CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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REP19/NFSDU

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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

Berlin, Germany

26 – 30 November 2018

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LIST OF ABBREVIATIONS

CAC	Codex Alimentarius Commission
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCCF	Codex Committee on Contaminants in Foods
CCFA	Codex Committee on Food Additives
CCFL	Codex Committee on Food Labelling
CCFO	Codex Committee on Fats and Oils
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
CRD	Conference Room Document
DE	Dextrose equivalent
DHA	Docosahexaenoic acid
DIAAS	Digestible Indispensable Amino Acid Score
EPA	Eicosapentaenoic acid
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
FOPL	Front of pack nutrition labelling
FUF	Follow-up formula
GSFA	General Standard for Food Additives
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JEMNU	Joint FAO/WHO Expert Meetings on Nutrition
NUGAG	WHO Nutrition Guidance Expert Advisory Group
NCD	Non-communicable disease
NRV	Nutrient reference value
NRV-NCD	Nutrient reference value-Non-communicable Disease
NRV-R	Nutrient reference values-requirements
PDCAAS	Protein Digestibility Corrected Amino Acid Score
PER	Protein Efficiency Ratio
PUFA	Polyunsaturated fatty acids
PWG	Physical Working Group
RUTF	Ready-to-use therapeutic foods
SAM	Severe acute malnutrition
TFA	Trans fatty acid
UNICEF	The United Nations Children Fund
WFP	World Food Programme
WHA	World Health Assembly
WHO	World Health Organization

INTRODUCTION

1. The fortieth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held in Berlin, Germany, from 26 to 30 November 2018 at the kind invitation of the Federal Government of Germany. Dr Anja Brönstrup and Hilke Thordsen-Böhm, Federal Ministry of Food and Agriculture of Germany, served as Chair and vice-Chair of the Session respectively. The Committee was attended by 73 member countries, one member organisation and 41 observer organisations. A list of participants is given in Appendix I.

OPENING OF THE SESSION

2. Mr. Hans-Joachim Fuchtel, Parliamentary State Secretary, Federal Ministry of Food and Agriculture, speaking on behalf of Ms. Julia Klöckner, Federal Minister of Food and Agriculture opened the Session and extended his warmest welcome to all the participants. He thanked the delegates for the great commitment and emphasized the outstanding importance of the Committee's work, especially to those who had special nutritional needs.

Division of competence[1]

3. 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)[2]

4. The Committee adopted the Provisional Agenda with the following additions under Agenda Item 13 – other business and future work:

   i. Proposal for new work on the general requirements for protein supplements intended for bodybuilding (proposed by Egypt);
   ii. Methods of analysis for provisions in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981) (proposed by the United States of America); and
   iii. Proposal for new work on International Prebiotic Guidelines for Use in Foods and Dietary Supplements (proposed by Sudan).

5. Additionally, the Committee agreed to the establishment of an in-session Working Group on the methods of analysis for provisions in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981), chaired by the United States of America, and working in English only, to consider the recommendations as presented in CRD3 regarding the analytical methods for vitamin K, folic acid and nine minerals and trace elements for referral to CCMAS.

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER SUBSIDIARY BODIES (Agenda Item 2)[3]

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

Guidance on the alignment of food additive provisions and alignment plan

7. The Codex Secretariat reminded the Committee that CCNFSDU38 (2016) had decided to postpone the alignment work until the guidance was made available. Now that the guidance had been published by the Codex Committee on Food Additives (CCFA), the Committee was encouraged to move forward with this task.

8. The Committee agreed to further discuss this matter in the second part of Agenda Item 10.

Consideration of the revocation of relevant food additive provisions

9. The Committee noted the correction made by the Codex Secretariat that potassium hydrogen malate (INS 351(i)) and potassium malate (INS 351(ii)) had been erroneously included in CX/NFSDU 18/40/2-Rev and that these food additives were not subject to revocation.

10. In response to the recommendation from CCFA50, the Committee agreed to revoke the provisions for monosodium tartrate (INS 335(i)), monopotassium tartrate (INS 336(i)) and dipotassium tartrate (INS 336(ii)) in the *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CXS 74-1981) due to the lack of JECFA specifications.

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1 CRD1 (Annotated Agenda – Division of competence between the EU and its Member States)
2 CX/NFSDU 18/40/1; CRD2 (Egypt); CRD3 (United States of America); CRD4 (Sudan); CRD27 (Nigeria); CRD30 (Sudan); CRD36 (Indonesia)
3 CX/NFSDU 18/40/2, CRD25 (Comments of African Union); CRD27 (Nigeria); CRD36 (Indonesia)

Prioritization mechanism to better manage the work of the Committee

11. The Committee noted the request of CCEXEC75 and agreed to the proposal of the Codex Secretariat that the Committee consider a strategic scheme for long-term work management, as had already been done in some other Codex Committees, and that this matter be discussed in conjunction with the Discussion Papers under Agenda Items 11 and 12 as well as matters proposed under Agenda Item 13.

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

12. While noting the discrepancy in provisions on Vitamin D between CXS 72-1981 (Vitamin D_3) and the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979) (Vitamin D_2 and Vitamin D_3), the Committee was unable to reach agreement on whether to include in CXS 72-1981 only Vitamin D_3 or both Vitamin D_2 and Vitamin D_3, due to diverging views on the equivalence and the suitability of the two forms.

13. The Committee agreed to retain the Vitamin D provision in CXS 72-1981 for the time being and consider reviewing this provision should the Committee decide to revise CXS 72-1981 in the future. The Committee noted that the issue of the forms of Vitamin D was also of relevance to the work under Agenda Items 4 and 5, and that it would consider this on a case-by-case basis under these items.

MATTERS OF INTEREST ARISING FROM FAO AND WHO (Agenda Item 3)[4]

14. The Representative of FAO called the attention of the Committee to various activities of FAO of interest to CCNFSDU: (1) The Joint FAO/WHO Expert Meetings on Nutrition (JEMNU) to provide scientific advice for the establishment of nitrogen to protein conversion factors for soy-based and milk-based ingredients used in infant formula and follow-up formula, noting that a call for data had been issued; (2) The publication of the Report of the FAO Expert Working Group on Protein Quality Assessment in Follow-up Formula for Young Children and Ready to Use Therapeutic Foods (RUTF), that was held in Rome in November 2017; noting that the main outcomes of the report had been presented by an FAO Expert during the physical Working Group meeting on RUTF (held on 24 November 2018); (3) FAO's support to the development and implementation of Food Based Dietary Guidelines (FBDGs) and recent work by countries on developing FBDGs for 0-2 years; (4) the UN Decade of Action on Nutrition 2016 – 2025, referring to the release of the first progress report of the Nutrition Decade that had been conveyed by the UN Secretary-General to the UN General Assembly, during its Seventy-second session.

15. The Representative of WHO highlighted the activities which may be of relevance and interest to the on-going work of the Committee. With reference to the UN Third High-level meeting on NCDs, the Representative informed the Committee of the efforts being made by WHO in setting up an accountability framework to monitor the private sector's actions in meeting the recommendations and targets set by WHO in achieving the reduction of salt/sodium, sugars and fat intake, including the elimination of industrially-produced trans-fatty acids (TFA). With reference to various new WHA resolutions, work, publications and tools developed to improve infant and young child feeding, the Representative informed the Committee of the new Information Note which had just been issued entitled "*Information Note: Clarification on the classification of follow-up formulas for children 6 – 36 months as breastmilk substitutes*" (http://www.who.int/nutrition/publications/infantfeeding/information-note-followup-formula-bms/en/). The Representative further highlighted all the relevant guideline development including the release of the draft guidelines on saturated and trans-fatty acids intake in adult and children in May/June 2018 for public consultation and also the launching of the REPLACE action package which would guide countries in developing and implementing the roadmap for eliminating industrially-produced TFA. The elimination of industrially-produced TFA is a priority target of the WHO's 13th General Programme of Work which would guide the work of WHO during the period 2019 – 2023. The Representative also mentioned the new development in the work areas related to the prevention of harmful use of alcohol and further information was made available in CRD35.

16. Some observers congratulated WHO for their work on the need for regulations and monitoring, and for the new Information Note on the clarification on the classification of follow-up formulas for children 6 – 36 months as breastmilk substitute; and a delegation encouraged more collaborative work between FAO and WHO under the framework of JEMNU to support the work of the Committee.

17. The Committee thanked FAO and WHO for the information and noted that certain parts of the information provided would be considered under relevant Agenda Items. The Committee noted the encouragement of a delegation for more collaboration work between FAO and WHO under the framework of JEMNU to support the work of the Committee.

[4] CX/NFSDU 18/40/3 Rev; CRD35 (Additional Information of WHO activities on alcohol)

REVIEW OF THE *STANDARD FOR FOLLOW-UP FORMULA* (CODEX STAN 156-1987) (Agenda Item 4a)[5] [6]

18. The Committee recalled that the essential composition requirements of follow-up formula for older infants and for the [product] for young children had been adopted at Step 5 by the Commission.

19. The Chair noted that there had been extensive discussion and agreement on the essential composition requirements, thus the reason for advancement of these provisions. The only outstanding issues to be agreed were those sections remaining in square brackets in Section B for [product] for young children, viz. carbohydrates, footnote 4 and the requirements for Vitamin D as well as footnote 2 to the provision for protein following the publication of the report of the FAO *Expert Working Group on Protein Quality Assessment in Follow Up Formula for Young Children and Ready to Use Therapeutic Foods* (refer to Agenda Item 3). The Committee therefore agreed to focus its discussion on these outstanding issues and further agreed to use CRD5, which contained editorial and technical amendments, as a basis for discussion.

Protein: footnote 2

20. The Committee considered a proposal of New Zealand which was drafted taking into account the recommendations of the FAO Expert Working Group for basing the protein quality on a PDCAAS score of 90 or higher, while also retaining the previous agreement that protein quality could be determined by PER, and if so, the quality of the protein should not be less than 85% of that of casein.

21. Views expressed were for either retaining only the PDCAAS method in line with the FAO Expert Working Group recommendation or to allow the determination of protein quality by both the PDCAAS and PER. Delegations in favour of retaining PER, noted that this method was widely used in practice and was useful for screening purposes. A proposal was made to also refer to DIAAS should it be recognized by FAO in the future, noting that this method was equivalent to PDCAAS, and according to the FAO Expert Working Group, it was the ideal metric for protein quality assessment, but was not ready for use at this time since true ileal digestibility values of individual amino acids were incomplete.

22. The FAO Expert provided clarifications with regard to the outcomes of the FAO Working Group on protein quality assessment. The Expert clarified that the FAO Working Group did not refer to the PER method due to the fact that this was considered a rather outdated method to assess protein quality in human foods as it was based on rat growth studies.

Conclusion

23. The Committee agreed to indicate that both PDCAAS and PER could be used for determination of protein quality for [product] for young children, with PDCAAS being the preferred method; and to also indicate that the DIAAS method could be used should it be recognized by FAO in the future.

Carbohydrates: footnote 4

24. The Committee recalled its earlier agreement that lactose should be the preferred carbohydrate in the product and the need to limit the amount of mono- and disaccharides to reduce the sweetness of the product.

25. The major discussion was on the need for carbohydrates other than lactose for products not based on milk protein (plant-based products), whether to clearly stipulate these carbohydrates and how to limit and measure sweetness. Views were expressed that sweetness would be difficult to objectively measure. The Committee therefore considered a proposal to rather refer to a combination of carbohydrate sources with an average/maximum dextrose equivalent (DE) of 15 (corresponding to the relative sweetness of lactose) for this purpose. Concerns were expressed with this approach as it was pointed out that DE might be wrongly considered as it was not a measure of sweetness, but of the amount of reducing sugars; and could result in young children taking in more sugar than they should; DE would be impossible to measure in the final product and that it was better to limit sweetness by limiting mono- and disaccharides.

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5 Proposed draft essential composition requirements for older infants and young children

6 REP18/NFSDU, Appendix II; CX/NFSDU 18/40/4 Rev.1 (Comments of Australia, Brazil, Canada, Colombia, Indonesia, Japan, New Zealand, Norway, Peru, Philippines, Switzerland, Syrian Arab Republic, United States of America, AOCS, EU Specialty Food Ingredients, EUVEPRO and ISDI); CX/NFSDU 18/40/4-Add.1 (Comments of Egypt, European Union, Singapore, United States of America, Vietnam); CRD5 (Editorial and technical amendments to the Essential Composition Requirements for Follow-up Formula for older infants and [Name of Product] for young children (Prepared by the Chair of the EWG of the review of the Standard for Follow-Up Formula); CRD6 (ISDI); CRD14 (Thailand); CRD23 (India); CRD29 (Russian Federation)

26. The Committee considered whether to retain the last part of the footnote on the types of non-carbohydrate ingredients that should not be added with the purpose of imparting or enhancing a sweet taste. It was noted that sweeteners, although not permitted in these products, together with flavouring should be addressed in the section on food additives. For the non-carbohydrate ingredients not considered food additives or flavourings, a proposal was made that they could be better addressed in the section on optional ingredients. This text was therefore transferred to section 3.2.1 and kept in square brackets for further consideration.

Conclusion

27. The Committee agreed to the amended footnote and to retain the proposals related to the use of DE for plant-based products, and to substances imparting or enhancing a sweet taste in section 3.2.1. in square brackets for further consideration.

Vitamin D

28. The Committee noted that there was previous agreement that Vitamin D should be a mandatory ingredient in the product, but that there was still a need to agree on the minimum and maximum levels and to clarify the form of Vitamin D.

29. There was general agreement with the values proposed, while some members reiterated the preference for lower minimum (1µg/100kcal) and maximum levels (3µg/100kcal) as the levels of up to 4.5 µg/100kcal could result in unsafe levels of Vitamin D being consumed.

30. There was wide support for Vitamin D (encompassing Vitamin D_2 and D_3) as opposed to Vitamin D_3. However, views were expressed that Vitamin D_3 should be the preferred form of Vitamin D as Vitamin D_2 was less efficacious and if added to the product, it should be added at such a level to be as efficacious as Vitamin D_3.

31. It was noted that footnote 7 was allowing competent national/regional authorities to deviate from the conditions regarding the levels and the forms of Vitamin D and that the footnote addressed the concerns raised.

Conclusion

32. The Committee agreed that the requirement would be for Vitamin D and agreed to the minimum and maximum values as well as the footnotes (7 and 8) as proposed.

Conclusion

33. The Committee agreed to retain the essential requirements for follow-up formula for older infants and for [product] for young children at Step 7 (Appendix II) and to request the EWG on follow-up formula (see Agenda Item 4b) to consider the proposals on DE for products not based on milk protein and related to substances imparting or enhancing a sweet taste in section 3.2.1, and to provide further recommendations for comments and consideration by the next session of the Committee.

REVIEW OF THE *STANDARD FOR FOLLOW-UP FORMULA* (CODEX STAN 156-1987) (Agenda Item 4b)[7], [8]

34. The Chair introduced the item and proposed to order the discussion as follows:

- Section A: follow-up formula for older infants: scope, product definition and labelling.
- Section B [Product] for young children: scope, product definition and labelling.
- Options for the structure of the Standard and the preamble.

35. New Zealand, the Chair of the electronic working group (EWG), speaking also on behalf of the co-Chairs France and Indonesia, introduced each of the recommendations in the order of the discussion above.

36. The Committee considered the recommendations of the EWG and in addition to editorial amendments, made the following decisions and comments.

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[7] Scope, product definition, labelling

[8] CX/NFSDU 18/40/5; CX/NFSDU 18/40/5-Add.1 (Comments of Argentina, Australia, Brazil, Cambodia, Canada, Colombia, Costa Rica, Côte d'Ivoire, Ecuador, Egypt, European Union, Ghana, India, Indonesia, Iran, Jamaica, Malaysia, Mali, Nepal, New Zealand, Norway, Peru, Philippines, Senegal, Sri Lanka, Switzerland, United States of America, Viet Nam, EU Specialty Food Ingredients, HKI, IBFAN, ISDI and UNICEF); CX/NFSDU 18/40/5-Add.2 (Kenya, Lao People Democratic Republic); CRD9 (Protein quality requirements for [Name of product] for young children (Prepared by the Chair of the EWG of the review of the Standard for Follow-Up Formula)); CRD14 (Thailand); CRD15 (IACFO); CRD24 (EFLA); CRD25 (African Union); CRD26 (Morocco); CRD27 (Nigeria); CRD29 (Russian Federation); CRD31 (Mexico); CRD32 (Republic of Korea)

Section A: follow-up formula for older infants

General discussion

37. The Committee had an exchange of views whether it was appropriate to discuss the scope of the Standard before there was agreement on the structure and the preamble. It was clarified that at CCNFSDU38, it was agreed to first focus on the details of the standard and to continue working on the Section A/B format before taking a decision on the structure and the preamble (REP17/NFSDU, paras 67 - 68). The Committee therefore agreed to follow the outline for discussion as proposed by the chair.

1. Scope

38. The Committee agreed to the scope with the inclusion of the term "sampling" under section 1.2. in relation to methods of analysis.

39. To concerns on how the WHO *International Code of Marketing of Breastmilk Substitutes*, the *Global Strategy for Infant and Young Child Feeding* and relevant WHA resolutions would be addressed, if not in the scope, it was clarified that these could be addressed through the provisions in the labelling section and in the future discussion on the preamble.

40. A delegation, supported by an observer, also proposed to reconsider the name of the product as the term follow-up formula implied that the product should be consumed after breastfeeding and was necessary. However, the Committee did not discuss this proposal.

2.1 Product definition

41. The Committee recalled that there was already agreement on section 2.1.2 and focused discussion on section 2.1.1.

42. There was general agreement that follow-up formula for older infants were breastmilk substitutes; and it was reiterated that it was not appropriate to refer to it as being "*specially"* manufactured. However, there was an exchange of views as to whether it was appropriate to refer to these products as part of a progressively diversified diet. A delegation expressed the view that it was not appropriate to refer to "progressively" in the definition as the diet of older infants, 6 – 12 months, was not progressive because they have just been introduced to complementary food. This deletion was supported by other delegations, some observers and WHO, noting that these products were not a necessary part of a diversified diet. Other delegations however were of the view that "progressively diversified diet" should be retained, as it was clarified that over this period, older infants were being introduced to a progressively diversified diet and that the products in question could form part of this diet.

43. The Committee, in the spirit of compromise, agreed to a definition that clarified that the product was a breastmilk substitute as a liquid part of a diet for older infants when progressively diversified complementary feeding is introduced.

9. Labelling

44. The Committee agreed to reinsert the last sentence in this section relating to the prohibition on the use of nutrition and health claims. It was noted that even though prohibitions on the use of nutrition and health claims were covered in section 1.4 of the *Guidelines for Use of Nutrition and Health Claims* (CXG 23 – 1997), it was necessary to emphasize the prohibitions for follow-up formula for older infants, which was also consistent with the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72 – 1981).

9.6 Additional labelling requirements

45. The Committee noted that this section was largely based on Article 9 of the *WHO International Code of Marketing of Breastmilk Substitutes*, and Recommendation 4 of the WHO *Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children* (specifically provision 9.6.2); and in some cases the provision used the wording as contained within the Guidance.

46. One observer called for the inclusion of the word "independent" in 9.6.1 (c).

47. There was discussion regarding 9.6.1(d) with the resultant agreed text referring to "not leading to cessation of continued breastfeeding" rather than referring to "not replacing breastmilk" as this concept was considered in conflict with the definition.

48. Regarding 9.6.2 the decision was taken to include young children in the list of prohibited pictures on the label of follow-up formula for older infants.

49. The Committee made further amendments, to align with the WHO guidance, to section 9.6.2.4 to emphasize that the product was not similar to breastmilk; and to section 9.6.4 to indicate that the product should be distinctly labelled to ensure that consumers could distinguish between infant formula, follow-up formula for older infants and [product] for young children, and foods for special dietary uses. In addition, a statement that cross-promotion was not allowed on the label was also introduced. Some delegations were not in favour of a provision on cross-promotion and raised concerns on whether it included advertising and marketing and that it went beyond the mandate of this Committee. The Chair confirmed that any reference to cross-promotion should be in relation to the label of the product. A suggestion was made to refer to cross-promotion on labelling rather than label. A question was then asked whether the term labelling extended to marketing and advertising.

50. Attention was drawn to the Codex definition of labelling in the *General Standard for Labelling of Pre-Packaged Food* (CXS 1-1981) that included "*any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food including that for the purpose of promoting its sale or disposal"*. The Representative of WHO clarified that the intent of the provision on cross-promotion was to avoid messages on labels that a product for a particular age group was also suitable for another age group or that reference was made to a similar product for another age group. Based on the clarification on the meaning of cross-promotion, the Committee agreed that the wording in the last section of 9.6.4 should refer to label/labelling and that "label/labelling" should remain in square brackets.

Section B: [product] for young children

1. Scope

51. There was agreement with the scope, consistent with the scope for follow-up formula for older infants.

2.1 Product definition

52. The key discussion was whether this product could be considered as a breastmilk substitute. The chair noted the polarizing views on this definition and raised the option of remaining silent on classifying [product] for young children as a breastmilk substitute.

53. Those supporting that the product was a breastmilk substitute expressed the following views:

- The product should be judged on its function rather than its composition.
- This was in line with the WHA Resolution 69.9 that these were considered as breastmilk substitutes and that it was critical to have policy coherence between the WHO and Codex .
- The WHO Information Note on Clarification of the classification of follow-up formulas for children 6 – 36 months as breastmilk substitutes indicated that there was scientific evidence that these products could be considered as breastmilk substitutes.
- The product was regulated as such in their countries.
- Evidence had shown that there was a decline in breastfeeding with the increase of these products on the market.

54. Those not supporting defining these products as breastmilk substitutes noted that, while breastfeeding should be promoted:

- The role and purpose of the product was different to that of breastmilk substitutes.
- The product was used as an alternative to cow's milk rather than breastmilk.
- When developing the essential composition requirements, it was based on the principles agreed by the Committee, principle 1: evidence to support contribution to the nutritional needs of young children where the consumption of the nutrient is widely inadequate with, the result that only 13 nutrients were identified for this product as opposed to 30 for follow up formula for older infants which were considered breastmilk substitutes.
- Many young children (12 – 36 months) in various parts of the world did not have adequate intake of protein, energy and micronutrients as they were weaned onto complementary foods.

55. There was no consensus on this matter and it was agreed to defer further discussion to the next session.

56. In view of time constraints, the Committee did not consider the rest of the recommendations of the EWG and agreed to defer discussion to the next session.

Conclusion

57. The Committee agreed to:

- advance Section A: follow up formula for older infants to Step 5 for adoption by CAC42 (Appendix III);

- send the labelling provisions for follow up formula for older infants to CCFL45 for endorsement;
- defer discussion on Section B: product definition and labelling of [product] for young children (Appendix IV), the structure of the Standard(s) and preamble(s) for discussion at CCNFSDU41; and
- re-establish the EWG chaired by New Zealand and co-chaired by France and Indonesia and working in English to address the issue of DE and the sentence in square brackets in section 3.2.1 (See para 33) and to complete the remaining sections as follows
    - purity requirements
    - vitamin compounds and mineral salts
    - consistency and particle size
    - specific prohibitions
    - food additives
    - contaminants
    - hygiene
    - packaging
    - fill of container
    - methods of analysis and sampling

PROPOSED DRAFT GUIDELINE FOR READY-TO-USE THERAPEUTIC FOODS (Agenda Item 5)[9]

58. South Africa, as Chair of the EWG and PWG, speaking also on behalf of the co-Chairs Senegal and Uganda, introduced the item and highlighted the recommendations of the PWG as contained in CRD28 Rev. He explained that the discussion of the PWG focused on sections where the EWG did not reach consensus and which had been put in square brackets.

59. The Committee agreed to consider the report of the PWG, addressed each recommendation, made appropriate editorial changes and clarified various sections as follows:

Recommendation 1

60. The Committee supported the recommendation to amend section 5.1.2 (Legumes and Seeds) to: i) include phytoestrogens; ii) prohibit the use of “field beans” or “Faba beans” because of the danger of favism; iii) delete the paragraph on processing technologies for reduction of anti-nutritional factors from this section, since these were covered under section 8 (Processing technologies). As a consequence, the square brackets were removed from the text.

61. One delegation noted that in some countries root-tubers were used as raw materials together with cereals. The Committee included tubers in Section 5.1.4 Cereals and “Tubers” and put the word tubers in square brackets for further consideration.

Recommendation 2

62. The Committee agreed to support the recommendation for the proposed text of Section 5.1.5 (Vitamins and Minerals); and inserted the word “buffer” to clarify the term metabolisable-base.

Recommendation 3

63. The Committee considered the proposed text for Section 5.2.1 (Available carbohydrates) and agreed with the proposal by UNICEF to integrate footnote 6 into the main text as this would ensure clarity, readability and better flow of concepts in this section. As a consequence the Committee:

- Clarified that the preferred form of carbohydrates to be used in the manufacture of RUTF were: plant starch, lactose, maltodextrin, and sucrose; and that glucose should not be used due to its high osmolality.

[9] CX/NFSDU 18/40/6; CX/NFSDU 18/40/6-Add.1 (Comments of Argentina, Brazil, Colombia, Ecuador, India, Jamaica, Japan, Malawi, Norway, Sri Lanka, EU Specialty Food Ingredients, HKI, ICAAS, IBFAN, IACFO, IDF, ISDI, MSF, UNICEF); CX/NFSDU 18/40/6-Add.2 (Canada, United States of America); CRD10 (European Union); CRD14 (Thailand); CRD16 (Revised guidelines (prepared by the chair of the EWG on RUTF)); CRD17 (Philippines); CRD21 (Egypt); CRD23 (India); CRD25 (African Union); CRD27 (Nigeria); CRD28 (Report of the PWG on the proposed draft guidelines for RUTF); CRD29 (Russian Federation); CRD36 (Indonesia)

- Agreed that “free sugars” could be added to RUTF and if added, it should not exceed 20% of total energy; and deleted the phrase that “free sugar added for sweetness should be used sparingly” as it would be difficult to implement and/or to enforce.
- Clarified that only precooked and/or gelatinized starched may be added.
- Amended the title of the section by deleting the word ‘Available’, as the text applied to carbohydrates in general and not sugars.
- Deleted footnote 6.

64. A view was expressed that added levels of free sugars of 20% of total energy were too high; and should be set at 15% instead. It was explained that limited data were available related to a product containing free sugars at less than 20% of total energy.

65. The Committee noted that there was a relationship between Section 5.2.1 (Carbohydrate), and the Section 6.3 (Lipids); and Section 6.2 (Proteins), and agreed to a proposal to have it finalised after considering the aforementioned sections. Section 5.2.1 was put in square brackets.

Recommendation 4

66. The Committee, clarified that Section 5 (Suitable Basic Raw Materials and Ingredients) covered all formulations of RUTF; and that all formulations should be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended. The Committee:

- Amended the second sentence to the chapeau of Section 5 to read: “Any formulation of RUTF shall comply with Section 3 of the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991) including the specification that their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended”.
- Agreed to delete Section 5.3 “The Use of other Matrices in RUTF formulation”.

67. One delegation called for the RUTF guidelines to be kept flexible to allow for use of other raw materials including fish and soy. An observer highlighted the need to further consider whether gluten-containing cereals should be permitted in such products because gluten intolerance in SAM infants and children may result in life threatening situations. This was supported by some other observers.

68. A delegation mentioned that those products were for children from six months were gluten-containing cereals were generally recommended to be introduced into the diet and that there were no specific data on gluten intolerance in SAM in infants and young children.

Recommendation 5 - Section 6.1 Energy

69. The Committee supported the recommendation to base the energy requirements of RUTF on the current energy values of 520 to 550 kcal/100g stipulated in the 2007 Joint Statement of the WHO, WFP, the United Nations System Standing Committee on Nutrition and UNICEF *Community Based Management of Severe Acute Malnutrition* and agreed to include proteins among the energy providing ingredients listed in the second sentence.

Recommendation 17 – Section 5.2.2 Food additives and flavours

70. The Chairperson noted the proposed stepwise approach to be used when addressing the question of food additives in RUTF was pragmatic and that it would include: i) identification of additives that were currently in use; ii) reviewing if such additives were already permitted for use in the existing CCNFSDU and other Codex standards e.g. CXS 72-1981, CXS 74-1981, CXS 192-1995 etc.; iii) developing a text that would make reference to the food additive provisions standards.

71. Codex Secretariat clarified that it may be appropriate to provide general guidance on food additives, or to identify the functional classes of food additives or have a general reference to the GSFA. The Secretariat further supported the proposed stepwise approach and to refer to other Codex standards or guidelines when developing the section on food additives. It was pointed out that besides identifying the food additives that were permitted for use in RUTF, it would be important to clearly identify the Food Category (F.C) within *the General Standard for Food Additives (CXS 192-1995)* under which RUTF fall; and then examine if the identified food additives under such (F.C) were already justified for use in this product. If not, the Committee should request CCFA to include the identified food additives in the respective food category of the GSFA.

72. One observer noted that the criteria for selection and justification for the use of food additives in RUTF should be clear and should take into account the child’s needs, since the product was for use by malnourished children. It was also emphasized that the additives to be used should have been evaluated by JECFA, and in this regard the CCNFSDU may have to consult CCFA.

73. The Committee supported the proposed stepwise approach, deleted the term "flavour" from the title as these were covered under the definition for food additives, and there was agreement that these should not be used in RUTF, and agreed to continue developing the section 5.2.2 "Food additives" based on the proposed stepwise approach, and taking into account the clarification made at the Session.

Other recommendations

74. Due to time constraints the Committee agreed to defer consideration of the remaining recommendations to its next session

Conclusion

75. The Committee agreed to:

a) Re-establish an EWG, chaired by South Africa and co-chaired by Senegal and Uganda, and working in English and French to continue developing Section 5.2.2 (Food additives) and Section 6.2 (Proteins), for circulation for comments and consideration at its next session; and

b) Hold the rest of the text at Step 4 Appendix V) and to consider the remaining recommendations of the PWG at its next session.

PROPOSED DRAFT DEFINITION FOR BIOFORTIFICATION (Agenda Item 6)[10]

76. Zimbabwe, as Chair of the EWG, speaking also on behalf of the co-Chair South Africa, introduced the item and noted that the EWG had prepared five recommendations for consideration by the Committee, including: the refined draft definition for biofortification and its accompanying footnotes; alternative terms to biofortification that may be used subject to a decision by national/regional authorities; where the definition would be best placed; and how it would be used.

77. The Chair recalled that since the initiation of new work on the proposed definition, there had been a lot of compromise on the various aspects of the definition and its accompanying footnotes with a view to provide flexibility to members to facilitate varying needs of different competent authorities.

Discussion

78. An Observer emphasized that consensus had been generated around the proposed draft definition as demonstrated by a number of footnotes used to address various concerns. She stressed that once finalised, the definition would support health policies related to combating micronutrient deficiency, in developing countries. The definition would allow global harmonisation and thus remove fragmentation of efforts in this area.

79. The Committee noted the support by several delegations for the definition and its accompanying footnotes noting that the definition was: clear; provided a common understanding of the topic of biofortification; and covered all the agreed criteria. Biofortification would assist in combating malnutrition in developing countries.

80. The Committee noted the following concerns of other delegations:

- The proposed definition was not clear. Conformity with the definition could not be verified as there were no criteria for measuring or expressing "significant amounts increased" stated in the definition. The absence of means to verify the compliance of labelled products made the definition impossible to realise and would create confusion to consumers.
- The proposed draft definition was too broad, and would allow the inclusion of genetically modified organisms; and this would thus lead to deception of consumers.
- The lack of a harmonized approach due to substantial flexibility could undermine the value of this work.
- The term "bio" was exclusively dedicated to organic production in some countries and therefore the introduction of the term biofortification, which included foods not produced organically, would be problematic; and that no single alternative/equivalent term had been identified.
- Without answering the questions from CCEXEC70 as to where the definition would be best placed and how it would be used, the Committee was not in a position to make further progress.

81. The Chair of the Committee reiterated that some concerns were addressed through the different footnotes.

[10] CX/NFSDU 18/40/7; CX/NFSDU 18/40/7-Add.1 (Comments of Argentina, Australia, Brazil, Canada, Colombia, Costa Rica, Cuba, Ecuador, Guatemala, Guyana, India, Iran, Iraq, Jamaica, Malaysia, New Zealand, Panama, Peru, Philippines, Senegal, Switzerland, United States of America, IFPRI, ICGMA, IUFOST, IBFAN); CX/NFSDU 18/40/7-Add.2 (Kenya, Nicaragua, FoodDrinkEurope); CRD11 (NHF); CRD14 (Thailand); CRD18 (European Union, IACFO); CRD25 (African Union); CRD26 (Morocco); CRD29 (Russian Federation); CRD37 (El Salvador)

82. The Committee recalled that the request to develop the definition originated from CCFL[11]. Delegations were of the view that it was the responsibility of CCFL to indicate how and where the definition would be used. As such the definition should be referred to CCFL for clarification of these issues.

83. The Committee agreed to make an amendment to the definition by inserting the term "nutrient" used in the *General Principles for the Addition of Essential Nutrients to Foods* (CXG 9-1987) in addition to "conventional". In addition, footnote 4 on nutrient was deleted as it was explained by the Codex Secretariat that there was no need to restate a term which was already defined in another Codex text.

Conclusion

84. The Committee, while holding this work at Step 4, agreed to forward the definition (Appendix VI) to the Codex Committee on Food Labelling (CCFL) and request CCFL:

i. To consider if the definition would meet their intended needs; and

ii. To clarify the intended use of the definition and where the definition would be best placed.

PROPOSED DRAFT NRV-NCD FOR EPA AND DHA LONG CHAIN OMEGA-3 FATTY ACIDS (Agenda Item 7)[12]

85. The Russian Federation, as Chair of the EWG, speaking also on behalf of the co-Chair Chile, introduced the item. It was noted that the response to the EWG's request for advice had been provided by WHO on 13 November 2019 (available as CRD20) and that the EWG did not have time to consider the response.

Recommendation 1

86. The Committee considered whether to discontinue the work for the time being or to postpone the discussion until further evidence became available.

87. Those in support of discontinuing the work noted the following views:

- NUGAG made a clear conclusion that there was not enough evidence at this point on the effect of EPA and DHA on CHD mortality based on the substantial review, and it was unlikely for the conclusion to change in the foreseeable future;
- Member countries were encouraged to collect more evidence; and
- Discontinuation would open up more room for the Committee to take on other work.

88. Those in support of postponing the work noted the following views:

- The issue was so important that searching for new evidence needed to continue; and
- New evidence from recently published three large-scale clinical trials as well as another study to be published at the end of 2019 would add an important contribution to the totality of evidence supporting an NRV-NCD for EPA and DHA and JEMNU should review this evidence.

89. The Chair of the Committee noted that since NUGAG had been already in the process of working in this area and they had just published a Cochrane review, it might not be feasible to request JEMNU to start work on this issue as the amount of work was too small to justify seeking financial resources for the convening of JEMNU.

90. With reference to the comments on the recent release of the three new large trials (i.e. ASCEND, REDUCE-IT and VITAL), the Representative of WHO noted that only one of the three trials (i.e. VITAL) was conducted in a general population of older adults (men above 50 years old & women above 55 years old) and the other two trials involved patients with diabetes (but without atherosclerotic or CVD) or patients with CVD or diabetes who had elevated triglyceride and were receiving statin therapy and were taking a very high dose of a specially prepared form of supplement which contained EPA alone. WHO reviewed these new data in detail and assessed how these data might impact on the outcomes of the RCT systematic review published in the Cochrane database of systematic reviews. Preliminary results of these analyses suggest a statistically non-significant reduction in relative risk for CHD mortality, which translates into a reduction in absolute risk from 1.7% to approximately 1.5%. But also observed with some concern, was a statistically non-significant 9% increase in the relative risk of arrhythmia with n-3 fatty acid supplementation.

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[11] REP 13/FL, para. 127

[12] CX/NFSDU 18/40/8-Add.1 (Comments of Australia, Brazil, Canada, Colombia, Ecuador, Ghana, Iran, Jamaica, New Zealand, Norway, Peru, Philippines, Sri Lanka, United States of America, CRN, EU Specialty Food Ingredients, FoodDrinkEurope, GOED, IADSA); CRD12 (GOED); CRD20 (Reply from WHO in response to the request for advice on establishing NRV-NCD for EPA and DHA); CRD25 (African Union); CRD29 (Russian Federation)

91. The Representative of WHO further noted that given these results, it was not anticipated, at present, a change in the interpretation of the overall existing body of evidence or the corresponding recommendations from the NUGAG Subgroup on Diet and Health. The Representative further stated that currently available evidence, including these three new big trials, did not support determining any specific dose information including the threshold of 250mg of EPA and DHA.

92. Noting that the EWG had requested advice from both FAO and WHO on advice for establishing NRV-NCD for EPA and DHA (Annex 1, CX/NFSDU 18/40/8), but that only WHO had replied (CRD 20), FAO was requested to give their view on the scientific evidence. The Representative of FAO acknowledged the new work by WHO, providing up-to date evidence in this area and had been informed of the two systematic reviews on n-3 fatty acids effects on cardiovascular diseases, commissioned by WHO. The Representative further noted that NUGAG was not a joint FAO/WHO process and hence FAO was not in a position to comment on the outcomes or preliminary outcomes, respectively, of these reviews. FAO therefore currently considered previous joint recommendations published by FAO/WHO on this topic as a reference still applicable for FAO.

93. The Chair noted that it was premature for the Committee to set NRV-NCD for EPA and DHA at this point in light of the fact that the overall conclusion of the NUGAG analysis did not change even after including the data from the recent three trials. She further noted that the Committee could reconsider this work once a new body of evidence became available in the future.

Conclusion

94. The Committee agreed to discontinue the work and inform CCEXEC77 and CAC42 accordingly. This decision would not preclude any member from bringing a new work proposal should new scientific evidence become available in the future.

Recommendation 2

95. The Chair noted that there was no urgent need for the Committee to work on the amendment of the General Principles and that it might be desirable to do so once new evidence became available to support the derivation of NRV-NCDs for EPA and DHA or once the Committee had other specific examples at hand.

96. The Committee agreed not to initiate new work on revision of the *General Principles for Establishing Nutrient Reference Values for the General Population* to the *Guidelines on Nutrition Labelling* (CXG 2-1985).

Recommendation 3

97. The Committee agreed to continue using the terms *convincing, generally acceptable, probable, possible and insufficient* as defined in the Joint FAO/WHO Expert Consultation[13] for the purpose of establishing NRV-NCD according to the General Principles.

Recommendation 4

98. The Committee agreed not to initiate discussion on reviewing criteria of the evidence that meets definition of convincing/generally accepted.

DISCUSSION PAPER ON CLAIM FOR "FREE" OF TRANS FATTY ACIDS (Agenda Item 8)[14]

99. Canada provided background to the previous discussions on the claim for "free" of TFAs as presented in CRD7 and provided two options for consideration by the Committee: i) setting the condition for the claim as Conditions (not more than): *1 g of TFA per 100 g of fat; and must meet the conditions for "low" in saturated fats*; ii) not setting conditions for a claim, outlining the considerations for and against each of the options.

Discussion

100. The Committee generally agreed that reducing TFAs in foods was an important public health goal.

101. However, different views were expressed on whether or not it was possible to set a condition for the claim.

102. Those delegations supporting discontinuation, expressed the following views that:

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[13] "Diet, nutrition and the prevention of chronic diseases: report of a joint WHO/FAO expert consultation, Geneva, 28 January – 1 February, 2002," WHO, Geneva, p. 149, 2003.

[14] REP18/NFSDU, Appendix VI; CX/NFSDU 18/40/9 (Comments of Argentina, Australia, Brazil, Colombia, Costa Rica, Cuba, Ecuador, Egypt, Guinea Bissau, Iran, Malawi, Mexico, New Zealand, Paraguay, Peru, Philippines, Singapore, South Africa, United States of America, FEDIOL, ICGMA and IDF); CX/NFSDU 18/40/9-Add.1 (Kenya, Malaysia, IFMA); CRD7 (Proposal of options (prepared by the Chair of the EWG of the proposed draft claim for "Free" of TFAs)); CRD14 (Thailand); CRD25 (African Union); CRD26 (Morocco); CRD29 (Russian Federation); CRD32 (Republic of Korea); CRD37 (El Salvador)

- It was not possible at this time to accurately measure TFAs in all foods and would be difficult to implement and enforce.
- The claim could be misleading as some foods which might not have TFAs in the first place, could also be labelled as "free" of TFAs.
- Labelling was important for consumers to make informed choices, but singling out a nutrient could be problematic.
- Some foods, while low in TFAs, would not be able to meet the claim because of the link to the condition for "low" in saturated fatty acids.
- Risk management of TFAs might require other regulatory approaches or guidance documents for the elimination of industrially produced TFA/PHO and/or the use of FOPL.
- Warnings rather than claims would be more effective.

103. Those delegations in favour of continuing the work expressed the views that:

- Having the condition for a claim could encourage the industry to reduce TFAs.
- In some of their countries such legislation or other regulatory or non-regulatory measures existed and that there was no problem with accurate measurement and enforcement.

104. One delegation stated that the conditions for the claim for free of TFAs should not be linked to SFA. This was supported by some observers who also noted that the proposal should be limited to industrially-produced TFAs.

105. On points raised on the concerns with linking the condition to "low" in saturated fatty acids, the Representative of WHO noted that the draft guidelines on saturated and *trans*-fatty acids intake in adults and children was released for public consultation in May 2018 and the recommendation of the updated WHO guideline on TFA intake being less than 1% of total energy intake is for total TFA. But given the large part of TFA consumption is related to industrially-produced TFA, the REPLACE action package released to guide country actions focuses on developing and implementing the measures for eliminating industrially-produced TFA. It should also be noted that a key strategic principle which WHO highlights in achieving the TFA target is without an increase in the intake of saturated fatty acids (SFA) with the aim of keeping SFA intake to less than 10% of total energy intake. The Representative, therefore, highlighted the importance of keeping the conditions for "low" in SFA as in the proposal before the Committee.

106. Alternative proposals were made to consider other risk management options, other than setting a condition for a labelling claim, such as requesting CCCF to set a maximum level for industrially produced TFAs or develop a code of practice to reduce or eliminate industrially produced TFAs.

107. The Codex Secretariat clarified that if CCCF were requested to establish a maximum level, JECFA would need to first undertake a risk assessment.

108. The FAO representative of JECFA Secretariat informed the Committee of the principles of a chemical risk assessment by the FAO/WHO scientific programme. The FAO/WHO's risk assessment always considered the work of other Committees and organizations. He informed the Committee of the principles of FAO/WHO risk assessment that was driven by the identification of the most sensitive toxicological endpoint, and the appropriate determination of the most susceptible part of the exposed population. This process was geared to inform the Codex committee of a health-based guidance value (or other measures) that could serve its deliberation to develop the most suitable risk management option.

109. However, the Committee felt it premature to request CCCF to consider another risk management option other than the establishment of a claim, and agreed that further information was needed to make a more informed decision.

110. The Committee also agreed to inform CCFO and CCFL on the work currently under way related to TFAs.

Conclusion

111. The Committee decided to suspend the discussion on the proposed draft condition for a claim for "free" of TFAs (Appendix VII), but that Canada would prepare a discussion paper on different risk management possibilities for the reduction of TFAs within the mandate of Codex for consideration by its next session.

NRV-R FOR OLDER INFANTS AND YOUNG CHILDREN (Agenda Item 9)[15]

112. Ireland, as the Chair of the EWG, speaking also on behalf of the co-Chairs the United States of America and Mexico, introduced the item and the recommendations of the EWG. She highlighted some of the inconsistencies with regard to age ranges in the Standards identified and how NRVs were referenced in some of these Standards. She further noted that the EWG had identified questions for CCFL (recommendation 7), but that referral to CCFL was dependent on agreement of recommendations 1 – 6. She also drew the attention of the Committee to CRD22 which outlined potential future work and proposed TORs of the EWG.

General Discussion

113. The Committee noted the general views as follows:

- Setting NRVs-R for older infants and young children was an important task as they could be used for labelling and food formulation for foods for healthy children.
- There was no urgent need to set NRVs-R for older infants and young children but there was merit in having voluntary labelling for foods covered by the four Codex texts for these age groups.
- Once the work by WHO and FAO on updating nutrient requirements for these age groups were conducted, NRVs-R could be derived quickly.

Recommendation 1 (Age groups)

114. The EWG Chair noted that the majority of the EWG members supported establishing two separate sets of NRVs-R for the older infants and your children based on the different nutritional requirements for these two age groups.

115. The Committee also noted the view that it was important to have a single set of NRVs-R (6 – 36 months) in case the product was intended for both the age groups in order to avoid confusing consumers (by having two sets of values on a label).

Conclusion

116. The Committee agreed to decide on whether or not to combine the two sets of NRVs-R depending on the actual values of nutrient requirements and in the meantime add Recommendation 1c on a separate set of NRVs-R for older infants and young children combined.

Recommendation 2 (Age range)

117. The Representative of WHO clarified that the initial age range for the planned update of the nutrient requirements for infants and young children was 0 – 24 months. However, it was planned to extend the age range to 36 months to align with the age range used by Codex.

118. The Committee agreed with recommendation 2 to standardize the age ranges through the Codex texts as proposed.

Recommendation 3 (Nutrient declaration) and recommendation 4 (Vitamin and mineral composition)

119. Different views were expressed on whether or not to include protein in the nutrients requiring an NRV-R.

120. The Committee agreed to continue the work to develop NRVs-R for the four Codex texts age groups identified and to exclude the *Guidelines for Vitamin and Mineral Food Supplements* (CXG 55-2015) from the list of Codex texts for which NRVs-R would be established for labelling of nutrient declaration as well as for which NRVs-R would be applied as reference criteria for vitamin and mineral composition.

Recommendation 5 (Location of NRVs-R)

121. The Committee noted diverging views and agreed that this issue needed further consideration.

Conclusion

122. The Committee agreed to re-establish an EWG chaired by Ireland, and co-chaired by Costa Rica and the United States of America, working in English and Spanish, with the following terms of reference:

- to further consider recommendations 3 to 6 taking into account the decision on recommendation 2 in the Discussion Paper (CX/NFSDU 18/40/10); and

[15] CX/NFSDU 18/40/10; CX/NFSDU 18/40/10-Add.1 (Comments of Kenya and ISDI); CRD14 (Thailand); CRD22 (TORs for a possible 2019 EWG on NRV-R for older Infants and young children (prepared by the Chair and co-chairs of the EWG); CRD25 (African Union); CRD29 (Russian Federation); CRD36 (Indonesia)

- to list and prioritize vitamins and minerals and also to consider the inclusion of protein for NRVs-R for older infants and young children required based on existing Codex texts and determine which ones were to be allocated/applied to which Codex texts.

FOOD ADDITIVES – MECHANISM / FRAMEWORK FOR CONSIDERING TECHNOLOGICAL JUSTIFICATION AND OTHER MATTERS (Agenda Item 10)[16]

123. The European Union as chair of the EWG, speaking also on behalf of the co-Chair, the Russian Federation introduced the item and presented the results of the EWG with the three recommendations for consideration, and noted under each of the recommendations there were a number of issues that needed further discussion before the framework could be finalised and applied.

124. The Codex Secretariat, recalled that CCFA48 [17] had agreed that CCNFSDU needed to confirm the technological need of food additives intended for use in infant formula prior to the inclusion in the CCFA /JECFA priority list; and that CCFA had also requested CCNFSDU to confirm the technological justification for gellan gum (INS 418). It was further emphasized that technological justification for any given food additive had to meet the conditions set out in Section 3.2 (Justification for the Use of Additives) of the preamble of the *General Standard for Food Additives* (CXS 192-1995).

125. The FAO Representative of JECFA Secretariat informed the Committee that the mandate of JECFA included the safety evaluation of food additives; and noted that safety evaluation of additives intended for use in food for infants, while routinely performed by JECFA, was a very complicated and resource intensive process. In the interest of making best use of the available resources it would be critical for CCNFSDU to determine the technological justification for a given additive prior to JECFA performing the food safety risk assessment for infants.

126. The Committee agreed to establish an in-session Working Group chaired by the EU with the following terms of reference to: review Annex A and Annex B of CX/NFSDU 18/40/11 and, provided a consensus was reached on the process and framework, appraise the technological need for the proposed use of xanthan gum (INS 415), pectin (INS 440) and gellan gum (INS 418) taking into account the information submitted by the applicant (Annex D) and the discussion in the EWG.

127. The Committee considered the report of the in-session working group (CRD 34), noted that the proposed framework would be used on all foods within the mandate of CCNFSDU (as agreed by CCNFSDU39 and further discussed in para 133) ; and that the framework could apply to three potential scenarios as presented in footnote 3 of CX/NFSDU 18/40/11. The Committee agreed to consider the recommendations of the in-session WG.

Recommendation 1: Process to appraise and justify the technological need

128. One Observer noted that the proposed process was clear and logical, and sought clarification whether it would not be possible for CCNFSDU to use directly the outcome of JECFA evaluations instead of for CCFA to communicate the outcome. This approach would reduce unintended delays.

129. The Codex Secretariat explained that the scheduling of the meeting and activities for CCNFSDU (November) and CCFA (March) provided ample time for cross-communication between these two Committees. Equally the Circular Letter (CL) issued by CCFA requesting for information on priority list of substances proposed for evaluation by JECFA had a deadline of mid-January of each year (e.g. 15 January 2019). Furthermore, JECFA monographs were publicly available and CCNFSDU could consider using the JECFA evaluation directly, and submit the proposed new additive provisions to CCFA for endorsement

130. The Committee supported the recommendation and agreed with the proposed process to appraise and justify the need for the use of additives in foods within the mandate of CCNFSDU (Appendix VIII, Annex I).

Recommendation 2: Framework for appraising the technological need

131. The Committee considered the scope, and the three main focus areas, clarified various issues and carried out the necessary amendments as appropriate.

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16 CX/NFSDU 18/40/11; CRD13 (ISDI); CRD14 (Thailand); CRD29 (Russian Federation); CRD34 (Report of the in-session WG on the Mechanism/framework for considering the technological justification of food additives)

17 REP16/FA, paras. 119-120)

Scope

132. On the question of whether the mandate of CCNFSDU included non-standardised foods, the Codex Secretariat clarified that one of the terms of reference for the Committee was to develop standards, guidelines or related texts for foods for special dietary uses, in cooperation with other committees where necessary; and therefore CCNFSDU deals with standardised foods only unless requested by CCFA to provide inputs on non-standardised foods.

133. The Committee reaffirmed that the framework would apply to foods within the mandate of CCNFSDU. It should thus also be used to assess non-standardised foods, should there be a request made by CCFA. Based on this clarification the scope was amended to take into account the clarification by including the following statement: "i.e. standardized foods or non-standardized foods following a request by CCFA" (Appendix VIII. Annex 2).

Q1 Identity and Intended Use

134. The Committee agreed with editorial changes to Question (Q1.2) to include the description of the food and its form (e.g. liquid or solid); and rephrased Q1.3 to take into account provision of information on the lowest use level required to accomplish the desired technological effect.

Q2 Compliance with Section 3.2 of the Preamble to the GSFA

135. The Committee noted a concern that the criteria outlined in Q2.3 and Q2.4 were rather qualitative; and could be difficult to evaluate. It was clarified that the criteria was embedded in the preamble to the GSFA, however it would be important that the information provided should assist to guide an objective evaluation.

136. The Committee agreed with the proposed questions.

Q3 Compliance with approach on the Use of food additives

137. The Committee agreed, that the framework should cover food intended for infants and young children, and agreed to Q3.

138. Due to time constraints, the Committee could not consider other aspects of Q3 and the application of the framework to appraise the technological justification of the three candidate additives.

Conclusion

139. The Committee agreed to establish a PWG to meet immediately prior to the next session, chaired by the European Union and co-chaired by the Russian Federation, working in English, French and Spanish, to further consider: i) the text in square brackets (Appendix VIII), ii) the questions under question Q3 in document CX/NFSDU 18/40/11; and iii) appraise the technological need for the proposed use of xanthan gum (INS 415), pectin (INS 440) and gellan gum (INS 418) taking into account the information submitted by the applicant (See CX/NFSDU 18/40/11 Annex D).

OTHER MATTERS

ALIGNMENT OF FOOD ADDITIVES IN CCNFSDU STANDARDS WITH THE GSFA

140. The Committee noted that with the finalisation of the CCFA guidance document on the alignment of food additive provisions in commodity standards (also see Agenda item 2), CCNFSDU was now in a position to proceed with the alignment of food additive provisions in standards under its purview. However, there was no interest in leading this work.

141. The Chair encouraged members to consider leading this important work and the Committee agreed to consider this matter again at its next session.

DISCUSSION PAPER ON HARMONIZED PROBIOTIC GUIDELINES FOR USE IN FOODS AND DIETARY SUPPLEMENTS (Agenda Item 11)[18]

142. Argentina introduced the item. The Chairperson reminded the Committee to take into account the request from CCEXEC75 on the need for a work prioritization mechanism when considering this item.

[18] CX/NFSDU 18/40/12; CX/NFSDU 18/40/12-Add.1 (Comments of Kenya, CRN, IADSA, IDF, IPA); CRD25 (African Union); CRD26 (Morocco); CRD29 (Russian Federation); CRD36 (Indonesia)

Discussion

143. Those delegations in support of the work noted that harmonized global guidelines would benefit the Codex community in light of the significant increase in global trade of probiotics for use in foods and dietary supplements in recent years and would assist national authorities in evaluating foods/supplements containing probiotics. One observer also supported new work on harmonized guidelines which would establish a definition with minimum characterization requirements as well as quality and labelling criteria for probiotics for use as an ingredient in foods and dietary supplements.

144. Those delegations and an observer not in favour of starting new work at this point, expressed the following view or concerns:

- There was no perceived need for such work.
- This work might not have the priority taking into account the current heavy workload of the Committee.
- The paper needed to be revised to provide more clarity especially on the scope of the work.
- Collection of information and data from Members should be first conducted to identify a globally applicable definition of probiotics.
- Infant foods should be excluded since safety was of concern due to a limited number of studies.

Conclusion

145. The Committee agreed that Argentina should redraft the discussion paper for consideration at its next session elaborating further on the sections on scope, definition as well as health and trade concerns in particular.

DISCUSSION PAPER ON GENERAL GUIDELINES TO ESTABLISH NUTRITIONAL PROFILES (Agenda Item 12)[19]

146. The Chair introduced the item and reminded the Committee that this item was on the agenda following a request from CCFL, but that she had noted comments that it might be premature to consider new work at this time taking into account that CCFL was yet to discuss their work on front-of-pack nutrition labelling (FOPL); that the Committee already had a huge workload and thus the need to prioritize work in the Committee. She also noted that WHO had done extensive work on cataloguing nutrient profiles.

147. Costa Rica, also speaking on behalf of Paraguay, as authors of the discussion paper noted that it was important to continue the work and to gather further information that could inform future work on guidelines for establishing nutrient profiles. She noted that all current work, including that of WHO would be taken into account and that the Committee should consider whether the questionnaire in CX/NFSDU 18/40/13 should be sent out to assist in further development of the paper.

Discussion

148. The Committee had an exchange of views on how to proceed.

149. The Representative of WHO stated that WHO would be happy to share the catalogue of the existing nutrient profile models developed for different applications which WHO had compiled. WHO Regional Offices also developed the regional nutrient profile models for restricting marketing of foods and non-alcoholic beverages to children or for multiple policy applications and in several regions, countries were adapting or using those nutrient profile models for multiple applications, such as regulating promotion and sales of food and beverages in and around schools and nutrition labelling, so those experiences could also be inputted to the process. The Representative, however, noted that it might be premature to develop a guideline on nutrient profile models for FOPL as proposed since CCFL had not yet determined how they would modify the section of supplementary information in the *Guideline on Nutrition Labelling* to incorporate the guidance on FOPL. The Representative indicated WHO's willingness to work with Costa Rica and Paraguay to support the further discussion on the development of guidelines to establish nutrient profile models for FOPL.

150. The Committee was also informed that following on the work of WHO, there was now a publication, in a peer reviewed journal accessible to the public on nutrient profile models. Other publications on this topic might also be available.

151. New Zealand, as co-chair of the CCFL work on FOPL informed the Committee that support from CCNFSDU was important to guide the work of CCFL but that a step-wise approach should be taken. A first step should be to do a stock-take of nutrient profile models building on the work of WHO. However, it was premature to consider the circular letter questionnaire as presented in the discussion paper.

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[19] CX/NFSDU 18/40/13; CX/NFSDU 18/40/13-Add.1 (Comments of Iran, Kenya); CRD25 (African Union); CRD26 (Morocco); CRD29 (Russian Federation); CRD36 (Indonesia); CRD37 (El Salvador)

152. To a question on whether nutrient profiles were within the mandate of Codex, as it could go beyond labelling issues, the Secretariat clarified that the aim was to develop guidance on establishing nutrient profiles to complement the work of CCFL on FOPL and in this sense was within the scope of Codex.

153. There was a recognition that it was premature to start new work; that the Committee should follow a stepwise approach starting with a stock-take of the different nutrient profile models building on the work of WHO and other publications.

Conclusion

154. The Committee agreed that Costa Rica and Paraguay would undertake the stock-take of nutrient profiles and further develop the discussion paper for consideration by its next session. The Committee noted the offer of the United States of America to support this work.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 13)[20]

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

155. The United States of America introduced the report of the in-session working group.

156. The Committee confirmed that the forms of analytes determined by the methods for Vitamin K and folic acid, respectively, were consistent with those specified in the relevant Codex texts.

157. The Committee agreed to:

- submit the methods for vitamin K, folic acid and nine minerals and trace elements to CCMAS for review and endorsement (Appendix IX); and
- request CCMAS to re-type or revoke the related existing methods.

Prioritization mechanism to better manage the work of the Committee

158. In response to the request of CCEXEC75, the Committee agreed to consider a forward work plan to prioritize and manage its overall work on a long-term basis.

159. The Committee agreed that the host country would prepare a paper summarizing the work completed so far, some of the previously identified work that had not gone forward in the Committee, the currently ongoing work; and emerging issues to assist the Committee in prioritizing its future work. The paper would also incorporate the proposals for work on prebiotic guidelines and protein supplements for bodybuilding, which were not discussed at the current session due to time constraints.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 14)

160. The Committee was informed that the 41st Session was scheduled to be held in Düsseldorf, Germany from 25 to 29 November 2019, the final arrangements being subject to confirmation by the host government in consultation with the Codex Secretariat.

[20] CRD2 (Comments of Egypt); CRD3 (United States of America); CRD4 (Sudan); CRD8 (CRN); CRD14 (Thailand); CRD19 (ISDI); CRD33 (Report of the in-session WG on the Methods of analysis in CXS 72-1981)

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Appendix II

DRAFT REVISED *STANDARD FOR FOLLOW-UP FORMULA* (CXS 156-1987)

- DRAFT ESSENTIAL COMPOSITION AND QUALITY FACTORS -

(held at Step 7)

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential composition

3.1.1 Follow-up formula for older infants is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of older infants. The nutritional safety and adequacy of follow-up formula for older infants shall be scientifically demonstrated to support growth and development of older infants.

3.1.2 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than 60 kcal (251 kJ) and not more than 70 kcal (293 kJ) of energy.

3.1.3 Follow-up formula for older infants 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) [1]as appropriate.

a) Protein [2), 3), 4)]

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

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. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.

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 of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981)); nevertheless for calculation purposes the concentrations of tyrosine and phenylalanine may be added together and the concentrations of methionine and cysteine may be added together.

4) Isolated amino acids may be added to follow-up formula for older infants 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 for older infants based on non-cows' 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) A lower minimum protein level between 1.6 and 1.8 g/100 kcal (0.38 and 0.43 g/100 kJ) in follow-up formula for older infants based on non-hydrolysed milk protein can be accepted. Such follow-up formula and follow-up formula for older infants based on hydrolysed protein should be evaluated for their safety and suitability and assessed by a competent national and/or regional authority based on clinical evidence.

b) Lipids

Total Fat [7), 8)]

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

[1] Guidance upper levels are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of young children and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in follow-up formula for older infants should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-up formula for older infants or due to technological reasons. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs.

[7] Partially hydrogenated oils and fats shall not be used in follow-up formula for older infants.

[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 follow-up formula for older infants. The erucic acid content shall not exceed 1% of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).

Linoleic acid

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

α-Linolenic acid

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

*N.S. = not specified

Ratio Linoleic acid/ α-Linolenic acid

Min	Max
5:1	15:1

c) Carbohydrates

Available carbohydrates [9]

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

[9] Lactose and glucose polymers should be the preferred carbohydrates in follow-up formula for older infants based on milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20% of available carbohydrate.

d) Vitamins

Vitamin A

Unit	Minimum	Maximum	GUL
µg RE[10]/100 kcal	75	180	-
µg RE[10]/100 kJ	18	43	-

[10] expressed as retinol equivalents (RE)

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

Vitamin D

Unit	Minimum	Maximum	GUL
µg[11] /100 kcal	1.0	3.0	-
µg[11] /100 kJ	0.24	0.72	-

[11] Calciferol. 1 µg calciferol = 40 IU Vitamin D.

Vitamin E

Unit	Minimum	Maximum	GUL
mg α-TE[12] /100 kcal	0.5 [13]	-	5
mg α-TE[12] /100 kJ	0.12 [13]	-	1.2

[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 αTE /g linoleic acid (18:2 n-6); 0.75 α-TE/g α-linolenic acid (18:3 n-3); 1.0 mg α-TE/g arachidonic acid (20:4 n-6); 1.25 mg α-TE/g eicosapentanoic acid (20:5 n-3); 1.5 mg α-TE/g docosahexaenoic acid (22:6 n-3).

Vitamin K

Unit	Minimum	Maximum	GUL
µg /100 kcal	4	-	27
µg /100 kJ	0.96	-	6

Thiamin

Unit	Minimum	Maximum	GUL

µg /100 kcal	60	-	300
µg /100 kJ	14	-	72

Riboflavin

Unit	Minimum	Maximum	GUL
µg /100 kcal	80	-	500
µg /100 kJ	19	-	120

Niacin[14)]

Unit	Minimum	Maximum	GUL
µg /100 kcal	300	-	1500
µg /100 kJ	72	-	359

[14)] Niacin refers to preformed niacin

Vitamin B_6

Unit	Minimum	Maximum	GUL
µg /100 kcal	35	-	175
µg /100 kJ	8~~.4~~	-	42

Vitamin B_{12}

Unit	Minimum	Maximum	GUL
µg /100 kcal	0.1	-	1.5
µg /100 kJ	0.02	-	0.36

Pantothenic acid

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

Folic acid

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

Vitamin C[15)]

Unit	Minimum	Maximum	GUL
mg /100 kcal	10	-	70 [16)]
mg /100 kJ	2.4	-	17 [16)]

[15)] expressed as L-ascorbic acid

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

Biotin

Unit	Minimum	Maximum	GUL
µg /100 kcal	1.5	-	10
µg /100 kJ	0.36	-	2.4

e) Minerals and Trace Elements

Iron[17)]

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

[17)] For **f**ollow-up formula for older infants based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36/100 kJ) and maximum of 2.5 mg/100 kcal (0.6 mg/100 kJ) applies.

Calcium

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

Phosphorus

Unit	Minimum	Maximum	GUL
mg /100 kcal	25	-	100 [18)]
mg /100 kJ	6	-	24 [18)]

[18)] This GUL should accommodate higher needs with follow-up formula for older infants based on soy protein isolate.

Ratio Calcium/Phosphorus

Min	Max
1:1	2:1

Magnesium

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

Sodium

Unit	Minimum	Maximum	GUL
mg /100 kcal	20	60	-
mg /100 kJ	4.8	14	-

Chloride

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

Potassium

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

Manganese

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

Iodine

Unit	Minimum	Maximum	GUL
µg /100 kcal	10	-	60
µg /100 kJ	2.4	-	14

Selenium

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

Copper[19)]

Unit	Minimum	Maximum	GUL
µg /100 kcal	35	-	120
µg /100 kJ	8	-	29

[19)] Adjustment may be needed in these levels for follow-up formula for older infants made in regions with a high content of copper in the water supply.

Zinc[20)]

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

[20)] For follow-up formula for older infants based on soy protein isolate a minimum value of 0.75 mg/100 kcal (0.18 mg/100 kJ).

3.2 Optional Ingredients

3.2.1 In addition to the compositional requirements listed under 3.1.3 Section A, 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.

3.2.2 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.

3.2.3 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 for older infants 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

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	12	-
mg /100 kJ	-	2.9	-

Total nucleotides

Levels may need to be determined by national authorities.

Docosahexaenoic acid [21)]

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	30
mg /100 kJ	-	-	7

[21)] If docosahexaenoic acid (22:6 n-3) is added to follow-up formula for older infants, a minimum level of 20 mg/100 kcal (4.8 mg/100 kJ) should be reached, and arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs.

Choline

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

Myo-inositol

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	40
mg /100 kJ	-	-	10

L-carnitine

Levels may need to be determined by national authorities.

L (+) lactic producing cultures

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

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

SECTION B: [NAME OF PRODUCT] FOR YOUNG CHILDREN

3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential composition

3.1.1 **[Name of product] for young children** is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of young children. The nutritional safety and adequacy of [Name of Product] for young children shall be scientifically demonstrated to support growth and development of young children.

3.1.4 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 (251 kJ) and not more than 70 kcal (293 kJ) of energy. National and/or regional authorities can deviate from the minimum energy content in line with national/regional dietary guidelines taking into account the nutritional needs of the local population.

3.1.2 [Name of product] for young children prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GUL)[1], as appropriate. The general principles for establishing these levels are identified in Annex I of this standard.

a) **Protein**[2), 3)]

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

[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. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.

[3)] PDCAAS is the preferred method to determine protein quality. However, PER can continue to be used. DIAAS could also be considered should it be recognized by FAO in the future. When determined using PDCAAS methodology, appropriate Digestibility values and the reference amino acid pattern (see Table 5 of the Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic food), the PDCAAS shall be not less than 90. In formulations with lower scores the quality and/or quantity of protein should be adjusted to achieve the desired value. Detail on how to calculate the PDCAAS is listed in the Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic food.
When determined by PER methodology the protein quality shall not be less than 85% of that of casein.

Lipids [3)]

Total fat

Unit	Minimum	Maximum	GUL
g /100 kcal	3.5	-	-
g /100 kJ	0.84	-	-

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

α-Linolenic acid

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

[1] Guidance upper levels are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of young children and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in follow-up formula for older infants should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of follow-up formula for older infants or due to technological reasons. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs.

Linoleic acid

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

b) Carbohydrates

Available carbohydrates[4)]

Unit	Minimum	Maximum[5)]	GUL
g /100 kcal	-	12.5	-
g /100 kJ	-	3.0	-

4) Lactose should be the preferred carbohydrates in [name of product] based on milk protein. [For products not based on milk protein, carbohydrate sources (like starch) with an average DE of 15 should be used. OR For products not based on milk protein, a combination of carbohydrate sources giving an average dextrose equivalent not higher than DE15 (corresponding to the relative sweetness of lactose), should be preferred.] **(for consideration by the EWG on follow-up formula)**

Mono- and disaccharides, other than lactose, should not exceed 2.5 g/100kcal (0.60 g/100kJ). National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose should not be added.

5) For [Name of the product] for young children with a protein level below 3.0 g/100 kcal a maximum level of available carbohydrates up to 14 g/100 kcal (3.3 g/100 kJ) may be permitted by competent national and/or regional authorities.

d) Vitamins

Vitamin A

Unit	Minimum	Maximum	GUL
µg RE[6)] /100 kcal	60	180	-
µg RE[6)] /100 kJ	14	43	-

6) 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[7)]

Unit	Minimum	Maximum	GUL
µg[8)] /100 kcal	1.5	4.5	-
µg[8)] /100 kJ	0.36	1.1	-

7) Competent national and/or regional authorities may deviate from the conditions as appropriate for the nutritional needs of their population.

8) Calciferol. 1 µg calciferol = 40 IU Vitamin D.

Riboflavin

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

Vitamin B_{12}

Unit	Minimum	Maximum	GUL
µg /100 kcal	0.1	-	2.0
µg /100 kJ	0.02	-	0.48

Vitamin C[9)]

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

9) expressed as L-ascorbic acid

e) Minerals and Trace Elements

Iron[10)]

Unit	Minimum	Maximum	GUL
mg /100 kcal	1.0	3.0	-
mg /100 kJ	0.24	0.72	-

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

Calcium

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

Zinc

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

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

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

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

3.2 Optional Ingredients

3.2.1 In addition to the compositional requirements listed under 3.1.3 Section B, other ingredients~~,~~ or substances may be added to [name of the product] for young children where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated by national and/or regional authorities and demonstrated by generally accepted scientific evidence. Optional ingredients listed in 3.2.3 Section A are also permitted. **[Substances shall not be added with the purpose of imparting or enhancing a sweet taste of [name of product]].** **(For consideration by EWG on follow-up formula)**

3.2.2 When any of these ingredients~~,~~ or substances is added the [name of product] for young children shall contain sufficient amounts to achieve the intended effect.

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

Appendix III

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

(for adoption at Step 5)

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

1 SCOPE

1.1 This section of the Standard applies to Follow-up Formula for Older Infants, as defined in Section 2.1, in liquid or powdered form.

1.2 This section of the Standard contains compositional, quality, safety, labelling, analytical and sampling requirements for Follow-up Formula for Older Infants.

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard shall be presented as Follow-up Formula for Older Infants.

2 DESCRIPTION

2.1 Product Definition

2.1.1 **Follow-up formula for older infants** means a product, manufactured for use as a breastmilk-**substitute**, as a liquid part of a diet for older infants when progressively diversified complementary feeding is introduced.

2.1.2 Follow-up formula for older infants 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

9. LABELLING

The requirements of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985), the *Guidelines on Nutrition Labelling* (CXG 2-1985) and the *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997) apply to follow-up formula for older infants. These requirements include a prohibition on the use of nutrition and health claims for foods for infants except where specifically provided for in relevant Codex Standards or national legislation.

9.1 The Name of the Product

9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

9.1.2 The name of the product shall be Follow-up Formula for Older Infants as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national [or regional] usage.

9.1.3 The sources of protein in the product shall be clearly shown on the label.

a) If [name of animal] milk is the only source of protein[*], the product may be labelled ‘Follow-up Formula for Older Infants Based on [name of animal] milk [protein].

b) If [name of plant] is the only source of protein[*], the product may be labelled ‘Follow-up Formula for Older Infants Based on [name of plant] [protein].

c) If [name of animal] milk and [name of plant] are the sources of protein[*], the product may be labelled ‘Follow-up Formula for Older Infants Based on [name of animal] milk protein and [name of plant] protein’ or ‘Follow-up Formula for Older Infants Based on [name of plant] protein and [name of animal] milk protein’.

* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.

9.1.4 A product which contains neither milk nor any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase.

9.2 List of Ingredients

9.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate functional classes for these ingredients and additives may be included on the label. The food additives INS number may also be optionally declared.

9.3 Declaration of Nutritive Value

The declaration of nutrition information ~~[~~for follow-up formula for older infants~~]~~ shall contain the following information which should be in the following order:

a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold ~~[~~as well as~~]~~ ~~[or]~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section A and any other ingredient as listed in paragraph 3.2 of Section A per 100 grams or per 100 millilitres of the food as sold as well as per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.

9.4 Date Marking and Storage Instructions

9.4.1 **(i)** The **"Best Before Date" or "Best Quality Before Date"** shall be declared by the day, month and year except that for products with a shelf-life of more than three months, [at least] the month and year [shall be declared] [The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).]

(ii) In the case of products requiring a declaration of month and year only, the date shall be introduced by the words "Best before end <insert date>; or "Best Quality before end <insert date>].

9.4.2 In addition to the date, any special conditions for the storage of the food shall be indicated ~~if~~ [where they are required to support the integrity of the food and, where] the validity of the date depends thereon.

Where practicable, storage instructions shall be in close proximity to the date marking.

9.5 Information for use

9.5.1 Ready to use products in liquid form should be used directly. Concentrated liquid products and powdered products, must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that product remaining after feeding should be discarded, shall appear on the label.

9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.

9.5.4 The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use.

9.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.

9.5.6 The label of follow-up formula for older infants shall include a statement that the product shall not be introduced before 6 months of age, is not to be used as a sole source of nutrition~~]~~ and that older infants should receive complementary foods in addition to the product.

9.6 Additional Labelling Requirements

9.6.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

a) the words "important notice" or their equivalent;

b) the statement "Breast-milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast-milk;

c) a statement that the product should only be used on advice of a health worker as to the need for its use and the proper method of use.

d) the statement; 'The use of this product should not lead to cessation of continued breastfeeding'.

9.6.2 The label shall have no pictures of infants, young children and women nor any other picture, text, or representation that might:

9.6.2.1 idealize the use of follow-up formula for older infants;

9.6.2.2 suggest use for infants under the age of 6 months (including references to milestones and stages);

9.6.2.3 recommend or promote bottle feeding;

9.6.2.4 undermine or discourage breastfeeding; or that makes a comparison to breast-milk~~,~~ or suggest~~s~~ that the product is similar, equivalent to or superior to breast-milk;

9.6.2.5 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national or regional regulatory authorities.~~]~~

9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.

9.6.4 Products shall be distinctly labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes**,** in particular as to the text, images and colours used, to enable consumers to make a clear distinction between them, Cross promotion between product categories is not permitted on the [label/labelling] of the product.

Appendix IV

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

[PREAMBLE]

*The Codex Alimentarius Commission acknowledges the need to [**protect and support** / **recognize**] breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where [**necessary** / **appropriate**], as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods and these products should not discourage breastfeeding.*

*The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, [**as appropriate**,] the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been [**endorsed** / **supported**] by member states [**may also**] provide guidance to countries in this context.*

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CXS 72 – 1981).

SECTION B

(held at Step 4)

SECTION B: [NAME OF PRODUCT] FOR YOUNG CHILDREN

1 SCOPE

1.1 This section of the Standard applies to [name of product] for young children, as defined in Section 2.1, in liquid or powdered form.

1.2 This section of the Standard contains compositional, quality, safety, labelling, analytical and sampling requirements for [name of product] for young children.

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard shall be presented as~~]~~ [name of product] for young children.

2 DESCRIPTION

2.1 **Product Definition**

*2.1.1 **[Name of product] for young children** means a product ~~specially~~ **~~[formulated and]~~** manufactured for use **~~[as a breast-milk substitute]~~**, as a liquid part of the **~~[progressively]~~** ~~[~~diversified~~]~~ diet of young children **[in order to contribute to the nutritional needs of young children]** **~~[when nutrient intakes may not be adequate to meet nutritional requirements].~~***

2.1.2 **[Name of product] for young children** [~~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 **young child** means a person from the age of more than 12 months up to the age of three years (36 months).

9. ~~[~~LABELLING

The requirements of the ~~Codex~~ General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985), the Guidelines on Nutrition Labelling (CXG 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) apply to [Name of Product] for young children. ~~These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.~~

9.1 The Name of the Product

9.1.1 *The text of the label and all other information accompanying the product shall be written in the appropriate language(s).*

9.1.2 *The name of the product shall be [Name of Product] for Young Children as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national ~~[~~or regional~~]~~ usage.*

9.1.3 *The sources of protein in the product shall be clearly shown on the label.*

a) If [name of animal] milk is the only source of protein~~[*]~~, the product may be labelled '[Name of Product] for Young Children Based on [name of animal] milk ~~[~~protein~~]~~'.

b) If [name of plant] is the only source of protein~~[*]~~, the product may be labelled '[Name of Product] for Young Children Based on [name of plant] ~~[~~protein~~]~~'.

*c) **if [name of animal] milk and [name of plant] are the sources of proteins*, the product may be labelled '[Name of Product] for Young Children Based on [name of animal] milk protein and [name of plant] protein' or '[Name of Product] for Young Children Based on [name of plant] protein and [name of animal] milk protein'.***

~~[~~ For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.~~]~~*

9.1.4~~5~~ *A product which contains neither milk nor any milk derivative **~~[~~**shall**~~]~~** **~~[may]~~** be labelled "contains no milk or milk products" or an equivalent phrase.*

9.2 List of Ingredients

9.2.1 *A complete list of ingredients ~~[including optional ingredients]~~ shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.*

*9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. **In addition, appropriate ~~functional~~ classes names for these ingredients and additives may be included on the label**. ~~[~~**The f**ood additive~~s~~ INS number may also be optionally declare**d ~~the INS number~~]**.*

9.3 Declaration of Nutritive Value

The declaration of nutrition information for [name of product] for young children shall contain the following information which should be in the following order:

a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold ~~[~~as well as~~]~~ ~~[or]~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section B and any other ingredient as listed in paragraph 3.2 of Section B per 100 grams or per 100 millilitres of the food as sold ~~[~~as well as~~]~~ ~~[or]~~ per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

c) In addition, the declaration of nutrients in a) and b) per [serving size and/or per] 100 kilocalories (or per 100 kilojoules) is permitted.

9.4 Date Marking and Storage Instructions

9.4.1 ***(i)*** *The **"Best Before Date" or "Best Quality Before Date"** shall be declared by the day, month and year except that for products with a shelf-life of more than three months, ~~[~~at least~~]~~ the month and year ~~[~~shall be declared~~]~~. ~~[~~The day and year shall be declared by uncoded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).~~]~~*

(ii) *In the case of products requiring a declaration of month and year only, the ~~[~~date shall be introduced by the words "Best before end <insert date>; or "Best Quality Before end <insert date>~~]~~.*

9.4.2 *In addition to the date, any special conditions for the storage of the food shall be indicated ~~if~~ [where they are required to support the integrity of the food and, where~~]~~ the validity of the date depends thereon.*

Where practicable, storage instructions shall be in close proximity to the date marking.

9.5 Information for use

9.5.1 *~~[~~Ready to use~~]~~ products in liquid form **should** ~~may~~ be used ~~[either]~~ directly. ~~or in the case of c~~Concentrated liquid products ~~[~~and powdered products~~]~~, must be prepared with **potable** water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. ~~[Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.]~~ Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.*

9.5.2 *Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that ~~formula [~~product~~]~~ remaining after feeding should be discarded, shall appear on the label.*

9.5.3 *The label shall carry clear graphic instructions illustrating the method of preparation of the product. ~~[Pictures of feeding bottles are not permitted on labels of (name of product) for young children.]~~*

9.5.4 ***[****The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use****].***

9.5.5 *Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.*

[*9.5.6* *The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a ~~[~~diversified~~]~~ ~~[balanced]~~ diet.****]***

9.6 Additional Labelling Requirements

[*9.6.1* *The label of [name of product] for young children shall have no image, text or representation **[,including pictures of feeding bottles,]*** that could undermine or discourage breastfeeding or which idealises the use of [name of product] for young children. The terms 'humanized', 'maternalized' or other similar terms must not be used on the label****.]***

[*9.6.2****]*** *Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes****[, and to enable consumers to make a clear distinction between them~~, in particular as to the text, images and colours used~~].]***

Appendix V

PROPOSED DRAFT GUIDELINES FOR READY TO USE THERAPEUTIC FOODS (RUTF)

(held at Step 4)

1. PREAMBLE

Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients. Children with SAM need efficacious and timely treatment and RUTF ~~is~~ **may be** part of the care. RUTF are primarily intended for children with uncomplicated SAM from 6-59 months. Although RUTF may be given to other age groups with various forms of malnutrition at the implementation level, the primary focus for these guidelines is children with SAM from 6-59 months. **[**Since RUTF are prescribed according to weight, National Authorities may decide to include the provision of RUTF in their national protocols for use by other age groups**]**.

These guidelines provide guidance for the production and labelling of RUTF. The guidelines are intended to facilitate the harmonization of requirements for RUTF at the international level and may provide assistance to governments wishing to establish national regulations. The guidelines are also intended for use as an instrument designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to RUTF and by varying definitions and nutrient compositions of RUTF. These guidelines should be used in accordance with technical recommendations ~~of~~ **that are based on** the relevant evidence and related Codex texts/documents by WHO, UNICEF and WFP[1]. Governments and other users should ensure adequate provisions are made for competent technical experts for the appropriate use of these guidelines.

1) A Joint Statement by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children's Fund. 2007. *Community-Based Management of Severe Acute Malnutrition*; A Joint Statement by the World Health Organization and the United Nations Children's Fund. 2009. *Child growth standards and the identification of severe acute malnutrition in infants and children*, Geneva: World Health Organization; World Health Organisation. 2013. Guideline: *Updates on the management of severe acute malnutrition in infants and children,* Geneva: World Health Organization; World Health Organisation. 2003. *Global Strategy for Infant and Young Child Feeding*, Geneva: World Health Organization; World Health Organisation. [1981. *International code of marketing of breast-milk substitutes,* Geneva: World Health Organization and subsequent relevant WHA Resolutions on infant and young child feeding]; *Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions* (CXC 20-1979); Food and Agriculture Organisation and World Health Organisation. 2016. FAO/WHO Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition, Rome: Food and Agriculture Organisation.

2. PURPOSE OF THE GUIDELINES

To provide guidance on technical and nutritional aspects of the production of Ready to Use Therapeutic Foods for children from the age of 6 to 59 months with severe acute malnutrition, including

i. Nutritional Composition
ii. Raw Materials and Ingredients
iii. Good Manufacturing Practices
iv. Microbiological and Chemical Contaminant Criteria
v. Methods of Analysis and Sampling
vi. Provisions for Packaging and Labelling

3. SCOPE

The provisions of these guidelines apply to Ready to Use Therapeutic Foods for children from age 6 to 59 months with severe acute malnutrition. Ready-to-Use Supplementary Foods (RUSF), micronutrient supplements[2], processed cereal based foods[3], formulated complementary foods for older infants and young children[4], canned baby foods[5] are not covered by these guidelines.

2) Guidelines for Vitamin and Mineral Food Supplements (CXG55-2005)

3 *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CXS 74-1981)

4 *Guidelines on Formulated Complementary Foods for Older Infants and Young Children* (CXG 8-1991)

5*Standard for Canned Baby Foods* (CXS 73-1981)

4. DESCRIPTION

4.1 Ready-to-Use Therapeutic Foods (RUTF) are foods for special medical purposes and are high-energy and contain adequate protein and other essential nutrients for the dietary management of children from 6 to 59 months with severe acute malnutrition without medical complications with appetite. These foods should be soft or crushable and should be easy for children to eat without any prior preparation.

4.2 Severe Acute Malnutrition is defined by weight for height (or length) less than –3 Z-score of the median WHO growth standards, or by mid upper arm circumference (MUAC)<11.5 cm, or by the presence of bilateral oedema.

5. SUITABLE RAW MATERIALS AND INGREDIENTS

RUTF are made of ingredients embedded in a lipid-rich matrix e.g. paste or biscuit, resulting in an energy and nutrient-dense food. The following raw materials, many of which can be sourced locally, are suitable ingredients for the production of RUTF under the specified conditions given below. Any formulation of RUTF shall comply with Section 3 of the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991) including the specification that their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended.

5.1 Basic Raw Materials and Ingredients

5.1.1 Milk and other Dairy Products

Milk and other dairy products used in the manufacturing of RUTF must comply with the *Standard for Milk Powders and Cream Powder* (CXS 207-1999) and the *Standard for Whey Powders* (CXS 289-1995), and other Codex milk and milk product standards as well as other guidelines and Codes of Practice recommended by Codex Alimentarius Commission which are relevant to these products. Relevant codes of practice include the *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004) and the *Code of Hygienic Practices for Low-Moisture Foods* (CXC 75-2015).

5.1.2 Legumes and Seeds

Legumes and seeds such as soybeans, lentils, chickpeas, cowpeas, beans, peanut, sesame and other types of legumes and seeds must comply with the relevant Codex Alimentarius texts when used in the manufacturing of RUTF.

Legumes and seeds must be appropriately processed to reduce, as much as possible, the anti-nutritional factors normally present, such as phytate, lectins (haemagglutenins), trypsin and chymotrypsin inhibitors, and phytoestrogens.

Field beans or Faba beans (Viciafaba L) should not be used in the formulation of RUTF because of the danger of favism.

5.1.3 Fats and Oils

Fats and oils used in the manufacturing of RUTF must comply with the relevant Codex Alimentarius texts.
Fats and oils are incorporated as technologically feasible for the purpose of achieving the energy density and providing essential fatty acids. Care must be taken to avoid oxidized fat which will adversely affect nutrition, flavour and shelf life.

Partially Hydrogenated fats and oils should not be used in RUTF.

5.1.4 Cereals [and tubers]

All milled cereals [and tubers] suitable for human consumption may be used provided that they are processed in such a way that the fibre content is reduced, when necessary, and that the effects of anti-nutritional factors such as phytates, tannins or other phenolic materials, lectins, trypsin, and chymotrypsin inhibitors which can lower the protein quality and digestibility, amino acid bioavailability and mineral absorption are removed or reduced, whilst retaining maximum nutrient value.

5.1.5 Vitamins and Minerals

Vitamin and mineral forms used must be soluble and easily absorbed by patients with SAM. Children with SAM have low or absent gastric acid which means that they should not be given inorganic salts of minerals that are insoluble or requiring an acid gastric environment for absorption, in order to avoid metabolic acidosis. It is important that RUTF should have a mineral composition that leads to a moderate excess of non-metabolisable base (buffers). The non-metabolizable base can be approximated by the formula: estimated absorbed millimoles (sodium + potassium + calcium + magnesium) - (phosphorus + chloride.

All added vitamins and minerals must be in accordance with the *Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979). Examples of mineral forms for RUTF formulation can be found in the *WHO Management of severe malnutrition: A manual for physicians and other senior health workers (1999).* The amount of vitamins and minerals added to achieve the target level must be adjusted based on the chemical form, interaction, and impaired absorption with other nutrients and non-nutrients and scientific evidence showing adequate stability and bioavailability in the finished product.

5.2 Other Ingredients

5.2.1 Carbohydrates

[Carbohydrates are used to achieve energy requirements in balance with proteins and lipids. Plant starch, lactose, maltodextrin and sucrose **are** the preferred carbohydrates in RUTF. Free sugars should be limited and should not exceed 20% of total energy. Only precooked and/or gelatinized starches may be added. Carbohydrates must adhere to the relevant Codex Alimentarius texts.

Honey should not be used in RUTF due to the risk of infant botulism from *Clostridium botulinum*.**]**

5.2.2 Food Additives

[This section will make reference to the *General Standard for Food Additives* (CXS 192-1995)].

6. NUTRITIONAL COMPOSITION AND QUALITY FACTORS

6.1 Energy

The energy density of the formulated RUTF should be between 5.2 to 5.5 kcal per gram. The energy density of RUTF can be achieved during manufacturing by the addition of energy containing ingredients (i.e. protein, fats and oils and/or available carbohydrates) and/or processing the basic raw materials and ingredients as indicated in Section 8.

6.2 Proteins

Protein should provide 10% - 12% ~~[(52kcal/100g – 66/100g)]~~ of the total energy. ["at least 50% of protein is provided by milk products"] OR a high quality protein source which has the PDCASS score of 100,]

~~[Ft: A high quality protein source will have a PDCASS score of 100. However, a PDCASS score of >90 can still be considered adequate for these formulations. In formulations with PDCASS score of <90 the quality of protein should be adequate to achieve the desired value.]~~

[The protein quality should be determined using PDCASS score of between 90-100. The efficacy of new formulations should not rely on protein quality considerations alone, and should be tested for their ability to support catch up growth in the target population, which in this scenario would be children of 0.5-4.9 years for RUTF.]

6.3 Lipids

Lipids should provide 45% to 60% of the total energy.

The level of linoleic acid should not be less than 333mg **~~316~~** mg per 100 kcal **and shall not be more than 1110 mg per 100 kcal.** The level of alpha-linolenic acid should not be less than 33 mg/100kcal **~~[and shall not be more than 280 mg per 100kcal.]~~** ~~The level of linoleic acid should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 1:1 and 15:1.~~

6.4 Please see Annex "Nutrition Composition for RUTF".

Vitamins and minerals

RUTF should contain the vitamin and minerals presented in the annex following minimum and maximum or guidance of upper values in the annex.

7. CONTAMINANTS

It is recommended that the products covered by the provisions of these guidelines **and the ingredients used in such products** comply with the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995), Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods (CAC/MRL 2-2015) and Codex Maximum Residue Limits for Pesticides. **Further guidance is given by Codex codes of practice and should be adhered to.**

Other Contaminants

The product should not contain contaminants or other undesirable substances (e.g. biologically active substances, metal fragments) in amounts which may represent a risk to the health of children. The product covered by the provisions of these Guidelines shall comply with those maximum residue limits and maximum levels established by the Codex Alimentarius Commission. **[~~A maximum of 10 ppb (µg/kg) for aflatoxin is allowed in the RUTF products.~~]**

8. PROCESSING TECHNOLOGIES

[Any technologies described below are given as examples of treatment mainly on raw materials. Any technologies used for raw materials for RUTF have to be validated according to *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008)]. [In addition to the practices described below, Good Hygiene Practices (*General principles of food hygiene* (CXC 1-1969)) should be implemented to avoid cross contamination during the packing and storage of raw materials.]

8.1 Preliminary Treatment of Raw Materials

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

- **[Cleaning or washing**: to eliminate dirt, damaged grains, foreign grains and noxious seeds, insects and insect excreta and any adhering material.]
- **Dehulling**: when necessary, pulses, legumes, oilseeds and certain cereals such as oats, barley, sorghum, millet and teff may be dehulled as completely as is feasible to reduce the fibre content to acceptable levels and to decrease, or if possible, to eliminate phytates, tannins and other phenolic materials, trypsin and chymotrypsin inhibitors which can lower the protein digestibility and amino acid bioavailability and mineral absorption**.**
- **Degermination:** where necessary and appropriate, degermination of wheat, corn, soy and other crops should be considered in order to reduce the phytate content.

8.2 Milling

- Milling or grinding of suitable raw materials should be carried out in such a way as to minimize the loss of nutritional value and to avoid undesirable changes in the technological properties of the ingredients.
- Dry raw materials may be milled together, if technologically feasible, or mixed after milling or grinding.
- Formulations containing milled cereals, legumes, pulses and/or oilseeds that have not been otherwise processed require adequate boiling to gelatinize the starch portions and/or eliminate anti-nutritional factors present in cereals, legumes and pulses. Boiling improves the digestibility and absorption of nutrients.
- **[~~The bulkiness of foods from food formulations containing dry ingredients obtained by milling of the raw materials can be reduced by adding, during the formulation, adequate amounts of enzymes such as alpha-amylase which, during the slow heating to boiling, predigest partially the starch and reduce the amount of water needed for the preparation of the food~~.]**

8.3 Toasting

- Toasting (dry heating) enhances the flavour and the taste of the food through dextrinization of starch. It also improves digestibility. **[~~and contributes to reducing the bulkiness of the formulated food. Moreover, it reduces microorganisms and enzyme activity and destroys insects, thus improving keeping qualities.~~]**
- Protein damage due to the Maillard reaction may occur in the presence of reducing carbohydrates. The toasting process should therefore be carefully controlled.
- Pulses as well as oilseeds such as soya beans, groundnuts and sesame seeds can be toasted as whole grains directly or after soaking.
- Toasted raw materials can be milled or ground for use as ingredients.
- [The use of appropriate enzymes may be considered to decrease anti-nutrients in ingredients.]

[~~8.4 Sprouting, Malting and Fermentation~~

- ~~Cereals and pulses can be induced to germinate by soaking or humidifying. It is necessary, however, to ensure that growth of mycotoxin producing microorganisms does not occur. The action of natural amylases contained in the grains results in the pre-digestion of the starchy portion of the grain (dextrinization) thus reducing the bulk of the food when prepared for feeding and, ultimately, increasing the nutrient density of the food. Sprouting, malting and fermentation can induce hydrolysis of phytates and decrease its inhibitory effect on mineral absorption, and may improve B vitamin content.~~
- ~~During the germination process, the seed coat of the grain splits and can be removed by washing. The malted raw material is milled or ground after drying.~~ **]**

8.5 Other Processing Technologies

Whenever feasible, RUTF **and/**or their raw materials should be treated with a validated microbial reduction treatment in order to inactivate pathogens such as *Salmonella*, noting that some pathogens have increased heat resistance characteristics at reduced water activities in food matrices.

Commonly used microbial reduction treatments that could be applied to RUTF or their raw materials include both thermal (e.g. roasting, steam treatment followed by a drying step) and non-thermal (e.g. antimicrobial fumigation) control measures. [**These practices should be in accordance with the** *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008) and *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007)**]**. ~~should be adhered to.~~]

9. GOOD MANUFACTURING PRACTICES AND GOOD HYGIENE PRACTICES

It is recommended that the products covered by the provisions of these guidelines be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CXC 1-1969), and *Code of Hygienic Practice for Low-Moisture Foods* (CXC 75-2015).

The product should comply with any microbiological criteria established in accordance with the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997) **and Annex 1 of *Code of Hygienic Practice for Low-Moisture Foods* (CXC 75-2015).**

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

10. METHODS OF ANALYSIS AND SAMPLING

It is recommended that methods of analysis and sampling of RUTF be in accordance with the *Recommended Methods of Analysis and Sampling* (CXS 234-1999), *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995), *The Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997), *Code of Hygienic Practice for Low Moisture Foods* (CXC 75-2015), and other relevant Codex Alimentarius texts. When needed, specific methods of analysis should be developed in accordance with appropriate *Guidelines on Measurement Uncertainty* (CXG 54-2004), *Protocol for the Design, Conduct and Interpretation of Method Performance Studies* (CXG 64-1995), and Harmonized IUPAC.

11. PACKAGING

It is recommended that RUTF be packaged in such a way to safeguard the hygienic and other qualities including nutritional properties of the food for the duration of its defined shelf-life.

The packaging materials shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.

12. LABELLING

It is recommended that the labelling of RUTF for children from 6 to 59 months be in accordance with the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-991), ~~*Codex General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985)~~, the *General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses* (CXS 146-1985), **[**~~*Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997)~~**]** and *Guidelines on Nutrition Labelling* (CXG 2- 1985).

The Name of the Food

The name of the food to be declared on the label shall indicate that the food is a Ready-To-Use Therapeutic Food for Children from 6 to 59 months. The appropriate designation indicating the true nature of the food should be in accordance with national legislation. The age from which the product is recommended for use shall appear in close proximity to the name of the food.

List of Ingredients

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

Additional Mandatory Labelling Requirements

The following statements shall appear on the label of RUTF:

- "USE UNDER MEDICAL SUPERVISION" shall appear on the label in bold letters in an area separated from the written, printed, or graphic information.
- "For the dietary management of severe acute malnutrition" shall appear on the label.
- A prominent warning statement consisting of an explanatory statement in bold letters indicating that RUTF are for special medical purposes and may pose a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended.
- The product is not to be used for parenteral, rectal or Nasogastric Tube (NG tube) administration.
- A statement indicating whether the product is or is not intended as the sole source of nutrition.
- A statement indicating that RUTF are not breastmilk substitutes and shall not be presented as such.
- [Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months.]

Instructions for use

- The label should indicate clearly from which age the product is recommended for use. This age shall not be less than six months for any product.
- Feeding instructions shall be given; preferably accompanied by graphical presentations.
- The time in which the product should be consumed after opening should be clearly indicated.

ANNEX

Table: Nutritional Composition for RUTF

Energy

Unit	**Minimum**	**Maximum**	**GUL**
g/100g	**5.2**	**5.5**	-
g/100kcal	520	550	-

Protein

Unit	**Minimum**	**Maximum**	**GUL**
g/100g	~~**12.8**~~ **13**	~~**16.2**~~ **16.5**	-
g/100kcal	~~**2.3**~~ **2.4**	~~**3.1**~~ **3.2**	-

Lipids

Unit	**Minimum**	**Maximum**	**GUL**
g/100g	~~**26**~~ **25.8**	~~**37**~~ **36.3**	-
g/100kcal	~~**5**~~ **4.7**	~~**6.7**~~ **7**	-

n-6 Fatty acids

Unit	**Minimum**	**Maximum**	**GUL-**
~~**mg/100g**~~ **Kcal/100kcal**	~~**3 1731.6**~~ **3**	~~**10 6111**~~ **1**	-
mg/100kcal	~~**576.9**~~ **3333**	~~**1818.2**~~ **1110**	-

n-3 Fatty acids

Unit	**Minimum**	**Maximum**	**GUL**
Kcal/100kcal	**0.3**	**2.5**	**-**
~~**mg/100g**~~	~~**0.3 172**~~	~~**2.5 1529**~~	-
mg/100kcal	~~**57.69**~~ **33**	~~**454.5**~~ **280**	-

Vitamin A

Unit	**Minimum**	**Maximum**	**GUL**
mg RE/100g	0.8	~~**[1.1] OR [1.2]**~~	-
mg/ RE/100kcal	0.15	~~**[0.2] OR [0.22]**~~	-
[2]µg RE/100kcal	150	~~**[200] OR [220]**~~	-

[2] 1µg RE = 3.33 IU Vitamin A = 1 µg **all-**trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

Vitamin D

Unit	**Minimum**	**Maximum**	**GUL**
[3] µg/100 g	15	~~**[20] OR [22]**~~	**[30]**
[3] µg100 kcal	2.7	[3.6] OR [4]	-

[3] 1 µg cholecalciferol = 40 IU vitamin D. **[Two forms of Vitamin D allowed in RUTF formulation are cholecalciferol (D3) and ergocalciferol (D2).]**

Vitamin E

Unit	Minimum	Maximum	GUL
[4] mg/100 g	20	-	-
[4] mg α-TE /100 kcal	~~4~~ **3.84**	-	-

[4] 1 mg α-tocopherol = 1 mg RRR-α-tocopherol (d**l**-α-tocopherol)

[4]1 mg RRR-α-tocopherol =2.00 mg *all-rac*-α-tocopherol (**dl~~i~~-** α-tocopherol)

Vitamin K

Unit	Minimum	Maximum	GUL
µg/100 g	15	30	-
µg/100 kcal	2.9	5.5	-

Vitamin B1

Unit	Minimum	Maximum	GUL
mg/100 g	0.5	-	-
mg/100 kcal	0.1	-	-

Vitamin B2

Unit	Minimum	Maximum	GUL
mg/100 g	1.6	-	-
mg/100 kcal	0.3	-	-

Vitamin C

Unit	Minimum	Maximum	GUL
mg/100 g	50	-	-
mg/100 kcal	9.6	-	-

Vitamin B6

Unit	Minimum	Maximum	GUL
mg/100 g	0.6	-	-
mg/100 kcal	0.12	-	-

Vitamin B12

Unit	Minimum	Maximum	GUL
µg/100 g	1.6	-	-
µg/100 kcal	0.3	-	-

Folic Acid

Unit	Minimum	Maximum	GUL
[5] µg/100 g	200	-	-
[5] µg/100 kcal	38.5	-	-

[5] 1 µg of folic acid = 1.7 µg of Dietary Folate Equivalents (DFE)

Niacin

Unit	Minimum	Maximum	GUL
mg/100 g	5	-	-
mg/100 kcal	~~0.96~~ **1**	-	-

Pantothenic Acid

Unit	Minimum	Maximum	GUL
mg/100 g	3	-	-
mg/100 kcal	0.6	-	-

Biotin

Unit	Minimum	Maximum	GUL
µg/100 g	60	-	-
µg/100 kcal	11.5	-	-

Sodium

Unit	Minimum	Maximum	GUL
mg/100 g	-	290	-
mg/100 kcal	-	53	-

Potassium

Unit	Minimum	Maximum	GUL
mg/100 g	1,100	~~**1400**~~ **1,600**	-
mg/100 kcal	212	~~**255**~~ **287**	-

Calcium

Unit	Minimum	Maximum	GUL
mg/100 g	300	~~**[600] or [785]**~~	-
mg/100 kcal	58	~~**[109] or [**~~143~~**]**~~	-

Phosphorus

Unit	Minimum	Maximum	GUL
mg/100 g	300	~~**[600] or [785]**~~	-
mg/100 kcal	~~**58**~~ **57.6**	~~**[109] or [143]**~~	-

Magnesium

Unit	Minimum	Maximum	GUL
mg/100 g	80	~~**[140] or [235]**~~	-
mg/100 kcal	15.4	~~**[26]**~~ **[25.4] or** ~~**[43]**~~ **[42.7]**	-

Iron

Unit	Minimum	Maximum	GUL
mg/100 g	10	14	-
mg/100 kcal	1.9	2.6	-

Zinc

Unit	Minimum	Maximum	GUL
mg/100 g	11	14	-
mg/100 kcal	2	~~**2.6**~~ **2.5**	-

Copper

Unit	Minimum	Maximum	GUL
mg/100 g	1.4	**2**	-
mg/100 kcal	0.27	0.33	-

Selenium

Unit	Minimum	Maximum	GUL
µg /100 g	20	40	-
µg /100 kcal	~~**4**~~ **3.84**	~~**7**~~ **7.3**	-

Iodine

Unit	Minimum	Maximum	GUL
µg /100 g	70	1**6**0	-
µg /100 kcal	~~**13.46**~~ **13.5**	25.5	-

Moisture Content

Unit	Minimum	Maximum	GUL
~~**Percentage(%)**~~ **[Water activity (aW)]**	**[0.2]**	~~**2.5**~~ **[0.45]**	-

Appendix VI

PROPOSED DRAFT DEFINITION FOR BIOFORTIFICATION

(held at Step 4)

Biofortification[1] is any process[2] other than conventional nutrient addition to food[3] whereby nutrient content is increased or become more bioavailable in all potential food sources[4] for the intended nutritional purposes[5].

[1)] Some Member governments may prefer to use an equivalent term.
[2)] Process to be determined by the competent national/regional authority.
[3)] **Conventional nutrient addition to food** is covered by the *General principles for the addition of essential nutrients to foods* (CXG 9-1987)**.**
[4)] e.g. animal, plant, fungi, yeasts, bacteria
[5)] Nutritional purpose:
- preventing/reducing the risk of, or correcting, a demonstrated deficiency in the population;
- reducing the risk of, or correcting, inadequate nutritional status or intakes in the population;
- meeting requirements and/or recommended intakes of one or more nutrients;
- maintaining or improving health; and/or
- maintaining or improving the nutritional quality of food.

Appendix VII

PROPOSED DRAFT CONDITIONS FOR A "FREE" OF TRANS FATTY ACIDS (TFAs) CLAIM IN THE *GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS* (CXG 23-1997)[1]

(held at Step 4)

Component	Claim	Conditions (not more than)
Trans fatty acids	Free	1 g per 100 g of fat And must meet the conditions for "low" in saturated fats[2]

[1] To be inserted between Saturated Fat and Cholesterol within the Table of conditions for nutrient content claims in the *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997)

[2] As per the Table conditions for nutrient content claims in the *Guidelines for Use of Nutrition and Health Claims,* the conditions for "low" in saturated fats are as follows: 1.5 g saturated fat per 100 g (solids), 0.75 g saturated fat per 100 ml (liquids) and 10% of energy of saturated fat.

Appendix VIII

MECHANISM / FRAMEWORK FOR CONSIDERING TECHNOLOGICAL JUSTIFICATIONOF FOOD ADDITIVES

(For further consideration by the PWG)

ANNEX 1

Process to appraise and justify the technological need for the use of additives in foods subject to CCNFSDU standards

- CCNFSDU collects requests and information in order to appraise the technological need by using the agreed framework[1].

- CCNFSDU checks the adequacy of the information provided and evaluates it against the criteria/ questions listed in the framework[2].

  - The outcome of the assessment is recorded in the report of a CCNFSDU meeting and if CCNFSDU agrees that the proposed use satisfies the established criteria then such use is considered as technologically justified.

  The steps which might follow:

  For the requests for which the JECFA assessment is envisaged:

  - The applicant may then request including the substance in the JECFA priority list following the standard procedure (i.e. replying to the CCFA CL "*Request for information and comments on the priority list of substances proposed for evaluation by JECFA*") and referring to the CCNFSDU report which confirmed the technological need. In particular, section 6 justification of use of the CCFA CL is responded to. Such requests are discussed at CCFA and if appropriate (i.e. the applicant commits to provide the data and the request is supported by a Codex Member) they are included in the JECFA priority list.

  - JECFA presents the safety assessment at CCFA and CCFA refers the results to CCNFSDU. Taking into account the outcome of the safety assessment the GSFA (and the commodity standard if not aligned yet with the GSFA) is updated or the matter is further discussed between CCFA and CCNFSDU should questions arise following the JECFA evaluation.

  For the requests for which the JECFA assessment is not envisaged:

  - Proposals for the use of additives in the CCNFSDU standards are forwarded to CCFA for endorsement and inclusion in the GSFA[3] and the commodity standard is updated if not aligned with the GSFA.

  - A reply is provided to CCFA in case of CCFA's inquiries concerning the technological justification for the use of additives in foods under the CCNFSDU's purview.

[1] This could be done e.g. by a Circular Letter (CL) issued by the Codex Secretariat (for food additive uses for which the JECFA assessment will be required) or via an EWG (e.g. in case of a new standard under development).
[2] If needed a specific EWG or an in-session WG could be established for this to prepare draft recommendations for the Committee.
[3] Procedural Manual 26th edition, p. 51.: "*when an active commodity committee exists, proposals for the use of additives in any commodity standard under consideration should be prepared by the committee concerned, and forwarded to the Committee on Food Additives for endorsement and inclusion in the General Standard for Food Additives*"

ANNEX 2

CCNFSDU framework for appraising the technological need

SCOPE

The framework applies for the use of additives in foods within the mandate of CCNFSDU (i.e. standardized foods or non-standardized foods following a request by CCFA).

Q1 IDENTITY AND INTENDED USE

Q1.1: Provide name and INS No of the food additive as listed in CAC/GL 36-1989 (for substances not yet included in CAC/GL 36-1989, chemical name of the substance).

Q1.2: Describe the food and its form (e.g. liquid, powder) for which the additive is intended to be used and indicate the relevant CCNFSDU standard and if known the GSFA food subcategory.

Q1.3: Indicate and justify the range of the proposed use level of the food additive needed to accomplish the desired technological effect at the lowest possible use level.

Q2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA

Q2.1: Describe the technological function of the food additive relative to the CAC/GL 36-1989 (include the functional class) and the advantage conferred by its use.

Q2.2: Does the use of an additive serve one or more of the needs set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA? Indicate which one(s).

a) To preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified in the circumstances dealt with in sub-paragraph (b) and also in other circumstances where the food does not constitute a significant item in a normal diet;
b) To provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;
c) To enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer;
d) To provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities.

Q2.3: Cannot the objectives set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA be achieved by other means that are economically and technologically practicable?

Q2.4: Would the use of this food additive in the intended food(s) modify any characteristic of the food that might mislead the consumer? For example the nature, substance, quality or nutritional quality of the food, the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques by which the consumer might be misled.

Q3 COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN

[Q3.1: Does the proposed food additive perform the same/similar technological purpose as other additives that have already been authorized for use in the same product category? If not, what is the justification for the need for an additive with a new functional class and/or technological purpose? If yes, what advantage(s) does the proposed additive provide over currently permitted options?]

Appendix IX

METHODS OF ANALYSIS FOR PROVISIONS IN THE *STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS* (CXS 72-1981)

(for endorsement by CCMAS)

Commodity	Provision	Method	Principle	Proposed Type
	Calcium	**AOAC 2015.06 / ISO 21424 | IDF 243**	**ICP mass spectrometry**	**II**
		ISO 8070 | IDF 119	Flame atomic absorption spectrophotometry	~~II~~ **III**
		AOAC 985.35	Flame atomic absorption spectrometry	III
	Copper	**AOAC 2015.06 / ISO 21424 | IDF 243**	**ICP mass spectrometry**	**II**
		AOAC 985.35	Flame atomic absorption spectrophotometry	~~II~~ **III**
		~~AOAC 984.27~~	~~ICP emission spectroscopy~~	~~III~~
	Iron	**AOAC 2015.06 / ISO 21424 | IDF 243**	**ICP mass spectrometry**	**II**
		AOAC 985.35	Flame atomic absorption spectrometry	III
		~~AOAC 984.27~~	~~ICP emission spectroscopy~~	~~III~~
	Magnesium	**AOAC 2015.06 / ISO 21424 | IDF 243**	**ICP mass spectrometry**	**II**
		ISO 8070 | IDF 119	Flame atomic absorption spectrophotometry	~~II~~ **III**
		AOAC 985.35	Flame atomic absorption spectrometry	III
	Manganese	**AOAC 2015.06 / ISO 21424 | IDF 243**	**ICP mass spectrometry**	**II**
		AOAC 985.35	Flame atomic absorption spectrometry	~~II~~ **III**
		~~AOAC 984.27~~	~~ICP emission spectroscopy~~	~~III~~
	Phosphorus	**AOAC 2015.06 / ISO 21424 | IDF 243**	**ICP mass spectrometry**	**II**
		~~AOAC 984.27~~	~~ICP emission spectroscopy~~	~~III~~
		AOAC 986.24	Spectrophotometry (molybdovandate)	~~II~~ **III**
	Potassium	**AOAC 2015.06 / ISO 21424 | IDF 243**	**ICP mass spectrometry**	**II**
		ISO 8070 | IDF 119	Flame atomic absorption spectrophotometry	~~II~~ **III**
		~~AOAC 984.27~~	~~ICP emission spectroscopy~~	~~III~~
	Sodium	**AOAC 2015.06 / ISO 21424 | IDF 243**	**ICP mass spectrometry**	**II**
		ISO 8070 | IDF 119	Flame atomic absorption spectrophotometry	~~II~~ III
		~~AOAC 984.27~~	~~ICP emission spectroscopy~~	~~III~~
	Zinc	**AOAC 2015.06 / ISO 21424 | IDF 243**	**ICP mass spectrometry**	**II**
		AOAC 985.35	Flame atomic absorption spectrometry	~~II~~ **III**
		~~AOAC 984.27~~	~~ICP emission spectroscopy~~	~~III~~
	Vitamin K	**AOAC 2015.09 / ISO 21446**	**HPLC**	**II**
	Folic acid	**AOAC 2011.06**	**LC-MS/MS**	**II**
		AOAC 992.05 / EN 14131	Microbioassay	~~II~~ **III**
		J AOAC Int. 2000:83; 1141-1148	Optical Biosensor Immunoassay	IV
		J Chromatogr. A., 928, 77-90, 2001	HPLC, incorporating immunoaffinity clean-up and conversion to 5-methyltetrahydrofolate	IV