



## Agenda Item 7

**CX/NFSDU 17/39/7**

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

**Thirty-ninth Session**

**Berlin, Germany**

**4 – 8 December 2017**

#### **PROPOSED DRAFT GUIDELINES FOR READY-TO-USE THERAPEUTIC FOODS**

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

Codex members and Observers wishing to submit comments at Step 3 on this draft should do so as instructed in CL2017/78-NFSDU available on the Codex webpage/Circular Letters 2017: <http://www.fao.org/fao-who-codexalimentarius/circular-letters/en/>. Comments will only be accepted through the online commenting system within the deadline indicated in the CL 2017/78-NFSDU

## 1. Background

The 37<sup>th</sup> Session of CCNFSDU (CCNFSDU37) agreed to start new work on guidelines for a single product known as “Ready to Use Therapeutic Foods” (RUTF) used in the management of severe acute malnutrition (SAM).<sup>1</sup>

This work was approved by CAC39.<sup>2</sup>

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

### 1.1 The process followed

Nominations to participate in the eWG were received from 23 Codex Members, 1 Codex Member Organization and 14 Codex Observers (Appendix 2). Two Consultation Papers were circulated to the eWG in March and May, respectively. The First Consultation Paper focused on the preamble to the RUTF Guidelines to set the scene for the appropriate use of the RUTF, and also made reference to the *Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions* (CAC/RCP 20-1979). The paper also had proposed text for the different sections of the guidelines for the eWG Members' inputs. Responses to the First Consultation Paper were received from 9 Codex Members, 1 Codex Member Organisation and 12 Codex Observers.

The focus of the Second Consultation Paper was on the finalization of the proposed text and content of the guidelines, taking into consideration the eWG comments to the First Consultation Paper. The paper also highlighted key areas that would still need further discussion or agreement by Members. The Chairs also requested the eWG Members to elaborate on key issues that might need further discussion by the Committee. Responses to the Second Consultation Paper were received from 10 Codex Members, 1 Codex Member Organisation and 9 Codex Observers.

## 2. Introduction

At CCNFSDU38 the Committee agreed on the wording and outline structure of the purpose of the guidelines. The Committee further agreed on the proposed scope of the guidelines, noting concerns from Members and Observers that while it was true that RUTF were given to other age groups, the priority target group for RUTF should remain 6-59 months as proposed in the guidelines. The Committee further agreed that an introduction or preamble should be included in the guidelines to set the scene, and to also elaborate on the appropriate use of RUTF. The preamble or introduction should also elaborate on how the guidelines should be used and also make reference to CAC/RCP 20-1979.

<sup>1</sup> REP16/NFSDU, paras 81-88, Appendix IV

<sup>2</sup> REP16/CAC, paras 102 – 107, Appendix V

<sup>3</sup> REP16/NFSDU, paras 3, Appendix IV

### 3. Preamble

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

#### Responses from the eWG Members

There was general support for the preamble from the eWG Members. Several Members provided specific inputs on the proposed text. Some Members indicated that the preamble should be concise in order to objectively describe the appropriate use of RUTF and align it to the existing Codex texts. One Member proposed that the first paragraph be deleted although it covers information on CAC/RCP 20-1979, since it is not a norm to mention the objectives of Codex in a specific guidelines or standards. Some Members were of the view that the emphasis on prevention captured in the preamble should be deleted since it was not relevant for RUTF. One Member suggested that the first paragraph be deleted and references to Codex Alimentarius (Procedure Manual) and CAC/RCP 20-1979 be included in the last paragraph. Furthermore, the Member also suggested that the term 'for special medical purposes' should be omitted from the text because dietary management of SAM could be achieved by modification of the normal diet.

One Member proposed the use of the terms 'undernourishment' or 'undernutrition' instead of 'malnutrition' throughout the document, since the term malnutrition refers to both undernutrition (e.g. stunting, wasting, underweight, etc.) and overnutrition (e.g. overweight, obesity and diet-related non-communicable diseases). Two Members were of the view that there was no sufficient scientific evidence that meets the WHO's definition of scientific substantiation on the efficacy of RUTF as the most appropriate treatment for SAM in all cases.

#### Conclusion

The Chairs note the responses from the eWG Members with reference to the inclusion of paragraph one which references CAC/RCP 20-1979, and paragraph three on prevention of SAM. The Chairs wish to remind the eWG Members that CCNFSDU38 agreed that a preamble should be included in the guidelines to set the scene, and also elaborate on the appropriate use of RUTF and also make reference to CAC/RCP 20-1979. The Committee further agreed that a preamble should also elaborate on the integration of RUTF into sustainable local family based solutions, in which prevention of SAM is critical<sup>4</sup>. The Chairs recommend that the proposed paragraphs 1 and 3 remain in the proposed preamble for the guidelines on RUTF.

#### Recommendation 1

That CCNFSDU agree to the draft text for the preamble as follows:

The major objectives of the work of the Codex Alimentarius Commission are to protect the health of the consumer and ensure fair practices in the trade in food through the elaboration and harmonization of definitions and requirements for food. In order to realize this objective CAC developed a *Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions* (CAC/RCP 20-1979) embodying the principles of sound consumer protection. The objective of this code is to establish standards of ethical conduct for all those engaged in international trade in food or for those responsible for regulating food and thereby protecting the health of the consumers and promoting fair trade practices. It is within this context that all those engaging in the international trade in food with specific reference to Ready-To-Use Therapeutic Foods (RUTF) commit themselves to the provisions of the code.

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

<sup>4</sup> REP17/NFSDU, paras 160-162

Investing in prevention of SAM through sustainable measures and interventions is crucial. Such interventions could include the improvement of access to high quality food and safe water through improving water and sanitation systems, improved access to health care, and the effective promotion of exclusive breastfeeding for the first six months of a child's life combined with continued breastfeeding up to 24 months and beyond. Thus, preventive programmes have an immense job to do in the context of poverty, and in the meantime children who already are suffering from SAM need to receive appropriate treatment.

These guidelines should therefore be used in accordance with the 2007 Joint statement of the UN agencies on Community-based management of severe acute malnutrition<sup>5</sup>, relevant WHO Child Growth Standards<sup>6</sup>, WHO guidelines in the management of Severe Acute Malnutrition in infants and children<sup>7</sup>, the Global Strategy for Infant and Young Child Feeding<sup>8</sup>, the International Code of Marketing of Breastmilk Substitutes<sup>9</sup> and subsequent relevant WHA Resolutions on infant and young child feeding. These guidelines have been prepared for the purpose of providing an agreed upon approach to the requirements which underpin the production of, and the labelling and claims for, RUTF. The guidelines are intended to facilitate the harmonization of requirements for RUTF at the international level and may provide assistance to governments wishing to establish national regulations in this area. The guidelines are also intended for use as an instrument designed to avoid or reduce difficulties which may be created by diverging legal, administrative and technical approaches to RUTF and by varying definitions and nutrient compositions of RUTF. These guidelines can also be used, if applicable, by governments in case of international trade disputes. Governments and other users should ensure adequate provisions are made for competent technical experts for the appropriate use of these guidelines.

#### 4. Purpose

At CCNFSDU38 the Committee agreed on the wording and outline structure of the purpose of the guidelines. The guidelines seek 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 their nutritional Composition; Raw Materials and Ingredients; Good Manufacturing Practices; Microbiological and Chemical Contaminant Criteria; Methods of Analysis and Sampling; and Provisions for Packaging and Labelling.

#### 5. Scope

At CCNFSDU38 the Chairs introduced the scope of the proposed guidelines on RUTF as follows:

*"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<sup>10</sup>, formulated complementary foods for older children and young children<sup>11</sup>, canned baby foods<sup>12</sup> are not covered by these guidelines. These guidelines should be used in accordance with the 2007 Joint Statement of the UN Agencies<sup>13</sup>, 2013 WHO document on Updates on the Management of Severe Acute Malnutrition in infants and children<sup>14</sup> or any other relevant upgrade of the latest version".*

<sup>5</sup>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

<sup>6</sup>WHO child growth standards and the identification of severe acute malnutrition in infants and children

A Joint Statement by the World Health Organization and the United Nations Children's Fund; Geneva: World Health Organization; 2009

<sup>7</sup>WHO. Guideline: *Updates on the management of severe acute malnutrition in infants and children*. Geneva: World Health Organization; 2013.

<sup>8</sup>WHO. *Global Strategy for Infant and Young Child Feeding*. Geneva: World Health Organization; 2003.

<sup>9</sup>WHO. *International code of marketing of breast-milk substitutes*. Geneva: World Health Organization; 1981.

<sup>10</sup>*Standard for Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981)*

<sup>11</sup>*Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 8-1991)*

<sup>12</sup>*Standard for Canned Baby Foods (CODEX STAN 73-1981)*

<sup>13</sup>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

<sup>14</sup>WHO. Guideline: *Updates on the management of severe acute malnutrition in infants and children*. Geneva: World Health Organization; 2013.

One Member raised a concern on whether Ready to Use Supplementary Foods (RUSF) should also be covered by the scope of the guidelines since the production, safety and quality requirements and nutritional composition were similar to the RUTF. There was general agreement that the guidelines will only focus on RUTF only as agreed in the previous committees and as per CAC approval. The Committee also noted that while it was true that RUTF were given to other age groups, the primary focus for treating severe acute malnutrition (SAM) was on the stated range of 6-59 months and this should remain the priority. Developing the guidelines with a more open age range would make it more difficult to set a definition of SAM or the compositional and nutritional requirements.

Regarding the question on the age limitation of 6–59 months, the Representative of WHO stated that WHO guidelines and other related documents use the age range of 6–59 months, but the definition of RUTF in the 2007 Joint Statement states “children from the age of six months”. The Representative from WHO confirmed that this was not a contradiction as RUTF were also used by older children (or even by adults who are severely malnourished) since the dose of RUTF is adjusted according to the body weight of the child under treatment. The Committee noted that while it was true that RUTF were given to other age groups at an operational level, such matters could be elaborated on in the introduction or preamble of the guidelines. The Committee proposed that a preamble should be included in the guidelines to set the scene and also elaborate on how the guidelines could be used at an operational level.

The Committee also proposed that the third sentence on the proposed scope of the guidelines which reads " These guidelines should be used in accordance with the 2007 Joint Statement of the UN Agencies<sup>15</sup>, 2013 WHO document on Updates on the Management of Severe Acute Malnutrition in infants and children<sup>16</sup> or any other relevant upgrade of the latest version", should be separated into a different paragraph or incorporated into the preamble/introduction.

The Committee agreed to the recommendation for the scope of the guidelines and tasked the eWG to elaborate on key aspects of the guidelines, with specific reference to the appropriate use of RUTF and the use of RUTF beyond the age of 59 months in the preamble or introduction. The Chairs have elaborated on these issues in the preamble and have also incorporated the second paragraph of the scope in the preamble. The scope of the guidelines will read as follows:

"The provisions of these guidelines apply to Ready to Use Therapeutic Foods for children from age 6 to 59 months with severe acute malnutrition. Ready-to-Use Supplementary Foods (RUSF), micronutrient supplements<sup>17</sup>, processed cereal based foods<sup>18</sup>, formulated complementary foods for older infants and young children<sup>19</sup>, canned baby foods<sup>20</sup> are not covered by these guidelines".

## 6. Description

During the 2016 eWG consultations, the Chairs used the current description in the 2007 Joint Statement by UN agencies as a departure point for the description of the RUTF. 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. There was an overwhelming support amongst eWG Members in 2016 that since the intended use for RUTF is for the dietary management of severe acute malnutrition, they should comply with the definition of food for special medical purposes (FSMP) as stipulated in the CODEX STAN 180-1991. This would assist in avoiding legal uncertainties, and also clarify that the products are specially processed or formulated.

Members also emphasised that the “description” should not cover other forms of RUTF that were not commercially produced as per the project document that was presented at CCFNSDU37. However, the description should not only be restricted to the current form of RUTF, but should also include other forms such as bars, etc. During the 2016 consultative process, the eWG Members also requested that definitions should be provided for severe acute malnutrition and young children. With regard to the definition of “young children”, several eWG Members felt that there was no need to include it since RUTF 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 texts.

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<sup>15</sup>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

<sup>16</sup>WHO. Guideline: *Updates on the management of severe acute malnutrition in infants and children*. Geneva: World Health Organization; 2013.

<sup>17</sup> Guidelines for Vitamin and Mineral Food Supplements (CAC/GL55-2005)

<sup>18</sup>Standard for Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981)

<sup>19</sup>Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 8-1991)

<sup>20</sup>Standard for Canned Baby Foods (CODEX STAN 73-1981)

During the 2017 consultative process, the eWG Members were requested to comment on the proposed description of RUTF. There was widespread support of the proposed description amongst the eWG Members (CM=9, CO=10, CMO=1). Two Members were of the view that since RUTF were meant for the treatment of older infants and young children suffering from severe acute malnutrition, the quality of evidence on the use of these products for the treatment of SAM should be critically examined to ensure that the products were safe for the intended purpose. Two Members also indicated that safe drinking water should be made available to children who should receive RUTF.

One Codex Member was of the view that the description of RUTF as a FSMP was a departure from the 2007 Joint Statement which focused on the community-based approach that provides for management of “those without medical complications with RUTF or other nutrient-dense foods at home”. Furthermore, the Member indicated whether the intended program goals to treat SAM with community-based management could be achieved with FSMPs, and its implications on the programmatic aspect of RUTF, with specific reference to creating barriers to the recommended community based approach and food aid programs.

## Conclusion

The Chairs note that there was an overwhelming support by the eWG Members during the 2016 consultation process that since the intended use for RUTF is for dietary management of severe acute malnutrition, they should comply with the definition of 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 when these products are traded. The approach of classifying RUTF as FSMPs would also assist Member states in clarifying that the products are specially processed or formulated and could only be used under medical supervision. The Chairs also note that the 2007 Joint Statement recognize the use of RUTF for treating children with SAM when there are no medical complications. Therefore, the purpose of these guidelines is to provide guidance on technical and nutritional aspects of the production of RUTF to producers and Member States when these products are traded. The preamble of these guidelines takes cognisance that RUTF are not the only solution in addressing the problem of SAM, but have a role to play.

### Recommendation 2

That CCNFSDU agree to the proposed text for the description of RUTF as follows:

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

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

## 7. Raw Materials and Ingredients

In 2016 the eWG was tasked with proposing the raw materials and ingredients for the RUTF. 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 RUTF. This approach would for variety and could increase the palatability when local and cultural acceptable ingredients were used and also might contribute in reducing costs of RUTF. The eWG Members also 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). 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 and acceptability studies to demonstrate the use on the new developed product to treat SAM in the same context as the current RUTF.

There was consensus amongst the eWG Members that 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 guidelines. A proposal was made that the proposed guidelines 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. In 2017 the Chairs requested the eWG Members to elaborate on the text that should be included under different sections of raw materials and ingredients. There was widespread support on the outline of the section by the eWG Members (CM=6, CO=8, CMO=1). Several Members made proposals with reference to the proposed text under each section of the proposed outline.

## 7.1 Proposed texts on Raw Materials and Ingredients

### 7.1.1 Opening Text

Several Members supported the proposed opening text on raw materials and ingredients (CM=7, CO=1, CMO=1). Six Members (CM=2, CO=4) did not support the proposed text and 4 Members did not indicate their preference. Two Members proposed that the reference to Section 3 of the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-1991) should be fully consistent with the language used in the standard to ensure a higher level of consumer protection. This would also ensure that not only the ingredients comply but the overall formulation of RUTF complies with Section 3 of CODEX STAN 180-1991. Two Members recommended that the composition of RUTF should primarily be based on relevant WHO documents (and their future modifications) and on the advice of UNICEF, World Food Programme as well as NGOs with extensive experience on the use of RUTF.

One Member was of the view that the compositional requirements for RUTF should be based on evidence that meets WHO's definition of scientific substantiation, under the GRADE classification' and should be aligned to the paragraph on general principles as articulated in CODEX STAN 180-1991. Five Members suggested that the words "paste and protein based" should be removed from the text since RUTF are made of a combination of various ingredients, and it would not be possible to prepare RUTF based on a protein matrix and still comply with the compositional requirements. It was reiterated by one Member that RUTF are not FSMPs and this could negatively impact the ability of donor countries to provide food assistance in emergency relief situations, and proposed using different text instead of referencing Section 3 of the CODEX STAN 180-1991. Several Members made specific inputs to the amendment of the proposed text.

### Conclusion

The Chairs note various comments received from the eWG Members during the consultation process, with specific reference to the proposed amendments to the draft text. The Chairs also note the proposal made by the eWG Members on referencing Section 3 of the CODEX STAN 180-1991 to ensure that there is consistency in the language used in the proposed text, but also to ensure that the overall formulation of RUTF complies with Section 3 of the standard.

### Recommendation 3

That CCNFSDU consider the proposed opening text on "Raw Materials and Ingredients" section of the proposed Guidelines on RUTF as follows:

RUTF are made of powdered or ground ingredients embedded in a lipid-rich matrix [e.g. paste and biscuit], resulting in an energy and nutrient-dense food. The following raw materials, many of which can be sourced locally, are suitable ingredients for the production of RUTF under the specified conditions given below. The formulation of RUTF shall comply with Section 3 of the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-1991).

### 7.1.2 Milk and other Dairy Products

Milk powder has been the main ingredient used in the production of RUTF. Most RUTF contains 25 percent milk or more, which may constitute about 60 percent of the ingredient cost of RUTF. It is well known that adequate protein quality is essential for treatment of SAM, even more so when food is scarce and infection rates are high. High quality proteins such as milk protein have been demonstrated to have benefits in terms of weight gain, linear growth, and recovery of muscle mass. For this reason, The Joint Statement of 2007 recommended that "at least half of the proteins contained in the foods should come from milk products". 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<sup>21,22</sup>. However, when a cheaper RUTF containing less milk powder (10%) was compared with standard RUTF (25% milk powder) there was no difference in terms of recovery. RUTF with less milk may lead to slightly more children relapsing and to less weight gain than the standard RUTF<sup>23</sup>.

<sup>21</sup> Hoppe C, Udam TR, Lauritzen L, et al. Animal protein intake, serum insulin-like growth factor I, and growth in healthy 2.5-y-old Danish children. *Am J Clin Nutr* 2004;80:447-52.

<sup>22</sup> Hoppe C, Molgaard C, Vaag A, et al. High intakes of milk, but not meat, increase s-insulin and insulin resistance in 8-year -old boys. *Eur J Clin Nutr* 2005; 59: 393-8.

<sup>23</sup> Oakley E, Reinking J, Sandige H, Trehan I, Kennedy G, Maleta K, et al. A ready-to-use therapeutic food containing 10% milk is less effective than one with 25% milk in the treatment of severely malnourished children. *The Journal of Nutrition* 2010; **140**:2248–52.

In 2017 consultations, there was widespread support for the proposed text on "milk and other dairy products" section by the eWG Members (CM=9, CO=4), with three Members not specifying their preference. Several Members indicated that the relevant milk and dairy related standards and codes should be reflected in the proposed text. One Member suggested that the wording "Milk and other Dairy Products" should be replaced by "Animal Source Foods" in order to allow the use of locally available ingredients such as meat, fish, poultry, eggs, milk and milk products which are nutrient dense and good sources of high quality proteins and micronutrients. One Member was of the view that the proposed text was restrictive and recommended that the original text be kept.

### Conclusion

The Chairs note the inputs by the eWG Members, with specific reference to including related Codex standards and Codes in the proposed text.

#### Recommendation 4

That CCNFSDU agree to the proposed text for the "Milk and other dairy products" section as follows:

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

### 7.1.3 Legumes and Pulses

Peanut butter made from peanuts that have been roasted and ground, without added oil, salt or preservatives are currently used in the standard RUTF. However, peanuts are highly prone to aflatoxin contamination and they are a well-known allergen. Moderate doses of aflatoxin consumption may depress child growth<sup>24</sup>. However other forms of RUTF with various ingredients have been tried and others are being tried and tested in different regions<sup>25</sup>. Legumes and pulses such as soybean, chickpea, pea have been tried and tested in different regions<sup>26</sup>. However, bioavailability of minerals in pulse-based foods can be significantly reduced by phytic acid. An area of concern with other RUTF formulation that replaces milk powder by legumes is the low content of absorbable phosphorus from legumes and pulses.

Several Members were in support of the proposed text (CM=9, CO=7, CMO=1) with minor additions. One Member commented that the amount of protein provided by legumes and pulses should be regulated with the aim to maintain the complementary effect of the milk protein. Another Member was concerned about the early introduction of RUTF to children before the age of one year due to allergic reaction concerns. Some Members suggested that the specific relevant Codex Alimentarius texts should be referenced in the text. One Member highlighted that pulses have a high content of lysine and deficient in methionine, which could necessitate the addition of methionine if the nature of the ingredients in the formulation are also deficient. Furthermore it was suggested that field beans (*Vicia faba* L.) while having a very good nutritional quality and being a high yield crop, should not be used in the formulation of RUTF because of the danger of favism<sup>27</sup>. Heat treatment may not inactivate the toxic principles vicin and co-vicin.

### Conclusion

The Chairs note the widespread support of the proposed draft text, as well as referencing the relevant Codex standards to assist Members who may not be familiar with the relevant Codex texts.

#### Recommendation 5

That CCNFSDU agree to the proposed text on legumes and pulses as follows:

<sup>24</sup> Turner PC, Collinson AC, Cheung YB, et al. Aflatoxin exposure in utero causes growth faltering in Gambian infants. *Int J Epidemiol* 2007;36:1119-25.

<sup>25</sup> Irena AH et al. Comparison of the effectiveness of a milk-free soy-maize-sorghum-based ready-to-use therapeutic food to standard ready-to-use therapeutic food with 25% milk in nutrition management of severely acutely malnourished Zambian children: an equivalence non-blinded cluster randomised controlled trial. *Maternal and Child Nutrition*, 2013:1-15.

<sup>26</sup> Ryan KN et al. A comprehensive linear programming tool to optimize formulations of ready to-use therapeutic foods: an application in Ethiopia. *AJCN*, 2014; 1-8.

<sup>27</sup> GBD 2013 Mortality and Causes of Death, Collaborators (17 December 2014). "Global, regional, and national age-sex specific all-cause and cause-specific mortality for 240 causes of death, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013." (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4340604>). *Lancet*. 385: 117–71. PMC 4340604 (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4340604>) . PMID 25530442 (<https://www.ncbi.nlm.nih.gov/pubmed/25530442>). doi:10.1016/S0140-6736(14)61682-2 (<https://doi.org/10.1016%2FS0140-6736%2814%2961682-2>).

Legumes and pulses, such as lentils, chickpeas, cowpeas, beans, peanut, sesame and other types of legumes and pulses must comply with the *Standard for Peanuts* (CODEX STAN 200-1995), *Code of Hygienic Practice for Groundnuts (Peanuts)* (CAC/RCP 22- 1979) and the *Code of Hygienic Practices for Low-Moisture Foods* (CAC/RCP 75-2015), and other relevant Codex Alimentarius text when used in the manufacturing of RUTF.

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

#### 7.1.4 Fats and Oils

Vegetable oils and fats are important ingredients in the diet of children with severe acute malnutrition as they supply both energy and essential fatty acids. Several types of oil made by standard commercial methods are being used in the formulation of RUTF, including soy oil, cottonseed oil, rapeseed oil, and corn oil. Rapeseed oil, corn and soy oil have the advantage of providing a good balance of essential fatty acids. Partially hydrogenated vegetable oils should not be used in the RUTF formulations because of potential effects of trans-fatty acids.

The Chairs requested the eWG Members to provide inputs on the proposed text in the consultation papers. Several Members supported the proposed text, with minor additions (CM=4, CO=6, CMO=1). Two Members commented that fats should not exceed the WHO recommendation of 30% energy from fats, and RUTF should contain appropriate levels of essential fatty acids to facilitate brain and neurological development in children, without making any claims. One Member proposed that a threshold on oxidized fat which should be of an objective quantitative measure of lipid peroxidation should be introduced in the text. Some Members were supportive of the restriction on the use of partially hydrogenated fats and oils in RUTF, since it is in line with the global public health approach. One Member commented that the guidelines should consider excluding some fatty acids or oils such as cotton and sesame in the formulation of RUTF. Several Members proposed that the text "containing significant amounts of industrially produced trans fatty acids" should be removed since it would be challenging to quantify the 'significant amount' in RUTF.

#### Conclusion

The Chairs note the inputs from the eWG Members on the proposed draft text. The Chairs also note the concern by the eWG Members on the inclusion of the following text "containing significant amounts of industrially produced trans fatty acids", that it could be misinterpreted and quantifying the significant amount of industry produced trans fatty acids could be a challenge. Therefore, the Chairs suggest that the text be removed.

#### Recommendation 6

That CCNFSDU agree to the proposed text on fats and oils and a statement that prohibit the use of partially hydrogenated fats and oils in RUTF.

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

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

#### 7.1.5 Cereals

Various cereals have been tried in the formulation of RUTF such as sorghum, oats, maize, rice, etc. It is believed that the use of local ingredients in the formulation of RUTF would increase product acceptability, support local farmers and communities, lower production costs and improve sustainability. Cereals such as maize are also prone to aflatoxin contamination. Therefore, precautionary measures need to be taken into consideration.

The Chairs requested the eWG Members to elaborate on the proposed text. Several Members supported the proposed text with minor additions (CM=5, CO=6, CMO=1). One Member questioned the scientific rationale for recommending the reduction of fibre in cereals if an adequate energy, nutrient density and nutrient bioavailability could be achieved. Furthermore, dietary fibre could also have beneficial effects in children with SAM. One Member also commented that the use of the wording "if possible" to eliminate anti-nutrients is weak and may not be helpful, and suggested the inclusion of acceptable maximum limits in the text.



One Member reiterated that cereals were the main staple food components in the developing countries and could be sourced locally with the possibility of adding micronutrients and amino acids as appropriate. However, some anti-nutritional factors such as phytates could be dealt with in cereals and their availability do not pose any harm. The Member is of the view that the proposed text could create an unjustified hurdle to local production of RUTF.

#### **Recommendation 7**

That CCNFSDU agree to the proposed text on the use of cereals in RUTF formulation as follows:

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

#### **7.1.6 Vitamins and Minerals**

The current RUTF include vitamin and mineral premix which are commercially produced to provide the same amount of micronutrients to the malnourished child as F-100, which is the standard therapeutic food. Vitamin and mineral forms used must be soluble and easily absorbed by patients with SAM. Children with SAM have low or absent gastric acid which means that they should not be given inorganic salts of minerals that are insoluble or requiring an acid gastric environment for absorption, in order to avoid metabolic acidosis. It is important that RUTF should have a mineral composition that will not alter the acid-base metabolism of patients with SAM. The non-metabolizable base can be approximated by the formula: estimated absorbed millimoles (sodium + potassium + calcium + magnesium) - (phosphorus + chloride).

The Chairs of the eWG proposed a text for vitamins and minerals taking into consideration the physiological needs of SAM children as well as the existing Codex texts. The eWG Members raised various concerns with the proposed text. Several Members indicated that the provisions in CAC/GL 10-1979 are adequate and contain all the necessary requirements that a nutrient need to meet for it to be used in the food covered by the advisory list which is also applicable to RUTF. With regard to the absorbability of vitamins and minerals to be used in RUTF, Members were of the view that it would also be covered by section 2.1(d) of the CAC/GL 10-1979. A proposal was made that if the second paragraph were to remain it should be rephrased in line with the provisions of section 4.2 of *The Guidelines on Formulated Complementary Foods for Older Infants and Young Children* (CAC/GL 8-1991). The Chairs noted the responses from the eWG Members and proposed that paragraph two be deleted since the provisions of paragraph two were already covered in CAC/GL 10-1979.

One Member suggested that the Technical Annex of the 2007 Joint Statement of the UN Agencies be referenced or included in this section as well as the corresponding updates regarding the micronutrient composition of RUTF. One Member was of the opinion that studies and methodologies that could be used to verify if the requirements in section 2.1 of the CAC/GL 10-1979 were being met in RUTF formulation are needed. Two Members proposed that the deleted paragraph which stated "Vitamin and mineral forms used must be soluble and easily absorbed by patients with SAM" be reinstated since it was articulated in the Annex of the 2007 Joint Statement. This would ensure that vitamin and minerals used in the formulation of RUTF were available and easily absorbed by SAM children.

#### **Conclusion**

The Chairs note that there is a concern on whether the provisions in CAC/GL 10-1979 are adequate to cover the absorbability of vitamins and minerals to be used in RUTF. The Chairs also note a proposal made by some Members with regard to referencing the Technical Annex of the 2007 Joint Statement which makes reference to the mineral salts and trace elements recommended for F-100 by WHO, as an example of a mineral mix with a suitable positive non-metabolizable base. Since the RUTF formulation is based on F-100, the 2007 Joint Statement recommends the mineral mix for F-100 since it has a suitable positive non-metabolizable base for SAM children.

The Committee needs to consider whether the provisions as outlined in CAC/GL 10-1979, especially the Criteria in Section 2 would ensure that any nutrient used in RUTF formulation meet all the necessary requirements in terms of all the necessary quality aspects, with specific reference to the mineral composition that will not alter the acid-base metabolism of SAM children. If the Committee agrees to specify the specific forms of mineral salts and trace elements recommended for SAM children, the Chairs recommend that the mineral mix that are stipulated in Appendix 4 of the WHO Management of severe malnutrition: A manual for physicians and other senior health workers, that would not alter the acid base metabolism of children with SAM be specified under the nutritional composition section of the guidelines. Specifying these forms of mineral salts and trace elements will address the issue of minerals forms that are permissible so that they do not alter the acid base metabolism of SAM children. The Chairs recommend that the proposed text on "Vitamins and Minerals" section of the guidelines should only make reference to CAC/GL 10-1979.

### Recommendation 8

**8.1** That CCNFSDU consider specifying forms of minerals salts and trace elements to be used in RUTF formulation, which will not alter the acid-base metabolism of SAM children.

**8.2** That CCNFSDU agree to the proposed text on vitamins and minerals as follows.

All added vitamins and minerals must be in accordance with the *Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CAC/GL 10-1979).

## 7.2 Other Ingredients

### 7.2.1 Digestible Carbohydrates

Lactose, sucrose, fructose and glucose polymers have been used in RUTF as sweeteners. The current RUTF generally contain about 25% free sugars. Sucrose is mainly used to increase the palatability of RUTF and may typically increase the energy density of the RUTF. Particular attention should be given to the sugar particle size, which if not properly ground, can cause oil separation from the RUTF paste and lead to leakage when opening the sealed part of the product. In 2015, WHO strongly recommended that both adults and children reduce the intake of free sugars to less than 10% of energy and further recommended a further reduction to less than 5% of energy<sup>28</sup>.

Free sugars are defined as "monosaccharides and disaccharides added to foods and beverages by the manufacturer, cook or consumer, and sugars naturally present in honey, syrups, fruit juices and fruit juice concentrates". Free sugars do not include intrinsic sugars and sugars naturally present in milk such as lactose. Added sugar may therefore help to increase energy intake both through increased energy density and through improved taste, an effect that may be especially important in situations where appetite is poor. However, when sugar is used for a longer period of time, there is a risk of reinforcing a preference for sweet foods, resulting in too high energy intake later in life. This may not be important during shorter periods of rehabilitation, which RUTF is meant for.

During the first consultation several Members suggested that the maximum acceptable levels of digestible carbohydrates which can be used to increase the energy density of RUTF should be defined. Two Members recommended that the addition of simple carbohydrates in the form of sugars should be limited to the WHO recommendations that added sugars should be no more than 5% of total energy, due to the potential undesirable effects such as hyperglycaemia, hyperinsulinemia and osmotic diarrhoea of high levels of free sugars in SAM children.

Four Members commented that carbohydrates were not used to increase the energy density of RUTF, therefore the wording "energy density" at the beginning of the paragraph should be removed. One Member indicated that sugars such as fructose and corn syrups should be prohibited in RUTF due to the possible adverse effects which may be exacerbated by SAM<sup>29,30</sup>. It was also proposed that examples of appropriate digestible carbohydrates should be included and referencing the appropriate Codex texts could also be helpful. Several Members queried the inclusion of the statement "Particular attention should be given to the sugar particle size, which if not properly ground, can cause oil separation from the RUTF pastes", and indicated that it might not be helpful in the guidelines.

<sup>28</sup> WHO. *Guideline: Sugars intake for adults and children*. Geneva: World Health Organization; 2015.

<sup>29</sup>Malik VS, Hu FB. Fructose and Cardiometabolic Health: What the Evidence from Sugar-Sweetened Beverages Tells Us. *J Am CollCardiol*. 2015 Oct 6;66(14):1615-24

<sup>30</sup>Hu FB, Malik VS. Sugar-sweetened beverages and risk of obesity and type 2 diabetes: epidemiologic evidence. *PhysiolBehav*. 2010 Apr 26;100(1):47-54.

One Member highlighted that the definition for the term 'digestible carbohydrate' was not in the Codex text, although it is used in the *Guidelines for Complementary Foods* (CAC/GL 8-1991). Furthermore, the *Guidelines for Nutrition Labelling* (CAC/GL 2-1985) provide a definition for the term 'available carbohydrate' (i.e. dietary carbohydrate excluding dietary fibre) and it was proposed that the RUTF guidelines should be consistent with the Guidelines for Nutrition Labelling to avoid confusion in the interpretation of texts. It was proposed that the definition for 'available carbohydrates' be indicated in a footnote and also reference CAC/GL 2-1985.

Three members noted that the rationale for why honey is not permitted in RUTF products should also be included. Regarding the wording on the prohibition of honey, one Member suggested the use of the words "infant botulism" to differentiate between the aetiology of foodborne botulism and infant botulism. Although infant botulism and foodborne botulism are both caused by *Clostridium botulinum*, they occur differently. Foodborne botulism is caused by ingestion of food contaminated with pre-formed neurotoxin while infant botulism occurs by intestinal colonization of infant intestines which lead to neurotoxin produced in the intestine.

### Available Carbohydrates: Footnote 1

The Chairs requested the eWG Members to comment on whether examples of digestible carbohydrates should be included in the guidelines or as a footnote, and appropriate Codex text be referenced. Several Members supported the inclusion of a footnote (CM=4, CO=4), with three Members objecting (CM=2, CO=1) to such a proposal. The inclusion of a footnote on the acceptable available carbohydrates would highlight the WHO observation that carbohydrate malabsorption was prevalent in children with SAM<sup>31</sup>. Some of the examples of the available carbohydrates that were given by the eWG Members that could be permitted in RUTF were sucrose, vegetable starch, glucose, glucose syrup as stipulated in the *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CODEX STAN 074-1981).

Maltodextrin DE 5-20 was also proposed as another example of available carbohydrates that could be referenced in the proposed footnote since it is mainly used as a bulking agent and its low sweetening power. One Member who was not in support of the proposed footnote and indicated that if examples of the available carbohydrates were to be provided, examples of digestible fats and proteins should also be provided.

### Conclusion

Although several Members indicated a need to set the maximum acceptable levels of available carbohydrates in RUTF, there was no consensus on whether such a limit should be aligned to the WHO recommendations on added sugar of not more than 10% or 5% of total energy. The Committee need to decide on whether the acceptable limit of available carbohydrates should be included in the guidelines bearing in mind that available carbohydrates are not used as a source of energy in RUTF and whether such limit should be aligned to the WHO recommendations on added sugars. Some Members reiterated that the addition of available carbohydrates in RUTF was to improve the palatability of the product, especially in children with low appetite, as is the case with SAM children. Some Members indicated that sugars such as fructose and corn syrups should be prohibited in RUTF due to the possible adverse effects which may be exacerbated by SAM. The use of these sugars could also reinforce a preference for sweet foods which could result in high energy intake later in life. However, it should be noted that RUTF are used for a shorter period of rehabilitation, which could last for 8 weeks. The Chairs also recommend that a footnote be included in the guidelines to provide guidance on the acceptable available carbohydrates in RUTF formulation.

### Recommendation 9

**9.1** That CCNFSDU agree to the proposed text on addition of available carbohydrates into RUTF formulation, and a statement that prohibit the use of honey in RUTF.

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

Available carbohydrates must adhere to the relevant Codex Alimentarius texts.

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

**9.2** That CCNFSDU agree to the inclusion of a footnote on the acceptable available carbohydrates in RUTF formulation and consider the proposed text for the footnote as follows:

<sup>1</sup>[Sucrose, vegetable starch, glucose, glucose syrup] should be the preferred carbohydrates in RUTF. Fructose and high fructose corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinised starches gluten-free by nature may be added].

**9.3** That CCNFSDU consider whether the acceptable limit of available carbohydrates should be included in the guidelines.

<sup>31</sup>[http://apps.who.int/iris/bitstream/10665/95584/1/9789241506328\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/95584/1/9789241506328_eng.pdf)

## 7.2.2 Food Additives and Flavours

Regarding the addition of food additives in RUTF, the 2016 eWG discussed whether RUTF 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). The food category 13.3 section reads as follows:

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

Table 2 of the GSFA include a list of additives allowed under Food Category No. 13.3. The proposed draft description of the RUTF stipulates that "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". Therefore, RUTF may be considered under the food category 13.3 of the GSFA standard. However, if the eWG believes that RUTF should be considered in a separate food category from 13.3 to specifically address specific additive provisions in this target group, the eWG may consider examining the existing additive provisions in the GSFA and determine which ones are justified or not for RUTF.

The 2016 eWG further discussed that if there are additives that are technologically justified for use in RUTF but there are no provisions for their use in the relevant food category, a consideration should be made to forward them to the CCFA for their advice together with the technological justification. 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 as a result of carry-over (e.g. carriers used in vitamin preparations that are used as ingredients in RUTF). Alternatively, the eWG may consider whether a similar provision is needed for RUTF as is the case with the infant formulas, which says 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.

During the first consultation in 2017, the Chairs posed a question to the eWG Members on whether they were in agreement with the proposal that RUTF should fall under Food Category 13.3 of the General Standard for Food Additives (CODEX STAN 192-1995). The eWG Members were also requested to provide an alternative if they were not in agreement with the proposal. Nine Members were in agreement that RUTF should fall under category 13.3 of the GSFA (CM=2, CO=7). Five Members were not in support of the proposed food category (CM=2, CO=3). Those who were in support of the FoodCatNo 13.3 indicated that although RUTF could fall under this category, it could require the amendment of the said category since RUTF are different from other products. Alternatively, the Committee could consider the use of 'notes' associated with the provisions listed in the GSFA to identify conditions of use specific to RUTF, or identify those additives not appropriate for use in RUTF. Members who were not in support of FoodCatNo 13.3 indicated that it might not be suitable for RUTF since it is a general category for dietetic foods for special medical purposes and it does not reflect the targeted age group for RUTF (6 – 59 months). Furthermore, some of the food additives in 13.3 might not be suitable for SAM children and the technological need for these additives has not been evaluated for RUTF. Some Members proposed other categories such as 13.2, 13.4, 13.5 and 13.6 to be suitable for RUTF. Some Members proposed for the creation of another sub-category in Category 13 specific for RUTF to allow for the determination of the specific additives that would be appropriate for this category.

The Chairs also requested the eWG Members to identify other food additives that are currently used in RUTF formulation, and whether they were justified in RUTF. Several eWG Members highlighted some of the additives that are currently used in RUTs, which include lecithin, mono- and di-glycerides of fatty acids, natural flavours, natural antioxidants (Ascorbyl palmitate and Mixed tocopherols) and emulsifiers lecithin [Ins No: 322(i)] and mono and diglycerides of fatty acids (INS no 4710). The mono and diglycerides of fatty acids (INS no 4710); lecithin [Ins No: 322(i)] are the preferred emulsifiers to maintain the oil within the paste, as they have GRAS status under section Sec. 582.4505 of the Code of regulations in the US FDA. Some Members indicated that the inclusion of non-nutritive additives such as benzoates, brilliant blue FCF, carmines, polydimethylsiloxane, polysorbates, and propylene glycol esters of fatty acids in RUTF should not be allowed as these additives were unnecessary. It was further proposed that any non-nutritive additives including flavorings, colorings and additives that alter the physical properties of RUTF such as thickening agents or emulsifiers should be avoided unless evidence is provided for their safety for children. In particular, Polysorbates, such as polysorbate 80, have been associated with altered species in the gut microbiome, microbiota encroachment and increased pro-inflammatory potential in mice, and may present a risk to children with SAM<sup>32</sup>. One member indicated that some RUTF suppliers also use a small amount of saturated oil (e.g. palm oil) as stabilizer.

Due to various proposals that were made by the eWG Members on how to handle additives in RUTF, the Chairs proposed an approach to address various concerns and divergence views. During the second consultation the Chairs proposed a stepwise approach in handling the use of additives in RUTF formulations.

### Proposed approach

The Chairs requested the eWG Members to comment on whether they were agreement with the following proposed approaches:

- a. Compilation of a list of food additives that are currently used in RUTF formulation which could be provided by the manufacturers of the RUTF products.
- b. The eWG identify the appropriate additives and recommend a positive list for endorsement on a technological basis by the CCFSDU. CCFSDU will then put forward a list for consideration from a safety perspective to the CCFA.
- c. Propose for the creation of another sub-category in Category 13, which will be specific for RUTF to allow for the determination of the specific additives that would be appropriate for this category.

There was widespread support by the eWG Members on the proposed stepwise approach to address the use of food additives in RUTF formulation (CM=8, CO=4, CMO=1). Two Members indicated that the pragmatic approach proposed by the Chairs would ensure a comprehensive overview of what additives are currently used in RUTF, and would also allow the Committee to carry-out its responsibility in appraising and justifying the technological need for the use of additives in RUTF. Furthermore, the proposed approach would allow the development of the Guidelines to continue and once a new sub-category in Food Category 13 in GSFA is established and populated with food additives for RUTF, the guidelines would then make reference to the new GSFA sub-category. Several Members proposed certain amendments to the proposed stepwise approach.

### Conclusion

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

Based on the responses from the eWG Members the Chairs recommend a stepwise approach in dealing with food additives in RUTF. Following a stepwise approach would allow the Committee to have a comprehensive overview of what additives are currently used in RUTF. This approach will also allow the Committee to carry-out its Responsibility with regard to appraising and justifying the technological need for the use of additives in RUTF.

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<sup>32</sup> Chassaing et al. Dietary emulsifiers impact the mouse gut microbiota promoting colitis and metabolic syndrome. *Nature*, 2015: 519, 92–96.

**Recommendation 10**

That CCNFSDU agree to the following proposed stepwise approach to address the use of food additives in RUTF formulation:

- a. The eWG compile a list of food additives currently used by the industry in the manufacturing of RUTF that include their technological rationale and function and approximate use levels.
- b. The eWG compare the food additives currently used in RUTF to food additives approved for use in existing Codex texts aimed at infants and young children to determine whether the food additives in RUTF have already been evaluated in infants and young children.
- c. The eWG recommend a proposed list of food additives for CCNFSDU to confirm the technological need.
- d. Once CCNFSDU confirms the technological need, CCNFSDU could forward a list of food additives used in RUTF to CCFA for their consideration on safety aspects, and also request input from CCFA on the appropriate food category assignment, as well as guidance on appropriate procedural steps to be followed.

**7.3 The Use of other Matrices in RUTF formulation**

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

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

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

**Conclusion**

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

**Recommendation 11**

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

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

## 8. NUTRITIONAL COMPOSITION AND QUALITY FACTORS

The current nutritional composition for RUTF is derived from the F-100 product which is currently used for in-patient management of SAM. The nutritional composition recommended in the '2007 Joint statement by UN agencies' was used as a departure point for reviewing the nutritional composition of RUTF. During the 2016 consultations with the eWG Members, there was overwhelming support of the current nutritional composition for RUTF and some Members indicated that various nutrients should be reviewed to align them with the latest scientific evidence available. It was also highlighted that the compositional design of F-100 did not include considerations of the need for higher nutrients for 'catch up' linear bone growth that experts now accept as important for this target group. Selected nutrients (Phosphorus, calcium, magnesium) needs for malnourished populations were reviewed later, and recommendations for these nutrients were increased to allow for catch up bone growth<sup>33</sup>.

### 8.1 Macronutrients

#### 8.1.1 Energy

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

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

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

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

### Conclusion

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

<sup>33</sup> WHO. *Technical note: supplementary foods for the management of moderate acute malnutrition in infants and children 6–59 months of age*. Geneva, World Health Organization, 2012.

[http://apps.who.int/iris/bitstream/10665/75836/1/9789241504423\\_eng.pdf?ua=1&ua=1](http://apps.who.int/iris/bitstream/10665/75836/1/9789241504423_eng.pdf?ua=1&ua=1)

**Recommendation 12**

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

**Energy****Draft Text**

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

**Energy Values**

Unit	Minimum	Maximum	GUL
Kcal/100g	520	550	-

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

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

**Conclusion**

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

**Recommendation 13**

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

**8.1.3 Proteins**

Dietary protein content and quality are of major importance in the treatment of malnourished children. If the content, quality, or availability is too low, it will limit growth and thereby recovery. If the intake is above the requirement, the surplus protein could be metabolized into energy, which is not an energy-efficient process. Too much protein could be a challenge for malnourished children because any surplus protein will be converted to urea, adding to the renal solute load<sup>34</sup>. Furthermore, too much protein might have a negative impact on appetite, which is especially harmful in malnourished children undergoing treatment<sup>35</sup>. In severe acute malnutrition, a high protein intake might compromise liver function. Cow's milk in F-100 formulation contains the protein amount of 28g/1000 kcal (11.2% of energy) and this amount is sufficient for rapid catch-up growth. The current recommendation is that protein should provide 10%-12% of the total energy.

<sup>34</sup> Golden MH. Proposed recommended nutrient densities for moderately malnourished children. Food Nutr Bull 2009;30: S267-343.

<sup>35</sup> Prentice AM. Macronutrients as sources of food energy. Public Health Nutr 2005; 8:932-9.



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

## Conclusion

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

### Recommendation 13

That CCNFSDU agree to the proposed protein values in RUTF.

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

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

### 8.1.3.1 Protein Quality

#### A. Review of the “50% of protein sources from milk products”

The 2007 Joint Statement recommended that “at least half of the proteins contained in the RUTF should come from milk products”. The 2016 eWG Members questioned the scientific justification of this statement and emphasized that PDCAAS and DIAAS should be the preferred methods to determine the quality of the protein. However other Members indicated that the statement “50% of protein sources from milk products” should not be removed from the nutritional composition of RUTF since there is no scientific evidence of RUTF with other protein source other than milk that have been demonstrated to be efficient for the management of SAM children. A study by Bahwere et al showed inferior recovery rates for product with less than 50% of protein from dairy source<sup>36</sup>. 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.<sup>37</sup>

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

<sup>36</sup>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 Clin Nutr](#). 2016.

<sup>37</sup> 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.

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

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

### Conclusion

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

### B. Evaluation of Protein Quality in RUTF

During the 2016 eWG, there was consensus amongst Members about the use of Protein Digestibility Corrected Amino Acid Score (PDCAAS) or Digestible Indispensable Amino Acid Score (DIAAS) as a measure of protein quality for the finished product as stipulated in the FAO Guidelines<sup>38</sup>. However, several Members indicated that the PDCAAS methodology has been recently criticized by FAO Expert Working group in preference of DIAAS since it is viewed as a more rigorous approach in determining protein quality. DIAAS values have not been established for all protein and therefore are not available for use at this stage. Although Members acknowledged that PDCAAS or DIAAS were the recommended methods to evaluate the dietary protein quality, several Members indicated that there are other methods. These methods include appropriate published data on digestibility of protein in potential RUTF ingredients, in combination with analysed or published amino acid composition to determine the PDCAAS or DIAAS could be used, as long as the ingredients in the foods mentioned in the published paper are in the same form as in the final RUTF product. A need for the determination of the PDCAAS and DIAAS score that would be appropriate for RUTF was proposed.

During the 38th session of CCNFSDU, the Representative of FAO confirmed that in the interim the PDCAAS method should be used as DIAAS was not yet completed. FAO would consider convening an expert consultation to provide guidelines. RUTF was added to the terms of reference of the expert consultation to develop guidelines in using PDCAAS methods.

### Conclusion

The Chairs will await the outcomes of the FAO Consultation on PDCAAS methods for RUTF. This will enable the eWG to make a decision on the determination of protein quality for RUTF.

#### Recommendation 14

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

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

<sup>38</sup>Report of an FAO Expert Consultation. Dietary protein quality evaluation in human nutrition. Rome, Italy. 2013.

### 8.1.4 Lipids/Fats

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

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

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

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

#### Conclusion

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

#### Recommendation 15

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

[Incorporation of fats and/or oils in RUTF serves to increase the energy density and the amount of essential fatty acids. At least 45% to 60% of energy derived from fat is desirable.

The level of linoleic acid should not be less than 576.9 mg per 100 kcal when used in the production of RUTF and should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.]

Fats/Lipids should provide 45%-60% of the total energy.

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

### 8.1.4.1 Essential fatty acids

The 2016 eWG Members were asked whether they were in support of reviewing and setting of minimum levels for essential fatty acids in RUTF. Recent evidence showed that the recommended content of omega 3 and omega 6 in RUTF such as Alpha Linoleic acid were not adequate<sup>39</sup>. It was noted that the current proposed range of 3% to 10% of energy for linoleic acid (LA, omega-6) was in line with other Codex texts but falls short of what was recently recommended by EFSA<sup>40</sup>. The current proposed range for alpha-linolenic acid (ALA, omega-3) also falls below the minimums established for ALA by other Codex texts and EFSA. A recommendation was made that LA and ALA should have specific minimums to help prevent essential fatty acid deficiency. A balance between LA and ALA is important to help maintain metabolic function and a balance between respective fatty acid derivatives specifically, arachidonic acid (ARA; 20:4 n-6) and docosahexaenoic acid (DHA; 22:6 n-3), respectively. In keeping with this concept it was proposed that a minimum ratio of LA:ALA of 5:1 and a maximum ratio of 15:1 also be considered. This ratio range would align RUTF with the current Codex Infant Formula Standard and the pending revisions to the Codex Follow-up Formula Standard.

There is scientific evidence that supports setting minimum levels for essential fatty acids in RUTF as highlighted in the study of Jones et al. (2015)<sup>41</sup> 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.

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

**Table 2: Essential Fatty acids recommendations from various Codex texts, EFSA and 2007 Joint Statement**

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

<sup>39</sup>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.

<sup>40</sup> 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.

<sup>41</sup> Ready-to-use therapeutic food with elevated n-3 polyunsaturated fatty acid content, with or without fish oil, to treat severe acute malnutrition: a randomized controlled trial. *BMC Medicine*. 13;93.2015

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

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

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

## Conclusion

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

### Recommendation 16

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

#### Essential Fatty acids values

Linoleic Acid = 3-10% of total energy

[The level of linoleic acid should not be less than 576.9 mg per 100 kcal]

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

[The level of alpha-linolenic acid should not be less than 57.69 mg per 100 kcal]

### 8.1.5 Setting Minimum and Maximum levels for vitamins and minerals for RUTF

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

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

## 9. Vitamins

### 9.1 Vitamin A

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

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

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

#### a. Setting a maximum/GUL for Vitamin A

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

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

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

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

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

### Conclusion

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

### Recommendation 17

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

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

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

## 9.2 Vitamin D

### Vitamin D Levels

Vitamin D is critical for metabolism of calcium for cartilage and bone maturation and linear growth catch-up. New evidence has been emerging that SAM children have a vitamin D deficiency. The eWG Members were requested to comment on the 2007 Joint Statement values for vitamin D during the First Consultation. There was no consensus amongst the eWG Members on the proposed minimum and maximum values for vitamin D as stipulated in the 2007 Joint Statement. Different views were expressed about the proposed values. Several Members commented that increasing the maximum slightly would allow for a safe overage level needed for the product to remain within specifications under the anticipated storage conditions and shelf life. This is due to the fact that the proposed maximum of 20 µg/100g may be exceeded if 15 µg/100 g of product is added in the vitamin premix, as some intrinsic Vitamin D can be provided from dairy sources. Some Members were of the opinion that the proposed maximum levels of Vitamin D were above the recommended dietary allowances for children from birth to 13 years, which might have serious side effects<sup>42</sup>.

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

<sup>42</sup><https://ods.od.nih.gov/factsheets/VitaminD-HealthProfessional/>

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

### Setting of Maximum or GUL for Vitamin D

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

### Conclusion

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

#### Recommendation 18

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

Unit	Minimum	Maximum	GUL
<sup>3</sup> µg/100 g	15	[20] OR [22]	[30]
<sup>3</sup> µg/100 kcal	2.7	[3.6] OR [4]	-
<sup>3</sup> 1 µg cholecalciferol = 40 IU vitamin D			

## 9.3 Vitamin E

### a. Vitamin E Levels

There was general support amongst the eWG Members on the current vitamin E values in the 2007 Joint Statement (CM=4, CO=5). However, one Member queried whether the proposed minimum value of 20 refers to mg tocopherol acetate (unit of expression in the 2007 Joint Statement) or α-tocopherol (the natural form and unit of expression as mg TE/ 100g), since a different value might result depending on the form of vitamin E used in the vitamin mineral premix. Therefore, it is important to clarify the unit of expression. Three Members were not supportive of the current values. Two Members expressed their concern that the proposed values were above the RDAs for children from birth to 13 years (4-7mg)<sup>43</sup>.

<sup>43</sup><https://ods.od.nih.gov/factsheets/VitaminE-HealthProfessional/>



### Vitamin E Forms and Conversion factors

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

\* 1 mg  $\alpha$ -tocopherol = 1 mg RRR- $\alpha$ -tocopherol (d- $\alpha$ -tocopherol)

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

#### b. Setting of Maximum or GUL

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

### Conclusion

Taking into consideration the views of the eWG Members the Chairs recommend that the current minimum value for vitamin E of 20 mg/100g (mg/100 kcal) be retained as stipulated in the 2007 Joint Statement, and the maximum/GUL not be defined. The Chairs note that the 2007 Joint Statement makes reference to the mineral mix recommended for F-100 by WHO as an example of a mineral mix with a suitable positive non-metabolizable base. The vitamin and mineral mix is indicated in Appendix 4 of the WHO guidelines<sup>44</sup>. The specific form of vitamin E recommended in the WHO guidelines is  $\alpha$ -tocopherol. Therefore, the minimum value of 20 refers to the  $\alpha$ -tocopherol form. The Chairs recommend that the conversion factors for both naturally occurring and synthetic forms of vitamin E be stipulated in the footnote to enable the correct calculation.

#### Recommendation 19

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

Unit	Minimum	Maximum	GUL
<sup>4</sup> mg/100 g	20	-	-
<sup>4</sup> mg $\alpha$ -TE /100 kcal	4	-	-
<sup>4</sup> 1 mg $\alpha$ -tocopherol = 1 mg RRR- $\alpha$ -tocopherol (d- $\alpha$ -tocopherol)			
<sup>4</sup> 1 mg $\alpha$ -tocopherol =2.00 mg <i>all-rac</i> - $\alpha$ -tocopherol (dl- $\alpha$ -tocopherol)			

## 9.4 Vitamin K

### Vitamin K values

There was general support by the eWG of the current values for vitamin K. Three Members were of the opinion that the proposed minimum and maximum values for Vitamin K were very high for infants from 0-12 months (2 – 2.5mcg)<sup>45</sup>. The current maximum value was also supported and a proposal was made that a higher value would be preferred to allow for process and analytical variation. One Member indicated that a GUL for vitamin K may not be necessary as there are no known toxic effects associated with high intakes of Vitamin K (excluding those on anti-coagulant medication whose INR levels are regularly monitored).

### Conclusion

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

<sup>44</sup> WHO. 1999WHO Management of severe malnutrition: A manual for physicians and other senior health workers. World Health Organization: Geneva.

<sup>45</sup><https://ods.od.nih.gov/factsheets/VitaminK-HealthProfessional/>

### 9.5 Vitamin B1

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

#### Conclusion

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

### 9.6 Vitamin B2

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

#### Conclusion

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

### 9.7 Vitamin C

There was widespread support amongst the eWG Members of the current values for vitamin C (CM=5, CO=5). There was general support not to include a maximum/GUL for vitamin C since it has minimal risk of toxicity and can be easily excreted by the body. Two Members indicated that the proposed values were above the RDAs for children from 0 to 8 years (25-40 mg)<sup>46</sup>. One Member recommended that a GUL be set for vitamin C.

#### Conclusion

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

### 9.8 Vitamin B6

The eWG Members were in support of the current minimum value for vitamin B6 (CM=5, CO=5). There was general support not to include a maximum/GUL for vitamin B6 since it has minimal risk of toxicity and can be easily excreted by the body. Two Members indicated that the proposed values were above the RDAs for children from 0 to 3 years 0.1 – 0.5 mg<sup>47</sup>. One Member recommended that a GUL be set for vitamin B6.

#### Conclusion

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

### 9.9 Vitamin B12

There was widespread support amongst the eWG Members of the current values for vitamin B12 (CM=5, CO=5). There was general support not to include a maximum/GUL for vitamin B12 since it has minimal risk of toxicity and can be easily excreted by the body. Two Members indicated that the proposed values were above the RDAs for children from 0 to 8 years (0.4 – 1.2mcg)<sup>48</sup>. One Member recommended that a GUL be set for vitamin B12.

#### Conclusion

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

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<sup>46</sup><https://ods.od.nih.gov/factsheets/Riboflavin-HealthProfessional/>

<sup>47</sup><https://ods.od.nih.gov/factsheets/VitaminB6-HealthProfessional/>

<sup>48</sup><https://ods.od.nih.gov/factsheets/VitaminB12-HealthProfessional/>

### 9.10 Folic Acid

Members were supportive of the current minimum value for folic acid at 200 µg/100 g (CM=6, CO=5). One Member suggested that a footnote to explain the conversion factor from µg folic acid to µg Dietary folate equivalents (DFE) be added for labelling purposes (i.e. 1 µg of folic acid = 1.7 µg of DFEs). Two Members were of the opinion that the proposed minimum value for folic acid for children between 0-3 years was above the RDAs (65 – 150 mcg DFE)<sup>49</sup>. Members did not support the setting of a maximum/GUL value as folic acid has a minimal risk of toxicity.

#### Conclusion

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

### 9.11 Niacin

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

#### Conclusion

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

### 9.12 Pantothenic Acid

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

#### Conclusion

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

### 9.13 Biotin

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

#### Conclusion

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

#### Recommendation 20

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

##### Vitamin K

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

##### Vitamin B1

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

<sup>49</sup><https://ods.od.nih.gov/factsheets/Folate-HealthProfessional/>

<b>Vitamin B2</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	1.6	-	-
mg/100 kcal	0.3	-	-
<b>Vitamin C</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	50	-	-
mg/100 kcal	9.6	-	-
<b>Vitamin B6</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	0.6	-	-
mg/100 kcal	0.12	-	-
<b>Vitamin B12</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
µg/100 g	1.6	-	-
µg/100 kcal	0.3	-	-
<b>Folic Acid</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
<sup>5</sup> µg/100 g	200	-	-
<sup>5</sup> µg/100 kcal	38.5	-	-
<sup>5</sup> 1 µg of folic acid = 1.7 µg of Dietary Folate Equivalents (DFE)			
<b>Niacin</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	5	-	-
mg/100 kcal	0.96	-	-
<b>Pantothenic Acid</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	3	-	-
mg/100 kcal	0.6	-	-
<b>Biotin</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
µg/100 g	60	-	-
µg/100 kcal	11.5	-	-

## 10. Minerals

### 10.1 Sodium

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

### Conclusion

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

## 10.2 Potassium

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

### Conclusion

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

## 10.3 Calcium

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

### Conclusion

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

## 10.4 Phosphorus

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

**Conclusion**

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

**10.5 Magnesium**

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

**Conclusion**

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

**10.6 Iron**

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

**Conclusion**

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

**10.7 Zinc**

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

**Conclusion**

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

**10.8 Copper**

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

**Conclusion**

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

**10.9 Selenium**

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

**Conclusion**

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

**10.10 Iodine**

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

**Conclusion**

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

<b>Recommendation 21</b>			
That CCNFSDU agree to the following recommendations for sodium, potassium, calcium, phosphorus, magnesium, iron, zinc, copper, selenium and iodine for RUTF as follows:			
<b>Sodium</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	-	290	-
mg/100 kcal	-	53	-
<b>Potassium</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	1,100	1,400	-
mg/100 kcal	212	255	-
<b>Calcium</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	300	[600] or [785]	-
mg/100 kcal	58	[109] or [143]	-
<b>Phosphorus</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	300	[600] or [785]	-
mg/100 kcal	58	[109] or [143]	-
<b>Magnesium</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	80	[140] or [235]	-
mg/100 kcal	15.4	[26] or [43]	-
<b>Iron</b>			

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

## 11. ADDITIONAL NUTRIENTS

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

One Member recommended that phytates should be limited and that a molar ratio in the finished product should be defined, even if the phytate content in raw materials is controlled. The following proposals were made with regard to a ratio: Phytate/Zinc <5 and Phytate/Iron <1<sup>50</sup>. However, it was reiterated by Members that the formulation of RUTF should be based on sound medical and nutritional principles and their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of SAM children.

### Conclusion

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

### Recommendation 22

<sup>50</sup> International Zinc Nutrition Consultative Group (IZiNCG) Technical Document #1, Assessment of the Risk of Zinc Deficiency in Populations and Options for Its Control, Christine Hotz and Kenneth H. Brown, guest editors. Food and Nutrition Bulletin, vol. 25, no. 1 (supplement 2) © 2004, The United Nations University. <http://izincg.org/files/izincgtechdocfnb2004.pdf>



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

## 12. CONTAMINANTS

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

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

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

In 2017 the Chairs proposed the draft text for this section. There was general support by the eWG Members on the proposed text and various comments were also proposed. One Member proposed that since there were no maximum levels (MLs) for RUTF in CODEX STAN 193-1995, the text in this section should refer to both the RUTF and the ingredients used in RUTF. It was also proposed that paragraph two on "Pesticides Residues" be deleted since the provisions of that paragraph are already covered by paragraph one which makes reference to Codex Maximum Residue Limits for Pesticides (i.e. the introductory text). This would assist in avoiding misinterpretation of the wording in both paragraphs. However, one Member suggested that the paragraph on "pesticides residues" should be retained.

### Aflatoxins maximum levels

Some Members in the 2017 eWG were of the view that the levels of aflatoxin for RUTF should be stipulated in the guidelines as per the 2007 Joint Statement recommendations, which recommend that aflatoxin levels in RUTF should not exceed 10ppb ( $\mu\text{g}/\text{kg}$ ) in order to minimize the risk of exposure to SAM children. Although CODEX STAN 193-1995 stipulates a maximum limit of 15  $\mu\text{g}/\text{kg}$  total aflatoxin for peanuts and other tree nuts used for further processing, this reference is applicable for the general population and may not be appropriate for children with SAM receiving RUTF as the main source of food for the treatment period of up to 8 weeks.

One Member reiterated that the section should not lay down specific levels, but should make a cross-reference to the levels provided by relevant CODEX texts (e.g. lead and aflatoxin M1 in milk) to ensure that the section remains up-to-date if those levels are revised in the future.

During the Second Consultation the Chairs requested the eWG Members on whether a statement should be included in the proposed text which stipulate the aflatoxins maximum level of 10ppb ( $\mu\text{g}/\text{kg}$ ) as indicated in the 2007 Joint Statement. There was no consensus amongst the eWG Members on whether the aflatoxins maximum level of 10ppb should be included in the proposed text.

Several Members indicated that the 2007 Joint Statement<sup>51</sup> stipulated that aflatoxins should not exceed 5 ppb, not 10 ppb as recommended in the Consultation Paper. Some Members also indicated that some development partners have stipulated a limit of less than 5ppb in their specifications for RUTF. Some Members proposed that the guidelines should make reference to the 2007 Joint Statement with regard to the MLs for aflatoxins. Some Members were of the view that a rationale was not provided for the recommended ML level of either 5 or 10 ppb and how it was established in the 2007 Joint Statement. Furthermore, the 2007 Joint Statement does not specify whether the ML level is for the total aflatoxin or aflatoxin M1. It would be beneficial for any adopted text to clearly indicate if the recommendation is for total aflatoxins or specific aflatoxins (e.g. aflatoxin M1).

<sup>51</sup>[http://www.who.int/nutrition/topics/Statement\\_community\\_based\\_man\\_sev\\_acute\\_mal\\_eng.pdf](http://www.who.int/nutrition/topics/Statement_community_based_man_sev_acute_mal_eng.pdf)

Several Codex MLs for aflatoxins exist in the *General Standard for Contaminants and Toxins in Food and Feed* (GSCTFF) (CODEX STAN 193-1995) for several types of ready-to-eat (RTE) tree nuts and other products such as milk. These include Aflatoxin M1 in milks (0.5 ppb); total Aflatoxin in Brazil nuts, almonds, pistachios, hazelnuts and peanuts intended for further processing (15 ppb); and total Aflatoxins in Brazil nuts, almonds, pistachios, hazelnuts when ready-to-eat (10 ppb). An ML for ready-to-eat peanuts is under development. However, the GSCTFF does not make any specific reference to specific maximum levels for aflatoxins in RUTF.

Some Members indicated that the question of whether the ML of 10 ppb ( $\mu\text{g}/\text{kg}$ ) for aflatoxins in RUTF or any other proposed ML is appropriate should be referred to Codex Committee on Contaminants in Food (CCCF) with the request to consider the appropriateness of setting MLs for aflatoxins in RUTF. A maximum level for aflatoxins in RUTF should be established taking into consideration the criteria for establishment of maximum levels in food and feed as stipulated in GSCTFF. Once the value is established and agreed to, it can be included in the GSCTFF and referenced as such. A concern was also raised on whether the ML of 10 ppb is appropriate for RUTF and whether the value meets the criteria of GSCTFF and a feasibility of establishing a sampling plan for RUTF, which is a product with different matrices as a result of a mixture of various raw materials.

### Conclusion

Although the eWG Members supported that the section should make reference to GSCTFF which stipulates a maximum limit of 15  $\mu\text{g}/\text{kg}$  total aflatoxin for peanuts and other tree nuts used for further processing, the Chairs note that none of the current Codex contaminant maximum levels (MLs) in the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) were set specifically to address SAM children receiving RUTF for the period of up to 8 weeks. While there is no evidence at this stage to suggest that the current MLs in the GSCTFF may not be suitable for SAM children, further consideration should be given to their applicability to this target group.

Furthermore, there has been no investigation of the risks of known contaminants within RUTF for SAM children, with specific reference to which contaminants to be controlled and their recommended limits. Further guidance on these issues is needed to provide guidance as to how best to protect the target group of RUTF, with specific reference to contaminants such as mycotoxins. The Chairs also note that RUTF that are produced locally and in various regions have different ML values for aflatoxins which range from 5 to 20  $\mu\text{g}/\text{kg}$ . The Chairs are of the view that these different MLs may not be appropriate for RUTF and may not be in line with the criteria of GSCTFF in establishing such limits.

The Chairs recommend that the aflatoxins maximum level of 10ppb as proposed by the eWG Members should not be included in the proposed text until a discussion is finalized on the best approach to handling possible contaminants in RUTF.

Noting the responses from the eWG Members, the Chairs are of the view that the Committee should further discuss the best approach in handling contaminants in RUTF. If the Committee decides to follow a pragmatic approach, the Chairs recommend a stepwise approach which could include, amongst others:

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

### 13. TECHNOLOGIES FOR AND EFFECT FOR PROCESSING

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

**Recommendation 23**

**23.1** that CCNFSDU agree not to include the aflatoxins maximum level of 10 ppb in the proposed text of the guidelines, until a best approach is agreed upon in handling contaminants in RUTF.

**23.2** that the Committee consider a stepwise approach which could include, amongst others:

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

**23.3** that the Committee agree to leave the proposed draft text for the "Contaminants" section in square brackets until a way forward is agreed upon in handling contaminants in RUTF.

**Draft text on Contaminants**

[It is recommended that the products covered by the provisions of these guidelines comply with the *General Standard for Contaminants and Toxins in Food and Feed* (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.

**Other Contaminants**

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

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

**Conclusion**

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

**Recommendation 24**

That CCNFSDU agree to the proposed text of " Technologies for and effect for processing" section of the Guidelines as follows:

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

**1. Preliminary Treatment of Raw Materials**

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

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

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

## 2. Milling

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

## 3. Toasting

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

## 4. Sprouting, Malting and Fermentation

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

## 5. Other Processing Technologies

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

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

## 14. GOOD MANUFACTURING PRACTICES AND GOOD HYGIENE PRACTICES

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

## Conclusion

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

### Recommendation 25

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

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

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

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

## 15. METHODS OF ANALYSIS AND SAMPLING

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

### Recommendation 26

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

It is recommended that methods of analysis and sampling of RUTF be in accordance with the *Recommended Methods of Analysis and Sampling* (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 other relevant Codex Alimentarius texts. When needed, specific methods of analysis should be developed in accordance with appropriate Codex Guidelines on Measurement Uncertainty (CAC/GL 54-2004), Protocol for the Design, Conduct and Interpretation of Method Performance Studies (CAC/GL 64-1995), and Harmonized IUPAC.

## 16. PACKAGING

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

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

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

## Conclusion

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

### 16.1 Packaging of RUTF into a single-use sachet

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

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

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

## Conclusion

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

### Recommendation 27

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

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

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

## 17. LABELLING

The 2016 eWG Members supported that the labelling of RUTF should be in accordance with the following existing Codex texts: *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (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), and *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) and Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985).

### 17.1 Mandatory Labelling Requirements Provisions and Mandatory "statements" for RUTF

In 2016 several Members indicated that a statement on breastfeeding should be included and all provisions of the International Code or WHA Resolutions and WHO recommendations, including WHA69.9 and 63.23 should be taken into consideration when labelling provisions are considered for RUTF. 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.

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

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

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

## 17.2 Additional Requirements for Labelling Purposes

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

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

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

## Conclusion

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

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

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

**Recommendation 28**

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

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

**The Name of the Food**

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

**List of Ingredients**

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

**Declaration of Nutritive Value**

~~The declaration of energy and nutrients on the label or in labelling shall contain the following information expressed per 100 grams of the Ready to Use Therapeutic Foods as sold or otherwise distributed as well as per feeding of the food ready for consumption:~~

- ~~(a) energy value, expressed in kilocalories.~~
- ~~(b) the amounts of protein, carbohydrates and fat, expressed in grams;~~
- ~~(c) the amounts of essential fatty acids, expressed in grams.~~
- ~~(d) the amounts of vitamins and essential minerals, expressed in metric units.~~
- ~~• Information on osmolality or osmolarity and on acid-base balance shall be given.~~
- ~~• In addition, information on the nature of the animal or plant proteins or protein hydrolysates shall be provided.~~

**Additional Mandatory Labelling Requirements**

**The following statements shall appear on the label of RUTF:**

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

**Instructions for use**

- The label should indicate clearly from which age the product is recommended for use. This age shall not be less than six months for any product.
- Feeding instructions shall be given; preferably accompanied by graphical presentations.
- [The product should be consumed within 24 hours after opening]



**18. Recommendations to CCFSDU**

The Chairs of the eWG have completed the task as per the programme of work. The main tasks for the eWG were to include a preamble to the RUTF guidelines to set the scene for the appropriate use of the RUTF, and also draft the texts for the different sections of the guidelines for the eWG Members' inputs. The Chairs also highlighted key areas that would still need further discussion or agreement by the Committee, to enable the eWG Members to finalize the guidelines. The Chairs of the eWG believe that the required tasks have been achieved. Significant amount of information has been gathered during the two rounds of consultations with the eWG Members and will form the basis for the finalization of the outstanding sections of the guidelines.

Following the discussions with the eWG Members, the Chairs propose that the Committee:

- Take note of the key recommendations as outlined in the report.
- Consider the proposed Draft Guidelines for RUTF (Appendix 1).
- Propose steps to address issues raised during the consultation with the eWG Members as outlined in the recommendations.

**PROPOSED DRAFT GUIDELINES FOR READY TO USE THERAPEUTIC FOODS (RUTF)****(STEP 3)****1. PREAMBLE**

The major objectives of the work of the Codex Alimentarius Commission are to protect the health of the consumer and ensure fair practices in the trade in food through the elaboration and harmonization of definitions and requirements for food. In order to realize this objective CAC developed a *Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions* (CAC/RCP 20-1979) embodying the principles of sound consumer protection. The objective of this code is to establish standards of ethical conduct for all those engaged in international trade in food or for those responsible for regulating food and thereby protecting the health of the consumers and promoting fair trade practices. It is within this context that all those engaging in the international trade in food with specific reference to Ready-To-Use Therapeutic Foods (RUTF) commit themselves to the provisions of the code.

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

Investing in prevention of SAM through sustainable measures and interventions is crucial. Such interventions could include the improvement of access to high quality food and safe water through improving water and sanitation systems, improved access to health care, and the effective promotion of exclusive breastfeeding for the first six months of a child's life combined with continued breastfeeding up to 24 months and beyond. Thus, preventive programmes have an immense job to do in the context of poverty, and in the meantime children who already are suffering from SAM need to receive appropriate treatment.

These guidelines should therefore be used in accordance with the 2007 Joint statement of the UN agencies on Community-based management of severe acute malnutrition<sup>1</sup>, relevant WHO Child Growth Standards<sup>2</sup>, WHO guidelines in the management of Severe Acute Malnutrition in infants and children<sup>3</sup>, the Global Strategy for Infant and Young Child Feeding<sup>4</sup>, the International Code of Marketing of Breastmilk Substitutes<sup>5</sup> and subsequent relevant WHA Resolutions on infant and young child feeding. These guidelines have been prepared for the purpose of providing an agreed upon approach to the requirements which underpin the production of, and the labelling and claims for, RUTF. The guidelines are intended to facilitate the harmonization of requirements for RUTF at the international level and may provide assistance to governments wishing to establish national regulations in this area. The guidelines are also intended for use as an instrument designed to avoid or reduce difficulties which may be created by diverging legal, administrative and technical approaches to RUTF and by varying definitions and nutrient compositions of RUTF. These guidelines can also be used, if applicable, by governments in case of international trade disputes. Governments and other users should ensure adequate provisions are made for competent technical experts for the appropriate use of these guidelines.

<sup>1</sup>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

<sup>2</sup>WHO. Child growth standards and the identification of severe acute malnutrition in infants and children, 2006  
A Joint Statement by the World Health Organization and the United Nations Children's Fund; Geneva: World Health Organization; 2009

<sup>3</sup>WHO. Guideline: *Updates on the management of severe acute malnutrition in infants and children*. Geneva: World Health Organization; 2013.

<sup>4</sup>WHO. *Global Strategy for Infant and Young Child Feeding*. Geneva: World Health Organization; 2003.

<sup>5</sup>WHO. *International code of marketing of breast-milk substitutes*. Geneva: World Health Organization; 1981.

## 2. PURPOSE OF THE GUIDELINES

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

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

## 3. SCOPE

The provisions of these guidelines apply to Ready to Use Therapeutic Foods for children from age 6 to 59 months with severe acute malnutrition. Ready-to-Use Supplementary Foods (RUSF), micronutrient supplements<sup>6</sup>, processed cereal based foods<sup>7</sup>, formulated complementary foods for older infants and young children<sup>8</sup>, canned baby foods<sup>9</sup> are not covered by these guidelines.

## 4. DESCRIPTION

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

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

## 5. RAW MATERIALS AND INGREDIENTS

RUTF are made of powdered or ground ingredients embedded in a lipid-rich matrix [e.g. paste and biscuit], resulting in an energy and nutrient-dense food. The following raw materials, many of which can be sourced locally, are suitable ingredients for the production of RUTF under the specified conditions given below. The formulation of RUTF shall comply with Section 3 of the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-1991).

### 5.1 Basic Raw Materials and Ingredients

#### 5.1.1 Milk and other Dairy Products

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

#### 5.1.2 Legumes and Pulses

Legumes and pulses, such as lentils, chickpeas, cowpeas, beans, peanut, sesame and other types of legumes and pulses must comply with the *Standard for Peanuts* (CODEX STAN 200-1995), *Code of Hygienic Practice for Groundnuts (Peanuts)* (CAC/RCP 22- 1979) and the *Code of Hygienic Practices for Low-Moisture Foods* (CAC/RCP 75-2015), and other relevant Codex Alimentarius text when used in the manufacturing of RUTF.

<sup>6</sup>*Guidelines for Vitamin and Mineral Food Supplements* (CAC/GL55-2005)

<sup>7</sup>*Standard for Processed Cereal-Based Foods for Infants and Young Children* (CODEX STAN 74-1981)

<sup>8</sup>*Guidelines on Formulated Complementary Foods for Older Infants and Young Children* (CAC/GL 8-1991)

<sup>9</sup>*Standard for Canned Baby Foods* (CODEX STAN 73-1981)

### 5.1.3 Fats and Oils

Fats and oils used in the manufacturing of RUTF must comply with the relevant Codex Alimentarius texts. Fats and oils are incorporated as technologically feasible for the purpose of achieving the energy density and providing essential fatty acids. Care must be taken to avoid oxidized fat which will adversely affect nutrition, flavour and shelf life. [The composition of fats and oils should allow for a product that flows during processing and ensures physical stability throughout the supply chain.

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

### 5.1.4 Cereals

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

### 5.1.5 Vitamins and Minerals

All added vitamins and minerals must be in accordance with the *Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CAC/GL 10-1979).

## 5.2 Other Ingredients

### 5.2.1 Available Carbohydrates<sup>1</sup>

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

Available carbohydrates must adhere to the relevant Codex Alimentarius texts.

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

<sup>1</sup>[Sucrose, vegetable starch, glucose, glucose syrup] should be the preferred carbohydrates in RUTF. Fructose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinised starches gluten-free by nature may be added].

### 5.2.2 Food Additives and Flavours

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

## 5.3 The Use of other Matrices in RUTF formulation

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

## 6. NUTRITIONAL COMPOSITION AND QUALITY FACTORS

### 6.1 Energy

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

### 6.2 Proteins

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

### 6.3 Fat

[Incorporation of fats and/or oils in RUTF serves to increase the energy density and the amount of essential fatty acids. At least 45% to 60% of energy derived from fat is desirable.

The level of linoleic acid should not be less than 576.9 mg per 100 kcal when used in the production of RUTF and should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.]

## 7. CONTAMINANTS

[It is recommended that the products covered by the provisions of these guidelines comply with the *General Standard for Contaminants and Toxins in Food and Feed* (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.

## Other Contaminants

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

## 8. TECHNOLOGIES FOR AND EFFECT FOR PROCESSING

### 8.1 Preliminary Treatment of Raw Materials

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

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

### 8.2 Milling

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

### 8.3 Toasting

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

### 8.4 Sprouting, Malting and Fermentation

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

## 8.5 Other Processing Technologies

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

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

## 9. MANUFACTURING PRACTICES AND GOOD HYGIENE PRACTICES

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

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

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

## 10. METHODS OF ANALYSIS AND SAMPLING

It is recommended that methods of analysis and sampling of RUTF be in accordance with the *Recommended Methods of Analysis and Sampling* (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 other relevant Codex Alimentarius texts. When needed, specific methods of analysis should be developed in accordance with appropriate *Guidelines on Measurement Uncertainty* (CAC/GL 54-2004), *Protocol for the Design, Conduct and Interpretation of Method Performance Studies* (CAC/GL 64-1995), and Harmonized IUPAC.

## 11. PACKAGING

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

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

## 12. LABELLING

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

### The Name of the Food

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

### List of Ingredients

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

### Declaration of Nutritive Value

~~The declaration of energy and nutrients on the label or in labelling shall contain the following information expressed per 100 grams of the Ready to Use Therapeutic Foods as sold or otherwise distributed as well as per feeding of the food ready for consumption:~~

- ~~(a) energy value, expressed in kilocalories.~~

- ~~(b) the amounts of protein, carbohydrates and fat, expressed in grams;~~
- ~~(c) the amounts of essential fatty acids, expressed in grams.~~
- ~~(d) the amounts of vitamins and essential minerals, expressed in metric units.~~
- ~~• Information on osmolality or osmolarity and on acid-base balance shall be given.~~
- ~~• In addition, information on the nature of the animal or plant proteins or protein hydrolysates shall be provided.~~

### **Additional Mandatory Labelling Requirements**

#### **The following statements shall appear on the label of RUTF:**

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

#### **Instructions for use**

- The label should indicate clearly from which age the product is recommended for use. This age shall not be less than six months for any product.
- Feeding instructions shall be given; preferably accompanied by graphical presentations.
- The product should be consumed within 24 hours after opening.

Table: Nutritional Composition for RUTF

<b>Energy</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
kcal/100g	520	550	-
<b>Protein</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
g/100g	12.8	16.2	-
g/100kcal	2.3	3.1	-
<b>Lipids</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
g/100g	26	37	-
g/100kcal	5	6.7	-
<b>n-6 Fatty acids</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
g/100g	3	10	-
mg/100kcal	576.9	1818.2	-
<b>n-3 Fatty acids</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
g/100g	0.3	2.5	-
mg/100kcal	57.69	454.5	-
<b>Vitamin A</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg RE/100g	0.8	[1.1] OR [1.2]	-
mg/ RE/100kcal	0.15	[0.2] OR [0.22]	-
<sup>2</sup> µg RE/100kcal	150	[200] OR [220]	-
<sup>2</sup> 1µg RE = 3.33 IU Vitamin A = 1 µg trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.			
<b>Vitamin D</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
<sup>3</sup> µg/100 g	15	[20] OR [22]	[30]
<sup>3</sup> µg/100 kcal	2.7	[3.6] OR [4]	-
<sup>3</sup> 1 µg cholecalciferol = 40 IU vitamin D			
<b>Vitamin E</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
<sup>4</sup> mg/100 g	20	-	-
<sup>4</sup> mg α-TE /100 kcal	4	-	-
<sup>4</sup> 1 mg α-tocopherol = 1 mg RRR-α-tocopherol (d-α-tocopherol)			
<sup>4</sup> 1 mg RRR-α-tocopherol = 2.00 mg <i>all-rac</i> -α-tocopherol (di- α-tocopherol)			
<b>Vitamin K</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>



µg/100 g	15	30	-
µg/100 kcal	2.9	5.5	-
<b>Vitamin B1</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	0.5	-	-
mg/100 kcal	0.1	-	-
<b>Vitamin B2</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	1.6	-	-
mg/100 kcal	0.3	-	-
<b>Vitamin C</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	50	-	-
mg/100 kcal	9.6	-	-
<b>Vitamin B6</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	0.6	-	-
mg/100 kcal	0.12	-	-
<b>Vitamin B12</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
µg/100 g	1.6	-	-
µg/100 kcal	0.3	-	-
<b>Folic Acid</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
<sup>5</sup> µg/100 g	200	-	-
<sup>5</sup> µg/100 kcal	38.5	-	-
<sup>5</sup> 1 µg of folic acid = 1.7 µg of Dietary Folate Equivalents (DFE)			
<b>Niacin</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	5	-	-
mg/100 kcal	0.96	-	-
<b>Pantothenic Acid</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	3	-	-
mg/100 kcal	0.6	-	-
<b>Biotin</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
µg/100 g	60	-	-
µg/100 kcal	11.5	-	-
<b>Sodium</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>

mg/100 g	-	290	-
mg/100 kcal	-	53	-
<b>Potassium</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	1,100	1,400	-
mg/100 kcal	212	255	-
<b>Calcium</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	300	[600] or [785]	-
mg/100 kcal	58	[109] or [143]	-
<b>Phosphorus</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	300	[600] or [785]	-
mg/100 kcal	58	[109] or [143]	-
<b>Magnesium</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	80	[140] or [235]	-
mg/100 kcal	15.4	[26] or [43]	-
<b>Iron</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	10	14	-
mg/100 kcal	1.9	2.6	-
<b>Zinc</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	11	14	-
mg/100 kcal	2	2.6	-
<b>Copper</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
mg/100 g	1.4	1.8	-
mg/100 kcal	0.27	0.33	-
<b>Selenium</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
µg /100 g	20	40	-
µg /100 kcal	4	7	-
<b>Iodine</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
µg /100 g	70	140	-
µg /100 kcal	13.46	25.5	-
<b>Moisture Content</b>			
<b>Unit</b>	<b>Minimum</b>	<b>Maximum</b>	<b>GUL</b>
Percentage(%)	-	2.5	-

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