Comments from the European Union

9 June 2016

To: Electronic Working Group, Chaired by South Africa

and co-chaired by Senegal and Uganda on

the development of a guideline for Ready-to-Use Therapeutic Foods (RUTF)

Answers to the second consultation paper of May 2016

The comments expressed in the document do not prejudice the coordinated position officially and finally taken by the European Union when requested by the Codex Secretariat.

The European Union (EU) would like to thank South Africa, Senegal and Uganda for their work on the second consultation paper to develop a guideline for Ready-to-Use Therapeutic Foods (RUTF).

The EU comments are included in the enclosed document, in the dedicated space after the corresponding question.

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**
To: tshitg@health.gov.za, naickn@health.gov.za, iwanyenya@nda.or.ug, and moussa.ndong@ugb.edu.sn

Name of Member Organisation: **EUROPEAN UNION**

1. PURPOSE

PURPOSE
1.1 Please provide comments and justification for your answers to the proposed text. The EU is of the view that the text should also refer to the upper age limit ("for children from ~~the age of six~~ **6 to 59** months…") in order to ensure consistency with the other sections of the document.

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.** The EU is of the view that the food categories to be excluded from the scope of the guideline should

be those for which doubts could arise on whether they are RUTF or not, and it is therefore necessary to clarify their exclusion. In this context, instead of referring to the broad concept of "complementary foods", it would be probably more useful to refer to "Formulated Complementary Foods for Older Infants and Young Children" (covered by the Codex Guidelines CAC/GL 8-1991). Also, if processed cereal based foods (covered by Codex Standard 74-1981) are included in the list, the same approach should be followed for "canned baby foods" (covered by Codex Standard 73-1981).

The EU would also like to obtain more information on what is covered by the expression "other products used to prevent or treat malnutrition".

3. DESCRIPTION

DESCRIPTION
3.1 Please provide comments on the suggested wording for the "Description". The EU agrees with the proposal to define "severe acute malnutrition" and with the additions proposed by the Chairs to the Description. In particular, as explained in the first round of consultation, the EU is in favour of referring to "dietary management" instead of "treatment", to ensure consistency with the language used in Codex Standard 180-1991 on foods for special medical purposes. The EU would however kindly suggest to also add a reference to the upper age limit (59 months) in the Description, given that the lower age limit of 6 months is mentioned. In addition, the EU would like to seek clarification on whether there is a specific reason to refer to "young children" (i.e. in CODEX language, children aged 12-36 months). Shouldn't the requirement that the foods are soft or crushable and easy to eat be valid also for infants aged 6-12 months or children aged 36-59 months? If this is the case, then it would be probably easier to refer, more generally, to "children" and not define "young children".
3.2 Are there any additional terms that should be defined? **Yes** ☐ **No** ☐ **Please suggest the terms and the provide justification for your proposals.**
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** ☒ **No** ☐ (see above)

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** ☐

4.3 If No, provide justification for your answer.

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** ☐

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.

The EU would like to seek clarification on the proposals related to the listing of ingredients in RUTF. Are the proposals relevant for the labelling of the products? If this is the case, then they should be discussed in the context of labelling requirements and not in this section.

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 EU would like to note that, since RUTF are foods for special medical purposes, they are in any case covered by the provisions of Codex Standard 180-1991. It is therefore important to ensure consistency with the language used in that Standard.

In particular, as regards the statement on alternative formulations for RUTF, language should be consistent with section 3 of Standard 180-1991, which states: "*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*" (…).

With respect to the reference to "treating" severe acute malnutrition, the EU would like to refer to its previous comments and to its preference for the expression "dietary management".

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.

The project document agreed at CCNFSDU37 underlines that the nutritional composition of RUTF should be based on relevant WHO documents and their future modification. The EU is therefore of the view that WHO should provide its opinion on all cases where the proposed composition diverges from the recommendations in WHO's documents.

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.

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.

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.

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** ☐ The EU agrees that this section should not lay down specific levels, but simply make a cross-reference to the levels provided by relevant CODEX texts (e.g. the General Standard for contaminants and toxins in food and feed). This would also ensure that the section remains up-to-date if those levels are revised in the future.

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?

The EU is of the view that this section should, where possible, cross-refer to relevant existing CODEX texts (e.g. CODEX General Standard 1-1985 for the labelling of pre-packaged foods for the requirements on the ingredients list, or Codex Standard 180-1991 for the labelling of and claims for foods for special medical purposes…).

Specific labelling provisions should be included in the guideline only where these are different from the existing requirements in other relevant CODEX texts, and are necessary to take into account the specificities of RUTF.

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.

The EU would like to note that 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 EU would also like to note that, 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*".

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