CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 5 **CX/NFSDU 18/40/6**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Fortieth Session

Berlin, Germany
26 - 30 November 2018

PROPOSED DRAFT GUIDELINES FOR READY-TO-USE THERAPEUTIC FOODS

(Prepared by the electronic working group led by South Africa, Senegal and Uganda)

Codex members and Observers wishing to submit comments at Step 3 on this draft should do so as instructed in CL 2018/64-NFSDU available on the Codex webpage/Circular Letters 2018: http://www.fao.org/fao-who-codexalimentarius/circular-letters/en/

1. Introduction

At the 39th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU39), the Committee agreed to continue the development of the Guidelines for Ready-to-Use Therapeutic Foods (RUTF) with the following terms of reference:

Terms of Reference for the Electronic Working Group:

a) an eWG, chaired by South Africa and co-chaired by Senegal and Uganda and working in English and French to continue drafting the guidelines for RUTF taking into account the decisions and comments made at the session and written comments submitted to CCNFSDU39, for comments and further discussion at the next session.

b) a pWG, to meet immediately prior to the next session, chaired by South Africa, co-chaired by Senegal and Uganda, working in English, French, Spanish, to further elaborate on the proposed draft guidelines for RUTF taking into account the conclusions and recommendations of the electronic working group and the comments received prior to CCNFSDU40.

2. Background

CCNFSDU37 agreed to start new work on guidelines for a single product known as “Ready-to-Use Therapeutic Foods” (RUTF) used in the management of severe acute malnutrition (SAM).[1]

This work was approved by CAC39.[2]

CCNFSDU37 further agreed to establish an electronic working group (eWG) chaired by South Africa, co-chaired by Senegal and Uganda and working in English and French to develop the guidelines for Ready-to-Use Therapeutic Foods.[3]

At CCNFSDU38 the Committee agreed on the outline structure and the purpose of the guidelines. The Committee further agreed on the proposed scope of the guidelines, noting concerns from Members and Observers that while it was true that RUTF were given to other age groups, the priority target group for RUTF should remain 6-59 months as proposed in the guidelines. The Committee further agreed that an introduction or preamble should be included in the guidelines to set the scene, and to also elaborate on the appropriate use of RUTF. The preamble or introduction should also elaborate on how the guidelines should be used and also make reference to the *Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions* (CXC 20-1979).

[1] REP16/NFSDU, paras 81-88, Appendix IV
[2] REP16/CAC, paras 102 – 107, Appendix V
[3] REP16/NFSDU, paras 3, Appendix IV

At CCNFSDU39, South Africa as Chair of the eWG, introduced the agenda item and noted that based on written comments the chairs had prepared a revised proposal (CRD15)[4]. The Committee considered the recommendations, made proposals, amendments and took decisions on various sections of the guidelines. The following areas were agreed on by the Committee: description; raw materials and ingredients section which include – the opening paragraph; milk and other dairy products; fats and oils; and cereals. The Committee also agreed on the proposed stepwise approach on handling contaminants in RUTF[5].

Due to time constraints the Committee couldn't discuss other recommendations. Sections that were not discussed at CCNFSDU39 will form part of the report to Codex Secretariat, which will inform the agenda of the physical Working Group to be held prior to CCNFSDU40 (24 November 2018).

2.1 The process followed by the 2018 Electronic Working Group

Nominations to participate in the eWG were received from 32 Codex Members, 1 Codex Member Organization and 14 Codex Observers (the list of participants is attached as **Appendix 2**).

The Chairs circulated one Consultation Paper to the eWG Members in March 2018. The focus of the Consultation Paper was on the preamble, vitamins and minerals, food additives and available carbohydrates sections of the RUTF Guidelines based on the comments and decisions made at CCNFSDU39. The Consultation paper also took into consideration the conclusions and comments made with regard to the proposed texts of the guidelines. Comments received from members prior to CCNFSDU39 were also be taken into consideration. The Chairs requested the eWG to provide information and evidence that would inform the finalization of the proposed texts of the guidelines. Responses to the Consultation Paper were received from 13 Codex Members, 1 Codex Member Organisation and 7 Codex Observers.

3. Preamble

CCNFSDU38 agreed that a preamble to the guidelines should be included to elaborate on key aspects of the guidelines, with specific reference to the appropriate use of the RUTF, integration of RUTF into sustainable local family based solutions and also how the guidelines should be used. It was also noted during the meeting that the primary focus for treating SAM was children from 6 to 59 months and this should remain a priority. However, RUTF are being given to other age groups.

CCNFSDU39 briefly discussed the preamble, and agreed that it would be considered after discussing the technical part of the guidelines. The Committee noted the clarification from the Secretariat that the first paragraph should be deleted as the current wording was not appropriate and reference to the *Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions* (CXC 20 – 1979) could be inserted at an appropriate point at the end of the preamble.

During the 2018 eWG consultative process, the Chairs proposed the draft texts for the Preamble of the RUTF guidelines based on the Committee's decisions during the 39th session, as well as written submissions by members prior to CCNFSDU39 when putting together the proposed texts for the preamble. The EWG members were requested to comment on the proposed texts for the preamble.

Responses from the eWG Members

There was general support for the preamble from the eWG Members (CM=8, CMO= 4, CO=1) as the text was viewed to be concise and provided context to the proposed guidelines. Several Members who supported and those who did not support (CM=3, CO=3) the proposed texts made specific inputs to the proposed texts. Several Members preferred the following texts in square brackets with minor editorials "safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients". One Member was of the view that there was not sufficient scientific evidence to support the use of commercially manufactured RUTF for management of SAM compared to other interventions. One Member proposed that the texts which explain that technical recommendations on RUTF are based on transparent and rigorous scientific review of relevant scientific evidence be added in paragraph 2. Furthermore, the Member also questioned the inclusion of references to the marketing of breastmilk substitutes in the texts, since RUTF were not breastmilk substitutes and was unclear which WHA resolutions were considered relevant to RUTF.

Conclusion

Due to the majority preference for supporting the proposed text, the Chairs recommend that the Committee agree to the proposed text below.

[4] NFSDU/39 CRD/15

[5] REP18/NFSDU, paras 97-119

Recommendation 1:

That CCNFSDU agree to the following text for the Preamble of the Guidelines for RUTF

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

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

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

4. Raw materials and ingredients

4.1 Vitamins and Minerals

The current RUTF include vitamin and mineral premix which are commercially produced to provide the same amount of micronutrients to the malnourished child as F-100, which is the standard therapeutic food. 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 will not alter the acid-base metabolism of patients with SAM. The non-metabolizable base can be approximated by the formula: estimated absorbed millimoles (sodium + potassium + calcium + magnesium) - (phosphorus + chloride).

The 2017 eWG Members proposed that the provisions in the *Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children* (CXG 10-1979) were adequate and contain all the necessary requirements that a nutrient had to meet for it to be used in the food covered by the advisory list. The list is also applicable to RUTF. Several Members of the 2017 eWG indicated that the provisions in CXG 10-1979, with regard to the absorbability of vitamins and minerals to be used in RUTF, would also be covered by section 2.1(d) of the CXG 10-1979 as reflected below:

CRITERIA FOR THE INCLUSION AND DELETION OF NUTRIENT COMPOUNDS FROM THE ADVISORY LISTS

2.1 Nutrient compounds that are to be added for nutritional purposes to foods for infants and young children may be included in the Lists only if:

(a) they are shown to be safe and appropriate for the intended use as nutrient sources for infants and young children,

(b) it is demonstrated by appropriate studies in animals and/or humans that the nutrients are biologically available,

(c) the purity requirements of the nutrient compounds conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission, or in the absence of such specifications, with another internationally recognized specification. If there is no internationally recognized specification, national purity requirements that have been evaluated according to or similar to a FAO/WHO process may be considered,

(d) the stability of nutrient compound(s) in the food(s) in which it is (they are) to be used can be demonstrated,

(e) the fulfilment of the above criteria shall be demonstrated by generally accepted scientific criteria.

CCNFSDU39 noted that the list for nutrients compounds recommended for SAM children that do not alter the acid-base metabolism should be an open list to allow for its updating based on emerging science. The Committee also agreed on the inclusion of those nutrients compounds that are recommended and also to specify the specific forms of mineral salts and trace elements recommended for SAM children as stipulated in Appendix 4 of the *WHO Management of severe malnutrition: A manual for physicians and other senior health workers (1999).* These specified forms of mineral salts and trace elements would not alter the acid base metabolism of children with SAM.

The WHO Management of severe malnutrition: A manual for physicians and other senior health workers (1999), Appendix 4 stipulates the following forms of mineral salts that are allowed in RUTF formulation:

- Potassium chloride
- Tripotassium citrate
- Magnesium chloride (MgCl2 · 6H2O)
- Zinc acetate
- Copper sulfate
- Sodium selenate
- Potassium iodide

The 2018 eWG Members were requested to comment on the proposed text which makes reference to the WHO guidelines of 1999 wherein examples are provided on the forms of minerals salts that could be used in RUTF formulation.

Responses from the eWG Members

There was general support on the proposed texts among the eWG Members. One Member was of the view that the mineral compounds referenced in the WHO 1999 guidelines were already listed in CXG 10-1979, such that there was no need to make reference to the WHO guidelines. One Member proposed that the following texts be added “The amount of micronutrients added to achieve the target level must be adjusted based on the chemical form and scientific evidence showing adequate stability and bioavailability in the finished product”. Adding the proposed texts would ensure that the chemical forms of micronutrients added during manufacturing were stable and bioavailable in the finished product. One Member also recommended that a paragraph below which was part of the consultation paper be added to the proposed texts as follows: “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 will not alter the acid-base metabolism of patients with SAM. The non-metabolizable base can be approximated by the formula: estimated absorbed millimoles (sodium + potassium + calcium + magnesium) - (phosphorus + chloride)”.

Conclusion

Based on the comments received from the eWG Members, the Chairs recommend that the Committee agree to the proposed texts below:

Recommendation 2:

That CCNFSDU agree to the following texts for the Vitamins and Minerals section

Vitamins and Minerals

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

All added vitamins and minerals must be in accordance with the Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children (CXG 10-1979). Examples of vitamin and 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 and scientific evidence showing adequate stability and bioavailability in the finished product.]

4.2 Available Carbohydrates

Lactose, sucrose, fructose and glucose polymers have been used in RUTF as sweeteners. The current RUTF generally contain about 25% free sugars. Sucrose is mainly used to increase the palatability of RUTF and for technological purposes. Particular attention should be given to the sugar particle size, which if not properly ground, can cause oil separation from the RUTF paste and lead to leakage when opening the sealed part of the product. In 2015, WHO strongly recommended that both adults and children reduce the intake of free sugars to less than 10% of energy and further recommended a further reduction to less than 5% of energy[6].

During the 2017 eWG, several Members recommended that the addition of available carbohydrates in the form of sugars should be limited to the WHO recommendations of 10% or 5% of total energy, due to the potential effects of added sugars (including fructose and corn syrups) in SAM children. However, there was no consensus on setting a limit to 10% or 5% of free sugars towards their contribution to total energy. A footnote was also proposed by the eWG Members to be included in the guidelines to provide guidance on the acceptable available carbohydrates in RUTF formulation.

The Committee was reminded that sugar was normally added to RUTF to enhance palatability of the product, and for technological reasons to act as a filler and a binder and extend the shelf-life. It was also highlighted that RUTF manufacturers were currently able to reduce sugar by 5%, but in future, with technological advances, sugar might be further reduced. The Representative of WHO reiterated that there were clear recommendations to reduce the consumption of sugars and this should be pursued. It was recommended that clearer relevant language could be included in the guidelines to address this issue.

CCNFSDU39 considered the footnote associated to available carbohydrates and made the following recommendations for further consideration by the eWG members:

“A consideration should be made on how the quantity of free sugar in RUTF should be restricted to align with the WHO guidelines and WHA recommendations, since 20% to 25% of free sugars used in RUTF formulation was too high”.

With regard to the proposed footnote on available carbohydrates, a proposal was made that a statement which could read “*Any carbohydrate added for sweetness should be used sparingly*” should be included in the footnote; and glucose syrup and corn syrup should be grouped together, as their reported negative health implications were similar.

With regard to coming up with clearer language that could be included in the guidelines on available carbohydrates, the Chairs requested the 2018 eWG Members to comment on the proposed draft texts for this section.

[6] WHO. *Guideline: Sugars intake for adults and children.* Geneva: World Health Organization; 2015.

Responses from the eWG Members

There was general support amongst the eWG Members on the proposed text (CM=7, CMO=1, CO=2), with 3 CM and 4 CO not supporting the proposed text. Two Members indicated that the energy production from substrates such as galactose and fructose is slower than normal in children with severe acute malnutrition, and could lead to hepatic steatosis when consumed at higher doses and would therefore support that fructose (or galactose) not be added as sources of energy to foods for malnourished children. Furthermore, one Member highlighted that there might not be any negative effects of small amounts of fructose added for palatability reasons, especially since RUTF was intended to be consumed only for a short period of time. Two Members were of the view that the statement which reads "gluten-free by nature" in the proposed text should be deleted since cereals were considered to be suitable ingredients for the production of RUTF. One Member reiterated that the quantity of free sugars used in RUTF should be restricted in line with the WHO Guidelines for Sugars intake for adults and children (2015), although the WHO guidelines do not apply to individuals in need of therapeutic diets, including for the management of severe and moderate acute malnutrition. Furthermore, the Member was of the view that the addition of available carbohydrates for the purpose of increasing palatability of RUTF should not be emphasized in the guidelines.

Conclusion

Based on the responses from the eWG Members, the Chairs recommend that the Committee agree to the proposed texts below:

Recommendation 3:

That CCNFSDU agree to the following texts for the Available Carbohydrates section

Available Carbohydrates[2]

The palatability of the RUTF can be increased by the addition of available carbohydrates. Available 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*.

[2)]Sucrose, plant starch, maltodextrin, should be the preferred carbohydrates in RUTF. Fructose, glucose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinized starches ~~[gluten-free]~~ by nature may be added. Any carbohydrate added for sweetness should be used sparingly.

4.3 Food Additives

Regarding the addition of food additives in RUTF formulation, the 2017 eWG members were asked whether they were in agreement with the proposal that RUTF could fall under Food Category 13.3 of the *General Standard for Food Additives* (CXS 192-1995). The eWG Members had mixed views. Those who were in support of the FoodCatNo 13.3 indicated that although RUTF could fall under this category, it would require the amendment of the said category since RUTF were different from other products. Alternatively, the Committee could consider the use of 'notes' associated with the provisions listed in the GSFA to identify conditions of use specific to RUTF, or identify those additives not appropriate for use in RUTF.

Members who were not in support of FoodCatNo 13.3 indicated that it might not be suitable for RUTF since it is a general category for dietetic foods for special medical purposes and it does not reflect the targeted age group for RUTF (6 – 59 months). Furthermore, some of the food additives in 13.3. might not be suitable for SAM children and the technological need for these additives has not been evaluated for RUTF. Some Members proposed other categories such as 13.2, 13.4, 13.5 and 13.6 to be suitable for RUTF. Some Members proposed for the creation of another sub-category in Category 13 specific for RUTF to allow for the determination of the specific additives that would be appropriate for this category. Several eWG Members also highlighted some of the additives that were being used in RUTF.

The Chairs noted that while the definition of RUTF may be similar to Food Category 13.3, the additives that are approved for use in 13.3 are based on the technological need for those products in that category. The proposed food category 13.3 may not be suitable for RUTF since it is a general category for dietetic foods for special medical purposes and it does not reflect the targeted age group of 6 to 59 months for RUTF. The Chairs also noted that some additives that are currently used in RUTF formulations may not fall within food category 13.3. Since the guidelines allow for product innovation in future, certain additives (e.g. use of plant derived gums and propylene glycol to address oil separation in the product) may be considered for use in RUTF formulations and may not be suitable for other existing food categories that were proposed by Members as suitable for RUTF. Although Members proposed other food categories such as 13.2 and 13.5, it would require a change of those food categories in order to accommodate RUTF. Making such a recommendation might pose other challenges since some of the additives that are currently used in RUTF formulations are not known.

Due to various proposals that were made by the eWG Members on how to handle additives in RUTF, the Chairs proposed a stepwise approach to address various concerns and divergence views. There was widespread support by the 2017 eWG Members on the proposed stepwise approach to address the use of food additives in RUTF formulation. Following a stepwise approach outlined below would allow the Committee to have a comprehensive overview of what additives are currently used in RUTF. This approach will also allow the Committee to carry-out its responsibility with regard to appraising and justifying the technological need for the use of additives in RUTF.

Proposed approach

a. The eWG compile a list of food additives currently used by the industry in the manufacturing of RUTF that include their technological rationale and function and approximate use levels.

b. The eWG compare the food additives currently used in RUTF to food additives approved for use in existing Codex texts aimed at infants and young children to determine whether the food additives in RUTF have already been evaluated in infants and young children.

c. The eWG recommend a proposed list of food additives for CCNFSDU to confirm the technological need.

In order to start implementing the stepwise approach in dealing with food additives, the Chairs requested the 2018 eWG Members to populate a table on the list of additives that were currently used in the manufacturing of RUTF. The information would enable the eWG to proceed to step 2, which would require a comparison of the food additives that are currently used in RUTF formulation to food additives approved for use in the existing Codex texts.

Responses from the eWG Members

Although there was general support for the stepwise approach and collecting the information on food additives used in RUTF, some Members were of the view that the guidelines should provide flexibility and provide a statement that is not prescriptive and allows for general guidance on food additives to allow national authorities flexibility to produce RUTF locally. Since RUTF are a low moisture, shelf-stable food that could be produced without food additives, the proposed guidelines should only allow incidental additives found in micronutrient premixes resulting from carryover that have no technical function. Two Members noted that most of the food additives were used for technical and/or appearance or consistency purposes of the product, which could impose known and unknown risks for older infants and young children with SAM. Furthermore, adverse effects have been reported in children due to certain additives which should be avoided. One Member highlighted that since RUTF were intended for children from 6 to 59 months, there should be a point of differentiation at 37 months of age, in line with the food categories set in CXS 192-1995 for foodstuffs intended for particular nutritional uses.

Although some Members indicated that RUTF was not produced in their countries, they were of the view that RUTF should use food additives permitted under the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981) and/or the *Standard for Follow-up Formula* (CXS 156-1987). All additives that are currently used in RUTF are included in these two standards and could be adopted and approved for use in RUTF.

Conclusion

The Chairs believe that the information provided by the eWG Members is sufficient to start a discussion on a stepwise approach proposed to deal with food additives in RUTF. The food additives and the technological justification provided by Members would allow the Committee to take a decision on the technological need on the individual additives in the next steps. The Chairs also note a proposal by some Members that food additives permitted in CXS 72-1981 and CXS 156-1987 should be allowed in RUTF. However, the Committee has a responsibility to come up with the technological justification for the use of such additives in RUTF. The Chairs recommend that the Committee take note of the information on food additives **(Table 1)** provided by Members to enable the eWG to engage with the provided information.

Recommendation 4:

It is recommended that:

4.1 CCNFSDU take note and agree with the proposed list of food additives **(Table 1)** and their technological justification that are currently used in RUTF.

4.2 CCNFSDU agree that the electronic working group recommend a proposed list of food additives to the Committee for consideration on their technological justification.

	Food Additive	**International Numbering System (Number if available)**	**Functional Class (e.g. color, emulsifier, stabilizer, etc.)**	**Technological Justification**	**Approximate Use Level**	**Maximum Use Level**
1	Mono & diglycerides	471	Emulsifier	Avoid oil separation Improves the binding properties so that it is not necessary to add extra amount of monoglycerides in paste Prevents oil separation without significant influence on meltdown properties Provides stability & maintain viscosity of paste Stabilize crystal lattice at ambient temperature & consequently cool transport is not required	1-2% 1.5% 1.8% 2% 1% 5 g/100 g 1.42g/100g	max 4000 mg/kg of the ready to use food max amount used= 1.65%
2	Ascorbyl palmitate	304	Antioxidants	Avoid oil oxidation (used in oil only) Antioxidants are important to ensure that the fat is not oxidised		Max 1 mg/100 ml of the product ready for consumption OR max 1 mg/100g of the product ready for consumption OR

						max 10 mg/kg of the product ready for consumption max amount used = 0.0165%
3	Tochopherol	307	Antioxidants	Avoid oil oxidation (used in oil only)		Less than 600 ppm
4	Citric acid	330	Antioxidant	Avoid oil oxidation (used in oil only)	GMP	
5	Lecithin	322	Emulsifier	Emulsifiers are needed to ensure uniform texture	0.5 g/100 mL (max)	max 5000 mg/kg of the ready to use food
7	Tocopherols rich extract	306	Antioxidant	Antioxidants are important to ensure that the fat is not oxidised		max amount used = 0.0165%
9	Ascorbic acid	300	Antioxidant	Antioxidants are important to ensure that the fat is not oxidised		GMP
10	Citric and fatty acid esters of glycerol	472c	Emulsifier	Emulsifying agents acts in such a way that the combined ingredients in the formulation, can be properly reconstituted, thereby creating a stable homogenous end-product.		max 9000 mg/kg of the ready to use food max amount used= 1.65%
11	Mixed tocopherol concentrate	307 b	Antioxidant	Antioxidants are substances that inhibits oxidation, hence counteracting deterioration of the formulation or product allowing it to have an extended shelf life.		Max 1 mg/100 ml of the product ready for consumption OR max 1 mg/100g of the product ready for consumption OR max 10 mg/kg of the product ready for consumption
12	Nitrogen	941	Packing Gas	Products are nitrogen flushed before sealing so that oxygen is displaced. This inhibits oxidation and thereby spoilage throughout the product's mentioned shelf life.	GMP	

13	Carbon dioxin	290	Packing Gas	Products are flushed with carbon dioxin before sealing so that oxygen is displaced. This inhibits oxidation and thereby spoilage throughout the product's mentioned shelf life.	GMP	
14	Sodium Tri-phosphates	451	Stabiliser	Only additions in oil an fat powders from oil manufacturers.		
15	Silicium dioxide	551	Free flowing agent			
16	NATA - 5	N/A	Emulsifier	it maintains a uniform mixture of immiscible phases		Max. Amount Used in RUTF formula: 1%
17	Grindsted PS - 209 (Composed of Mono-diglyceride & Triglyceride	-2	Emulsifier	To prevent oil separation	0.527%	
18	Fortium APT 10 (composed of mono & di-glycerides, propylene glycol, mixed tocopherols, and ascorbyl palmitate)		Antioxidant	To inhibit oxidation	0.030 %	
19	N-ATA 1	-2	Stabiliser	Keeps oil from separating		2.5% 1.28%

Outstanding Issues from CCNFSDU39

The following issues were not discussed at CCNFSDU39 due to time constraints:

- The use of other matrices in RUTF Formulation
- Nutritional Composition and Quality Factors
- Vitamins
- Minerals
- Technologies for and effect for processing
- Good manufacturing practices and good hygiene practices
- Methods of analysis and sampling
- Packaging
- Labelling

Recommendations that were made by the 2018 EWG are presented on the outstanding sections that couldn't be discussed for the consideration by the Committee. Written comments that were submitted by Members at CCNFSDU39 were also taken into consideration when putting together the recommendations.

5. The Use of other Matrices in RUTF Formulation

In 2016 the eWG Members supported that the section on “Raw materials and Ingredients” should not only be limited to the list provided, but should also make provision for other raw materials that were locally available and could be used in the production of RUTF. This would allow for variety and increase palatability when local and cultural acceptable ingredients were used and also to reduce costs of RUTF. A proposal was made that a statement should be added to explain that new formulation with other ingredients can be proposed, only with published efficacy study and acceptability study to demonstrate the use on the new developed product to treat SAM in the same context as the current RUTF. Various Members highlighted that since RUTF were foods for special medical purposes, they should be covered by the provisions of CXS 180-1991 to ensure consistency with the language used in the Standard, with specific reference to section 3 of the standard.

In 2017 consultations, the Chairs requested the eWG Members to comment on the proposed text referencing section 3 of the CXS 180-1991. The eWG Members were requested to comment on the proposed text as well as providing their rationale if they were of the view that the provisions of section 3 of CXS 180-1991 were not sufficient for RUTF. Several eWG Members were in support of the proposed text (CM=6, CO=8), with five Members not in support of the text and the approach (CM=2, CO=3). One Member emphasized that the guidelines should allow for flexibility in formulation and manufacturing as well as technological innovation, provided that there is scientific evidence to support the effective delivery of the nutritional requirements for the target group. Some Members were not in support of the addition of the word "composition" in the proposed text since it does not address the concerns of the eWG Members with regard to new RUTF formulations.

One Member proposed that the title should be changed to "the use of other ingredients in RUTF formulation" as it would be more aligned with the proposed text. One Member reiterated that all RUTF formulations must be based on sound independent scientific evidence to demonstrate their effectiveness in the treatment of SAM when compared to other formulations and high energy and nutrient family foods. Furthermore, whilst other new formulations are being considered with other ingredients in accordance with the general principles mentioned in the *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991) several scientific studies have reported that use of formulation with other ingredients are less effective in terms of recovery rates in comparison to standard, peanut and milk (25%) based formulation. One Member also recommended that section on “Specific prohibitions” on the use of products treated by ionizing/irradiation, use of salt and partially hydrogenated fats should be added under the “Raw Materials and Ingredients” section.

Conclusion

The eWG Members reiterated that the proposed guidelines should allow for flexibility in formulation and manufacturing of RUTF as well as the technological innovation, provided that there is scientific evidence to support the effective delivery of the nutritional requirements for the target group. The Chairs note that various Members highlighted that since RUTF were foods for special medical purposes, they should be covered by the provisions of CXS 180-1991 to ensure consistency with the language used in the Standard, with specific reference to section 3 of the standard. Based on the responses from the eWG Members the Chairs recommend that section 3 of the CXS 180--1991 be referenced to ensure that all new formulations of RUTF comply to the provisions of section 3.

Recommendation 5:

That CCNFSDU agree to the proposed text which reference Section 3 of the CXS 180-1991 on the use of other matrices in RUTF formulations as follows:

The Use of other Matrices in RUTF Formulation

RUTF may be manufactured with formulations different from the one laid down in these guidelines provided that these formulations comply with Section 3 of the *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991).

6. Nutritional Composition and Quality Factors

The current nutritional composition for RUTF is derived from the F-100 product which is currently used for in-patient management of SAM. The nutritional composition recommended in the '2007 Joint statement by UN agencies' was used as a departure point for reviewing the nutritional composition of RUTF. During the 2016 consultations with the eWG Members, there was overwhelming support of the current nutritional composition for RUTF and some Members indicated that various nutrients should be reviewed to align them with the latest scientific evidence available. It was also highlighted that the compositional design of F-100 did not include considerations of the need for higher nutrients for 'catch up' linear bone growth that experts now accept as important for this target group. Selected nutrients (Phosphorus, calcium, magnesium) needs for malnourished populations were reviewed later, and recommendations for these nutrients were increased to allow for catch up bone growth[7].

6.1 Macronutrients

6.1.1 Energy

The current nutritional composition of RUTF on energy stipulates that the product should at least provide 520-550 kcal per 100g (5.2 to 5.5 kcal per gram). The energy density is one of the most important qualities of RUTF for children with SAM. These children have an increased energy need for catch-up, and some will have a poor appetite with an inability to eat large amounts. Several programmatic studies have shown that RUTF are very effective in treating severely wasted children and one of the reasons is likely to be their high energy density of about 5 kcal/g. It is therefore important that mandating the energy density of RUTF will enable a product which is nutritionally appropriate for SAM children, and ensure that the ranges specified for macronutrient and micronutrients in the guidelines are within a nutritionally appropriate energy density range.

The Chairs requested the eWG Members to provide comments on the proposed energy values, as well as the draft texts to be included in the guidelines. Several Members supported the proposed values since they were consistent with the recommendations in the 2007 Joint Statement (CM=5, CO=6). One Member commented that the energy values of 520-550 kcal/100g seemed very high and was concerned that if fat would be used to reach the proposed levels it might have effect on malnourished children's metabolism. Two Members proposed that the additional energy required by SAM children should depend on the amount of breastmilk the older infant and young child would be receiving. Two Members indicated that the proposed minimum and maximum ranges of only 30 kcal/100g were quite tight and a proposal was also made that a wider range of energy density should be considered for feasibility reasons.

One Member commented that the proposed range of at least 5.2- to 5.5 kcal would not enable RUTF to be soft or crushable as outlined in the description since the proposed range of the energy density needs higher proportion of lipids/fats with less water, which would result in increased stickiness, thus a lower limit of the energy density should be given to the RUTF formulation. One Member commented whether there was any justification to the maximum value for energy and proposed that the same approach should be followed as applied to vitamins and minerals with no maximum values. Two Members were of the view that all nutrients should be expressed as per 100kcal and not per 100g to align with other Codex standards.

Several Members were in support of the proposed text (CM=8, CO=2), with five (CM=2, CO=3) not in support of the text. One Member indicated that the energy content of the product is mainly achieved by a balance between proteins, sugars and lipids. Therefore, all efforts should be directed into achieving the compositional requirements of the RUTF by using appropriate ingredients rather than increasing the energy density which does not seem to be the most appropriate approach.

Conclusion

Based on the comments received from the eWG Members the Chairs recommend that the current values of 520 to 550 kcal/100g be kept unchanged as per 2007 Joint Statement, until there is sufficient evidence to increase or decrease the values for SAM children.

[7] *WHO. Technical note: supplementary foods for the management of moderate acute malnutrition in infants and children 6–59 months of age*. Geneva, World Health Organization, 2012.
http://apps.who.int/iris/bitstream/10665/75836/1/9789241504423_eng.pdf?ua=1&ua=1

Recommendation 6:

That CCNFSDU agree to the proposed text on energy and the energy values as follows:

Energy

Draft Text

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

Energy Values

Unit	Minimum	Maximum	GUL
Kcal/100g	520	550	-

6.1.2 Carbohydrates

Setting a Minimum and Maximum/GUL for the total available Carbohydrates

The eWG Members were requested to provide an opinion on whether it was desirable to set a minimum value of available carbohydrates for RUTF. Several Members were of the opinion that there was no reason to define a minimum for carbohydrates since the value could be obtained by difference from the total energy, lipids and proteins. It was also indicated that carbohydrates are used in RUTF to achieve the final energy density, after the protein and lipids contributions have been taken care of. Another Member was of the view that currently there were no minimum or a maximum for carbohydrates in RUTF formulation, and by specifying these values it would make development of other RUTF formulations difficult as flexibility from carbohydrates is needed to meet the lipid and protein specifications for RUTF. It would be more useful to indicate the nature of the carbohydrate such as pre-gelatinized, and indicating the type of sugars included such as lactose versus sucrose. One Member proposed a maximum added sugar content of up to 10% of energy content to be specified in the guidelines.

Conclusion

The Chairs note the responses from the eWG Members and propose that minimum and maximum/GUL values for carbohydrates not be set to allow the appropriate balance between fats, energy and proteins to determine the minimum and maximum levels of carbohydrates.

Recommendation 7:

That CCNFSDU agree not to set the minimum and maximum/GUL values for carbohydrates.

6.1.3 Proteins

Dietary protein content and quality are of major importance in the treatment of malnourished children. If the content, quality, or availability is too low, it will limit growth and thereby recovery. If the intake is above the requirement, the surplus protein could be metabolized into energy, which is not an energy-efficient process. Too much protein could be a challenge for malnourished children because any surplus protein will be converted to urea, adding to the renal solute load[8]. Furthermore, too much protein might have a negative impact on appetite, which is especially harmful in malnourished children undergoing treatment[9]. In severe acute malnutrition, a high protein intake might compromise liver function. Cow's milk in F-100 formulation contains the protein amount of 28g/1000 kcal (11.2% of energy) and this amount is sufficient for rapid catch-up growth. The current recommendation is that protein should provide 10%-12% of the total energy.

[8] Golden MH. Proposed recommended nutrient densities for moderately malnourished children. Food Nutr Bull 2009;30: S267-343.

[9] Prentice AM. Macronutrients as sources of food energy. Public Health Nutr 2005; 8:932-9.

There was general support amongst the eWG Members on proposed range of protein to provide 10%-12% of the total energy (CM=3, CO=7). The reasons given by Members in support of these values were that the range of 10-12% protein has been demonstrated to be efficacious in the treatment of SAM and is the range set out in the 2007 Joint statement. Some Members noted that the amount of protein could differ depending on the RUTF formulation, and also considering that the coefficient of digestibility of cereal protein is lower than milk products, a proposal was made to add the word "available" to the proposed statement to read as follows: "Available protein should provide 10%-12% of the total energy." The inclusion of the proposed word would allow for equivalency of nutritional efficacy of innovative formulations which may contain other lower-digestibility protein sources. Three eWG Members were opposed to the proposed ranges (CM=2, CO=1). One Member considered the proposed values unnecessary since the range as a percentage of total energy was already defined.

Conclusion

The Chairs recommend keeping the proposed range of protein to provide 10% to 12% of the total energy as stipulated in the 2007 Joint Statement, as well as noting the comments from the eWG Members.

Recommendation 8:

That CCNFSDU agree to the proposed protein values in RUTF.

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

Unit	Minimum	Maximum	GUL
g/100g	12.8	16.2	-
g/100kcal	2.3	3.1	-

6.1.3.1 Protein Quality

A. Review of the "50% of protein sources from milk products"

The 2007 Joint Statement recommended that "at least half of the proteins contained in the RUTF should come from milk products". The 2016 eWG Members questioned the scientific justification of this statement and emphasized that PDCAAS and DIAAS should be the preferred methods to determine the quality of the protein. However other Members indicated that the statement "50% of protein sources from milk products" should not be removed from the nutritional composition of RUTF since there is no scientific evidence of RUTF with other protein source other than milk that have been demonstrated to be efficient for the management of SAM children. A study by Bahwere et al showed inferior recovery rates for product with less than 50% of protein from dairy source[10]. The inclusion of milk powder as an ingredient improves the amino acid profile (has a high Protein Digestibility Corrected Amino Acid Score) and it is a good contributor of bioavailable calcium and potassium. In addition, it has a specific stimulating effect on linear growth and insulin growth factor 1 (IGF-1) levels in the child and does not contain anti-nutrients.[11]

The 2016 eWG Members supported a need for RUTF formulations without a minimum of 50% of protein from milk products to allow for product innovation. Clear guidance would be required with regard to setting protein quality requirements for RUTF which would serve as a guide in designing new RUTF formulations. This might require clinical studies to be conducted before such products are released for use. A proposal was made that the wording "50% of protein sources from milk products" be deleted and instead, protein quality be described using PDCAAS or DIAAS. However, this is on the assumption that the dairy source content would still be needed for protein quality.

The 2017 eWG Members were requested to comment on whether the statement "at least 50% of protein is provided by milk products" should be retained in the nutritional quality and composition of RUTF. The eWG Members were still divided on the issue on whether such a statement should still be included. The Chairs requested the eWG Members whether they would support the proposal that the statement "50% of protein sources from milk products" be kept in square bracket until there is guidance from FAO. There was widespread support by Members to keep the statement in square brackets until there is guidance on the determination of protein quality from FAO (CM=9, CO=4).

[10]Bahwere et al. Cereals and pulse-based ready-to-use therapeutic food as an alternative to the standard milk- and peanut paste–based formulation for treating severe acute malnutrition: a non-inferiority, individually randomized controlled efficacy clinical trial. Am J ClinNutr. 2016.

[11] WHO. Technical note: supplementary foods for the management of moderate acute malnutrition in infants and children 6–59 months of age. Geneva, World Health Organization, 2012.

One Member highlighted that although there is a recognition that other local and culturally acceptable protein sources may be appropriate, there should be scientific evidence that support the comparable effectiveness with RUTF formulations containing protein from milk products. Including a measure of protein quality that is internationally standardized and validated in collaborative studies such as PDCAAS in this guidelines may assist in providing flexibility with the statement in brackets. Some Members were of the view that the statement should be removed from the guidelines since there is no scientific justification for it. Two Members commented that the statement should be retained in the guidelines since the available scientific evidence suggests that effectiveness of RUTF formulations using ingredients other than milk powder as a protein source like soya is sub-optimal.

Conclusion

The Chairs note that stipulating that RUTF should contain a minimum of 50% of protein from milk products may have the potential of limiting product formulation and innovation. On the other hand, the existing evidence has demonstrated that RUTF containing less dairy ingredients may not be very effective in treating children with SAM**.** In the absence of scientific evidence to include such guidance in the guidelines, maintaining a minimum percentage of protein from milk products may be desirable. The Chairs also note that protein quality should be measured by either the use of PDCAAS or DIAAS for the finished product. Neither the PDCAAS nor the DIAAS values have been established for RUTF. The Chairs are recommending that until guidance is available from FAO on the use of PDCAAS for RUTF, the proposed statement should be kept in the square brackets.

B. Evaluation of Protein Quality in RUTF

During the 2016 eWG, there was consensus amongst Members about the use of Protein Digestibility Corrected Amino Acid Score (PDCAAS) or Digestible Indispensable Amino Acid Score (DIAAS) as a measure of protein quality for the finished product as stipulated in the FAO Guidelines[12]. However, several Members indicated that the PDCAAS methodology has been recently criticized by FAO Expert Working group in preference of DIAAS since it is viewed as a more rigorous approach in determining protein quality. DIAAS values have not been established for all protein and therefore are not available for use at this stage. Although Members acknowledged that PDCAAS or DIAAS were the recommended methods to evaluate the dietary protein quality, several Members indicated that there are other methods. These methods include appropriate published data on digestibility of protein in potential RUTF ingredients, in combination with analysed or published amino acid composition to determine the PDCAAS or DIAAS could be used, as long as the ingredients in the foods mentioned in the published paper are in the same form as in the final RUTF product. A need for the determination of the PDCAAS and DIAAS score that would be appropriate for RUTF was proposed.

At CCNFSDU38, the Representative of FAO confirmed that in the interim the PDCAAS method should be used as DIAAS was not yet completed. FAO would consider convening an expert consultation to provide guidelines. RUTF was added to the terms of reference of the expert consultation to develop guidelines in using PDCAAS methods.

At CCNFSDU39, the Representative of FAO confirmed that the FAO Expert Working Group on protein quality assessment in follow-up formula for young children and Ready to Use Therapeutic Foods took place in Rome from 6 to 9 November 2017. The report of the FAO Expert Working Group will be discussed at the Physical Working Group Meeting in November.

Recommendation 9:

That CCNFSDU agree to keeping the statement "at least 50% of protein is provided by milk products" in square brackets until there is further guidance from FAO on determining protein quality using PDCAAS.

["at least 50% of protein is provided by milk products"]

6.1.4 Lipids

Fat is an important source of energy for infants and young children. Children with severe acute malnutrition have an increased need for energy for catch-up growth and thus require a diet with a high energy density. The most important factor influencing energy density in RUTF is the fat content, as the energy density of fat (9 kcal/g) is more than double that of protein and carbohydrate (4 kcal/g). The high energy density in RUTF is achieved by the addition of fats and oils and in the current RUTF formulations the percentage of energy from fat is between 45% and 60%. Given the high energy needs of malnourished children and the positive results obtained with foods with a high fat content in the treatment of severe acute malnutrition, it seems prudent to aim at a fat intake close to the upper limit of the range.

[12]Report of an FAO Expert Consultation. Dietary protein quality evaluation in human nutrition. Rome, Italy. 2013.

There was widespread support by the 2017 eWG Members of the proposed fat ranges since they were in line with the 2007 Joint Statement. Two Members were of the view that the proposed ranges were too high and should be aligned to the WHO's recommendations of fats contribution to total energy of not more than 30%.

Determination of Minimum and Maximum/GUL values for fats/lipids

There was general support to determine the fat values, as well as the maximum level since it is already referred to in the 2007 Joint Statement. This would also ensure that there was consistency throughout the guidelines. It was proposed that a minimum value should be 26g, with a maximum of 37g.

Conclusion

Noting the responses from the eWG Members, the Chairs recommend that the current range of fat values of 45% to 60% of fat contribution to total energy be retained, and the maximum values as stipulated in the 2007 Joint Statement. The Chairs are also recommending the draft text for the "fat/lipids" section for consideration by the Committee.

Recommendation 10:

That CCNFSDU agree to the proposed text on fats/lipids and the proposed minimum and maximum fats/lipids values as follows:

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

The level of linoleic acid should not be less than 333 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33mg/100kcal. The level of linoleic acid should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.]

Unit	Minimum	Maximum	GUL
g/100g	26	37	-
g/100kcal	5	6.7	-

6.1.4.1 Essential fatty acids

The 2016 eWG Members were asked whether they were in support of reviewing and setting of minimum levels for essential fatty acids in RUTF. Recent evidence showed that the recommended content of omega 3 and omega 6 in RUTF such as Alpha Linoleic acid were not adequate[13]. It was noted that the current proposed range of 3% to 10% of energy for linoleic acid (LA, omega-6) was in line with other Codex texts but falls short of what was recently recommended by EFSA[14]. The current proposed range for alpha-linolenic acid (ALA, omega-3) also falls below the minimums established for ALA by other Codex texts and EFSA. A recommendation was made that LA and ALA should have specific minimums to help prevent essential fatty acid deficiency. A balance between LA and ALA is important to help maintain metabolic function and a balance between respective fatty acid derivatives specifically, arachidonic acid (ARA; 20:4 n-6) and docosahexaenoic acid (DHA; 22:6 n-3), respectively. In keeping with this concept it was proposed that a minimum ratio of LA:ALA of 5:1 and a maximum ratio of 15:1 also be considered. This ratio range would align RUTF with the current Codex Infant Formula Standard and the pending revisions to the Codex Follow-up Formula Standard.

There is scientific evidence that supports setting minimum levels for essential fatty acids in RUTF as highlighted in the study of Jones et al. (2015)[15] which aimed at developing an RUTF with elevated short-chain n-3 PUFA and measure its impact, with and without fish oil supplementation, on children's PUFA status during treatment of severe acute malnutrition. The authors concluded that PUFA requirements of children with SAM are not met by current formulations of RUTF, or by an RUTF with elevated short-chain n-3 PUFA without additional preformed long-chain n-3 PUFA. It was also recommended that the long-chain omega-6 and omega-3 fatty acids (LCPUFA) docosahexaenoic acid (DHA; omega-3) and arachidonic acid (ARA; omega-6) should be taken into consideration. However, it was emphasized that scientific justification to change the current levels should be convincing with specific reference to SAM children.

[13]Michaelsen KF, et al., 2011. Food sources and intake of n-6 and n-3 fatty acids in low-income countries with emphasis on infants, young children (6–24 months), and pregnant and lactating women. Maternal and Child Nutrition 7 (Suppl. 2), pp. 124–140.

[14] EFSA, 2014. Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014 ;2(7) :3760, 106 pp. doi:10.2903/j.efsa.2014.3760.

[15] Ready-to-use therapeutic food with elevated n-3 polyunsaturated fatty acid content, with or without fish oil, to treat severe acute malnutrition: a randomized controlled trial. BMC Medicine. 13;93.2015

The 2016 eWG Members indicated that several existing Codex Standards related to foods and formula for infants and young children have established minimum levels for the essential fatty acids linoleic acid (LA; 18:2 n-6) and alpha-linolenic acid (ALA; 18:3 n-3). Harmonization with these guidelines would be important to ensure the nutritional quality of RUTF. The table below summarizes these recommendations, and others, as compared to those proposed in the Nutritional Composition for RUTF.

Table 1: Essential Fatty acids recommendations from various Codex texts, EFSA and 2007 Joint Statement

Fatty Acid	Codex Stan 72-1981 (Infant Formula)	CAC/GL 9-1991 (Formulated Complementary Foods)	Codex Stan 156-1987 (Follow-up formula, revision in progress, agreement on LA levels at Step 4)	EFSA, 2014. (Essential composition of infant and follow-on formula)	RUTF Nutritional Composition
Linoleic Acid	300 mg/100 kcal (~2.7% E)	333 mg/100 kcal (~3.0% E)	300 mg/100 kcal (2.7% E) or 500 mg/100 kcal (4% E)	500-1200 mg/100 kcal (~4-9.6%E)	3-10% of total energy
Alpha-linolenic acid	50 mg/100 kcal (0.5% E)	Not specified	50 mg/100 kcal (0.5% E)	50 mg/100 kcal (0.5% E)	0.3-2.5% of total energy

The 2017 eWG Members were requested to provide comments (with justification) on whether the current RUTF nutritional composition on essential fatty acids should remain or changed to align with other existing Codex text or EFSA recommendations. The eWG Members were divided on this matter. Several Members preferred the current values to stay (CM=3, CO=2, CMO=1), and others proposed different values (CM=1, CO=3). Some Members commented that the current RUTF nutritional composition on essential fatty acids should remain at its current levels to align with the recommendations in the 2007 Joint Statement, until there is new scientific evidence to suggest new values for SAM children. Two Members proposed that the current values should be reviewed and aligned to the current and pending values for infant formula standards. This is due to the fact that infants and young children in developed and developing world were not meeting the ALA requirements, and noting that an amount of 30 mg DHA and an equal amount of ARA, should be added to RUTF to meet the adequate intake levels indicated for children 6-24 months. Some Members commented that the current values should be aligned to those proposed by EFSA.

However, it was expressed by some Members that the EFSA proposed values were not relevant in this context as they are meant for children in the general population within the EU, whereas the current RUTF recommendations are based on the needs of children suffering from SAM. One Member indicated that more scientific evidence was needed to assess the added benefit of adding balanced PUFA content to RUTF because adding them directly in RUTF would increase costs substantially and/or reduce shelf-life of the product. In the Second Consultation the Chairs proposed whether the eWG Members were in agreement with the retention of the current essential fatty acids values in RUTF. Several Members supported the retention of the current values (CM=9, CO=2), with three Members disagreeing (CM=1, CO=2) with the current values.

One Member who did not support the retention of the current values commented that the there was sufficient scientific evidence regarding the insufficiency of existing RUTF formulations to promote the essential fatty acid status and, in particular, the DHA and ALA status of SAM children compared to that of healthy children. Therefore, RUTF formulation should be harmonized with existing and emerging standards for healthy children. Furthermore, there is little justification for denying SAM children the same access to a minimum threshold for key fatty acids as healthy children and revising the lower bound for ALA to 0.5% of total energy from the current 0.3%, would be beneficial, including a level of at least 20 mg DHA/100 kcal (suggested GUL - 50 mg DHA/100 kcal), and an equal amount of ARA as per EFSA recommendations.

Conclusion

The Chairs note the diverse views of the eWG Members on the values for essential fatty acids. Due to the absence of scientific evidence on specific requirements for SAM children, the Chairs recommend that the current values as stipulated in the 2007 Joint Statement be retained.

Recommendation 11:

That CCNFSDU agrees to retaining the linoleic acid and alpha-linolenic acid values as stipulated in the 2007 Joint Statement in the current RUTF nutritional composition as follows:

Essential Fatty acids values

Linoleic Acid = 3-10% of total energy

The level of linoleic acid should not be less than 333 mg per 100 kcal

Alpha- linolenic acid = 0.3-2.5% of total energy

The level of alpha-linolenic acid should not be less than 33 mg per 100 kcal

6.1.5 Setting Minimum and Maximum levels for vitamins and minerals for RUTF

The 2016 eWG made a proposal that further consideration should be given to setting minimum, guiding upper level (GUL) or maximum levels for vitamins and minerals taking into account the likely nutritional deficiency or inadequacy of the target group. With regard to setting the Maximum levels some Members were of the view that only those vitamins and minerals that could pose a health risk as a result of excessive intake should be considered. One Member also queried that setting maximum levels for RUTF might not be desirable since maximum levels may vary depending on the duration of RUTF consumption, recovery time, and age group. This may need further elaboration on whether the stipulated minimum and maximum levels are applicable only at product release - or throughout the shelf life of a product. Some Members indicated that the guidelines should state whether the minimum levels as stated in the nutritional composition would be applicable only at product release or throughout the shelf life, since it could make a substantial difference to feasibility and ultimately costs of the product.

In order to start a discussion on the current nutritional composition of RUTF, the Chairs requested the 2017 eWG Members to consider the current nutritional composition and provide alternatives if there were any with scientific justification.

7. Vitamins

7.1 Vitamin A

Vitamin A is essential to vision, cell differentiation, and the immune response. It occurs in foods as two different groups of compounds: preformed biologically active vitamin A and provitamin A carotenoid. Preformed biologically active vitamin A (retinol, retinoic acid, and retinaldehyde) is only present naturally in foods of animal origin. The provitamin A carotenoids require enzymatic cleavage before they are converted into biologically active forms of vitamin A. The bioavailability of provitamin A depends on the food matrix and processing. Several Members indicated that CXS 72-1981 and other recognized authoritative scientific bodies recommend that vitamin A activity in infant formula and follow-up infant formula should be provided by retinol or retinyl esters, while any content of carotenoids should not be included in the calculation and declaration of vitamin A activity in these products.

This is recommended because of the existing uncertainties as to the relative equivalence of provitamin A carotenoids and retinol in infants. Provitamin A carotenoids contribute to the adequacy of vitamin A intake but mathematical equivalencies between the provitamin A carotenoid content of foods and the amounts that converted to retinol (i.e. carotenoid bioconversion factor) are only estimates. Their actual contribution varies substantially due to factors that include: food matrix in which the carotenoid is present, consumers' vitamin A adequacy status (which limits conversion), genetic factors, food processing, species of carotenoids, molecular linkages, amount of carotenoids consumed in a meal and fat in the diet. Therefore, beta-carotene may not be desirable form contributing to the Vitamin A requirements.

In the First Consultation paper the Chairs requested the 2017 eWG Members to comment on the proposed values for vitamin A. The eWG Members were divided in supporting the current values on Vitamin A as stipulated in the 2007 Joint Statement. Eight Members were in support of the current values and six Members were not supportive of the current values. One Member recommended a lower level of 0.6 mg RE/100g be allowed during storage due to degradation of vitamin A. Some Members indicated that the current values were too high for the target group since they were above the recommended dietary allowances recommendations. Those who were in support of the current values commented that it should be specified that the preformed retinol (e.g. retinol acetate or retinyl palmitate) be provided and not the beta-carotene form only. One Member recommended a value of 0,7 mg RE (4-7 Years old) per day. There was an agreement amongst the eWG Members on the minimum recommended value as stipulated in the 2007 Joint Statement.

a. Setting a maximum/GUL for Vitamin A

There was general support amongst the eWG Members to set a maximum level for vitamin A due to its toxic effect at a higher dose. Due to Vitamin A instability and its degrading effect during the shelf-life of the product, maximum level of between 1.2 - 1.5 mg RE/100g was recommended by some Members. This would also allow for appropriate overages to be added to sustain a 24-month shelf-life of the product. In the Second Consultation paper the Chairs requested the eWG Members to state their preferred maximum value for vitamin A between 1.2 or 1.5 mg RE/100g proposed values. There was no consensus amongst the eWG Members on the preferred maximum value for vitamin A. Three Members preferred the retention of the current value of 1.1 mg RE/100g (CM=3). Two Members who supported the retention of the current maximum value indicated that a rationale for the increased maximum should be based on sound scientific advice provided by a recognized authoritative scientific bodies. Most of these products are consumed well before their best-before date, therefore vitamin A content when consumed is expected to still be within the current proposed range most of the time.

Four Members preferred a value of 1.2 mg RE/100g (CM=2, CO=2), and two Members a value of 1.5 mg RE/100g (CO=2). The reasons for preferring a higher maximum value include the narrow limits placed on Vitamin A which might pose a challenge during analysis due to its instability. A wider range may be preferable due to high uncertainty of analytical methods and the matrix of the product. It was further stated that the manufacturing process didn't allow narrow ranges because of large variability in processing conditions and raw materials. The degradation of some vitamins over time might necessitates a reduction in shelf life or a large overage of vitamins so that the product could still meets label claims at the end of shelf life.

One Member suggested setting a GUL instead of a maximum level since the exact levels may be difficult to reach due to analytical uncertainty, overages included, and also natural variations of ingredients.

b. The contribution of beta-carotene to the vitamin A requirement in RUTF

There was widespread support amongst the eWG Members that beta-carotene should not contribute to the vitamin A requirements since it has not been evaluated for efficacy as a source of vitamin A in RUTF in the treatment of SAM. One Member highlighted that this recommendation would be in line with The *Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72 – 1981), which specifically notes the requirement of pre-formed retinol and indicated that counting beta-carotene would not be considered acceptable. This is recommended because of the existing uncertainties as to the relative equivalence of provitamin A carotenoids and retinol in infants. One Member indicated that Beta-carotene is an approved form of provitamin A in the advisory list of nutrient compounds for use in foods for special dietary uses intended for infants and young children (CXG 10-1979) including FSMPs, therefore it should also be considered.

Conclusion

Taking into account the view of the eWG Members on whether to retain the current maximum value or increase it, the Chairs are of the view that the maximum value for vitamin A should not be increased at this stage until there is enough justification for such increase. However, if the Committee decide to increase the maximum value of vitamin A due to its instability and its degrading effect during the long shelf life of the product, a maximum value of 1.2 mg RE/100g is recommended to accommodate these uncertainties. The Chairs note the responses from the eWG Members and recommend that beta-carotene should not contribute to the vitamin A requirements in the formulation of the RUTF.

Recommendation 12:

That CCNFSDU agree to the minimum, maximum and associated footnote for vitamin A as follows:

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

[2] 1µg RE = 3.33 IU Vitamin A = 1 µg 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.

7.2 Vitamin D

Vitamin D Levels

Vitamin D is critical for metabolism of calcium for cartilage and bone maturation and linear growth catch-up. New evidence has been emerging that SAM children have a vitamin D deficiency. The eWG Members were requested to comment on the 2007 Joint Statement values for vitamin D during the First Consultation. There was no consensus amongst the eWG Members on the proposed minimum and maximum values for vitamin D as stipulated in the 2007 Joint Statement. Different views were expressed about the proposed values. Several Members commented that increasing the maximum slightly would allow for a safe overage level needed for the product to remain within specifications under the anticipated storage conditions and shelf life. This is due to the fact that the proposed maximum of 20 µg/100g may be exceeded if 15 µg/100 g of product is added in the vitamin premix, as some intrinsic Vitamin D can be provided from dairy sources. Some Members were of the opinion that the proposed maximum levels of Vitamin D were above the recommended dietary allowances for children from birth to 13 years, which might have serious side effects[16].

In the Second Consultation the eWG Members couldn't reach a consensus on the preferred minimum, maximum and GUL values for vitamin D. Three Members supported a minimum of 14 µg/100g and five Members a value of 15 µg/100g. The maximum values of 20 µg/100g and 22 µg/100g were supported by five and four Members respectively. Two Members reiterated that the rationale for the revisions of vitamin D levels should be based on sound scientific advice provided by a recognized authoritative scientific bodies. Two Members who were in support of the broader ranges for vitamin D indicated that the proposed values should be technologically feasible to ensure that manufacturers comply with the required values.

It was also recommended that the forms (i.e. cholecalciferol (D3) and/or ergocalciferol (D2) of vitamin D to be used in RUTF formulation be defined to assist the manufacturers, and several Members supported this approach. Some Members were of the view that the recommended forms of vitamins and minerals permitted in RUTF were already captured under the Vitamins and Minerals section of the Guidelines, that "All added vitamins and minerals must be in line with the *Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979)". Therefore, there is no need to specify the forms of vitamin D in the document. It was proposed that a footnote be added to provide a conversion factor to International Units (IU).

Setting of Maximum or GUL for Vitamin D

There was general support to either have a maximum value or a GUL for vitamin D. It was indicated that by widening the current range it would enable the specification for RUTF formulation to be technologically achievable. A GUL limit should be stipulated to control the dosing of vitamin D. A GUL that would allow for slightly higher inputs would assist the manufacturers to maintain a 24-month shelf life of the product due to the degrading effects of vitamin D during processing and storage. A GUL of 30µg/100 g was proposed which is in line with the upper limit listed in WHO Technical note: supplementary foods for the management of moderate acute malnutrition in infants and children 6–59 months of age (2012). One Member supported a proposed GUL of 30 µg/100g.

Conclusion

Taking into account the views of the eWG Members the Chairs recommend that a minimum value of 15 µg/100g be retained as recommended in the 2007 Joint Statement. The Committee may decide to increase the maximum value from 20 µg/100g to 22 µg/100g to allow for a safe overage level needed for the product to remain within specifications under the anticipated storage conditions and shelf life. The Chairs are proposing that the Committee consider setting a GUL for vitamin D at a level of 30 to control the dosing of vitamin D during the manufacturing process. The Chairs also recommend that although the two forms of vitamin D allowed in RUTF formulation, namely cholecalciferol (D3) and ergocalciferol (D2), are already specified in CXG 10-1979, such forms should still be specified in the nutritional composition section to provide further guidance to member states.

Recommendation 13:

That CCNFSDU agree to the minimum, maximum/GUL and associated footnote for vitamin D as follows:

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

[3] 1 µg cholecalciferol = 40 IU vitamin D

[16] https://ods.od.nih.gov/factsheets/VitaminD-HealthProfessional/

7.3 Vitamin E

a. Vitamin E Levels

There was general support amongst the eWG Members on the current vitamin E values in the 2007 Joint Statement (CM=4, CO=5). However, one Member queried whether the proposed minimum value of 20 refers to mg tocopherol acetate (unit of expression in the 2007 Joint Statement) or α-tocopherol (the natural form and unit of expression as mg TE/ 100g), since a different value might result depending on the form of vitamin E used in the vitamin mineral premix. Therefore, it is important to clarify the unit of expression. Three Members were not supportive of the current values. Two Members expressed their concern that the proposed values were above the RDAs for children from birth to 13 years (4-7mg)[17].

Vitamin E Forms and Conversion factors

It was also proposed that the forms of alpha-tocopherol included (natural or synthetic and/or its ester forms) and the unit of expression (e.g. mg alpha tocopherol) should be specified in order to avoid different values being generated. One Member proposed that d-alpha-tocopherol should also be allowed to be used in RUTF since it is included in CXG 10-1979. One Member noted that CCNFSDU38 agreed to submit 1 mg α-tocopherol (1mg RRR-α-tocopherol) as the dietary equivalent for vitamin E to CAC40 for adoption at Step 5/8 (Appendix III). For consistency with the *Guidelines in Nutrition Labelling* (CXG 2-1985), it was suggested that the footnote state:

* 1 mg α-tocopherol = 1 mg RRR-α-tocopherol (d-α-tocopherol)

Two Members proposed that the conversion factors for the naturally occurring and synthetic forms of vitamin E and their esters be provided to enable the correct calculation of the dl alpha form of tocopherol, as it has half the biological activity of the naturally occurring form.

b. Setting of Maximum or GUL

There was no support to establish a maximum or GUL for vitamin E by the eWG Members since it was considered to be a safe nutrient for children for the standard treatment period for SAM. However, it was recommended that the permitted forms of vitamin E should be included to guide the manufacturers, and also a footnote for the conversion factors.

Conclusion

Taking into consideration the views of the eWG Members the Chairs recommend that the current minimum value for vitamin E of 20 mg/100g (mg/100 kcal) be retained as stipulated in the 2007 Joint Statement, and the maximum/GUL not be defined. The Chairs note that the 2007 Joint Statement makes reference to the mineral mix recommended for F-100 by WHO as an example of a mineral mix with a suitable positive non-metabolizable base. The vitamin and mineral mix is indicated in Appendix 4 of the WHO guidelines[18]. The specific form of vitamin E recommended in the WHO guidelines is α-tocopherol. Therefore, the minimum value of 20 refers to the is α-tocopherol form. The Chairs recommend that the conversion factors for both naturally occurring and synthetic forms of vitamin E be stipulated in the footnote to enable the correct calculation.

Recommendation 14:

That CCNFSDU agree to the minimum and associated footnote for vitamin E as follows:

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

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

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

[17] https://ods.od.nih.gov/factsheets/VitaminE-HealthProfessional/

[18] WHO. 1999WHO Management of severe malnutrition: A manual for physicians and other senior health workers. World Health Organization: Geneva.

7.4 Vitamin K

Vitamin K values

There was general support by the eWG of the current values for vitamin K. Three Members were of the opinion that the proposed minimum and maximum values for Vitamin K were very high for infants from 0-12 months (2 – 2.5mcg)[19]. The current maximum value was also supported and a proposal was made that a higher value would be preferred to allow for process and analytical variation. One Member indicated that a GUL for vitamin K may not be necessary as there are no known toxic effects associated with high intakes of Vitamin K (excluding those on anti-coagulant medication whose INR levels are regularly monitored).

Conclusion

Based on the responses from the eWG Members the Chairs recommend that the minimum and maximum values for vitamin K be retained as stipulated in the 2007 Joint Statement.

7.5 Vitamin B1

The eWG Members were supportive of the current values for vitamin B1 (CM=4,CO=6). There was general support not to include a maximum/GUL for vitamin B1 as there were minimal risk of toxicity. There are no established adverse effects from consumption of excess Vitamin B1 in food or through long- term oral supplementation. Vitamin B1 is water-soluble and any excess will be excreted from the body.

Conclusion

The Chairs recommend that the current minimum value for Vitamin B1 be retained as stipulated in the 2007 Joint Statement, and the maximum/GUL not be defined.

7.6 Vitamin B2

There was widespread support amongst the eWG Members of the current values for vitamin B2 (CM=4, CO=5). There was general support not to include a maximum/GUL for vitamin B2 since there were no established adverse effects from consumption of excess Vitamin B1 in food. Two Members indicated that the proposed values were above the RDAs for children from 0 to 8 years. One Member recommended that a GUL be set for vitamin B2.

Conclusion

Taking into consideration the eWG Members views, the Chairs recommend that the current minimum value for Vitamin B2 be retained as stipulated in the 2007 Joint Statement, and the maximum/GUL not be defined.

7.7 Vitamin C

There was widespread support amongst the eWG Members of the current values for vitamin C (CM=5, CO=5). There was general support not to include a maximum/GUL for vitamin C since it has minimal risk of toxicity and can be easily excreted by the body. Two Members indicated that the proposed values were above the RDAs for children from 0 to 8 years (25-40 mg)[20]. One Member recommended that a GUL be set for vitamin C.

Conclusion

The Chairs recommend that the current minimum value for vitamin C be retained as stipulated in the 2007 Joint Statement, and the maximum/GUL not be defined.

7.8 Vitamin B6

The eWG Members were in support of the current minimum value for vitamin B6 (CM=5, CO=5). There was general support not to include a maximum/GUL for vitamin B6 since it has minimal risk of toxicity and can be easily excreted by the body. Two Members indicated that the proposed values were above the RDAs for children from 0 to 3 years 0.1 – 0.5 mg[21]. One Member recommended that a GUL be set for vitamin B6.

Conclusion

The Chairs recommend that the current minimum value for vitamin B6 be retained as stipulated in the 2007 Joint Statement, and the maximum/GUL not be defined.

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[19] https://ods.od.nih.gov/factsheets/VitaminK-HealthProfessional/
[20] https://ods.od.nih.gov/factsheets/Riboflavin-HealthProfessional/
[21] https://ods.od.nih.gov/factsheets/VitaminB6-HealthProfessional/

7.9 Vitamin B12

There was widespread support amongst the eWG Members of the current values for vitamin B12 (CM=5, CO=5). There was general support not to include a maximum/GUL for vitamin B12 since it has minimal risk of toxicity and can be easily excreted by the body. Two Members indicated that the proposed values were above the RDAs for children from 0 to 8 years (0.4 – 1.2mcg)[22]. One Member recommended that a GUL be set for vitamin B12.

Conclusion

The Chairs recommend that the current minimum value for vitamin B12 be retained as stipulated in the 2007 Joint Statement, and the maximum/GUL not be defined.

7.10 Folic Acid

Members were supportive of the current minimum value for folic acid at 200 µg/100 g (CM=6, CO=5). One Member suggested that a footnote to explain the conversion factor from µg folic acid to µg Dietary folate equivalents (DFE) be added for labelling purposes (i.e. 1 µg of folic acid = 1.7 µg of DFEs). Two Members were of the opinion that the proposed minimum value for folic acid for children between 0-3 years was above the RDAs (65 – 150 mcg DFE)[23]. Members did not support the setting of a maximum/GUL value as folic acid has a minimal risk of toxicity.

Conclusion

The Chairs recommend that the current minimum value for folic acid be retained as stipulated in the 2007 Joint Statement, and the maximum/GUL not be defined.

7.11 Niacin

The eWG Members were in support of the current minimum value for niacin (CM=6, CO=5). There was general support not to include a maximum/GUL for niacin since it has minimal risk of toxicity and can be easily excreted by the body.

Conclusion

The Chairs recommend that the current minimum value for niacin be retained as stipulated in the 2007 Joint Statement, and the maximum/GUL not be defined.

7.12 Pantothenic Acid

The eWG Members were supportive of the current minimum value for pantothenic acid at 3 mg/100 g (CM=6, CO=5). There was general support not to include a maximum/GUL since it has minimal risk of toxicity and adverse effects from consumption of excess pantothenic acid in food are not well established.

Conclusion

The Chairs recommend that the current minimum value for pantothenic acid be retained as stipulated in the 2007 Joint Statement, and the maximum/GUL not be defined.

7.13 Biotin

There was widespread support amongst the eWG Members of the current values for biotin (CM=5, CO=5). There was general support not to include a maximum/GUL for biotin as there are no well-established adverse effects from consumption of excess biotin in food. One Member recommended that a GUL might be sufficient for biotin.

Conclusion

The Chairs recommend that the current minimum value for biotin be retained as stipulated in the 2007 Joint Statement, and the maximum/GUL not be defined.

Recommendation 15:

That CCNFSDU agree to the following recommendations for vitamin K, vitamin B1, vitamin B2, vitamin C, vitamin B6, vitamin B12, folic acid, niacin, pantothenic acid and biotin for RUTF as follows:

Vitamin K

Unit	Minimum	Maximum	GUL
µg/100 g	15	30	-

[22] https://ods.od.nih.gov/factsheets/VitaminB12-HealthProfessional/
[23] https://ods.od.nih.gov/factsheets/Folate-HealthProfessional/

µg/100 kcal	2.9	5.5	-
Vitamin B1			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	0.5	-	-
mg/100 kcal	0.1	-	-
Vitamin B2			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	1.6	-	-
mg/100 kcal	0.3	-	-
Vitamin C			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	50	-	-
mg/100 kcal	9.6	-	-
Vitamin B6			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	0.6	-	-
mg/100 kcal	0.12	-	-
Vitamin B12			
Unit	**Minimum**	**Maximum**	**GUL**
µg/100 g	1.6	-	-
µg/100 kcal	0.3	-	-
Folic Acid			
Unit	**Minimum**	**Maximum**	**GUL**
[5] µg/100 g	200	-	-
[5] µg/100 kcal	38.5	-	-
[5] 1 µg of folic acid = 1.7 µg of Dietary Folate Equivalents (DFE)			
Niacin			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	5	-	-
mg/100 kcal	0.96	-	-
Pantothenic Acid			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	3	-	-
mg/100 kcal	0.6	-	-
Biotin			
Unit	**Minimum**	**Maximum**	**GUL**
µg/100 g	60	-	-
µg/100 kcal	11.5	-	-

8. Minerals

8.1 Sodium

There was general support by the eWG Members for the maximum sodium value as set in the 2007 Joint Statement. One Member indicated that a minimum value for sodium was not desirable as intrinsic contribution of common raw materials is common and higher.

Conclusion

Noting the responses from the eWG Members, the Chairs recommend that the maximum value for sodium of 290 mg/100g be retained as recommended in the 2007 Joint Statement.

8.2 Potassium

Potassium is required for cellular physiology, convalescent growth, and for those who may have diarrhoea or need electrolyte replacement. There is a tissue deficit of potassium in severely malnourished patients brought about by an adaptation to conserve energy, where there is a slowing down of the sodium-potassium-ATP pump. This cellular pump normally maintains a high intracellular potassium concentration. Correcting the tissue deficit of potassium in severely malnourished children has been shown to reduce mortality rates. The eWG Members were supportive of the current minimum and maximum values for potassium as set out in the 2007 Joint Statement, as it takes into account the specific needs of the SAM patient and has been demonstrated to attenuate deficiencies (CM=6, CO=6). There was general support by the eWG to set a maximum value for potassium. Three Members supported the maximum potassium value of 1,600 mg/100g to ensure that the formulation of RUTF was technologically feasible (CM=1, CO=2. Some Members proposed that the guidelines should include the use and specify different forms of potassium such as potassium chloride tri-potassium citrate or potassium phosphate, or a combination, in order to formulate palatable products. However, several Members indicated that various forms of added vitamins and minerals permitted in RUTF were already captured by the statement under the "vitamins and minerals" section which makes reference to the *Codex Advisory list of nutrients for use in foods for special dietary uses for infants and young children* (CXG 10-1979).

Conclusion

Noting the responses from the eWG Members the Chairs recommend that the current recommended minimum and maximum values of 1100 mg/100g and 1400 mg/100g for potassium be retained until there is sufficient evidence to change them. This recommendation is in line with the proposed values in the 2007 Joint Statement. The Chairs are also recommending that various forms of potassium permitted in RUTF not be specified but a reference should be made to the *Advisory list of nutrients for use in foods for special dietary uses for infants and young children* (CXG 10-1979) for all permitted forms of potassium.

8.3 Calcium

Although there was general support for the current potassium values by the eWG Members (CM=6, CO=5), a Member proposed potassium values of 500-750 mg to allow for catch-up bone growth as stipulated in the WHO 2013 updates on SAM guidelines. Another Member supported the inclusion of a maximum of 785 mg calcium to allow for flexibility in ingredient choices that contain naturally occurring calcium as recommended by the WHO Technical note on supplementary foods for the management of moderate acute malnutrition in infants and children 6–59 months of age of 2012, which reviewed the recommended nutrient intakes for moderately malnourished populations and concluded that the 785mg of calcium as a maximum was a safe level for the malnourished populations. One Member also recommended that the range should be wider to be technologically feasible, with a minimum of 250 mg/100g and a maximum of 600 mg/100g. The proposed values would allow for variation in processing conditions and raw materials, and a 5-10% overage which would be required to account for losses during the manufacturing of RUTF. Only three eWG Members (CM=1, CO=2) supported different minimum and maximum values for calcium which were different from the 2007 Joint Statement recommendations.

Conclusion

Noting the responses from the eWG Members, the Chairs recommend that the 2007 Joint Statement proposed values for calcium at a minimum of 300 mg/100g and maximum of 600 mg/100g be retained. The Chairs also note the recommended maximum value of 785 mg calcium in the WHO Technical note on supplementary foods for the management of moderate acute malnutrition in infants and children 6–59 months of age of 2012, which reviewed the recommended nutrient intakes for moderately malnourished populations and concluded that the 785mg of calcium as a maximum was a safe level for the malnourished populations. If the Committee decide to change the maximum value for calcium, the Chairs recommend a maximum value of 785 mg/100g to be in line with the WHO Technical Note recommendations of 2012.

8.4 Phosphorus

Several eWG Members supported the current phosphorus values (CM=6, CO=6). Two Members were not supportive of the current values for various reasons. One Member proposed a range of 450-750 to allow for catch up bone growth in SAM children. Another Member also proposed the inclusion of a maximum of 785 mg, to allow for flexibility in ingredient choices that contain naturally occurring phosphorus. Two Members supported a maximum value of 785 mg/100g to allow for catch-up bone growth and allow for a Calcium/Phosphorus ratio of 1-1.5 in the final product that accounts for phosphorus from raw materials and plant sources. Several Members agreed with the setting of a maximum level or GUL for phosphorus.

Conclusion

Noting the responses from the eWG Members the Chairs are recommending that the minimum phosphorus value of 300 mg/100g be retained as proposed in the 2007 Joint Statement. Due to lack of support from the eWG Members on the revised maximum value for phosphorus, the Chairs are recommending that a maximum value of 600 mg/100g be retained to be in line with the 2007 Joint Statement's recommendations. If the Committee decide to change the maximum value based on the rationale indicated above, the Chairs recommend a maximum value of 785 mg/100g.

8.5 Magnesium

Nine Members supported the current magnesium values, with 4 Members proposing different values for various reasons. One Member suggested a range of 75-225mg to allow for catch-up bone growth as the 80-140 mg range only accounts for added Magnesium in the vitamin mineral premix and does not account for contributions from raw ingredients. One Member proposed the inclusion of a maximum of 235 mg to allow for flexibility in ingredient choices that contain naturally occurring magnesium as recommended in the WHO Technical note for supplementary foods for the management of moderate acute malnutrition in infants and children 6–59 months of age of 2012, which indicated the 235 mg as *a* safe maximum for the malnourished populations. One Member recommended that the range of a minimum of 70 mg/100g and a maximum of 140 mg/100g so that it is wide enough to be technologically feasible. Three Members supported a minimum value of 70 mg/100g of magnesium. One Member supported a maximum value of 235 mg/100g of magnesium.

Conclusion

The Chairs recommend that the minimum value of 80mg/100g and maximum of 140 mg/100g be retained as supported by the majority of the eWG Members, as well as the 2007 Joint Statement. Should the Committee decide to change the maximum value for magnesium to align it with the WHO Technical note for supplementary foods for the management of moderate acute malnutrition in infants and children 6–59 months of age of 2012, the Chairs recommend a maximum value of 235 mg/100g.

8.6 Iron

There was support amongst the eWG Members for the current minimum and maximum iron values as stipulated in 2007 Joint Statement (CM=5, CO=7).

Conclusion

The Chairs recommend that the minimum value of 10 mg/100g and a maximum of 16 mg/100g of iron as stipulated in the 2007 Joint Statement be retained.

8.7 Zinc

During the consultative process there was widespread support amongst the eWG Members for the current minimum and maximum zinc values as stipulated in 2007 Joint Statement (CM=5, CO=7). The eWG Members also supported the inclusion of a maximum or GUL for zinc.

Conclusion

The Chairs recommend that the minimum value of 11 mg/100g and a maximum of 14 mg/100g of zinc as stipulated in the 2007 Joint Statement be retained.

8.8 Copper

There was widespread support by ten eWG Members of the minimum and maximum values of 1.4 mg/100g and 1.8 mg/100g respectively as stipulated in the 2007 Joint Statement. One Member suggested that the range should be wider to be technologically feasible and recommended a maximum of 2.0 mg/100g. Several Members supported the setting of a maximum or GUL for copper in view of considerable hepatotoxicity of excessive copper intake.

Conclusion

Based on the responses from the eWG Members the Chairs recommend minimum and maximum values of 1.4 mg/100g and 1.8 mg/100g respectively, which are in line with the 2007 Joint Statement.

8.9 Selenium

The eWG Members were supportive of the current minimum and maximum values for selenium as per the 2007 Joint Statement (CM=4, CO=8). There was support to set a maximum value for selenium. The Chairs propose that the current selenium values be retained.

Conclusion

Noting the responses from the eWG Members the Chairs recommend that that the minimum value of 20 µg /100g and a maximum of 40 µg /100g of selenium as stipulated in the 2007 Joint Statement be retained.

8.10 Iodine

There was general support by the eWG Members on the current iodine values of 70 to 140 µg /100 g (CM=3, CO=6). One Member noted that intrinsic iodine from dairy sources that may vary by origin and type of dairy products used could contribute to the total iodine present in RUTF. One Member proposed that the current iodine range should be wide enough to be technologically feasible. The Member further recommended the iodine maximum value of 160 µg /100g. However only two Members supported a maximum iodine value of 160 µg/100 g, which would allow for iodine from dairy sources that may contribute to the total iodine present in RUTF. One Member proposed that a GUL would be better than a maximum level due to the instability of iodine in the product.

Conclusion

The Chairs note the comments from the eWG Members and recommend that the current minimum and maximum values of 70 µg/100 g and 140 µg/100 g respectively of iodine be retained. These proposed values are stipulated in the 2007 Joint Statement.

Recommendation 16:

That CCNFSDU agree to the following recommendations for sodium, potassium, calcium, phosphorus, magnesium, iron, zinc, copper, selenium and iodine for RUTF as follows:

Sodium

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

Potassium

Unit	Minimum	Maximum	GUL
mg/100 g	1,100	1,400	-
mg/100 kcal	212	255	-

Calcium

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

Phosphorus

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

Magnesium

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

Iron			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	10	14	-
mg/100 kcal	1.9	2.6	-
Zinc			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	11	14	-
mg/100 kcal	2	2.6	-
Copper			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	1.4	1.8	-
mg/100 kcal	0.27	0.33	-
Selenium			
Unit	**Minimum**	**Maximum**	**GUL**
µg /100 g	20	40	-
µg /100 kcal	4	7	-
Iodine			
Unit	**Minimum**	**Maximum**	**GUL**
µg /100 g	70	140	-
µg /100 kcal	13.46	25.5	-

9. Additional Nutrients

In 2016, the eWG Members supported that additional nutrients may be added to RUTF composition provided that there was sufficient scientific evidence for the addition of the nutrient. The Chairs requested the 2017 eWG Members if there were other additional nutrients that should be considered in the formulation of RUTF. One Member indicated that SAM children could benefit from manganese, choline and lysine. One Member also indicated that the addition of new additives and probiotics should be supported by statistically significant and reproducible evidence showing nutrition delivery, food safety, shelf life, and/or cost-effectiveness. Two Members were of the view that optional ingredients or nutrients should not be permitted as they could result in unsuitable and culturally inappropriate foods being fed to young children.

One Member recommended that phytates should be limited and that a molar ratio in the finished product should be defined, even if the phytate content in raw materials is controlled. The following proposals were made with regard to a ratio: Phytate/Zinc <5 and Phytate/Iron <1[24]. However, it was reiterated by Members that the formulation of RUTF should be based on sound medical and nutritional principles and their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of SAM children.

Conclusion

The Chairs note the views of the eWG Members with regard to the inclusion of additional nutrients in RUTF formulation. The Chairs recommend that the formulation of RUTF should be informed by scientific evidence in meeting the nutritional requirements of SAM children, as such there is no need to include other nutrients at this stage.

[24] International Zinc Nutrition Consultative Group (IZiNCG) Technical Document #1, Assessment of the Risk of Zinc Deficiency in Populations and Options for Its Control, Christine Hotz and Kenneth H. Brown, guest editors. Food and Nutrition Bulletin, vol. 25, no. 1 (supplement 2) © 2004, The United Nations University. http://izincg.org/files/izincgtechdocfnb2004.pdf

Recommendation 17:

That CCNFSDU consider that the current formulation of RUTF, as well as the proposed nutrients as stipulated in the 2007 Joint Statement be the basis for RUTF formulation, unless there is scientific evidence on any additional nutrients that has been demonstrated to be safe and beneficial in meeting the nutritional requirements of SAM children.

10. Contaminants

Chemical contaminants within RUTF are an important consideration and these risks need to be defined. Many RUTF contain peanuts, and other ingredients that may be a source of chemical contaminants. In 2016 the Chairs requested eWG Members to comment on the proposed contaminants and other potential contaminants that should be taken into consideration during the development of the Guidelines. Several Members emphasised that a special consideration with regard to mycotoxins should be given in the guidelines because mycotoxins are not effectively controlled during manufacturing and beyond. The *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995) was proposed to be used as a guide since aflatoxins found in peanuts was covered by this standard.

It was proposed that the guidelines should cover all types of contaminants (e.g. biological and chemical contaminants), and should also refer to the maximum levels (MLs) for aflatoxin and deoxynivalenol (DON) established in the CXS 193-1995. It was further proposed that this section should not lay down specific levels, but simply make a cross-reference to the levels provided by relevant CODEX texts. This would ensure that the section remains up-to-date if those levels are revised in the future. A proposal was made that provisions related to veterinary drugs and pesticides in food be kept separate from the recommendations on contaminants since they could be reference under different Codex text.

At CCNFSDU38, the Committee agreed that the eWG should discuss first the raw materials and ingredients before deciding on which other committees should be involved on the discussion with regard to other possible contaminants in RUTF. However, a general reference to GSCTFF should be made in the guidelines.

At CCNFSDU39, the Chair indicated that there was there was general agreement amongst the 2017 eWG Members that the guidelines should cover all types of contaminants (e.g. biological and chemical contaminants). However, there has been no investigation of the risks of known contaminants within RUTF for SAM children, with specific reference to which contaminants to be controlled and their recommended limits. Further guidance on these issues is needed to provide guidance as to how best to protect the target group of RUTF, with specific reference to contaminants such as mycotoxins. Although there was general support by the eWG Members that the section should make reference to GSCTFF, it was noted that none of the current Codex contaminant maximum levels (MLs) (with specific reference to aflatoxins) in the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995) were set specifically to address SAM children receiving RUTF for the period of up to 8 weeks. While there is no evidence at this stage to suggest that the current MLs in the GSTCFF may not be suitable for SAM children, further consideration should be given to their applicability to this target group.

It was also noted that RUTF that are produced locally and in various regions have different ML values for aflatoxins which range from 5 to 20 µg/kg. The appropriateness and the determination of these different MLs may not be appropriate for RUTF and may not be in line with the criteria of GSCTFF in establishing such limits. Noting the responses from Members, the Chairs proposed to CCNFSDU39 a stepwise approach in handling contaminants in RUTF, which included the following:

- Finalizing a discussion by the Committee on the raw materials and ingredients for RUTF, which would enable the Committee to identify the potential risks with regard to contaminants.
- Request expert advice on possible contaminants and their recommended limits for the target group.
- Consider approaching the Codex Committee on Contaminants in Food (CCCF) with the request to setting MLs for aflatoxins and other contaminants in RUTF.
- Once the ML values are established and agreed to, they may be included in the GSCTFF and referenced as such in the guidelines.

The Representative of WHO expressed support to the proposals by the eWG to manage contaminants in products such as RUTF, and noted that one way would be to make a cross reference to the relevant standards where the ML could be found (such as CXS 193-1995). However, to better help and guide producers of RUTF to comply with the ML for contaminants (stated in CXS 193-1995) consideration could be given to listing the relevant ML for contaminants for RUTF products in the guidelines. The Representative of FAO also emphasized the important need to having safe RUTF. Both the WHO and FAO Representatives stressed the importance of having proper risk management measures in place for contaminants like aflatoxins focusing more on the raw material, rather than in the finished product.

FAO reminded the Committee that CCCF is the committee under the Codex system that focuses on all aspects of contaminants in foods and CCNFSDU may consider to ask CCCF for advice on this critical questions. FAO reminded the Committee further that contaminants are best controlled through a careful management of the ingredients and the supply chains in general and pointed out that suitable provisions from various Code of Practices, GAP, GMP and a close control of the ingredients used for the production of RUTF are already existing. The Committee was encouraged to consider the suitability of these provisions in addition of or in place of a maximum limit for contaminants on the final product.

The Secretariat also clarified that while a reference to the GSCTFF was the preferred option as outlined in the Format for Codex Commodity Standards in the Procedural Manual, exceptions to this rule were allowed. However, any maximum levels would still require endorsement by CCCF and clear justification should be provided on why a general reference to the GSCTFF was not appropriate, and any MLs sent to CCCF should also be accompanied by an explanation on the scientific basis of the ML.

The Committee agreed to follow a stepwise approach.

Conclusion

In order to kick start the discussion with the eWG Members on the stepwise approach in handling contaminants in RUTF, the Chairs, through the technical assistance of UNICEF requested an expert advice with the identification of the chemical hazards in the supply chain of the ingredients used in RUTF that may result in chemical contamination of the finished product. This will include the possible contaminants to be considered in the elaboration of the RUTF Guidelines and advice on contaminants that should be controlled, with recommended limits for the identified contaminants for the target group receiving RUTF. The information gained from this process will enable the Committee to further engage with CCCF. The preliminary report on contaminants in RUTF will be discussed at the Physical Working Group in November.

11. PROCESSING TECHNOLOGIES

During the 2016 eWG, several Members proposed that the section should follow the outline in the *Guideline on Formulated Complementary Foods for Older Infants and Young Children* (CXG 8-1991) particularly sections 4 and 5 since the text was highly relevant because of similar purpose and intended age groups. Consideration should also be given in the guidelines to allow, as reasonably possible, technologies which would allow foreign matter control beyond metal, such as x-ray. It was also highlighted that currently suppliers of RUTF were relying only on magnetic control, which does not cover other foreign matters than ferrous metal.

During 2017 consultative process the Chairs proposed a draft text for the section in line with the outline in the CXG 8-1991. There was widespread support on the proposed text amongst the eWG Members, with minor additions to the text. One Member indicated that the proposed wording was too general with no limits that could be monitored as part of risk management.

Conclusion

Noting the responses from the eWG Members the Chairs compiled the draft text for the section in line with the outline of CXG 8-1991, with specific reference to section 4 and 5.

Recommendation 18:

That CCNFSDU agree to the proposed text of " Processing Technologies" section of the Guidelines as follows:

In addition to the practices described below, Good Hygiene Practices (General principles of food hygiene CXC 1-1969) should be implemented to avoid cross contamination during the packing and storage of raw materials.

1. Preliminary Treatment of Raw Materials

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

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

- **Degermination:** where necessary and appropriate, degermination of wheat, corn, soy and other crops should be considered in order to reduce the phytate content.

2.Milling

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

3.Toasting

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

4. Sprouting, Malting and Fermentation

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

5. Other Processing Technologies

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

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

12. GOOD MANUFACTURING PRACTICES AND GOOD HYGIENE PRACTICES

The eWG Members in 2016 were in support to making reference to *the Code of Hygienic Practice for Low-Moisture Foods* (CXC 75-2015) and other Codex texts under this section. In 2017 the Chairs requested the eWG Members to comment on the proposed text during the First Consultation Paper. There was widespread support by the eWG Members on the proposed text.

Conclusion

The Chairs note the responses from the eWG and recommend the proposed text for "Good manufacturing practices and good hygiene practices" section of the Guidelines.

Recommendation 19:

That CCNFSDU agree to the proposed draft text for "good manufacturing practices and good hygiene practices" section as follows:

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

The product should comply with any microbiological criteria established in accordance with the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).

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

13. METHODS OF ANALYSIS AND SAMPLING

The 2016 eWG Members highlighted a challenge with analysing the vitamins and minerals content of RUTF due to their high fat content. Analytical results at time of product being released into the market should be taken into consideration in terms of risks/benefits/costs. The use of validated methods would be essential to get reliable and repeatable results. The 2017 eWG Members were requested by the Chairs to provide inputs on the proposed text for the section. There was widespread support for the proposed text by the eWG Members with minor additions to the text.

Recommendation 20:

That CCNFSDU agrees to the proposed text for "the methods of analysis and sampling" section of the guidelines as follows:

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

14. PACKAGING

The Chairs requested the eWG Members in 2016 to comment on the section related to “Packaging” in the guidelines. Various Members emphasized that packaging of these products should receive special attention since it was crucial in preserving the quality of the product along the shelf life and during transportation. The following specific points were raised with regard to packaging:

- The packages used should be appropriate, in order to avoid as much as possible, the use of stabilizers.
- Packaging should provide adequate protection against contamination during storage and handling.
- Primary and secondary packaging should be addressed.
- Suitability of the packaging for food contact and “mouth contact” to ensure that the primary packaging prevent children from “eating ink”.
- Suitability of the packaging for preserving quality all along the shelf life.

The Chairs proposed the text and requested inputs from the eWG Members on the packaging requirements for the RUTF. The proposed text was supported by the majority of the eWG Members and minor additions were proposed to the text.

Conclusion

Based on the responses from the eWG Members the Chairs recommend that the proposed text be considered for inclusion in the guidelines.

14.1 Packaging of RUTF into a single-use sachet

Children consuming RUTF are supposed to be fed every 3 hours throughout the day. The volume of RUTF consumed by children at one feeding is smaller than the volume of a sachet, which in many cases weigh between 90 and 100 grams. The current weight of 92 grams of each sachet was established by calculating the calories needed over the average treatment period of a SAM child for recovery. During the 2016 eWG, the Chairs posed a question to the eWG Members to comment on whether RUTF should be packaged into single-use sachets to minimize the risk of contamination at home.

The eWG Members were divided on this issue, and as a result there was no consensus. Several Members were also concerned about the costs implications for smaller sachets. However other Members indicated that NGOs with extensive experience in the area of RUTF have never made such a request of single-use sachets and their opinions would be beneficial.

The Chairs posed a question to the 2017 eWG Members in the First Consultation Paper on whether there was a need to consider single-use sachets for RUTF to minimize the risk of contamination at home. Several Members were not in support of such a proposal. Some Members were of the view that single-use sachets would bring more complexity and confusion at the operational level, and that there was no evidence to support the notion that an opened product during treatment is a significant contamination risk. As a low moisture food, the growth of microbiological hazards is minimal within the matrix of RUTF.

Conclusion

Noting the responses from the eWG Members the Chairs are of the view that the current RUTF sachets be retained until there is enough evidence for the need of single-use sachets at an operational level.

Recommendation 21:

That CCNFSDU agrees to the proposed text for "packaging" section of the guidelines as follows:

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.

15. LABELLING

The 2016 eWG Members supported that the labelling of RUTF should be in accordance with the following existing Codex texts: *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991), *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985), *General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses* (CXS 146-1985), and *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997) and *Guidelines on Nutrition Labelling* (CXG 2-1985).

15.1 Mandatory Labelling Requirements Provisions and Mandatory "statements" for RUTF

In 2016 several Members indicated that a statement on breastfeeding should be included and all provisions of the International Code or WHA Resolutions and WHO recommendations, including WHA69.9 and 63.23 should be taken into consideration when labelling provisions are considered for RUTF. Whale the 2007 Joint Statement by the WHO, WFP, UNSCN and UNICEF "*Community-Based Management of Severe Acute Malnutrition*" recognises the essential contribution of exclusive breastfeeding for the first six months of a child's life to prevent severe acute malnutrition, it also notes that treatment is needed for those children who already are suffering from severe acute malnutrition.

In the First Consultation Paper the Chairs requested the 2017 eWG Members to comment on the proposed text for mandatory labelling requirements and mandatory "statements" for RUTF. Majority of the eWG Members were in support of the proposed text and the outline. Several Members also made inputs to the wording of the proposed text. Some Members reiterated that specific labelling provisions should be included in the guidelines only where they were different from the existing Codex texts and are necessary to take into account the specific requirements of RUTF. It was reiterated that the guidelines should cross-refer to the relevant texts. For example, the Additional Mandatory Labelling Requirements in the guidelines that are already covered by Section 4.3 of CXS 180-1991 should be removed.

Two Members commented that a statement on "*The product should be consumed within 24 hours after opening*" should be included in the labelling requirements to minimise the risk of in-use contamination of the product. One Member indicated that regarding the wording on instruction for use, it might not be practical to indicate the suggested number of feedings per day since the feed volumes were based on weight. One Member indicated that the word "treatment" should be used instead of "management".

Three Members commented that the International Code of Marketing of Breast-milk Substitutes should be referenced in the first paragraph of the section on labelling of RUTF. One Member indicated that referencing so many Codex texts for the labelling requirements might cause confusion, as the referenced texts may have conflicting labelling requirements. The Member suggested that removing the references to the Codex texts in CXS 1-1985 and CXG 23-1997 since the *Codex General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses* (CXS 146-1985) already references CXS 1-1985 and it may not be necessary to reference it again in the guidelines.

15.2 Additional Requirements for Labelling Purposes

In 2016 the eWG Members were requested to propose additional requirements for labelling of the RUTF that are not covered by the existing Codex texts. The following suggestions were made by the eWG Members with regard to the additional requirements:

- A statement on breastfeeding should appear under the additional requirements.
- The shelf-life of the RUTF.
- The timeframe for the consumption of RUTF once a packet is opened.

The Chairs proposed various statements to be included as additional requirements for labelling of RUTF. Two Members wanted the rationale for the inclusion of the statements on breastfeeding in the guidelines and wondered if it was necessary, taking into account that the 2007 Joint Statement by the WHO, WFP, UNSCN and UNICEF "*Community-Based Management of Severe Acute Malnutrition*", while recognising the essential contribution of exclusive breastfeeding for the first six months of a child's life to prevent severe acute malnutrition, also notes that treatment is needed for those children who already are suffering from severe acute malnutrition. Two Members requested that a statement which reads " This product may contain allergens" should be included. Two Members made reference to the EU legislation which regulate health and nutrition claims on FSMPs.

Conclusion

The Chairs note that the debate on whether to use the word "treatment" or "dietary management" was deliberated on in 2016 and there was widespread support for aligning the text with the *Standard for Labelling of and Claims for Foods for Special Medical Purposes* CXS 180-1991. The Chairs recommend that the proposed text for the "labelling" section and additional labelling requirements where possible cross-refer to the existing Codex texts to avoid unnecessary duplication. The Chairs recommend that the Committee should consider only referencing the most relevant Codex texts to avoid confusion that may arise as a result of conflicting labelling requirements.

The Chairs are recommending that the sub-section on "declaration of nutritive value be removed since it is already outlined in section 4.2 of CXS 180-1991. The Chairs are also proposing removing the references to the Codex texts in CXS 1-1985 and CXG 23-1997 since the *General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses* (CXS 146-1985) already references them. This will ensure that the guidelines are streamlined to avoid misinterpretation and confusion on the interpretation of certain labelling provisions in the existing Codex texts.

The Chairs also note that some Members proposed addition of certain statements in the labelling of RUTF. The Chairs are of the opinion that some of the proposed statements and text will be taken care of by the relevant Codex texts. The Chairs are of the view that referencing of the International Code of Marketing of Breast-milk Substitutes and other WHA resolutions is already covered in the "Preamble" section of the guidelines, and it may not be necessary to reference it again under the labelling section.

Recommendation 22:

That CCNFSDU agree with the proposed draft text for the "labelling" section of the guidelines as follows:

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

The Name of the Food

The name of the food to be declared on the label shall indicate that the food is a Ready to Use Therapeutic Food for Children from 6 to 59 months. The appropriate designation indicating the true nature of the food

should be in accordance with national legislation. The age from which the product is recommended for use shall appear in close proximity to the name of the food.

List of Ingredients

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

Additional Mandatory Labelling Requirements

The following statements shall appear on the label of RUTF:

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

Instructions for use

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

16. Recommendations to CCNFSDU

The Chairs of the eWG have completed the task as per the programme of work. Following the discussions with the eWG Members, the Chairs propose that the Committee:

- Consider the key recommendations as outlined in the report;
- Discuss the proposed Draft Guidelines for RUTF (Appendix 1); and
- Propose steps to address issues raised during the consultation with the eWG Members as outlined in the recommendations, in particular recommendation 4 (food additives).

Appendix 1

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

(for comments through CL 2018/64-NFSDU)

1. PREAMBLE

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

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

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

2. PURPOSE OF THE GUIDELINES

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

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

3. SCOPE

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

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

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

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

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

4. DESCRIPTION

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

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

5. SUITABLE RAW MATERIALS AND INGREDIENTS

RUTF are made of ingredients embedded in a lipid-rich matrix e.g. paste or biscuit, resulting in an energy and nutrient-dense food. The following raw materials, many of which can be sourced locally, are suitable ingredients for the production of RUTF under the specified conditions given below. The 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).

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

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

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

5.1.5 Vitamins and Minerals

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

All added vitamins and minerals must be in accordance with the *Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979). Examples of vitamin and 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 and scientific evidence showing adequate stability and bioavailability in the finished product.**]**

5.2 Other Ingredients

5.2.1 Available Carbohydrates[6]

The palatability of the RUTF can be increased by the addition of available carbohydrates. Available 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*.

[6)]Sucrose, plant starch, maltodextrin, should be the preferred carbohydrates in RUTF. Fructose, glucose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinized starches ~~[gluten-free]~~ by nature may be added. Any carbohydrate added for sweetness should be used sparingly.

5.2.2 Food Additives and Flavours

[This section will make reference to the *General Standard for Food Additives* (CXS 192-1995)]. [25]

5.3 The Use of other Matrices in RUTF formulation

RUTF may be manufactured with formulations different from the one laid down in these guidelines provided that these formulations comply with Section 3 of the *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991).

6. NUTRITIONAL COMPOSITION AND QUALITY FACTORS

6.1 Energy

The energy density of the formulated RUTF should be between 5.2 - to 5.5 kcal per gram. The energy density of RUTF can be achieved during manufacturing by the addition of energy containing ingredients (i.e. 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% - 12% of the total energy. ["at least 50% of protein is provided by milk products"]

6.3 Lipids

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

The level of linoleic acid should not be less than 333 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33 mg/100kcal. The level of linoleic acid should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.

6.4 Please see Annex "Nutrition Composition for RUTF".

7. CONTAMINANTS

[It is recommended that the products covered by the provisions of these guidelines comply with the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995), Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods (CAC/MRL 2-2015) and Codex Maximum Residue Limits for Pesticides].

[Other Contaminants

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

8. PROCESSING TECHNOLOGIES

[In addition to the practices described below, Good Hygiene Practices (*General principles of food hygiene* (CXC 1-1969)) should be implemented to avoid cross contamination during the packing and storage of raw materials.]

8.1 Preliminary Treatment of Raw Materials

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

[25] See recommendation 4 in the report above

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

8.2 Milling

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

8.3 Toasting

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

8.4 Sprouting, Malting and Fermentation

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

8.5 Other Processing Technologies

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

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

9. MANUFACTURING PRACTICES AND GOOD HYGIENE PRACTICES

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

The product should comply with any microbiological criteria established in accordance with the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).

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

10. METHODS OF ANALYSIS AND SAMPLING

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

11. PACKAGING

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

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

12. LABELLING

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

The Name of the Food

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

List of Ingredients

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

Additional Mandatory Labelling Requirements

The following statements shall appear on the label of RUTF:

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

Instructions for use

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

ANNEX

Table: Nutritional Composition for RUTF

Energy

Unit	Minimum	Maximum	GUL
kcal/100g	520	550	-

Protein

Unit	Minimum	Maximum	GUL
g/100g	12.8	16.2	-
g/100kcal	2.3	3.1	-

Lipids

Unit	Minimum	Maximum	GUL
g/100g	26	37	-
g/100kcal	5	6.7	-

n-6 Fatty acids

Unit	Minimum	Maximum	GUL
g/100g	3	10	-
mg/100kcal	576.9	1818.2	-

n-3 Fatty acids

Unit	Minimum	Maximum	GUL
g/100g	0.3	2.5	-
mg/100kcal	57.69	454.5	-

Vitamin A

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

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

Vitamin D

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

[3] 1 µg cholecalciferol = 40 IU vitamin D

Vitamin E

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

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

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

Vitamin K

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

Vitamin B1

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

Vitamin B2

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

Vitamin C

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

Vitamin B6

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

Vitamin B12

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

Folic Acid

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

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

Niacin

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

Pantothenic Acid

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

Biotin

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

Sodium

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

Potassium

Unit	Minimum	Maximum	GUL
mg/100 g	1,100	1,400	-
mg/100 kcal	212	255	-

Calcium

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

Phosphorus

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

Magnesium

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

Iron

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

Zinc

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

Copper

Unit	Minimum	Maximum	GUL
mg/100 g	1.4	1.8	-
mg/100 kcal	0.27	0.33	-

Selenium

Unit	Minimum	Maximum	GUL
µg /100 g	20	40	-
µg /100 kcal	4	7	-

Iodine

Unit	Minimum	Maximum	GUL
µg /100 g	70	140	-
µg /100 kcal	13.46	25.5	-

Moisture Content

Unit	Minimum	Maximum	GUL
Percentage(%)	-	2.5	-

Appendix 2

List of participants

Members

1. Uganda
2. Senegal
3. South Africa
4. European Union
5. New Zealand
6. Belgium
7. Brazil
8. Unites States of America
9. Thailand
10. India
11. Chile
12. Norway
13. Canada
14. France
15. Ireland
16. Japan
17. Uruguay
18. Mexico
19. Ecuador
20. Costa Rica
21. Botswana
22. Austria
23. Colombia
24. Croatia
25. Morocco
26. United Kingdom
27. Egypt
28. Burkina Faso
29. Malaysia
30. Korea
31. Nigeria
32. Kazakhstan
33. Iran

Observers

1. FAO
2. ILCA
3. IDF
4. ISDI
5. IACFO
6. ESPGHAN
7. Action Contre la Faim
8. ICAAS
9. CEFS
10. UNICEF
11. MSF
12. IBFAN
13. EU Specialty Food Ingredients
14. World Sugar Research Organization