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

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

Second Consultation Paper

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Please respond by **24th June 2016**

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Name of Member Country/Organisation: IBFAN

1. PURPOSE

PURPOSE
Please provide comments and justification for your answers to the proposed text. **The purpose should include examination of the evidence that use of RUTFs are suitable therapeutic foods for the treatment of older infnats and young chilren 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. SCOPE

SCOPE
2.1 Do you agree with revised text? *Yes* ☐ *No* ☒

2.2 Please suggest the wording and justification for your proposals.

IBFAN COMMENT: The provisions of these guidelines apply to Ready to Use Therapeutic Foods for the short term treatment of older infants and young children from 6 to ~~36~~ 24 months with severe acute malnutrition, in combination with the treatment of the underlying causes of malnutrition.

Commercial complementry foods are not needed as therapeutic foods after the age of 24 months. The use of high nutrient and energy dense family foods is a sustainable way to address the need for the treatment and the rehabilitation of malnourished young children and should be introduced as a preferred means to provide optimal nutrition.

The underlying causes of infectious diseases, malaria and parasites must be treated to prevent SAM.

The protection, promotion and support for breastfeeding, including sustained breastfeeding must be central to addressing optimal development, growth and health outcomes for children.

The single product approach to the treatment of SAM is not sustainable and does not address the complex causes of malnutrition. The guidelines should include information to national governments on how to address the underlying causes of malnutrition and on comprehensive approaches to prevent and treat SAM. These should be appropriate to national and cultural needs. The risk of mortality associated with SAM cannot be mitigated by RUTF alone, and their use must be integrated into sustainable, local, family based solutions, with additional focus on building health care systems.

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.

No. Since the food on the list are not defined e.g. complementary foods is a generic term for a range of foods both family or commerialy produced, it is nor feasable to detemine what foods are meant to be excluded from the list. Family foods should be a part of the recommendations and use for the treatment of the various forms of malnutrition.

3. DESCRIPTION

DESCRIPTION

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

Ready to Use Therapeutic Foods (RUTF) are commercialy produced high-energy, fortified with industrial micronutrients, ready-to-eat foods and may be suitable for the treatment of children >6 months to 24 months, who are suffering from severe acute malnutrition as outlined in the 2007 Joint Statement by WHO, WFP, UNSCN and UNICEF. Such ready to use commercially produced and and fortified with industrial micronutrients should be manufactured from ingredients that do not promote unintended consequences such as obesity, cardiac disease, cancers or diabetes. These foods should be manufactured from ingredients that are safe, hygienic

and have a high bioavailability to prevent malabsorbtion and increased diarrhral disease resulting from gut damage as a conseqence of malnutrition. Older infants and young children receiving treatment require additional fluids.

The use of RUTFs must not displace breastfeeding. Breastfeeding support should be provided to maintain sustained breastfeeding and relaction counselling should be provided for mothers wishing to relactate,

IBFAN Comment: Any decisions regarding the safety or 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'*

There is a risk that the composition of the products, especially the high sugar content, will encourage a preference for sweetened foods over traditional family foods and increase the possibility of childhood obesity, cardiac disease, cancers or diabetes. There is evidence that the disease burden from SAM is decreasing while childhood obesity is rising.

1 **Extrapolated from UN Inter-agency Group for Child Mortality *Estimation report on levels and trends in Child Mortality 2015* (WHO, UNICEF, World Bank Group, United Nations).**

2 ***Global obesity rise puts UN goals on diet-related diseases 'beyond reach'* Westernised diets blamed as figures predict failure to meet 2025 target of no increase in obesity or diabetes beyond 2010 levels. *"… Child obesity figures are also rising in many developing countries, particularly in the Middle East, Latin America, China and parts of south-east Asia…"* www.theguardian.com/socie-ty/2015/oct/09/obesitys-global-spread-un-goals-diet-related-diseases-fail**

3.2 Are there any additional terms that should be defined?

Yes "crushable"

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

The term "Young children" is already defined by Codex as 12-36 months. (CODEX STAN 074-1981, REV. 1-2006)

2.2 OTHER DEFINITIONS

2.2.1 The term infant means a person not more than 12 months of age.

2.2.2 The term young children means persons from the age of more than 12 months up to the age of three years (36 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)?

No

IBFAN COMMENT: The provision of RUTFs as a treatment food is but one part of a full range of "dietary management" for the treatment and rehabilitation of malnourished children. The transition to family foods and the support for ssutained breastfeeding and/or counselling for relaction are all vital components of an individualized treatment plan for a malnourished child.

It is not necessary to be consistent with the Codex Standard For The Labelling of and Claims For Foods For Special Medical Purposes (CODEX STAN 180-1991) The labelling and marketing requirements of this Standard are ambiguous and inadequate to protect health. It should not be used as a model in this context.[1] It is not enough to forbid public advertising yet leave the door wide open for other forms of promotion: such as claims and promotion via health professionals,

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

fundraising appeals, press releases, donations etc.
RUTFs should only be used for the 'treatment' of severe acute malnutrition and not for 'prevention' purposes. For this reason, and to avoid confusion, the term 'treatment' should be used consistently:
The Guidelines must warn of the risk that RUTFs often divert scarce resources from nutrition education on the use of high nutrient nd energy risch family foods and the provision of training, counseling and support for breastfeeding.

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?

No

4.3 If No, provide justification for your answer.

Cow' milk proteins may cause increased gut damage in malnourished children. Human milk has gut healing properties and protects the normal microbiome of the malnourished child. Other foreign proteins will cause increased gut damage, malabsorption and delayed healing.

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 ☐

Please provide the rationale and justification for your proposals.

There is a need for independent evaluation of the composition and efficacy of RUTFs. Any decisions regarding the safety or 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'

WHA Resolution **(WHA 55.25)** *URGES 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;*

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

Yes

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

Yes

4.7 Please provide the rationale and justification for your answer.

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

No ☐

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

The use of RUTFs cannot be justified unless the underlying causes of malnutrition are addressed. Any decision to use RUTFs must be integrated into sustainable, local, family based solutions, with additional focus on building health care systems. National governments must ensure a comprehensive prevention and treatment for SAM that is appropriate to national needs and cultural practices and not based on single product approaches.

The Mother and baby are an inseperable biological unit (see the WHO Global Strategy for Infant and Young Child Feeding.)

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 ☐ **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.

IBFAN Comment: The Guidance should define the essential composition/max min levels of products wherever possible. Optional ingredients can be listed but should not be used as an opportunity for promotions claims. RUTF packaging and information must not use promotional claims of any kind.
There is a need for independent evaluation of the composition and efficacy of RUTFs. Any decisions regarding the safety or 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'

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?
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.
Same comment as for 5.2

Additional Nutrients

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

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

Same comment as for 5.2
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.**
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. Same as for 5.2
Pre and pro-biotic
5.10 Should pre- and pro-biotic be considered as optional ingredients in RUTF? There is no substantive scientific evidence that these ingredient have benefits in healthy non-malnourished children See the Cochrane reviews Ready-to-use therapeutic food for home-based treatment of severe acute malnutrition in children from six months to five years of age (Review) Schoonees A, Lombard M, Musekiwa A, Nel E, Volmink J The Cochrane Library 2013, Issue 6 **Please provide the rationale and justification for your answer.**

6. CONTAMINANTS

CONTAMINANTS
6.1 Do you agree with the proposed wording and sub-sections? **No** ☐ Add to the list: Food additives and Biological active agents such as estrogenic compounds in soy.

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** ☐ Same as for 5.2

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 **Same as for 5.2**

9. HYGIENE

HYGIENE
9.1 Are there any other issues that should be considered under this section? **Same as for 5.2**

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? **No** ☐ **At what age level is this to be set? A 6 month will require no more than 100 kcal in addition to breastmilk a 9 month old 200 kcal and so on …** **10.2 What should be the volume ranges of single-use sachets?** **How can this be individulaized to meet the specific needs of a malnnourished infant/young child?** **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?
Mandatory Statements for Labelling Purposes **11.2 Do you agree with the wording and the proposed mandatory statements?** **No** **Please provide comments on the above suggested wording.** **The following mandatory statements were proposed by eWG Members.**

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 idealised 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

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

IBFAN Comment: Nutritionally empty sugar calories should not be used as an ingredient for RUTFs. Malnourished children need nutritionlly dense foods not empty calories. Moreover this may program children to prefer sweet foods and increase the risk for NCDs.