CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5b **CX/NFSDU 19/41/6**

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

Forty-first Session

Dusseldorf, Germany
24 - 29 November 2019

PROPOSED DRAFT GUIDELINE FOR READY-TO-USE THERAPEUTIC FOODS

SECTION 5.2.2 (FOOD ADDITIVES) AND SECTION 6.2 (PROTEIN)

(Prepared by the Electronic Working Group chaired by South Africa and co-chaired by Senegal and Uganda)

Codex members and Observers wishing to submit comments at Step 3 on this draft should do so as instructed in CL 2019/79-NFSDU available on the Codex webpage/Circular Letters 2019: http://www.fao.org/fao-who-codexalimentarius/circular-letters/en/.

1. INTRODUCTION

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 refer to the *Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions* (CXC 20-1979).

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 could not discuss other recommendations. Sections that were not discussed at CCNFSDU39 formed part of the report to Codex Secretariat, which informed the agenda of the physical Working Group held prior to CCNFSDU40 on the 24th November 2018.

At CCNFSDU40, South Africa as Chair of the EWG and PWG introduced the agenda item and highlighted the recommendations of the PWG as contained in CRD28 Rev. The discussion of the PWG focused on sections of the guidelines where the EWG could not reach consensus on. The Committee considered the report of the PWG, addressed proposed recommendations, and made appropriate editorial changes and clarifications to various sections of the guidelines. The Committee supported the following PWG recommendations:

[1] REP16/NFSDU, paras 81-88, Appendix IV
[2] REP16/CAC, paras 102 – 107, Appendix V
[3] REP16/NFSDU, paras 3, Appendix IV
[4] NFSDU/39 CRD/15
[5] REP18/NFSDU, paras 97-119

- Recommendation 1 on section 5.1.2 (Legumes and Seeds) with regard to the proposed texts to include phytoestrogens;
- Recommendation 2 of the PWG with regard to the proposed text of Section 5.1.5 (Vitamins and Minerals), with the insertion of the word “buffer” to clarify the term metabolizable-base in the proposed texts;
- Recommendation 4 of Section 5 (Suitable Raw Materials and Ingredients) by amending the second sentence of the opening texts and agreed to delete Section 5.3 (The Use of other Matrices in RUTF Formulation), by incorporating the texts in Section 5.3. into Section 5; and
- Recommendation 5 on Section 6.1(Energy): to base the energy requirements of RUTF on the current energy values of 520 to 550 kcal/100g as stipulated in the 2007 Joint Statement of the WHO, WFP, the United Nations System Standing Committee on Nutrition and UNICEF Community Based Management of Severe Acute Malnutrition.

Due to time constraints, the Committee could not reach consensus on the following recommendations by the PWG: Recommendation 3 for Section 5.2.1 (Available carbohydrates) and Recommendation 17 for Section 5.2.2 (Food Additives and flavours). Other remaining recommendations by the PWG were also not discussed due to time constraints and were deferred to CCNFSDU41. Recommendations that were not discussed at CCNFSDU40 have been reproduced in Appendix I to inform the discussion in CCNFSDU41.

2. TERMS OF REFRENCE

At the 40th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), the Committee agreed to re-establish:

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 continue developing Section 5.2.2 (Food additives) and Section 6.2 (Proteins) for consideration at the Committee’s next session; and

b) Hold the rest of the text at Step 4[6] and to consider the remaining recommendations of the PWG at its next session.

3. PARTICIPATION AND METHODOLOGY

Nominations to participate in the EWG were received from 28 Codex Members, 1 Codex Member Organization and 15 Codex Observers (the list of participants is attached as **Appendix III**).

The Chairs circulated two Consultation Papers to the EWG Members in March and June 2019 respectively. The focus of the **First Consultation Paper** was on Section 5.2.2-Food Additives, Section 6.2-Proteins and the Processing Technologies section. Responses from the first consultation paper were received from 10 Codex Members, 1 Codex Member Organization and 6 Codex Observers. The **Second Consultation Paper** focused on:

- the responses received from the EWG Members on the First Consultation Paper; and
- Sections that may require further discussion by the Committee, based on the responses receive from the EWG Members.

Responses from the second consultation paper were received from 6 Codex Members, 1 Codex Member Organization and 7 Codex Observers. The Chairs requested the EWG to provide information and recommendations that would inform the finalization of the proposed texts of the guidelines during the consultative processes. The outcomes of the First and the Second Consultation Papers informed this agenda paper for CCNFSDU41.

4. SUMMARY OF DISCUSSION

4.1 Food Additives

4.1.1 Table on Food Additives currently used by the industry in the manufacturing of RUTF, and their comparison to food additives permitted for use in existing Codex texts aimed at infants and young children

[6] REP19/NFSDU, Appendix V

The Chairs circulated a revised table 1 that compared the additives currently used in RUTF to food additives approved for use in existing Codex texts aimed at infants and young children. The revised table also included the Food Category (FC) where such additives were permitted in. This process was meant to deal with steps (a) and (b) in the proposed stepwise approach. The EWG Members were requested to indicate if they were in agreement with the contents of Table 1, with specific reference to their current use in RUTF formulation, and their comparison to the existing Codex texts on additives for infants and young children.

Responses from EWG Members

There was widespread support among the EWG Members about the contents of Table 1 on additives as regard to their use in RUTF. However, two Members highlighted that the technological justification provided was simplistic and of a general nature and suggested that it could be improved to describe how these additives listed work in RUTF. One Member was of the view that the column on "proposed used level" should be removed since it was confusing and the Committee could interpret the values indicated as the current values in use of RUTF formulation. Some Members comments were editorial in nature with regard to missing food categories in the table and spelling typos of some of the additives and their INS numbers.

Conclusion

The Chairs have incorporated the proposed edits to **Table 1** and updated it to reflect the EWG Members' views. The column on "proposed used level" has been removed from Table 1 to avoid confusion, which could lead to wrong interpretation in terms of the values used in RUTF formulation. With regard to the use of mixed tocopherol concentrate (INS 307b) and ascorbic acid (INS 300), some manufacturers of RUTF have indicated that the benefits of these additives is as a result of carry-over from nutrient preparation wherein these additives were functional in those preparations. The table will form the basis for further discussions on additives in RUTF. Based on the comments received from the EWG Members, the Chairs recommend that CCNFSDU agree to the proposed contents on additives in **Table 1**.

Recommendation 1:

That CCNFSDU agree to the proposed list of food additives and their functional class in **Table I** (in this document) for use in RUTF and that the table be utilised as the basis for further discussions on additives in RUTF.

4.1.2 Approach on the use of additives in RUTF

The Chairs requested the EWG Members in the First Consultation Paper to indicate their preferred option for referencing Codex texts in RUTF Guidelines, taking into consideration the views expressed by CCNFSDU40 of applying the same approach as in other CCNFSDU Guidelines (i.e. *Guidelines on Formulated Complementary Foods for Older Infants and Young Children* (CXG 8-1991). The approach used in other CCNFSDU Guidelines has been that food additives approved for use in existing Codex texts for infants and young children with specific reference to *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981), the *Standard for Follow-up Formula* (CXS 156-1987) and *Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children* (CXG 10-1979) could also be adopted and approved for use in RUTF.

The Chairs also highlighted to the EWG Members that referencing the existing Codex texts may not be appropriate since certain additives may be excluded for use in RUTF as they have been technologically justified for products in those standards or guidelines. The Chairs indicated that CXG 8-1991 offered precedent and possibility for RUTF Guidelines to reference all additives allowed in CXS 72-1981 and CXS 156-1987, and could also give the provision to footnote/reference the RUTF Guidelines in the appropriate Food Category description. Two options were put forward by the Chairs to the EWG Members based on various proposals that could be explored in referencing Codex texts in RUTF Guidelines. The two options are reflected below:

a. Option 1: Referencing the Codex Standards (CXS 72-1981) and CXS 156-1987

It is noted that referencing the existing standards within CCNFSDU could be an approach that the EWG Members may consider to pursue given the fact that such an approach would meet the technological needs of additives required to manufacture RUTF. Furthermore, such an approach would be in consistent with other guidelines (e.g. CXG 8-1991), with an option of footnotes/reference the RUTF Guidelines in the appropriate Food Category description. If this approach can be adopted, the proposed texts would be as follows:

"Food Additives listed in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981), the *Standard for Follow-up Formula* (CXS 156-1987) *may be used in Ready-to-Use Therapeutic Foods to the maximum limits given in those products".

b. Option 2: Referencing the Food Categories within GSFA (CXS 192-1995)

Alternatively, the EWG Members may consider referencing the Food Categories within the GSFA instead of the Codex commodity Standards. If there are specific exclusions or special considerations with the additives in the identified Food Categories, the use of Notes to denote these exclusions can be considered. If this approach is acceptable, the proposed texts could read as follows:

"Food Additives listed in the General Standard for Food Additives Food Category 13.1.1 (Infant Formulae), 13.1.2 (Follow-up Formulae) and 13.1.3 (Formulae for Special Medical Purposes for Infants) may be used in Ready-to-Use Therapeutic Foods to the maximum limits given in those Food Categories".

Responses from the EWG Members

Four Members were in favour of Option 1 compared to 10 Members who were in favour of Option 2. Members in favour of Option 1 highlighted that it would avoid confusion with the GSFA food categories, as the approach was consistent with Codex practices. Furthermore, it would provide a straightforward path to address additives in the Guidelines without any delay, since a precedent has been set in other Guidelines (i.e. CXG 8-1991) by referencing food additives in the existing CCNFSDU standards.

Members who preferred Option 2 indicated that referencing provisions in food categories in the GSFA was consistent with the Codex Procedure Manual and the work by CCFA on alignment of provisions between commodity standards and the GSFA would no longer allow commodity standards to include any food additive provisions to reference, which would make Option 1 not viable in the long term. It was also indicated that the additive provisions in Food Categories 13.1.1, 13.1.2 and 13.1.3 include all additives that have a technological need for the manufacturing of RUTF. If there were specific exclusions or special considerations with additive provisions in Food Categories 13.1.1, 13.1.2 and 13.1.3, the use of Notes in the GSFA may be considered to denote these cases.

Two Members (including Codex Member Organization) who were not in favour of either option 1 or 2 indicated that the proposed additives to be allowed in the two proposed options would be more than the list of food additives in Table 1 of the consultation paper. Therefore, following the proposed options could broaden the list of food additives compared to what has been identified in Table 1 of the consultation paper.

4.1.3 Identification of a Food Category where RUTF could fall

During the first consultation with the EWG Members, the Chairs recommended that RUTF could fall under Food Category 13.3: Dietetic foods intended for special medical purposes (excluding products of food category 13.1) with the possibility of exploring the required amendments that could happen (e.g. use of notes or creating a sub-category, etc.) in this FC to identify conditions of use specific to RUTF.
The descriptor of FC 13.3 states that:

> "Foods for special dietary use that are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foods or certain nutrients contained therein, or who have other special medically-determined nutrient requirement, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two".

This decision was based on the analysis of the existing Food Categories within the GSFA where RUTF could fall. Furthermore, the rationale for choosing FC 13.3 was based on the description of the RUTF, which stipulate, "RUTF are foods for special medical purposes, 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".

The Chairs proposed FC 13.3 since it was dealing with foods intended for special medical purposes, which RUTF are. Therefore, RUTF may be considered under this food category 13.3 of the GSFA. However, this would require certain amendments as described above within this category.

Responses from the EWG Members

Several EWG Members (M=9) were in agreement with the proposed recommendation that RUTF could fall under Food Category 13.3 with associated amendments that would be required. It was indicated that RUTF could fall under FC 13.3 as a concept, but would require the amendment of the said category to reflect the characteristics of RUTF. However, a sub-category for RUTF in FC 13.3 should be created to identify conditions of use specific to RUTF, with a prescriptive closed list of additives. It was also highlighted that the use of other categories such as FC 13.5 would not be appropriate since RUTF was a therapeutic food designed for the management of SAM, and is a food for special medical purposes.

Members who were not in favour (M=3) of Food Category 13.3 with associated amendments highlighted that FC 13.3 was a general category for dietetic foods for special medical purposes and might not be a perfect match for RUTF since FC13.3 did not reflect the targeted age group for RUTF of 6-59 months. Furthermore, the list of additives permitted in FC 13.3 was wider than additives that would be required in RUTF formulation. The identified FC 13.3 has not been evaluated for RUTF and in particular SAM children and did not reflect the targeted age group of 6-59 months. It was also highlighted that FC 13.3 was not listed in Annex to Table 3, which meant that all Table 3 additives could be used in foods falling under FC 13.3.

Members who were unsure (M=3) about the proposed Food Category were of the view that although FC 13.3 could be an appropriate option if other additives that were not needed in RUTF formulation could be managed by the use of qualifying notes, CCFA should be consulted for advice in order to establish the best way to handle additives in RUTF.

Table I: Food Additives currently used by the industry in the manufacturing of RUTF, and their comparison to food additives permitted for use in existing Codex texts aimed at infants and young children

Item	Food Additive	International Numbering System (INS)	ADI	Functional Class	Technological Justification	Maximum Use Level**	Currently Permitted in CXS 72-1981 or CXS 156-1987 or CXG 10-1979	Currently Permitted in Food Category in the General Standard for Food Additives (GSFA, CXS 192-1995)
Emulsifiers								
1	Mono & diglycerides of fatty acids	471	17th JECFA (1973) ADI not specified	Emulsifier	Forms or maintains a uniform emulsion of two or more phases in a food (definition GL 36-1989)	4000 mg/kg of RUTF	CXS 72-1981 CXS 156-1987	13.1.1; 13.1.2; 13.1.3; 13.2
2	Citric and fatty acid esters of glycerol	472c	Not of concern at proposed use levels 79th JECFA (2014)	Emulsifier	Forms or maintains a uniform emulsion of two or more phases in a food	9000 mg/kg of RUTF	CXS 72-1981	13.1; 13.2
3	Lecithin	322(i)	17th JECFA (1973) ADI not specified	Emulsifier	Forms or maintains a uniform emulsion of two or more phases in a food.	Up to 5000 mg/kg of RUTF	CXS 72-1981 CXS 156-1987 CXS 73-1981 CXS 74-1981	13.1.1; 13.1.2; 13.1.3; 13.2
Antioxidants								
4	Ascorbyl palmitate	304	17th JECFA (1973) ADI 0 - 1.25 mg/kw bw	Antioxidant	Prolongs the shelf-life of foods by protecting against deterioration caused by oxidation.	max 10 mg/kg of RUTF	CXS 72-1981 CXS 156-1987 CXS 73-1981 CXS 54-1981	13.1.1; 13.1.2; 13.1.3; 13.2
5	Citric acid	330	17th JECFA (1973)	Acidity regulator	Prolongs the shelf-life of foods by protecting against deterioration caused by oxidation.	GMP	CXS 72-1981 CXS 156-1987 CXS 73-1981	13.1.1; 13.1.2; 13.1.3; 13.2

Item	Food Additive	International Numbering System (INS)	ADI	Functional Class	Technological Justification	Maximum Use Level**	Currently Permitted in CXS 72-1981 or CXS 156-1987 or CXG 10-1979	Currently Permitted in Food Category in the General Standard for Food Additives (GSFA, CXS 192-1995)
			ADI not specified				CXS 74-1981	
6	Tocopherol concentrate, mixed*	307b	17th JECFA (1973): ADI 0-2 mg/kg for alpha-tocopherol and mixed tocopherols concentrate	Antioxidant	Prolongs the shelf-life of foods by protecting against deterioration caused by oxidation.	10 mg/kg of RUTF	CXS 72-1981 CXS 156-1987 CXS 73-1981 CXS 74-1981	13.1.1; 13.1.2; 13.1.3; 13.2; 13.3
7	Ascorbic acid	300		Antioxidant	Prolongs the shelf-life of foods by protecting against deterioration caused by oxidation.	GMP	CXS 156-1987 CXS 74-1981	13.1.2; 13.2
Packaging gas								
8	Nitrogen	941	24th JECFA (1980): no ADI necessary	Packaging 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	CXS 72-1981 CXS 156-1987 CXS 73-1981	13.1.1; 13.1.3; 13.2
9	Carbon dioxide	290	29th JECFA (1985): ADI not specified	Packaging 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	CXS 72-1981 CXS 156-1987 CXS 73-1981	13.1.1; 13.1.3; 13.2
Carrier								
10	Sillicon dioxide, amorphous	551	80th JECFA (2015): ADI not specified	Carrier	Used to dissolve, dilute, disperse or otherwise physically modify a food additive or nutrient without altering its function (and without exerting any technological effect itself) in order to facilitate its handling, application or use of the food addi-	10 mg/kg of RUTF	CXG 10-1979	13.2 (may also be used as is also authorized for foods for infants and young children by CXG 10-1979)

Item	Food Additive	International Numbering System (INS)	ADI	Functional Class	Technological Justification	Maximum Use Level**	Currently Permitted in CXS 72-1981 or CXS 156-1987 or CXG 10-1979	Currently Permitted in Food Category in the General Standard for Food Additives (GSFA, CXS 192-1995)
					tive or nutrient. (Definition CXG 36-1989)			

***Only 307b is allowed for 13.1.1 and 13.1.3 while for 13.1.2, 307 a, b, c are permitted**

****Maximum use levels for RUTF are less than or equal to the maximum use levels for the currently permitted food categories**

4.2 Discussion on the approach on the use of additives in RUTF (4.1.2) and the identification of a Food Category where RUTF could fall (4.1.3)

The Chairs noted that referencing the Codex texts in the Guidelines and the identification of the Food Category within the GSFA where RUTF could fall should be discussed together. It is important to approach these two critical aspects together since they are inter-related to facilitate the way forward.

The Chairs also noted that the Codex Procedure Manual provides clear guidance for interacting with CCFA and the preference for a reference to the GSFA for the use of food additives in commodity standards. However, there is no established process for interaction with CCFA with handling food additives in the guidelines.

Although several Members preferred option 2 with regard to referencing the Codex texts in RUTF Guidelines, it is clear that more work would still need to be done to ensure that option 2 and the associated additives reflect the technological needs for RUTF formulation.

Although majority of the EWG Members were in favour of the proposed Food Category 13.3: Dietetic foods intended for special medical purposes (excluding products of food category 13.1) with the possibility of exploring the required amendments that could happen (e.g. use of notes or creating a sub-category, etc.), this might require more work to reflect the needs of RUTF. If this approach could be pursued, it may not prevent Table 3 additives from being used in RUTF formulation since there are no mechanisms in place to disallow the use of Table 3 additives in RUTF. The proposed FC 13.3 is a general category for dietetic foods for special medical purposes and might not be a perfect match for RUTF since FC13.3 does not reflect the targeted age group for RUTF of 6-59 months.

Several Members were also of the view that the discussion on additives in RUTF should reflect the targeted age group of 6 to 59 months, and a strong technological justification for certain additives (e.g. Table 3 additives) should be explored. A need to consult CCFA in order to establish the best way to handle these issues and to deal with them in the context of the GSFA was supported by several Members.

Noting the divergence views of the EWG Members on the approach on the use of additives in RUTF and the identification of a category where RUTF could fall, the Chairs requested the EWG Members during the second consultation on whether CCNFSDU should seek advice from CCFA on the best way to approach the GSFA Food Categories for RUTF Guidelines. This would enable the Committee to decide on how to reference the Codex texts in the RUTF Guidelines. There was widespread support from the EWG Members (M=11) on approaching CCFA for guidance. One Member who was opposed to this approach was of the view that creating a new food category could lead to a two-year delay in finalizing the guidelines. The Member further indicated that referencing the additives sections in the commodity standards (i.e. CXS 72-1981 and CXS 156-1987) was a straightforward path to address the additive section for these guidelines, since there was a precedent using this practice in CXG 8-1991.

4.2.1 Advisory note from the Codex Secretariat on additives in the proposed draft RUTF guidelines

In consultation with the Codex Secretariat regarding the approach to additives in RUTF guidelines, the Secretariat advised that the proposed questions to be raised with CCFA be rephrased and also provided the following advisory note in relation to the discussions by the EWG members.

i. Table 3 additives in relation to the RUTF guidelines

During the consultative process with the EWG Members majority of them were of the view that RUTF could fall under Food Category 13.3: Dietetic foods intended for special medical purposes (excluding products of food category 13.1) with the possibility of exploring the required amendments that could happen (e.g. use of notes or creating a sub-category, etc.). However some members were concerned that the proposed approach might not prevent Table 3 additives from being used in RUTF formulation since there was no mechanism in place to disallow the use of Table 3 additives in RUTF.

The Codex Secretariat view was that Table 3 additives would be excluded provided that CCNFSDU clearly states it. Table 3 provides a column of standards where the listed additives are permitted. Therefore a statement written below could be included and it would exclude the additives in Table 3:

“Only Emulsifiers; antioxidants; packaging gas and carriers used in accordance to table 1 and table 2 in the GSFA listed in FC 13.1.1; 13.1.2; 13.1.3; 13.2;13.3 are permitted for use”.

ii. Proposals to CCFA on the proposed new sub-food category, Food Category title, descriptor and possible amendments to FC in the GSFA

During the consultative process the Chairs requested the 2019 EWG Members to put a set of proposals to CCFA with regard to specific issues on how additives and Food Categories could be explored further for RUTF Guidelines. This would enable CCFA to further explore the amendment of the GSFA by either creating a new sub-food category under Food Category 13.0 or make the necessary amendments to the existing Food Categories. Several proposals were put forward with regard to the food category title, description of the food category and possible amendments that could be done within the GSFA in relation to the RUTF guidelines.

The Codex Secretariat was of the view that the proposals dealing with the revision of the GSFA be left out of the agenda paper as these would be dealt with appropriately under recommendation 2, should CCFA find out the FC 13.3 does not appropriately cover RUTF. Similarly other issues like exclusion of the use of other additives in Table 1, Table 2 and Table 3, would be addressed under the process of alignment of GSFA by CCFA.

The Chairs are of the view that the proposed approach by the Codex Secretariat would simplify the questions to be posed to CCFA, and also that the recommendations on the proposed food category title and its description be parked for future consideration. Such information would become valuable should CCFA require further information or unable to confirm if RUTF could belong to FC 13.3 as proposed in recommendation 2.

Recommendation 2:

Seeking advice from CCFA

It is recommended that CCNFSDU agree to ask CCFA to confirm if RUTF Guidelines belong to FC 13.3; and if FC 13.3 is the right FC, then CCFA should consider aligning the proposed food additives listed in **Table I** of this document with F.C 13.3 of the GSFA.

4.3 Carry-Over of Additives and Carriers

The current provisions with regard to carry-over of additives in the *Guidelines on Formulated Complementary Foods for Older Infants and Young Children* (CXG 8-1991) and the *Standard for Infant Formula* (CXS 72-1981) and *Standard for Processed Cereal-based Foods for Infants and Young Children* (CXS 74-1981) were highlighted to the EWG Members. The provisions in both the standards and the guidelines make reference to the provisions in the Preamble of the GSFA (CXS 192-1995). Based on the existing provisions for carry-over of food additives contained in the Codex standards applicable to foods for older infants and young children, the Chairs proposed the texts to the EWG Members for their inputs in the first and the second consultation papers, to address the carry-over of additives in RUTF Guidelines.

There was wide spread support amongst the EWG Members on the proposed texts for “Carry Over” of additives and carriers. In the first consultation paper, one Member was of the view that the proposed texts did not address the general prohibition on the carry-over of additives into infant foods as set out in Section 4.3 of the GSFA Preamble, since RUTF was meant for infants and young children. Therefore, RUTF should be subjected to this general prohibition as prescribed in the GSFA. The Committee should determine what additives should be carried over and request CCFA to add provisions to Table 1 and 2 of the appropriate food category. Another Member also indicated that the proposed texts did not allow carry-over of additives from ingredients unless those additives were already permitted for use in RUTF or in CXG 10-1979. Furthermore, a discussion should be held on how the proposed texts could be modified to address both older infants and young children with SAM.

Although the proposed texts was taken from other existing CCNFSDU standards, the message being communicated by the stipulated conditions in (a) and (b) could lead to misinterpretation and confusion. The Chairs proposed some edits to the texts in the second consultation, which was acceptable by the majority of the EWG Members. One Member who was not supportive of the proposed texts and edits in the second consultation paper highlighted that preference should be made to reference the food additive sections in commodity standards (i.e., CXS 72-1981 and CXS 156-1987). This approach would ensure that a section on carry-over would not be necessary, as the proposed text addressed in those standards would be relevant.

Conclusion

Based on the EWG responses, the Chairs propose the “carry-over of additives and carriers” texts below for the Committee’s consideration.

Recommendation 3:

That CCNFSDU agree to the following texts on "Carry-Over of Additives and Carriers" in RUTF Guidelines:

Proposed Texts

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

a) The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to the *General Standard for Food Additives* (CXS 192-1995)

b) The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in the *General Standard for Food Additives* (CXS 192-1995); and

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

4.4 Protein quality assessment in RUTF

The Chairs highlighted in the First Consultation on the divergent views amongst the PWG Members at CCNFSDU40 on whether to retain or remove the statement "at least 50% of protein is provided by milk products" in the proposed texts. Furthermore, whether an additional statement was needed to capture the evidence requirement of new formulations and future innovations that would not contain 50% dairy sourced proteins. The Chairs also highlighted that the report of the FAO Expert Working Group recommended the use of PDCAAS in defining the protein quality in RUTF. The Chairs proposed the texts to the EWG Members in the first consultation with the edited version of the statement on protein. Although several Members were in support of the proposed texts in the first consultation, those who were not in favour of the proposed texts were of the view that the statement "At least 50% of protein should be provided by milk products" should be retained as is, in the proposed texts. Various reasons were given which include, amongst others:

- Several studies have demonstrated that RUTF containing lower amounts of dairy ingredients or other non-dairy protein sources (e.g. soy, maize, sorghum, etc.) were inferior in terms of recovery and growth in children with SAM compared to milk-containing RUTF[7,8,9,10].
- Milk proteins have been shown to have an effect on stimulating linear growth through the production of insulin-like growth factor 1 (IGF-1)[11]
- Dairy ingredients also contain bioactive peptides with other benefits and physiological functionalities, including antimicrobial, antioxidative, immunomodulatory, mineral-binding and growth promoting activities[12].
- The body of evidence for RUTF is based on products that include dairy proteins.

[7] Oakley, E., Reinking, J., Sandige, H., et al. 2010. A ready-to-use therapeutic food containing 10% milk is less effective than one with 25% milk in the treatment of severely malnourished children. *Journal of Nutrition*. 140(12):2248-2252.

[8] Irena, AH., Bahwere, P., Owino, VO., et al. 2015. Comparison of the effectiveness of a milk-free soy-maize-sorghum-based ready-to-use therapeutic food to standard ready-to-use therapeutic food with 25% milk in nutrition management of severely acutely malnourished Zambian children: an equivalence non-blinded cluster randomised controlled trial. *Maternal & Child Nutrition*. 11(4):105-119.

[9] Bahwere P., Balaluka, B., Wells, JC, et al. 2016. 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 noninferiority, individually randomized controlled efficacy clinical trial. *American Journal of Clinical Nutrition*. 103(4):1145-1161.

[10] Effectiveness of milk whey protein-based ready-to-use therapeutic food in treatment of severe acute malnutrition in Malawian under-5 children: a randomised, double-blind, controlled non-inferiority clinical trial. *Maternal & Child Nutrition*. 10(3):436-451.

[11] Hoppe C, Mølgaard C, Dalum C, Vaag A, Michaelsen KF. Differential effects of casein versus whey on fasting plasma levels of insulin, IGF-1 and IGF-1/IGFBP-3: results from a randomized 7-day supplementation study in prepubertal boys. Eur J Clin Nutr 2009;63:1076–83

[12] Park, Y.W. and Nam, M.S. Bioactive Peptides in Milk and Dairy Products: A Review. Korean J. Food Sci. An. 2015 Vol. 35 (6):831-840.

- The FAO Expert Working Group report recommended that new formulation for RUTF should be tested for their efficacy and their ability to support growth or related outcomes of interest in the target population and not just relying on fulfilling the protein quality recommendation.

One Member highlighted that high quality protein sources could be derived from vegetable proteins and that the option to allow RUTF to include local sources of vegetable proteins that have been supplemented with amino acids would provide more flexibility for National governments to formulate RUTF.

Given the current scientific evidence which is in favour of RUTF formulation with dairy products in terms of the outcomes on growth, recovery rates or related outcomes of SAM children, the Chairs recommended in the Second Consultation Paper that the statement "at least 50% of protein is provided by milk products" be retained in the proposed texts on protein in RUTF. However, new formulations on RUTF would still be required to be tested for their efficacy and their ability to support growth or related outcomes of interest in SAM children to ensure that they fulfil both the protein quality recommendations and related outcomes. Evidence that has been generated on RUTF to date has been based on RUTF products with dairy proteins in their formulation.

There was widespread support of the amended texts on protein quality in the Second Consultation Paper amongst the EWG Members. However, there were proposed minor edits to the proposed texts from those who were in support of the proposed texts. Some Members who were not in favour of the proposed revised texts were of the view that the statement "at least 50% of protein is provided by milk products" should be made mandatory to RUTF formulation. Two Members also suggested that the proposed texts should be consistent with preamble and additive sections in the expression of the target group, i.e. to use 6 to 59 months, rather than 0.5 to 4.9 years. One Member proposed that a separate paragraph to address the sources of protein that have been shown to be effective in RUTF formulations should be added.

Conclusion

Although some Members also proposed that a statement on the efficacy of RUTF, which should be demonstrated through scientific evidence should be added, such provisions are already catered for, since it is a requirement for foods for special medical purposes (refer to Section 5 (Suitable Raw Materials and Ingredients of the proposed RUTF Guidelines). Therefore, it would not be necessary to include such a statement in the proposed texts. Based on the comments received from the EWG Members, the Chairs propose the following draft texts below for the Committee's consideration.

Recommendation 4:

Recommendation 4.1:

That CCNFSDU agree to the proposed protein values of the Guidelines for RUTF.

Unit	Minimum	Maximum	GUL
g/100g	13	16.5	-
g/100kcal	2.4	3.2	-

Recommendation 4.2:

That CCNFSDU agree to the proposed texts on protein quality assessment in RUTF Guidelines.

Proposed texts

Protein should provide 10% to 12% of the total energy. Protein quality should be determined using PDCAAS, calculated according to the reference amino acid requirement and scoring patterns related to catch up growth of 10 g/kg/day in the target population of children 6 to 59 months for RUTF. The PDCAAS shall not be less than 90, when determined using PDCAAS methodology, appropriate fecal Digestibility values and the reference amino acid pattern in the *Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic foods.* High quality protein will be achieved with RUTF formulations containing a minimum of 50% of protein from milk products.

In formulations with lower scores, the quality and/or quantity of protein should be adjusted to achieve the desired value. The quality of protein can be achieved by adding the limiting amino acids. Any added amino acids should be solely in the L-form, and included only in amounts necessary to improve the protein quality of the RUTF.

Detail on how to calculate the PDCAAS is listed in the ***Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic foods***[13].

4.5 Processing Technologies

Although the 2016 and 2017 EWG Members supported the section on processing technologies to 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 group. However, a proposal was made that some of the proposed sections in CXG 8-1991 may not be relevant to RUTF since RUTF should be manufactured in compliance with the *Code of Hygienic Practices for Low-Moisture Content Foods* (CXC 75-2015). Most of the processes that have been described under section 4 and 5 of CXG 8-1991 may not be applicable to RUTF (e.g. cleaning and washing, milling (i.e. paragraph on bulkiness), some texts on toasting, sprouting, malting and fermentation).

In order for this section to remain relevant and to avoid including texts from CXG 8-1991 that may not be relevant to low moisture content foods, the Chairs proposed new texts during the consultative process with the 2019 EWG Members. This approach enable the Committee to future proof the guidelines and to ensure that the texts remain relevant to low moisture content foods.

Responses from the EWG Members

The majority of the 2019 EWG Members (M=10) were supportive of the proposed revised texts in the second consultation paper. One Member who was not supportive of the draft texts proposed the addition of the following texts: “Because RUTF is a low moisture product that has been fortified with fat-soluble micronutrients, manufacturing/processing should ensure levels of water activity in ranges where oxidation of fat and fat-soluble vitamins is minimized”. The Member indicated that the evidence showed that a range of water activity between 0.2-0.45 would ensure best results in terms of fat and fat-soluble vitamin stability.

Conclusion

Based on the comments received from the EWG Members the Chairs propose the following texts for the Committee’s consideration:

Recommendation 5:

That CCNFSDU agree to the proposed texts on “Processing Technologies in RUTF Guidelines.

Proposed Texts

Processing Technologies

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

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

RUTF and/or their raw materials should be treated with a validated microbial reduction treatment in order to inactivate pathogens such as *Salmonella*, noting that some pathogens have increased heat resistance characteristics at reduced water activities in food matrices. Commonly used microbial reduction treatments that could be applied to RUTF and/or their raw materials include both thermal and non-thermal control measures.

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

[13] Report of the Expert Working Group on Protein Quality Assessment in Follow-up Formula for Young Children and Ready to Use Therapeutic Foods. FAO, Rome, 2018.pp38

5. CONCLUSIONS

The main tasks of the EWG were to continue drafting the guidelines for RUTF, continue with the development of Section 5.2.2 (Food additives) and Section 6.2 (Proteins), and make amendments to other draft texts where necessary. The Chairs of the EWG are of the view that the work accomplished to date would enable the Committee to make decisions and progress the guideline for RUTF to the next step. Although the EWG could not make recommendations with specific reference to the additives section, the Chairs believe that the recommendations made by the EWG would enable the Committee to make appropriate decisions.

6. RECOMMENDATIONS

Taking into consideration the recommendations made by the EWG, the Committee is therefore invited to consider:

i. The key recommendations with regard to sections 5.2.2 and 6.2;

ii. Recommendations made by the EWG with regard to seeking advice from CCFA on how to handle food additives in RUTF (Recommendations 2 and 3); and

iii. Proposed draft Guidelines for Ready-to-Use Therapeutic Foods in Appendix II.

APPENDIX I

OUTSTANDING RECOMMENDATIONS FROM THE 2018 PHYSICAL WORKING GROUP AND THE 2018 ELECTRONIC WORKING GROUP [14]

Due to time constraints CCNFSDU40 agreed to defer consideration of the remaining recommendations from the 2018 PWG and EWG to its next session. The outstanding recommendations are presented below for the Committee's consideration.

Outstanding Recommendations of the 2018 Physical Working Group

7. Available Carbohydrates

CCNFSDU40 considered the proposed text for Section 5.2.1 (Available carbohydrates) and agreed with the proposal by UNICEF to integrate footnote 6 into the main text, as this would ensure clarity, readability and better flow of concepts in this section. Furthermore, the Committee clarified that the preferred form of carbohydrates to be used in the manufacture of RUTF were; plant starch, lactose, maltodextrin, and sucrose; and that glucose should not be used due to its high osmolality. The Committee also agreed that "free sugars" could be added to RUTF and if added, it should not exceed 20% of total energy. The phrase referring to "free sugar added for sweetness should be used sparingly" was deleted from the text, as it would be difficult to implement and/or to enforce. It was further clarified that only precooked and/or gelatinized starches may be added. The Committee also agreed to amend the title of the section by deleting the word 'Available', as the text applied to carbohydrates in general and not sugars.

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

The Committee noted that there was a relationship between Section 5.2.1 (Carbohydrate), and the Section 6.3 (Lipids); and Section 6.2 (Proteins), and agreed to a proposal to have it finalised after considering the aforementioned sections, and therefore agreed to leave Section 5.2.1 in square brackets for discussion at CCNFSDU41.

Recommendation 6:

That CCNFSDU agree to the proposed texts on Carbohydrates in RUTF Guidelines.

Draft Texts

Carbohydrates

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

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

8. Nutritional Composition and Quality Factors

The current nutritional composition for RUTF is derived from the F-100 product, which is currently used for inpatient 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 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 (e.g. phosphorus, calcium, magnesium) needs for malnourished populations were reviewed later, and recommendations for these nutrients were increased to allow for catch up bone growth[15].

[14] See Agenda Item 5a of the provisional agenda for CCNFSDU41

[15] *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

Editorial amendments with regard to the Rounding Issues to the Nutritional Composition for the Proposed Draft Guidelines on RUTF

The rounding-off of certain values was identified by the Chairs of the electronic working group as requiring minor editorial amendments and corrections to the Sections relating to the Nutritional Composition of the Proposed Draft Guidelines on RUTF. All of the amendments have been included in the recommendations and also in Table 1 on Nutritional composition in Annexure A.

The 2018 PWG noted some inconsistencies in the rounding off applied to values in the development of the guidelines. The Chairs noted the discrepancies and considered it imperative to apply a systematic approach that will be applied consistently throughout the guidelines. This will align the guidelines with other internationally agreed upon conventional rounding methods. The rounding logic that has been applied aligns fairly well with the current drafting of other standards such as the draft Follow-Up-Formula standard. The following rounding up logic was applied:

Rounding logic
Values >5 round to nearest whole number
Values 1-5 report to 1 decimal point
Values<1 Report to 2 decimal points

8.1 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.

The 2018 PWG Members agreed to maintain the current values as stipulated in the 2007 UN Joint Statement of the fat contribution to the total energy of between 45% and 60%.

Recommendation 7:

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

Lipids

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

Unit	Minimum	Maximum	GUL
g/100g	26	37	-
g/100kcal	5	7	-

8.2 Essential Fatty Acids

Some members of the 2018 PWG highlighted that the high levels of linoleic acid (omega 6) in the current RUTF may result in poor conversion of alpha linolenic acid (omega 3) into DHA, due to competition for enzymes pathways during metabolism. Based on current evidence the ratio of 1:1 of ALA:LA seems to produce the most optimal DHA levels in SAM children. Therefore, the linoleic (LA) acid in the lower part of the permitted range would be preferable.

Several PWG Members were in favour of deleting the text on ALA:LA ratio in RUTF formulation for SAM children, in favour of absolute values. There was an agreement amongst the PWG on the proposed n-6 fatty acids and n-3 fatty acids as stipulated in the 2007 Joint Statement.

Recommendation 8:

That CCNFSDU agree to the proposed text on essential fatty acids and the proposed minimum and maximum n-3 and n-6 fatty acids values as follows:

Lipids

The level of linoleic acid should not be less than 333mg ~~316~~ mg per 100 kcal and shall not be more than 1110 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33 mg/100kcal.

n-6 Fatty acids

Unit	Minimum	Maximum	GUL
Kcal/100kcal	**3**	**10**	**-**
mg/100kcal	333	1110	-

n-3 Fatty acids

Unit	Minimum	Maximum	GUL
Kcal/100kcal	**0.3**	**2.5**	**-**
mg/100kcal	33	280	-

8.3 Vitamins and minerals

The 2018 PWG discussed the proposed minimum, maximum and GUL values on vitamins and minerals in Annex "Nutrition Composition for RUTF". The PWG also agreed to include some introductory text on vitamins and mineral.

Recommendation 9:

That CCNFSDU agree to the proposed introductory text on vitamins and minerals:

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

8.3.1 Vitamins

i. Vitamin A

The maximum value of vitamin A of 1.2 mg RE/100g and its accompanying footnote was agreed on by the 2018 PWG in order to account for vitamin A's instability and its degrading effect during the long shelf life of the product.

Recommendation 10:

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

ii. Vitamin D

The maximum value of vitamin D of 22 µg/100 g and its accompanying footnote was agreed on by the 2018 PWG in order to account for vitamin D's raw material variability, degradation during shelf life of the product. The forms of vitamin D were not discussed in the PWG.

Recommendation 11:

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	3	~~[3.6] OR~~ [4]	-

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

iii. Vitamin E

Taking into consideration the views of the 2018 PWG 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[16]. The specific form of vitamin E recommended in the WHO guidelines is α-tocopherol. Therefore, the minimum value of 20 refers to the 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 12:

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	3.8	-	-

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

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

iv. Other Vitamins

There was agreement amongst the 2018 PWG Members to retain the current values on vitamin K, vitamin B1, vitamin B2, vitamin C, vitamin B6, vitamin B12, folic acid, niacin, pantothenic acid and biotin as stipulated in the 2007 Joint Statement.

Recommendation 13:

That CCNFSDU agree to the following recommendations for vitamin E, 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	-
µg/100 kcal	3	5.5	-

Vitamin B1

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

Vitamin B2

Unit	Minimum	Maximum	GUL

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

mg/100 g	1.6	-	-
mg/100 kcal	0.3	-	-
Vitamin C			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	50	-	-
mg/100 kcal	10	-	-
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	1	-	-
Pantothenic Acid			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	3	-	-
mg/100 kcal	0.6	-	-
Biotin			
Unit	**Minimum**	**Maximum**	**GUL**
µg/100 g	60	-	-
µg/100 kcal	11.5	-	-

8.3.2 Minerals

There was agreement amongst the 2018 PWG Members to retain the current values on the minerals as stipulated in the 2007 Joint Statement with the exception of the maximum values on potassium, calcium and magnesium were increased to allow for variability in raw materials. A member raise the suggestion of including a ratio of phytic acid to iron and zinc however the PWG agreed not to include such a ratio in this section as it will be addressed by section 8 of the proposed guidelines.

Recommendation 14:

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

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~~ 1,600	-
mg/100 kcal	212	~~255~~ 287	-

Calcium

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

Phosphorus

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

Magnesium

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

Iron

Unit	Minimum	Maximum	GUL
mg/100 g	10	14	-
mg/100 kcal	2	2.6	-

Zinc

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

Copper

Unit	Minimum	Maximum	GUL
mg/100 g	1.4	2	-

mg/100 kcal	0.27	0.33	-

Selenium

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

Iodine

Unit	**Minimum**	**Maximum**	**GUL**
µg /100 g	70	160	-
µg /100 kcal	13.5	25.5	-

Moisture Content

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

9. Contaminants

The Chairs in 2018, 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 would 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 2018 Physical Working Group discussed the expert report on contaminants in RUTF on RUTF Guidelines. UNICEF representative presented an expert report in appropriate criteria and limits for contaminants in RUTF. The PWG agreed to the recommendations in the report to reference the existing codex standards and codes of practice throughout the RUTF guidelines.

Recommendation 15:

That CCNFSDU agree to the proposed texts on “Contaminants” in the RUTF Guidelines

Draft texts:

Contaminants

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

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

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 (ug/kg) for aflatoxin is allowed in the RUTF products]]~~

Outstanding Recommendations of the 2018 Electronic Working Group

The 2018 PWG did not discuss the following recommendations due to time constraints:

10. 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 16:

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

Draft Texts

Good Manufacturing Practices and Good Hygiene Practices

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

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

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

11. 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 17:

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

Draft Texts

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* (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.

12. Packaging

The Chairs requested the 2016 EWG Members 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 majority of the EWG Members supported the proposed text and minor additions were proposed to the text.

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 18:

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

Draft Texts

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.

13. 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).

13.1 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 Prepackaged 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.

13.2 Additional Requirements for Labelling Purposes

The 2016 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 referred to the EU legislation that 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 because 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 Breastmilk 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.

There was an agreement in the EWG that the proposed text for the "labelling" section and additional labelling requirements where possible should cross-refer to the existing Codex texts to avoid unnecessary duplication. It was reiterated by the EWG Members that only the most relevant Codex texts should be referenced to avoid confusion that may arise as a result of conflicting labelling requirements.

Recommendation 19:

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

Proposed texts

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.

14. 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.

Recommendation 20:

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

Draft texts:

Preamble

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

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

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

APPENDIX II

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

(Includes those sections already agreed as well as recommendations as presented in Appendix I for further consideration in CCNFSDU41)

1. PREAMBLE

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

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

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

2. PURPOSE OF THE GUIDELINES

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

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

3. SCOPE

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

[2)]Guidelines for Vitamin and Mineral Food Supplements (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. Any formulation of RUTF shall comply with Section 3 of the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991) including the specification that their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended.

5.1 Basic Raw Materials and Ingredients

5.1.1 Milk and other Dairy Products

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

5.1.2 Legumes and Seeds

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

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

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

5.1.3 Fats and Oils

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

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

5.1.4 Cereals and [Tubers]

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

5.1.5 Vitamins and Minerals

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

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

5.2 Other Ingredients

5.2.1 Carbohydrates

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

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

5.2.2 Food Additives and Flavours

5.2.2.1 [This section is awaiting the Committees decision on how to handle additives in RUTF].[17]

5.2.2.2 Carry-over of Additives and Carriers

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

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

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% to 12% of the total energy. Protein quality should be determined using PDCAAS, calculated according to the reference amino acid requirement and scoring patterns related to catch up growth of 10 g/kg/day in the target population of children 6 to 59 months for RUTF. The PDCAAS shall not be less than 90, when determined using PDCAAS methodology, appropriate faecal Digestibility values and the reference amino acid pattern in the *Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic foods.* High quality protein will be achieved with RUTF formulations containing a minimum of 50% of protein from milk products.

In formulations with lower scores, the quality and/or quantity of protein should be adjusted to achieve the desired value. The quality of protein can be achieved by adding the limiting amino acids. Any added amino acids should be solely in the L-form, and included only in amounts necessary to improve the protein quality of the RUTF.

Detail on how to calculate the PDCAAS is listed in the ***Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic foods***.

[17] See recommendation 2 and 3 in the report above

6.3 Lipids

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

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

6.4 Please see Annex "Nutrition Composition for RUTF".

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

7. CONTAMINANTS

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

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

Other Contaminants

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

8. PROCESSING TECHNOLOGIES

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

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

RUTF and/or their raw materials should be treated with a validated microbial reduction treatment in order to inactivate pathogens such as *Salmonella*, noting that some pathogens have increased heat resistance characteristics at reduced water activities in food matrices. Commonly used microbial reduction treatments that could be applied to RUTF and/or their raw materials include both thermal and non-thermal control measures.

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

9. GOOD MANUFACTURING PRACTICES AND GOOD HYGIENE PRACTICES

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

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

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

10. METHODS OF ANALYSIS AND SAMPLING

It is recommended that methods of analysis and sampling of RUTF be in accordance with the *Recommended Methods of Analysis and Sampling* (CXS 234-1999), *General Standard for Contaminants and Toxins in Food and Feed* (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.

11. PACKAGING

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

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

12. LABELLING

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

The Name of the Food

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

List of Ingredients

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

Additional Mandatory Labelling Requirements

The following statements shall appear on the label of RUTF:

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

Instructions for use

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

ANNEX

Table: Nutritional Composition for RUTF

Energy

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

Protein

Unit	**Minimum**	**Maximum**	**GUL**
g/100g	13	16.5	-
g/100kcal	2.4	3.2	-

Lipids

Unit	**Minimum**	**Maximum**	**GUL**
g/100g	26	37.6	-
g/100kcal	5	7	-

n-6 Fatty acids

Unit	**Minimum**	**Maximum**	**GUL**
Kcal/100kcal	**3**	**10**	**-**
mg/100kcal	333	1110	-

n-3 Fatty acids

Unit	**Minimum**	**Maximum**	**GUL**
Kcal/100kcal	**0.3**	**2.5**	**-**
mg/100kcal	33	280	-

Vitamin A

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

[2] 1µg RE = 3.33 IU Vitamin A = 1 µg 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	3	[3.6] OR [4]	-

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

Vitamin E

Unit	Minimum	Maximum	GUL
[4] mg/100 g	20	-	-
[4] mg α-TE /100 kcal	3.8	-	-

[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	3	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	10	-	-

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	1	-	-

Pantothenic Acid

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

Biotin

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

Sodium

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

Potassium

Unit	Minimum	Maximum	GUL
mg/100 g	1,100	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]~~ [25.4] or ~~[43]~~ [42.7]	-

Iron

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

Zinc

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

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	7.3	-

Iodine

Unit	**Minimum**	**Maximum**	**GUL**
µg /100 g	70	140	-
µg /100 kcal	13.5	25.5	-

Moisture Content

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

APPENDIX III

LIST OF PARTICIPANTS

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