CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 8 **CX/NFSDU 16/38/9-Add.1**

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

Thirty-eighth Session

Hamburg, Germany

5 – 9 December 2016

PROPOSED DRAFT GUIDELINE FOR READY-TO-USE THERAPEUTIC FOODS

Comments of Brazil, Canada, Colombia, Cuba, Ecuador, El Salvador, Paraguay, Philippines, ELC, HKI, IACFO, IBFAN, IDF, ISDI and UNICEF

BRAZIL

General Comments

Brazil appreciates the work done by South Africa, Senegal and Uganda and thanks for the opportunity to present the following comments about the proposed draft guideline for Ready-to-Use Therapeutic Foods.

Specific Comments

Recommendation 1

PURPOSE

Brazil agrees with the proposed structure of the purpose.

However, with regard to the target population of RUTF, we understand that the text should make reference to older infants, and not only children, as the product is intended to individuals from 6 to 59 months.

Thus, we suggest the following amendments:

To provide guidance on technical and nutritional aspects of the production of Ready to Use Therapeutic Foods for **older infants and** 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

Recommendation 2

SCOPE

Brazil understands that the scope should include a need for governments to ensure that relevant WHA resolutions were fully implemented to be in line with the text in CAC/GL 8-1991. We also understand that the text should make reference to older infants, and not only children, as the product is intended to individuals from 6 to 59 months.

We highlight that the title of the CAC/GL 8-1991 should be corrected in order to refer to “older infants” and not “older children”.

Moreover, we suggest including a reference or a definition for Ready-to-Use Supplementary Foods (RUSF) in the text for purposes of clarification about which types of products are considered RUSF.

Thus, we suggest the following amendments:

The provisions of these guidelines apply to Ready to Use Therapeutic Foods for **older infants and** children from 6 to 59 months with severe acute malnutrition. Ready-to-Use Supplementary Foods (RUSF)[x], micronutrient supplements, processed cereal based foods[6], formulated complementary foods for older ~~children~~ **infants** and young children[7], canned baby foods[8] are not covered by these guidelines. These guidelines should

be used in accordance with the 2007 Joint Statement of the UN Agencies[9], 2013 WHO document on Updates on the Management of Severe Acute Malnutrition in infants and children[10], **Global Strategy for Infant and Young Child Feeding WHA 55.25 (2002) and the recommendations of World Health Assembly resolution 63.14 (2010)**, or any other relevant upgrade of the latest version.

[X]reference or definition for RUSF.

Recommendation 3

DESCRIPTION

With regard to the description, Brazil understands that the description should make reference to older infants as the product is intended to older infants from 6 months.

In relation to the second sentence ('These foods should be soft or crushable and should be easy for **young children** to eat without any prior preparation'), we ask clarification for mentioning only 'young children' as the product is intended for older infants and children from 6 to 59 months. The definition of young children (12 to 36 months) does not cover nor infants from 6 months neither children from 36 to 59 months.

Thus, we suggest the following amendments:

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

Recommendation 4

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

Recommendation 5

With regard to the use of other matrices for RUTF formulation, Brazil agrees that section 3 of the CODEX STAN 180-1991 may be used as a reference for further discussion.

We are of the opinion that the guidelines should allow the use of other ingredients provided that there is scientific evidence to support the effective delivery of the nutritional requirements for the target group.

We would like to mention the study of Ryan et al. (2014)[1], which evaluated a comprehensive linear programming (LP) tool to create novel RUTF formulations for Ethiopia. According to this study, palatable final formulations contained a variety of ingredients, including fish, different dairy powders, and various seeds, grains, and legumes. We also point out the study of Bahwere et al. (2014)[2] which tested the effectiveness in treating severe acute malnutrition (SAM) of a new RUTF formulation WPC (Whey protein concentrate)-RUTF.

[1]Ryan, K N et al. A comprehensive linear programming tool to optimize formulations of ready-to-use therapeutic foods: an application to Ethiopia. *Am J Clin Nutr*, 2014;100:1551–8.

[2]Bahwere et al. Effectiveness of milk whey protein-based ready-to-use therapeutic food in treatment of severe acute malnutrition in Malawian under-5 children: a randomised, double-blind, controlled non-inferiority clinical trial. Maternal & Child Nutrition, 10, pp. 436–451, 2014.

Recommendation 6

With regard to the raw materials and ingredients, Brazil suggests excluding the second and third sentences of the first paragraph. We think that a guideline should not emphasize specific ingredients. In relation to the third sentence, we understand that the concept is captured by section 4.3.

In relation to section 4.1, we suggest replacing "Milk and other Dairy Products" for "Animal Source Foods" in order to allow the extent of use of locally available ingredients and to align with CAC/GL 8-1991. Animal source foods such as meat, fish, poultry, eggs, milk and milk products are nutrient dense and good sources of high quality proteins and micronutrients.

We would like to mention the study of Ryan et al. (2014)[1] which evaluated a comprehensive linear programming (LP) tool to create novel RUTF formulations for Ethiopia. According to this study, palatable final formulations contained a variety of ingredients, including fish, different dairy powders, and various seeds, grains, and legumes.

We also suggest including fruits and vegetables which are mentioned in CAC/GL 8-1991.

Thus, we suggest the following amendments:

RAW MATERIALS AND INGREDIENTS

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

4.1 Basic Raw Materials and Ingredients

4.1.1 ~~Milk and other Dairy Products~~ **Animal Source Foods**

4.1.2 Legumes and Pulses

4.1.3 Fats and Oils

4.1.4 Cereals

4.1.5. Fruits and Vegetables

4.1.~~5~~ 6 Vitamins and Minerals

4.2 Other Ingredients

4.2.1 Digestible Carbohydrates

4.2.2 Food Additives and Flavours

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

4.2.3 [Other Nutritional Ingredients]

4.3 The Use of other Matrices in RUTF formulation

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

Recommendation 7

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

Recommendation 8

Brazil agrees that CCNFSDU consider reviewing the existing minimum levels and setting up of maximum levels for selected nutrients for RUTF.

Recommendation 9

Brazil agrees that CCNFSDU consider revising and setting of the minimum and maximum levels of the essential fatty acids for RUTF based on the available scientific evidence.

We would like to point out that there is scientific evidence that supports setting minimum levels for essential fatty acids in RUTF as for example the study of Jones et al. (2015)[3] 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 severe acute malnutrition (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. Clinical and growth implications of revised formulations need to be addressed in large clinical trials.

According to Brenna et al. (2015)[4], the results of two small studies (Hsieh et al., 2015[5]; Jones et al., 2015) are consistent with well-established effects in animal studies and highlight the need for basic and operational research to improve fat composition in support of omega-3-specific development in young children as RUTF use expands.

[3] Jones et al. 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* (2015) 13:93.

[4] Brenna et al. Balancing omega-6 and omega-3 fatty acids in ready-to-use therapeutic foods (RUTF). *BMC Medicine* (2015) 13:117.

[5] Hsieh JC et al. High oleic ready-to-use therapeutic food maintains docosahexaenoic acid status in severe malnutrition: a randomized, blinded trial. J Pediatr Gastroenterol Nutr. 2015.

Recommendation 10

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

Recommendation 11

Brazil understands that the Committee should await the finalization of the DIAAS values for RUTF.

Recommendation 12

Brazil thinks that the inclusion of the statement "at least 50% of protein provided by milk products" should be better discussed by CCNFSDU. We think that the quality of the protein should be measured by using the latest available methods as recommended by FAO (PDCAAS or DIAAS).

Recommendation 12

Brazil agrees that the Committee consider the best approach in identifying the possible contaminants and consider the proposed contaminants for discussion.

Recommendation 17

Brazil agrees that CCNFSDU consider further discussion on the packaging of RUTF products to ensure that packaging survive at least as long as the stated shelf life of the products so that risk is reduced to a minimum.

Recommendation 19

Brazil agrees that the Committee consider the proposed Codex texts to inform the labelling provisions for RUTF for discussion. We also agree that the Committee should discuss the approach that the eWG should follow in determining the mandatory statements that should be included in the labelling requirements for RUTF.

With regard to **recommendations 13 to 16 and 18**, Brazil will await further discussion to send specific comments.

CANADA

GENERAL COMMENTS

Canada thanks South Africa, Senegal and Uganda for chairing the eWG and preparing the proposed draft guideline and recommendations for the use Ready to Use Therapeutic Foods (RUTF) in the management of severe acute malnutrition (SAM), for consideration by the Committee.

Canada supports the Proposed Draft Guidelines for RUTF, as per Appendix 1. Canada generally supports the 19 recommendations with specific comments/ amendments regarding sections 2.2 and 2.5.4 and 2.5.5

SPECIFIC COMMENTS

2.2 SCOPE

Recommendation 2

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

Canada is proposing the following changes to the scope; please see the suggested wording below.

SCOPE

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

2.5.4 Measuring protein quality

Recommendation 11

Canada could support the use of a protein quality score method to determine acceptable protein quality in new RUTFs instead of having a minimum % protein from milk. DIAAS would be preferable but it is not ready for adoption due to a lack of acceptable data on ileal digestibility. In the meantime, a decision could be made to use PDCAAS on an interim basis until DIAAS is ready to be used. Once data is available to apply DIAAS, the

standard should be updated to replace PDCAAS with DIAAS. This should be noted in the standard, possibly as a footnote.

Along with a decision to use a scoring method, a decision is also needed on the target score for RUTF. A PDCAAS score of 1 or a DIAAS score of ≥100 is considered optimum in the dietary assessment of healthy populations above 0.5 years of age. While a score of 1 could be the target for achieving protein quality in RUTFs, the amount of protein could be increased to compensate for a formula with a lower protein quality, to a degree. The exact degree of compensation that is possible needs to be determined by experts in this field along with the setting of appropriate minimum and maximum amounts of protein.

Another consideration is that different optimal reference amino acid scoring pattern might be applicable for RUTFs, which are intended for children with SAM (Briend *et al*, 2015)[1]. A DIAAS (or PDCAAS if still in use) specifically based on the reference amino acid scoring pattern for children with SAM should be adopted once such a pattern is determined.

In addition, Canada would like to reiterate that while methods such as PDCAAS or DIAAS could be used to evaluate the dietary protein quality of a RUTF formulation as a first step (once a target score is agreed upon), the new RUTF product should then be tested in a clinical setting to ensure that the new product is effective in children with SAM.

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

Recommendation 12

As noted above, Canada suggests that the Committee consider using a target score with either PDCAAS or DIAAS to determine acceptable protein quality in new RUTFs, instead of setting a minimum amount of protein from milk products. While we support the wording outlined above if the reference to protein from milk products is retained, we note that using a target score, rather than a minimum milk protein requirement, allows for greater flexibility in the formulation of products with available and possibly less expensive ingredients. We also have a question about how the minimum of 50% of protein from milk products was reached.

We understand that the 2007 Joint Statement by the WHO, WFP, SCF and UNICEF[2] states that "at least half of the proteins contained in the foods should come from milk products". However, we note a discrepancy between the recommended requirement of "50% of protein provided by milk products" and the fact that the standard peanut paste-based RUTF used in the study by Manary, 2005[2] and Bahwere *et al*, 2015[3], appears to contain closer to 60% of protein provided by milk products (calculated value). We would like to know the scientific rationale for referencing at least 50% of the proteins from milk products rather than a higher value.

As a secondary concern, since the two main protein sources (peanuts and milk) suggested or required for RUTF are food allergens, it may be helpful to consider developing an alternative for individuals who are allergic to milk and/or peanut. The document in its present form does not seem to mention this secondary concern. While allergies only affect a small percentage of the overall population, they are more common in children than adults, particularly milk allergy as it is often outgrown. Some of the more obvious alternative protein choices like soy or eggs are also priority allergens; therefore, the Committee might want to consider if other viable alternatives exist.

COLOMBIA

COMMENTS:

Colombia would like to thank South Africa, Senegal and Uganda for the work carried out on the draft and make two general comments:

1. The first is related to the term malnutrition, as this term refers to both an excess and a deficit, i.e. it is used to refer to both obesity and undernourishment. Therefore, Colombia proposes that in this draft the term undernourishment be used rather than malnutrition for the age group that it addresses.

2. The second general comment is that there are various translations of the Spanish version of the document. Colombia therefore suggests that the chairs review the Spanish version of the document in detail.

Recommendation 1: Colombia recommends that in Methods of Analysis and Sampling, the section be developed by the CCMAS or that it be taken from the corresponding standard with the aim of issuing a specific request and not referring to a corresponding chapter.

[1] Briend A, Akomo P, Bahwere P, De Pee S, Dibari F, Golden MH, Manary M, Ryan K, Developing food supplements for moderately malnourished children, 2015

[2] Community-Based Management of Severe Acute Malnutrition, A Joint Statement by the World Health Organization, The World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children's Fund. 2007

Recommendation 2: Colombia agrees with the scope of application.

Recommendation 3: Colombia proposes:

DESCRIPTION

1. For the purpose of greater clarity of the translation the following corrections should be made:

Ready-to-Use Therapeutic Foods (RUTF) are energy-rich foods for special ~~medicinal~~ **medical** (by translation) purposes that have been enriched and are ready to use and that help in the ~~dietary~~ **nutritional** treatment of children ages six to 59 months with severe acute malnutrition. These foods should be bland, ~~grindable~~ **chewable** and easy for small children to eat without the need for prior preparation.

2. Change the term malnutrition to undernourishment, as the former is used for both an excess and a deficit of calories.

In addition, it is proposed that two z-scores below the median WHO growth patterns be used and that the mid-upper arm circumference be changed to 11.5 cm.

Severe acute ~~malnutrition~~ **undernourishment** is defined as a relationship between weight and height of less than three z-scores below the median WHO growth patterns, or a median mid-upper arm circumference of less than 11.5 cm or 115 mm, or the presence of a bilateral edema.

Recommendation 4: Colombia supports the work and subsequent debate to decide on the most appropriate focus for regulating the use of food additives in RUTF 13.1, 13.2 and 13.3 in agreement with the CCFA.

13.1 in the case of infant formula and the category

13.2 in the case of complementary foods for infants and young children

13.3 dietary foods for special medicinal uses

Recommendation 5: Colombia agrees with the inclusion of the following text:

“The formulation of foods for special medical purposes should be based on sound medical and nutritional principles. Their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended.”

Recommendation 6: Colombia does not agree with the suggestion in Recommendation 6.

Colombia proposes that it be consistent with section 2.4 in terms of the main ingredients, such as ground peanuts, milk products, sugar, vegetable oil, vitamins and minerals, as follows:

4.1. Basic raw materials and ingredients

4.1.1 Milk and milk products

4.1.2 Peanuts

4.1.3 Vegetable oils

4.1.4 Sugars

4.1.5 Vitamin and mineral premix

4.1.6 Other ingredients

4.1.7 Food additives and flavours

4.1.8 Emulsifying agents

Recommendation 7: Colombia agrees with the recommendation to review the current nutritional composition of RUTF in order to adapt them to the most recent scientific evidence and to amend the conversion factors to adapt them to the International System of Units conversion factors and conventional rounding.

Recommendation 8: Colombia agrees with the recommendation to review the existing minimum levels and to establish maximum levels for the nutrients selected for RUTF.

Recommendation 9: Colombia agrees with the recommendation to review the minimum and maximum levels of essential fatty acids in RUTF based on the available scientific evidence and the appropriateness of establishing new minimum and maximum levels.

Recommendation 10: Colombia agrees with the recommendation to examine the benefit of adding essential nutrients to the composition of RUTF, provided that there is scientific justification for doing so.

Recommendation 11: Colombia agrees with the recommendation to wait for finalization of the DIAAS values for RUTF.

Recommendation 12: Colombia offers the following comment, based on the permitted ingredients as outlined in the foregoing sections:

"at least 50% of the protein provided by milk and/or other milk products".

Recommendation 12: Colombia agrees with the recommendation that the Committee consider the best approach in identifying the possible contaminants and consider the proposed contaminants for discussion based on the target group.

Recommendation 13: Colombia agrees with the recommendation to consider the reference to section 5.2.2. "specific process step" of the CAC/RCP 75-2015 to accommodate the use of other technologies for microbial reduction in RUTF products.

Recommendation 14: Colombia agrees with the recommendation that the provisions of the Code of Practice and the FAO/WHO report on the microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition (2016) be followed; and that they be put forward for consideration and discussion by the Committee.

Recommendation 15: Colombia agrees with the recommendation that the provisions of the Code of Practice and the FAO/WHO report on the microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition (2016) be followed; and that they be put forward for consideration and discussion by the Committee.

Recommendation 16: Colombia agrees with the recommendation that the provisions of the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999) (in English), the General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995) (in English), the Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CAC/GL 21-1997), the Code of Hygienic Practice for Low-Moisture Foods (CAC/RCP 75-2015), and the report by the FAO/WHO on the microbiological safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition (2016) be followed; and that they be put forward for consideration and discussion by CCNFSDU.

Recommendation 17: Colombia agrees with recommendation to discuss the packaging of RUTF products to ensure that the packaging survives at least as long as the stated shelf life of the products so that risk is reduced to a minimum.

Recommendation 18: Colombia agrees with the recommendation that there be further discussion by the eWG and various stakeholders involved in the distribution of RUTF with regard to the packaging of RUTF in single-use packets.

Recommendation 19: Colombia supports a discussion regarding the approach that the eWG should follow in determining the mandatory statements that should be included in the labelling requirements for RUTF.

CUBA

Cuba agrees and does not have any additional comments.

ECUADOR

General comment

Ecuador generally supports the Proposed Draft Guideline for Ready-To-Use Therapeutic Foods (RUTF), as it takes account of:

minimum requirements, including appropriate ingredients in RUTF.

- Nutritional composition based on the adoption of the nutritional composition of RUTF as specified in the 2007 Joint Statement by WHO, WFP and UNICEF, among other organizations.
- Hygienic practice for production, handling, processing, storage and distribution and associated microbiological criteria for RUTF with reference to the General Principles of Food Hygiene and other relevant Codex texts.

However, it is including the following comments:

Specific comments

Comment no. 1

SECTION 4, RAW MATERIALS AND INGREDIENTS should be amended to include the following:

In general, the main ingredients are ground peanuts, dairy products, sugar, vegetable oil, vitamins and minerals **or other country-specific ingredients whose composition makes them high energy and nutritional.**

Comment: It is considered necessary to add the last phrase to the first paragraph because each country may have different raw materials or ingredients that are unique to their geographic location and that have scientific information regarding their energy and nutritional content.

Comment no. 2

It is suggested that Section **9, METHODS OF ANALYSIS AND SAMPLING** include as a sampling reference the codex document: *General Guidelines on Sampling (CAC/GL 50 -2004)* The following paragraph is proposed:

It is recommended that the methods of analysis and sampling of RUTF follow **the *General Guidelines on Sampling (CAC/GL 50 - 2004)***, *Recommended Methods of Analysis and Sampling* (CODEX STAN 234-1999), the *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), the *Code of Hygienic Practice for Low-Moisture Foods* (CAC/RCP 75-2015), and the report by the FAO/WHO on the microbiological safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition (2016).

Comment: It is considered important to include as a reference the codex document on the *General Guidelines on Sampling* (CAC/GL 50 -2004), as this document indicates that it is necessary to have sampling plans that ensure that fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard.

Comment no. 3

It is suggested that Section **10, PACKAGING** indicate the name of the Codex standard that might apply. The following text is proposed:

Special attention will be paid to the packaging material of RUTF, which shall comply with the provisions of the texts of the Codex, **such as, for example, the General Principles of Food Hygiene, CAC/RCP 1-1969, Rev (1997)** and other applicable international standards. This section will also cover primary and secondary labelling.

Comment: Include as a reference the General Principles of Food Hygiene CAC/RCP 1-1969, Rev. (1997), as this document provides the general guidelines for packaging, which state:

Packaging design and materials should provide adequate protection for products to minimize contamination, prevent damage, and accommodate proper labelling. Packaging materials or gases where used must be non-toxic and not pose a threat to the safety and suitability of food under the specified conditions of storage and use. Where appropriate, reusable packaging should be suitably durable, easy to clean and, where necessary, disinfect.

EL SALVADOR

Specific comments:

Recommendation 1: Support the proposed structure of the eWG for the purpose of the Guidelines for Ready-to-Use Therapeutic Foods (RUTF)

Recommendation 2: Support the proposed area of application for the eWG.

Recommendation 3: It is suggested that the term “severe acute undernourishment” be used in place of “severe acute malnutrition”, as the term malnutrition refers to both undernourishment and excess consumption of calories. It is recommended that the current Spanish version of the UNICEF glossary be used.

Recommendation 4: Support the idea that the CCNFSDU should examine the option of engaging in further discussions to determine the most appropriate focus for the use of food additives in RUTF.

Recommendation 5: Support the use of the text on the use of other materials for the formulation of RUTF in Section 3 of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991), which is as follows:

“The formulation of foods for special medical purposes should be based on sound medical and nutritional principles. Their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended.”

The comments on recommendations 6 to 19 will be sent later.

PARAGUAY

(i) General comments

We support the continued processing of the document, taking account of the importance of Ready-to-Use Therapeutic Foods in the treatment of severe acute undernourishment, which continues to be a problem even in developed countries, and their use to combat undernourishment due to scarcity.

(ii) Specific comments

3. DESCRIPTION

3.1. Ready-to-Use Therapeutic Foods (RUTF) are ~~energy-rich~~ foods for special medical purposes **that meet the energy requirements established in Table 1** that have been enriched and are ready to use and that help in the dietary treatment of children ages six to 59 months with severe acute malnutrition. These foods should be bland, grindable and easy for small children to eat without the need for prior preparation.

We think that the energy provided should be established in a clear manner, so it is better to refer to the table in which the maximum and minimum values have already been established. The concept "rich in energy" could be interpreted in different ways.

~~**4.2.3.** ***[Other nutritional ingredients]***~~

4.3. Use of other materials in the formulation of RUTF

[New formulations**]** ~~or~~ [~~new compositions~~] with other ingredients **permitted** for use in RUTF could be used, always in conformity with the provisions of Section 3 of the *Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-1991).

We propose the elimination of item **4.2.3 [Other nutritional ingredients]**, taking into account that the use of other nutritional ingredients has already been covered in item 4.3 **Use of other materials in the formulation of RUTF**.

Likewise, we propose the elimination of the phrase [new compositions] and the removal of the brackets around the phrase "new formulations", as it is more appropriate because it refers to potential new formulations, which is the expression used in the document, and to include the term "permitted".

6.2. [Pesticide residues]

6.3. [Veterinary drug residues]

6.4. [Heavy metals]

~~**6.5. [Radioactivity]**~~

~~**6.6. [Melamine]**~~

6.7. [Other contaminants]

We propose removing the brackets and eliminating items 6.5 and 6.6, as these can be established in item **6.7 Other contaminants**, in which countries can determine which ones are the most appropriate based on the origin of the raw material used.

PHILIPPINES

General Comments

The Philippines supports the Proposed Draft Guidelines on Ready to Use Foods and Recommendations 1 to 19 of the Electronic Workin Group. The proposed guidelines and EWG recommendations are consistent with the previous submitted Philippine positions on ready to use foods based on generally accepted scientifc evidence.

RATIONALE

Specific Comments

Recommendation 1

The Philippines supports Recommendation 1 on the structure of the Guidelines from nutritional composition to provisions for Packaging and Labeling. This structure covers the basic composition of a guidelines consistent with existing Codex texts and standards

Recommendation 2

We are in agreement with Recommendation 2 since the guidelines should be specific to RUTF and should state that non-RUTF products are excluded to provide clarity and avoid confusion.

Recommendation 3

We believe that inclusion of definitions for ready to use foods and severe acute malnutrition are critical in the guidelines to have common universal understanding of these terms. The definition for RUTF clearly describes this product and its intended uses and specific age group.

Recommendation 4

We are in agreement that the use of food additive in RUTF needs time for further discussion and decision.

Recommendation 5

The Philippines supports the adoption of the use of formulation of foods for special medical purposes and their qualifications since RUTF is considered as food for special medical purposes intended for the dietary management of severe acute malnutrition. It is important to include the above paragraph to clarify that the formulation of RUTF should have medical and nutritional basis and be clinically proven to be safe and beneficial for intended users. The findings of Oakely et al (2010) emphasized that clinical evidence should be considered before recommending any changes to the formulation of RUTF.

Recommendation 6

It is important to identify the basic composition of ready to use foods including other ingredients and the use of other forms of RUTF formulation. This basic composition was also identified in a scientific review (Wagh and Deore, 2014).The Philippines proposed the highlighted statement in the square brackets. It is critical to state the use of local foods and to take into account local food consumption patterns in the basic composition of RUTF for cost-effective and safe ingredients in combinations that meet international specifications. This is consistent with the decision in the 37th CCNFSDU Session.

Osendarp et al 92015) identified locally adapted formulations to include commodities such as chickpea, sesame, soybean, maize, and sorghum in East Africa; soy and whey permeate in Malawi rice-lentils or chickpeas in Bangladesh, Pakistan, and Ethiopia; and almonds in Afghanistan

Recommendation 7

The Philippines is in agreement with the review of the nutritional composition for RUTF consistent with the current scienific evidence including the WHO Recommendations (WHO, 2007, WHO, 2012) and to also considerthe conversion factors of International Standard Units. Manary (2006) demonstrated that RUTF meets the compositional requirement specified by the WHO for therapeutic food. According to Oakley et al (2010) considering the critical clinical status of children with SAM, any change in the composition of RUTF should be evaluated in a clinical trial before they are used on a widespread basis.

Recommendation 8

We are of the opinion that there is a need to review the existing minimum levels and formulate maximum levels ofselected nutrients for ready to use foods. Having the right amount of nutrients for RUTFis important to serve its intended use of addressing severe acute malnutrition. We believe that it will be relevant to wait for the WHO Scientific Review on the effectiveness of RUTF in considering the minimum and maximum levels of selected nutrients for RUTF.

Recommendation 9

We support the revising and setting the minimum and maximum levels of the essential fatty acids for RUTF based on the latest scientific evidence. The current formulation of ready to use foods do not meet the young children's requirement for polyunsaturated fatty acids.

Recommendation 10

We support inclusion of additional nutreints to ready to use foods provided there is sufficient scientific substantiation for it.

Recommendation 11

The Philippines supports this recommendation for the provision of clarification by CCNFSDU on the finalization of DIAAS or current existing methodology on protein quality be included.

Recommendation 12

We are in agreement to include the "at least 50% of protein provided by milk products" in the essential composition of ready to use foods to ensure protein sufficiency.

Recommendation 12

We support this recommendation that CCNFSDU identify the best option to specifiy possible contaminants and the proposed discussion. We propose that only contaminants which are critical in RUTF be included.

Recommendation 13

The Philippines supports inclusion of the use of other technologoes for microbial control in ready to use foods.

Recommendation 14

We suport that for consistency with relevant Codex texts and guidelines the hygienic practices for RUTF be in conformance with Code of Hygienic Practive for Low-Moisture Foods and General Principles of Food Hygiene.

Recommendation 15

It is important that to use the Code of Hygienic Practic for Low Moisture Foods and FAO/WHO Report on Microbial Safety of lipid-based RUTF to ensure the microbial safety of this type of product.

Recommendation 16

The Philippines support that the methods of analysis and sampling of RUTF be consistent with the relevant Codex texts and guidelines outlined in this recomendation to ensure accuracy and validation in testing read to use foods.

Recommendation 17

We support consideration of discussion in the CCNFSDU Session on packaging of ready to use foods to make sure apppropriateness and stability of packaging materials used in RUTF within its shelf life.

Recommendation 18

We are in agreement that detailed discussion be provided in considering the distriubution of ready to use foods contained in single-use sachet to ensure its suitability as packaging material.

Recommendation 19

We are of the opinion that considetation of the mandatory labeling information on the packaging of RUTF be considered for further discussion in the Session since this is an important part of the guidelines. Information provided to intended users or consumers of RUTF are critical for its use.

References

Manary MJ. Local production and provision of ready-to-use therapeutic food (RUTF) spread for the treatment of severe malnutrition. Food Nutr Bull.2006;**27**:S83–8.

Oakley E, Reinkin J, Sandige H, Trehan I, Kennedy G, Maleta K and Manary M, **A Ready-To-Use Therapeutic Food Containing 10% Milk Is Less Effective Than One with 25% Milk in the Treatment of Severely Malnourished Children.** J. Nutr.; **2010** vol. 140 no. 12 :**2248-2252**

Osendarp S, Rogers B, Ryan K, Manary M, Akomo P, Bahwere P, Belete H, Zeilani M, Islam M, FilippoDibari F, and de Pee S. Ready-to-use foods for management of moderate acute malnutrition: Considerations for scaling up production and use in programs; Food and Nutrition Bulletin (2015), vol. 36, no. 1 (supplement): S59-S64.

Wagh, VD and Deore, BR. Ready to Use Therapeutic Food (RUTF): An Overview. Advances in Life Sciences and Health; 2014.

WHO. Community-based management of severe acute malnutrition. Geneva (Switzerland): World Health Organization/World Food Programme/United Nations System Standing Committee on Nutrition/The United Nations Children's Fund; 2007.

WHO. Updates on the management of severe acute malnutrition in infants and children. Geneva (Switzerland); World Health Organization/World Food Programme/United Nations System Standing Committee on Nutrition/The United Nations Children's Fund; 2013. p. 1–123.

ELC - Federation of European Specialty Food Ingredients Industries

1. PURPOSE OF THE GUIDELINES (recommendation 1)

ELC supports the purpose as written, even though we firmly believe the other population above 59 months could benefit from consuming RUTFs in order to quickly recover from SAM.

2. SCOPE (recommendation 2)

ELC supports the scope as proposed by the chairs.

3. DESCRIPTION (recommendation 3)

ELC supports the description of RUTFs. In the definition of SAM, we believe that the brackets around “length” should be removed and the “or” before length should be replaced by “and/or”.

The definition of SAM would read as follows: . "*Severe Acute Malnutrition is defined as weight for height ~~(or length)~~**and/or length** less than –3 Z-score of the median WHO growth standards, or mid upper arm circumference (MUAC) <115 cm, or the presence of bilateral oedema."*

4. RAW MATERIALS AND INGREDIENTS

ELC supports **recommendation 4** as laid down in CX/16/38/9 regarding the approach for food additives. It's key to assess the current practices and define the best approach for food additives in RUTFs.

If indeed, the consensus is to consider these products as FSMPs, then there is a need for consistency and ELC believes that RUTFs should therefore be covered by the General standard for food additives and in particular category 13.3 (dietetic foods intended for special medical purposes). However, there may be some overlap also with CAC GL 8 1991 on formulated complementary foods for older infants and young children.

4.3 The Use of other Matrices in RUTF formulation

ELC believes that an important criteria is the palatability and ultimately the acceptability by the target population. This idea is from our point of view included in the current wording in square brackets included in the paragraph under "4. RAW MATERIALS AND INGREDIENTS " [*However other forms of RUTF with various ingredients are being tried and tested in different regions*].

In case the alternative wording as proposed in **recommendation 5** is included under point 4.3, we believe it should be amended in order to reflect the need for acceptability. One key element is that the children suffering SAM do really consume the products in order to recover as fast as possible. Therefore we suggest, should recommendation 5 be agreed upon, to amend it as follows:

"*The formulation of foods for special medical purposes should be based on sound medical and nutritional principles. Their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended*. ***Palatability and ultimately acceptability by the target population needs to be tested***".

If point 4.3. remains as is, we noted that the verb "are" is missing in the last sentence which should read *[New formulations] or [Composition] of RUTF with other ingredients may be used if they **are** formulated in accordance with Section 3 of the Standard for Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991).*

5. NUTRITIONAL COMPOSITION AND QUALITY FACTORS and Table 1: Nutritional Composition for RUTF

ELC believes that a typical serving size should be included. As far as we are aware, a typical serving size is 100 g which explains why the composition in the table above is expressed by 100 g. The amounts of nutrients which are needed to recover from SAM are the ones above. In case a smaller serving size would be proposed, it's important to ensure the right amount of nutrients is provided to this extremely vulnerable population.

The nutritional composition for **lipids** should be clarified as instead of giving the composition of n-6 and n-3 fatty acids families, it should be given as indicated in the amended Table 1 below (please see also comments linked to recommendation 9).

In addition, we support the inclusion of a ratio for LA:ALA with a minimum of 5:1 and a maximum of 15:1. This could be done through a footnote or directly in the table.

As indicated in our previous contribution, we also support the inclusion of the long-chain fatty acids from n-6 and n-3 families respectively as they bring specific benefits to this specific population who cannot synthetize them from the precursors (see amended table 1 below).

We also would like to comment on the composition for **proteins**, "10-12% total energy ([at least 50% of protein provided by milk products]) as we believe the restriction of 50% protein of milk products is restrictive and will stifle product innovation. We therefore recommend to revise the statement as written "at least 50% of protein provided by milk products" with a qualifier that other protein source other than milk proteins can be utilized in the case the same efficacies can be demonstrated by scientific evidence (please see also comments linked to recommendation 12).

We noticed that for **selenium**, the mention of "/100 g" is missing.

Nutritional Composition for RUTF Nutrients	Per 100g **(typical serving size)**
Energy	520-550 Kcal/100g
Proteins	10%-12% total energy (50% of protein sources from milk products**; other protein source other than milk proteins can be utilized in the case**

	the same efficacies can be demonstrated by scientific evidence)
Lipids	45%-60% total energy
~~n-6 fatty acids~~ Linoleic acid	3%-10% of total energy
Arachidonic acid	0.2-0.5% of total energy
~~n-3 fatty acids~~ Alpha-linolenic acid	0.3%-2.5% of total energy
Docosahexaenoic acid	**0.2-0.5% of total energy**
ratio for LA:ALA	**minimum of 5:1 and a maximum of 15:1**
Moisture content	2.5% maximum
Vitamin A RE	0.8-1.1 mg/100 g
Vitamin D	15-20 µg/100 g
Vitamin E	20 mg/100 g minimum
Vitamin K	15-30 µg/100 g
Vitamin B1	0.5 mg/100 g minimum
Vitamin B2	1.6 mg/100 g minimum
Vitamin C	50 mg/100 g minimum
Vitamin B6	0.6 mg/100 g minimum
Vitamin B12	1.6 µg/100 g minimum
Folic Acid	200 µg/100 g minimum
Niacin	5 mg/100 g minimum
Pantothenic acid	3 mg/100 g minimum
Biotin	60 µg/100g minimum
Sodium	290 mg/100g maximum
Potassium	1,100-1,400 mg/100 g
Calcium	300-600 mg/100 g
Phosphorus (excluding phytate)	300-600 mg/100 g
Magnesium	80-140 mg/100 g
Iron	10-14 mg/100g
Zinc	11-14 mg/100 g
Copper	1.4-1.8 mg/100 g
Selenium	20-40 µg**/100 g**
Iodine	70-140 µg/100 g

ELC supports **recommendation 7** that CCNFSDU consider reviewing the current nutritional composition for RUTF in line with the latest scientific evidence and also amend the conversion factors in line with the International Standard Unit conversion factors and conventional rounding.

Recommendation 8: We believe it is important to set minimum levels of nutrients, to safeguard efficacy. Maximum levels for RUTF products might not be needed for all nutrients since maximum levels are mainly relevant for long-term consumption whereas RUTF is usually given for only a short time frame.

With regards to the specific question on essential fatty acids as set in **recommendation 9**, as indicated in our comments to CP2, ELC strongly supports the setting of minimum and maximum for the following fatty acids: LA, ALA, DHA and ARA as well as a ratio between LA:ALA to harmonize with existing Codex standards and those undergoing revision.

The current Table does not provide adequate guidance regarding Essential Fatty Acids addition as it does not individually identify levels for each, but rather provides a broad range for the entire n-3 and n-6 families. More

specific data is available and should be considered (see suggested edits to Table above in bold text). Setting minimum levels for DHA and ARA is seen as critical as the conversion of LA and ALA to ARA and DHA is limited and the direct intake of ARA and DHA, and intake of DHA and ARA precursors (LA and ALA), is apparently compromised in these population groups (Michaelsen et al., 2011). Specifically, Forsyth and co-workers (2016) recently reported that "The key finding of this analysis of 76 developing countries is that the estimated daily intake of DHA and ARA in infants and young children between the ages of 6–36 months is significantly lower than current recommendations, and almost all of the countries in the developing world are failing to meet conservative recommendations of 100 mg/day for DHA and 140 mg/day for ARA." "The intake of ARA and DHA from complementary foods in the low income countries was almost negligible in several countries including Nepal, Bangladesh, Ethiopia and Rwanda" (Forsyth et al. 2016)

ELC supports **recommendation 10** on the addition of additional nutrients to the RUTF composition on condition that there is scientific justification for them.

References:

Forsyth et al., 2016. Estimated Dietary Intakes of Arachidonic Acid and Docosahexaenoic Acid in Infants and Young Children Living in Developing Countries. Ann Nutr Metab 2016;69:64–74.

Michaelsen 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 mcn_302 124..140 Maternal and Child Nutrition (2011), 7 (Suppl. 2), pp. 124–140.

Recommendation 12: We would kindly like to request a modification of the statement "at least 50% of protein provided by milk products" with the following statement "at least 50% of protein provided by milk products: other protein source other than milk products can be utilized in the case the same efficacies can be demonstrated by scientific evidence" in order to allow for innovation.

Under Section 2.5.5, "Review of the 50% of protein source and milk product" and Recommendation 12 on pp. 10 , the eWG chairs recommend the following wording for consideration: "At least 50% of protein provided by milk products." The recommendation as written will stifle product innovation by restricting RUTF formulations to minimum of 50% of protein from milk products. The most practical approach accounting for future developments in technological and ingredient innovations and advances in nutritional/clinical efficacy studies, it is important to revise the statement as written "at least 50% of protein provided by milk products" with a qualifier that other protein source other than milk proteins can be utilized in the case the same efficacies can be demonstrated by scientific evidence. Therefore we recommend revising the statement as follows, "at least 50% of protein provided by milk products: **other protein source other than milk products can be utilized in the case the same efficacies can be demonstrated by scientific evidence**." This will allow for ongoing and future product innovations in the pipelines using ingredient formulations that use protein sources such as milk products, cereals, legumes, amino acids and others that meets protein quality requirements for managing Sever Acute malnutrition (SAM). Furthermore, allowing other protein sources other than the minimum 50% of protein provided from milk products can address cultural and geographical acceptance by users of these products in developing countries and allow sustainable sourcing of plant based protein ingredients that can be used in the RUTF formulations.

HKI – Helen Keller International

SCOPE OF THE GUIDELINES under recommendation 2

We understood that RUTF was meant for dietary management of severe acute malnutrition with no medical complications as per the 2007 Joint statement. Yet the scope content does not mention the term "serious medical complications". We suggest consideration of the following phrasing: The provisions of these guidelines apply to Ready to Use Therapeutic Foods for treating children 6 to 59 months with severe acute malnutrition with no serious medical complications.

PROPOSED GUIDELINES FOR READY TO USE THERAPEUTIC FOODS (RUTF) (at STEP 3).

4.1 Basic Raw materials and Ingredients

Based on the following statement "*However other forms of RUTF with various ingredients are being tried and tested in different regions*" how flexible would the guidelines be in incorporating new evidence?

The term "Basic" seems vague and we fear this could create potential confusion. We suggest the guidelines clearly mention that: RUTF requires that each of the 5 food groups (Milk and other Dairy products, Legumes and Pulses, Fats and Oils, Cereals and Vitamins and Minerals) be present.

10. PACKAGING of RUTF in single-use sachets

We support point 70 under point 2.10.1. The daily RUTF ration is based on 92 g sachet adjusted to the child weight. We fear that any attempt for single-use sachets will bring more complexity and confusion at both

operational and producer levels. In addition, this may have cost implications which in turn could affect production capacity and therefore further limit access to RUTF.

Regarding the risk of contamination issue (point 71&72 under 2.10.1). It is not clear if this refers to bacterial contamination specifically? And/or contamination in general?

Research studies during the early development of RUTF showed bacteria cannot grow in RUTF due to low water activity in RUTF (not water-based food) limiting the risk of contamination. Is there any evidence documenting the risk of contamination once a sachet is open for few hours? We believe that the caregiver's role is central in handling and the use of RUTF including appropriate hygiene conditions. Therefore, the risk of contamination could be limited by strengthening instructions given to caregivers at point of use.

11.4 Mandatory statements.

Discussion on breastfeeding labelling

The 2013 WHO Updates on the Management of Severe Acute Malnutrition does acknowledge that breastfeeding should be continued *ad libitum*.

Table 1: Nutritional Composition for RUTF

It is not clear whether the nutrients profile refers to the product at time of production or any point of the shelf life of the product.

We have not commented on sections that refer to Codex standards/texts in place, as we believe they can pass as such.

IACFO - International Association of Consumer Food Organizations

The comments of IBFAN are supported by IACFO.

IBFAN - International Baby Food Action Network

IBFAN supported by IACFO.

General comments:

IBFAN is concerned that the proposed guideline places too much emphasis on a product-based approach to the treatment of malnutrition. We request that the committee considers:

- how to ensure that more sustainable and appropriate strategies to manage and prevent malnutrition are not undermined;
- how to ensure the efficacy and safety of RUTFs
- the appropriateness of Codex as a forum for the in depth discussion needed on this topic
- the risk of bias in the evidence base, promotion and use of RUTF.

1 Food Security

The first step in the sustainable management of malnutrition is to ensure the establishment of appropriate emergency preparedness protocols as are now used for breastmilk substitutes in emergencies.[3]

Strategies to improve access to food must aim to reduce dependence on quick fixes and improve food security in the long term. It follows that land and sea grabbing, deforestation and mono cropping that all too often undermine peoples' rights to food must be controlled and discouraged.[4]

Reports from IBFAN's global network demonstrate that the focus on production and distribution of products can divert attention away from and discourage recommended practices of optimal Infant and Young Child Feeding (IYCF) and the use of family foods that are invariably more sustainable, bio diverse, minimally processed and nutritious.

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[3] *Potentials, Experiences and Outcomes of a Comprehensive Community Based Programme to Address Malnutrition in Tribal India* Vandana Prasad* and Dipa SinhaPotentials, Experiences and Outcomes of a Comprehensive International Journal of Child Health and Nutrition, 2015, Vol. 4, No. 3 11

[4] **Landgrabbing** https://wd Dipa SinhaPotentials, Experiences and Outcomes of a Comprehensive International Journal of Child Health and Nutrition, 2015, Vol. 4, No. 3 11ww.youtube.com/watch?v=ieioj-036hA
May 11, 2015 The *world's farmland is at risk. Demand for land has soared as investors look for places to grow food for export, grow crops for biofuels or simply buy up land for profit. The film gives an inside look into the world of investors in the international agro-business and shows the consequences for families kicked off the land. Land Grabbing shows how "colonialism 2.0" works.* Script: Christian Brüser, Kurt Langbein http://www.langbein-partner.com/
European Union and the Global Landgrab: TNI/FIAN/IGO/FDCL paper.
https://www.tni.org/files/download/european_union_and_the_global_land_grab-a5.pdf

2 Lack of evidence of efficacy of RUTF

Since the 2014 CCNFSDU IBFAN and developing countries, including those targeted with programs based on RUTF, have been calling for evidence of the efficacy and safety of these products and whether they can provide the diversified diet children need. WHO's systematic review on the effectiveness and safety of RUTF formulations is yet to be reported. In 2014 CCNFSDU noted that *"…..it was premature to decide on the development of a Codex standard or guideline for RUTF. The Chairperson therefore suggested that the decision be postponed until the next session of the Committee when the review from WHO would be available and there would be a better basis for a decision."* The Guidelines should not be finalized before the WHO systematic reviews are reported.

Cochrane systematic reviews determined that evidence is limited regarding the benefits of RUTF compared to flour porridge as home treatment for severely malnourished children.[5]

3 The risks of using Codex to establish safeguards for therapeutic foods

Codex standards or guidelines are a compromise between the marketing needs of the food and drinks industries and the protection of public health and safety. A Codex instrument (a standard or guideline) that is weak on health protection can leave a government open to challenges (through WTO or other means) if it brings in more stringent legislation to control the nutrition content, quality, safety, marketing and trade of products. Any guideline should provide national governments with specific text that will help governments overcome such challenges.

The RUTF Guideline must reflect the intent of WHA 55.25 that urged Member States "*as a matter of urgency:(4) to ensure that the introduction of micronutrient interventions and the marketing of nutritional supplements do not replace, or undermine support for the sustainable practice of, exclusive breastfeeding and optimal complementary feeding…'*

It must consider a wide range of issues such as:

- the extent of the burden of SAM as well as the related mortality;
- the need for national and regional planning that responds to local needs;
- seasonal changes and circumstances;
- the importance of nutrition education (free from commercial influence) especially on complementary feeding and the support for exclusive and sustained breastfeeding;
- the use of bio-diverse, nutritious, minimally processed family foods;
- the impact of infections (malaria, diarrheal disease and parasites) – a major cause of malnutrition especially after 6 months of age;
- the cost of imported RUTF compared to family based food approaches and the appropriateness of diverting substantial development funds to their provision.

These broad social and ethical issues cannot be decided in fora where global commercial forces dominate, as they do in Codex. Any Codex guidelines must prevent RUTFs being used by the food industry to promote the notion that micronutrients are 'typically lacking' and 'hard to get' and that processed fortified foods invariably confer special health benefits. Such marketing obscures the fact that processing and storage can deplete nutrients and undermines confidence in family foods.

5 Categorizing RUTFs and RUFs as Foods for Special Medical Purposes (FSMP)

The categorizing of therapeutic products as 'Special Medical Purposes' will not provide protection from inappropriate use. The labelling and marketing requirements of the Codex Standard for FSMPs are ambiguous and inadequate.[6] Advertising to the general public is not the only concern. Promotional claims, NGO and agency fundraising appeals, press releases, donations can all be problematic. [7] [8]

6 Conflict of Interest

IBFAN is concerned that manufacturers of RUTF seem to have a disproportionate influence on the CCNFSDU discussion on RUTF and its efficacy. Historically the studies that were used to proclaim the "efficacy" of RUTF,

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[5] *Ready-to-use therapeutic food as home-based treatment for severely malnourished children between six months and five years old, Cochrane Database, June 2013 Anel Schoonees[1], Martani Lombard[2], Alfred Musekiwa[1, 3], Etienne Nel[4], Jimmy Volmink[1, 5, *]*

[6] Codex Standard For The Labelling of and Claims For Foods For Special Medical Purposes Codex Stan 180-1991

[7] www.plumpyfield.com,

[8] http://www.edesiaglobal.org/about-us/our-founders-story/

compared RUTF with *no interventions* [9] or interventions with *a corn or wheat soy blend* [10] or *F100.*[11] Studies showing the efficacy of family foods were not taken into consideration. [12]

(ii) Specific comments:

2.1 PURPOSE

Please add:

vii. **Instructions for use**

Rationale:

Since the guidelines are for the treatment of severe malnourished children it is critical that the purpose should include examination of the evidence that the use of RUTFs are suitable therapeutic foods for the treatment of older infants and young children suffering from malnutrition.

The purpose should include an examination of the quality of the evidence used as a basis for development of these guidelines – risk of bias (independence), safety, risk analysis of benefit versus harm, and a statement on the quality of evidence as well as an evidence based recommendation regarding the efficacy and safety of RUTFs – this should include the social and economic implications, and the monitoring of health outcomes and any unintended side effects if implemented.

2.2 SCOPE

Please add:

These guidelines should be used in accordance with the **International Code of Marketing of Breastmilk Substitutes and all relevant WHA resolutions for the protection of exclusive breastfeeding for the first six months of life and sustained breastfeeding to two years or beyond and optimal complementary feeding** and…

The Guideline should be restricted to RUTF only – NOT to RUSF or other products marketed and used for the prevention of malnutrition.

Rationale:

IBFAN strongly opposes the notion that products other than RUTF should be included. The decision to go forward with the Guidelines was based on UNICEF's clear message that the scope would not be expanded and that RUTF products would not be placed on the market. Codex must take special care to ensure that it does not inadvertently boost the international trade for the many unnecessary risky products such as Plumpy Mum that are supposedly designed to boost maternal nutrition.

It is essential that the International Code and WHA resolutions on infant and young child feeding underpin the use, labelling and marketing of these products. Resources must be found to ensure the training necessary to ensure that knowledge regarding breastfeeding skin-to-skin is available as the first priority wherever possible for all malnourished infants and young children, Breastfeeding assists in the healing of the damaged gut, it helps maintain the microbiome, provides critical immunological constituents that are not available in packaged commercial foods.

2.3 DESCRIPTION

Ready to Use Therapeutic Foods (RUTF) are high-energy, fortified **with industrial nutrients**, ready-to-eat foods and **may be used as part of** ~~for special medical purposes that are suitable for~~ the dietary ~~management~~ **treatment** of children from 6 to ~~59~~ **24** months with severe acute malnutrition **as outlined in the 2007 Joint Statement by WHO, WFP, UNSCN and UNICEF. The composition of the product and its ingredients should not exacerbate the incidence of obesity, cardiac disease, cancers or diabetes. These foods should be manufactured from ingredients that are safe, hygienic and have a high bioavailability to**

[9] Collins & Sadler Ethiopia 2002[1]; Isanaka et al, Niger, 2006[2], 2009[3]; V. Gaboulaud et al. Niger 2006[4]; Ferguson et al. Malawi 2008[5]; Eklund & Girma Ethiopia 2008[6];

[10] Manary et al Malawi 2004[7]; Michael A. Ciliberto et al. Malawi 2005[8]; Patel, Sandige et al, Malawi 2005)[9];

[11] Diop et al. Senegal, 2003[10]);*Nutriset's Plumpy Nut against analogues made in other countries* Diop et al. Senegal 2004[11]; Sandige et al. Malawi 2004[12]

[12] *"…Andre Briend, the French nutritionist who developed Plumpy'nut in collaboration with Nutriset, went on to work for the World Health Organization, and co-authored a nutrition policy paper on new developments in the treatment of severe malnutrition in the community published in 2006 by the UN's Standing Committee on Nutrition. The WHO, World Food Programme, and UNICEF issued a statement endorsing ready to use therapeutic foods (RUTFs) in 2007….."* Arie S. Hungry for profit. British Medical Journal 9 October 2010, 341, c5221.

prevent malabsorbtion and increased diarrheal disease resulting from gut damage as a consequence of malnutrition. Older infants and young children receiving treatment require additional fluids.

The use of RUTFs must not displace breastfeeding. Training and support for breastfeeding should be provided to maintain sustained breastfeeding wherever possible. All staff should be trained in keeping the mother and baby dyad together; relactation counselling and skin-to-skin care.

These foods should be soft or ~~crushable (~~?) and should be easy for young children to eat without any prior preparation.

Rationale:

The use of these products should be limited to therapeutic, medically indicated uses only and then only as part of the full range of treatments and care that are required for the rehabilitation of malnourished children. These products should not be used for "preventive" purposes. The use of the word treatment – rather than management - should be used to avoid confusion. The protection and support of breastfeeding as a fundamental component of the treatment is essential.

Recommendation 4

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

Rationale:

The use of food additives is an additional body-burden for severely malnourished children and should not be used. Artificial flavours not only contribute to the chemical body-burden but may also affect the child's taste palate, introducing commercially flavoured foods risks undermining children's acceptance of normal family foods.

Recommendation 5

"*The formulation of foods for special medical purposes should be based on sound medical and nutritional principles. Their use should have been demonstrated, by scientific evidence;* the safety and composition of these products must be based on evidence that meets WHO's definition of scientific substantiation: "Relevant convincing / generally accepted scientific evidence or the comparable level of evidence under the GRADE classification' *~~to be safe and beneficial~~ in ~~meeting~~ supplementing the nutritional requirements of the persons for whom they are intended."*

RAW MATERIALS ANS INGREDIENTS

4.2.2 Digestible Carbohydrates

There is no recommendation to limit the extent of added sugars. This should be part of the discussion.

The use of various forms of added sugars - can contribute to obesity and create preferences for sweet foods. Added sugars are nutritionally empty sources of energy.

Recommendation 10

IBFAN is opposed to the addition of optional ingredients and consider that they should be kept to an absolute minimum. Optional or novel ingredients compound the risks safety and pose challenges to Government regulatory authorities. Codex should use a precautionary approach and pre-authorise any optional ingredient. Suitability and safety must be demonstrated through a systematic review to determine safety and efficacy

In addition to the safety risks, optional ingredients open the door to promotional claims that are rarely scientifically substantiated.

a) all ingredients are pre-authorised following rigorous independent scrutiny, (with particular care over new technologies, such as nanotechnologies;

b) systematic reviews of all available evidence is carried out *independently* of the manufacturers and distributers of the products in question;

c) evidence is reviewed on a regular basis to ensure infants are not exposed to levels of nutrients that may impact negatively on growth, development and health;

d) there is regular post market surveillance to monitor side effects and the frequency of such reviews;

2.10 PACKAGING

2.10.1

Portion sizes must consider the impact on breastfeeding. Infants at the age of six to eight months require only about 200 calories in addition to breastmilk. There is only a gradual increase in caloric requirement from

additional foods during the second half of the first year. Breastmilk provides the bulk of the energy, nutrients and immunology, hence the support for breastfeeding is essential during this critical period of growth and development.

2.11 LABELLING

IBFAN strongly supports the addition of additional statements as previously recommended by the eWG. The labelling provisions in existing Codex texts are far from adequate:

For example with the following statements are needed:

a. This product should be provided free by the public health authorities on prescription only for therapeutic /treatment purposes.

b. This product is not for resale and must not be placed on the market.

c. This product must not replace or undermine sustained breastfeeding or the use of locally available nutritious, bio-diverse family foods

d. This product is a high fat, ~~high sugar product~~ and the long-term effects of using this category of products in children are not known. The product **should only be used for [state specific treatment period]**

e. This product must not be not labelled, promoted or idealized by health or nutrition claims or other means such as press releases, fundraising appeals etc.

f. This product is for the **treatment** of severe acute malnutrition **only and should not be used as a routine complementary food.**

g. This product must be used under the strict supervision of an **independent medical practitioner.**

h. This product must not be used for preventative purposes

i. The provision and distribution of this product must comply with all provisions of the International Code or WHA Resolutions and WHO recommendations, including WHA69.9

IDF - International Dairy Federation

IDF has the following comments regarding the recommendations made by the chairs of the eWG:

Recommendation 5:

It is understandable that the Chairs have proposed language similar to CODEX STAN 180-1991. A minor concern is that the proposed language may inadvertently lead to use of product formulations which have some benefit but are less effective than standard products used today. One may assume equivalency studies would be conducted during product testing, but this is not a requirement and is left open to interpretation by the proposed language.

Recommendation 6:

Similar to our minor concern in Recommendation 5, IDF feels that recommendation 6 on new formulation or composition of RUTF has proposed language which may inadvertently lead to product formulations which have some benefit but are less effective than standard products used today.

Recommendation 8:

We agree that minimum limits for nutrients should be reviewed to assure they are in agreement with the latest science. Use of maximum nutrient levels in the guideline are useful to assure that ratios of nutrients are kept within acceptable levels (e.g. calcium: phosphorous) when formulating products, thus caution is warranted to limiting maximum levels only to minerals that could pose a health risk. IDF would request guidance from WHO on all cases where the proposed composition diverges from the recommendations in WHO's documents to help assure consistency.

Recommendation 9: We would agree that essential fatty acid levels should be set using the latest science. However, we agree with a recent cautionary commentary that additional studies on this issue are needed, and that furthermore, impact on product shelf life and cost be assessed.[1]

Recommendation 11: IDF strongly believe that DIAAS should be the protein quality score used in the guideline. Three key reasons include:

1) DIAAS has been recommended by FAO to replace PDCAAS due to PDCAAS deficiencies in protein quality scoring;

2) the limited ingredients used in RUTF production should preclude any concerns of use of DIAAS in the guideline; many values have already been determined using the preferred pig model, and

3) foods with the highest DIAAS (protein quality) scores have been shown to have the highest correlations with weight gain.

- The Food and Agriculture Organization (FAO)[2] has recommended that digestible indispensable amino acid score (DIAAS) replace PDCAAS which has been criticized due to limitations, including:
  - PDCAAS values are truncated to 100%, or 1, which limits high quality proteins relative to poorer quality proteins and fails to recognize the advantages of surplus amino acids to complement poorer quality proteins in mixtures
  - Faecal N digestibility likely overestimates the delivery of dietary amino acids to the body
  - Anti-nutritional factors in plant proteins or processed foods may lead to higher endogenous amino acids losses. Thus PDCAAS may inappropriately reflect high scores
  - The amino acid reference pattern used is based on minimum requirements for growth and maintenance using the pattern for 2-5 year old children and does not reflect optimal intakes.
- **Rutherfurd et al., (2015)** compared use of DIAAS and PDCAAS in animals. They found that untruncated PDCAAS values were generally higher than DIAAS values, particularly for the poorer quality proteins tested.[3] Thus, the combined deficiencies of PDCAAS, truncating high-quality proteins above 100%, and higher values obtained from lower quality proteins indicate that the use of DIAAS is more suited to the development of RUTF.
- DIAAS values in 21 foods used in human nutrition have been determined.[4,5] Examples include yellow dent maize, nutridense maize, dehulled barley, dehulled oats, polished white rice, rye, sorghum, wheat, casein, milk protein concentrate, skim milk powder, whey protein concentrate, whey protein isolate, soy flour, soy protein isolates and pea protein concentrate.
  - Examples of scores obtained include:
    - in 8 raw cereal grains, DIAAS values range from 29 in sorghum to 77 in dehulled oats with maize, wheat, rye, rice, and barley being intermediate
    - DIAAS values in casein, milk protein concentrate, skim milk powder, whey protein concentrate, and whey protein isolate are between 124 and 139
    - soy flour and soy protein isolates have DIAAS values close to 100, whereas pea protein concentrate has a DIAAS value of 73
- **Manary et al., (2016)** examined the role of protein quality in promoting growth of malnourished children, taking into account the effect that physiological status has on protein needs.[6] Children with acute inflammation and/or severe acute malnutrition need proteins that provide the amino acids to support the synthesis of acute-phase proteins. Data indicate that protein synthesis improves when more protein is provided, and amino acid oxidation is reduced when high quality protein is provided. The authors also presented data showing that foods with the highest DIAAS (protein quality) scores had the highest correlations with weight gain. They concluded that dairy proteins have the highest protein quality scores and are particularly suited for promoting growth of malnourished children.

Recommendation 12: IDF strongly agrees with recommendation 12 that "at least 50% of protein provided by dairy products". Studies that have directly compared RUTF which contain at least 50% of the protein from milk dairy vs other forms of RUTF have shown they are more effective in the dietary management of children ages 6 to 59 months with SAM[13]. Moreover, the language allows use of different dairy protein sources which provide formulation flexibility to lower costs.

- Overall findings from four studies indicate that RUTF containing lower amounts of dairy ingredient, ie dairy protein replaced with non-dairy protein sources, are not as effective for the treatment of SAM. However, replacing skim milk powder with another dairy protein source (whey) can be equally effective.
  - **Oakley et al., (2010)** conducted a randomized, double-blind clinical study comparing the efficacy of a RUTF containing 10% milk supplemented with soy vs. a RUTF with 25% milk, with care taken to balance both macro- and micro-nutrients.[7] Results showed consumption of the 25% milk RUTF formulation resulted in a significantly better rate of recovery and growth rate. Rates of weight, height, and MUAC gain were also higher with the 25% Milk RUTF.
  - **Irena and co-workers (2015)** tested the hypothesis that a milk-free RUTF made with soy, maize and sorghum would have equivalent effects as RUTF containing 25% milk on recovery rates.[8] They found that the milk-containing RUTF produced significantly better rates of weight gain and

recovery vs. the non-milk RUTF; recovery was particularly improved among children less than 2 years

- **Bahwere et al., (2016)** compared the efficacy of a milk-free RUTF made with soy, maize and sorghum (SMS-RUTF) with a standard peanut based RUTF containing 25 percent milk.[9] The study found that SMS-RUTF was not inferior to the peanut based milk RUTF for recovery rate, weight gain and length of stay in children greater than 24 months of age. However, in children 6 to 24 months of age, recovery rate with SMS-RUTF supplementation was inferior to the peanut based milk RUTF.
- **Bahwere et al., (2014)** compared the effects of RUTF containing whey protein (WPC34) vs a RUTF containing dried skimmed milk (DSM).[10] Overall results indicated that RUTF containing whey is equally effective as an RUTF containing dry skim milk.

- A linear programming tool for modeling new RUTF formulations has been developed and tested **(Ryan et al., 2014)**. These researchers used this tool to demonstrate that through the use of linear programming, low-cost, optimized country-specific, alternative RUTF products for SAM recovery could be developed.[11] The products contained a variety of dairy ingredients (milk powder, acid whey, whey protein concentrate 34 percent and whey protein concentrate 80 percent), and demonstrated how dairy ingredients can be used in variable combinations to meet local preferences, lower cost and achieve excellent acceptability. The use of locally-available ingredients also lower costs.
- **Weber et al., (2016)** used linear programming to formulate and produce RUTF using local ingredients for testing in Ethiopia, Ghana, Pakistan and India.[12] Products were then tested for acceptability in 50 children from each country with MAM due to ethical reasons of conducting an acceptability trial with children with SAM. The RUTF produced all included dairy proteins other than milk and were compared to standard peanut-based RUTF containing milk. Ingredient costs of the formulations were about 60% of standard RUTF. RUTF products were consumed and preferred equally as well as standard RUTF in Ethiopia, Ghana and India. In Pakistan, while the products were equally consumed, mothers perceived the children preferred the standard peanut based RUTF made with milk. The products will undergo further testing prior to being used in equivalency trials.
- Equivalency trials are now underway in some of the countries using the new formulated products.

References:

1. Brenna JT, Akomo P, Bahwere P, et al. Balancing omega-6 and omega-3 fatty acids in ready-to-use therapeutic foods (RUTF). *BMC Med.* 2015;13(1):1-4.

2. Food and Agriculture Organization. Dietary protein quality evaluation in human nutrition, Report of an FAO expert consultation 31 March - April 2011, Auckland, New Zealand,. 2013.

3. Rutherfurd SM, Fanning AC, Miller BJ, Moughan PJ. Protein digestibility-corrected amino acid scores and digestible indispensable amino acid scores differentially describe protein quality in growing male rats. *J. Nutr.* Feb 2015;145(2):372-379.

4. Stein H. Evaluating protein quality of human foods using the pig as a model. *J. Anim. Sci.* 2016;94(supplement2):20-21 (Abstract 045).

5. Cervantes-Pahm SK, Liu Y, Stein HH. Digestible indispensable amino acid score and digestible amino acids in eight cereal grains. *Br. J. Nutr.* May 2014;111(9):1663-1672.

6. Manary M, Callaghan M, Singh L, Briend A. Protein Quality and Growth in Malnourished Children. *Food and nutrition bulletin.* Mar 2016;37 Suppl 1:S29-36.

7. Oakley E, Reinking J, Sandige H, 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. *J. Nutr.* Dec 2010;140(12):2248-2252.

8. Irena AH, Bahwere P, Owino VO, 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 & child nutrition.* Dec 2015;11 Suppl 4:105-119.

9. Bahwere P, Balaluka B, Wells JC, 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 noninferiority, individually randomized controlled efficacy clinical trial. *Am. J. Clin. Nutr.* Apr 2016;103(4):1145-1161.

10. Bahwere P, Banda T, Sadler K, et al. Effectiveness of milk whey protein-based ready-to-use therapeutic food in treatment of severe acute malnutrition in Malawian under-5 children: a randomised, double-blind, controlled non-inferiority clinical trial. *Maternal & child nutrition.* Jul 2014;10(3):436-451.

11. Ryan KN, Adams KP, Vosti SA, Ordiz MI, Cimo ED, Manary MJ. A comprehensive linear programming tool to optimize formulations of ready-to-use therapeutic foods: an application to Ethiopia. *Am. J. Clin. Nutr.* Dec 2014;100(6):1551-1558.

12. Weber JM, Ryan KN, Tandon R, et al. Acceptability of locally produced ready-to-use therapeutic foods in Ethiopia, Ghana, Pakistan and India. *Maternal & child nutrition.* Jan 18 2016.

13. Michaelsen KF, Hoppe C, Roos N, et al. (2009) Choice of foods and ingredients for moderately malnourished children 6 months to 5 years of age. Food and Nutrition Bulletin 30: S343-404.

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(i) GENERAL COMMENTS

Based on first and second consultations in the eWG, the Chairs propose to modify throughout the guideline the age range from "for children from the age of 6 months" to "for children from the age of 6 to 59 months". However, RUTF can be used for the dietary management of all people (children as well as adults) with severe acute malnutrition, including children from 6 months. Restricting the scope, would exclude older individuals suffering from severe acute malnutrition.

As such, ISDI recommends that the target population should be **"individuals with severe acute malnutrition, specifically children from 6 months onwards".**

(ii) SPECIFIC COMMENTS

As mentioned in the general section, ISDI recommends a broader age indication and proposes the following:

To provide guidance on technical and nutritional aspects of the production of Ready to Use Therapeutic Foods for **individuals from 6 months onwards**, ~~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

Recommendation 2:

ISDI suggests that the scope should *not* include the provision that the guideline should be used in accordance with the 2007 Joint Statement of the UN and the 2013 WHO document or any other relevant upgrade. This is because it is contradictory to sections of the guideline which request further flexibility and/or broader nutrient ranges. Suggesting that this guideline should be used in accordance with the aforementioned text, may lead to confusion of member states. Additionally, inclusion of 'or any relevant upgrade' should be specific to 'technical' and again could lead to potential confusion. ISDI also recommends a broader age indication and proposes the text reads as follows:

The provisions of these guidelines apply to Ready to Use Therapeutic Foods for **individuals from 6 months onwards**, ~~children from 6 to 59 months~~ with severe acute malnutrition. Ready-to-Use Supplementary Foods (RUSF), micronutrient supplements, processed cereal based foods6, formulated complementary foods for older children and young children7, canned baby foods8 are not covered by these guidelines. ~~These guidelines should be used in accordance with the 2007 Joint Statement of the UN Agencies9, 2013 WHO document on Updates on the Management of Severe Acute Malnutrition in infants and children10 or any other relevant upgrade of the latest version.~~ **The 2007 Joint Statement of the UN Agencies9 and the 2013 WHO document on Updates on the Management of Severe Acute Malnutrition in infants and children10 are the foundations of the guideline.**

Recommendation 3:

ISDI proposes the following wording:

Ready to Use Therapeutic Foods (RUTF) are high-energy, fortified, ready-to-eat foods for special medical purposes that are suitable for the dietary management of **individuals from 6 months onwards**, ~~children from~~

~~6 to 59 months~~ with severe acute malnutrition. These foods should be soft or crushable and should be easy for young children to eat without any ~~prior~~ preparation. **No water is required for preparation**.

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

Recommendation 4:

ISDI agrees with the proposal that addition discussions are needed on how to handle the use of food additives in RUTF. Below are some additional comments related to GFSA and secondary additives.

General Standards for Food Additives (GSFA)

There does not appear to be a category currently in the GSFA that is appropriate for these products. While it does make sense that RUTF would be included somewhere under Category 13, these products are unique enough that it is not likely that any of the current categories within 13 would be an appropriate fit. While the definition of these products may be similar to Category 13.3, the additives that are approved for use in 13.3 are based on the technological need for those additives in those products. However, the products currently in 13.3, such as liquid meal replacement beverages, are very different than RUTF products, and thus there would be a technological need for a very different set of additives.

Since RUTF is so characteristically different than the other products in 13.3, options for addressing RUTF in the GSFA include:

1. Creation of another sub-category in Category 13 specific for RUTF
    - This would allow for the determination of the specific additives that would be appropriate for this category, however, it would also create significant administrative burden on CCFA (owner of the GSFA) and CCNFSDU (owner of the commodity standard) to manage the evaluation and addition of additives to that new category.
    - This would be particularly challenging because of the potential for a broad range of products in this category
2. Describe in the RUTF standard that these products should be considered “general food”, thus enabling the use of additives that have been approved for general use (Table 3 of GSFA) – *Recommended*
    - This approach has the benefits of giving manufacturers the flexibility to produce RUTF in multiple ways, thereby enabling access to these products, as well as reducing the administrative burden on Codex in managing both GSFA and a commodity standard

Secondary additives

In paragraph 28 there is discussion of whether consideration should be given to adding a restriction on the carry-over of ingredients into these products (similar to infant formula). While ISDI agrees that infants and children consuming RUTFs would be considered to be in a medically vulnerable state, the greatest risk (and basis for the medically vulnerable state) is the lack of nutrition. The carry-over of ingredients, such as the carriers in vitamin preparations mentioned in paragraph 28, pose no risk to consumer health, especially at the trace levels that they would be found in finished RUTF.

There are situations where it is necessary to add compounds to ingredients (such as vitamin preparations) to assure the quality and safety of the ingredients prior to the production of finished products. These compounds (referred to as secondary additives by CCFA) have a technological function in the ingredients, but due to their presence at trace amounts after being added to products, no longer have a technological effect in finished products. These compounds typically have a long history of safe use, and their presence at trace amounts make them highly unlikely to impact consumer health.

Imposing restrictions on the carry-over of these ingredients (similar to infant formula) could have multiple negative consequences including:

1. Restricting manufacturers in terms of the ingredients that can be used to produce products
    - Based on the variety of products in this category, it may be hard to anticipate the wide range of food ingredients that would be technologically required to produce these products.
    - Ultimately, this could make RUTF products less readily available. Again, this is in conflict to the purpose of this category of foods, which is to provide nutrition to individuals who do not have access to food.
2. Creating administrative burden on the Codex committees (CCFA and CCNFSDU)

- If all secondary additives would need to be approved, and based on the wide variety of products in this category, there would be tremendous burden on the Codex committees to evaluate and approve all of the additives that may need to be added for a technological purpose, not just as ingredients (which would be consistent with the other commodity categories), but then also secondary additives (which is not done for the majority of other commodity categories)

Lastly, CCFA is discussing the process for managing secondary additives. It could be beneficial to allow that discussion to progress in parallel to the development of the RUTF standard before committing to any language in the RUTF standard related to secondary additives.

Recommendation 5: None

Recommendation 6:

ISDI is of the opinion that "paste and protein based" should be removed. RUTF cannot be prepared with a protein based matrix without grossly exceeding the current upper limit for protein content. Also, it will not be possible to achieve the energy requirements. ISDI also recommends that a section 3.4.3 entitled "Specific prohibition" should be added similar to what is included in for example CODEX STAN 72-1981 and CODEX STAN 74-1981. The following wording is proposed.

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

4.1 Basic Raw Materials and Ingredients

4.1.1 Milk and other Dairy Products

4.1.2 Legumes and Pulses

4.1.3 Fats and Oils

4.1.4 Cereals

4.1.5 Vitamins and Minerals

4.2 Other Ingredients

4.2.1 Digestible Carbohydrates

4.2.2 Food Additives and Flavours

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

4.2.3 [Other Nutritional Ingredients]

4.3 The Use of other Matrices in RUTF formulation

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

4.3 Specific prohibitions

- The product and its components shall not have been treated by ionizing/irradiation.

- The addition of salt (NaCl) to RUTFs is not permitted.

- The use of partially hydrogenated fats for these products is prohibited.

Recommendation 7: None.

Recommendation 8:

The recommendation for reviewing the nutritional composition and conversion factors is aligned with the ISDI proposal and clearly demonstrates that more work is required. The recommendation is welcomed. ISDI recommends that anti-nutrient factors be included in the NUTRITIONAL COMPOSITION AND QUALITY FACTOR section as well.

If it is recommended that phytates should be limited, a molar ratio in the finished product should be defined, even if the phytate content in raw materials is controlled. The following should then be considered in the paragraph 3.8 TECHNOLOGIES FOR AND EFFECT FOR PROCESSING:

- Phytate/Zinc <5

- Phytate/Iron <1

Reference

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

http://izincg.org/files/izincgtechdocfnb2004.pdf

Recommendation 9:

ISDI is of the opinion that there is no need to change the levels of essential fatty acids in RUTF (minimum and maximum are already given in table 1), unless there is specific scientific evidence to support it.

Recommendation 10: None.

Recommendation 11:

ISDI recommends the usage of PDCAAS, because the existing database for the calculation of DIAAS is not available on each raw material. If DIAAS is included in the guideline people won't be able to use it. Existing guidelines does not make reference to PDCAAA or DIAAS.

Recommendation 12a: None

Recommendation 12b (Contaminants):

ISDI agrees that more discussion is needed on how to manage contaminants for RUTF.

We are in agreement with the proposal described in paragraphs 51 and 53 that contaminants should not be described in the RUTF guideline, but instead should reference the GSCTFF (CODEX STAN 193-1995). This is the approach that has been taken for other commodity standards, and in fact, in 2016 the infant formula standard (CODEX STAN 72-1981) was updated in a way that aligns with this recommendation.

We also agree that the GSCTFF already contains controls for many of the contaminants that would be relevant for the ingredients proposed to be used in RUTF, and this supports the rationale for the reference to the contaminant standard. As stated in paragraph 54, if there is a concern that the contaminant limits in the GSCTFF are not sufficient to protect these consumers, the appropriate action would be to forward a request to CCCF for an evaluation of contaminants for this specific food category.

However, the request to CCCF should be to evaluate whether new MLs need to be established for RUTF. It should not be a request to include RUTF with the MLs established for infant formula. It is possible that the risk assessment for RUTF could conclude that the MLs for RUTF should align with those for infant formula, however, the risk assessment (and importantly the exposure assessment that is part of the overall risk assessment) that was conducted for contaminants in infant formula used very specific consumption and occurrence data to generate those MLs. It is unlikely that the consumption and occurrence data for RUTF would align exactly with that for infant formula, therefore it is not appropriate to simply align the RUTF with the infant formula MLs without a quantitative risk assessment (per the Codex Procedural Manual).

ISDI agrees that consumer health should be a primary consideration when developing the RUTF guideline. However, we again point out that the largest risk that these consumers have is the lack of access to food. Caution should be taken to ensure that if MLs for contaminants are determined specifically for this category, that they are not developed in a way that restricts access to these products.

For clarification, the reference to pesticides should be for the commodities (e.g. grains, nuts) used in the production of these products, as opposed to the RUTF category. The pesticides MRLs are typically established for commodities, since this is the only opportunity for controlling their presence in finished food products. As per other commodity standards (such as the infant formula standard), it would not be necessary to specifically call out pesticides in the RUTF guideline, as pesticides are instead controlled on the ingredient level.

In addition to the above, ISDI suggest the recommended text reads as follows:

It is recommended that the contaminants for RUTF be in accordance with the general standard for contaminants and toxins in food and feed (CODEX STAN 193-1995). Maximum Residue Limits (MRLs) and risk management recommendation (RMRs) for residues of Veterinary drugs in foods (CAC/MRL 2-2025) and Codex maximum residue limits for pesticides.

1. Mycotoxins
2. [Pesticides Residues]
3. [Veterinary Drug Residues]
4. [Heavy metals]

5. [Radioactivity]
6. [Melamine]
7. ~~[Other Contaminants]~~

Recommendation 13

Reference to paragraph 5.2.2 “specific process steps” of the CAC/RCP 75-2015 is reliable and relates to the finished product. It is recommended that “CAC/GL 8-1991” is also mentioned, because it relates to the first steps of production.

Recommendation 14:

ISDI suggest that the guideline should not make references to FAO/WHO report on Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition (2016). Suggesting that this guideline should be used in accordance with the aforementioned text, may lead to confusion of member states. ISDI thus recommend the following:

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

Recommendation 15:

ISDI suggest that the guideline should not make references to FAO/WHO report on Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition (2016). Suggesting that this guideline should be used in accordance with the aforementioned text, may lead to confusion of member states. ISDI thus recommend the following:

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

Recommendation 16:

ISDI suggest that the guideline should not make references to FAO/WHO report on Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition (2016). ISDI welcomes the addition of references to the methods of analysis and sampling standards as part of the guideline. When needed, specific methods of analysis should be developed in accordance with appropriate Codex Guidelines.

ISDI thus recommend the following:

The Chairs recommend that methods of analysis and sampling of RUTF be in accordance with the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999), General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995), The Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CAC/GL 21-1997), Code of Hygienic Practice for Low Moisture Foods (CAC/RCP 75-2015), ~~and FAO/WHO report on Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition (2016)~~ for further discussion and consideration by CCNFSDU. **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), Harmonized IUPAC Guidelines for Single-Laboratory Validation of Methods of Analysis (CAC/GL 49-2003).**

Recommendations 17, 18 and 19: None.

UNICEF - United Nations Children's Fund

General comments:

The draft proposed framework for the guideline covers all main aspects needed.

Specific comments:

(1) 2.2 scope. UNICEF believes all technical guidance contained in recommendation 1 ‘purpose’ is applicable to RUSF, and therefore the recommendation 2 at 2.2 scope may create confusion to the users of the proposed guideline, as these products are very similar.

Specifically excluding RUSF, a product that is almost identical to RUTF in terms of ingredients, but is used for *moderately* acute as opposed to *severely* acute malnutrition, would seem not to be an efficient use of the committee's resources, and may cause confusion to the users of the guideline. The guideline currently being elaborated for RUTF contains information for manufacturers and normative agencies to ensure these specialized medical foods are products that are safe and produced hygienically. Indeed, a risk assessment documented in the FAO /WHO report *Microbiological safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition,* determined that the two products have the same food safety risk profile. Providing a guideline as a reference for these lipid based nutritional supplements used to manage medically diagnosed malnutrition (moderate or severe) in children is desirable for their proper national regulation.

UNICEF therefore suggests that Recommendation 2 is edited to: The provisions of these guidelines apply to Ready to Use Therapeutic Foods for children from 6 to 59 months with severe acute malnutrition. ~~Ready-to-Use Supplementary Foods (RUSF),~~ Micronutrient supplements, processed cereal based foods[6], formulated complementary foods for older children and young children[7], canned baby foods[8] are not covered by these guidelines. These guidelines should be used in accordance with the 2007 Joint Statement of the UN Agencies[9], 2013 WHO document on Updates on the Management of Severe Acute Malnutrition in infants and children[10] or any other relevant upgrade of the latest version.

(2) In reference to Recommendation 4, UNICEF can provide some background information on the use of food additives in RUTF. The use of food additive is limited to natural flavours and natural antioxidants (Ascorbyl palmitate and Mixed tocopherols) in the current global supply.

(3) 2.5 0 Nutritional Composition and Quality factors: UNICEF suggests that in addition to the moisture of 2.5% maximum, a **water activity of 0.6 maximum** is also defined in the guideline.

(3) Recommendation 12: the role and body of scientific data of the importance of animal sourced protein in RUTF has been evolving for the last 10 years. Most recently there are data indicating that some high quality vegetable sources may be as effective as dairy sourced protein, however the body of data currently supports the use of dairy in RUTF. Perhaps to allow for innovation of recipes in this area, and an opportunity to include high quality locally sourced proteins Recommendation 12 could be edited to:

'at least 50% of protein provided by milk products, or other high quality protein sources **if proven equivalent'**

(4) Recommendation 11: based on a healthy 1-3 year old population, RUTF has a PDCAAS of 1.0 and DIAAS of 1.042. When an uninfected malnourished population is used as a reference for the protein quality scoring estimates, the PDCAAS is estimated at 0.840 and the DIAAS at 0.797 for RUTF. The protein quality could therefore be enhanced to account for the needs of the recovering malnourished state.