

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: **France**

1. PURPOSE

PURPOSE

1.1 Please provide comments and justification for your answers to the proposed text.

2. SCOPE

SCOPE

2.1 Do you agree with revised text?

Yes No

2.2 Please suggest the wording and justification for your proposals.

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
<p>3.1 Please provide comments on the suggested wording for the “Description”.</p> <p>France is in favour of referring to “dietary management” instead of “treatment”. The aim of the product is the dietary management of severe acute malnutrition. It seems to us that these products fall under the definition of FSMP, therefore consistency with the Codex Standard 180-1991 should be ensured.</p> <p>In the second paragraph, we think that “young children” should be replaced by a more general term. In the codex context, “young children” means children aged 12 to 36 months. It seems in that case that the sentence should also be valid for infants between 6 and 12 months, and for children older than 36 months.</p> <p>The last sentence could be: “these foods ... without any prior preparation and without any addition of water.”</p> <p>The fact that no water should be added is an important information.</p>
<p>3.2 Are there any additional terms that should be defined?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Please suggest the terms and the provide justification for your proposals.</p> <p>As mentioned above, it is not sure at that stage that the term “young children” will be used in the document, as the targeted age range is not 12-36 months.</p>
<p>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)?</p> <p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p> <p>See above.</p>

4. BASIC RAW MATERIALS AND INGREDIENTS

BASIC RAW MATERIALS AND INGREDIENTS
<p>4.1 Please provide comments to the proposed wording on RUTF. Please provide justification and rationale for your comments.</p> <p>RUTF are made of powdered or ground ingredients embedded in a lipid-rich matrix, or protein-based matrix, resulting in energy and nutrient-dense food. The main ingredients are generally ground peanuts, dairy products, sugar, vegetable oil, and a premix containing vitamins and minerals. However other forms of RUTF with various ingredients are being tried and tested in different regions.</p> <p>In the criteria set by the document for nutritional composition, lipids should represent 45 to 60 % of the total energy whereas proteins represent 12 to 12% of the energy. Therefore it seems difficult to consider that the product could be made with a “protein based matrix”.</p>

The use of the word “premix” does not seem appropriate in this context. The chapter is about “basic raw materials and ingredients”, it gives information on the final composition of the product. But it should be flexible on the way nutrients can be added to the product (premix or individually).

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

Yes No

4.3 If No, provide justification for your answer.

3.4.2.3 Mineral and Vitamin ~~premix~~

See above.

It is not clear to us if the guidelines will put together all the rules applicable to these products or if the document will only take on board the points for which the rules will be different from the existing Codex Standards. If the aim is to bring together in the document all the constraints, then a part should be added on the “specific prohibition”, as it is the case in the Codex STAN 72-1981 ou STAN 74-1981. It would deal with the addition of salt, the use of irradiation etc...

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 No

Please provide the rationale and justification for your proposals.

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

Yes No

It is not clear to us if the question is dealing with the guidelines or with the labelling of the product.

Considering the guidelines, it seems difficult to list the ingredient in descending order as it vary with the composition of each product. Considering the product itself, it would be interesting to list the ingredients in descending order of proportion.

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.

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

Yes No

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

The sentence is incomplete.

Proposal :

“new formulation of RUTF with other ingredients may be used if scientific data on efficacy and acceptability exists and have demonstrated that the use of the newly developed product to treat

SAM in the same context as the current RUTF is considered as efficacious and as acceptable”

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

Minimum should be set for all vitamins and minerals. Maximum is particularly important when there is a risk linked to a too high level of a nutrient.

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.

It would be helpful if the values could be expressed in international units.

In addition, RUTF should not promote acidosis. Metabolic acidosis may be related to SAM due to diarrhoea and or decreased renal function. In the 2007 UN Statement, guidelines are provided as to how calculate the equilibrium of non-metabolized bases. This should be integrated in the guidelines. As described in the “2007 Joint statement by UN agencies”:

The added minerals should be water-soluble and should not form insoluble components when mixed together. The food should have a mineral composition that will not alter the acid base metabolism of children with severe acute malnutrition. In particular, it should have a moderate positive non-metabolizable base sufficient to eliminate the risk of metabolic acidosis. The non-metabolizable base can be approximated by the formula: estimated absorbed millimoles (sodium + potassium + calcium + magnesium) - (phosphorus + chloride). The mineral mix recommended for F100 by WHO is an example of a mineral mix with a suitable positive non-metabolizable base.

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?

The values proposed in the reference document (cf table 1) are appropriate.

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.

Additional Nutrients

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

Manganese is already present in the raw materials.

Robust scientific evidence is needed before deciding to add it to the recommendations of the UN agencies. If it is added, the input of raw materials should be taken into account.

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.

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.

DIAAS should be used each time it is possible (it is the most recent reference). However, attention should be paid to the model chosen for the assessment of protein quality. It should be adapted to children with rapid growth as it is the case for children treated with RUTF.

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.

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

As we understand it, this paragraph is only dealing with the processing of raw materials.

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?

The reference to the CAC/RCP 66-2008 is a bit misleading. Indeed, as the use of powdered formulae for infants and young children need the addition of water (which is not the case for RUTF), the disposition of CAC/RCP 66-2008 is not adapted for RUTF.

Considering *Enterobacter Sakazakii*, an important work has been done by WHO/FAO in 2013 and the conclusion was that this parameter should not apply to this products.

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

The opinion of the NGOs using these products is very important to assess the evolution of the risk/benefit balance the document lead to a change in the size of the sachets (level of reduction of the risk / increase of the price of the product).

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?

The link between the CODEX STAN 180-1991 and the text of the guidelines is not clear. There are 2 options:

- keep in the document only the paragraph of the codex STAN 180-1991 which are appropriate, in that case, a reference to STAN 180-1991 is misleading; or
- explain in the document that the only points described in the guidelines are those for which we want to deviate from STAN 180-1991.

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.

Some of the proposed mandatory statements are already required for all foods for special medical purposes. This is for example the case of the statement that the product must be used under medical supervision (see section 4.4.1 of Codex Standard 180-1991), or that the product is intended for the dietary management of severe acute malnutrition (see section 4.5.1 of Codex Standard 180-1991). The wording should be the same.

In addition, while the 2007 Joint Statement by the WHO, WFP, UNSCN and UNICEF "*Community-Based Management Of Severe Acute Malnutrition*" recognises the essential contribution of exclusive breastfeeding for the first six months of a child's life to prevent severe acute malnutrition, it also notes that treatment is needed for those children who already are suffering from severe acute malnutrition. In light of this, the EU would like to obtain more information on the scientific rationale for the proposed statement "*breastfeeding is the most important for the rehabilitation of acute malnutrition and that the RUTF should not replace breastfeeding*".

Considering the d: "*RUTF should not replace breastfeeding and locally available family food*", the second part of the sentence is misleading. RUTF are used in cases when the family food is not able to cover the need of the children.

The c proposal could be replaced by a sentence explaining that the product should not be used more than 3 months; The message would be clearer for parents.

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

"RUTF should not be shared with other members of the family"