CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7 **CX/NFSDU 17/39/7-Add.2**

Original language only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-ninth Session

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4 – 8 December 2017

PROPOSED DRAFT GUIDELINES FOR READY-TO-USE THERAPEUTIC FOODS

Comments of Kenya, Malaysia, Tanzania, Thailand and International Association of Consumer Food Organizations (IACFO)

KENYA

Comment: We generally support the proposed draft and in particular the proposed compositional levels of the Ready To Use Products.

Justification: The proposed levels are based the 2007 Joint statement of the UN agencies on Community-based management of severe acute malnutrition

MALAYSIA

5. RAW MATERIALS AND INGREDIENTS

5.2.1 Available Carbohydrates[1]

Malaysia supports the statement in square bracket, therefore proposes to remove all the square brackets as follows:

> [1][Sucrose, vegetable starch, glucose, glucose syrup should be the preferred carbohydrates in RUTF. Fructose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinised starches gluten-free by nature may be added].

6. NUTRITIONAL COMPOSITION AND QUALITY FACTORS

6.2 Proteins

Malaysia is of the opinion that it is not necessary to specify the source of protein but it is important to define minimum of protein to give flexibility of product.

6.3 Fat

Malaysia does not support the proposed energy density derived from fat is 45% to 60% because the value is consider high. In addition, Malaysia is of the opinion that fatty acid are also important to be taken into consideration for the dietary management of children with severe acute malnutrition.

12. LABELLING

Malaysia proposes to include the reference of Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985). As such, Malaysia proposes the section of the list of ingredients to be deleted as it would be covered under CODEX STAN 1-1985.

Additional Mandatory Labelling Requirements

Malaysia has no objection on the statement in the last bullet "[Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months]".

ANNEX

Malaysia is of the view that the information provided in Annex are incomplete and thus, it would premature for Malaysia to comment.

TANZANIA

Background of Ready To Use Therapeutic Foods

The work on RUTF was adopted by the 37th Session of CCNFSDU where an eWG co-chaired by South Africa, Uganda and Senegal was established to develop either a standard or guideline for the RUTF. In the 38th Session, the committee discussed and agreed to develop a guideline as opposed to a standard, which would provide guidance mainly to encourage the use of locally available foods in the production of RUTF. In addition, the session agreed on the general structure of the guidelines. At the end of the 38th session an eWG co-chaired by the 3 countries was established to develop a draft guidelines for discussion in step 3 during the 39th Session. The eWG developed 28 recommendations touching on the various clauses of the guidelines. A number of African countries actively participated in the eWG.

Issue Recommendation 1: That CCNFSDU agree to the draft text for the preamble as drafted in the recommendation

Comment: Tanzania propose the preamble be amended and rearranged as indicated in the highlights below:

The major objectives of the work of the Codex Alimentarius Commission are to protect the health of the consumer and ensure fair practices in the trade in food through the elaboration and harmonization of definitions and requirements for food. In order to realize this objective CAC developed a Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CAC/RCP 20-1979) embodying the principles of sound consumer protection. ***~~The objective of this code is to establish standards of ethical conduct for all those engaged in international trade in food or for those responsible for regulating food and thereby protecting the health of the consumers and promoting fair trade practices.~~*** *It is within this context that all those engaging in the international trade in food with specific reference to Ready-To-Use Therapeutic Foods (RUTF) commit themselves to the provisions of the code.*

Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate ***and bioavailable*** *amounts of vitamins, minerals and other critical nutrients. Children with SAM need timely treatment and RUTF is a critical part of the treatment. RUTF are high energy, fortified, ready-to-eat foods for special medical purposes suitable for the dietary management of children with SAM. RUTF are primarily intended for children with uncomplicated SAM from 6-59 months. Although RUTF are given to other age groups with various forms of malnutrition at the implementation level, the primary focus for these guidelines is children with SAM from 6-59 months. Since RUTF are prescribed according to weight, National Authorities may decide to include the provision of RUTF in their national protocols for use by other age groups.*

Investing in prevention of SAM through sustainable measures and interventions is crucial. Such interventions could include the improvement of access to high quality food and safe water through improving water and sanitation systems, improved access to health care, and the effective promotion of exclusive breastfeeding for the first six months of a child´s life combined with continued breastfeeding up to 24 months and beyond. Thus, preventive programmes have an immense job to do in the context of poverty, and in the meantime children who already are suffering from SAM need to receive appropriate treatment. These guidelines should therefore be used in accordance with the 2007 Joint statement of the UN agencies on Community-based management of severe acute malnutrition5, relevant WHO Child Growth Standards6, WHO guidelines in the management of Severe Acute Malnutrition in infants and children7, the Global Strategy for Infant and Young Child Feeding8, the International Code of Marketing of Breastmilk Substitutes9 and subsequent relevant WHA Resolutions on infant and young child feeding.

These guidelines have been prepared for the purpose of providing an agreed upon approach to the requirements which underpin the production of, and the labelling and claims for, RUTF. The guidelines are intended to facilitate the harmonization of requirements for RUTF at the international level and may provide assistance to governments wishing to establish national regulations in this area.

These guidelines should ***~~therefore~~*** *be used in accordance with the 2007 Joint statement of the UN agencies on Community-based management of severe acute malnutrition5, relevant WHO Child Growth Standards6, WHO guidelines in the management of Severe Acute Malnutrition in infants and children7, the Global Strategy for Infant and Young Child Feeding8, the International Code of Marketing of Breastmilk Substitutes9 and subsequent relevant WHA Resolutions on infant and young child feeding.*

The guidelines are also intended for use as an instrument designed to avoid or reduce difficulties which may be created by diverging legal, administrative and technical approaches to RUTF and by varying definitions and nutrient compositions of RUTF. These guidelines can also be used, if applicable, by governments in

case of international trade disputes. Governments and other users should ensure adequate provisions are made for competent technical experts for the appropriate use of these guidelines.

Rationale: In the first paragraph, the deletion (as indicated with strike through) was proposed to avoid repetition since the same information is in subsequent paragraphs and that the information is elaborated in the referenced text of CAC/RCP 20-1979. The introductory sentence of the third paragraph, which is describing prevention rather than treatment, is proposed for deletion (as indicated with strike through) as it is in contrary to the intention of the guidelines which emphasizes on treatment. The rest of sentences of paragraph 3 are moved to paragraph 5 to improve on the logical flow of the guidelines

Issue Recommendation 2: That CCNFSDU agree to the proposed text for the description of RUTF as follows:

Ready to Use Therapeutic Foods (RUTF) *are high-energy, fortified, ready-to-eat foods for special medical purposes for the dietary management of children from 6 to 59 months with severe acute malnutrition without medical complications. These foods* ~~***should***~~ ***are*** *soft or crushable and* ~~***should be***~~ *easy for children to eat without any prior preparation.*

Severe Acute Malnutrition *is defined by weight for height (or length) less than –3 Z-score of the median WHO growth standards, or by mid upper arm circumference (MUAC)<11.5 cm, or by the presence of bilateral oedema.*

Comment: Tanzania support proposed definitions with the slight modification as highlighted.

Rationale: It is a definition and thus it should not provide requirement rather provide a clear definition of the product.

Issue Recommendation 3: That CCNFSDU consider the proposed opening text on "Raw Materials and Ingredients" section of the proposed Guidelines on RUTF as follows:

RUTF are made of powdered or ground ingredients embedded in a lipid-rich matrix [e.g. paste and biscuit], resulting in an energy and nutrient-dense food. The following raw materials, many of which can be sourced locally, are suitable ingredients for the production of RUTF under the specified conditions given below. The formulation of RUTF shall comply with Section 3 of the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991.

Comment: Tanzania accept the proposed text

Rationale: It emphasizes the importance of sourcing the raw materials locally from the available foods of the community/country.

Issue Recommendation 4: That CCNFSDU agree to the proposed text for the "Milk and other dairy products" section as follows:

Milk and other dairy products used in the manufacturing of RUTF must comply with the *Standard for Milk*

Powders and Cream Powder (CODEX STAN 207-1999) and the Standard for Whey Powders (CODEX STAN 289-1995), and other guidelines and Codes of Practice recommended by Codex Alimentarius Commission which are relevant to these products. Relevant codes of practice include the Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004) and the Code of Hygienic Practices for Low-Moisture Foods (CAC/RCP 75-2015).

Comment: Tanzania support the proposed text

Rationale: It is making reference to codex standards for the raw material.

Issue Recommendation 5: That CCNFSDU agree to the proposed text on legumes and pulses as follows:

Legumes and pulses, such as ***soybean*** *lentils, chickpeas, cowpeas, beans, peanut, sesame and other types of legumes and pulses must comply with the Standard for Peanuts (CODEX STAN 200-1995), Code of Hygienic Practice for Groundnuts (Peanuts) (CAC/RCP 22- 1979) and the Code of Hygienic Practices for Low-Moisture Foods (CAC/RCP 75-2015), and other relevant Codex Alimentarius text when used in the manufacturing of RUTF. Legumes and pulses must be appropriately processed to reduce, as much as possible, the anti-nutritional factors normally present, such as phytate, lectins (haemagglutenins), trypsin and chymotrypsin inhibitors.*

Comment: Tanzania accept the proposed text with addition of soybean as indicated

Rationale: Soybean is used in most countries and thus it is important to include it in the list.

Issue Recommendation 6: That CCNFSDU agree to the proposed text on fats and oils and a statement that prohibit the use of partially hydrogenated fats and oils in RUTF.

Fats and oils used in the manufacturing of RUTF must comply with the relevant Codex Alimentarius texts. Fats and oils are incorporated as technologically feasible for the purpose of achieving the energy density and providing essential fatty acids. Care must be taken to avoid oxidized fat which will adversely affect nutrition, flavour and shelf life. Partially Hydrogenated fats and oils should not be used in RUTF.

Comment: Tanzania support the proposed text

Rationale: It is guiding on the safety and quality of fat to be used in the manufacture of the RUTF given that it will be consumed by a vulnerable population.

Issue Recommendation 7: That CCNFSDU agree to the proposed text on the use of cereals in RUTF formulation as follows:

All milled cereals suitable for human consumption may be used provided that they are processed in such a way that the fibre content is reduced, when necessary, and that the effects of anti-nutritional factors such as phytates, tannins or other phenolic materials, lectins, trypsin, and chymotrypsin inhibitors which can lower the protein quality and digestibility, amino acid bioavailability and mineral absorption are removed or reduced, whilst retaining maximum nutrient value.

Comment: Tanzania support the proposed text

Rationale: The text provides guidance on the quality of milled cereals to be used.

Issue Recommendation 8:

8.1 That CCNFSDU consider specifying forms of minerals salts and trace elements to be used in RUTF formulation, which will not alter the acid-base metabolism of SAM children.

8.2 That CCNFSDU agree to the proposed text on vitamins and minerals as follows.

All added vitamins and minerals must be in accordance with the *Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CAC/GL 10-1979).

Comment: Tanzania support the proposed text

Rationale: It provides reference to published Codex standards for use in preparing the RUTF.

Issue Recommendation 9:

9.1 *That CCNFSDU agree to the proposed text on addition of available carbohydrates into RUTF formulation, and a statement that prohibit the use of honey in RUTF.*

The palatability of the RUTF can be increased by the addition of appropriate available carbohydrates.

Available carbohydrates must adhere to the relevant Codex Alimentarius texts.

Honey should not be used in RUTF due to the risk of infant botulism from Clostridium botulinum.

9.2 *That CCNFSDU agree to the inclusion of a footnote on the acceptable available carbohydrates in RUTF formulation and consider the proposed text for the footnote as follows:*

[1]*[Sucrose, vegetable starch, glucose, glucose syrup] should be the preferred carbohydrates in RUTF. Fructose and high fructose corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinised starches gluten-free by nature may be added].*

9.3 *That CCNFSDU consider whether the acceptable limit of available carbohydrates should be included in the guidelines.*

Comment: Tanzania support the proposed text

Rationale: Honey has been associated with *Clostridium botulinum* contamination and thus its prohibition in its use in RUTF is highly acceptable. With regard to the food note, we propose opening the brackets. As much as vegetable starch is best due to it being complex carbohydrates, the use of mono and di-saccharides poses no health risk to the children at this age whose glycemic index may also be low.

Issue Recommendation 10: That CCNFSDU agree to the following proposed stepwise approach to address the use of food additives in RUTF formulation:

a. *The eWG compile a list of food additives currently used by the industry in the manufacturing of RUTF that include their technological rationale and function and approximate use levels.*

b. *The eWG compare the food additives currently used in RUTF to food additives approved for use in existing Codex texts aimed at infants and young children to determine whether the food additives in RUTF have already been evaluated in infants and young children.*

c. *The eWG recommend a proposed list of food additives for CCNFSDU to confirm the technological need.*

d. *Once CCNFSDU confirms the technological need, CCNFSDU could forward a list of food additives used in RUTF to CCFA for their consideration on safety aspects, and also request input from CCFA on the appropriate food category assignment, as well as guidance on appropriate procedural steps to be followed.*

Comment: Tanzania support the proposed text

Rationale: It is in accordance with the codex procedural manual of referring issues to the competent Codex committee for adoption.

Issue Recommendation 11: That CCNFSDU agree to the proposed text which reference Section 3 of the CODEX STAN 180-1991 on the use of other matrices in RUTF formulations as follows:

RUTF may be manufactured with formulations different from the one laid down in these guidelines provided that these formulations comply with Section 3 of the Standard for Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991).

Comment: Tanzania support the proposed text

Rationale: It is making a normative reference to Codex standard.

Issue Recommendation 12: That CCNFSDU agree to the proposed text on energy and the energy values as follows:

Energy

The energy density of the formulated RUTF should be at least ~~5.2 to 5.5 Kcal per g~~ 520 to 550 kcal per 100 gram. The energy density of the RUTF can be achieved during manufacturing by the addition of energy containing ingredients (i.e. fats and oils and/or digestible carbohydrates) and/or processing the basic raw materials and ingredients as indicated in the Section on "Technologies for and effects of processing.

Comment: Tanzania support the proposed text with the slight change

Rationale: To make it consistent with the table which qualifies the energy per 100 g of the product.

Issue Recommendation 13:

That CCNFSDU agree not to set the minimum and maximum/GUL values for carbohydrates.

Comment: Tanzania support the proposed text

Rationale: This is already taken care of by the provision of minimum and maximum energy requirements.

Issue Recommendation 14: That CCNFSDU agree to keep the statement "at least 50% of protein is provided by milk products" in square brackets until there is further guidance from FAO on determining protein quality using PDCAAS.

["at least 50% of protein is provided by milk products"]

Comment: Tanzania support the proposed text.

Rationale: The guidance from FAO will be important in determining the percentage of protein from milk in the products.

Issue Recommendation 15: That CCNFSDU agree to the proposed text on fats/lipids and the proposed minimum and maximum fats/lipids values as follows:

[Incorporation of fats and/or oils in RUTF serves to increase the energy density and the amount of essential fatty acids. At least 45% to 60% of energy derived from fat is desirable.

The level of linoleic acid should not be less than 576.9 mg per 100 kcal when used in the production of

RUTF and should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.]

Fats/Lipids should provide 45%-60% of the total energy.

Comment: Tanzania support the proposed text with amended as indicated.

Rationale: The sentence was deleted because it is already mentioned in previous recommendation on energy requirement while the part of 40 - 60 % is further down the recommendation.

Issue Recommendation 16: That CCNFSDU agrees to retain the linoleic acid and alpha-linolenic acid values as stipulated in the 2007 Joint Statement in the current RUTF nutritional composition as follows:

Essential Fatty acids values

Linoleic Acid = 3-10% of total energy

[The level of linoleic acid should not be less than 576.9 mg per 100 kcal]

Alpha- linolenic acid = 0.3-2.5% of total energy

[The level of alpha-linolenic acid should not be less than 57.69 mg per 100 kcal]

Comment: Tanzania support the proposed text and opening the of the square brackets

Rationale: It provides guidance which will ensure high quality fat is used during production of the product especially related to the essential fatty acids.

Issue Recommendation 17: That CCNFSDU agree to the minimum, maximum and associated footnote for vitamin A

Comment: Tanzania support the minimum as proposed and recommend the higher upper limit of 1.2

Rationale: Children who are SAM have a very low level of vitamin A and thus higher level in RUTF will improve their nutritional status.

Issue Recommendation 18: That CCNFSDU agree to the minimum, maximum/GUL and associated footnote for vitamin D

Comment: Tanzania support the minimum and propose the lower proposed level of maximum(20 µg/100 g)

Rationale: Children suffering from SAM in developing countries will still be exposed to sunlight and thus they will be able to synthesis Vitamin D.

Issue Recommendation 19: That CCNFSDU agree to the minimum and associated footnote for vitamin E

Comment: Tanzania support the proposed text

Rationale: the guideline provides a conversion factor to α-TE which is the most important form of Vitamin E.

Issue Recommendation 20: That CCNFSDU agree to the following recommendations for vitamin K, vitamin B1, vitamin B2, vitamin C, vitamin B6, vitamin B12, folic acid, niacin, pantothenic acid and biotin for RUTF

Comment: We support the proposed nutrients and level. We propose that the table be editorially improved such that all vitamin Bs are grouped together i.e.by moving Vitamin C to the end of the vitamin list.

Rationale: For ease of referencing and reading.

Issue Recommendation 21: That CCNFSDU agree to the following recommendations for sodium, potassium, calcium, phosphorus, magnesium, iron, zinc, copper, selenium and iodine for RUTF

Comment: Tanzania support the proposed nutrients and levels

Rationale: The nutrient levels will achieve the intended objective of improving the nutritional status of the target population.

Issue Recommendation 22: That CCNFSDU consider that the current formulation of RUTF, as well as the proposed nutrients as stipulated in the 2007 Joint Statement be the basis for RUTF formulation, unless there is scientific evidence on any additional nutrients that has been demonstrated to be safe and beneficial in meeting the nutritional requirements of SAM children.

Comment: Tanzania support the joint statement

Rationale: The joint statement is an acceptable scientific basis that may be used in the formulation of the RUTF.

Issue Recommendation 23: Draft text on Contaminants

[It is recommended that the products covered by the provisions of these guidelines comply with the General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995), Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods (CAC/MRL 2-2015) and Codex Maximum Residue Limits for Pesticides.

Other Contaminants

The product should not contain contaminants or other undesirable substances (e.g. biologically active substances, metal fragments) in amounts which may represent a risk to the health of children. The product covered by the provisions of these Guidelines shall comply with those maximum residue limits and maximum levels established by the Codex Alimentarius Commission. ~~A maximum of 10 ppb (µg/kg) for aflatoxin is allowed in the RUTF products~~.]

Comment: The aflatoxin limit should make reference to national or regional legislation/regulation

Rationale: Aflatoxin contamination of food is a major public health concern in Africa and given that these guidelines are promoting the use of local foods in production of RUTF, there is need to provide for the maximum level of aflatoxin. In the absence of such limit in Codex Stan 193-1995, a statement, 'the maximum level of aflatoxin should be comply with those limit set by the national or regional competent body' should be introduced.

Issue Recommendation 24: That CCNFSDU agree to the proposed text of "Technologies for and effect for processing" section of the Guidelines

Comment: Tanzania support the proposed text except on the last paragraph where it gives irradiation as an acceptable form of non-thermal method of eliminating microorganism.

*"..Commonly used microbial reduction treatments that could be applied to RUTF or their raw materials include both thermal (e.g. roasting, steam treatment followed by a drying step) and non-thermal (e.g. **~~irradiation~~**, antimicrobial fumigation) control measures. [Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69-2008) and Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) (CAC/GL 63-2007) should be adhered to]"*

Rationale: Ionising irradiation is not allowed for treatment of products (such infant formula) to be consumed by infants and young children (Clause 3.7 of CODEX STAN 72-1981) and thus it should be deleted.

Issue Recommendation 25: That CCNFSDU agree to the proposed draft text for "good manufacturing practices and good hygiene practices"

Comment: Tanzania support the proposed text.

Rationale: It is making reference to existing codex standards and guidelines.

Issue Recommendation 26: That CCNFSDU agrees to the proposed text for "the methods of analysis and sampling" section of the guidelines as follows:

It is recommended that methods of analysis and sampling of RUTF be in accordance with the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999), General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995), The Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CAC/GL 21-1997), Code of Hygienic Practice for Low Moisture Foods (CAC/RCP 75-2015), and other relevant Codex Alimentarius texts. When needed, specific methods of analysis should be developed in accordance with appropriate Codex Guidelines on Measurement Uncertainty (CAC/GL 54-2004), Protocol for the Design, Conduct and Interpretation of Method Performance Studies (CAC/GL 64-1995), and Harmonized IUPAC (International Union of Pure and Applied Chemistry).

Comment: Tanzania support the proposed text

Rationale: Makes reference to relevant Codex Standards

Issue Recommendation 27: That CCNFSDU agrees to the proposed text for "packaging" section of the guidelines as follows:

It is recommended that RUTF be packaged in such a way to safeguard the hygienic and other qualities including nutritional properties of the food for the duration of its defined shelf-life. The packaging materials shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.

Comment: Tanzania support the proposed text

Rationale: The recommendation emphasizes the need to ensure the safety of the RUTF throughout the shelf life.

Issue Recommendation 28: Labelling

Comment: Tanzania propose deletion of the statement, 'A statement indicating whether the product is or is not intended as the sole source of nutrition' under mandatory labeling requirement. Additionally we propose open up of other square brackets related to the product being used within 24 hours and that related to exclusive breast feeding.

Rationale: In normal use of RUTF, it is used along with other foods and thus this statement serves no purpose in the guidelines. In regard to the brackets suggested for opening we fully support their content as they will ensure hygiene related to keeping opened products for long as well as promoting and protecting breastfeeding practices.

THAILAND

General comments

We agree with the document in principle.

Specific comments

Our comments for specific sections of the document are as follows:

- Appendix 1

- Section 2. PURPOSE OF THE GUIDELINES

- iv. Microbiological and Chemical Contaminant Criteria

- The word "Chemical Contaminant" should be amended to "Other Criteria", as Section 7: Contaminants covers sub-section "Other Contaminants" that concerns criteria for both chemical and physical contaminants. So, this section should read:

"iv. Microbiological and ~~Chemical~~ ***other*** Contaminant Criteria"

- Section 4. DESCRIPTION

- 4.1 Ready to Use Therapeutic Foods (RUTF)

- The word "adequate protein" should be added before "fortified", so the section should read:

"4.1 Ready to Use Therapeutic Foods (RUTF) are high-energy***, adequate protein,*** fortified, ready-to-eat foods for special medical purposes for the dietary management of children from 6 to 59 months with severe acute malnutrition without medical complications. These foods should be soft or crushable and should be easy for children to eat without any prior preparation.**"**

- 4.2 Severe Acute Malnutrition

- The word "nutritional" should be added before "oedema", so the section should read:

"4.2 Severe Acute Malnutrition is defined by weight for height (or length) less than –3 Z-score of the median WHO growth standards, or by mid upper arm circumference (MUAC)<11.5 cm, or by the presence of bilateral***, nutritional*** oedema"

- Section 5. RAW MATERIALS AND INGREDIENTS

- 5.1 Basic Raw Materials and Ingredients

- 5.1.3 Fats and Oils

- The last sentence in a square bracket should be deleted; as it is unnecessary considering that the products are already required to comply with the specified criteria. The section should then read:

"Fats and oils used in the manufacturing of RUTF must comply with the relevant Codex Alimentarius texts. Fats and oils are incorporated as technologically feasible for the purpose of achieving the energy density and providing essential fatty acids. Care must be taken to avoid oxidized fat which will adversely affect nutrition, flavour and shelf life. ~~**[The composition of fats and oils should allow for a product that flows during processing and ensures physical stability throughout the supply chain.]**~~

Partially Hydrogenated fats and oils should not be used in RUTF."

-5.2 Other Ingredients

-5.2.1 Available Carbohydrates

1) We would like to request for clear and strong scientific evidence which recommends that honey should not be used in RUTF due to the risk of infant botulism from Clostridium botulinum.

2) The last paragraph

We would like to propose that instead of sucrose, other carbohydrate sources such as maltodextrin should be used in RUTFF. So, a square bracket should be removed from this paragraph and the text should then read:

"~~1[Sucrose,~~ *V*egetable starch*, maltodextrin*, glucose, glucose syrup~~]~~ should be the preferred carbohydrates in RUTF. Fructose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinised starches gluten-free by nature may be added~~]~~."

-5.2.2 Food Additives and Flavours

- From our views, the addition of food additives in RUTF should be as needed, and to facilitate the elaboration of Guidelines for RUTF, the additives under Food Category 13.1, 13.2, and 13.3 should be selected and used for RUTF at this stage.

In the future, however, a proposal could be made for the specific list of food additives for RUTF. So, it is proposed that the section should read:

"~~[This section will make reference to the General Standard for Food Additives (CODEX STAN 192-1995)].~~ *In order to facilitate the guidelines setting process, food additive under Food Category 13.1, 13.2, and 13.3 should be selected to be used as necessary in the RUTF. In the future, the list of food additive for the RUTF should be proposed.*"

-Section 6. NUTRITIONAL COMPOSITION AND QUALITY FACTORS

-6.2 Proteins

- We agree with the proposed text. For protein sources, in our opinion, they should come from local production, it is recommended that protein could come from legumes and pulses, other than milk. So, our proposed text should read as follows:

"~~[~~"at least 50% of protein is provided by milk products *or from legumes and pulses*"~~]~~ "

-6.3 Fat

- We agree with the proposed text with the removal of a square bracket from the sentence. And, in our opinion, the text "At least 45% to 60%" should be replaced with "Around 50%". So, the section should read:

"~~[~~Incorporation of fats and/or oils in RUTF serves to increase the energy density and the amount of essential fatty acids. ~~At least 45% to 60%~~ *Around 50%* of energy derived from fat is desirable.

The level of linoleic acid should not be less than 576.9 mg per 100 kcal when used in the production of RUTF and should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.~~]~~"

-Section 7. CONTAMINANTS

-Other Contaminants

- The last sentence concerning a maximum level for alflatoxin in RUTF products should be deleted, as the section previously specifies that the products shall comply with Codex maximum residue limits and maximum levels. The section should then read:

"The product should not contain contaminants or other undesirable substances (e.g. biologically active substances, metal fragments) in amounts which may represent a risk to the health of children. The product covered by the provisions of these Guidelines shall comply with those maximum residue limits and maximum levels established by the Codex Alimentarius Commission. ~~[A maximum of 10 ppb (µg/kg) for aflatoxin is allowed in the RUTF products.]~~"

-Section 8. TECHNOLOGIES FOR AND EFFECT FOR PROCESSING

-8.3 Toasting

- the last bullet

A square bracket should be removed from this bullet, so it should read:

"~~[~~The use of appropriate enzymes may be considered to decrease anti-nutrients in ingredients.~~]~~"

-8.5 Other Processing Technologies

- the second paragraph

A square bracket should be removed from the second sentence of this paragraph that makes the paragraph read:

"Commonly used microbial reduction treatments that could be applied to RUTF or their raw materials include both thermal (e.g. roasting, steam treatment followed by a drying step) and non-thermal (e.g. irradiation, antimicrobial fumigation) control measures ~~[~~Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69-2008) and Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) (CAC/GL 63-2007) should be adhered to~~]~~"

-Section 10. METHODS OF ANALYSIS AND SAMPLING

- The last sentence of the section should be deleted, as the proposed text mentioned former makes sufficient references to relevant Codex texts. So, the section should read:

"It is recommended that methods of analysis and sampling of RUTF be in accordance with the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999), General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995), The Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CAC/GL 21-1997), Code of Hygienic Practice for Low Moisture Foods (CAC/RCP 75-2015), and other relevant Codex Alimentarius texts. ~~When needed, specific methods of analysis should be developed in accordance with appropriate Guidelines on Measurement Uncertainty (CAC/GL 54-2004), Protocol for the Design, Conduct and Interpretation of Method Performance Studies (CAC/GL 64-1995), and Harmonized IUPAC.~~"

-Section 12. LABELLING

- **the first paragraph**

References to Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) and General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985) should be removed. So the section should read:

" It is recommended that the labelling of RUTF for children from 6 to 59 months be in accordance with the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991), ~~Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985),~~ the General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses (CODEX STAN 146-1985)~~, Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)~~ and Guidelines on Nutrition Labelling (CAC/GL 2- 1985)."

- **Declaration of Nutritive Value**

In our opinion, sub-section on "Declaration of Nutritive Value" should be remained, because it is important and useful information, although the first paragraph already refers to CODEX STAN 180-1991. The section should then read:

"Declaration of Nutritive Value

The declaration of energy and nutrients on the label or in labelling shall contain the following information expressed per 100 grams of the Ready to Use Therapeutic Foods as sold or otherwise distributed as well as per feeding of the food ready for consumption:

(a) energy value, expressed in kilocalories.

(b) the amounts of protein, carbohydrates and fat, expressed in grams;

(c) the amounts of essential fatty acids, expressed in grams.

(d) the amounts of vitamins and essential minerals, expressed in metric units.

- Information on osmolality or osmolarity and on acid-base balance shall be given.
- In addition, information on the nature of the animal or plant proteins or protein hydrolysates shall be provided."

-Additional Mandatory Labelling Requirements

- **The first paragraph**

- bullet 5

To avoid confusion, bullet 5 should be removed, since RUTF are used for treating severe acute malnutrition (SAM), however not intended as the sole source of nutrition in the treatment.

- bullet 7

Bullet 7 should be removed, because advisory texts already mentioned in preamble that “breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 2 4 months”. So, it is unnecessary to mention the texts in a label.

So, the paragraph should read:

“The following statements shall appear on the label of RUTF:

- "USE UNDER MEDICAL SUPERVISION" shall appear on the label in bold letters in an area separated from the written, printed, or graphic information.
- "For the dietary management of severe acute malnutrition" shall appear on the label.
- A prominent warning statement consisting of an explanatory statement in bold letters indicating that RUTF are for special medical purposes and may pose a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended.
    - The product is not to be used for parenteral, rectal or Nasogastric Tube (NG tube) administration.
- ~~A statement indicating whether the product is or is not intended as the sole source of nutrition.~~
- A statement indicating that RUTF are not breastmilk substitutes and shall not be presented as such.
- ~~[Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months.]~~”

-ANNEX

-Table: Nutritional Composition for RUTF

- We agree with the proposed levels of nutrients as follows:

Vitamin A

Unit	**Minimum**	**Maximum**	**GUL**
mg RE/100g	0.8	~~**[1.1] OR [**~~**1.2**~~**]**~~	**-**
mg/ RE/100kcal	0.15	~~**[0.2] OR [**~~**0.22**~~**]**~~	**-**
[2]µg RE/100kcal	150	~~**[200] OR [**~~**220**~~**]**~~	**-**

[2]1µg RE = 3.33 IU Vitamin A = 1 µg trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

Vitamin D

Unit	**Minimum**	**Maximum**	**GUL**
[3] µg/100 g	15	~~[~~20~~] OR [22]~~	~~[~~30~~]~~
[3] µg100 kcal	2.7	~~[~~3.6~~] OR [4]~~	-

[3] 1 µg cholecalciferol = 40 IU vitamin D

Calcium

Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	300	~~[~~600~~] or [785]~~	-
mg/100 kcal	58	~~[~~109~~] or [143]~~	-

Phosphorus

Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	300	~~[~~600~~] or [785]~~	-
mg/100 kcal	58	~~[~~109~~] or [143]~~	-

Magnesium

Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	80	~~[~~140~~] or [235]~~	-

mg/100 kcal	15.4	~~[~~26~~] or [43]~~	-

INTERNATIONAL ASSOCIATION OF CONSUMER FOOD ORGANIZATIONS (IACFO)

General Comments:

- IACFO and IBFAN are of the opinion that current scientific evidence does not support the wide spread use of RUTF products compared to the use of culturally appropriate energy dense family foods for the community management of SAM or MAM and the support of sustained breastfeeding.
- National Authorities should ensure that any decisions to provide food products are based on sound independent evidence. Such 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'*. The evidence should cover the effectiveness of RUTF as a treatment food, resource implications, sustainability, social and economic risks, how outcomes were measured and risk of bias. (See IBFAN's review of literature in the IBFAN Brief on the Use of RUTF).
- Access to nutritious and appropriate foods is just one aspect of a full package of treatments and care that are required for sustained rehabilitation of malnourished children and the prevention of recurrence. The protection and support of breastfeeding and culturally appropriate complementary feeding must be a fundamental and an essential component of a rehabilitation package. Other critical components must include: nutrition education; the treatment of infections; support for maternal care; the strengthening of health systems; the prevention of early child bearing; literacy and the improvement of water supply, sanitation and hygiene.
- The widespread use of RUTF products has and continues to trigger diversion of public funds away from support for sustainable solutions such as breastfeeding and locally sourced, culturally appropriate, bio-diverse family foods.
- To safeguard against needless and inappropriate use of these products IACFO and IBFAN are of the opinion that these products should not be on the open market. The marketing and trade of RUTF products introduces a commercial element that increases the risk of unnecessary and inappropriate use. During the 2015 CCNFSDU session, the Chair suggested that conditions relating to marketing could not be addressed by Codex (Para 82, REP16/NFSDU). This issue needs to be clarified and addressed urgently.
- Products that are intended for infant and young child feeding and are legally available on the open market require stringent marketing restrictions in order to protect breastfeeding, complementary feeding and child health from commercial influence. For this reason the marketing of breastmilk substitutes and related products are all covered by the International Code of Marketing and subsequent relevant WHA Resolutions. The Codex Standard covering Formulas for Special Medical Purposes (FSMP)(CODEX STAN 72 – 1981**) is an inadequate safeguard for vulnerable children. Indeed the adoption of the Standard** has led to increased promotion and, growth in the FSMP market, with subsequent inappropriate use. RUTF are intended for therapeutic use only and although the International Code and WHA resolutions provide some important safeguards, extra safeguards are needed to prevent misuse.
- Since Codex Guidelines are voluntary instruments for the safety aspects to be effective, they must be implemented into national law. Codex texts dealing with food safety are already integrated into the regulatory mechanisms of many countries. National authorities can use these to improve the safety of products (eg. *Codex Code of Practice for Low-Moisture Foods* (CAC/RCP 75-2015).
- Importantly, this Codex Guideline is being developed through a process which is not adequately safeguarded from conflicts of interest. Undue influence from manufacturers and distributors, their associations and the organizations funded by them is likely to subvert the public health purpose. It will lead to increased global trade of a single commodity and its widespread use at the expense of sustainable solutions. Manufacturers and distributors might also put pressure on governments to accept imports of products that may not be needed or wanted.
- To facilitate sound decision making on this important topic, the support to the process being pursued in the CCNFSDU, needs to include more robust evidence of the validity of using RUTF in community management of SAM. Lack of such evidence and concern about the marketing and misuse of these products was among the reasons UNICEF's proposal was rejected in the 35th CCNFSDU session in Bali. The situation has not changed and there continues to be a serious lack of such evidence.

IACFO and IBFAN do not see the need for creating a Codex instrument for products that are intended

for therapeutic use in the management of SAM. Increased marketing will lead to increased use of these products and the replacement of locally sourced, culturally appropriate and bio-diverse foods. If there is to be a Codex instrument relating to RUTF it must have adequate safeguards to mitigate the risks of needless use and misuse.

Recommendation 1

Preamble

The preamble is improved from previous versions, referring to the need for prevention and several important safeguards. However it still fails to address key concerns.

1. Para 1 While it is true that one of the objectives of Codex is to protect health, and that the Code of Ethics contains important safeguards, the preamble fails to mention that another evident aim of Codex is to facilitate global trade. The last Paragraph of the Preamble is an admission of this purpose and states: '***These guidelines can also be used, if applicable, by governments in case of international trade disputes.'***
2. The Preamble rightly mentions the importance of the International Code and Resolutions and the Codex Code of Ethics in International Trade in Food including Concessional and Food Aid. It fails to include a specific statement that the products must not be placed on the market and not promoted in any way. This is essential.
3. Para 2 claims that RUTF are a critical part of the treatment of SAM – this ignores the use of energy dense local family foods and promotes a single product based solution.

Rationale: As mentioned above, products intended for infant and young child feeding and that are legally allowed to be on open sale, require stringent marketing restrictions in order to protect breastfeeding, complementary feeding and child health from commercial influence. Since 1981 the WHO has recommended that the marketing of all such products are covered by the International Code of Marketing of Breastmilk Substitutes and subsequent relevant WHA Resolutions, and not should not be promoted. The Code and Resolutions are also highlighted in the Codex Code of Ethics.

RUTF are a different matter in that they are intended for therapeutic use only. In view of the risks of misuse they should not be on open sale in retail outlets. For this reason the International Code and Resolutions, while important safeguards, do not provide sufficient safeguards. The Codex Standard covering Formulas for Special Medical Purposes (FSMP) (CODEX STAN 72 – 1981) is also inadequate. Although FSMPs are intended for use only in very specific conditions, the existing controls are far from adequate and inappropriate marketing of these products has continued regardless with widespread misuse use of these products.

Rather than make an unqualified claim that RUTF is a 'critical part of treatment' of SAM, the Preamble must acknowledge that current scientific evidence does not demonstrate that RUTF products are better than culturally appropriate energy dense family foods for the community management of SAM and the support of sustained breastfeeding. National Authorities must base any decisions to provide food products on sound independent evidence that meets WHO's definition of scientific substantiation. *'Relevant convincing / generally accepted scientific evidence or the comparable*

Investing in prevention of SAM through sustainable measures and interventions is crucial. In addition to access to nutritious and appropriate foods, a full package of treatment and care is required for sustained rehabilitation of malnourished children and the prevention of recurrence. These include effective promotion **and support** of exclusive breastfeeding for the first six months of a child´s life combined with continued breastfeeding to 24 months and beyond; nutrition education; the treatment of infections; support for maternal care; prevention of early child bearing; the strengthening of health systems; the improvement of water and sanitation systems; and improved access to health care. Thus, preventive programmes have an immense job to do in the context of poverty, and in the meantime children who already are suffering from SAM need to receive appropriate treatment.

The Statement in Para 2 of the Preamble should be altered as follows:

"Children with SAM need timely and appropriate treatment **DELETE***: ~~and RUTF is a critical part of the treatment.~~ RUTF are high energy, fortified, ready-to-eat foods ~~for special medical purposes suitable~~ for that can – if considered appropriate and under strict conditions – be used for the dietary management of children with SAM.* **INSERT***:* Energy dense home-prepared family foods are as effective as RUTF for the treatment of uncomplicated SAM.

RUTF are primarily intended for children with uncomplicated SAM from 6-59 months. Although RUTF are given to other age groups with various forms of malnutrition at the implementation level, the primary focus for

these guidelines is children with SAM from 6-59 months. Since RUTF are prescribed according to weight, National Authorities may decide to include the provision of RUTF in their national protocols for use by other age groups."

RATIONALE: The statement as proposed in the Preamble is misleading. The attached briefing includes evidence that energy dense home-prepared family foods can be as effective as RUTF for the treatment of uncomplicated SAM. The use of RUTF is a market driven intervention, which can provide energy with added nutrients, however it is only one option, that is costly, not culturally appropriate, not community based, not bio-diverse, encourages dependency on imported products and is not sustainable.

The second part of Para 4 should be changed as follows:

"These guidelines have been prepared for the purpose of providing an agreed upon approach to the requirements which underpin the production of, and the labelling **DELETE** ~~and **claims for,**~~ **INSERT: OF** RUTF.

The guidelines are intended to **DELETE**~~**: facilitate the harmonization of requirements for RUTF at the international level and may**~~ provide assistance to governments wishing to establish national regulations in this area.

DELETE: ~~**The guidelines are also intended for use as an instrument designed to avoid or reduce difficulties which may be created by diverging legal, administrative and technical approaches to RUTF and by varying definitions and nutrient compositions of RUTF. These guidelines can also be used, if applicable, by governments in case of international trade disputes. Governments and other users should ensure adequate provisions are made for competent technical experts for the appropriate use of these guidelines.**~~

ADD: Governments **DELETE:** ~~**and other users should**~~ have a duty to ensure that adequate provisions are made for competent technical experts for the appropriate use of these guidelines. National Governments must be free to ban the import of RUTF and safeguard their national nutrition policies.

ADD: These Guidelines are not intended to provide program recommendations for the treatment and management of SAM and national authorities should develop programs that are appropriate to their cultural, economic and social needs that are based on sound independent scientific evidence.

RUTF products should not be promoted in any manner nor sold in the open market.

Recommendation 6

Fats and Oils

ADD: The addition of fats and oils must be in accordance with the recommended limit of less than 30% of total energy as set by the WHO Fact Sheet No. 394. http://www.WHO.int/mediacentre/factsheets/fs394/en/

Recommendation 8

Vitamins and Minerals

It should be noted that the scope proposes that the Guidelines can be applicable for children from 6 to 59 months, while the *Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CAC/GL 10-1979) is intended for older infants and young children 0 to 36 months.

Recommendation 9

Available carbohydrates

The palatability of the RUTF can be increased by the addition of appropriate available carbohydrates. **The addition of added sugars to not exceed the WHO recommendation of 5% of total energy.**

Remove the brackets and add: NOT be used.

[Sucrose, vegetable starch, glucose, glucose syrup] should be the preferred carbohydrates in RUTF. Fructose and high fructose corn syrup as ingredients should **NOT be used** in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinised starches gluten-free by nature may be added].

Recommendation 10

Food Additives and Flavours

IACFO and IBFAN are of the opinion that additives and flavours are an added health risk to children with SAM compromised with gut damage and in a food that is fortified with industrial nutrients. Moreover food

additives and flavours are used for cosmetic purposes. Therefore IACFO and IBFAN do not agree that food additives and flavours should be used as ingredients for RUTF.

Recommendation 11

"RUTF may be manufactured with formulations different from the one laid down in these guidelines provided that these formulations comply with Section 3 of the *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-1991)."[1]

COMMENT: If such variety of formulation is envisaged the question must be raised: why is a global Guideline necessary? Why make a claim about the benefits of harmonisation? If it is agreed that a Guideline is necessary – it is essential that it does not subvert the *"UN Strategy to build capacity within countries to produce RUTF"*[1] or undermine national nutrition strategies.

Section 3 of the FSMP Standard does not help. It is ambiguous and does not provide an adequate safeguard for the protection of vulnerable children. [1] For example it refers loosely to unqualified 'scientific evidence' and its only marketing safeguard is a prohibition of advertising to the general public. This leaves the door open for the many other more subtle forms of promotion, such as sponsorship, advertising to health professionals, health and nutrition claims, fundraising appeals, press releases, donations etc. The EU Commission has recognized that its weak FSMP legislation has been exploited by the baby food industry and that claims and marketing of FSMPs for infants and young children have been misleading and have led to growth in the market and widespread inappropriate use. EU legislation that will come into force in 2020 will ban health and nutritional claims for FSMPs.[2]

Can products that are not produced according to these guidelines be labelled as RUTF?

IACFO and IBFAN do not agree that any formulation can be used for the treatment of SAM. If RUTF is considered necessary – National Governments have a duty to ensure that the formulation is culturally appropriate, safe and adequate.

See attached briefing for the documented evidence showing that formulation with other ingredients resulted in reduced effectiveness in the treatment of SAM.

Recommendation 12

Energy

Add:

The energy density of the formulated RUTF should be at least 5.2 - to 5.5 kcal per gram. The energy density of the RUTF can be achieved during manufacturing by the addition of energy containing ingredients (i.e. fats and oils and/or digestible carbohydrates **in amounts that do not exceed the WHO recommendations for added fats and free sugars**) and/or processing the basic raw materials and ingredients as indicated in the Section on "Technologies for and effects of processing.

IACFO and IBFAN are of the opinion that the energy density of 5.2 – 5.5 kcal/g should have a solid scientific basis.

Recommendation 14

The recommendation of 50% of protein provided by milk products needs to be evidence based. Such a high level of cow's milk proteins may aggravate compromised ability to digest non-breastmilk proteins.

Recommendation 27

IACFO and IBFAN propose that the package size should be researched to determine:

a) the risk of contamination of opened and stored packages

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[1] **Section 3 of the *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-1991)** 3. GENERAL PRINCIPLES 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. The labels, accompanying leaflets and/or other labeling and advertising of all types of foods for special medical purposes should provide sufficient information on the nature and purpose of the food as well as detailed instructions and precautions for their use. The advertising of these products to the general public should be prohibited. The format of the information given should be appropriate for the person for whom it is intended.

[2] COMMISSION DELEGATED REGULATION (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes

b) the possibility of overfeeding the product and the risk of reducing breastmilk intake.

Recommendation 28

IACFO and IBFAN recommend the additional labelling provisions:

A clear statement on the label: This product is not to be sold on the open market.

Nutrition, health and convenience claims are not permitted for RUTF products.

There should be no idealised pictures or text

To be used under medical supervision by an independent qualified health care worker.

Rationale: why has the reference to: *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) been deleted? This contains the essential safeguard in Para 1.4 *Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.*