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

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

Second Consultation Paper

May 2016

Please respond by **24th June 2016**

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Name of Member Country/Organisation: Brazil

1. PURPOSE

PURPOSE
1.1 Please provide comments and justification for your answers to the proposed text. We agree with the wording and the proposed text in this section.

2. SCOPE

SCOPE
2.1 Do you agree with revised text? **Yes** ☐ **No** (x) **2.2 Please suggest the wording and justification for your proposals.** We think 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. Thus, we suggest including a new sentence with these references as proposed below: "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. These guidelines should be used in accordance with the 2007 Joint Statement of the UN Agencies[i],

2013 WHO document on Updates on the Management of Severe Acute Malnutrition in infants and children or any other relevant upgrade of the latest version. The scope of a guideline will only refer to RUTF that are produced in food manufacturing facilities and traded either nationally or internationally.

These guidelines should be used in accordance with the Global Strategy for Infant and Young Child Feeding WHA 55.25 (2002) and the recommendations of World Health Assembly resolution 63.14 (2010)."

SCOPE

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

Yes ☐ **No (x)**

2.4 Please provide comments and justification for your answers.

We think that canned baby foods should also be mentioned in the proposed list of products to be excluded from the scope.

3. DESCRIPTION

DESCRIPTION

3.1 Please provide comments on the suggested wording for the "Description".

Ready to Use Therapeutic Foods (RUTF) are high-energy, fortified, ready-to-eat foods for special medical purposes produced in food manufacturing facilities, that are suitable for the [**~~treatment~~/dietary management]** of **older infants** from 6 months **and children up to 59 months** with severe acute malnutrition.

These foods should be soft or crushable and should be easy for **older infants and** ~~young~~ **children up to 59 months** to eat without any prior **[cooking, mixing or dilution/preparation].**

We understand that the description should make reference to older infants as the product is intended to older infants from 6 months. We highlight that the reference to young children in the description does not cover children from 36 to 59 months.

3.2 Are there any additional terms that should be defined?

Yes (x) **No** ☐

Please suggest the terms and the provide justification for your proposals.

We suggest including the definition of older infants:

Older infants means persons from the age of 6 months and not more than 12 months of age.

We think that the definition of "young children" should not be included as the product is intended not only for young children but to children up to 59 months.

3.3 Do you support the replacement of the word "treatment" by "dietary management" in order to

align with the existing Codex text (i.e. CODEX STAN 180-1991)?

Yes (x) **No ☐**

4. BASIC RAW MATERIALS AND INGREDIENTS

BASIC RAW MATERIALS AND INGREDIENTS

4.1 Please provide comments to the proposed wording on RUTF. Please provide justification and rationale for your comments.

4.2 Do you agree with the proposed outline on basic raw materials and ingredients?

Yes ☐ **No (x)**

4.3 If No, provide justification for your answer.

In order to allow the extent of use of locally available ingredients and to align with CAC/GL 8-1991, we suggest replacing "Milk and other Dairy Products" for "Animal Source Foods". 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.

[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.

4.4 Are there still other raw materials and ingredients that have not been covered in the proposed section on "Basic Raw Materials and Ingredients"?

Yes (x) **No ☐**

Please provide the rationale and justification for your proposals.

We suggest including fruits and vegetables that may be good sources of micronutrients. These ingredients are mentioned in CAC/GL 8-1991.

4.5 Do you agree that the ingredients should be listed in descending order of proportion?

Yes ☐ **No ☐**

4.6 Do you agree that the appropriate class names and specific names be declared for all ingredients?

Yes ☐ **No ☐**

4.7 Please provide the rationale and justification for your answer.

We understand that these issues should be discussed under the labelling section. We also think that the guidelines should follow the General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985).

4.8 Do you agree that the proposed statement be included under this section?

Yes (x) **No** ☐

4.9 Please provide comments on the wording and the proposed text.

We are of the opinion that the guidelines should allow the use of other ingredients provided that there was scientific evidence to support the effective delivery of the nutritional requirements for the target group. We 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. We also point out the study of Ryan et al. (2014)[1], that have already been mentioned.

[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.

5. NUTRITIONAL COMPOSITION AND QUALITY FACTORS

NUTRITIONAL COMPOSITION

Vitamins and Minerals

5.1 Do you support the setting of minimum and maximum levels for vitamins and minerals for the RUTF products?

Yes (x) **No** ☐

5.2 Are there any proposals you want to make with regard to the minimum and maximum levels? Please provide the rationale and the scientific evidence for your proposals.

Essential Fatty acids (omega-3 and omega-6)

5.3 Do you support the revision and setting of minimum levels for essential fatty acids in RUTF?

Yes, we do. 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 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.

5.4 Are there any proposals you want to make with regard to the minimum levels? Please provide the rationale and the scientific evidence for your proposals.

5.5 Do you support the addition of other nutrients such as manganese in the nutritional composition for RUTF?

We are not aware of the scientific evidence that supports the need of addition of manganese. We think that it is necessary further discussion with regard to possible adverse effects, such as neurological toxicity, of this mineral.

5.6 Please indicate the nutrients to be added and provide scientific justification for your proposals.

Measuring Protein Quality

5.7 Should this statement "50% of protein sources from milk products" be removed or amended?

5.8 If Yes, provide the draft wording for the proposed statement and the justification.

Yes, we agree with removing this statement. We think that the quality of the protein should be measured by using the latest available methods as recommended by FAO (PDCAAS/ DIAAS).

5.9 Should other methods be considered if the PDCAAS digestibility of a protein could not be determined due to other technical reasons? For example, biological assays or calculated from published data on essential amino acid patterns of dietary proteins and their digestibility.

Pre and pro-biotic

5.10 Should pre- and pro-biotic be considered as optional ingredients in RUTF?

Please provide the rationale and justification for your answer.

Based on the current discussion on the revision of follow-up formula at CCNFSDU, there is no necessity to add non-digestible oligosaccharides, "probiotics" or "synbiotics", to infant and follow-up formulae. The Second Consultation Paper of the eWG on the REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA points out that EFSA, ESPGHAN and German risk assessment institute BFR stated that there is insufficient data and that further evidence of safety in long term studies is needed. Norwegian Committee for Food Safety has concluded there is not sufficient data to draw any conclusions on long term safety of lactic acid producing cultures in products for infants. Thus,

considering that RUTF is intended to older infants and children up to 59 months, we understand that further discussion is necessary.

6. CONTAMINANTS

CONTAMINANTS
6.1 Do you agree with the proposed wording and sub-sections? **Yes** ☐ **No** ☐

7. TECHNOLOGIES FOR AND EFFECT FOR PROCESSING

TECHNOLOGIES FOR AND EFFECT FOR PROCESSING
7.1 Do you agree with the revised section and proposed sub-sections? **Yes** ☐ **No** ☐

8. METHODS OF ANALYSIS AND SAMPLING

METHODS OF ANALYSIS AND SAMPLING
8.1 Are there any other issues that should be considered under this section?

9. HYGIENE

HYGIENE
9.1 Are there any other issues that should be considered under this section?

10. PACKAGING

PACKAGING
10.1 Do you agree that RUTF should be packaged into single-use sachets to minimize the risk of contamination at home? **Yes** ☐ **No** ☐

10.2 What should be the volume ranges of single-use sachets?

10.3 What should be the nutritional content ranges (e.g. macronutrients) of a single-use sachet?

11. LABELLING

LABELLING

11.1 Do you have additional comments on the proposed wording for this section?

With regard to the proposed text "CODEX STAN 180-1991 for the labelling of and claims for foods for special medical purposes and other relevant Codex texts will inform the content of this section", we suggest amending it in order to include other Codex texts on labelling, as following:

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

Mandatory Statements for Labelling Purposes

11.2 Do you agree with the wording and the proposed mandatory statements?

Yes ☐ **No** ☐

Please provide comments on the above suggested wording.

We agree with the proposed mandatory statements, however, we think that the wording may be improved and should be discussed later on after the discussion about the other labelling requirements, as for example, the name of the product, instruction for use and additional requirements.

11.3 Are there any other additional statements that should be considered under this section? Please provide the rationale and justification for their inclusion.

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