

CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture
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Organization

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REP20/NFSDU

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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REPORT OF THE FORTY- FIRST SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

DÜSSELDORF, Germany

24 – 29 November 2019

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SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step	Para.
CCEXEC79 CAC43	Adoption	Review of the <i>Standard for Follow-up Formula</i> : Section B: Proposed draft scope, definition and labelling	CXS 156-1987	5	85
		Proposed draft Guideline for ready-to-use therapeutic foods	-	5	122
		Provisions for xanthum gum (INS 415) and pectins (INS 440)	CXS 72 – 1981	-	166
	Discontinuation	Condition for a claim for “free of” TFAs	CXG 2 – 1985	-	131
		Definition for biofortification	-	-	138
CCEXEC79	Information	Revised timeline for work on: (i) Review of the <i>Standard for Follow-up Formula</i> ; and (ii) NRVs-R for persons aged 6 – 36 months	CXG 2 – 1985 CXS 156 - 1987	-	85, 150
		Prioritization mechanism	-	-	176
		Review of the <i>Standard for Follow-up Formula</i> : Section A: scope, description and labelling; and Essential composition requirements for Section A and Section B	CXS 156-1987	7	28 and 49
CCNFSDU42	Discussion	Review of the <i>Standard for Follow-up Formula</i> : remaining sections:		4	86
	Information / Endorsement	Review of the <i>Standard for Follow-up Formula</i> : (i) Sections 9.2.2, 9.4.1 and 9.6.5, – labelling provisions for Section A (ii) labelling provisions for Section B	CXS 156-1987	7	28
Labelling provisions for the Proposed draft Guidelines for Ready to Use Therapeutic Foods (RUTF)		-	5	85	
Labelling provisions for the Proposed draft Guidelines for Ready to Use Therapeutic Foods (RUTF)		-	5	122	
CCFL46 and CCFO27	Information	Work on condition for claim for “free of” TFA; Risk management options for TFAs / PHOs	-	-	131
CCFL46	Information / advice	Advice on the extent the work concerning nutrient profiles in CCNFSDU can support the work of CCFL on FOPNL	-	-	192
CCMAS41	Development / Advice / endorsement	Performance criteria for Type III methods for determination of nine minerals in CXS72	CXS 234 - 1999	-	9

Responsible Party	Purpose	Text/Topic	Code	Step	Para.
		Methods to measure sweetness in Drink/Product for young children with added nutrients / Drink for young children	CXS 156 – 1987	-	49
		Methods of analysis for provisions in various Standards	CXS 72 - 1981 CXG 23 - 1997 CXS 156 – 1987		196 - 199
CCFA52	Information / Action	Proposed draft Guideline for RUTF	-	5	122
		Xanthan gum and pectins in CXS 72 and in Food category 13.1.3 of the GSFA		-	166
		Alignment of food additive provisions in CCNFSDU standards		-	172
		Food additive provisions in CXS 181 and CXS 203		-	173
EWG (New Zealand, France, Indonesia) CCNFSDU42	Drafting	Review of the <i>Standard for Follow up Formula</i> : Definition of Drink/Product for young children with added nutrients / Drink for young children; and Nitrogen to protein conversion factors	CXS 156-1987	6	85
EWG (Ireland, Costa Rica and United States of America) CCNFSDU42	Drafting	General Principles for the establishment of NRVs-R for persons aged 6 – 36 months	CXG 2 - 1985	2/3	150
EWG (European Union and Russian Federation) CCNFSDU42	Discussion	Technological justification for several food additives	-	-	167
PWG (Germany) CCNFSDU42	Redrafting / reviewing	Prioritization mechanism / emerging issues or new work proposals	-	-	176
EWG (Costa Rica, Paraguay, European Union and United States of America) CCNFSDU42	Discussion	General guidelines on nutrient profiles	-	-	192
Argentina and Malaysia / EWG on prioritization CCNFSDU42	Discussion	Harmonized probiotic guidelines for use in foods and dietary supplements	-	-	185

LIST OF ABBREVIATIONS

CAC	Codex Alimentarius Commission
CCEXEC	Executive Committee of the Codex Alimentarius Commission
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
CCCPL	Codex Committee on Cereals, Pulses and Legumes
CRD	Conference Room Document
DE	Dextrose equivalent
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
FOPNL	Front of pack nutrition labelling
FSMP	Foods for Special Medical Purposes
GSFA	General Standard for Food Additives
ICC	International Association for Cereal Science and Technology
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JEMNU	Joint FAO/WHO Expert Meetings on Nutrition
NUGAG	WHO Nutrition Guidance Expert Advisory Group
NRV	Nutrient reference value
NRV-R	Nutrient reference values-requirements
PWG	Physical Working Group
RUTF	Ready-to-use therapeutic foods
SAM	Severe acute malnutrition
TFA	Trans fatty acid
UL	Tolerable upper intake level
UNICEF	The United Nations Children Fund
WHA	World Health Assembly
WHO	World Health Organization

INTRODUCTION

1. The forty-first Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held in Düsseldorf, Germany, from 24 to 29 November 2019 at the kind invitation of the Federal Government of Germany. Dr Anja Brönstrup and Ms Hilke Thordsen-Böhm, both from the 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. Ms. Julia Klöckner, Federal Minister of Food and Agriculture, Germany, welcomed delegates via a video message. Dr Lorenz Franken, Director General for Consumer Health Protection, Food and Nutrition and Product Safety in the Federal Ministry of Food and Agriculture, Germany, gave the opening address. He noted how participation in Codex work played a key role in harmonizing food safety and quality and in the fight against malnutrition and the protection of consumers worldwide.
3. The Vice-Chairperson of the Codex Alimentarius Commission (CAC), Prof Purwiyatno Hariyadi (Indonesia), on behalf of the Chairperson and Vice-Chairpersons of the Commission, and Mr Tom Heilandt, Codex Secretary also addressed the meeting.

Division of competence¹

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

ADOPTION OF THE AGENDA (Agenda Item 1)²

5. 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 Establishing Harmonized Guidelines for the Qualification of Nutrition and Health Claimed Food (proposed by Republic of Korea);
 - ii. Proposal for the introduction of ICC Standard No. 185 (AOAC Method 2017.16) to replace AOAC Method 2009.01 for the analysis of dietary fibre (proposed by the International Association for Cereal Science and Technology (ICC)); and
 - iii. 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)
6. Additionally, the Committee agreed to:
 - i. establish an in-session working group on methods of analysis, chaired by the United States, working in English only, to consider:
 - the proposal from ICC regarding the introduction of ICC Standard No. 185 (AOAC Method 2017.16) to replace AOAC Method 2009.01 (see CRD6), and
 - the proposal from the United States regarding analytical methods for provisions in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981), namely: thiamine, riboflavin, niacin, Vitamin B6; choline, carnitine; fructans; beta carotene, lycopene; biotin (CRD7).
 - ii. establish an in-session working group on Ready-to-use Therapeutic Foods (RUTF), chaired by South Africa and co-chaired by Senegal, working in both English and French, with the following terms of reference:
 - to consider the recommendations of the EWG in document (CX/NFSDU 19/41/6) (food additives and protein quality assessment section);
 - to consider the values and text of Annex “Nutrition Composition for RUTF”; and
 - if time permits, to consider recommendations 5, 6 and 15 – 20 listed in Appendix to CX/NFSDU 19/41/6.

¹ CRD1 (Annotated Agenda – Division of competence between the EU and its Member States)

² CX/NFSDU 19/41/1; CRD6 (ICC); CRD7 (United States of America); CRD20 (Republic of Korea)

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

7. 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:

Methods of Analysis

8. The Committee agreed that the in-session WG established under Agenda Item 1 would also consider the matters referred by CCMAS as follows:
- Whether the methods for Vitamin K in follow-up formula currently in CXS 234-1999 (AOAC 999.15 / EN 14148) should be replaced by the method endorsed as Type II method for infant formula (AOAC 2015.09 / ISO 21446);
 - Whether AOAC 2011.14 / ISO 15151 | IDF 229 as Type III method for calcium, copper, iron, magnesium, manganese, phosphorous, potassium, sodium and zinc in infant formula can be included in CXS 234-1999; and
 - Whether the currently used microbiological methods for nicotinamide, niacin, pantothenic acid, pyridoxine, cobalamin and Vitamin D (see Appendix II of CX/NFSDU 17/39/2 Rev) should be retained or not.

Numerical Method Performance Criteria

9. The Committee agreed to request CCMAS to develop performance criteria for Type III methods for determination of the nine minerals (calcium, copper, iron, magnesium, manganese, phosphorous, potassium, sodium and zinc) in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS72-1981), noting that this approach would provide flexibility to members to choose methods for general use; and to inform CCMAS that Type II methods should continue to be listed in CXS 234-1999 as specific methods were preferred for dispute settlement purposes.

Methods of analysis for gluten free

10. The Committee noted that it was premature to consider the proposed methods as presented in CX/NFSDU 19/41/2, Appendix I, Part C as research is still ongoing to determine the most appropriate method for determination of gluten.
11. The Committee agreed to wait for the completion of ring trial tests and to consider this matter at a future date when more information became available.

Editorial amendment to section 5.2 of the *Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten* (CXS 118 – 1979)

12. The Committee agreed to align section 5.2 with the wording from the Procedural Manual “*For checking the compliance with this standard, the methods of analysis and sampling contained in the Recommended Methods of Analysis and Sampling (CXS 234 – 1999) relevant to the provisions in this standard, shall be used.*” The Committee noted that the method for determination of gluten, the enzyme-linked immunoassay (ELISA) R5 Mendez Method is listed in CXS 234-1999 and any changes to the method related to the determination of gluten remained the responsibility of CCNFSDU.

Conclusion

13. The Committee agreed to submit this editorial amendment to CXS118-1979 to CAC43 for adoption.

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

14. The Representative of FAO called the attention of the Committee to the following issues to be considered under relevant Agenda items: 1)The results of 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 the main outcomes of the report, along with the systematic review that had been presented during a side event (held on 23 November 2019); and 2)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 that was published in 2018.

³ CX/NFSDU 19/41/2

⁴ CX/NFSDU 19/41/3

15. The Representative of WHO highlighted some of the activities noted in the document CX/NFSDU 19/41/3 which may be of relevance to the on-going work of the Committee, including updating of nutrient requirements for infants and young children aged 0 – 36 months, various on-going guideline development and WHO's scaled-up action on eliminating industrially-produced *trans*-fatty acids (TFA). With reference to the updating of nutrient requirements for infants and young children aged 0 – 36 months, she informed the Committee that the scoping reviews of the first 3 priority nutrients (i.e. calcium, vitamin D and zinc) had been completed and the first expert panel meeting was planned in January 2020 to finalize the scope and PICO questions for the systematic reviews which needed to be undertaken to guide the updates.
16. Regarding the on-going guideline development, the Representative highlighted the guideline development on efficacy, safety and effectiveness of RUTF with reduced milk-protein content, complementary feeding of infants and children, the work of the WHO Nutrition Guidance Expert Advisory Group (NUGAG) Subgroup on Diet and Health which will also review the issues related to the use of low-sodium salt substitutes and the NUGAG Subgroup on Policy Actions which will review the evidence reviews conducted on nutrition labelling policies, marketing policies and fiscal/pricing policies. The Representative also highlighted the WHO's accelerated efforts in eliminating industrially-produced TFA by 2023 which include monitoring of legislative and regulatory actions in countries.
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.

REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987): DRAFT SCOPE, DESCRIPTION AND LABELLING FOR FOLLOW-UP FORMULA FOR OLDER INFANTS (Agenda Item 4a)⁵

18. The Committee recalled that the draft scope, description and labelling for follow-up formula for older infants had been adopted at Step 5 by CAC42 and circulated for comments at Step 6. The Committee further noted that CCFL45 had endorsed the labelling provisions with amendments, discussed the text on cross-promotion (the last part of 9.6.4) and noted that it required further consideration in the Committee.
19. The Chair noted that there had been extensive discussion and agreement on the scope, description and labelling sections of the Standard allowing to advance these provisions in the Step process. She further noted that some editorial corrections were necessary to the section on labelling in line with decisions taken at earlier sessions and that the only point remaining for discussion was the part on the prohibition of cross-promotion in 9.6.4.
20. In addition to the editorial corrections e.g. removal of square brackets or corrections for purposes of clarity; and reference to “food additives” rather than “additives” in 9.2.2, the Committee also took the following decisions:
 - Replaced the reference to 4.7.1 of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1 – 1985) (GSLPF) with 4.7 of that standard to ensure that ‘storage instructions’ in section 4.7.2 of the GSLPF are captured; and
 - Referred to “follow-up formula for older infants” instead of “products” in 9.6.4 as provisions for follow-up formula for older infants needed to be regulated within the standard itself and should not address other products not covered by the Standard.

Discussion

21. The Committee discussed how to address the prohibition of “cross-promotion” in the standard by either retaining the text in the last part of 9.6.4 or finding an alternative text.
22. Those members and observers in support of retaining the text including the term “cross-promotion” expressed the view that cross-promotion was problematic and had a negative effect on the health of infants and young children as it misleads caregivers and discourages breastfeeding; and therefore needed to be prohibited; that there was a definition of ‘cross-promotion’ from WHA 63.14; WHA 69.7 Add.1 and other WHO documents that could help to clarify its meaning and that a definition could be included in the text, for example as a footnote. These delegations also expressed their preference for referring to “labelling” rather than “label”.

⁵ REP19/NFSDU, Appendix II; CX/NFSDU 19/41/4 (comments of Argentina, Australia, Brazil, Burkina Faso, Cambodia, Canada, Costa Rica, European Union, Ghana, Indonesia, Iran, Iraq, Kuwait, Mali, New Zealand, Nepal, Norway, Peru, Senegal, Somalia, Sri Lanka, Switzerland, United States of America, Vietnam, HKI, ISDI, UNICEF); CX/NFSDU 19/41/4 Add.1 (Ecuador, Indonesia, Kenya, Mali, Senegal, HKI, IBFAN, WPHNA); CRD3 (NZ) CRD21 (ROK); CRD25 (Thailand); CRD27 (Nepal); CRD32 (Nigeria); CRD33 (Dominican Republic); CRD35 (India); CRD41 (Malaysia); CRD42 (Mexico); CRD45 (Laos); CRD48 (Uruguay)

23. Other members and an observer expressed the view that the use of the term “cross-promotion” should be avoided as it was not defined in Codex; and that its use could lead to confusion due to the different interpretations of the term. These delegations proposed to either delete this part of 9.6.4 or to more succinctly capture the concept of cross-promotion in the text rather than referring to the term itself and having to define it. Varying views were expressed on whether to refer to “label” or “labelling”.
24. A delegation also expressed the view that restricting cross promotion could be beyond the mandate of the Committee and Codex.
25. The Committee acknowledged that the intent of 9.6.4. was to avoid consumer confusion through the clear differentiation in labelling between the different products, whereas the intent of not permitting cross-promotion was to prevent reference to [name of product] for young children and formula for infants 0 – 6 months on follow-up formula for older infants.
26. To reconcile the positions on how to reflect this concept, the Committee considered a proposal to delete the last part of 9.6.4 and to include a new section 9.6.5 to address the issue of cross-promotion. After considerable discussion, the Committee agreed to the following text: “*The labelling of follow-up formula for older infants shall not refer to infant formula, [name of product] for young children, or formula for special medical purposes intended for infants, including numbers, text, statements, or images of these products*”.
27. The Committee noted a proposal to replace “refer” by “resemble”. However, this statement as stated in paragraph 26 was supported in the spirit of compromise and to recognise the will of the Committee to progress this work.

Conclusion

28. The Committee agreed:
 - i. to hold the scope, description and labelling provisions at Step 7 (Appendix II);
 - ii. to send the labelling provisions in 9.6.5 to CCFL46 for endorsement; and
 - iii. to inform CCFL of the editorial and other corrections to sections 9.2.2 (see agenda item 4c, para 67), 9.4.1 and 9.6.4.

REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CXs 156-1987): ESSENTIAL COMPOSITION REQUIREMENTS FOR FOLLOW-UP FORMULA FOR OLDER INFANTS AND [PRODUCT] FOR YOUNG CHILDREN (Agenda Item 4b)⁶

29. The Committee recalled that CCNFSDU40 had agreed on the essential composition requirements for follow up formula for older infants and [name of product] for young children which was held at Step 7, but that two open points remained to be resolved, namely, footnote 4⁷ to the provision for carbohydrates, and section 3.2.1 for [name of product] for young children, and that the EWG on follow-up formula had developed two recommendations on these topics.

Carbohydrates: footnote 4 (Recommendation 1 – option 1 in CX/NFSDU 19/14/5)

30. New Zealand as chair of the EWG recalled that CCNFSDU40 had reached agreement on parts of footnote 4 for [name of product] for young children, including the limit for mono- and disaccharides and that sucrose and/or fructose should not be added to the product. How to limit sweetness in products not based on milk protein remained an issue. The EWG had discussed relevant text that had been left in square brackets making reference to a specific DE limit, which was meant to ensure that carbohydrate sources in products not based on milk protein are not sweeter than lactose which is the preferred carbohydrate in products based on milk protein. Two further proposals, not making reference to sweetness and DE limits were also considered by the 2019 EWG and were included in CX/NFSDU 19/41/5.
31. The EWG Chair explained that there was no consensus in the EWG on the different options and the Committee should take into account the already agreed restrictions and prohibitions in footnote 4 and decide on the best option to limit the sweetness of [name of product] for young children not based on milk protein.
32. The EWG Chair further explained that there appeared to be agreement on the intent of the footnote text which was to limit the sweet taste of products and recalled the original text proposed at CCNFSDU39:

“For products based on non-milk protein, carbohydrate sources (like starch) that have no contribution to sweet taste should be preferred.” (Herein referred to as Option 2)

⁶ REP19/NFSDU, Appendix II; CX/NFSDU 19/41/5; CRD9 (comments of Kenya, Mali, Senegal, HKI; CRD21 (ROK); CRD27 (Nepal); CRD32 (Nigeria); CRD42 (Mexico); CRD45 (Laos)

⁷ The footnote number reflects the footnote number in CX/NFSDU 19/41/5 which has been corrected to footnote 5 in Appendix III to this report.

33. At CCNFSDU39 this statement was not agreed to because of concern around the ability to measure “sweet taste” and hence a statement on DE was introduced.
34. The EWG Chair therefore proposed to reconsider this statement as it addressed the original intent which had been supported by the Committee. She also provided a further option which could address the concerns raised at CCNFSDU39:

“For products based on non-milk protein, carbohydrate sources that are no sweeter than lactose should be used.” (Herein referred to as Option 3)

Discussion

35. There was general agreement with the principle to restrict sugars and to limit sweetness of these products, however, there were varying views on the different options, with delegations divided between supporting Option 2 or 3.
36. Delegations in favour of Option 2 expressed the view that this was the best option to protect children from the negative effects of overly sweet foods, which, because of addition of sugars or other carbohydrates could lead to an increased risk of obesity and dental caries, and because sweet-tasting products could lead to the development of a preference for sweeter foods in later life.
37. A proposal was made to change the phrase “should be preferred” to “should be used” in Option 2.
38. Other delegations expressed the view that neither provision was necessary because footnote 4 already contained a provision limiting mono- and disaccharides to no more than 2.5 g/100kcal ensuring that the product was no sweeter than breastmilk and cow’s milk. These delegations stated however, that they could support Option 3, and agreed with a proposal to amend the statement to refer to ‘not substantially sweeter’ for purposes of flexibility.
39. One delegation clarified that they preferred Option 3 because Option 2 would result in non-milk protein (soy-based) products to be substantially less sweet than milk protein-based product which was not the intention and it might be appropriate for these products to be at least as sweet but not more sweet, than the product containing lactose.
40. An Observer drew the attention of the Committee to ‘reduced’ or ‘low-lactose’ products for young children which needed to be considered when establishing provisions for carbohydrates.
41. The Committee then considered merging the two options and to develop a compromise text.
42. The Committee also considered a proposal to ask CCMAS to look into the availability of methods to measure sweetness noting that standards development organizations (SDOs) were discussing ways to measure sweetness.
43. An Observer noted that there was merit in asking CCMAS to review methods, even if they were sensory methods on the understanding that relative sweetness of lactose is, in their view, based on the 2016 Study: Functionality of sugars in foods and health. Comprehensive Reviews in Food Science and Food Safety 15:433-470.
44. In this context, the Secretariat clarified that generally questions on methods did not prevent the progress of a Standard nor its adoption.

Conclusion (Recommendation 1)

45. The Committee agreed the following compromise text:
- “for products based on non-milk protein, carbohydrate sources that have no contribution to sweet taste should be preferred and in no case be sweeter than lactose.”*

Section 3.2.1 (Recommendation 2)

46. A delegation pointed out that in addition to known ingredients that enhance or impart a sweet taste that are not included in the category of carbohydrates, there was currently considerable momentum to develop such non-sugar ingredients to strengthen policies for reducing sugars intake . Ingredients that impart or enhance a sweet taste might not necessarily in all cases be classified as food additives and it was expected that the number of ingredients would increase in future. While such ingredients might be used to reduce sugar intakes in adults in line with national public health policies, for the age group of infants and young children, their use might negatively influence the development of taste preferences. In order to future-proof the standard, the provision should ensure that the use of such ingredients were covered by the standard. This delegation, together with other delegations supported changing “substances” to “ingredients” to make it clear that it was about optional ingredients.
47. The Committee further noted that the text (see para 48) might be wrongly placed as the section in question

was about optional ingredients being added for nutritional purposes and not about enhancing sweet taste and therefore agreed to move the text to a new section 3.2.4.

Conclusion (Recommendation 2)

48. The Committee agreed to Recommendation 2 as amended:

“Ingredients shall not be added with the purpose of imparting or enhancing a sweet taste of [name of product] for young children”, and its placement in a new section 3.2.4.

Conclusion

49. The Committee agreed:

- i. That work on outstanding points on the essential composition for [name of product] for young children had been concluded, and to hold the essential composition requirements at Step 7 (Appendix III); and
- ii. to ask CCMAS whether there were internationally validated methods to measure sweetness of carbohydrate sources for these products.

REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987): PROPOSED DRAFT PRODUCT DEFINITION AND LABELLING FOR [PRODUCT] FOR YOUNG CHILDREN (Agenda Item 4c)⁸

50. The Chairperson recalled the decision of the CCFNSDU40 to defer discussion on Section B of the standard, namely: product definition and labelling of [product] for young children, the structure of the standard and preamble, to the current session (CCNFSDU41).
51. New Zealand, chair of the 2018 EWG, recalled that the consideration of the definition of [name of product] for young children by the EWG had been a challenging issue and members had been polarised in their views, in particular on the inclusion of the text ‘as a breast-milk substitute’ in the definition.
52. The EWG had also been divided on the proposed deletion of the text in the last two sentences; [in order to contribute to the nutritional needs of young children] [when nutrient intakes may not be adequate to meet nutritional requirements]. It had been commented by some members that the definition should appropriately capture the role and purpose of this product.
53. Given the near equal split in views on the inclusion or exclusion of the text ‘as a breast-milk substitute’ in the definition and given that the 2017 EWG supported excluding this text, the recommendation to the current session was to follow the 2017 EWG and exclude it.

Discussion

2.1 Product Definition

2.1.1

54. The chair of the EWG recalled the principles that had guided the proposed mandatory (core) composition of this product, notably that the product was manufactured to contribute key nutrients from milk while acknowledging that breast milk, formulas for infants and milk were all suitable for this age group and any levels specified in the standard would need to accommodate these foods.
55. The proposed draft definition as shown below was discussed.

[Name of product] for young children means a product ~~specifically [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].~~

56. Delegations reiterated their arguments, previously presented in REP19/NFSDU (paras 53, 54), for and against stating in the product definition that the product was a breast-milk substitute.
57. The main arguments for stating in the product definition that [name of product] for young children is a breast-milk substitute included:

⁸ REP19/NFSDU, Appendix IV; CX/NFSDU 19/41/5 Add.1; Comments of Australia, Brazil, Burkina Faso, Canada, Colombia, Costa Rica, Guatemala, Iran, Indonesia, Malaysia, Mali, Nepal, Peru, Philippines, Senegal, Sri Lanka, United States of America, Vietnam, CCTA, ISDI, EU Specialty Food Ingredients, HKI; CRD10 (Indonesia, Mali, Philippines, Senegal, HKI, ISDI, WPHNA); CRD25 (Thailand); CRD27 (Nepal); CRD31 (IBFAN); CRD42 (Mexico); CRD45 (Laos); CRD50 (Proposed text for section 9.6 Additional Labelling Requirements).

- the matter of function has to be considered and not only that of composition;
- the products are frequently marketed as breast milk substitutes and classified as breastmilk substitutes in national regulations, mainly in low and middle-income countries;
- any product that is the liquid part of the diversified diet displaces breast milk, especially when the product is a milk type product;
- WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children classifies these products as breast-milk substitutes.⁹

58. The central arguments for not defining the [name of product] for young children as a breast-milk substitute included:

- the product does not cover all nutritional requirements of a child and can therefore not be defined as a breast-milk substitute;
- it is misleading to describe the product as designed to replace breast milk and could be harmful to the health of infants and young children if it were perceived by consumers as such;
- defining such products as breast-milk substitutes will give them status as alternatives to breast milk;
- the product is used as an alternative to cow's milk rather than breast milk and was developed to contribute to the needs of young children when they couldn't get enough micronutrients in their diets.

59. Further discussion followed together with suggested amendments to the text. One proposal was to revise the text to read:

[Name of product] for young children means a product manufactured for use as a liquid part of the diversified diet of young children that functions as a substitute for either breast milk or other milks but is not nutritionally adequate to meet the requirements of young children.

60. This definition; particularly the phrase 'functions as a substitute ...' and '... but is not nutritionally adequate ...' received considerable support, but did not allow the Committee to reach consensus. However, in a spirit of compromise and in order to reach consensus, the Committee reached agreement on a revised definition that followed the guidance of the EWG that Codex remain silent on the issue of whether the product was or was not to be described as a breast-milk substitute but with the addition of a footnote to state the fact that these products are regulated as breastmilk substitutes in some countries.

[Name of product] for young children means a product manufactured for use as a liquid part of the diversified diet of young children [which may contribute to the nutritional needs of young children].

Footnote: In some countries these products are regulated as breast-milk substitutes.

61. The Codex Secretary clarified that while it was preferable to come to clear definitions without having to use footnotes, such footnotes had been used in Codex on occasion to find consensus and resolve issues of different usage of products in different jurisdictions as was the case here with [name of product] for young children.

62. The United States of America expressed its reservation with respect to the footnote to the product definition (section 2.1.1), noting that the use of footnotes, when it is difficult to reach consensus, has proven to be problematic in other committees, and given that a footnote does not reflect a conclusion by Codex but simply states that some countries regulate these products in a certain way at this time. In the US view, the Committee had made many significant revisions to the existing standard; Codex Standards should be forward looking and global in nature.

2.1.2

63. The Committee agreed to maintain a text identical to that for follow-up formula for older infants that was already at Step 7.

[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.

⁹ Definition as presented in [A69/7 Add.1](#) to the 69th WHA.

2.2 Other Definitions

2.2.1

The Committee agreed to the text as presented in 2.2.1.

9 Labelling

9.1 The name of the product

64. The Committee agreed to maintain the text corresponding to that for the Section A: follow-up formula for older infants.

9.2 List of ingredients

9.2.1

65. The Committee agreed to maintain the identical text to that for follow-up formula for older infants.

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

66. The Committee agreed to revise the text as it is mandatory to declare functional classes and therefore replace 'may' with 'shall'. It was noted that this wording was a deviation from the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985), section 4.2.3.3, but that the Procedural Manual provided for such deviations¹⁰.

67. A consequential amendment, substituting 'may' for 'shall', was therefore also made to the Section A: follow-up formula for older infants (see Appendix II, section 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 food additives shall be included on the label. The food additive INS number may also be optionally declared.

9.3 Declaration of Nutritive Value

68. The Committee agreed to maintain the text as proposed by CCFL which was similar to the text in the draft standard for follow-up formula for older infants except for paragraph c) regarding serving size. It was acknowledged that explicit mention of serving size was a repetition of indications in the *Guidelines on Nutrition Labelling* (CXG 2-1985), section 3.4.5, but considered helpful to include in the text as it could prove to be beneficial when dealing with claims.

- c) In addition, the declaration of nutrients in a) and b) per ~~per serving size and/or per~~ 100 kilocalories (kcal) (or per 100 kilojoules) (kJ) and/or per serving size, provided that the serving size is quantified on the label, is permitted.

9.4 Date Marking and Storage Instructions

69. The Committee agreed to introduce the same amendments proposed by CCFL and discussed under agenda item 4a as for the Section A: follow-up formula for older infants including the reference to section 4.7 of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985):

The date marking and storage instructions shall be in accordance with section 4.7 of the *General Standard for the Labelling of Prepackaged Foods*.

9.5 Information for use

70. For sections 9.5.1 through 9.5.5 the Committee agreed to use the same text as amended and agreed for Section A: follow-up formula for older infants.

9.5.6

71. The Committee considered the proposed text:

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 part of a **[diversified]** **[balanced]** diet.

¹⁰ Section II: Elaboration of Codex texts

72. The Committee amended the text to clarify the appropriate term for the intended minimum age and to introduce the information that the product 'is not to be used as a sole source of nutrition'.
73. The amended text reads:

The label of **[name of product] for young children** shall include a statement that the product shall not be introduced to infants 12 months of age or less and is not to be used as a sole source of nutrition.

9.6 Additional Labelling Requirements

74. The Chairperson of the EWG recalled the work that had led up to the drafting of section 9.6 and that the EWG had decided to present a succinct version of the text to the Committee as shown below:

[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].**

75. The Committee noted that it would not be appropriate to draft the text for this section of the standard drawing on the wording in the Section A: follow-up formula for older infants.

76. The Committee therefore elaborated a revised text which was presented in CRD50.

77. In the discussions on this revised text and subsequent proposed amendments (e.g. adding the text 'Breast milk is the best food for your young child and you should continue to breastfeed'), one member organisation suggested, consistent with decisions taken for section 2.1.1, that a footnote could be employed to serve those countries where the [product] for young children was considered to be a breast-milk substitute.

78. With respect to Section 9.6.5, a Member clarified their understanding that the intention of this provision is that the product labelling cannot include numbers that refer to the other listed products, statements or text that describe or refer to the other listed products, or pictures or pack-shots of the other listed products.

79. The Committee agreed on the text for section 9.6 as presented in CRD50 with an amendment under 9.6.2: the statement 'Breastfeeding is recommended up to two years and beyond' and without footnotes.

80. One Observer expressed their preference for the wording 'resembles' in place of 'refers to' in section 9.6.5.

Name of [product] for young children

81. The Committee considered two names for the product:

'Drink for young children with added nutrients' and 'Drink for young children'.

82. Discussion centred on the need for a name that was neutral and specific without being too generic, as indicated in section 4.1 of the *General Standard for the Labelling of Prepackaged Foods* which also provides the option to have more than one name for a product.

83. While, some members expressed concern with the first option, as it could be construed as a nutrition claim, it was suggested that two names could be retained in a spirit of compromise. Some Members also proposed to use the term "product", because it may also be available in powder form.

84. The Committee agreed that the names of the product would be 'Drink/Product for young children with added nutrients' and 'Drink for young children', with countries able to choose between these options.

Conclusion

85. The Committee agreed to:

- i. forward the proposed draft scope, definition and labelling section to Step 5 for adoption by CAC43 (Appendix IV);
- ii. to inform CCEXEC79 that the deadline for completion of work on the Review of the Standard for Follow-up Formula would be adoption by CAC in 2022;
- iii. send the labelling provisions to CCFL for endorsement; and

- iv. re-establish the EWG chaired by New Zealand and co-chaired by France and Indonesia and working in English to:
- a. Finalise the definition of 'Drink/Product for young children with added nutrients' and 'Drink for young children', by reviewing the outstanding text '[which may contribute to the nutritional needs of young children]';
 - b. Consider the linkages and impact between the definition and name for 'Drink/Product for young children with added nutrients' and 'Drink for young children'; and
 - c. Consider the report and options provided by JEMNU in the *Nitrogen to protein conversion factors for soy-based and milk-based ingredient used in infants and follow-up formula*, and to what extent it needs to be considered for the revision of the draft standard/s for follow up formula for older infants and 'Drink/Product for young children with added nutrients' and 'Drink for young children'.

REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987): PROPOSED DRAFT FOLLOW UP FORMULA FOR OLDER INFANTS AND [PRODUCT] FOR YOUNG CHILDREN (Agenda Item 4d)¹¹

86. Due to time constraints, the Committee agreed to defer discussion on this item to CCNFSDU42 (Appendix V).
87. The Chairperson also informed the Committee that as previously agreed, the structure of the standard and the proposed preamble¹² would be considered after completion of the other sections of the standard.

PROPOSED DRAFT GUIDELINE FOR READY-TO-USE THERAPEUTIC FOODS (Agenda Item 5a and 5b)¹³

88. The Chairperson recalled the decisions reached by the Committee at its previous sessions on the various aspects of the guideline. In terms of approach, CCNFSDU agreed that the proposed guideline would cover RUTF as foods for special medical purposes (FSMP) and that the preamble or the introduction (Section 1) should set the scene. CCNFSDU had considered and agreed the following sections (held at Step 4) - Purpose of the guideline (Section 2); Scope (Section 3); the age range of 6-59 months (Section 4 Description); Suitable raw materials and ingredients (Section 5); and Energy (Section 6.1).
89. South Africa, as Chair of the EWG and in-session WG, speaking also on behalf of the co-Chairs Senegal and Uganda, introduced the item and highlighted the recommendations of the in-session WG as contained in CRD49.
90. The Committee agreed to discuss the remaining sections based on recommendations contained in CRD49 and document CX/NFSDU 19/41/6; addressed each recommendation, made appropriate editorial changes and clarified various sections.

Section 5.1.4 Cereals and [Tubers]

91. The Committee confirmed that in some countries or regions "Tubers" were used as raw materials in preparation of RUTF, and that tubers were classified under "tubers, roots and derived products" as per the FAO definition and classification of commodities. Consequently, the heading of the section together with its descriptive text were amended to replace [tubers] with "Roots, Tubers and derived products" and based on these changes the square brackets were deleted.
92. An Observer proposed to insert after "milled cereals" the words "gluten-free by nature", because 5.6 % of children in Africa were suffering from Coeliac disease and therefore gluten containing foods might cause life-threatening situations for SAM children. South Africa as chair of the eWG informed the Committee that RUTF was manufactured from diverse raw materials and ingredients depending on the country or region and that it would not be practical to require that all raw materials should be gluten-free. The Committee therefore agreed to not accept the proposal.

¹¹ CX/NFSDU 19/41/5, CX/NFSDU 19/41/5 Add.1 (comments of Australia, Brazil, Burkina Faso, Canada, Colombia, Costa Rica, Guatemala, Iran, Indonesia, Malaysia, Mali, Nepal, Peru, Philippines, Senegal, Sri Lanka, United States of America, Vietnam, CCTA, ISDI, EU Special Food Ingredients, HKI) ; CX/NFSDU 19/41/5 Add. 2 (Chile, Costa Rica, Ecuador, Kenya, Mali, Senegal, HKI, WPHNA) CRD28 (EU); CRD32 (Nigeria)

¹² REP19NFSDU Appendix IV

¹³ CX/NFSDU 19/41/6; REP19/NFSDU, Appendix V; CL 2018/64-NFSDU; CX/NFSDU 19/41/6 Add.1 (comments of Argentina, Brazil, Colombia, Ecuador, India, Jamaica, Japan, Malawi, Norway, Sri Lanka, EU Speciality Food Ingredients, HKI, ICAAS, IBFAN, IACFO, IDF, ISDI, MSF, UNICEF); CX/NFSDU 19/41/6 Add.2 (Kenya, Senegal); CRD11 (EU, Senegal); CRD19 (AOECS); CRD23 (ISDI); CRD24 (Japan); CRD25 (Thailand); CRD31 (IBFAN); CRD32 (Nigeria); CRD34 (EU)

Section. 5.2.1 Carbohydrates

93. The Committee reaffirmed that the use or addition of free sugars in the manufacture of RUTF should be limited and that this should not exceed 20% of total energy. It was also agreed that use of fructose and glucose should not be allowed, and a sentence limiting use of these two ingredients was inserted into the text. The text was endorsed and square brackets were removed from the section.
94. The Representative of WHO stated that WHO has been indicating that free sugars' content being 20% of total energy was too high and was not in line with the WHO's guideline on sugars intake, but understood that at present that would be the lowest which could be achieved in order to maintain the integrity of the product. However, further efforts were being made by the suppliers of RUTF to explore the possibilities of lowering the contents of free sugars and therefore the Representative requested UNICEF to provide updates on this effort.
95. The observer from UNICEF explained that they were currently aiming to limit the addition of free sugars to 20% of the energy, which is considered reasonable. However due to the need to ensure a stable supply base, and avoid disruption in the supply chain for RUTF due to changes in specifications, reduction in percentage of added sugar would take a bit of time.

Section 5.2.2. Food additives

96. The Committee endorsed the recommendation, agreed to the text on food additives as well as the revised Table A – (Additives in RUTF formulation); and made the following further changes:
- Expressed the maximum use levels for Ascorbyl palmitate (INS 304) and Tocopherol concentrate mixed (307b) as mg/kg RUTF instead of mg/100ml basis; and agreed on a maximum use level of 10 mg/kg;
 - Deleted the expression “singly or in combination” on the maximum use levels for Ascorbyl palmitate (INS 304) and tocopherol concentrate mixed (INS 307b).
97. A Member Organisation welcomed the limitation of additives used in RUTF and that this was appropriately ensured through the inclusion of a table that provided a closed list of additives. They noted that in principle, only additives falling under the food category 13.1.3 of the GSFA (Formulae for special medical purposes for infants) for which an appropriate technological justification has been provided should be permitted in RUTF. The use of Ascorbic acid (INS 300) and Silicon dioxide, amorphous (INS 551) though not included in food category 13.1.3, their inclusion in the Table A was however acceptable and that these two additives would comply with all the criteria of use in RUTF.
98. Concerning the placement of the additives, whether in the GSFA or in the guidelines for RUTF, the Codex Secretariat clarified that the Procedural Manual provided for deviations from the procedural requirements of referencing of GSFA, however such deviations have to be fully justified by the Committee.
99. The Committee agreed to include the table of additives in the guidelines noting that this would be the most pragmatic way; and that this would avoid unnecessary delays in the finalization of the guidelines.

Section 6. Nutritional composition and quality factors

100. The Committee inserted an introductory statement to ensure linkage between the provisions outlined in the section and those in the Annex.

6.2 Proteins

101. The Committee agreed to the proposal from the in-session WG to the revised text on proteins and endorsed it.
102. On the proposal by a delegation to replace “milk proteins” with “whey proteins” (as these were preferable to “casein” due to their better digestibility properties), the Chairperson noted that it would not be appropriate to refer to a specific type of protein.

Section 6.5. Water Activity

103. The Committee transferred the provision on water activity from the Annex to the main body of the standard as a new section 6.5. It was further agreed that only the maximum value of 0.6, should be set.

Section 7. Contaminants

104. The Committee considered the section and deleted the extra reference to contaminants arising from pesticide residues (other contaminants); and further agreed with the explanation of the Codex Secretariat to delete proposed maximum values for aflatoxin of 10 ppb as the value would require to be scientifically justified.

Section 8. Processing technologies

105. The Committee endorsed the recommendation on the proposed text for processing technology noting that the section was relevant to the processing and handling of low Moisture foods like RUTF.

Section 9: GMP and Good Hygiene Practices

106. The Committee agreed to make reference to other relevant Codex texts noting that this will ensure future proofing of the Standard. Concerning the proposal to include a reference to the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CXC 66 -2008), it was clarified that CXC 66 -2008 was applicable to powdered formulas and did not apply to RUTF.

Section 10. Methods of Analysis and Sampling

107. Taking into account the explanation by the Codex Secretariat that CXS 234-1999 was currently under review and that this standard would become the single reference source for methods analysis, the Committee amended the text and made reference to CXS 234-1999 only.

Section 11: Packaging

108. The Committee endorsed the recommendation related to packaging.

Section 12. Labelling

109. The Committee endorsed the labelling provisions as proposed by the In-session working group and agreed that:
- i. The name of the food should make reference to the fact that the target group is SAM children;
 - ii. The provisions of section 4.4 and 4.5 in the *Standard for the Labelling and Claims for Foods for Special Medical Purposes* (CXS 180-1991) applied to the additional mandatory labelling requirements for RUTF.

Annex

110. The Committee considered the provisions in the Annex – Table of Composition for RUTF and made the following general decisions:
- a) Agreed that the Minimum and Maximum requirements would be expressed per 100 kcal only for both micro- and macronutrients;
 - b) Confirmed the minimum and maximum values for energy;
 - c) Endorsed recommendations for the proposed minimum and maximum values for: proteins; lipids; vitamins D, E and K, B1; B2; C; B6; B12; Folic acid; Niacin; Pantothenic acid; Biotin; Sodium; Potassium; Calcium; Phosphorus; Iron, Zinc, Copper, Selenium and Iodine.
111. A concern was expressed by one delegation that the nutritional requirements were based on weight of a child and that proposed values for mineral nutrients could exceed the tolerable upper intake level (UL). The Chairperson clarified that RUTF was a short-term intervention for children with SAM, and that the UL values were more applicable to a target population of healthy people and long-term intake of nutrients.

Essential Fatty acids

112. The Committee considered a proposal to decrease the maximum level of n-6 fatty acids to 780 mg/100kcal and to increase the minimum level of n-3 fatty acids to 110 mg/kcal to avoid negative effects that may arise from depletion of n-3 fatty acids in children with SAM and which may negatively affect their mental development. The Committee noted that more time was needed to examine the implication of the proposed values and agreed to put the values in square brackets for further consideration. The corresponding values in section 6.3 were placed in square brackets accordingly.

Vitamin A

113. The Committee agreed to the proposal to adjust the maximum value for Vitamin A to a higher value of 308 µg RE/100kcal as this level would take into account raw material variability and degradation of the nutrient through the supply chain i.e. during transportation and storage of premix, RUTF processing and harsh conditions during transport and storage of finished products (i.e. shelf life of 24 months).

Vitamin D

114. The Committee confirmed that the identified forms of Vitamins D i.e. cholecalciferol (D3) and ergocalciferol (D2) were consistent with the *Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children* (CAC/GL 10-1979). It was further observed that both these forms of the Vitamin may be used. Consequentially the square brackets were deleted.

Vitamin E

115. The Committee noted that both the natural or synthetic forms of the nutrient are used in RUTF, and that the conversion factors in the footnotes were important in ensuring that the correct dosage was added to RUTF during manufacture.

Calcium and Magnesium

116. One Observer expressed concern over the high ratio of calcium to magnesium as well as over the generally low minimum and maximum levels being set for magnesium, stating that extensive science supporting higher levels exists and had been previously submitted to the Committee. It was proposed that the levels for magnesium be doubled to be closer to the proposed values for calcium, which was supported by a member and another observer. The Committee agreed to place the proposed values for magnesium in square brackets for further consideration at the next session.

Water Activity

117. The Committee transferred the provision to the main body of the guideline, as the provision was related to the general quality factors (see Section 6.5. Water Activity).

Preamble

118. The Committee considered the preamble recalling the previous decision that this section would be discussed after considering all other sections, and that the section would in general take into account: the appropriate use of RUTF; integration of RUTF into sustainable local family-food-based solutions and how the guidelines on RUTF would be used.
119. The Committee agreed to simplify the text of the preamble to include aspects on basic composition of the product; target age group; and that RUTF was one of the options of dietary management of children with uncomplicated SAM, and the source information that was included in a footnote and to retain the preamble in square brackets for further consideration.
120. One delegation made a proposal, regarding the footnote on the Preamble, to remove the reference to the *Joint Statement on Community-Based Management of Severe Acute Malnutrition* and also the 1981 International code of marketing of breast-milk substitutes and subsequent relevant WHA resolutions on infant and young child feeding as these products did not fall under the Code.
121. In response, the Representative of WHO indicated that the proposed draft guidelines for RUTF were based on the 2007 Joint Statement and therefore, it would be important to keep this reference and also the reference to the Code, as well as related WHA resolutions on infant and young child feeding. These would be very relevant and important and should be included in the footnote.

Conclusion

122. The Committee agreed to:
- i. Forward the Guidelines for Ready-to-Use Therapeutic Foods to Step 5 for adoption by CAC43 (Appendix VI); and
 - ii. Send the labelling provisions to CCFL for endorsement; and
 - iii. Send the food additive provisions to CCFA for endorsement (Appendix VI Table A).

TRANS-FATTY ACIDS¹⁴**PROPOSED DRAFT CLAIM FOR “FREE OF” TRANSFATTY ACIDS (Agenda Item 6a)****DISCUSSION PAPER ON RISK MANAGEMENT POSSIBILITIES FOR THE REDUCTION OF TFAs (Agenda Item 6b)**

123. Canada introduced the item, recalled the history of discussions in CCNFDU on the condition for a claim for “free of” trans fatty acids (TFA) and outlined the approach taken in developing the discussion paper. She proposed that the committee first consider the Codex risk management roles associated with: options C (prohibiting partially hydrogenated oils (PHO)); E (mandatory declaration of TFA on food labels); and G (mandatory distinct declaration of PHO and fully hydrogenated oils in ingredient lists), as these would require amendments to existing standards developed by CCFL and Codex Committee on Fats and Oils (CCFO), which could be completed in a timely manner.
124. The Committee agreed to consider the recommendations as outlined in CX/NSDU 19/41/7 Rev.

¹⁴ REP19/NFSDU, Appendix VII; CX/NFSDU 19/41/7; CRD12 (Indonesia, Kenya, Senegal, IMACE); CRD25 (Thailand); CRD26 (IDF); CRD28 (EU); CRD32 (Nigeria)

Discussion

125. One Member Organization pointed out that following an in-depth impact assessment in 2018, it was concluded that a legal limit for the presence of industrially manufactured TFA in food performed best and a 2% maximum limit in this regard had been established subsequently. It was further suggested that both option B (adopting regulations that limit TFA levels in processed food) and option C (prohibiting partially hydrogenated oils) could mitigate the TFA intake level. Option E (i.e. adopting regulations related to the mandatory declaration of TFA on labels of prepackaged processed foods) was neither cost-effective nor efficient since foods in bakeries and street food which might contain high TFA contents would not normally be labelled. As potential role for Codex to support member countries, most risk management options (4 out of 7) referred to CCMAS to provide advice on reference methods for TFA analysis. Options B and C referred to CCFO and to amend commodity standards to include trans-fat limits and possibly a PHO ban.
126. One Member pointed out that they could not support option E (i.e. amending the *Guidelines on Nutrition Labelling* (CXG 2-1985)) as this matter had already been considered by CCFL, and that the declaration of trans-fatty acids in nutrition labelling had already been included in footnote 6 of the *Guidelines on Nutrition Labelling* (CXG 2-1985).
127. The Committee noted the support for option A, option B and/or option C expressed by other Members.
128. The Representative of WHO expressed WHO's appreciation to the comprehensive analysis done by Canada on risk management possibilities within the Codex mechanism. As also reiterated in Agenda item 3, the elimination of industrially produced TFA by 2023 was WHO's target and scaled-up actions had been undertaken by WHO and its partners since last year. In this context, WHO was encouraging countries to implement mandatory TFA limitation (described as risk management option B) and PHO ban (described as risk management option C) which WHO considered as the best practice regulatory actions for eliminating industrially produced TFA. Therefore, WHO supported proposed actions by CCFO as suggested by Canada in the document CX/NFSDU 19/41/7-Rev.
129. The Representative further stated that WHO would also support the risk management option E which is to request CCFL/CCNFSDU to make TFA a mandatory nutrient to be declared in nutrient declaration. Unfortunately, TFA was not included in the mandatory nutrients to be declared when total sugars, saturated fatty acids and sodium became the mandatory nutrients to be declared as various countries indicated the lack of TFA data was one of the obstacles in making TFA declaration as mandatory. Therefore, the resolution was to note in a footnote in the *Guidelines on Nutrition Labelling* (CXG2 – 1985) as an option for countries where the intake level of TFA is a public health concern to implement the declaration of TFA. She pointed out that presently many more countries had TFA data. For example, within the last year, approximately 20 countries had conducted TFA assessments in their food supplies as part of accelerated efforts in eliminating industrially produced TFA by 2023. So the situation was different today and TFA data were available in many more countries.
130. With regards to the comments to seek advice from CCMAS on suitable reference methods of analysis regarding TFA, it was explained that the request was relevant to possible work on labelling which was not under the mandate of CCNSFDU.

Conclusion

131. The Committee agreed:
 - i. To discontinue work on the claim for "free" of TFAs and to inform CCEXEC79 and CAC43 accordingly;
 - ii. To inform:
 - CCFL of the Committee's decision to discontinue the work on the condition for a claim for "free" of TFAs and to consider possible actions in CCFL;
 - CCFO of the Committee's discussions, and to consider work in CCFO on possible ways to reduce TFAs or eliminate PHOs.
 - iii. That any member could make proposals to other Codex committees for new work to address the issue of TFAs and could take necessary actions at the national level taking into account the work of WHO.

PROPOSED DRAFT DEFINITION FOR BIOFORTIFICATION (Agenda Item 7)¹⁵

132. The Committee recalled the decision of CCNFSDU40 and the view of CCFL45 and highlighted the recommendation of CCEXEC77 i.e. to clarify how a definition would be useful in the context of Codex work and to consider discontinuation of this work if no use was identified (see agenda item 2).
133. Zimbabwe, as the previous Chair of the EWG, speaking also on behalf of the previous co-Chair South Africa, introduced the history of the discussions, explained that extensive work had been undertaken and that the purpose of biofortification was to solve the problem incurred by micronutrient deficiency. He reiterated the importance of the definition in particular for developing countries and proposed possible approaches for the use of a definition e.g. in WHO documents (noting that WHO was possibly working on a definition for biofortification), or in Codex commodity committees such as the Codex Committee on Cereals, Pulses and Legumes (CCCPL).
134. An Observer drew the Committee's attention to questions relating to: (i) whether biofortification fell within "fortification" as contained in the *General Principles for the Addition of Essential Nutrients to Foods* (CXG 9-1987); (ii) to consider definitions of the three methods i.e. "agronomic fortification", "fortification using conventional breeding techniques" and "fortification using the techniques of modern biotechnology" were acceptable; (iii) whether "addition" in the context of the nutrition texts of commodity standards should be defined and whether biofortification could be considered as an "addition"; and (iv) whether this matter could be referred to CCCPL for its consideration on the possibility to add a section in their standards regarding the nutrient profiles.
135. She also informed that a potential location for biofortification in Codex texts could be an amendment to the *Codex Principles for the Addition of Essential Nutrients* (CXG 9-1987) to include the addition of essential nutrients to foods by indirect methods, including biofortification.
136. The Committee noted: (i) that when this item was first considered by CCNFSDU34 (2012), there were no explanations on different types of biofortification; as well as whether they should be included in the *General Principles for the Addition of Essential Nutrients to Foods* (CXG 9-1987); and (ii) the view of an Observer, that while biofortification of foods could be beneficial, a much larger problem existed from the significant decline in nutritional content of existing farm produce due to poor agricultural practices in both developed and developing countries; and that this should be addressed.
137. In response to a question about the recent work of WHO on biofortification, the Representative of WHO noted that if the question was referring to the 2016 WHO/FAO technical consultation held in New York and the publication of a series of background papers which were prepared for the consultation, as previously informed to the Committee, it was not a guideline development meeting and therefore did not develop any recommendations. The Representative further noted that there was a description of biofortification of staple foods in the WHO e-Library of Evidence for Nutrition Actions (eLENA). It originated from the fortification work done in 2006 and was updated with the information from the 2016 WHO/FAO technical consultation. At present WHO was not planning to undertake any further work on biofortification.

Conclusion

138. The Committee agreed to discontinue the work and to inform CCEXEC79 and CAC43 accordingly. The Committee noted that any member could, in future, present a proposal for work in this field to any other Codex Committee taking into account the work and conclusion of CCNFSDU.

DISCUSSION PAPER ON NRVs-R FOR OLDER INFANTS AND YOUNG CHILDREN (Agenda Item 8)¹⁶

139. Ireland, chair of the EWG, introduced the item, and highlighted the work of the EWG and its key recommendations.
140. She explained that seven recommendations were being put forward for consideration by the Committee, and that there was clear support for recommendations 1, 3, 5 and 6 in the EWG, but that recommendations 2, 4 and 7 had generated mixed feedback and required more detailed discussion by the Committee.

¹⁵ REP19/NFSDU, Appendix VI; CRD5 (IFPRI); CRD13 (EU); CRD21 (Republic of Korea); CRD35 (India); CRD36 (Russian Federation); CRD45 (Lao People's Democratic Republic)

¹⁶ CX/NFSDU 19/41/8; CRD14 (Indonesia, Senegal); CRD21 (ROK); CRD25 (Thailand); CRD28 (EU)

Discussion

Recommendation 1 (age ranges)

141. The Committee noted that the proposed age ranges for harmonisation of definitions for older infants would remove the concept of “infants” in four Codex texts, which would be replaced with a new concept of older infants that was only used so far in the *Guidelines on formulated complementary foods for older infants and young children* (CXG 8 – 1991) and in the draft version of the revised *Standard for follow-up formula* (see Agenda item 4). The preference was therefore to maintain the established concepts and not to create new terminology. It was noted that in all other relevant Codex texts, infants were considered to be persons of not more than 12 months of age.
142. The Chair of the eWG explained that when considering recommendations from FAO/WHO and other Recognized Authoritative Scientific Bodies (RASBs), different age ranges were used, and it was necessary to clearly define the age ranges for which the work on NRVs was intended.

Conclusion

143. The Committee therefore agreed that NRVs would be developed for persons from 6 months to not more than 12 months and persons from more than 12 months to 36 months (from 1 day after the 1st birthday to day of the 3rd birthday).

Recommendations 2 and 4

144. A Member Organisation expressed the view that establishment of NRVs-R in the *Guidelines on Nutrition Labelling* might introduce uncertainties for nutrition labelling of certain foods that could be considered as foods for special dietary use and that locating the NRVs-R in these guidelines could lead to the creation of a new product category at the Codex level. The NRVs-R should be established for the age groups agreed under recommendation 1 for voluntary micronutrient declaration under the conditions to be determined within the frame of each of the texts for the 4 standards: i) processed cereal-based foods for infants and young children; ii) canned baby foods; iii) formulated complementary foods for older infants and young children, and iv) follow-up formula for older infants; and located in these standards and guidelines. This was supported by some Members.
145. Other Members expressed support to locate the NRVs-R in the *Guidelines on Nutrition Labelling* as the other NRV-Rs were already located in these guidelines; and that NRVs-R should apply to general foods for young children. These members explained that in their countries there were already products targeted at young children that were not foods for special dietary use and that these foods would benefit from NRVs for the purpose of labelling to guide appropriate choices by consumers.

Conclusion

146. The Committee agreed that the general principles for the establishment of NRVs-R for the identified age groups would be established in the *Guidelines on Nutrition Labelling* and that once the NRVs-R were established consideration should be given to how they were presented in the *Guidelines on Nutrition Labelling* in order to clarify to which foods these would apply to.

Recommendation 5 and 6

147. The Committee agreed to add potassium to the list for which NRV-Rs would be established.
148. The Committee noted the diverse views expressed, and agreed to include protein in the list of nutrients to be considered for deriving NRVs-R, but giving it low priority.

Project Document

149. The Committee considered the revised project document, noted the changes made and agreed to the revised timeline.

Conclusion

150. The Committee agreed:
- iv. to continue its work on NRVs-R for persons aged 6 to 36 months following the work programme as spelt out in the revised project document (Appendix VII);
 - v. to inform CCEXEC79 of the revised timeline for completion of work;
 - vi. to establish an EWG, chaired by Ireland, and co-chaired by Costa Rica and the United States of America, working in English and Spanish, to develop general principles to guide the establishment of NRVs-R for persons aged 6 to 36 months that describe:

- a. the most appropriate approach to derive NRVs-R, based on an analysis of Dietary Intake Reference Values (DIRVs) from FAO/WHO and the 6 RASBs; and
- b. the purpose(s) of these NRVs-R for labelling and, if appropriate, for composition for *Guidelines on Formulated Complementary Foods for Older Infants and Young Children*;

The EWG should take into account discussions at CCNFSDU41.

151. The Committee also noted there would be a need for scientific advice which would focus on how the requirements for each of the 24 nutrients were derived by FAO/WHO and 6 RASBs and evaluate and rank these nutrient requirements based on quality of evidence to help inform the work of the Committee.

MECHANISM/Framework FOR CONSIDERING THE TECHNOLOGICAL JUSTIFICATION OF FOOD ADDITIVES (Agenda Item 9a)¹⁷

152. The European Union, chair of the PWG that met immediately prior to the session, speaking also on behalf of the co-Chair, the Russian Federation, introduced the item, explained the discussions in the PWG, presented the decisions of the PWG and highlighted that the PWG had reached consensus on all the tasks assigned with the exception of the technological justification of gellan gum (INS 418) which had to be decided on by the plenary.
153. The Committee considered the PWG recommendations (as contained in CRD2), took decisions and made comments as follows:

Recommendation 1: Q3.1 of the framework

154. The Committee endorsed the recommendation regarding Q3.1 as follows:

“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?”

Recommendations 2 and 3: Appraisal of the technological need for xanthan gum (INS 415) and pectins (INS 440)

155. The Committee endorsed the recommendations that:
 - the use of xanthan gum (INS 415) as a thickener in formulas for special medical purposes intended for infants at the maximum level (ML) of 0.1g/100mL, limited to powdered hydrolysed protein and/or amino acid-based formula, is technologically justified; and
 - the use of pectins (INS 440) as a thickener in formulas for special medical purposes intended for infants at the ML of 0.2g/100mL, limited to liquid infant formula containing hydrolysed protein is technologically justified.

Recommendation 4: Appraisal of the technological need for gellan gum

156. The Committee noted that: (i) the additive for appraisal was low-acyl clarified gellan gum; (ii) additional information in response to the questions raised at the PWG meeting had been provided by the applicant (CRD44); and (iii) the eighty-seventh meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) had completed the safety evaluation for the substance and concluded there were no safety concerns under the intended conditions of use, and the specifications were assigned as “tentative”.
157. The Committee was reminded to focus its discussions on the technological justification rather than safety aspects which were outside the scope of CCNFSDU.
158. Delegations expressed divergent views on whether sufficient information had been provided on the technological justification for use of the additive in CXS72-1981.
159. Some delegations proposed to defer the consideration of this matter to the next session as more time would be required in order to analyse the additional information provided; others were of the view that the information provided by the applicant was sufficient to justify the technological need as there was an advantage by enabling a lower use level of the additives in formulas for special medical purposes for infants.

¹⁷ REP19/NFSDU, Appendix VIII; CX/NFSDU 18/40/11; CRD2 (Report of the PWG on the Mechanism/framework for considering the technological justification of food additives); CRD8 (EU); CRD36 (Russian Federation); CRD44 (ISDI)

160. In response to a question relating to the inconsistency of information provided, the applicant confirmed that the substance was used in hydrolysed protein and/or amino acid-based formula in liquid form rather than powdered form (CRD18).
161. The Committee agreed to request the applicant to provide more information on the substance in particular its advantages over currently permitted food additives (i.e. Q3 of the framework).

Others

Inclusion of xanthan gum (INS 415) and pectins (INS440) in CXS 72-1981

162. Following the conclusion on the technological need for xanthan gum (INS 415) and pectins (INS 440), the Committee considered the recommendations referred by the forty-ninth Session of the Codex Committee on Food Additives (CCFA) pertinent to the inclusion of the two food additives in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981).
163. In light of the fact that the table of food additives in CXS 72-1981 was located in Section A (i.e. infant formula), although these food additives should exclusively be permitted for use in section B (i.e. formulas for special medical purposes intended for infants), the Committee agreed to continue with the current practice i.e. listing these two food additives in Section A of CXS 72-1981, noting that this issue would be corrected through the alignment work.

Appraisal of the technological need for the relevant food additives in CRD15rev of CCFA49

164. One Member Organization, noting that there were additives in CXS 72-1981 for which no appropriate safety assessment for infants (below 12 weeks of age) had been undertaken by JECFA, proposed to initiate a review of technological justifications of additives in CRD15rev of CCFA49 by using the new framework, and to start with the food additives with an ADI specified. The Member Organization further proposed the process to implement this exercise i.e. to set a deadline to collect information, to review the information and to provide recommendations for consideration by the Committee.
165. An Observer supported the proposal and expressed the need to receive sufficient time in order to allow them to consult with their members and generate the required information.

Conclusion

166. The Committee agreed to:
- publish the document titled “CCNFSDU framework for appraising the technological need” as an information document on the Codex website (Appendix VIII Part A);
 - forward to CAC43 for adoption the provisions for xanthan gum (INS 415) and pectins (INS 440) as thickeners in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants*, (CXS 72-1981) (Appendix VIII Part B); and
 - inform CCFA of the aforementioned decisions and request CCFA to include xanthan gum (INS 415) and pectins (INS 440) in food category 13.1.3 “Formulae for special medical purposes for infants” of the *General Standard for Food Additives* (CXS 192-1995).
167. The Committee further agreed to establish an EWG, chaired by the European Union and co-chaired by the Russian Federation, working in English with the following terms of reference:
- to collect information from the applicants on the following additives: low acyl clarified gellan gum, ascorbyl palmitate (INS 304), mixed tocopherol concentrates (INS307b) and phosphates (INS 339(i), 339 (ii) and 339(iii) and INS 340(i), 340(ii), and 340(iii)) with the framework for considering technological justifications for use in CXS 72-1981; and
 - to review the information provided by the applicants and provide recommendation to the Committee on the technological justification of each additive.

ALIGNMENT OF FOOD ADDITIVE PROVISIONS IN CCNFSDU STANDARDS WITH THE GSFA (Agenda Item 9b)¹⁸

168. Germany introduced the document and explained how the principles for alignment in the guidance document developed by CCFA had been applied for its elaboration.
169. The Chairperson noted that the document would form the basis for further discussion by CCFA. She explained that before forwarding the document to CCFA, the Committee should consider the minimum requirements for alignment (i.e. correct name of each food additive, INS numbers, functional class, and food category).
170. Delegations expressed their appreciation to Germany for the extensive work performed to prepare the document and supported its submission to CCFA for continuation of the alignment work.
171. The Committee agreed that "phosphoric acid (INS 338)", which had been inadvertently omitted, would be included in Part C of the document (i.e. the *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CXS 74-1981)).

Conclusion

172. The Committee agreed to forward the document with the correction as indicated in para 171 for consideration by CCFA.
173. With regard to the questions from CCFA51 relating to the appropriate food additive provisions and MLs for the *Standard for Formula Foods for Use in Weight Control Diets* (CXS 181-1991) and the *Standard for Formula Foods for Use in very Low Energy Diets for Weight Reduction* (CXS 203-1995) (see agenda item 2), the Committee agreed to inform CCFA that the food additive provisions of the GSFA, in particular those for the food category 13.4 and those of Table 3, are applicable to foods conforming to the two standards

PRIORITIZATION MECHANISM TO BETTER MANAGE THE WORK OF CCNFSDU (Agenda Item 10)¹⁹

174. Germany as host Secretariat introduced the item and recalled that CCEXEC75 requested CCNFSDU to consider a prioritization mechanism to better manage its work. CCNFSDU40 agreed to request the host Secretariat to prepare a discussion paper addressing the concerns of CCEXEC. The discussion paper put forward a number of proposals for CCNFSDU to better manage its work: a uniform approach on submission of work proposals; additional prioritisation criteria besides what is set out in the Procedural Manual; use of a circular letter to collect new work proposals; and establishing an ad-hoc working group to review submitted work proposals.

Discussion

175. The Committee welcomed the discussion paper along with the various proposals and approach put forward on work management and noted the following comments made by delegations:
 - a. A prioritisation mechanism would support in the selection of its work; and allow for establishing long-term planning and work management of the Committee.
 - b. The criteria for the establishment of work priorities of the Codex Procedural Manual provide a robust starting point for establishing a mechanism for CCNFSDU; and this should be the starting point when setting additional requirements.
 - c. The prioritisation mechanism should include: i) collection of new topics and the preparation of a summary document; ii) a meeting to review and prioritise the proposals. Beside submitting new work or identifying new topics, the process should also consider how members should take forward or progress such topics.
 - d. The prioritisation process/framework should be simple and not very burdensome. Some aspects of the proposed mechanism e.g. decision tree would need clarification and review.
 - e. A framework for identification of emerging issues (topics) should also be considered or included as part of CCNFSDU work management;
 - f. A pilot phase should be encouraged and undertaken to try out the mechanism.
 - g. In-session working group to review the proposals and prioritise the proposals would be more sustainable and preferable than holding a physical working group as it would also ensure a higher level of participation.

¹⁸ CX/NFSDU 19/41/9; CRD25 (Thailand); CRD35 (India); CRD40 (ISDI)

¹⁹ CX/NFSDU 19/41/10; CRD15 (CRN, IADSA); CRD21 (ROK); CRD22 (Canada); CRD25 (Thailand); CRD32 (Nigeria)

- h. The availability or the need to request scientific advice may not have a direct link with the prioritisation as some work with highest priority may require extensive scientific advice yet the resources may not be available.

Conclusion

176. The Committee agreed to:

- i. The prioritisation mechanism (Appendix IX) and to start it on a pilot basis to assess its usefulness. The framework for prioritisation, after review by the PWG and finalisation by the Committee, would be published as an information document on the Codex website for internal use by the Committee.
- ii. Inform CCEXEC that it would be piloting a prioritisation process in line with its request.
- iii. Request the Secretariat to issue a Circular Letter (CL) requesting emerging issues and proposals for new work; and
- iv. Hold a physical working group, chaired by Germany, working in English, French and Spanish, meeting immediately prior to the next session with the following terms of reference:
 - a. Adjust the draft framework as necessary of the prioritization mechanism outlined in the draft guideline for the preliminary assessment and identification of work priorities for CCNFSDU with regard to simplification of the criteria and the process.
 - b. Conduct a case-by-case review of the proposals submitted by the members in response to the CL requesting members and observers to provide information on emerging issues or proposals for new work.

DISCUSSION PAPER ON HARMONIZED PROBIOTIC GUIDELINES FOR USE IN FOODS AND DIETARY SUPPLEMENTS (Agenda Item 11)²⁰

177. Argentina introduced the item and highlighted that the proposed new work aimed at developing an appropriate international framework or harmonised guidelines for probiotics for the use in foods and dietary supplements that would facilitate trade as well as ensure safety to protect the health of consumers. Probiotics were produced and traded globally as live cultures for use as ingredients in foods or dietary supplements. The proposed new work was expected to support national legislative frameworks; and provide a general understanding through setting a definition, minimum characterization requirements, safety criteria, quality and labelling criteria.

Discussion

178. Delegations in support of CCNFSDU initiating new work on the topic, highlighting the need for such a guideline, noted that the guidelines could be established taking into account existing FAO and WHO definitions and guidelines; and that such guidelines should provide high level guidance and principles; should focus on the use of probiotics as ingredients; and should address the need for regulatory harmonisation
179. Delegations opposed to initiating new work, noted that many of the provisions suggested in the draft discussion paper were already addressed by other Codex standards and guidelines. For example, Codex has adopted principles and horizontal guidelines on labelling, claims, contaminants, safety and hygiene covering all foods, including supplements. Therefore, undertaking the work could risk creating significant duplication, by repeating in a vertical guideline what has already been agreed.
180. These delegations were of the view that FAO and WHO have already undertaken work in this area including establishing a definition for probiotics, and the definition was already widely used as a basis for regulating probiotics and there was no need to use Codex resources to address these issues again.
181. An Observer noted that it had conducted a survey among its members and that it had not identified any trade barriers for the trade of probiotics as food supplements.
182. While responding to the concern whether dietary supplements were covered under the scope of CCNFSDU, the Codex Secretariat clarified that Codex previously elaborated "*Guidelines for Vitamin and Mineral Food Supplements (CXG 55-2005)*" and that they apply only in those jurisdictions where such products as defined in the guideline were regulated as foods (Section 2.1 of the Guidelines).
183. Some delegations confirmed that in their countries dietary supplements including probiotics were regulated under food.

²⁰ CX/NFSDU 19/41/11; CRD16 (Indonesia, CRN, IADSA, IPA, YLFA); CRD21 (ROK); CRD25 (Thailand); CRD32 (Nigeria); CRD35 (India); CRD36 (Russian Federation) ; CRD 39 (Malaysia)

184. The Committee noted that the paper along with the proposed project document needed further clarification especially with regard to the scope and identification of the gaps that needed to be addressed.

Conclusion

185. The Committee agreed that the proposal could be submitted in accordance with the prioritization mechanism (see Agenda item 10) for consideration by the WG on prioritization. The Committee noted the offer of Argentina and Malaysia to prepare a revised proposal.

DISCUSSION PAPER ON GENERAL GUIDELINES TO ESTABLISH NUTRIENT PROFILES (Agenda Item 12)²¹

186. The Chairperson introduced the agenda item recalling that CCFL44 had informed CCNFSDU about new work on front of pack nutrition labelling (FOPNL) and had asked CCNFSDU to consider how it could contribute.
187. Costa Rica presented the item noting that current Codex texts did not contain any information on the establishment of nutrient profiles which were used on the FOPNL. As regards nutrient profiles for use for front of pack labelling, Costa Rica underlined the need to provide harmonised guidance for nutrient profiles based on scientific evidence and suggested a course of action for the Committee in establishing an EWG to analyze the discussion paper and to define a scope for the development of guidelines to establish nutrient profiles for FOPNL.

Discussion

188. The Committee noted that it would be useful to have guidance in order to establish nutrient profiles for the use in FOPNL and that this guidance would be complementary to the work in CCFL on front of pack nutrition labelling.
189. Regarding the work carried out so far and presented in CX/NFSDU 19/41/12, delegations made the following observations:
- the scope of the work needs to be clearly defined also to ensure that it does align well with the CCFL work;
 - the link between nutrient profile models and front of pack labelling needs to be clarified;
 - it is important to recognize the significance of nutrient profiling, and much work available is based on a large body of science;
 - the work could result in guidelines which would also be useful for health claims and an important tool for general health guidelines;
 - general guidelines for establishing science-based nutrient profiles together with the progression of work on the front of pack nutrition labelling guidelines at CCFL will provide a common set of guidelines for countries and other stakeholders to use when developing the profiles to support their labelling systems.
190. The Codex Secretariat advised that due to the proximity of the upcoming sessions of both CCFL and CCNFSDU in 2020 (October and November, respectively), there would a need for close coordination with the chairpersons of the EWGs on FOPNL.
191. The Representative of WHO noted that, if the Committee through the EWG intended to work on the principles for developing general guidelines for establishing nutrient profiles, then, it needed to take into consideration the work of CCFL as the nutrient profile is a tool for supporting the development of front of pack labelling, and the nutrient profile should not pre-empt the guidance on the types of front of pack labelling.

Conclusion

192. The Committee agreed:
- a. to establish an EWG, chaired by Costa Rica and co-chaired by Paraguay, the EU and the United States of America, working in Spanish and English with the following terms of reference:
 - i. Analyse document CX/NFSDU 19/41/12 ; and
 - ii. Develop a discussion paper and project document which defines the scope for developing general guidelines for the establishment of nutrient profiles for use in front of pack nutrition labelling.

²¹ CX/NFSDU 19/41/12; CRD17 (Senegal and ISDI); CRD25 (Thailand); CRD32 (Nigeria); CRD33 (Dominican Republic); CRD34 (European Union); CRD36 (Russian Federation); CRD42 (Mexico); CRD46 (Nicaragua)

- b. to inform CCFL of the ongoing discussion in CCFNSDU and to ask CCFL to what extent the work concerning nutrient profiles in CCFNSDU can support the work of CCFL on FOPNL and to what extent it is taken into account:

OTHER BUSINESS AND FUTURE WORK (Agenda Item 13)²²

Methods of analysis

193. The United States of America introduced the report of the in-session working group (CRD52) and highlighted the recommendations of the WG.

194. The Committee considered the recommendations and took the following decisions:

Dietary fibre: Applicable to the *Guidelines for Use of Nutrition and Health Claims (CXG 23-1997): Table of Conditions for Claims*

195. The Committee noted a concern expressed by a Member Organization that the method was intrinsically linked to the condition for a claim in the *Guidelines for Use of Nutrition and Health Claims* and should be considered more closely, and in case concerns were raised at CCMAS it should be referred back to CCFNSDU.

196. The Committee agreed to submit to CCMAS the method for dietary fibre, ICC Standard No. 185 / AOAC 2017.16 / as Type I method to replace AOAC 2009.01 / AACC Intl 32-45.01.

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

197. The Committee agreed to:

- submit the methods to CCMAS for review, endorsement as Type II and inclusion in CXS 234-1999:
 - i. AOAC 2015.14 / ISO DIS 21470 for thiamine, riboflavin, niacin, vitamin B₆;
 - ii. AOAC 2015.10 / ISO DIS 21468 for choline and carnitine;
 - iii. AOAC 2016.13 / ISO 23443 for beta-carotene and lycopene;
 - iv. AOAC 2016 17 / ISO DIS 22579 | IDF 241 for fructans;
 - v. AOAC 2016.02 / ISO DIS 23305 for biotin.
- request CCMAS to re-type the existing Type II methods for aforementioned nutrients as Type III in CXS 234-1999; and
- inform CCMAS that it could include AOAC 2011.14 / ISO 15151 | IDF 229 for calcium, copper, iron, magnesium, manganese, phosphorous, potassium, sodium and zinc as Type III in CXS 234-1999.

Microbiological methods

198. The Committee agreed to inform CCMAS that the microbiological methods for nicotinamide, niacin, pantothenic acid, pyridoxine, cobalamin, and Vitamin D were still in use and to retain these methods.

Methods of analysis for provisions in the *Standard for Follow-Up Formula (CXS 156 -1987)*

199. The Committee agreed to inform CCMAS to replace AOAC 999.15 / EN 14148 for vitamin K with AOAC 2015.09 / ISO 21446 as Type II.

New work proposal on establishing harmonized guidelines for the qualification of nutrition and health claimed food

200. The Committee noted the proposal of Republic of Korea for new work on establishing harmonized guidelines for qualification of nutrition and health claimed food and agreed that the proposal should be resubmitted in accordance with the prioritization mechanism (see agenda item 10) for consideration by CCFNSDU42.

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

201. The Committee was informed that the 42nd session was scheduled to be held from 23 to 27 November 2020, the final arrangements being subject to confirmation by the host government in consultation with the Codex Secretariat.

²² CRD6 (ICC); CRD7 (USA); CRD20 (ROK); CRD30 (ISDI)

APPENDIX I

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LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES**

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APPENDIX II

**REVIEW OF THE STANDARD FOR FOLLOW UP FORMULA:
SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS
(At Step 7)**

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 food additives shall 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 g or per 100 ml of the food as sold as well as ~~€~~ per 100 ml 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 g or per 100 ml of the food as sold as well as per 100 ml 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 (kcal) (or per 100 kilojoules kJ) is permitted.

9.4 Date Marking and Storage Instructions

9.4.1 The date marking and storage instructions shall be in accordance with section 4.7 of the *General Standard for the Labelling of Prepackaged Foods*.

9.4.2 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 preparation 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 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 suggests 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 Follow-up formula for older infants shall be distinctly labelled in such a way as to avoid any risk of confusion with Infant Formula, Drink/Product for young children with added nutrients or Drink for young children, and Formula for Special Medical Purposes intended for infants, in particular as to the text, images and colours used, to enable consumers to make a clear distinction between them.

9.6.5 The labelling of follow-up formula for older infants shall not refer to infant formula, Drink/Product for young children with added nutrients or Drink for young children, or formula for special medical purposes intended for infants, including numbers, text, statements, or images of these products.

APPENDIX III

**REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CXS 156-1987):
DRAFT ESSENTIAL COMPOSITION AND QUALITY FACTORS –
(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) ¹as 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.

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.

b) Lipids**Total Fat** ^{7), 8)}

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

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

⁸⁾ Lauric acid and myristic acid 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 all-trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

Vitamin D

Unit	Minimum	Maximum	GUL
µg 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

Niacin¹⁴⁾

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

¹⁴⁾ Niacin refers to preformed niacin

Vitamin B₆

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

Vitamin B₁₂

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 C¹⁵⁾

Unit	Minimum	Maximum	GUL
mg /100 kcal	10	-	70 ¹⁶⁾

mg /100 kJ	2.4	-	17 ¹⁶⁾
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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

Iron¹⁷⁾

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

¹⁷⁾ For follow-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

Copper¹⁹⁾

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.

Zinc²⁰⁾

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) applies.

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 of their population.

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 acid-producing cultures

Only L (+) lactic acid-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: DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR DRINK FOR YOUNG CHILDREN

3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential composition

- 3.1.1 The product as defined in Section 2.1 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 the product as defined in Section 2.1 shall be scientifically demonstrated to support growth and development of young children.
- 3.1.2 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than 60 kcal (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.
- 3.1.3 The product as defined in Section 2.1 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.

b) Lipids⁴⁾

Total fat

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

⁴⁾ Partially hydrogenated oils and fats shall not be used in the product as defined in Section 2.1.

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 the product as defined in Section 2.1 should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of the product as defined in Section 2.1 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.

α -Linolenic acid

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

Linoleic acid

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

c) Carbohydrates**available carbohydrates⁵⁾**

Unit	Minimum	Maximum ⁶⁾	GUL
g /100 kcal	-	12.5	-
g /100 kJ	-	3.0	-

⁵⁾ Lactose should be the preferred carbohydrate in the product as defined in Section 2.1 based on milk protein.

For products based on non-milk protein, carbohydrate sources that have no contribution to sweet taste should be preferred and in no case be sweeter than lactose.

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.

⁶⁾ For the product as defined in Section 2.1 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
μ g RE ⁷⁾ /100 kcal	60	180	-
μ g RE ⁷⁾ /100 kJ	14	43	-

⁷⁾ expressed as retinol equivalents (RE)

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

Vitamin D⁸⁾

Unit	Minimum	Maximum	GUL
μ g ⁹⁾ /100 kcal	1.5	4.5	-
μ g ⁹⁾ /100 kJ	0.36	1.1	-

⁸⁾ Competent national and/or regional authorities may deviate from the conditions as appropriate for the nutritional needs of their population.

⁹⁾ Calciferol. 1 μ g calciferol = 40 IU Vitamin D.

Riboflavin

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

Vitamin B₁₂

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

Vitamin C¹⁰⁾

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

¹⁰⁾ expressed as L-ascorbic acid

e) Minerals and Trace Elements**Iron¹¹⁾**

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

¹¹⁾ For the product as defined in Section 2.1 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 the product as defined in Section 2.1.

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 the product as defined in Section 2.1 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.

3.2.2 When any of these ingredients or substances is added the product as defined in Section 2.1 shall contain sufficient amounts to achieve the intended effect.

3.2.3 Additional nutrients may also be added to the product as defined in Section 2.1 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.

3.2.4 Ingredients shall not be added with the purpose of imparting or enhancing a sweet taste of the product as defined in Section 2.1.

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

SECTION B

(at Step 5)

SECTION B: DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR DRINK FOR YOUNG CHILDREN

1 SCOPE

- 1.1 This section of the Standard applies to the product 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 the product as defined in Section 2.1.
- 1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard shall be presented as the product defined in Section 2.1.

2 DESCRIPTION

2.1 Product Definition

- 2.1.1 **Drink/product for young children with added nutrients or Drink for young children** means a product manufactured for use as a liquid part of the diversified diet of young children [which may contribute to the nutritional needs of young children]¹
- 2.1.2 **Drink/product for young children with added nutrients or Drink for young children** 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 *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 the product as defined in Section 2.1. 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 ““Drink/Product for Young Children with Added Nutrients” or “Drink 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 “Drink/Product for Young Children with Added Nutrients Based on [name of animal] milk protein” or “Drink 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 “Drink/Product for Young Children with Added Nutrients Based on [name of plant] protein” or “Drink for Young Children Based on [name of plant] protein”.

¹ In some countries these products are regulated as breast-milk substitutes.

c) if [name of animal] milk and [name of plant] are the sources of proteins*, the product may be labelled "Drink/Product for Young Children with Added Nutrients Based on [name of animal] milk protein and [name of plant] protein" or "Drink for Young Children Based on [name of animal] milk protein and [name of plant] protein" or "Drink/Product for Young Children with Added Nutrients Based on [name of plant] protein and [name of animal] milk protein" or "Drink 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 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 food additives shall 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 the product as defined in Section 2.1 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 g or per 100 ml of the food as sold {as well as} {per} per 100 ml 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 g or per 100 ml of the food as sold {as well as} {per} per 100 ml 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 (kcal) (or per 100 kilojoules) (kJ) and/or per serving size, provided that the serving size is quantified on the label, is permitted.

9.4 Date Marking and Storage Instructions

9.4.1 The date marking and storage instructions shall be in accordance with section 4.7 of the *General Standard for the Labelling of Prepackaged Foods*.

9.4.2 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 preparation 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 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 the product as defined in Section 2.1 shall include a statement that the product shall not be introduced to infants 12 months of age or less, and is not to be used as a sole source of nutrition.

9.6 Additional Labelling Requirements

- 9.6.1 The label of the product as defined in Section 2.1 shall have no image, text or representation, including pictures of feeding bottles, that could undermine or discourage breastfeeding or which idealises the use of the product as defined in Section 2.1. The terms 'humanized', 'maternalized' or other similar terms must not be used on the label.
- 9.6.2 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:
- a) the statement "Breastfeeding is recommended up to two years and beyond."
 - b) a statement that the mother/caregiver should seek advice of a health worker on proper feeding of the young child.
- 9.6.3 The label shall have no pictures of infants, older infants, young children and women or any other picture, text, or representation that:
- 9.6.3.1 undermines or discourages breastfeeding; or that makes a comparison to breast-milk, or suggests that the product is similar, equivalent to or superior to breast-milk;
 - 9.6.3.2 might 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
- 9.6.4 The product as defined in Section 2.1 shall be distinctly labelled in such a way as to avoid any risk of confusion with infant formula, follow-up formula for older infants, and formula for special medical purposes intended for infants, in particular as to the text, images and colours used, to enable consumers to make a clear distinction between them.
- 9.6.5 The labelling of the product as defined in Section 2.1 shall not refer to infant formula, follow-up formula for older infants, or formula for special medical purposes intended for infants, including numbers, text, statements, or images of these products.

APPENDIX V

REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA:

Remaining sections for Sections A and B

(at Step 4)

[Section A: Follow up formula for older infants**3.3 Purity requirements****3.3.1 General**

All ingredients shall be clean, of good quality, safe and suitable for ingestion by [older] infants. ~~from the 6th month on and young children.~~ They shall conform with their normal quality requirements, such as colour, flavour and odour

3.3.2 Vitamin Compounds and Mineral Salts (Recommendation 4a)

3.3.2.1 Vitamin compounds and mineral salts used in accordance with Sections 3.3.1 and 3.3.2 should be selected from the *Advisory List for Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children* approved by the Codex Alimentarius Commission (CXG 10-1979).

3.3.2.2 The amounts of sodium derived from vitamin and mineral ingredients shall be within the limit for sodium in Section 3.1.

3.4 Consistency and Particle Size

When prepared according to the directions of use, the product shall be free of lumps and of large, coarse particles.

3.5 Specific prohibitions

The product and its components shall not have been treated by ionizing radiation.

4. Food additives

The following additives are permitted:

INS	Additive	Maximum level in 100 mL of the product ready for consumption
4.1 Thickener		
412	Guar gum	0.1 g
410	Carob bean gum	0.1 g
1412	Distarch phosphate	0.5 g singly or in combination in soy-based products only; 2.5 g singly or in combination in hydrolyzed protein and/or amino acid-based products only
1414	Acetylated distarch phosphate	
1413	Phosphated distarch phosphate	
1422	Acetylated distarch adipate	
407	Carrageenan	0.03 g singly or in combination in milk and soy-based products only; 0.1 g singly or in combination in hydrolyzed protein and/or amino acid-based liquid products only
440	Pectins	1 g
4.2 Emulsifier		
322	Lecithin	0.5 g
471	Mono- and Di-glycerides	0.4 g
4.3 Acidity Regulator		
500ii	Sodium hydrogen carbonate	Limited by GMP
500i	Sodium carbonate	
331i	Sodium dihydrogen citrate	
331iii	Trisodium citrate	Within the limits for sodium in Section 3.1
524	Sodium hydroxide	
501ii	Potassium hydrogen carbonate	

501i	Potassium carbonate	Limited by GMP
332i	Potassium dihydrogen citrate	
332ii	Tripotassium citrate	
525	Potassium hydroxide	
526	Calcium hydroxide	Limited by GMP
270	L (+) Lactic acid	Limited by GMP
330	Citric acid	Limited by GMP
4.4 Antioxidant		
307b	Mixed tocopherols concentrate	3 mg singly or in combination
307a, c	α-tocopherol	
304	L-ascorbyl palmitate	5 mg singly or in combination, expressed as ascorbic acid (INS 300, 301,302,304)
300	Ascorbic acid, L-	
301	Sodium ascorbate	
302	Calcium ascorbate	
[4.5 Packaging Gases		
290	Carbon dioxide	GMP
941	Nitrogen	GMP]

4.6 Flavourings

Natural Fruit Extracts: GMP

Vanilla extract: GMP

Ethyl vanillin [(JECFA no. 893)]: 5 mg/100 ml

Vanillin [(JECFA no. 889)]: 5 mg/ 100 ml

[The flavourings used in products covered by this standard should comply with the Guidelines for the Use of Flavourings (CXG 66-2008)]

4.7 Carry-Over Principle

Option 1:

Section 4 of the *General Standard for Food Additives* (CXS 192-1995) shall apply.

Option 2:

Only the food additives listed in this Section or in the *Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children* (CXG 10-1979) may be present in the foods described in [section 2.1 of this Standard], as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

- a) The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and b) The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the *General Standard for Food Additives* (CXS 192- 1995)
- b) The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the *General Standard for Food Additives* (CXS 192- 1995).

5. Contaminants

The products covered by this Standard shall comply with the Maximum levels of the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995).

The products covered by this Standard shall comply with the maximum residues limits for pesticides established by the Codex Alimentarius Commission.

6. Hygiene

6.1 It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CXC 1- 1969), and

other relevant Codex texts such as the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CXC 66-2008).

[the Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods (CXC 40-1993) and the Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods (CXC 23-1979)]

6.2 The products 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).

7. Packaging

7.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as a packing media.

7.2 The containers, including 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.

8. Fill of containers

In the case of products in ready-to-eat form, the fill of container shall be:

- (i) not less than 80% v/v for products weighing less than 150 g (5 ½ oz.);
- (ii) not less than 85% v/v for products in the weight range 150-250 g (5 ½ - 9 oz.); and
- (iii) not less than 90% v/v for products weighing more than 250 g (9 oz.) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.

10. Methods of Analysis and sampling

For checking the compliance with this Standard, the methods of analysis contained in the *Recommended Methods of Analysis and Sampling* (CXS 234-1999) relevant to the provisions in this standard, shall be used.]

Section B: Drink/product for young children with added nutrients or drink for young children

3.3 Purity requirements

3.3.1 General

All ingredients shall be clean, of good quality, safe and suitable for ingestion by ~~infants from the 6th month on and~~ young children. They shall conform with their normal quality requirements, such as colour, flavour and odour.

3.3.2 Vitamin Compounds and Mineral Salts

Vitamin compounds and mineral salts used in accordance with Sections 3.3.1 and 3.3.2 should be selected from the *Advisory List for Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children* approved by the Codex Alimentarius Commission (CXG 10-1979).

~~The amounts of sodium derived from vitamin and mineral ingredients shall be within the limit for sodium in Section 3.2.6~~

3.4 Consistency and particle size

When prepared according to the directions of use, the product shall be free of lumps and of large, coarse particles.

3.5 Specific prohibitions

The product and its components shall not have been treated by ionizing radiation.

4. Food additives

The following additives are permitted:

INS	Additive	Maximum level in 100 mL of the product ready for consumption
4.1 Thickener		
412	Guar gum	0.1 g

410	Carob bean gum	0.1 g
1412	Distarch phosphate	0.5 g singly or in combination in soy-based products only; 2.5 g singly or in combination in hydrolyzed protein and/or amino acid-based products only
1414	Acetylated distarch phosphate	
1413	Phosphated distarch phosphate	
1422	Acetylated distarch adipate	
407	Carrageenan	0.03 g singly or in combination in milk and soy-based products only; 0.1 g singly or in combination in hydrolyzed protein and/or amino acid-based liquid products only
440	Pectins	1 g
4.2 Emulsifier		
322	Lecithin	0.5 g
471	Mono- and Di-glycerides	0.4 g
4.3 Acidity Regulator		
500ii	Sodium hydrogen carbonate	Limited by GMP
500i	Sodium carbonate	
331i	Sodium dihydrogen citrate	
331iii	Trisodium citrate	
524	Sodium hydroxide	
501ii	Potassium hydrogen carbonate	Limited by GMP
501i	Potassium carbonate	
332i	Potassium dihydrogen citrate	
332ii	Tripotassium citrate	
525	Potassium hydroxide	
526	Calcium hydroxide	Limited by GMP
270	L (+) Lactic acid	Limited by GMP
330	Citric acid	Limited by GMP
4.4 Antioxidant		
307b	Mixed tocopherols concentrate	3 mg singly or in combination
307a, c	α-tocopherol	
304	L-ascorbyl palmitate	5 mg singly or in combination, expressed as ascorbic acid (INS 300, 301,302,304)
300	Ascorbic acid, L-	
301	Sodium ascorbate	
302	Calcium ascorbate	
[4.5 Packaging Gases		
290	Carbon dioxide	GMP
941	Nitrogen	GMP]

4.6 Flavourings (Recommendation 10b)

Natural Fruit Extracts: GMP

Vanilla extract: GMP

Ethyl vanillin [(JECFA no. 893)]: 5 mg/100 ml

Vanillin [(JECFA no. 889)]: 5 mg/ 100 ml

[The flavourings used in products covered by this standard should comply with the Guidelines for the Use of Flavourings (CXG 66-2008)]

4.7 Carry-Over Principle**Option 1:**

Section 4 of the *General Standard for Food Additives* (CXS 192-1995) shall apply.

Option 2:

Only the food additives listed in this Section or in the *Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children* (CXG 10-1979) may be present in the foods described in [section 2.1 of this Standard], as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

- a) The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and b) The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the *General Standard for Food Additives* (CXS 192- 1995); and

The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the *General Standard for Food Additives* (CXS 192- 1995)

5. Contaminants

The products covered by this Standard shall comply with the Maximum levels of the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995).

The products covered by this Standard shall comply with the maximum residues limits for pesticides established by the Codex Alimentarius Commission.

6. Hygiene

6.1 It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CXC 1- 1969), and other relevant Codex texts such as the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CXC 66-2008)

[the *Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods* (CXC 40-1993) and the *Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods* (CXC 23-1979)]

6.2 The products 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).

7. Packaging

7.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as a packing media.

7.2 The containers, including 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.

8. Fill of containers

In the case of products in ready-to-eat form, the fill of container shall be:

- (i) not less than 80% v/v for products weighing less than 150 g (5 ½ oz.);
- (ii) not less than 85% v/v for products in the weight range 150-250 g (5 ½ - 9 oz.); and
- (iii) not less than 90% v/v for products weighing more than 250 g (9 oz.) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.

10. Methods of analysis

For checking the compliance with this Standard, the methods of analysis contained in the *Recommended Methods of Analysis and Sampling* (CXS 234-1999) relevant to the provisions in this standard, shall be used].

PROPOSED DRAFT GUIDELINES FOR READY TO USE THERAPEUTIC FOODS (RUTF) (at Step 5)

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 intervention and RUTF is one of the options for the dietary management of children with uncomplicated SAM from 6-59 months. 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 WFP¹.

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 supplements², processed cereal based foods³, formulated complementary foods for older infants and young children⁴, canned baby foods⁵ are not covered by these guidelines.

²Guidelines for Vitamin and Mineral Food Supplements (CXG 55-2005)

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

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

⁵Standard 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 (haemagglutinins), trypsin, chymotrypsin inhibitors and phytoestrogens.

Field beans or Faba beans (*Vicia faba* 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, Roots and Tubers and their derived Products

All milled cereals, roots and tubers and their derived products 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-metabolizable buffer base. The non-metabolizable buffer 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. Glucose and fructose should not be used. 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

Only the food additives listed in this Section (Table A: Food Additives in RUTF Formulation) or in the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979) may be present in the foods described in section 4.1 of this Guideline. Other than by direct addition, an additive may be present in RUTF as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

- The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to the *General Standard for Food Additives* (CXS 192-1995)
- The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in the *General Standard for Food Additives* (CXS 192-1995); and
- The food into which the additive is carried over does not contain the additive in greater quantity than would be introduced by the use of the raw materials or ingredients under proper technological conditions or good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the *General Standard for Food Additives* (CXS 192-1995).

Table A: Food Additives in RUTF Formulation

Functional Class	Food Additive	International Numbering System (INS)	Maximum Use Level
Emulsifier	Mono- and di-glycerides of fatty acids	471	4000 mg/kg
	Citric and fatty acid esters of glycerol	472c	9000 mg/kg
	Lecithin	322(i)	5000 mg/kg
Antioxidant	Ascorbyl palmitate	304	10 mg/kg
	Tocopherol concentrate, mixed	307b	10 mg/kg
	Ascorbic acid, L	300	GMP
Acidity regulator	Citric acid	330	GMP
Packaging gas	Nitrogen	941	GMP
	Carbon dioxide	290	GMP
Carrier	Silicon dioxide, amorphous	551	10 mg/kg

6. NUTRITIONAL COMPOSITION AND QUALITY FACTORS

The nutritional composition of RUTF shall comply with the requirements set out in the table in the Annex. Furthermore, the following requirements shall be complied with.

6.1 Energy

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

6.2 Proteins

Protein should provide 10% to 12% of the total energy.

Protein quality should be determined using Protein Digestibility Corrected Amino Acid Score (PDCAAS), calculated according to the reference amino acid requirement and scoring patterns related to catch up growth of 10 g/kg/day in the target population for RUTF which is children with SAM aged 6 to 59 months.

For all RUTF formulations, the PDCAAS shall not be less than 90. The PDCAAS shall be calculated using, appropriate digestibility values and the reference amino acid pattern as stipulated in the *Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic foods (2018)*.

High quality protein will be achieved with RUTF formulations containing a minimum of 50% of protein from milk products.

In formulations with lower PDCAAS scores, the quality and/or quantity of protein should be adjusted to achieve the desired value. The addition of limiting amino acids, solely in the L-form, shall be permitted only in amounts necessary to improve the protein quality of the 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 ~~346~~ 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.]

6.4 Vitamins and Minerals

RUTF should contain the vitamins and minerals presented in the annex: Nutritional Composition of RUTF. RUTF should comply with the minimum and maximum or guidance upper levels in the annex.

6.5 WATER ACTIVITY

RUTF is a low-moisture food with a water activity of 0.6 or below.

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 (CXM 2-2015) and Codex Maximum Residue Limits for Pesticides.

Further guidance is given by codex Codes of practice and should be adhered to.

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.

8. PROCESSING TECHNOLOGIES

Processing technologies used for RUTF and their ingredients shall be validated to prove that they do not alter the nutritional value of RUTF and that they allow the reduction of anti-nutritive factors. Milling or grinding, roasting, toasting are examples of processing technologies that can be used on ingredients.

Any technologies used should take into consideration the target group and any impact on the integrity of the nutrient content of the products. In addition to the practices described above, Good Hygiene Practices should be implemented for manufacturing of RUTF, according to the *General Principles of Food Hygiene (CXC 1-1969)* and *Code of Hygienic Practices for Low Moisture Foods (CXC 75-2015)* to avoid cross contamination during the storage of raw materials and the manufacturing process.

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 and/or their raw materials include both thermal and non-thermal control measures.

For additional information on validation of control measures, refer to the *Guidelines for the Validation of Food Safety Control Measures (CXG 69-2008)*. Additionally, refer to the *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) (CXG 63-2007)*.

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), and other relevant Codex texts.

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).

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).

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 with SAM be in accordance with the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991), the *General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses* (CXS 146-1985), and *Guidelines on Nutrition Labelling* (CXG 2- 1985).

12.1 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 with SAM. 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.

12.2 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).

12.3 Additional Mandatory Labelling Requirements

Provisions of section 4.4 and 4.5 of the *Standard for the Labelling of and Claims for Food for Special Medical Purposes* (CXS 180-1991) shall apply.

12.4 The following additional statements shall appear on the label of RUTF:

- The product is not to be used for Nasogastric Tube (NG tube) administration.
- The product should be used in conjunction with breastfeeding.
- Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for up to two years or beyond.

12.5 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 within which the product should be consumed after opening should be clearly indicated.

Table: Nutritional Composition of RUTF

Energy			
Unit	Minimum	Maximum	GUL
kcal/100g	520	550	-
Protein			
Unit	Minimum	Maximum	GUL
g/100kcal	2.5	3.0	-
Lipids			
Unit	Minimum	Maximum	GUL
g/100kcal	5	7	-
n-6 Fatty acids			
Unit	Minimum	Maximum	GUL
mg/100kcal	330	[1111] or [780]	-
n-3 Fatty acids			
Unit	Minimum	Maximum	GUL
mg/100kcal	[33] or [110]	280	-
Vitamin A			
Unit	Minimum	Maximum	GUL
² µg RE/100kcal	145	308	-
² 1µg 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
³ µg/100 kcal	2.7	4.2	-
³ 1 µg calciferol = 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 α-TE /100 kcal	3.6	-	-
⁴ 1 mg α-tocopherol = 1 mg RRR-α-tocopherol (d-α-tocopherol)			
⁴ 1 mg RRR-α-tocopherol = 2.00 mg <i>all-rac</i> -α-tocopherol (dl- α-tocopherol)			
Vitamin K			
Unit	Minimum	Maximum	GUL
µg/100 kcal	2.7	6	-
Vitamin B1			
Unit	Minimum	Maximum	GUL
mg/100 kcal	0.09	-	-

Vitamin B2

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.29	-	-

Vitamin C

Unit	Minimum	Maximum	GUL
mg/100 kcal	9	-	-

Vitamin B6

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.11	-	-

Vitamin B12

Unit	Minimum	Maximum	GUL
µg/100 kcal	0.29	-	-

Folic Acid

Unit	Minimum	Maximum	GUL
⁵ µg/100 kcal	36	-	-

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

Niacin

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.91	-	-

Pantothenic Acid

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.55	-	-

Biotin

Unit	Minimum	Maximum	GUL
µg/100 kcal	11	-	-

Minerals**Sodium**

Unit	Minimum	Maximum	GUL
mg/100 kcal	-	56	-

Potassium

Unit	Minimum	Maximum	GUL
mg/100 kcal	200	308	-

Calcium

Unit	Minimum	Maximum	GUL
mg/100 kcal	55	151	-

Phosphorus

Unit	Minimum	Maximum	GUL
mg/100 kcal	55	151	-

Magnesium

Unit	Minimum	Maximum	GUL
mg/100 kcal	[15] or [30]	[45] or [90]	-

Iron

Unit	Minimum	Maximum	GUL
mg/100 kcal	1.8	2.7	-

Zinc

Unit	Minimum	Maximum	GUL
mg/100 kcal	2	2.7	-

Copper

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.25	0.35	-

Selenium

Unit	Minimum	Maximum	GUL
µg /100 kcal	3.6	8	-

Iodine

Unit	Minimum	Maximum	GUL
µg /100 kcal	13	27	-

APPENDIX VII

PROJECT DOCUMENT OF A PROPOSAL FOR NEW WORK TO REVISE NUTRIENT**REFERENCE VALUES OF VITAMINS AND MINERALS (CXG 2-1985)****UPDATED TO INCLUDE TIMELINES FOR NRVS-R FOR PERSONS AGED 6-36 MONTHS OF AGE**

(for information only)

1. PURPOSE AND THE SCOPE OF THE PROPOSED NEW WORK

Section 3.4.4 of the Codex Guidelines for Nutrition Labelling (CX/GL 2-1985) provides that numerical information on vitamins, minerals and protein should be expressed as a percentage of the reference labelling value referred to as "Nutrient Reference Value" (NRV). Since the first introduction of this guideline in 1985, Section 3.4.4 was amended once in 1993 following the Report of a Joint FAO/WHO Consultation on Recommended Allowances of Nutrients for Food Labelling Purposes (Helsinki, Finland, 12-16 September 1988). At that time, it was indicated that the definition and review of these values was on on-going process, subject to revision according to new scientific data by the Committee of Food Labelling (CCFL). The CCFL also recognized a need for general principles to guide the choice and amendment of NRVs, and had requested the advice of the Committee on Nutrition and Foods for Special Dietary Uses in this respect (ALINORM 93/40).

Currently the list of NRVs in Codex Guidelines for Nutrition Labelling covers 9 vitamins (A, D, C, thiamin, riboflavin, niacin, B6, folic acid and B12), 5 minerals (Calcium, Magnesium, Iron, Zinc, Iodine) and protein, which were in general based on the Reference RDAs for adult men. These values are indicated as a basis for expressing nutrient content in nutrition labelling of food supplements in the Codex Guidelines for Vitamin and Mineral Food Supplements (CXG 55-2005). Also the Codex Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) indicates NRVs as a basis for criteria for nutrition and health claims.

At the 25th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) agreed that the current list of NRVs in the Codex Guidelines for Nutrition Labelling was incomplete and required additions and updates. It was also pointed out that a set of principles should be developed for the establishment of NRVs taking into account the experience of member countries in the establishment of reference values for the purpose of labelling.

The purpose of the proposed new work is to develop the science-based general principles for establishing NRVs and to revise the list of NRVs in the Codex Guidelines for Nutrition Labelling, taking full account of the prior work related to nutrient reference values.

2. ITS RELEVANCE AND TIMELINES

WHA Resolution 57.17 endorsing the Global Strategy requested the Codex Alimentarius Commission to continue to give full consideration within the framework of its operational mandate, to measures which it might take to contribute towards the improvement of health standards of foods consistent with the aims and objectives of the Global Strategy.

Accordingly, the 28th Session of the Commission agreed to ask WHO and FAO to prepare a document focused on actions that could be taken by Codex including specific proposals for new work for consideration by the CCNFSDU and the CCFL. At its 29th Session of the Commission, it was agreed to complete a document containing concrete proposals for possible actions by Codex and to circulate for comments and consideration by the CCNFSDU and CCFL.

The CCNFSDU and CCFL had discussed extensively the proposals for actions and both Committees agreed for CCNFSDU to revise the NRVs of vitamins and minerals in the Guidelines for Nutrition Labelling (ALINORM 07/30/26). Therefore the proposal of this new work is timely as well as relevant.

3. THE MAIN ASPECTS TO BE COVERED

This work would involve a process to develop the general principles for establishment of vitamin and mineral NRVs for the general population as a first step.

The next step would be a process to review all available reference values and their scientific basis by the principles agreed upon and, if appropriate, update and extend the current list of vitamin and mineral NRVs in the Guidelines for the Nutrition Labelling.

Once the above is completed, the Committee would establish vitamin and mineral NRVs for labelling for individuals 6 months to 36 months of age. The Committee could then begin to work to establish principles that would apply to NRVs for this age group, using as a basis the principles identified for NRVs for the general

population and modifying them as appropriate. Once those principles are developed, the NRVs for this age group would be established.

4. AN ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries: This proposed new work would provide Codex and national/regional authorities principles to be used in establishing NRVs, thus assisting in establishing appropriate level of protection for consumers. The project could particularly assist countries that have limited experience with NRVs, particularly for selecting NRVs for labelling purposes.

Diversification of national legislations and apparent resultant or potential impediments to international trade: This proposed new work would provide internationally-recognized scientific general principles that Codex and national/regional authorities may use to carry out establishing NRVs for labelling purposes. Such internationally-agreed principles can help ensure consistent approaches for establishing NRVs for labelling purposes.

Scope of work and establishment of priorities between the various sections of the work: The scope of the work relates to work previously undertaken by Codex on a high priority basis.

Work already undertaken by other organizations in this field: This proposed new work is consistent with, complements, and builds upon work already undertaken by CCFL.

5. RELEVANCE TO THE CODEX STRATEGIC OBJECTIVES

This proposal is consistent with the following strategic goals presented in the Codex Strategic Plan 2008-2013:

- Promoting Sound Regulatory Frameworks (Activity 1.3);
- Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis (Activities 2.3).

And the Codex Strategic Plan 2020-2025:

- Identify needs and emerging issues (Goal 1, Objective 1.1)
- Use scientific advice consistently in line with Codex risk analysis principles (Goal 2, Objective 2.1)
- Promote the submission and use of globally representative data in developing and reviewing Codex standards (Goal 2, Objective 2.2)

6. INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS

The Codex *Guidelines on Nutrition Labelling* (CXG 2-1985) and Codex *Guidelines for Vitamin and Mineral Food Supplements* (CXG 55-2005) indicate the NRVs as a basis for expressing nutrient content in nutrition labelling of all foods including conventional foods and food supplements. The Codex *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997) also indicates NRVs as a basis for criteria for nutrition and health claims.

7. IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE.

Scientific advice from FAO/WHO could be identified at a later stage. There might be a need for scientific advice which would focus on the requirements for each of the 24 nutrients were derived by FAO/WHO and 6 RASBs and evaluate and rank these nutrient requirements based on quality of evidence to help inform the work of the Committee.

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

None foreseen

9. UPDATED TIMELINE FOR COMPLETION OF THE NRVs-R WORK INVOLVED FOR PERSONS 6-36 MONTHS OF AGE

<u>Activity</u>	<u>Year/Step</u>
Developing General Principles for the establishment of these NRVs-R for persons aged 6 to 36 months and how they should be used including which foods they should apply to	2021/Step 5
Establishing NRVs-R for each nutrient	2021-2023/Step 5
Amending text in relevant Codex texts	2024/Step 5
Adoption by the Commission	2025

APPENDIX VIII, Part A

**CCNFSDU framework for appraising the technological need for food additives
(Information document)****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 CXG 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 CXG 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?

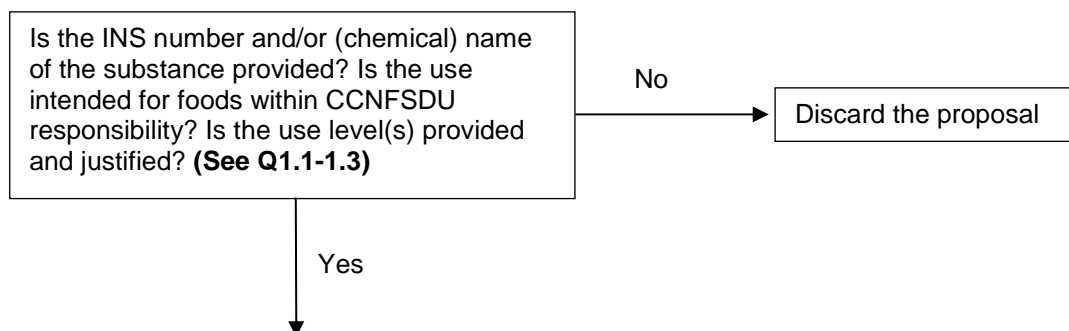
Q2.4: Would the use of this food additive in the intended food(s) modify any characteristic of the food that might mislead the consumer? For example the nature, substance, quality or nutritional quality of the food, the use of faulty raw materials or of undesirable (including unhygienic) practices or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

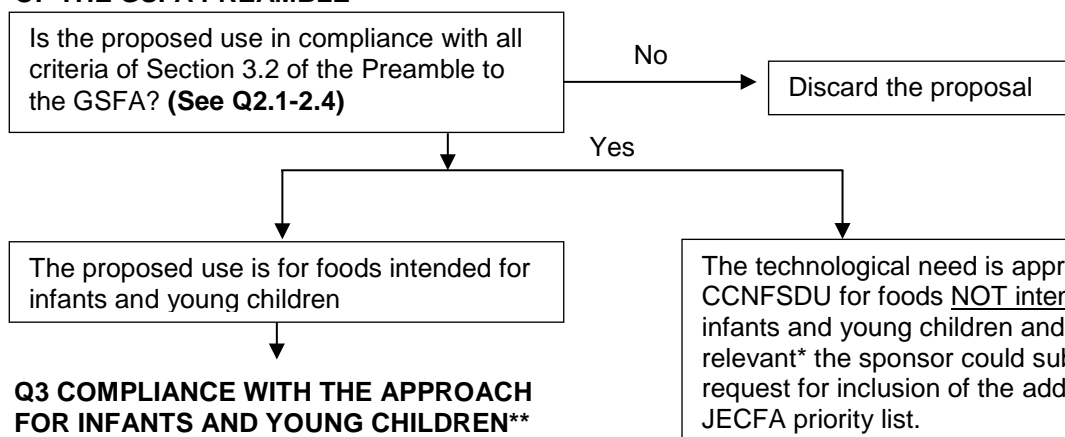
Q3.1: Does the proposed food additive perform the same/similar technological purpose as other additives that have already been authorized for use in the same product category? If not, what is the justification for the need for an additive with a new functional class and/or technological purpose? If yes,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

Annex I: Decision tree on the CCNFSDU framework for appraising the technological need for food additives

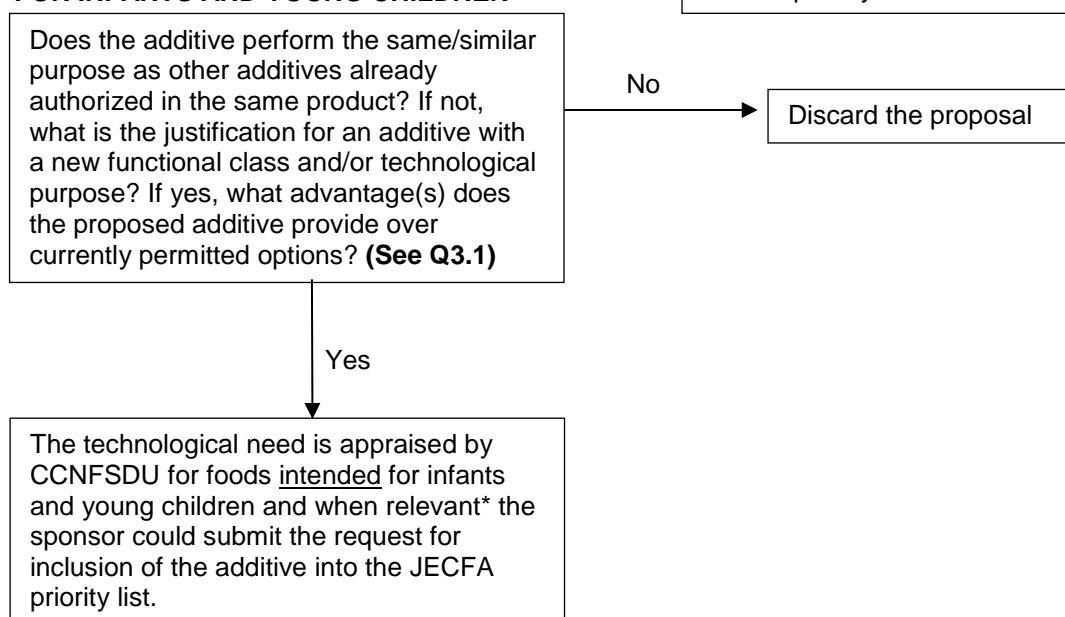
Q1 IDENTITY AND INTENDED USE



Q2 COMPLIANCE WITH SECTION 3.2 OF THE GSFA PREAMBLE



Q3 COMPLIANCE WITH THE APPROACH FOR INFANTS AND YOUNG CHILDREN**



* The framework applies to three potential scenarios:

- To appraise and justify the technological need prior to a possible inclusion of the additive in the JECFA priority list;
- To appraise the technological need for the use of additives within the CCNFSDU standards that does not warrant the JECFA assessment (e.g. in case of a development of new standards for additives already assessed by JECFA);
- To answer requests from CCFA concerning the technological justification for the use of additives in foods under the purview of the CCNFSDU.

** The outcome of assessing Q3 (i.e. YES/NO) is whether the proposed use complies with the approach for the use of additives in baby foods.

Annex II: Form for appraising the technological need for the use of additives in foods within the mandate of CCNFSDU (i.e. standardized or non-standardized foods following a request by CCFA)

THE PROPOSAL IS SUBMITTED BY:		
Q1 IDENTITY AND INTENDED USE		
Q1.1 Name and INS number of the food additive as listed in CXG 36-1989: <i>For substances not yet included in CXG 36-1989, chemical name of the substance.</i>		
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		
CCNFSDU standard		
Reference	Name of the standard	Comments (e.g. limitation of use to specific products)
GSFA food category		
Food category No	Name of the GSFA food category	
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		
Proposed (range of) lowest possible use level to accomplish the desired effect <i>(expressed on the final product as consumed)</i>		Justification of the level(s) proposed
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 CXG 36-1989 (include the functional class) and the advantage conferred by its use		
<i>Technological function relative to the CXG 36-1989:</i>		
<i>Advantage from the use of the additive:</i>		
Q2.2 Does the use of the food 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)		
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? <i>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.</i>		

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 food additives that have already been authorized for use in the same product category? *If not, what is the justification for the need for a food additive with a new functional class and/or technological purpose? If yes, what advantage(s) does the proposed food additive provide over currently permitted options?*

APPENDIX VIII, Part B

Amendment to the *Standard for Infant Formula and Formulas for Special medical purposes Intended for Infants (CXS 72-1981)*
(New food additive provisions)

(for adoption by CAC43)

Section A: Standard for infant formula**4. FOOD ADDITIVES**

INS	Additive	Maximum level in 100ml of the product ready for consumption
4.1 Thickeners		
440	Pectins	0.2g in liquid hydrolysed protein infant formula only.
415	Xanthan gum	0.1g in powdered hydrolysed protein and/or amino acid based infant formula only

APPENDIX IX

**DRAFT GUIDELINE FOR THE PRELIMINARY ASSESSMENT AND IDENTIFICATION OF WORK
PRIORITIES FOR CCNFSDU**

(For use by the PWG for CCNFSDU42)

1. The following guideline is intended to assist the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to identify and prioritize its work.
2. Proposals for new work should follow the process and criteria outlined in the Procedural Manual for *Proposals to Undertake New Work or Revise a Standard*, in addition to the following criteria specific to CCNFSDU.

Criteria for Prioritization of New Work Proposals

Criteria	Further information
Revision of existing texts	Describe the rationale for the proposed revision of an existing CCNFSDU text. Is it necessary due to new scientific findings and/or other developments? Can these new findings or developments cause a safety concern to a special group of people?
Request from CAC	Has the CAC requested CCNFSDU to work on a CCNFSDU text or to start new work?
Request from other Codex committees	Has another Codex Committee asked to consider a revision of an existing CCNFSDU text or to consider new work?
Availability of scientific advice	Is scientific advice available or will be provided soon?
Target group	Describe the target group of the proposal. Does the proposal refer to a vulnerable target group (infants, the aged, patients, etc.) or is the target group large (e.g. whole population)?
Impact on public health	Describe the impact on public health (high/medium/low?).
Impact on food safety	Describe the impact on food safety (high/medium/low?).
Impact on fair trade practices	Describe the impact on fair trade practices (high/medium/low?).

Process for Considering and Prioritizing Proposals for New Work

3. Proposals for new work and/or revision of an existing text should be submitted following a Codex Circular Letter (CL) before each session. This ensures that all proposals will be submitted within a deadline and all members have adequate time to consider them.
4. New work proposals should be submitted as a discussion paper together with a project document according to the Procedural Manual and address also the additional criteria outlined above.
5. The criteria should be addressed in a self-assessment and should include a detailed rationale. Pertinent references should accompany the assessment.
6. The rationale of the criteria “impact on public health”, “impact on food safety” and “impact on fair trade practices” includes a rating, whether the appropriate impact is high, medium or low. The choice of the respective impact level has to be justified.
7. Proposals for new work received in response to the CL will be transmitted to the CCNFSDU host country Secretariat. The CCNFSDU host country Secretariat will prepare a summary document presenting the proposals for new work and the associated self-assignment against the above criteria. The document will be distributed by the Codex Secretariat to Codex members and observers for review.
8. Revisions of existing texts necessary due to new scientific findings and/or other developments and requests from CAC or other Codex Committees on CCNFSDU texts will be prioritized.

9. The *ad hoc* Working Group for the Establishment of CCNFSDU Work Priorities will meet as decided by the Committee, e.g. on the day prior to the plenary session of CCNFSDU or intra-session, to develop recommendations for consideration by the Committee during the CCNFSDU session. The *ad hoc* Working Group will be co-chaired by the host country and a voluntary delegation. The following Terms of Reference (ToR) of the *ad hoc* Working Group are proposed:

- a. To conduct a case-by-case review of every proposal on the basis of a decision tree and the detailed rationale including the rating (high/medium/low impact) as presented in the discussion paper and to propose a list of work proposals ranked according to their priority.
- b. To prepare a report to be presented to the plenary to enable CCNFSDU to evaluate and decide on the new work proposals.

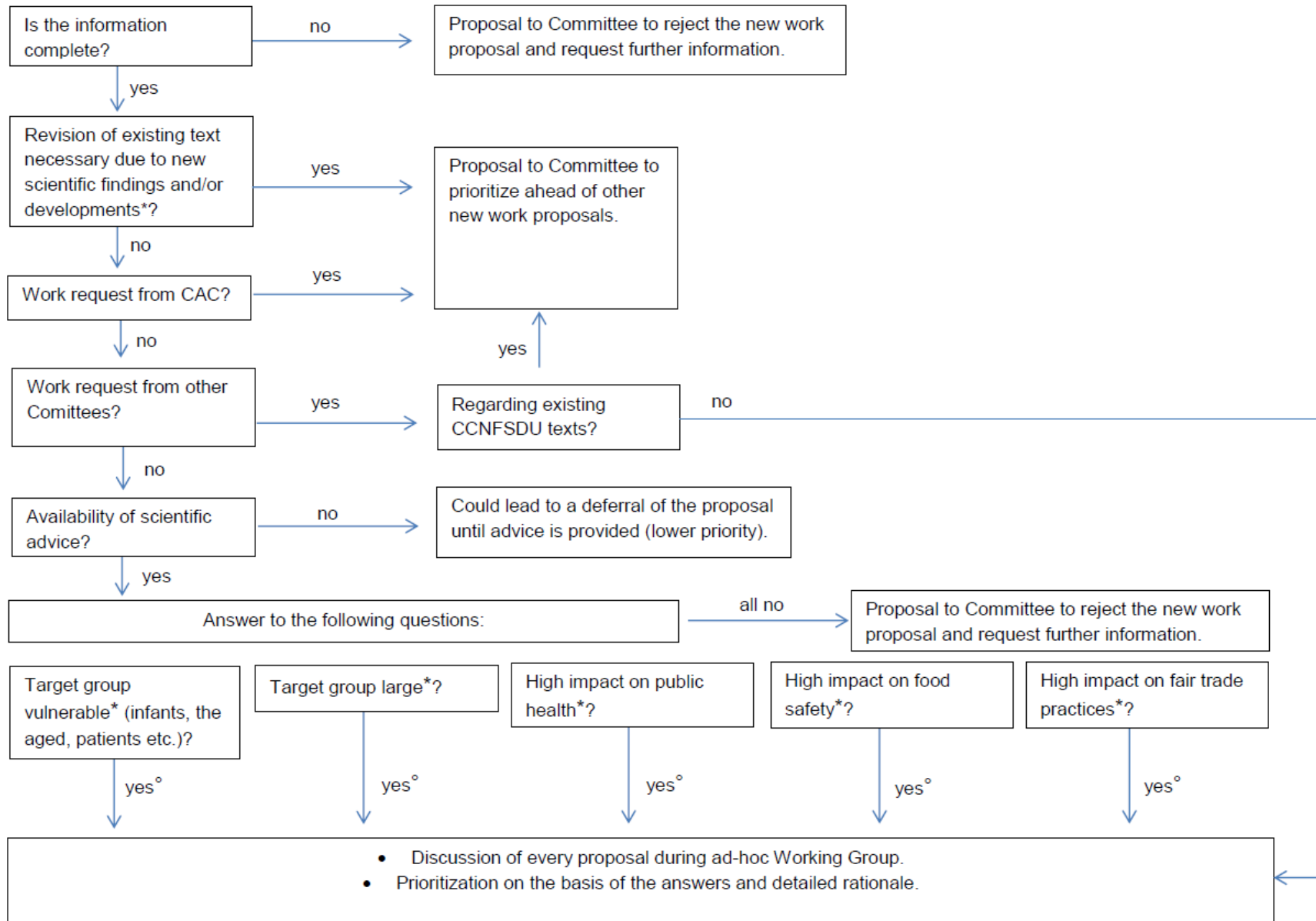
10. It is proposed that, at the CCNFSDU session, the *ad hoc* Working Group Chair introduces the recommendations to the Committee. The Committee will then accept or reject a proposal for new work and/or revision of an existing text, or return it to the proposing party for additional information. Depending on the workload of CCNFSDU, the Committee may decide to not accept any new work proposal at a session.

11. If accepted by the Committee, a proposal will be submitted to CAC with a request for approval as new work.

Decision Tree

12. The following decision tree serves as a tool for the *ad hoc* Working Group to classify new work proposals:

DECISION TREE FOR THE PRELIMINARY ASSESSMENT AND PRIORITIZATION OF NEW WORK PROPOSALS FOR CCNFSDU



* Detailed rationale including pertinent references is essential. ° One "yes" answer would suffice to be taken into account.