CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 8 **CX/NFSDU 16/38/9**

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

Thirty-eighth Session

Hamburg, Germany

5 – 9 December 2016

PROPOSED DRAFT GUIDELINE FOR READY-TO-USE THERAPEUTIC FOODS

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

(At Step 3)

Governments and interested international organizations are invited to submit comments on **Recommendations 1 – 19** and on the **proposed draft outline for the proposed draft Guideline for RUTF as presented in Appendix I** at Step 3, and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission*) **to**: German Secretariat of CCNFSDU, email ccnfsdu@bmel.bund.de with copy to Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Rome, Italy, email codex@fao.org **by 30 September 2016.**

Format for submitting comments: In order to facilitate the compilation of comments and prepare a more useful comments document, Members and Observers, which are not yet doing so, are requested to provide their comments in the format outlined in the Annex to this document.

1. Background

1. The 37th Session of the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU37)agreed to start new work on a guideline for a single product known as “Ready to Use Therapeutic Food” (RUTF) used in the management of severe acute malnutrition (SAM).[1]

2. This work was approved by CAC39[2].

3. 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 with the following terms of reference:

i. To develop a guideline for Ready to Use Therapeutic Foods, covering the following main aspects:

- Minimum requirements for appropriate ingredients to be included in RUTF taking into consideration the effects of anti-nutritive factors that can affect macro and micro nutrient absorption. Consideration of inclusion of a protein quality score such as PDCAAS or DIAAS within the nutritional composition requirements.
- Nutritional composition based on the adoption of the nutritional composition as specified in existing 2007[3] Joint Statement by WHO/WFP/UNICEF and UNSCN for RUTF and their future modification.
- Hygienic practice for production, handling, processing, storage and distribution and associated microbiological criteria for RUTF with reference to the General Principles of Food Hygiene and other relevant Codex texts.
- Appropriate criteria and limits for relevant microbiological hazards and chemical contaminants (e.g. heavy metals, mycotoxins and pesticides) with reference to the *General Standard for Contaminants and Toxins in Food and Feed*.
- Labelling of RUTF in accordance with the *General Standard for the Labelling of Pre-packaged Foods* and other relevant Codex texts.

[1] REP16/NFSDU, paras 81-88, Appendix IV
[2] REP16/CAC, paras 102 – 107, Appendix V
[3] Joint Statement on Community-Based Management of Severe Acute Malnutrition 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.

- Reference Methods of Analysis and Sampling
- Nutrient compounds used for the RUTF.

1.1 The process Followed

4. Nominations to participate in the eWG were received from 21 Codex Members and 11 Codex Observers (Appendix 2). Two Consultation Papers were circulated to the eWG in March and May, respectively. The focus of the first Consultation Paper was on the following key areas:

- The development of a draft framework and the scope of a guideline for RUTF as per the stipulated terms of reference.
- To provide an opportunity for eWG members to comment on other additional issues that should be taken into consideration during the development of a guideline.
- To request the eWG members to provide information and evidence that will inform the content of a guideline.

5. A draft framework for the RUTF guideline was circulated to the eWG Members for inputs. About 18 submissions were received from the First Consultation Paper from 11 Codex Members and 7 Codex Observers. The Second Consultation Paper took into consideration the findings of the First Consultation Paper and included a summary of eWG members' comments regarding the proposed framework and the scope of a Guideline for RUTF, summary of evidence and information that will inform the content of a Guideline and highlight other additional issues that should be taken into consideration during the development of a Guideline. The Second Consultation Paper also requested eWG members to continue reviewing and providing inputs on the development of a framework and the scope of a Guideline for RUTF, and also highlighted key areas that still need further discussion or agreement by Members. About 17 submissions were received from the Second Consultation Paper from 7 Codex Members and 10 Codex Observers.

2. PROPOSED FRAMEWORK/OUTLINE OF A GUIDELINE FOR READY TO USE THERAPEUTIC FOODS (RUTF)

2.1 PURPOSE

6. At CCNFSDU37, the main aspects that a guideline should cover were outlined. This section attempted to cover all the general aspects of a guideline. As part of the First Consultation Paper, the eWG members were requested to provide inputs on the proposed purpose of a draft Guideline for RUTF.

7. The Chairs proposed the following text in the First Consultation Paper as reflected below:

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

i. Nutritional composition
ii. Formulation of RUTFs
iii. Hygienic requirements
iv. Microbiological and chemical contaminant criteria
v. Analysis and sampling
vi. Provisions for packaging
vii. Processing/production standards
viii. Provisions for labelling and instructions for use

8. Several responses were received and various issues also emerged. Majority of eWG Members indicated that the proposed purpose covered the main aspects of a Guideline. Members proposed various texts and also merging of some sections of the proposed purpose such as point (iii) and (vii) which would cover the same areas in a Guideline. It was proposed that these two areas be merged and replaced by Good Manufacturing Practices, which would cover the *General Principles of Food Hygiene* (CAC/RCP 1-1969) and *Code of Hygienic Practice for Low Moisture Foods* (CAC/RCP 75-2015). Members also emphasized that the age range of 6 to 59 months be consistently used throughout the Guideline to avoid confusion with other Codex definitions.

Recommendation 1
Based on the collective comments of the eWG, the Chairs propose the following structure for the Purpose of a Guideline for RUTF for consideration and discussion by the Committee:

PURPOSE

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

2.2 SCOPE

9. The discussion paper presented by UNICEF and Senegal indicated that the scope of a guideline should only refer to RUTF that are produced in food manufacturing facilities and traded internationally, as well as being produced domestically for domestic use[4]. The eWG Members were requested to give comments on the proposed "Scope" of a Guideline and various submissions were received. There was general support amongst eWG members on the proposed scope. Certain amendments were proposed to the text. Several eWG Members indicated that reference to "domestic production" should be clarified or avoided in a guideline since the use of this term could be mistaken for food prepared at home or interpreted differently. However RUTF could be produced in a local food manufacturer as explained in the Joint Statement of 2007. Several members indicated that the target group and the age group for the RUTF products should be clearly outlined in the scope. Various wordings were proposed by eWG members.

10. Several eWG Members suggested that other products such as: Ready-to Use Supplementary Foods (RUSF), micronutrient supplements, processed cereal based foods, complementary foods and other products used to prevent or treat malnutrition should be excluded from the Guideline. It was proposed that instead of referring to the broad concept of "complementary foods", it would be more useful to refer to "Formulated Complementary Foods for Older Infants and Young Children" (covered by the *Guidelines on Formulated Complementary Foods for Older Infants and Young Children* - CAC/GL 8-1991), processed cereal based foods (covered by the *Standard for Processed Cereal-Based Foods for Infants and Young Children* – CODEX STAN 74-1981), canned bay foods (covered by the *Standard for Canned Baby Foods*– CODEX STAN 73-1981) and others where the Codex texts already exist.

11. One Member suggested that the following sentence should be removed from the proposed text of the scope "the scope of a guideline will only refer to RUTF that are produced in food manufacturing facilities and traded either nationally or internationally", since the mandate of Codex is to establish international food standards to promote fair trade which addresses the trade aspect of the sentence.

12. However one eWG Member noted that it would be useful to include other products with similar composition and intended use such as RUSF to avoid confusion resulting from multiple guidelines for similar products. It was felt that excluding RUSF from the scope of the guidelines at this time may not adequately reflect the differing circumstances and needs throughout the world since the evidence distinguishing between RUTF and RUSF for management of acute malnutrition is limited[5]. It was proposed that further discussion about inclusion of other products with similar composition and intended use in this guideline be considered after the WHO report on lipid based nutrient supplements (including RUTF and RUSF) for the treatment and prevention of under-nutrition in pregnant women and children 6–59 months of age (REP16/NFSDU) has been released.

13. One Member also indicated that the scope of the guideline should be in line with the relevant World Health Assembly (WHA) resolutions (i.e. WHA 55.25 (2002) and WHA 63.14 (2010)). It was emphasized that the text should make reference to older infants, and not only children, as the product is intended for individuals from 6 to 59 months.

Recommendation 2

Based on the collective comments of the eWG, the Chairs propose the following text for the Scope of a Guideline for RUTF for consideration and discussion by the Committee:

[4] CX/NFSDU 15/37/8

[5] Schoonees A, Lombard M, Musekiwa A, Nel E, Volmink J. Ready-to-use therapeutic food for home-based treatment of severe acute malnutrition in children from six months to five years of age. *Cochrane Database of Systematic Reviews* 2013, Issue 6. Art. No.: CD009000. DOI: 10.1002/14651858.CD009000.pub2.

SCOPE
The provisions of these guidelines apply to Ready to Use Therapeutic Foods for children from 6 to 59 months with severe acute malnutrition. Ready-to-Use Supplementary Foods (RUSF), micronutrient supplements, processed cereal based foods[6], formulated complementary foods for older children and young children[7], canned baby foods[8] are not covered by these guidelines. These guidelines should be used in accordance with the 2007 Joint Statement of the UN Agencies[9], 2013 WHO document on Updates on the Management of Severe Acute Malnutrition in infants and children[10] or any other relevant upgrade of the latest version.

2.3. DESCRIPTION

14. Various descriptions of what RUTFs are exist. The current definition in the 2007 Joint Statement by UN agencies read as follows: "Ready to Use Therapeutic Foods (RUTF) are high-energy, fortified, ready-to-eat foods suitable for the treatment of children >6 months with severe acute malnutrition as outlined in the 2007 Joint Statement by WHO, WFP, UNSCN and UNICEF. These foods should be soft or crushable and should be easy for young children to eat without any preparation". This description was used as the departure point for the description of RUTFs. The Chairs also acknowledged that some regions treat severe acute malnutrition based on therapeutic diets using locally available nutrient-dense foods, without the use of commercially produced products. As part of the Consultation Papers, eWG Members were requested to provide inputs on the proposed "Description" of a draft Guideline for RUTF, as well as other issues that the Chairs should consider.

15. Several eWG Members made proposals to the wording of the "Description of RUTFs". There was an overwhelming support amongst eWG Members that since the intended use for RUTFs is for dietary management of severe acute malnutrition, they should comply with the definition of food for special medical purposes (FSMP) as stipulated in the *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-1991). This would assist in avoiding legal uncertainties, and also clarify that the products are specially processed or formulated. It was proposed that the wording "dietary management" of severe acute malnutrition should be used rather than "treatment" for consistency with CODEX STAN 180-1991.

16. Members also emphasised that the "description" should not cover other forms of RUTFs that were not commercially produced as per the project document that was presented at CCNFSDU37. However the description should not only be restricted to the current form of the product, but should also include other forms of RUTFs such as bars, etc. It was also highlighted that the wording "not commercially produced" was vague, and care should be taken not to undermine the R&D efforts and trials by imposing unnecessary constraints on product use. However, patients should be protected from poor quality products.

17. The eWG Members also requested that definitions should be provided for severe acute malnutrition and young children. With regard to the definition of a "young children", several eWG Members felt that there was no need to include it since RUTFs were not only intended for young children but also for children up to 59 months. In order to avoid confusion regarding the target population to which the guidelines apply, it was proposed that the scope should only refer to children from 6 to 59 months, which will encompass all other age groups as defined in other Codex documents.

Recommendation 3
Based on the collective comments of the eWG, the Chairs propose the following text for the Description of a Guideline for RUTF for consideration and discussion by the Committee:

DESCRIPTION
Ready to Use Therapeutic Foods (RUTF) are high-energy, fortified, ready-to-eat foods for special medical purposes that are suitable for the dietary management of children from 6 to 59 months with severe acute malnutrition. These foods should be soft or crushable and should be easy for young children to eat without any prior preparation.

[6] *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CODEX STAN 74-1981)
[7] *Guidelines on Formulated Complementary Foods for Older Infants and Young Children* (CAC/GL 8-1991)
[8] *Standard for Canned Baby Foods* (CODEX STAN 73-1981)
[9] Joint Statement on Community-Based Management of Severe Acute Malnutrition 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
[10] WHO. Guideline: *Updates on the management of severe acute malnutrition in infants and children*. Geneva: World Health Organization; 2013.

Severe Acute Malnutrition is defined as weight for height (or length) less than –3 Z-score of the median WHO growth standards, or mid upper arm circumference (MUAC) <115 cm, or the presence of bilateral oedema.

2.4. BASIC RAW MATERIALS AND INGREDIENTS

18. This section will include various ingredients that could be used in making RUTF. Electronic Working Group Members were requested to provide inputs on "Raw Materials and Ingredients" section of a Guideline, and also indicate other key aspects that should be considered. The Chairs proposed the following text and a proposed list of ingredients in the table below to be included in a Guideline:

RUTF are made of powdered or ground ingredients embedded in a lipid-rich paste, or protein-based matrix, resulting in energy and nutrient-dense food. The main ingredients are ground peanuts, milk products, sugar, and a premix containing oil, vitamins and minerals. However other forms of RUTF with various ingredients are being tried and tested in different regions.
This section will include various ingredients that could be used in making RUTF. Below is the proposed list of raw materials and ingredients according to the current formulation which is derived from F-100, with the addition of peanut butter.

1.5.1 Basic Raw Materials and Ingredients
1.5.1.1 Milk and Milk products
1.5.1.2 Peanuts
1.5.1.3 Vegetable oils
1.5.1.4 Sugars
1.5.1.5 Mineral and Vitamin Premix
1.5.2 Other ingredients
1.5.2.1 Food additives and flavours
1.5.2.2 Emulsifying agents

19. There was consensus amongst eWG members that the section on "Raw materials and Ingredients" should not only be limited to the list provided, but should also make provision for other raw materials that were locally available and could be used in the production of RUTFs, to allow for variety and increase palatability when local and cultural acceptable ingredients were used and also to reduce costs of RUTFs. Two Members emphasized that other matrices could be used provided that there was scientific evidence to support the effective delivery of the nutritional requirements for the target group (e.g. energy, protein quality and micronutrients) from other matrices. A proposal was made that a statement should be added to explain that new formulation with other ingredients can be proposed, only with published efficacy study and acceptability study to demonstrate the use on the new developed product to treat SAM in the same context as the current RUTF products.

20. It was proposed that only the first four ingredients be included and expressed as food groups and not as individual foods to allow for RUTF innovation and to 'future proof' the guideline. A proposal was made that the proposed guideline follow the outline given in CAC/GL 8-1991 so that it includes food additives and flavours but not vitamins and minerals which are mentioned under nutritional composition.

21. A concern was raised that RUTFs cannot be prepared with a protein based matrix without grossly exceeding the current upper limit for protein content (10-12% of total energy). Therefore it would not be possible to achieve the proposed energy requirements.

22. Various proposals were made with regard to the text. For example it was suggested that the word "matrix" instead of "paste" be used because RUTF may come in different forms such as peanut-based paste, biscuits, etc. It was acknowledged that the proposed wording leaves room for flexibility to cover the composition of RUTFs that may be developed in future and o it also accommodate the different eating habits in various regions.

23. One Member raised a concern about the inclusion of sugar as a main ingredient since it was nutritionally inferior compared to other sources of carbohydrates such as potato, sweet potato, rice, cassava, etc. Furthermore the Member was also concerned about the addition of flavourings and additives and industrial ingredients into RUTF that would be given to older infants and young children who had serious gut damage due to malnutrition and other infections. These ingredients could set up a preference for sweet and flavoured foods which are the risk factors for obesity, cardiac diseases, diabetes and cancers.

24. A comment was made that the ingredients should be listed in descending order of proportion and should include the percentage of all major ingredients, as well as their sources (e.g. GMO crops). The specific name and appropriate class names should be declared for all ingredients and food additives. Majority of the eWG Members indicated that the listing of ingredients and the use of class names should be dealt with under the labelling section, in line with the existing Codex standards and texts on labelling of RUTFs.

2.4.1 Food Additives in RUTF

25. A proposal was made that CCNFSDU should work with the Codex Committee on Food Additives (CCFA) in accordance with the guidance set out in the Procedural Manual for Relations Between Commodity Committees to identify appropriate food additive provisions for RUTF since these products are intended for use by infants > 6 months of age, and children, with severe acute malnutrition.

26. However it was noted that the RUTF products for children would appear to fall under food category 13.3 (Dietetic foods intended for special medical purposes (excluding products of food category 13.1) of the *General Standard for Food Additives* (GSFA). There were cases where foods intended for consumption by infants were often treated separately and given their own food category (for example, food category 13.1 relating to infant formulas, or 13.2 relating to complementary foods for infants and young children). If the CCNFSDU believes that RUTF products should be considered in a separate food category from 13.3 to specifically address additive provisions in infants and young children, or if they should be treated altogether separately from the GSFA, then CCNFSDU should engage CCFA to determine the best means of providing for the use of food additives in these products.

27. If RUTF products do fall within the existing GSFA food category system, the Committee should examine the existing additive provisions in the GSFA and determine which ones are justified for RUTF products and which ones are not justified. Also, if there are additives that are technologically justified for use in RUTF products but there are no provisions for their use in the relevant food category, then these should be forwarded to the CCFA, together with the technological justification, for endorsement for entry into the GSFA.

28. It was further recommended that CCNFSDU should also seek CCFA's advice with respect to the use of additives in ingredients that are used in RUTF formulations and that could, therefore, be present in the finished RUTF products as a result of carry-over (e.g. carriers used in vitamin preparations that are used as ingredients in RUTFs). There is a rule regarding infant formulas (food category 13.1) that all additives, including those that are carried-over, must be provided for in Tables 1 and 2 of the general standard on food additives (GSFA), as required by Section 4.3 of the Preamble of the GSFA. Consideration should be given as to whether a similar rule is needed for RUTFs for infants, and perhaps for children as well, given that they are in a medically vulnerable state.

Recommendation 4

The Chairs propose that CCNFSDU consider conducting further discussions and decide on the best approach to handle the use of food additives in RUTF.

2.4.2 The use of other matrices in RUTF formulation

29. A proposal was made that a statement should be included under this section with regard to the use of other matrices in RUTF formulation. Members agreed that other matrices should be used in the formulation of RUTF provided that there was scientific evidence to support the effective delivery of the nutritional requirements for the target group (e.g. energy, protein quality and micronutrients) from the proposed matrices. The following wording was proposed and eWG Members were requested to provide inputs:

"New formulations of RUTF with other ingredients may be used if scientific data on efficacy and acceptability exist and have demonstrated that the use of the new developed product to treat SAM in the same context as the current RUTF."

30. Various Members highlighted that since RUTF were foods for special medical purposes, they should be covered by the provisions of CODEX STAN 180-1991 to ensure consistency with the language used in the Standard, with specific reference to section 3 of the standard.

Recommendation 5

The Chairs would like to make the following proposal for consideration and discussion. The proposed wording with regard to the use of other matrices for RUTF formulation as indicated above be replaced by the wording as it appears in section 3 of the CODEX STAN 180-1991, which reads as follows:

"The formulation of foods for special medical purposes should be based on sound medical and nutritional principles. 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".

Recommendation 6

Based on the collective comments of the eWG, the Chairs propose the following text for the Raw Materials and Ingredients Section of a Guideline for RUTF for consideration and discussion by the Committee:

RAW MATERIALS AND INGREDIENTS

RUTF are made of powdered or ground ingredients embedded in a lipid-rich paste and protein-based matrix, resulting in energy and nutrient-dense food. The main ingredients are generally ground peanuts, milk products, sugar, plant oil, vitamins and minerals. [However other forms of RUTF with various ingredients are being tried and tested in different regions].

4.1 Basic Raw Materials and Ingredients

4.1.1 Milk and other Dairy Products
4.1.2 Legumes and Pulses
4.1.3 Fats and Oils
4.1.4 Cereals
4.1.5 Vitamins and Minerals

4.2 Other Ingredients

4.2.1 Digestible Carbohydrates
4.2.2 Food Additives and Flavours
This section will make reference to the *General Standard for Food Additives* (CODEX STAN 192-1995).
4.2.3 [Other Nutritional Ingredients]

4.3 The Use of other Matrices in RUTF formulation

[New formulations] or [Composition] of RUTF with other ingredients may be used if they formulated in accordance with Section 3 of the *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-1991).

2.5. NUTRITIONAL COMPOSITION AND QUALITY FACTORS

31. The nutritional composition recommended in the '2007 Joint statement by UN agencies' was used as a basis for the development of a guideline and is reflected in the table below. Electronic Working Group Members were requested to provide inputs on the "Nutritional Composition and Quality Factors" section of a guideline, and also to suggest other nutrients for consideration.

Nutritional Composition for RUTF

Nutrients	**Per 100g**
Energy	520-550 Kcal/100g
Proteins	10%-12% total energy (50% of protein sources from milk products)
Lipids	45%-60% total energy
n-6 fatty acids	3%-10% of total energy
n-3 fatty acids	0.3%-2.5% of total energy
Moisture content	2.5% maximum
Vitamin A RE	0.8-1.1 mg/100 g
Vitamin D	15-20 µg/100 g
Vitamin E	20 mg/100 g minimum
Vitamin K	15-30 µg/100 g
Vitamin B1	0.5 mg/100 g minimum
Vitamin B2	1.6 mg/100 g minimum
Vitamin C	50 mg/100 g minimum
Vitamin B6	0.6 mg/100 g minimum
Vitamin B12	1.6 µg/100 g minimum
Folic Acid	200 µg/100 g minimum
Niacin	5 mg/100 g minimum
Pantothenic acid	3 mg/100 g minimum

Biotin	60 µg/100g minimum
Sodium	290 mg/100g maximum
Potassium	1,100-1,400 mg/100 g
Calcium	300-600 mg/100 g
Phosphorus (excluding phytate)	300-600 mg/100 g
Magnesium	80-140 mg/100 g
Iron	10-14 mg/100g
Zinc	11-14 mg/100 g
Copper	1.4-1.8 mg/100 g
Selenium	20-40 µg
Iodine	70-140 µg/100 g

32. Several Members were in support of the current nutritional composition for RUTF. Some Members indicated that various nutrients should be reviewed to align them with the latest scientific evidence available. Certain nutrients such as phosphorus, calcium and magnesium for malnourished populations were reviewed in the latest WHO Guideline to allow for catch up bone growth[11]. It was also proposed that the units, conversions factors and various forms of nutrients be reviewed.

33. A question was asked whether beta carotene should contribute to the Vitamin A requirements since it was not allowed in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981) which noted that counting beta-carotene was not acceptable.

Recommendation 7

That Chairs recommend that CCNFSDU consider reviewing the current nutritional composition for RUTF in line with the latest scientific evidence and also amend the conversion factors in line with the International Standard Unit conversion factors and conventional rounding.

2.5.1 Setting Minimum and Maximum levels for vitamins and minerals for RUTF products

34. A proposal was made that further consideration should be given to setting minimum, GUL or maximum levels taking into account the likely nutritional deficiency or inadequacy of the target group. For example, the narrow limits placed on certain micronutrients such as Vitamin A and Vitamin D should be reviewed and made broader due to the analytical uncertainty for Vitamin A and Vitamin D of around 20-30% depending on the laboratory used. However a Member recommended that WHO should provide its opinion on all cases where the proposed composition diverges from the recommendations in WHO's documents.

35. With regard to setting the Maximum levels some Members were of the view that only those vitamins and minerals that could pose a health risk as a result of excessive intake should be considered. One Member also queried that setting maximum levels for RUTF products might not be desirable since maximum levels may vary depending on the duration of RUTF consumption, recovery time, and age group. This may need further elaboration on whether the stipulated minimum and maximum levels are applicable only at product release - or throughout the shelf life of a product.

Recommendation 8

That the Committee consider reviewing the existing minimum levels and setting up of maximum levels for selected nutrients for RUTF.

2.5.2 Revision of Essential Fatty acids and setting of minimum levels

36. The eWG Members were asked whether they were in support of reviewing and setting of minimum levels for essential fatty acids in RUTF. It was noted that the current proposed range of 3-10% of energy for LA was in line with other Codex texts but falls short of what was recently recommended by EFSA[12]. The current proposed range for ALA also falls below the minimums established for ALA by other Codex texts and EFSA. Recent evidence showed that the recommended content of omega 3 and omega 6 in RUTF such as Alpha

[11]WHO. Guideline: *Updates on the management of severe acute malnutrition in infants and children*. Geneva: World Health Organization; 2013.

[12] EFSA, 2014. Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014;12(7):3760, 106 pp. doi:10.2903/j.efsa.2014.3760.

Linoleic acid were not adequate[13]. A recommendation was made that the essential fatty acids linoleic acid (LA; omega-6) and alpha-linolenic acid (ALA; omega-3) should have specific minimums to help prevent essential fatty acid deficiency. There is scientific evidence that supports setting minimum levels for essential fatty acids in RUTF as highlighted in the study of Jones et al. (2015)[14] which aimed at developing an RUTF with elevated short-chain n-3 PUFA and measure its impact, with and without fish oil supplementation, on children's PUFA status during treatment of severe acute malnutrition. The authors concluded that PUFA requirements of children with SAM are not met by current formulations of RUTF, or by an RUTF with elevated short-chain n-3 PUFA without additional preformed long-chain n-3 PUFA. It was also recommended that the long-chain omega-6 and omega-3 fatty acids (LCPUFA) docosahexaenoic acid (DHA; omega-3) and arachidonic acid (ARA; omega-6) should be taken into consideration. However, it was emphasized that scientific justification to change the current levels should be convincing with specific reference to SAM children.

Recommendation 9

That the Committee consider revising and setting of the minimum and maximum levels of the essential fatty acids for RUTF based on the available scientific evidence.

2.5.3 Additional nutrients

37. Several Members supported that additional nutrients may be added to RUTF composition provided that there was sufficient scientific evidence for the addition of the nutrient. The inclusion of manganese and chloride were proposed by other members and requested a further discussion on their role in SAM children.

38. One Member highlighted that continued review of scientific evidence for the bioavailability, or the proportion of nutrients that are absorbed and used by the body, such as iron, Vitamin A, pre-gelatinization of starches, and protein from different food matrices was important.

Recommendation 10

That CCNFSDU consider the addition of additional nutrients to the RUTF composition on condition that there is scientific justification for them.

2.5.4 Measuring protein quality

39. There was consensus amongst the eWG Members about the use of Protein Digestibility Corrected Amino Acid Score (PDCAAS) or Digestible Indispensable Amino Acid Score (DIAAS) as a measure of protein quality for the finished product as stipulated in the FAO Guidelines[15]. However several Members indicated that the PDCAAS methodology has been recently criticized by FAO Expert Working group in preference of DIAAS since it is viewed as a more rigorous approach in determining protein quality. DIAAS values have not been established for all protein and therefore are not available for use at this stage.

40. Although Members acknowledged that PDCAAS or DIAAS were the recommended methods to evaluate the dietary protein quality, several Members indicated that other methods such as appropriate published data on digestibility of protein in potential RUTF ingredients, in combination with analysed or published amino acid composition to determine the PDCAAS or DIAAS could be used, as long as the ingredients in the foods mentioned in the published paper are in the same form as in the final RUTF product. A need for the determination of the PDCAAS and DIAAS score that would be appropriate for RUTF products was proposed.

Recommendation 11

That CCNFSDU provide clarity on whether the eWG should await the finalization of the DIAAS values for RUTF or whether the currently existing methodologies such as PDCAAS could be included in the guideline.

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

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

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

2.5.5 Review of the "50% of protein sources from milk products"

41. The Joint Statement of 2007 recommended that "at least half of the proteins contained in the foods should come from milk products", and the protein quality should be achieved through the requirement for "50% of protein sources from milk products". Several members questioned the scientific justification of this statement and emphasized that PDCAAS and DIAAS should be the preferred methods to determine the quality of the protein.

42. However other Members indicated that the wording "50% of protein sources from milk products" should not be removed from the nutritional composition of RUTF since there is no scientific evidence of products with other protein source other than milk that have been demonstrated to be efficient for the management of SAM for the target group. A study by Bahwere et al showed inferior recovery rates for product with less than 50% of protein from dairy source[16]. The inclusion of milk powder as an ingredient improves the amino acid profile (has a high Protein Digestibility Corrected Amino Acid Score) and it is a good contributor of bioavailable calcium and potassium. In addition, it has a specific stimulating effect on linear growth and insulin growth factor 1 (IGF-1) levels in the child and does not contain anti-nutrients.[17]

43. Several Members supported a need to allow for RUTF formulations without a minimum of 50% of protein from milk products to allow for product innovation. Clear guidance will be required with regard to setting protein quality requirements for RUTF products which would serve as a guide in designing new RUTF formulations and may require clinical studies to be conducted before such products are released for use. In the absence of scientific evidence to include such guidance in a guideline, maintaining a minimum percentage of protein from milk products may be desirable.

44. One Member proposed that the minimum protein sources from milk products be increased to 60%. It may be preferable to increase this minimum to 60 % similar to the RUTF described in the paper by Manary, 2005[18]unless the scientific basis for 50% can be provided to the Committee.

45. A proposal was made that the wording "50% of protein sources from milk products" be deleted and instead, protein quality be described using PDCAAS or DIAAS. However this is on the assumption that the dairy source content is needed for protein quality.

46. Several Members recommended that the wording be amended to allow the flexibility of the sources of protein since a precise 50% of protein sources from milk products is not practical. A concern was raised that the use of the term "source" in the wording was not clear as the term "*source"* might refer to an ingredient or a nutrient. It was proposed that the term "sources" be deleted from the statement since it might cause confusion about the nature of the ingredients that could be used. The term "sources" might suggest that isolated proteins would be acceptable whereas whole milk protein has a different amino acid profile than casein or whey proteins and would therefore change the contribution to protein quality.

47. The following wording was proposed:

"at least 50% protein provided by milk products"

"at least 50% of protein sources from milk products"

"at least 50% protein provided by milk"

"at least 50% of protein from milk products"

Recommendation 12

As a result of the comments received from the eWG the Chairs recommend the following wording for consideration:

"at least 50% of protein provided by milk products"

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

[17] 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.

[18]Manary M.J. Local production and provision f ready-to-use therapeutic food for the treatment of severe childhood malnutrition. Food and Nutrition Bulletin 27 (3 Suppl.), S83-S89, 2006.

2.5.6 Addition of Pre and pro-biotic

48. Several Members indicated that there was limited scientific evidence that pre and probiotics have a beneficial effect in this target group. Also, maintaining stability of a probiotic would be challenging in the RUTF matrix, as many manufacturers use heat in its processing. Inclusion of pre and probiotics should only be included as optional ingredients if scientific validity and stability are demonstrated. The general principle for FSMP as outlined in the CODEX STAN 180-1991, that the formulation of FSMP should be based on sound medical and nutritional principles was reiterated. Clinical trials to demonstrate the safety, tolerance, and efficacy of pre-and pro-biotics should be conducted before considering these ingredients in RUTF.

2.6. CONTAMINANTS

49. Chemical contaminants within RUTF are an important consideration and these risks need to be defined. Many RUTF products contain peanuts, and other ingredients that may be a source of chemical contaminants. The Chairs requested eWG Members to comment on the proposed contaminants and other potential contaminants that should be taken into consideration during the development of a Guideline.

50. Several Members emphasised that a special consideration with regard to mycotoxins should be given in the Guideline because mycotoxins are not effectively controlled during manufacturing and beyond. The *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) was proposed to be used as a guide since aflatoxins found in peanuts was covered by this standard.

51. One Member proposed that the guideline should cover all types of contaminants (e.g. biological and chemical contaminants), and should also refer to the maximum levels (MLs) for aflatoxin and deoxynivalenol (DON) established in the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995). However it was proposed that this section should not lay down specific levels, but simply make a cross-reference to the levels provided by relevant CODEX texts (e.g. the *General Standard for Contaminants and Toxins in Food and Feed*). This would also ensure that the section remains up-to-date if those levels are revised in the future.

52. One Member questioned the inclusion of other contaminants such as pesticides, radioactivity, melamine, etc. and their relevance to RUTF due to lack of evidence. Other contaminants may also be managed by specific raw material requirements, with no need to test in the finished product. In order to identify appropriate food contaminant provisions for RUTF products, CCNFSDU may consider approaching the Codex Committee on Contaminants in Foods (CCCF). Although the eWG Members have been tasked to develop the Guidelines for RUTF rather than commodity standards, the Committee may wish to consider whether the format used for commodity standards would be helpful insofar as food contaminants are concerned.

53. The Codex Procedural Manual indicates that the preferred approach for addressing food contaminants in commodity standards is to include a section on food contaminants that makes a general reference to the GSCTFF. The GSCTFF does not contain any provisions specific to the category of Dietetic foods intended for special medical purposes. However there are guideline levels (GLs) for various radionuclides in 'infant foods' and 'foods other than infant foods', which might be appropriate to extend to RUTF. Further, the GSCTFF lists Codex maximum levels (MLs) for some of the ingredients listed in Section 3.4.1 of the Guidelines for RUTF. For instance, there are MLs for total aflatoxins in peanuts and for aflatoxin M1 as well as lead in milk. There is also an ML for lead in infant formula, which includes formula for special medical purposes. Recognizing that RUTFs are a highly specialized product for vulnerable sub-populations, general references to the food contaminant GLs and MLs in the GSCTFF may not be appropriate.

54. The Procedural Manual also provides for these situations and indicates that a commodity committee can submit a proposal for new work to the CCCF which provides justification as to why a general reference to the *General Standard for Contaminants and Toxins in Food and Feed* would not be appropriate for products concerned. As discussed in relation to food additives, above, the RUTF products would appear to fall under food category 13.3, Dietetic foods intended for special medical purposes. If the Committee is of the view that RUTF products would not fall under food category 13.3, or believes that they should be treated separately from the general standards, the Committee may consider engaging CCCF to determine the best means of identifying potential risks from food contaminants and determining the best ways to mitigate exposure to those contaminants in RUTF.

Recommendation 12

That the Committee consider the best approach in identifying the possible contaminants and consider the proposed contaminants for discussion**.**

CONTAMINANTS

It is recommended that the contaminants for RUTF be in accordance with the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995), Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods (CAC/MRL 2-201 5) and Codex Maximum Residue Limits for Pesticides.

1. Mycotoxins
2. [Pesticides Residues]
3. [Veterinary Drug Residues]
4. [Heavy metals]
5. [Radioactivity]
6. [Melamine]
7. [Other Contaminants]

2.7. TECHNOLOGIES FOR AND EFFECT FOR PROCESSING

55. The development of this section will be guided by the applicable international standards and other relevant Codex texts. The Chairs requested the eWG Members to identify issues that should be taken into consideration when developing this section of a guideline.

56. Several Members proposed that the section should follow the outline in the *Guideline on Formulated Complementary Foods for Older Infants and Young Children* (CAC/GL 8-1991) particularly sections 4 and 5 since the text was highly relevant because of similar purpose and intended age group. Although the RUTF matrix differs from the one usually described in this guideline, resulting in different technologies and processing, this could serve as the basis for this section of a Guideline.

57. It was also recommended that the Guideline should allow for the use of technologies such as thermal processing which is referenced in section 5.2.2. “specific process step” of the CAC/RCP 75-2015 that allow inactivation of pathogens such as *Salmonella spp*, and is stipulated as follows: “Whenever feasible, low-moisture foods 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 for low-moisture foods or their raw materials include both thermal (e.g. roasting, steam treatment followed by a drying step) and non-thermal (e.g. irradiation, antimicrobial fumigation) control measures.” Furthermore, some manufacturers are already using thermo-processing technologies to reduce *Cronobacter sakazakii* and *Salmonella* in RUTF production.

58. One Member recommended that consideration should also be given in the Guideline to allow, as reasonably possible, technologies which would allow foreign matter control beyond metal, such as x-ray. It was also highlighted that currently suppliers of these products were relying only on magnetic control, which does not cover other foreign matters than ferrous metal.

Recommendation 13

That the Committee consider the reference to section 5.2.2. "specific process step" of the CAC/RCP 75-2015 to accommodate the use other technologies for microbial reduction in RUTF products.

2.8. GOOD MANUFACTURING PRACTICES AND GOOD HYGIENE PRACTICES

59. The eWG Members were requested to provide inputs on this section, with specific reference to the hygiene and microbial safety for RUTF. Several suggestions were made with regard to the naming of the section and the content that it should include. Several Members proposed that the Guideline should specify the need for preventive food safety and quality control, based on systematic methods, including but not limited to: a) HACCP, b) prerequisite programs; c) hygienic zoning and d)environmental monitoring; e) product verification testing as advocated for in ISO/FSSC 22000 and other related standards.

60. The eWG Members were in support to making reference to *the Code of Hygienic Practice for Low-Moisture Foods* (CAC/RCP 75-2015) and other Codex texts under this section.

2.8.1 Microbial safety of RUTF

61. During consultation the Chairs proposed that the existing Codex texts as well as the Joint WHO/FAO technical consultation meeting reports for 2012 and 2014 and their recommendations would be used as the basis for the development of microbiological safety standards for RUTF in the Guideline. At CAC37 the *Codeof Hygienic Practice for Low Moisture Foods* was adopted as a final Codex Code of Practice[19]. RUTF are mentioned in this Codex Code. An Annex to the *Code of Hygienic Practice for Low Moisture Foods*, which include a microbiological criteria for *Salmonella* in low-moisture foods was adopted by CAC in June 2016.

62. The WHO/FAO 2012 expert consultation meeting also conducted a risk assessment of the microorganisms listed in the 2007 Joint statement and reviewed a panel of foodborne pathogens that cause illnesses of diverse severity in childhood infections and assessed their likelihood of being transmitted by low moisture foods. Out of the seven microorganisms originally listed in the 2007 Joint statement, the highest hazard deemed to be likely to be found in RUTF was *Salmonella spp*. The committee recommended that *Salmonella* should be the main priority hazard and its control as the primary food safety programme goal. At CAC39 (2016) an annex of examples of microbiological criteria was approved and the annex will be appended to the *Code of Hygienic Practice for Low Moisture Foods*.

63. There was general consensus amongst the eWG Members that the 2012 and 2014 Expert Consultation meetings and other existing Codex texts adequately addressed the risks of pathogens in RUTF.

Recommendation 14

Hygiene

The Chairs recommend that the hygienic practices for RUTF be in accordance with the *Code of Hygienic Practice for Low-Moisture Foods* (CAC/RCP 75-2015), *General Principles of Food Hygiene* (CAC/RCP 1-1969) and FAO/WHO report on Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition (2016) for consideration and discussion by the Committee.

Recommendation 15

Microbiological safety for RUTF

The Chairs recommend that the microbial safety of RUTF be in accordance with the *Code of Hygienic Practice for Low-Moisture Foods* (CAC/RCP 75-2015) and FAO/WHO report on Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition (2016) for consideration and discussion by the Committee.

2.9. METHODS OF ANALYSIS AND SAMPLING

64. The eWG Members were requested to comment on this section of a guideline and also identify other issues that should be taken into consideration when developing the guidelines. There was general support from the eWG Members that this section should make reference to the following Codex documents and FAO/WHO reports:

- *Recommended Methods of Analysis and Sampling* (CODEX STAN 234-1999),
- *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995),
- The *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CAC/GL 21-1997),
- *Code of Hygienic Practice for Low Moisture Foods* (CAC/RCP 75-2015), and
- FAO/WHO report on Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition (2016).

65. Several Members highlighted a challenge with analyzing 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

[19] *Code of Hygienic Practice for Low Moisture Foods* (CAC/RCP 75-2015)

into consideration in terms of risks/benefits/costs. The use of validated methods would be essential to get reliable and repeatable results.

Recommendation 16

The Chairs recommend that methods of analysis and sampling of RUTF be in accordance with the *Recommended Methods of Analysis and Sampling* (CODEX STAN 234-1999), *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995), *The Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CAC/GL 21-1997), *Code of Hygienic Practice for Low Moisture Foods* (CAC/RCP 75-2015), and FAO/WHO report on Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition (2016) for further discussion and consideration by CCNFSDU.

2.10. PACKAGING

66. The Chairs requested eWG Members to comment on the section related to "Packaging" in a Guideline. Several Members proposed that the packaging of the product should be such that once opened it could be resealed to limit contamination from handling and storage in ambient temperatures without refrigeration. Two Members proposed that a risk assessment should be done to assess the risk of anticipated handling and storage in areas of poverty (without refrigeration) where there is high prevalence of malnutrition. It was proposed that RUTF be individually packaged in a single RUTF portion/serve (to reduce the risk of contamination, preserve the food and reduce waste). However this might require that the energy content range of a single pack be prescribed.

67. It was suggested that packaging material as well as packaging design for RUTF should be informed by the results of shelf life studies. There should be evidence in terms of appropriateness of film thickness, water vapour transmission rate (WVTR), oxygen transmission rate (OTR), absorption and transmission of light by polymers, and any other attribute which would provide information regarding the protection of nutritional, sensorial and safety quality of the product. Data should support maintaining food integrity throughout the supply chain and taking into account the various extreme environmental conductions found in the regions where product is intended to be distributed.

68. 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.
- Suitability for packaging for hard transport.

Recommendation 17

Based on comments received from the eWG Members, the Chairs propose that CCNFSDU consider further discussion on the packaging of RUTF products to ensure that packaging survive at least as long as the stated shelf life of the products so that risk is reduced to a minimum.

2.10.1 Packaging of RUTF into a single-use sachets

69. 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 92 grams. Therefore care givers are required to give children sachets that have been opened for hours under questionable hygienic conditions which pose the risk of contamination. Appropriate volumes and the nutritional content ranges (e.g. energy content) should be determined so that RUTF can be packaged into single-use sachets to minimize the risk of contamination in the home. 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.

70. Some Members indicated that it would be difficult to define what the volume of a single-use sachet would be. The Joint Statement of 2007 includes a range of volume recommendations based on the age of a child. 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. 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.

71. In order to address the risk of contamination packaging innovation could be explored, for example, by the use of resalable containers. In the absence of evidence around the reduction of the sachet sizes to reduce the risk of contamination, such ideas of packaging innovation could be explored. It was highlighted that there was no scientific justification to define the nutritional ranges for single-use sachets. Therefore the volume ranges should not be prescribed or at least two volumes options could be considered.

72. Other Members supported a discussion of single-use sachets to avoid cross-contamination and facilitate community based feeding of RUTF. These Members indicated that smaller sachets may be more appropriate for feeding of 6 to 18 month olds, and could be based on the recommended calorie intake per body weight per day for management of SAM. Sachets of 100g or 50g were proposed for ease in providing caloric requirements.

Recommendation 18

Based on comments received from the eWG Members, the Chairs propose that CCNFSDU consider further discussion by the eWG and various stakeholders involved in the distribution of RUTF with regard to packaging of RUTF into single-use sachet.

2.11. LABELLING

73. The Chairs requested eWG Members to comment on what should be addressed under this section. The majority of the eWG Members supported that the labelling of Ready to Use Therapeutic Foods (RUTF) be in accordance with the following existing Codex texts:

- *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-1991),
- *General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985),
- *General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses* (CODEX STAN 146-1985),
- *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997).

74. Some of these documents were also referred to in the discussion paper prepared by UNICEF and Senegal and presented at CCNFSDU37. However additional labelling requirements should be considered taking into account the specific requirements of RUTF.

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

75. Several Members proposed mandatory labelling requirements for the RUTF. However some of the proposed labelling requirements are already covered by the existing CODEX texts and are a requirement for all foods for special medical purposes. The Chairs acknowledge that specific labelling provisions for RUTF should be included in the guideline only where these would be different from the existing requirements in other relevant CODEX texts, and are necessary to take into account the specificities of RUTF. Several Members proposed mandatory statements to be included in the labelling of RUTF products. 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 should be taken into consideration when labelling provisions are considered for RUTF products. While 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.

Recommendation 19

That the Committee consider the proposed Codex texts to inform the labelling provisions for RUTF for discussion.

That the Committee discuss the approach that the eWG should follow in determining the mandatory statements that should be included in the labelling requirements for RUTF.

3. Recommendations to CCNFSDU

76. The Chairs of the eWG have completed the task as per their programme of work. The main tasks for the eWG were to development a draft framework and the scopeof a guideline, including the possible content for RUTF in line with the terms of reference, and also gather any additional issues that should be taken into consideration during the development of a guideline. The Chairs of the eWG believe that they have achieved these tasks and the Committee is in the position to move ahead with the development of a Guideline for RUTF. Significant amount of information has been gathered during the two rounds of consultations with the eWG Members and will form the basis for the development of these guidelines.

77. Following the discussions with the eWG Members, it is proposed that the Committee:

- Take note of the key recommendations as outlined in the report for further discussion.
- Take note of Annex 1 as a proposed Outline for a Guideline for RUTF for further discussion.
- Propose steps to address issues raised during the consultation with the eWG Members as outlined in the recommendations.
- Consider an ongoing electronic working group to continue with the development of a Guideline for RUTF.

Appendix 1

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

(at STEP 3)

1. 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

2. SCOPE

The provisions of these guidelines apply to Ready to Use Therapeutic Foods for children from 6 to 59 months with severe acute malnutrition. Ready-to- Use Supplementary Foods (RUSF), micronutrient supplements, processed cereal based foods[20], formulated complementary foods for older children and young children[21], canned baby foods[22] are not covered by these guidelines. These guidelines should be used in accordance with the 2007 Joint Statement of the UN Agencies[23], 2013 WHO document on Updates on the Management of Severe Acute Malnutrition in infants and children[24] or any other relevant upgrade of the latest version.

3. DESCRIPTION

3.1Ready to Use Therapeutic Foods (RUTF) are high-energy, fortified, ready-to-eat foods for special medical purposes that are suitable for the dietary management of children from 6 to 59 months with severe acute malnutrition. These foods should be soft or crushable and should be easy for young children to eat without any prior preparation.

3.2 Severe Acute Malnutrition is defined as weight for height (or length) less than –3 Z-score of the median WHO growth standards, or mid upper arm circumference (MUAC) <115 cm, or the presence of bilateral oedema[21].

4. RAW MATERIALS AND INGREDIENTS

RUTF are made of powdered or ground ingredients embedded in a lipid-rich paste and protein-based matrix, resulting in energy and nutrient-dense food. The main ingredients are generally ground peanuts, milk products, sugar, vegetable oil, vitamins and minerals. *[However other forms of RUTF with various ingredients are being tried and tested in different regions*].

4.1 Basic Raw Materials and Ingredients

4.1.1 Milk and other Dairy Products

4.1.2 Legumes and Pulses

4.1.3 Fats and Oils

4.1.4 Cereals

4.1.5 Vitamins and Minerals

4.2 Other Ingredients

4.2.1 Digestible Carbohydrates

4.2.2 Food Additives and Flavours

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[20] *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CODEX STAN 74-1981)
[21] *Guidelines on Formulated Complementary Foods for Older Infants and Young Children* (CAC/GL 8-1991)
[22] *Standard for Canned Baby Foods* (CODEX STAN 73-1981)
[23] Joint Statement on Community-Based Management of Severe Acute Malnutrition 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
[24] WHO. Guideline: *Updates on the management of severe acute malnutrition in infants and children*. Geneva: World Health Organization; 2013.

This section will make reference to the *General Standard for Food Additives* (CODEX STAN 192-1995).

4.2.3 *[Other Nutritional Ingredients]*

4.3 The Use of other Matrices in RUTF formulation

[New formulations] or [Composition] of RUTF with other ingredients may be used if they formulated in accordance with Section 3 of the *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-1991).

5. NUTRITIONAL COMPOSITION AND QUALITY FACTORS

5.1 General Aspects

5.2 Energy

5.3 Proteins

5.4 Fat

5.5. Vitamins and Minerals

5.6 Consistency and Particle Size

6. CONTAMINANTS

It is recommended that the contaminants for RUTF be in accordance with the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995). Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods (CAC/MRL 2-2015) and Codex Maximum Residue Limits for Pesticides.

6.1 Mycotoxins

6.2 [Pesticides Residues]

6.3 [Veterinary Drug Residues]

6.4 [Heavy metals]

6.5 [Radioactivity]

6.6 [Melamine]

6.7 [Other Contaminants]

7. TECHNOLOGIES FOR AND EFFECT FOR PROCESSING

7.1 Preliminary Treatment of Raw Material

7.2 Milling

7.3 Toasting

7.4 Sprouting, Malting and Fermentation

7.5 Other Processing Technologies

8. GOOD MANUFACTURING PRACTICES AND GOOD HYGIENE PRACTICES

8.1. Hygiene

It is recommended that the hygienic practices for RUTF be in accordance with the *Code of Hygienic Practice for Low-Moisture Foods* (CAC/RCP 75-2015), *General Principles of Food Hygiene* (CAC/RCP 1-1969) and FAO/WHO report on Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition (2016).

8.2 Microbiological safety for RUTF

It is recommended that the microbial safety of RUTF be in accordance with the *Code of Hygienic Practice for Low-Moisture Foods* (CAC/RCP 75-2015) and FAO/WHO report on Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition (2016).

9. 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* (CODEX STAN 234-1999), *General Standard for Contaminants and Toxins in Food and Feed*(CODEX STAN 193-1995), The *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CAC/GL 21-1997), *Code of Hygienic Practice for Low*

Moisture Foods(CAC/RCP 75-2015), and FAO/WHO report on Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition (2016).

10. PACKAGING

Special attention will be paid to the packaging material for RUTF products and will be aligned with Codex texts and other International Standards where they exist. Primary and secondary packaging will also be covered under this section.

11. LABELLING

11.1 Applicable Standards and Guidelines

It is recommended that the labelling of Ready to Use Therapeutic Foods (RUTF) be in accordance with the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991), Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985), the Codex General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses (CODEX STAN 146-1985) and the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)."

11. 2 Mandatory Provisions

To be aligned with the existing Codex Texts.

11. 3 Additional Requirements

11.3.1 Shelf life

11.4 Mandatory Statements

Table 1: Nutritional Composition for RUTF

Nutrients	**Per 100g**
Energy	520-550 Kcal/100g
Proteins	10%-12% total energy (*[at least 50% of protein provided by milk products*])
Lipids	45%-60% total energy
n-6 fatty acids	3%-10% of total energy
n-3 fatty acids	0.3%-2.5% of total energy
Moisture content	2.5% maximum
Vitamin A RE	0.8-1.1 mg/100 g
Vitamin D	15-20 µg/100 g
Vitamin E	20 mg/100 g minimum
Vitamin K	15-30 µg/100 g
Vitamin B1	0.5 mg/100 g minimum
Vitamin B2	1.6 mg/100 g minimum
Vitamin C	50 mg/100 g minimum
Vitamin B6	0.6 mg/100 g minimum
Vitamin B12	1.6 µg/100 g minimum
Folic Acid	200 µg/100 g minimum
Niacin	5 mg/100 g minimum
Pantothenic acid	3 mg/100 g minimum
Biotin	60 µg/100g minimum
Sodium	290 mg/100g maximum
Potassium	1,100-1,400 mg/100 g
Calcium	300-600 mg/100 g
Phosphorus (excluding phytate)	300-600 mg/100 g
Magnesium	80-140 mg/100 g
Iron	10-14 mg/100g
Zinc	11-14 mg/100 g
Copper	1.4-1.8 mg/100 g
Selenium	20-40 µg
Iodine	70-140 µg/100 g

Appendix 2

List of Participants

CODEX MEMBERS

1. ARGENTINA	2. AUSTRALIA	3. BRAZIL
4. CANADA	5. CHINA	6. EUROPEAN UNION
7. FRANCE	8. GHANA	9. INDIA
10. IRELAND	11. NEW ZEALAND	12. NORWAY
13. POLAND	14. SENEGAL	15. SOUTH AFRICA
16. SWITZERLAND	17. THAILAND	18. UGANDA
19. UNITED STATES OF AMERICA	20. URUGUAY	21. ZAMBIA

CODEX OBSERVERS

1. WORLD RESEARCH SUGAR ORGANIZATION	2. FOODDRINKEUROPE
3. ILCA	4. INTERNATIONAL DAIRY FEDERATION
5. UNICEF	
6. IACFO	7. ELC
8. MSF	9. IFT
10. ICAAS	11. IBFAN

GENERAL GUIDANCE FOR THE PROVISION OF COMMENTS

In order to facilitate the compilation and prepare a more useful comments' document, Members and Observers, which are not yet doing so, are requested to provide their comments under the following headings:

(i) General Comments

(ii) Specific Comments

Specific comments should include a reference to the relevant section and/or paragraph of the document that the comments refer to.

When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in **underlined/bold font** and deletion in ~~strikethrough font~~.

In order to facilitate the work of the Secretariats to compile comments, Members and Observers are requested to refrain from using colour font/shading as documents are printed in black and white and from using track change mode, which might be lost when comments are copied / pasted into a consolidated document.

In order to reduce the translation work and save paper, Members and Observers are requested not to reproduce the complete document but only those parts of the texts for which any change and/or amendments is proposed.