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: IACFO

1. PURPOSE

PURPOSE
1.1 Please provide comments and justification for your answers to the proposed text. **Before proceeding with the development of the Guidance the following questions should be asked :** **What is the quality of the evidence?** Any decisions regarding this Guidance and its need should be evidence-based rather than 'consensus-based.' All evidence should meet WHO's definition of scientific substantiation: *'Relevant convincing / generally accepted scientific evidence or the comparable level of evidence under the GRADE classification.'* **Do RUTFs improve the health of children aged 6 to 59 months with severe acute malnutrition?** **What Populations are being targeted (and a definition given)?** **What interventions have been tested?** **What were the comparison groups?** **What outcomes were measured and over how long was this measured?** **Was there a Risk of Bias in the overall quality of evidence?** **Was there an analysis of Benefit vs Harm** **How will this recommendation be implemented** **What are the economic/resource implications and audit priorities.**

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.** *Commercial complementry foods are not needed as therapeutic foods after the age of 24 months. High nutrient and energy dense family foods ~~should be promoted and available~~ are suitable for the treatment and rehabilitation of malnourished young children* **IACFO comment: The Guidance should never refer to the 'promotion' of any commercial products for malnourished infants and young children.** **The guidance should alert national governments to the need to address the underlying causes of malnutrition and comprehensive programmes for the prevention and treatment of SAM that are appropriate to national needs and cultural practices (rather than focusing on single product approaches.) 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** ☐ **2.4 Please provide comments and justification for your answers.**

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~~ that may be suitable for the treatment of children >6 months to 24 months ~~while breastfeeding is sustained and~~ who are suffering from severe acute malnutrition (SAM) as outlined in the 2007 Joint Statement by WHO, WFP, UNSCN and UNICEF. The use of RUTFs in the treatment of SAM must not displace the provision of training, counseling and support for sustaining lactation (and relactation for those mothers who are willing). Infants and young children also need adequate fluids. Commercial Ready to use products that are fortified with industrial micronutrients should be manufactured from ingredients that are safe, hygienic and have a high bioavailability to prevent malabsorbtion and increased diarrhreal disease resulting from gut damage as a conseqence of malnutrition.

IACFO 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 will encourage a preference for sweetened foods over traditional family foods and increase chances 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-dis-eases-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

IACFO COMMENT: NO. 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, 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:

As mentioned above, the Guidelines must warn of the risk that RUTFs often divert scarce resources and development funds from the provision of training, counseling and support for lactation (and relactation for those mothers who are willing.)

4. BASIC RAW MATERIALS AND INGREDIENTS

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

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 an

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.** IACFO 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.** See IACFO Comment 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.** See IACFO Comment 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.

See IACFO Comment 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** ☐
See comments 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

See comments 5.2

9. HYGIENE

HYGIENE

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

See IACFO Comment 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.