DEVELOPMENT OF A GUIDELINE FOR READY TO USE THERAPEUTIC FOODS (RUTF)

(Chaired by South Africa and co-chaired by Senegal and Uganda)

Second Consultation Paper

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Please respond by 24th June 2016
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1. INTRODUCTION

At the 37th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) the Committee 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 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.
- Reference Methods of Analysis and Sampling
- Nutrient compounds used for the RUTF.

2. OVERVIEW

The eWG consists of **21** Codex Members and **12** Codex Observers. Representatives of UNICEF will participate as observers to the eWG. The list of Codex members and Observers is attached as **Annexure 1**. Responses to the First Consultation Paper were received from **11** Members and **7** Observers. The list is attached as **Annexure 2**.

Consultation Paper 1

The first consultation paper focused on the following key areas:

- 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.

Consultation Paper 2

This Second Consultation Paper takes into consideration the findings of the First Consultation Paper and includes 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.
    - Highlight other additional issues that should be taken into consideration during the development of a Guideline.
- Continued review and development of a framework and the scope of a Guideline for RUTF.
- Highlight key areas that still need further discussion or agreement by Members.

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

3.1 PURPOSE

As part of the First Consultation Paper, eWG members were requested to provide inputs on the proposed purpose of a draft Guideline for RUTF. The Chairs proposed the following text 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

The electronic working group members were requested to comment on whether the proposed "Purpose" of a Guideline covered all the main aspects and what other areas would they recommend for consideration under this section. Several responses were received and various issues also emerged. The summary of eWG members' responses are summarized below:

Several Members indicated that the proposed purpose covered the main aspects of a Guideline.

Two Members requested that the shelf-life of the product be included into the purpose of a Guideline. Furthermore, the shelf life of these products should be supported by stability studies to ensure that the nutritional properties of the products would be within the nutrition composition requirements during the shelf life of the products.

One Member highlighted that point (iii) and (vii) would cover the same areas in a Guideline and recommended that they be merged and replaced by Good Manufacturing Practices, which would cover the General Principles of Food Hygiene (CAC/RCP 75-2015). The Chairs agree that these two sections should be collapsed and replaced by Good Manufacturing Practices.

Two Members did not support the intended purpose and use of RUTF products due to insufficient scientific data to substantiate the efficacy and safety of these products. One Member also highlighted that the purpose should include the need to protect breastfeeding and a need for governments to ensure that The International Code of Marketing of Breastmilk Substitutes and WHA resolutions were fully implemented. Furthermore the purpose of a guideline should explain that these foods are temporary treatment foods and should be used under medical supervision. Risks in relation to marketing and promotion of RUTF products should be managed to avoid the spill-over effect and misuse of these products.

Two Members proposed that criteria for the release of the RUTF products to the market should be defined in order to avoid longer shelf life of more than a year, which could add to the development costs and inefficiencies in the supply chain/logistics process. Some of the ingredients such as Vitamin A could become unstable over a long period of time.

One Member commented that the nutritional quality with specific reference to protein quality (DIAAS) and availability of micronutrients should be taken into consideration under the "Nutritional composition" section of a guideline. It was also highlighted that section (viii) should provide more detailed attention to the "instruction for use" since these products were intended for children with severe acute malnutrition (SAM).

One members questioned whether topic "ii. Formulation of RUTFs was intended to refer to "Raw materials and ingredients". It was also highlighted that there was no difference between "nutritional composition" and "Formulation of RUTFs" sections.

One member recommended that a section on Technologies for and Effects of Processing" be added under the purpose as it was also done in the Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 8-1991).

One member felt that the proposed guideline should give guidance to users and not address specific provisions such as analysis and sampling which would be covered by a standard.

The Chairs would like to acknowledge comments received from the eWG Members. The Chairs agree that all the concerns that the Members raised are important and will be addressed in specific sections within a Guideline, e.g. the shelf-life of a product and specific text on marketing of these products will be addressed under the labelling section. However the purpose will not cover all the specific sections as outlined in a Guideline.

Based on the responses received from eWG members, the Chairs propose the following wording and text in this section:

PURPOSE

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

Please provide comments and justification for your answers to the proposed text

3.2 SCOPE

As part of the First Consultation Paper, eWG members were requested to provide inputs on the proposed purpose of a draft Guideline for RUTF, as well as other issues that the eWG should consider. The Chairs proposed the following text as reflected below:

The provisions of these guidelines apply to formulated Ready to Use Therapeutic Foods.
These guidelines should be used in accordance with the WHO, 2013 document on Updates on the management of severe acute malnutrition in infants and children[i].

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.

The eWG members were requested to give comments on the proposed "Scope" of a Guideline and the responses are reflected below:

There was general support amongst eWG members on the proposed scope. Certain amendments were proposed to the text.

Four eWG members indicated that 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.

Seven 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. However one eWG member noted that it would be useful to include other products with similar composition and intended use such as RUSF and this could avoid confusion resulting from multiple guidelines for similar products.

Based on the comments received from EWG Members, The Chairs propose the following revised text of the "Scope".

SCOPE

The provisions of these guidelines apply to Ready to Use Therapeutic Foods for children from 6 to 59 months with severe acute malnutrition.
These guidelines should be used in accordance with the 2007 Joint Statement of the UN Agencies[ii], 2013 WHO document on Updates on the Management of Severe Acute Malnutrition in infants and children or any other relevant upgrade of the latest version. The scope of a guideline will only refer to RUTF that are produced in food manufacturing facilities and traded either nationally or internationally.

Do you agree with revised text? Please suggest the wording and justification for your proposals.

The Chairs propose the following products to be excluded from the scope, based on inputs received from Members:

The following products will be excluded from the scope of these guidelines:

- Ready-to- Use Supplementary Foods (RUSF),
- micronutrient supplements,
- processed cereal based foods,
- complementary foods and,
- other products used to prevent or treat malnutrition

Do you agree with the proposed list of products to be excluded from the scope of the guidelines?

Please provide comments and justification for your answers.

3.3 DESCRIPTION

As part of the First Consultation Paper, eWG members were requested to provide inputs on the proposed "Description" of a draft Guideline for RUTF, as well as other issues that the eWG should consider. The Chairs proposed the following text during the first consultation:

Various descriptions of RUTFs 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 will be our departure point for the purposes of these guidelines. However some regions treat severe acute malnutrition based on a therapeutic diet using locally available nutrient-dense foods, without the use of commercially produced products.

Comments received from eWG members on the questions asked are reflected below:

Several eWG members made proposals to the wording of the "Description of RUTFs". They include:

- RUTF are high-energy, fortified, portion controlled ready-to-eat foods suitable for the treatment of children >6 months with SAM 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.
- RUTF are high-energy, fortified, ready-to-eat foods **for special medical purposes, as defined in Codex Stan 180-1991**, suitable for the **dietary management** of children >6 months with severe acute malnutrition.
- "Ready to Use Therapeutic Foods (RUTF) are high-energy, fortified, ready-to-eat foods suitable for the treatment of children from the age of six 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 (e.g. no need to cook, mix with meal or dilute in liquid)"
- "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.
- "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 **are** soft or crushable and easy for young children to eat without any preparation"
- Ready to Use Therapeutic Foods (RUTF) are high-energy, fortified, ready-to-eat foods suitable for the treatment of children over 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 **prior cooking, mixing or dilution**"

One Member indicated that the wording "age >6 months" was ambiguous. A proposal was made that it should either be "from 6 months" or "from 7 months" depending on the intended meaning. A proposal was made that the second sentence should be as a separate point within the description section as there was no other section that appears to be more appropriate than description section.

One member commented 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 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.

Three Members highlighted that the age range of the products should be clarified under the description.

One Member commented that a description of RUTF should first define prepared energy dense and high nutrient foods that reflect cultural and locally accessible foods, and since they are used as complementary foods RUTFs are to be used as complements or additions to breastfeeding. 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.

One Member highlighted that the description did not stipulate if it would only cover commercially produced products or not, although this was mentioned in the "scope".

Two Members indicated that the following terms should be defined:

- Young children – it should be aligned to other existing Codex texts.
- Severe acute malnutrition
- RUTF

One Member commented that that a description on how RUTF would be differentiated from other products covered by CAC/GL 8 -1991 should be included, and that these products should be used only if appetite test reveals good appetite.

Four eWG Members commented that the "description" should not cover other forms of RUTFs that were not commercially produced. One member also highlighted that CCNFSDU37 agreed that the guideline should not cover non-commercially produced RUTFs.

Two Members highlighted that 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, liquid, etc.

One Member indicated that RUTFs produced under emergency situations, especially those produced in hospitals that provide therapeutic feeding programs should be covered in the description.

The Chairs acknowledge comments received from Members and the proposed wording for the description of RUTF.

Based on eWG responses, the Chairs propose the following draft text.
DESCRIPTION
Ready to Use Therapeutic Foods (RUTF) are high-energy, fortified, ready-to-eat foods for special medical purposes produced in food manufacturing facilities, that are suitable for the [**treatment/dietary management]** of children from 6 months with severe acute malnutrition. These foods should be soft or crushable and should be easy for young children to eat without any prior **[cooking, mixing or dilution/preparation].**
Please provide comments on the above suggested wording.
The Chairs propose that the following terms be defined:
• Severe Acute Malnutrition • Young children
Are there any additional terms that should be defined? Please suggest the terms and the provide justification for your proposals.
Dietary Management vs Treatment The intended use for RUTFs is for dietary management of severe acute malnutrition which make them to comply with the definition of food for special medical purposes (FSMP) as stipulated in CODEX STAN

180-1991. A proposal was made that the wording "dietary management" of severe acute malnutrition should be used rather than "treatment" for consistency with CODEX STAN 180-1991. It was also suggested that the change in the wording, as well as stipulating that these products fall within the definition of FSMP may assist in avoiding legal uncertainties.
Taking into account the above comment; do you support the replacement of the word "treatment" by "dietary management" in order to align with the existing Codex text (i.e. CODEX STAN 180-1991)?

3.4 RAW MATERIALS AND INGREDIENTS

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. In the First Consultation Paper the Chairs proposed the below mentioned text and a proposed list of ingredients 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[iii]. 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[iv].

3.4.1 Basic Raw Materials and Ingredients
3.4.1.1 Milk and Milk products
3.4.1.2 Peanuts
3.4.1.3 Vegetable oils
3.4.1.4 Sugars
3.4.1.5 Mineral and Vitamin Premix
3.4.2 Other ingredients
3.4.2.1 Food additives and flavours
3.4.2.2 Emulsifying agents

Below are the responses from eWG members

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.

Two Members recommended the inclusion of starches or cereals and legumes as part of the potential macro ingredients that could be used in RUTF production, 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 RUTF currently used.

Four Members proposed that "Milk and Milk products could be replaced by "Milk and other dairy products" to include other dairy ingredients such as lactose, whey, etc.

Two Members indicated that "peanuts" should be amended to cover all possible pulses such as soya, peas, lentils, chickpeas, etc.

Two members requested that "vegetable oils" should be extended to cover other long chain essential fatty acids such as nut-based oils.

One Member proposed that a separation should be made for the ingredients added for their nutritive purpose from the ingredients added for technological purposes.

One Member proposed that "sugars" should be replaced by "digestible carbohydrates". It was proposed that several sources of carbohydrates could be added such as lactose, maltodextrin as per CODEX STAN 1212-1999.

One Member suggested that restrictions or special prohibitions could be addressed under this section with regard to ionizing/irradiation, addition of salt, use of partially hydrogenated fats, etc.

A proposal was made that the ingredients should be listed in descending order of proportion and should include the percentage of all major ingredients. The specific name and appropriate class names should be declared for all ingredients and food additives. A proposal was made that the list should include Carbohydrate (sugar) along with percentage used. Also, the source should be specified that whether it will be from GMO crop. Sources should also be specified in the ingredients list for Protein, energy and lipid.

The following text was proposed:

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

b. RUTF are made of powdered or ground ingredients embedded in a lipid-rich matrix, resulting in energy and nutrient-dense food. The main ingredients currently are peanuts, vegetable oils, dairy ingredients, sugar, and a premix containing~~,~~ vitamins and minerals. However other forms of RUTF with various ingredients such as soy, maize, sorghum, amino acids, are being tried and tested in different regions and it is essential that innovation and competition are encouraged by not restricting ingredient options.

c. RUTF are made of powdered or ground ingredients embedded in a lipid-rich **paste matrix**, **or protein-based matrix**, resulting in energy- and nutrient-dense food paste. The main ingredients **currently** are **ground** peanuts, **vegetable oils**, **milk products dairy 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 **and it is essential that innovation and competition are encouraged by not restricting ingredient options.**

d. RUTF are made of powdered or ground ingredients embedded in a lipid-rich, resulting in energy and nutrient-dense food. The main ingredients are peanuts, **vegetable oils**, **dairy ingredients**, sugar, and

a premix containing vitamins and minerals. However other forms of RUTF with various ingredients are being tried and tested in different regions.

One Member suggested the use of the word "matrix" instead of "paste" because RUTF may come in different forms such as peanut-based paste, biscuits, etc.

One Member commented that vegetable oils are macro ingredient in RUTF and not just a carrier for vitamins and minerals and should be listed as a primary ingredient.

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 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.

One Member recommended that only the first four ingredients be included and expressed as food groups and not as individual foods e.g. peanuts to allow for RUTF innovation and to 'future proof' the guideline.

One Member suggested 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.

One Member suggested that a discussion of including provisions for assessment and/or maximal amounts of anti-nutrients such as phytates be considered.

Based on comments received, the proposed revisions to this section are outlined below:
BASIC RAW MATERIALS AND INGREDIENTS
The Chairs propose the following revised text:
RUTF are made of powdered or ground ingredients embedded in a lipid-rich matrix, or protein-based matrix, resulting in energy and nutrient-dense food. The main ingredients are generally ground peanuts, dairy products, sugar, vegetable oil, and a premix containing vitamins and minerals. However other forms of RUTF with various ingredients are being tried and tested in different regions.
Please provide comments to the above proposed wording. Please provide justification and rationale for your comments.
Based on the responses received from the eWG, the Chairs propose that this section follow the outline in CAC/GL8-1991 and also include the main ingredients as food groups to allow for variety when local and culturally acceptable ingredients are used.
3.4.1. Basic Raw Materials and Ingredients 3.4.1.1. Milk and other Dairy Products 3.4.1.2. Legumes and Pulses 3.4.1.3. Fats and Oils 3.4.1.4 Cereals **3.4.2. Other ingredients**

3.4.2.1. Digestible Carbohydrates 3.4.2.2. Food Additives and Flavours 3.4.2.3. Mineral and Vitamin Premix
Do you agree with the proposed outline on basic raw materials and ingredients? **If No, provide justification for your answer.** **Are there still other raw materials and ingredients that have not been covered in the proposed section on "Basic Raw Materials and Ingredients"? Please provide the rationale and justification for your proposals.**
A proposal 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.
Do you agree that the ingredients should be listed in descending order of proportion? **Do you agree that the appropriate class names and specific names be declared for all ingredients?** **Please provide the rationale and justification for your answer.**
The use of other matrices in RUTF formulation The Chairs agree 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 Chairs propose the following wording to be included under this section: **"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."**
Do you agree that the proposed statement be included under this section? **Please provide comments on the wording and the proposed text.**

3.5 NUTRITIONAL COMPOSITION AND QUALITY FACTORS

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. In the First Consultation Paper the Chairs proposed that the nutritional composition as stipulated in the Joint Statement by UN Agencies of 2007 would be used as the basis for the development of a Guideline. The section below and the texts were proposed:

The nutritional composition recommended in the '2007 Joint statement by UN agencies' will be used as a basis to develop a guideline. The recommended nutritional composition for RUTF is outlined in table 1

below.

3.5.1 General Aspects
3.5.2 Energy
3.5.3 Proteins
3.5.4 Fat
3.5.5 Vitamins and Minerals
3.5.6 Consistency and Particle Size

Table 1: 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

Comments received from eWG members highlighted the following issues that should be taken into consideration when the nutritional composition of a Guideline is developed:

Several Members were in support of the current nutritional composition for RUTF.

One Member indicated that the narrow limits placed on certain micronutrients such as Vitamin A and Vitamin D should be reviewed and made broader. It was also highlighted that the analytical uncertainty for Vitamin A and Vitamin D of around 20-30% depending on the laboratory used was mentioned as a point that should be considered. This makes it difficult to ascertain if the analysed products were within or outside the specifications when an analysis was carried out.

One Member raised a question whether the minimum and maximum amounts as reflected in Table 1 apply only to added micronutrients and not to the contributions from the base ingredients. A proposal was made that 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. It was proposed that Section 6.6.3 in the Codex Guidelines on Formulated Complementary Foods for Older Infants and Young children which refers to two other relevant Codex texts related to vitamins and minerals could be adapted for use in a Guideline.

One Member highlighted that recent evidence showed that the recommended content of omega 3 and omega 6 in RUTF such as Alpha Linoleic acid were not adequate. 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. 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. Optional addition of these fatty acids should be considered.

One member proposed that carbohydrates should constitute the remainder of the energy required after energy coming from protein and fat has been taken into account. The addition of the carbohydrate content was deemed not to be of critical importance.

Eight Members recommended that the protein quality should be measured using PDCAAS or DIAAS for the finished product as stipulated in the FAO Guidelines.

Two Members proposed that a “50% protein from diary source” as stipulated in the nutritional composition could not be justified on scientific basis; rather the PDCAAS and DIASS should be used instead. It was also proposed that if dairy products were included in the product as a non-protein nutrients (i.e., enzymes, growth factors), these should be clearly stated.

A proposal was made that the wording “50% protein from dairy source” should 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.

One Member proposed that if the PDCAAS digestibility of a protein could not be determined due to other technical reasons, the protein quality should be measured by biological assays or calculated from published data on essential amino acid patterns of dietary proteins and their digestibility.

A proposal was made that the addition of methionine, lysine, tryptophan or other limiting amino acids, solely in the L-form should only be contemplated on the basis of non-availability of mixtures of vegetable and/or animal proteins that could make it possible to obtain an adequate protein quality [As referred from CAC/GL 8-1991].

It was noted that 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”. A concern was raised that the First Consultation Paper stipulated the term “source” which is not clear as the term “*source”* might refer to an

ingredient or a nutrient. It was also highlighted that a precise 50% of protein sources from milk products is not practical. A proposal was made to change the following text: "50% of protein sources from milk products" to "at least 50% protein provided by milk products".

The role of Pre and Probiotics was also mentioned by a Member as an area for consideration due to the role of these on the microbiota.

Three Members highlighted that the bioavailability and the effects of anti-nutrients such as phytates in ingredients should be assessed for RUTF products. Phytates could inhibit the absorption of divalent ions, such as iron, zinc, or calcium. However one Member noted that the maximum phytates content should not be prescribed because since there were proven ways of reducing their prohibitory effect. Therefore the desired level of bioavailability of affected nutrients should be specified since this is what matters. **The Chairs propose that this concern will be dealt with other section which deals with technologies and effects of processing.**

One Member also noted the following issues with regard to Table 1 on nutritional composition of RUTF:

- That Vitamin A is expressed as RE and whether beta carotene should contribute to Vitamin A requirements since RE is being used.
- Whether niacin is preformed only, this would imply that none of the tryptophan/protein can contribute to the niacin content.
- Whether Vitamin E required is only the alpha tocopherol form.
- Whether selenium should be expressed per 100g
- Whether there was an intention to exclude the contribution of phytate to phosphorus so that the total phosphorus could be higher.

The Chairs agree that the units, conversions factors and various forms of nutrients should be reviewed.

One Member proposed that further discussions on the role of chloride to support healthy electrolyte balance should be considered and also the safety concerns identified in the 2007 Joint Statement should also be addressed.

The inclusion of Manganese in the nutrition composition of RUTF was also proposed by a Member since manganese deficiency could contribute to poor growth.

One member proposed that carbohydrates/sugar should be mentioned in Table one since sugar is one of the major ingredients used in making RUTF.

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, of nutrients such as iron, Vitamin A, pre-gelatinization of starches, and protein from different food matrices was important.

One Member proposed that trans-fatty acids should be taken into account as a method of measuring lipid quality.

One Member indicated that the renal load and osmolality should be taken into consideration since the product will be used by infants and young children who are sick, their kidney/liver functions and gut functions not yet matured or even damaged due to disease conditions.

Taking into account comments received from the eWG, the Chairs request eWG Members to provide comments on the following specific areas with regard to the nutritional composition for RUTF:
NUTRITIONAL COMPOSITION
Vitamins and Minerals
Do you support the setting of minimum and maximum levels for vitamins and minerals for the RUTF products? Are there any proposals you want to make with regard to the minimum and maximum levels? Please provide the rationale and the scientific evidence for your proposals.
Essential Fatty acids (omega-3 and omega-6)
Do you support the revision and setting of minimum levels for essential fatty acids in RUTF? Are there any proposals you want to make with regard to the minimum levels? Please provide the rationale and the scientific evidence for your proposals.
Additional Nutrients
Do you support the addition of other nutrients such as manganese in the nutritional composition for RUTF? Please indicate the nutrients to be added and provide scientific justification for your proposals.
Measuring Protein Quality
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". There has been an overwhelming support that the quality of the protein should be measured by using the latest available methods as recommended by FAO (PDCAAS/ DIAAS).
Should this statement "50% of protein sources from milk products" be removed or amended? **If Yes, provide the draft wording for the proposed statement and the justification.**
Should other methods be considered if the PDCAAS digestibility of a protein could not be determined due to other technical reasons? For example, biological assays or calculated from published data on essential amino acid patterns of dietary proteins and their digestibility.
Pre and pro-biotic
Should pre- and pro-biotic be considered as optional ingredients in RUTF? Please provide the rationale and justification for your answer.

3.6 MICROBIAL SAFETY

Microbiological safety for RUTF

As part of the First Consultation Paper 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. The 2012 meeting report has been published in the FAO/WHO Microbiological Risk Assessment Series at: http://www.fao.org/3/a-i5347e.pdf.

At the 37th session of the CAC the Code of Hygienic Practice for Low Moisture Foods was adopted as a final Codex Code of Practice[v]. RUTF are mentioned in the Codex Code. A proposed draft Annex to the Code of Hygienic Practice for Low Moisture Foods, which will include examples of microbiological criteria for low-moisture foods is underway at Codex Committee on Food Hygiene[vi].

The WHO/FAO 2012 expert consultation meeting also conducted a risk assessment of the microbes listed in the 2007 Joint statement and reviewed a panel of 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 microbes originally listed in the 2007 Joint statement, the greatest hazard deemed to be likely to be found in RUTF was Salmonella spp. The committee recommended that Salmonella should be the main priority infectious hazard and its control as the primary food safety programme goal. New criteria for Salmonella are being proposed and will be incorporated in a guideline.

The Chairs requested eWG Members to comment on whether these reports and other existing Codex Codes adequately addressed the risks of pathogens in RUTF, and whether there were other additional issues that should be taken into consideration when determining the content of this section. The responses from eWG members are reflected below.

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

One Member reiterated that the section should make reference to the provisions included in the Codex texts, such as the Annexure to the Code of Hygienic Practice for Low Moisture Foods.

Two Members proposed that the "Microbial Safety" section be included as subsection of 3.10. Hygiene, since it refers to the same issues.

One Member proposed three approaches that could be used to establish a microbiological criterion for RUTF products:

- The first approach refers to existing criteria for analogous low moisture foods and the susceptibility of the consuming population in Annex I to the Code of Hygienic Practice for Low-Moisture Foods.
- The second approach considers existing product data such as HACCP, PEM, Zoning Principles, prerequisite programs, knowledge of risk to the consuming population and on using testing as a means of assuring that the process is operating consistently
- A third approach, that can be highly effective, particularly in manufacturing facilities that apply proactive prevention or intervention steps to reduce or minimize Salmonella levels, is the use of a "moving window" sampling plan and highlights an alternative way in which the information from that testing is considered and acted upon. . As described in CAC/GL 21-1997

It was also highlighted by one Member that more studies were required on microbiological parameters in the context of different countries (both under the developing and developed context) with specific reference to Cronobacter *spp., w*hich is known to cause serious health hazards to infants.

One Member proposed that the Guidelines should make a clear distinction between Criteria for pathogenic microorganisms and criteria for process hygiene. Criteria for pathogenic microorganisms (Salmonella) should be respected in the final product, after primary packaging or anytime thereafter (until the primary package is opened). Criteria for process hygiene (Enterobacteriaceae) should be respected in the final product or at any previous moment that provides the information necessary for the verification. As such, these tests were intended to be used for verification of the hygiene programs.

The Chairs agree that this section will become a sub-section of Hygiene. The existing Codex texts will be appropriately quoted under this section.

3.7 CONTAMINANTS

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. This section will cover all possible chemical contaminants related to these products in line with other relevant Codex texts.

3.7.1 Pesticides Residues
3.7.2 Mycotoxins
3.7.3 Heavy metals
3.7.4 Radioactivity
3.7.5 melamine
3.7.6 Other Contaminants

The Chairs requested EWG Members to comment on the proposed contaminants and others that should be taken into consideration during the development of a Guideline. The following comments were received from EWG members:

One Member proposed that the guideline should cover all types of contaminants (e.g. biological and chemical contaminants). Mycotoxins should be considered a biological contaminant.

One Member proposed that veterinary drug residues should also be mentioned since there was a specific mentioning of pesticides in this section of a Guideline.

Various 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. Therefore system control in place should be preventive in nature throughout the value chain. The Codex 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.

One Member proposed that this section 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).

One Member proposed that the standards for all contaminants both industrial and microbial products such as aflatoxin should be set to consider immune-compromised older infants and young children.

The Chairs agree that the section will cover both biological and chemical contaminants. The existing Codex texts will be referred to.

Based on the responses received from the eWG Members, the Chairs propose the following amended outline for this section:
CONTAMINANTS
3.7.7 Pesticides Residues **3.7.8 Veterinary Drug Residues** **3.7.9 Mycotoxins** **3.7.10 Heavy metals** **3.7.11 Radioactivity** **3.7.12 Melamine** **3.7.13 Other Contaminants**
Do you agree with the above proposed wording and sub-sections?

3.8 TECHNOLOGIES AND PROCESSING

The Chairs requested eWG Members to comment on the "Technologies and Processing section of a Guideline. The following comments were received from EWG members:

Three Members proposed that the section should follow the Codex 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.

One Member proposed that the title of this section could be "technologies for and effect of processing", as in the Codex CAC/GL 8-1991. Furthermore the section should only deal with the treatment of raw materials since the process to manufacture the product itself was strongly linked to the volume, the equipment, the raw material used, etc.

One Member recommended that the Guideline should allow for the use of technologies such as thermal processing, or equivalent, as an additional pathogen control step for bacteria such as Salmonella spp. Thermal processing of the finished product may not be feasible in many cases, given the greatly increased heat resistance of Salmonella at reduced water activities. Consideration should also be given in the Guideline to allow, as reasonably possible, technologies which 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.

One Member commented that the food processors are responsible in ensuring that the processing steps and technologies address issues of anti-nutritional factors, homogeneity, microbial reduction steps, palatability of the final product depending on formulation used for RUTF.

The Chairs agree that this section will follow the format in the Codex CAC/GL 8-1991.

The Chairs propose the following amendments based on the responses received:
TECHNOLOGIES FOR AND EFFECT FOR PROCESSING
3.8.1 Preliminary Treatment of Raw Material 3.8.2 Milling 3.8.3 Toasting 3.8.4 Sprouting, Malting and Fermentation 3.8.5 Other Processing Technologies
Do you agree with the revised section and proposed sub-sections?

3.9 ANALYSIS AND SAMPLING

The Chairs requested eWG Members to comment on the section related to the "Analysis and Sampling" in a Guideline. The following comments were received from eWG members:

Two Members proposed that the title should be changed to "Method of analysis and sampling", which could be aligned to other Codex Texts such as the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981) which uses the term "Methods of Analysis and Sampling" and refers to the *Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999).*

The following Codex texts were recommended for reference, especially for microbial and contaminants not addressed in CODEX STAN 234-1999:

- *General Standard for Contaminants and Toxins in Food and Feed*(CODEX STAN 193-1995),
- *Code of Hygienic Practice for Low Moisture Foods*(CAC/RCP 75-2015),
- *General Principles of Food Hygiene* (CAC/RCP 75-2015).
- *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969); *Code of Hygienic practice for Powdered Infant Formulae for Infants and young children*(CAC/RCP 66-2008) and its annexes;
- and the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).

Two Members highlighted a challenge with analyzing the vitamins and minerals content of RUTF due to their lipid 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.

One Member commented that the stability of the product all along shelf life should be taken into account with specific reference to its nutritional, organoleptic, microbiological status.

In order to get reliable results, a Member proposed that Protein quality scores should be done using up to date methods of assessment (DIAAS).

The Chairs have revised this section based on responses from eWG Members:
METHODS OF ANALYSIS AND SAMPLING
Are there any other issues that should be considered under this section?

3.10 HYGIENE

The Chairs requested eWG Members to comment on the section related to "Hygiene" in a Guideline. The following comments were received from eWG members:

Two Members supported reference to the Code of Hygienic Practice for Low-Moisture Foods (CAC/RCP 75-2015) in this section.

Other relevant texts and International standards proposed for this section include:

- Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969);
- Code of Hygienic Practice for Low Moisture Foods (CAC/RCP 75-2015),
- Code of Hygienic practice for Powdered Infant Formulae for Infants and young children (CAC/RCP 66-2008) and its annexes;
- The Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

Three Members proposed that the production of RUTF products should follow the FSMP and Pharma GMP.
It was 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.
One Member proposed that the Title for the referred Codex document should be changed to "CODE OF HYGIENIC PRACTICE FOR LOW-MOISTURE FOODS (CAC/RCP 75-2015)".

One Member suggested that the Guideline should include stringent rules for C. Sakazakii as RUTFs were intended for use by undernourished, immune-compromised infants and children. Reference could be made to Resolution WHA58.32 on Infant and young child nutrition, 2005 http://www.who.int/nutrition/topics/WHA58.32_iycn_en.pdf; and WHO guidelines on Safe preparation, storage and handling of powdered infant formula. See: http://www.who.int/foodsafety/publications/micro/pif_guidelines.pdf)

The Chairs agree that this section will make reference to the "Code of Hygienic Practice for Low-Moisture Foods (CAC/RCP 75-2015) and other Codex texts. Microbiological safety for RUTF will also be incorporated under this section.

3.11 PACKAGING

The Chairs requested eWG Members to comment on the section related to "Packaging" in a Guideline. The following comments were received from EWG members:

Two 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 may require that the energy content range of a single pack be prescribed.

One Member suggested that packaging material as well as packaging design for RUTF should be the result of shelf life studies. There should be evidence in terms of appropriateness of film thickness, water vapor 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.

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 be such to 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.

The Chairs acknowledge responses from Members. Special attention will be paid to the packaging material for RUTF products and will be aligned with Codex texts where it exists. Primary and secondary packaging will also be covered under this section.

Based on **eWG** responses, the Chairs request **eWG** members to consider the following recommendations and provide inputs.
Packaging of RUTF into a single-use sachets 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.
Do you agree that RUTF should be packaged into single-use sachets to minimize the risk of contamination at home? **What should be the volume ranges of single-use sachets?** **What should be the nutritional content ranges (e.g. macronutrients) of a Single-use sachet?**

3.12 LABELLING

General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985) and General Standard for the Labelling of and claims for pre-packaged Foods for Special Dietary Uses (CODEX STAN 146-195), and other relevant Codex texts will inform the content of this section.

3.12.1 Applicable standards and Guidelines
3.12.2 Mandatory Provisions
3.12.2.1 The Name of the Product
3.12.2.2 List of Ingredients
3.12.2.3 Declaration of Nutritive Value
3.12.2.4 Storage Instructions
3.12.2.5 Instruction for Use
3.12.2.6 Additional Requirements
3.12.2.6.1 Shelf life

The Chairs requested eWG Members to comment on the section related to "Labelling" as articulated above. The following comments were received from EWG members:

Four Members suggested that the labelling section should follow the CODEX STAN 180-1991 for the labelling of and claims for foods for special medical purposes as a starting point. This document was 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 specificities of RUTF

Three members recommended that a visible statement on the importance of breastfeeding should be included as part of the additional requirements and that CAC/MISC 2-1976: Statement of infant feeding be considered.

Two Members also proposed that the label for RUTF should specifically state that the product is for the management of severe acute malnutrition, the appropriate age for use of the product, other relevant information relevant to the storage, handling and use of the product.

A proposal was made by a Member to consider whether the same information should be required on both the inner and outer packages, and less on the inner package of a RUTF.

The following statements were proposed by various Members to become mandatory on the labelling of these products:

- not for resale,
- breastfeeding is the most important for the rehabilitation of acute malnutrition and that the RUTF should not replace breastfeeding
- this is a high fat, high sugar product and long-term effects of using this category of products in children are not known
- RUTFs should not replace breastfeeding and locally available family foods.
- the product is for the management of severe acute malnutrition,
- The product must be used under medical supervision.

One Member commented that the Guidelines should take into account all relevant information to ensure that RUTFs do not replace/substitute the breastfeeding. The application of the guidelines should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding(See: WHA resolution, WHA 55.25 on Infant and young child nutrition, See: http://www.breastfeedingcanada.ca/documents/ResolutionWHA5525.pdf).

The guidelines should take into account the recommendations of World Health Assembly resolution 63.14 (2010) which calls for global action to reduce the impact on children of marketing of foods high in saturated fats, trans-fatty acids, free sugars, or salt.

One Member commented that the Net weight of the product should be emphasized.

Based on eWG responses the Chairs propose the following wording under this section
LABELLING
CODEX STAN 180-1991 for the labelling of and claims for foods for special medical purposes and other relevant Codex texts will inform the content of this section.
3.12.1 Applicable standards and Guidelines 3.12.2 Mandatory Provisions 3.12.2.1 The Name of the Product 3.12.2.2 List of Ingredients 3.12.2.3 Declaration of Nutritive Value 3.12.2.4 Storage Instructions 3.12.2.5 Instruction for Use 3.12.2.6 Additional Requirements 3.12.2.6.1 Shelf life 3.12.2.6.2 Mandatory Statements
Do you have additional comments on the proposed wording or for this section?
The Chairs propose that specific instructions and mandatory statements will be included under the sub-section on “Additional Requirements”.
Mandatory Statements for Labelling Purposes
The following mandatory statements were proposed by eWG Members. a. This product is not for resale. b. Breastfeeding is the most important for the rehabilitation of acute malnutrition and that the RUTF should not replace breastfeeding. c. RUTF is a high fat, high sugar product and long-term effects of using this category of products in children are not known. d. RUTF should not replace breastfeeding and locally available family foods. e. RUTF is a product for the management of severe acute malnutrition. f. The product must be used under medical supervision.

Do you agree with the wording and the proposed mandatory statements? **Please provide comments on the above suggested wording.** **Are there any other additional statements that should be considered under this section? Please provide the rationale and justification for their inclusion.**

3.13 ADDITIONAL COMMENTS

Electronic Working Group Members were requested to provide any additional information or recommended specific sections that should be considered in the Guideline.

One Member proposed that a marketing prohibition should be placed on these products so that they will not be sold for general use but available on prescription for medically indicated uses and with the supervision of an independent health worker.

The Chairs suggest that this point be covered under the labelling section, under sub-section on "Mandatory Statements".

One Member commented that addition of Food additives and flavors should be looked at during the development of a Guideline for the vulnerable groups.

The Chairs agree and this will addressed under the Suitable Raw Materials and Ingredients section.

One Member commented that these products should not be distributed or marketed in any manner for general use nor for the prevention of malnutrition. Therefore RUTF should not be seen as a replacement for health family foods, but an expensive treatment therapeutic food of questionable use.

The Chairs suggest that this point will be addressed under the Labelling section.

References

[i] WHO. *Guideline*: Updates on the Management of Severe Acute Malnutrition in Infants and Children. Geneva: World Health Organization; 2013.

[ii] 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.

[iii] 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.

[iv] World Health Organization. Management of Severe Malnutrition. A manual for physicians and other senior health workers. Geneva: World Health Organization, 1999.

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

[vi] http://www.fao.org/fao-who-codexalimentarius/meetings-reports/detail/en/?meeting=CCFH&session=47

ANNEXURE 1

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. INFACT CANADA
7. IACFO
8. ELC
9. MSF
10. IFT
11. ICAAS
12. IBFAN

ANNEXURE 2

CODEX MEMBERS

1. CHINA
2. EUROPEAN UNION
3. BRAZIL
4. AUSTRALIA
5. ZAMBIA
6. USA
7. FRANCE
8. INDIA
9. UGANDA
10. SOUTH AFRICA
11. SENEGAL

CODEX OBSERVERS

1. MSF
2. ELC
3. ISDI
4. IBFAN
5. ICAAS
6. IDF
7. VALID