50 Rue de l'Association
Brussels
Belgium
Tel: +32 2 209 11 55
Email: secretariat@iadsa.org

Ms Michelle Stout
IADSA
50 Rue de l'Association
Brussels
Belgium
Tel: +32 2 209 11 55
Email: secretariat@iadsa.org

Mr Kazuo Sueki
IADSA
50 Rue de l'Association
Brussels
Belgium
Tel: +3222091155
Email: secretariat@iadsa.org

INTERNATIONAL BABY FOOD ACTION NETWORK
Mrs Elisabeth Sterken
International Baby Food Action Network (IBFAN)
Rockport, Ontario, K0E 1V0 Canada
Rockport, Ontario
Canada
Email: esterken@infactcanada.ca

Mr Percy Chipepera
IBFAN Africa
P.O. Box 781 Mbabane, Swaziland.
percychips@yahoo.com
Mbabane
Swaziland
Tel: +268 2404 5006
Email: percychips@yahoo.com
INTERNATIONAL CO-OPERATIVE ALLIANCE

Mr Kazuo Onitake  
Japanese Consumers' Co-operative Union  
Co-OP Plaza 3-29-8, Shibuya, Shibuya-Ku  
Tokyo  
Japan  
Tel: +81-3-5778-8109  
Email: kazuo.onitake@jccu.coop

Mr Hitoshi Inoue  
Japanese Consumers' Co-operative Union  
CO-OP Plaza, 3-29-8, Shibuya, Shibuya-Ku  
Tokyo  
Japan  
Tel: +81-3-5778-8109  
Email: hitoshi.72.inoue@jccu.coop

INTERNATIONAL COUNCIL ON AMINO ACID SCIENCE

Mr Yuji Ikehara  
ICAAS  
Email: ICAAS@kelleneurope.com

Mr Hiromi Ota  
ICAAS  
Email: ICAAS@kelleneurope.com

INTERNATIONAL COUNCIL OF BEVERAGES ASSOCIATIONS

Mr Robert Earl  
International Council of Beverages Associations  
1101 16th Street NW  
Washington, D.C.  
United States of America  
Email: robertearl@coca-cola.com

Ms Aleksandra Wesolowska  
International Council of Beverages Associations  
Chaussee de Mons 1424  
Brussels  
Belgium  
Tel: +32-2-559-2915  
Email: awesolowska@coca-cola.com

INTERNATIONAL CHEWING GUM ASSOCIATION (ICGA)

Mr Christophe Leprêtre  
ICGA  
Suite 501 1001 G Street, N.W.  
Washington  
United States of America  
Tel: 003226455060  
Email: lepretre@khlaw.com

INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS ASSOCIATIONS

Ms Kristen Scott  
Grocery Manufacturers Association  
1350 I Street, NW Washington, DC  
Washington, DC  
United States of America  
Tel: 202 637 4805  
Email: kscott@gmaonline.org

Dr Wayne Wargo  
Abbott Nutrition (R&D)  
3300 Stelzer Road D104110/RP4-2  
Columbus, Ohio  
United States of America  
Tel: 614 624 3456  
Email: wayne.wargo@abbott.com

INTERNATIONAL DAIRY FEDERATION

Ms Karine Simbelie  
ATLA, French Dairy Processors’ Association  
42, rue de Chateaudun F-75009 Paris , France  
Email: karine.simbelie@atla.asso.fr

Ms Luisa Candido  
Dairy UK  
United Kingdom  
Email: lcandido@dairyUK.org

Ms Aurélie Dubois Lozier  
International Dairy Federation  
Boulevard Auguste Reyers 70 B  
Brussels  
Belgium  
Tel: +17736980355  
Email: adubois@fil-idf.org

Ms Mélanie Janin  
ATLA, French Dairy Processors’ Association  
42, rue de Chateaudun F-75009  
Paris  
France  
Email: melanie.janin@atla.asso.fr

Mr Harrie Van Den Biggaart  
Qlip N.V.  
Oostzeestraat 2a, P.O. Box 119  
Zutphen  
Netherlands  
Tel: +31 (0) 88 7547010  
Email: bijgaart@qlip.nl

INTERNATIONAL FOOD ADDITIVES COUNCIL

Ms Sabine Klages-buechner  
International Food Additives Council  
Unterden Linden 21  
Berlin  
Germany  
Email: sabine.klages-buechner@dupontholding.com
INSTITUTE OF FOOD TECHNOLOGISTS
Prof Rosemary Walzem, Rd, Ph.d.
Institute of Food Technologists
Department of Poultry Science Faculty of Nutrition
242D Kleberg Center MS 2472 Texas A&M University
College Station, TX 77843-2472
Texas A&M University
United States of America
Tel: 979.845.7537
Email: rwalzem@poultry.tamu.edu

Dr Susan Carlson
University of Kansas Medical Center
United States of America
Email: scarlson@kumc.edu

Ms Sheila Gautier
DSM
United States of America
Email: sheila.gautier@dsm.com

INTERNATIONAL GLUTAMATE TECHNICAL COMMITTEE
Dr Kaori Ono
Ajinomoto Co., Inc.
15-1, Kyobashi 1-Chome, Chuou-ku, Tokyo
Japan
Tel: +81-3-5250-8184
Email: kaori_ono@ajinomoto.com

INTERNATIONAL LACTATION CONSULTANT ASSOCIATION
Mrs Maryse Arendt
ILCA
Initiativ Liewensufank a.s.b.l. 20 rue de Contern - L-5955 Itzig T. - F. (+352) 36 61 34
Tel: (+352) 36 05 97 13
Email: maryse.arendt@liewensufank.lu

INTERNATIONAL LIFE SCIENCES INSTITUTE
Ms Mariela Berezovsky
ILSI Brasil
rua Isabel de Castela 450
Sao Paulo
Brazil
Tel: 55-11-38191530
Email: mariela@ilsibrasil.br

Mr Antonio Mantoan
Mead Johnson Nutrition
Av Nacoes Unidas 14171 8 Andar Marble Tower
Sao Paulo
Brazil
Tel: 55-11-9973-0977
Email: antonio_mantoan@mjn.com

Ms Shivali Nandwani
Abbott Laboratories (S) Pte Ltd
1 Maritime Square #12-01 HarbourFront Centre
Singapore
Tel: 65-8111-1344
Email: shivali.nandwani@abbott.com

INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES
Mr Michael Barry
ISDI-International Special Dietary Food Industries
Email: secretariat@isdi.org

Ms Marie Odile Gailing
ISDI-International Special Dietary Foods Industries
Email: secretariat@isdi.org

Ms Louise Gottsche
ISDI-International Special Dietary Foods Industries
Email: secretariat@isdi.org

Mr Jean Christophe Kremer
ISDI-International Special Dietary Foods Industries
Avenue Jules Bordet 142
Brussels
Belgium
Tel: +32 2 761 16 90
Email: secretariat@isdi.org

Mr Eric Lew
ISDI-International Special Dietary Foods Industries
Email: secretariat@isdi.org

Ms Brinda Mahadevan
ISDI-International Special Dietary Foods Industries
Email: secretariat@isdi.org

Ms Nuria Moreno Odero
ISDI-International Special Dietary Foods Industries
Email: secretariat@isdi.org

Mr Manfred Ruthsatz
ISDI-International Special Dietary Foods Industries
Email: secretariat@isdi.org

Mr Jaap Schrijver
ISDI-International Special Dietary Foods Industries
Email: secretariat@isdi.org

Mr Peter Van Dael
ISDI-International Special Dietary Foods Industries
Email: secretariat@isdi.org

Ms Louis Vareille
ISDI-International Special Dietary Foods Industries
Email: secretariat@isdi.org

Ms Ziting Zhang
ISDI-International Special Dietary Foods Industries
Email: secretariat@isdi.org
Mr Tom Heilandt
Secretary of the Codex Alimentarius Commission
Food and Agriculture Organization of the United Nations (FAO)
Viale delle Terme di Caracalla
Roma
Italy
Tel: +39 06 570 54384
E-mail: Tom.Heilandt@fao.org

Mr Patrick Sekitoleko
Food and Agriculture Organization of the United Nations (FAO)
Viale delle Terme di Caracalla
Rome
Italy
Tel: +39 06 5705 6626
Email: Patrick.Sekitoleko@fao.org

Mrs Lingping Zhang
Food and Agriculture Organization of the United Nations (FAO)
Viale delle Terme di Caracalla
Rome
Italy
Email: lingping.zhang@fao.org

Mr David Massey
FAO/WHO Food Standards Programme
Food and Agriculture Organization of the United Nations
Viale delle Terme di Caracalla
Rome
Italy
Tel: (+39) 06 5705 3465
Email: david.massey@fao.org

Mr Warren Lee
Food and Agriculture Organization of the United Nations
Viale delle Terme di Caracalla
Rome
Italy
Tel: 0039 06 5705 4077
Email: Warren.Lee@fao.org

Dr Chizuru Nishida
World Health Organization
20, Avenue Appia
Geneva 27
Switzerland
Tel: +41 22 791 3317
Email: nishidae@who.int

Dr Jason Montez
World Health Organization
20, Avenue Appia
Geneva 27
Switzerland
Tel: +41 22 791 4519
Email: montezj@who.int

Mr Marcus Stahlhofer
WORLD HEALTH ORGANIZATION
20, AVENUE APPIA
GENEVA 27
Switzerland
Tel: +41 22 791 2909
Email: stahlhoferm@who.int

CCNFSDU SECRETARIAT / SECRÉTARIAT DU CCNFSDU / SECRETARÍA DE CCNFSDU

Mrs Ursula Siebert
Federal Ministry of Food and Agriculture
Rochusstrasse 1
Bonn
Germany
Tel: +49 228 99 529 4109
Email: ccnfsdu@bmel.bund.de

Ms Alina Steinert
Federal Ministry of Food and Agriculture
Rochusstrasse 1
Bonn
Germany
Tel: +49 228 99 529 4459
Email: ccnfsdu@bmel.bund.de
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

<table>
<thead>
<tr>
<th>Vitamins</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A (µg RAE or RE)</td>
<td>800</td>
</tr>
<tr>
<td>Vitamin D (µg)</td>
<td>5*</td>
</tr>
<tr>
<td>Vitamin E (mg)</td>
<td>9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Minerals</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium (mg)</td>
<td>310</td>
</tr>
<tr>
<td>Iron (mg)**</td>
<td>14 (15% dietary absorption; Diversified diets, rich in meat fish, poultry, and/or rich in fruit and vegetables) 12 (10% dietary absorption; Diets rich in cereals, roots or tubers, with some meat, fish, poultry and/or containing some fruit and vegetables)</td>
</tr>
<tr>
<td>Copper (µg)</td>
<td>900</td>
</tr>
<tr>
<td>Phosphorus (mg)</td>
<td>700</td>
</tr>
</tbody>
</table>

* 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

<table>
<thead>
<tr>
<th>Vitamin</th>
<th>Dietary equivalents</th>
</tr>
</thead>
</table>
| 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 |

**Vitamin A**

<table>
<thead>
<tr>
<th>Vitamin A activity equivalents</th>
<th>1 µg retinol activity equivalents (RAE) =</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR</td>
<td>1 µg retinol</td>
</tr>
<tr>
<td></td>
<td>12 µg β-carotene</td>
</tr>
<tr>
<td></td>
<td>24 µg other provitamin A carotenoids</td>
</tr>
<tr>
<td>1 µg retinol equivalents (RE) =</td>
<td>1 µg retinol</td>
</tr>
<tr>
<td></td>
<td>6 µg β-carotene</td>
</tr>
<tr>
<td></td>
<td>12 µg other provitamin A carotenoids</td>
</tr>
</tbody>
</table>

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

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


C. Amendments to Section 3.4.4.1 NRVs-R

<table>
<thead>
<tr>
<th><strong>Vitamins</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Niacin (mg NE)</td>
<td>15**</td>
</tr>
<tr>
<td>Iodine (µg)</td>
<td>150**</td>
</tr>
</tbody>
</table>

** 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

<table>
<thead>
<tr>
<th>Vitamin D (µg)</th>
<th>[10 µg or 15 µg]</th>
</tr>
</thead>
</table>

Conversion factors

<table>
<thead>
<tr>
<th>Vitamin</th>
<th>Dietary equivalents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin E</td>
<td>1 mg α-tocopherol =</td>
</tr>
<tr>
<td></td>
<td>1 mg RRR-α-tocopherol</td>
</tr>
<tr>
<td></td>
<td>(d-α-tocopherol)</td>
</tr>
</tbody>
</table>
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** *(7,8)*

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>g/100 kcal</td>
<td>4.4</td>
<td>6.0</td>
<td></td>
</tr>
<tr>
<td>g/100 kJ</td>
<td>1.1</td>
<td>1.4</td>
<td></td>
</tr>
</tbody>
</table>

*(7)* Commercially hydrogenated oils and fats shall not be used in follow-up formula.

*(8)* 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**

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg/100 kcal</td>
<td>300</td>
<td>-</td>
<td>1400</td>
</tr>
<tr>
<td>mg/100 kJ</td>
<td>72</td>
<td>-</td>
<td>335</td>
</tr>
</tbody>
</table>
α-Linolenic acid

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg/100 kcal</td>
<td>50</td>
<td>N.S.*</td>
<td>-</td>
</tr>
<tr>
<td>mg/100 kJ</td>
<td>12</td>
<td>N.S.</td>
<td>-</td>
</tr>
</tbody>
</table>

*N.S. = not specified

Ratio linoleic acid / α-Linolenic acid

<table>
<thead>
<tr>
<th></th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ratio</td>
<td>5:1</td>
<td>15:1</td>
</tr>
</tbody>
</table>

c) Carbohydrates

Available carbohydrates

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>g/100 kcal</td>
<td>9.0</td>
<td>14.0</td>
<td>-</td>
</tr>
<tr>
<td>g/100 kJ</td>
<td>2.2</td>
<td>3.3</td>
<td>-</td>
</tr>
</tbody>
</table>

9) 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

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>µg RE/100 kcal</td>
<td>75</td>
<td>180</td>
<td>-</td>
</tr>
<tr>
<td>µg RE/100 kJ</td>
<td>18</td>
<td>43</td>
<td>-</td>
</tr>
</tbody>
</table>

10) expressed as retinol equivalents (RE)

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

Vitamin D

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>µg 11) /100 kcal</td>
<td>1.0</td>
<td>3.0</td>
<td>-</td>
</tr>
<tr>
<td>µg 11) /100 kJ</td>
<td>0.24</td>
<td>0.72</td>
<td>-</td>
</tr>
</tbody>
</table>

11) Calciferol. 1 µg calciferol = 40 IU vitamin D.

Vitamin E

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg α-TE/100 kcal</td>
<td>0.512)</td>
<td>-</td>
<td>5</td>
</tr>
<tr>
<td>mg α-TE/100 kJ</td>
<td>0.1213)</td>
<td>-</td>
<td>1.2</td>
</tr>
</tbody>
</table>

12) 1 mg α-TE (alpha-tocopherol equivalents) = 1 mg d-α-tocopherol

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

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>µg /100 kcal</td>
<td>60</td>
<td>-</td>
<td>300</td>
</tr>
<tr>
<td>µg /100 kJ</td>
<td>14</td>
<td>-</td>
<td>72</td>
</tr>
</tbody>
</table>

**Riboflavin**

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>µg /100 kcal</td>
<td>80</td>
<td>-</td>
<td>500</td>
</tr>
<tr>
<td>µg /100 kJ</td>
<td>19</td>
<td>-</td>
<td>119</td>
</tr>
</tbody>
</table>

**Niacin**

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>µg /100 kcal</td>
<td>300</td>
<td>-</td>
<td>1500</td>
</tr>
<tr>
<td>µg /100 kJ</td>
<td>72</td>
<td>-</td>
<td>360</td>
</tr>
</tbody>
</table>

*Niacin refers to preformed niacin*

**Vitamin B₆**

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>µg /100 kcal</td>
<td>35</td>
<td>-</td>
<td>175</td>
</tr>
<tr>
<td>µg /100 kJ</td>
<td>8.4</td>
<td>-</td>
<td>41.8</td>
</tr>
</tbody>
</table>

**Vitamin B₁₂**

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>µg /100 kcal</td>
<td>0.1</td>
<td>-</td>
<td>1.5</td>
</tr>
<tr>
<td>µg /100 kJ</td>
<td>0.024</td>
<td>-</td>
<td>0.36</td>
</tr>
</tbody>
</table>

**Pantothenic acid**

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>µg /100 kcal</td>
<td>400</td>
<td>-</td>
<td>2000</td>
</tr>
<tr>
<td>µg /100 kJ</td>
<td>96</td>
<td>-</td>
<td>478</td>
</tr>
</tbody>
</table>

**Folic acid**

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>µg /100 kcal</td>
<td>10</td>
<td>-</td>
<td>50</td>
</tr>
<tr>
<td>µg /100 kJ</td>
<td>2.4</td>
<td>-</td>
<td>12</td>
</tr>
</tbody>
</table>

**Biotin**

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>µg /100 kcal</td>
<td>1.5</td>
<td>-</td>
<td>10</td>
</tr>
<tr>
<td>µg /100 kJ</td>
<td>0.4</td>
<td>-</td>
<td>2.4</td>
</tr>
</tbody>
</table>

**e) Minerals and Trace Elements**

**Iron**

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg /100 kcal</td>
<td>1.0</td>
<td>2.0</td>
<td>-</td>
</tr>
<tr>
<td>mg /100 kJ</td>
<td>0.24</td>
<td>0.48</td>
<td>-</td>
</tr>
</tbody>
</table>

*For Follow-up formula based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36 mg/100 kJ) a maximum of 2.5 mg/100 kcal (0.6/100 kJ) applies.*
## Calcium

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg /100 kcal</td>
<td>50</td>
<td>-</td>
<td>180</td>
</tr>
<tr>
<td>mg /100 kJ</td>
<td>12</td>
<td>-</td>
<td>43</td>
</tr>
</tbody>
</table>

## Phosphorus

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg /100 kcal</td>
<td>25</td>
<td>-</td>
<td>100&lt;sup&gt;18)&lt;/sup&gt;</td>
</tr>
<tr>
<td>mg /100 kJ</td>
<td>6</td>
<td>-</td>
<td>24&lt;sup&gt;18)&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

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

### Ratio calcium/phosphorus

<table>
<thead>
<tr>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:1</td>
<td>2:1</td>
</tr>
</tbody>
</table>

## Magnesium

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg /100 kcal</td>
<td>5</td>
<td>-</td>
<td>15</td>
</tr>
<tr>
<td>mg /100 kJ</td>
<td>1.2</td>
<td>-</td>
<td>3.6</td>
</tr>
</tbody>
</table>

## Sodium

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg /100 kcal</td>
<td>20</td>
<td>60</td>
<td>-</td>
</tr>
<tr>
<td>mg /100 kJ</td>
<td>5</td>
<td>14</td>
<td>-</td>
</tr>
</tbody>
</table>

## Chloride

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg /100 kcal</td>
<td>50</td>
<td>160</td>
<td>-</td>
</tr>
<tr>
<td>mg /100 kJ</td>
<td>12</td>
<td>38</td>
<td>-</td>
</tr>
</tbody>
</table>

## Potassium

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg /100 kcal</td>
<td>60</td>
<td>180</td>
<td>-</td>
</tr>
<tr>
<td>mg /100 kJ</td>
<td>14</td>
<td>43</td>
<td>-</td>
</tr>
</tbody>
</table>

## Manganese

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>µg /100 kcal</td>
<td>1</td>
<td>-</td>
<td>100</td>
</tr>
<tr>
<td>µg /100 kJ</td>
<td>0.24</td>
<td>-</td>
<td>24</td>
</tr>
</tbody>
</table>

## Iodine

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>µg /100 kcal</td>
<td>10</td>
<td>-</td>
<td>60</td>
</tr>
<tr>
<td>µg /100 kJ</td>
<td>2.4</td>
<td>-</td>
<td>14.3</td>
</tr>
</tbody>
</table>

## Selenium

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>µg /100 kcal</td>
<td>2</td>
<td>-</td>
<td>9</td>
</tr>
<tr>
<td>µg /100 kJ</td>
<td>0.48</td>
<td>-</td>
<td>2.2</td>
</tr>
</tbody>
</table>
Copper

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>µg /100 kcal</td>
<td>35</td>
<td>-</td>
<td>120</td>
</tr>
<tr>
<td>µg /100 kJ</td>
<td>8.4</td>
<td>-</td>
<td>29</td>
</tr>
</tbody>
</table>

19) 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

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg /100 kcal</td>
<td>-</td>
<td>12</td>
<td>-</td>
</tr>
<tr>
<td>mg /100 kJ</td>
<td>-</td>
<td>3</td>
<td>-</td>
</tr>
</tbody>
</table>

Total nucleotides
Levels may need to be determined by competent national and/or regional authorities.

Choline

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg /100 kcal</td>
<td>-</td>
<td>-</td>
<td>50</td>
</tr>
<tr>
<td>mg /100 kJ</td>
<td>-</td>
<td>-</td>
<td>12</td>
</tr>
</tbody>
</table>

Myo-inositol

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg /100 kcal</td>
<td>-</td>
<td>-</td>
<td>40</td>
</tr>
<tr>
<td>mg /100 kJ</td>
<td>-</td>
<td>-</td>
<td>9.6</td>
</tr>
</tbody>
</table>

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\(^2, 3, 4\)

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>g/100 kcal</td>
<td>[1.8] or [1.65](^2, 3)</td>
<td>[3.5] or [3.0] or [2.5]</td>
<td>-</td>
</tr>
<tr>
<td>g/100 kJ</td>
<td>[0.43] or [0.39](^2, 3)</td>
<td>[0.84] or [0.72] or [0.60]</td>
<td>-</td>
</tr>
</tbody>
</table>

\(^2\) 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.

\(^3\) 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.

\(^4\) 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.

\(^5\) 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.

\(^6\) 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**

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>µg /100 kJ</td>
<td>[0.24] or [1]</td>
<td>-</td>
<td>6.5</td>
</tr>
</tbody>
</table>

**Vitamin C\(^{1b}\)**

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg /100 kcal</td>
<td>[4] or [10]</td>
<td>-</td>
<td>70(^6)</td>
</tr>
<tr>
<td>mg /100 kJ</td>
<td>[1] or [2.4]</td>
<td>-</td>
<td>17(^6)</td>
</tr>
</tbody>
</table>

\(^{1b}\) expressed as ascorbic acid

\(^{16}\) 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\(^{20}\)

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg /100 kcal</td>
<td>0.5</td>
<td>-</td>
<td>[1.0] or [1.5]</td>
</tr>
<tr>
<td>mg /100 kJ</td>
<td>0.12</td>
<td>-</td>
<td>[0.24] or [0.36]</td>
</tr>
</tbody>
</table>

\(^{20}\)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\(^{20}\)**

<table>
<thead>
<tr>
<th>Unit</th>
<th>Minimum</th>
<th>Maximum</th>
<th>GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of fatty acids</td>
<td>[0.3]</td>
<td>-</td>
<td>0.5</td>
</tr>
</tbody>
</table>

\(^{20}\) 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.]
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, 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.

---

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\(^1\), 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.\(^2\) Children with severe wasting or SAM have a risk of death eleven times higher that of children without SAM.\(^3\)

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


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)
- Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CAC/GL 21-1997)
- General Principles of Food Hygiene (CAC/RCP 1-1969)
- 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.
## APPENDIX V

### 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

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

10. METHODS OF ANALYSIS AND SAMPLING

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

---

4 To be finalized.
### INFORMATION DOCUMENT ON DERIVATION OF NUTRIENT REFERENCE VALUES - REQUIREMENTS (NRVs-R) FOR LABELLING PURPOSES IN THE GUIDELINES ON NUTRITION LABELLING (CAC/GL 2-1985)

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>NRV-R</th>
<th>INL₉₈, AI, or both</th>
<th>RASB source documents for derivation of NRVs-R</th>
<th>CCNFS DU Report</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vitamins</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin A</td>
<td>800 µg (RAE or RE)</td>
<td>INL₉₈</td>
<td>IOM (2001)</td>
<td>REP 16/NFS DU, 2015</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>100 mg</td>
<td>INL₉₈</td>
<td>Average EFSA (2013), NIHN (2013)</td>
<td>REP 15/NFS DU, 2014</td>
</tr>
<tr>
<td><strong>Minerals</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium</td>
<td>1,000 mg</td>
<td>INL₉₈</td>
<td>WHO/FAO (2004)</td>
<td>REP 13/NFS DU, 2012</td>
</tr>
<tr>
<td>Zinc</td>
<td>11 mg, 14 mg</td>
<td>INL₉₈</td>
<td>iZiNGC (2004)</td>
<td>REP 15/NFS DU, 2014¹</td>
</tr>
<tr>
<td>Copper</td>
<td>900 µg</td>
<td>INL₉₈</td>
<td>IOM (2001)</td>
<td>REP 16/NFS DU, 2015</td>
</tr>
<tr>
<td>Manganese</td>
<td>3 mg</td>
<td>AI</td>
<td>Average EFSA (2013), IOM (2001)</td>
<td>REP 15/NFS DU, 2014</td>
</tr>
<tr>
<td>Molybdenum</td>
<td>45 µg</td>
<td>INL₉₈</td>
<td>IOM (2001)</td>
<td>REP 15/NFS DU, 2014</td>
</tr>
<tr>
<td>Phosphorus</td>
<td>700 mg</td>
<td>INL₉₈</td>
<td>IOM (1997)</td>
<td>REP 16/NFS DU, 2015</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protein</td>
<td>50 g</td>
<td>INL₉₈</td>
<td>WHO/FAO (2007)</td>
<td>REP 14/NFS DU, 2013</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not established</td>
<td></td>
<td></td>
<td>REP 15/NFS DU, 2014</td>
</tr>
<tr>
<td>Chromium</td>
<td>Not established</td>
<td></td>
<td></td>
<td>REP 16/NFS DU, 2015</td>
</tr>
<tr>
<td>Chloride</td>
<td>Not established</td>
<td></td>
<td></td>
<td>REP 16/NFS DU, 2015</td>
</tr>
</tbody>
</table>

¹ Also footnote and dietary description

### ABBREVIATIONS

NRV-R: Nutrient Reference Values – Requirements  
INL₉₈: Individual Nutrient Level 98  
AI: Adequate Intake  
RASB: Recognized Authoritative Scientific Body