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

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

First Consultation Paper

March 2017

Please respond by **28th April 2017**

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Name of Member Country/Organisation: IACFO International Association of Consumer Food Organisations

General Comments:

IACFO is of the opinion that RUTF products should not be available, sold or promoted on the open market. RUTF products are for therapeutic purposes. Inappropriate marketing can result in unnecessary use with loss of confidence in local family foods and sustained breastfeeding.

IACFO supports the use of local foods to develop culturally suitable and nutrient rich RUTFs and that national authorities are best to provide solutions to address the treatment of SAM. The Guidelines must state that National authorities retain the ability to provide national solutions and prevent unnecessary imports of expensive RUTF products.

In emergency situations RUTF products may be the only available solution to feed and save children's lives but no international trade standards are needed. IACFO does not agree that RUTFs be placed on a global "Essential Drug List".

1. Preamble

Preamble

Question 1:

Please provide comments on the draft text of the Preamble

IACFO's General comments: The proposed preamble is too long. It should be a concise statement of the purpose of this guideline and not a 'rationale' for the use of RUTFs. IACFO is of the opinion that there is insufficient evidence to justify the use of commercially manufactured RUTF as a single approach for community management of SAM. There is inadequate data on the efficacy of RUTF when compared to other dietary interventions.

Specific comments:

1. The reference in paragraph 3 below, on IYCF practices is not consistent with the globally

accepted definition in the Global Strategy for IYCF recommendations – "protecting, promoting and supporting exclusive breastfeeding and timely and adequate complementary feeding with continued breastfeeding for two years or beyond".

2. To be consistent with the Code of Ethics (CAC/RCP 20-1979) the text should refer to compliance with the International Code and all subsequent relevant WHA resolutions.
3. The text provided in the section on 'description' in the first consultation paper (March 2017) circulated to the eWG refers to "Codex standard for the labelling of and claims for foods for special medical purposes codex stan 180-1991." The codex stan 180-1991, in the para on **General Principles** 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." Since adequate scientific evidence of benefits of use of RUTF is still not available, codex stan 180-1991 should not be referred in the proposed guidelines for use of RUTF. This is not appropriate unless there is '*Relevant convincing / generally accepted scientific evidence or the comparable level of evidence under the GRADE classification* Such evidence is not – as far as we are aware – available.

Draft Text of the Preamble

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 the code is to establish standards of ethical conduct for all those engaged in international trade in food and in food aid or responsible for regulating it and thereby to protect the health of the consumers and promote fair trade practices, at all times observing the International Code of Marketing of Breast milk Substitutes and relevant resolutions of the World Health Assembly (WHA).

Improving access to nutritious and appropriate foods is one aspect of a full range 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 is a fundamental and essential component of treatment.

RUTFs are unique foods specific for the treatment of SAM and therefore should not be marketed as other foods. Nor should they be promoted, nor make any idealizing claims about preventing malnutrition. Safeguards are needed to ensure that its use does not undermine continued breastfeeding and sustainable and culturally appropriate family food based complementary feeding.

Unethical marketing can negatively impact optimal child health sustained and continued breastfeeding to two years or beyond, family food based complementary feeding and can potentially lead to increased undernutrition and malnutrition. It is within this context that all those engaging in the international trade in food and food aid with specific reference to Ready-to-use therapeutic foods (RUTF) commit themselves to ~~the provisions of the code~~ to prevent needless use and misuse and ensure that the are available only for those who ~~are the~~ may require ~~target groups for~~ their treatment ~~products~~.

Children with severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate amounts of vitamins and minerals.. ~~Children with SAM urgently need treatment which is currently provided in the form of RUTF. RUTF are high energy, fortified, ready-to-eat foods suitable for the treatment of children with severe acute malnutrition. Although RUTFs are given to other age groups with various forms malnutrition at the implementation level,~~ The primary focus for these guidelines will be to help governments to develop standards for commercially manufactured ready to use foods that may be used for the treatment of children with SAM from 6-59 months. ~~Since RUTF is 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 severe acute malnutrition through preventative interventions such as improving access to high-quality foods and to health care; effectively promoting globally accepted IYCF recommendations as defined in the Global Strategy for Infant and Young Child Feeding - *"protecting, promoting and supporting exclusive breastfeeding and timely and adequate complementary feeding with continued breastfeeding for two years or beyond".* ~~exclusive breastfeeding for the first six months of a child's life where appropriate;~~ promoting improved complementary feeding practices for all children aged 6–24 months, ~~(where possible~~ using culturally appropriate and locally available foods); and improving water and sanitation systems and hygiene practices to protect children against communicable diseases is critical. Thus, preventive programmes have an immense job to do in the context of poverty, and in the meantime children who already are suffering from severe acute malnutrition need treatment.

Therefore these guidelines should be used in accordance with the 2007 Joint Statement of the UN Agencies[1], 2013 WHO document on Updates on the Management of Severe Acute Malnutrition in infants and children[2] the Global Strategy for Infant and Young Child Feeding the International Code and subsequent relevant WHA Resolutions on infant and young child feeding. The use of these products should be limited to therapeutic, medically indicated uses only and then only as part of the full range of treatments and care that are required for the rehabilitation of malnourished children.

~~These guidelines have been prepared for the purpose of providing an agreed approach to the requirements which underpin production of, and the labelling and claims for, Ready-to-use therapeutic foods. The Guidelines are intended to facilitate the harmonization of requirements for RUTF products at the international level and may provide assistance to governments wishing to establish national regulations in this area. The guidelines are also intended for use as an instrument designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to RUTF and by diverging interpretations of what RUTFs are and what they are not. These Guidelines can also be used, if applicable, by governments in case of international trade disputes. Governments and other users should be provided with the technical competent technical experts needed for good use of these guidelines.~~

2. Description

Description

[1] Joint Statement on Community-Based Management of Severe Acute Malnutrition by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the

[2] WHO. Guideline: *Updates on the management of severe acute malnutrition in infants and children*. Geneva: World Health Organization; 2013.

Question 2:

Please provide comments on the draft text and provide justification for your comments

The codex stan 180-1991, in the para on **General Principles** 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."
IACFO is not aware of sufficient scientic 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.*' affirming the efficacy of RUTF as the most appropriate treatment for SAM in all cases. Codex stan 180-1991 should not be referenced in the proposed guidelines for use of RUTF.

If the term fortified' is used it needs to be defined.

Since the guidelines are for the treatment of older infants and young children suffering from severe acute malnutrition, it is critical that the purpose should include examination of the evidence that the use of RUTFs is a suitable therapeutic food category for this purpose. The purpose should include an examination of the quality of the evidence used as a basis for development of these guidelines – risk of bias (independence), safety, risk analysis of benefit versus harm, and a statement on the quality of evidence as well as an evidence based recommendation regarding the efficacy and safety of RUTFs – this should include the social and economic risks.

Foods for Special Medical Purposes (FSMP) are a category of foods that is very often ill-defined. The EU Commission and many EU Member States acknowledge that the exploitation of lax EU rules has led to a growth in the market for products claiming to be FSMPs. Manufacturers use this categorization to avoid composition, marketing and other safeguards.

> *"...Differing interpretation and enforcement of the definition of FSMPs by national authorities has contributed to a proliferation of these products in the market (the examples of products based on rice protein, not allowed for infant and follow-on formula, and of some anti-regurgitation products were mentioned). This in turn led to the use of wider and often similar distribution channels as those for infant formula and inevitably to labelling, advertising and marketing practices that were taking advantage of the absence of relevant rules for these products.'*
>
> *Summary Record of the Standing Committee on the Food Chain and Animal Health,* 22 June 2012

The new EU legislation [3] that will come into force in 2019 introduces several new safeguards including a ban on nutrition and health claims:

(16) Consumers of food for special medical purposes have different nutritional needs than the normal population. The expression of nutrition information on the energy value and the amount of nutrients of food for special medical purposes as a percentage of daily reference intake values set out in Regulation (EU) No 1169/2011 would mislead consumers and should therefore not be allowed. (17) The use of nutrition and health claims authorised under Regulation (EC) No 1924/2006 to promote food for special medical purposes would not be appropriate, since consumers of such products are patients suffering from a disease, disorder or condition and are, therefore, not part of the general healthy population. In addition, food for special medical purposes is to be used under medical supervision and its consumption should not be promoted through the use of nutrition and health

[3] 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

claims directly targeting consumers. For those reasons, the use of nutrition and health claims should not be allowed for food for special medical purposes."

If RUTF are to be categorised as FSMPs it is essential that they are covered by additional marketing and manufacturing safeguards.

Proposed Text for Comments

Ready to Use Therapeutic Foods (RUTF) are high-energy, fortified, ready-to-eat foods ~~for special medical purposes~~ that are suitable for the dietary ~~management~~ treatment of older infants and young children from 6 to 59 months with severe acute malnutrition. These foods should be soft or crushable and should be easy for older infants and young children to eat without any prior preparation. The provision of safe drinking water for all children treated with RUTFs should be accessable.

3. Milk and other Dairy Products

Milk and other Dairy Products

Question 3:

Please provide comments on the draft text and provide justification for your comments

Please add: If powdered infant formula is used as an ingredient it must comply with the Code of Hygienic Practice for powdered formula for infants and young children (CAC/RCP 66 – 2008)

Proposed Text for Comments

Milk and other dairy products used in the manufacturing of RUTF products must comply with the relevant standards, guidelines and other Codes of Practice recommended by Codex Alimentarius Commission which are relevant to these products.

4. Legumes and Pulses

Legumes and Pulses

Question 4:

Please provide comments on the draft text and provide justification for your comments

IACFO agrees. The ingredients must comply with the appropriate Codex standards and guidelines

Proposed text for comments

Legumes and pulses, such as lentils, chickpeas, cowpeas, beans and other types of legumes and pulses must comply with the relevant Codex Alimentarius texts.

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.

5. Fats and Oils

Fats and Oils
Question 5: **Please provide comments on the draft text and provide justification for your comments** **Fats should not exceed the WHO recommendation of 30% energy from fats. RUTFs should have as a mandatory requirement appropriate levels of linoleic and linolenic acids as per scientific evidence in order to facilitate optimal brain and neurological development for this critical age group. No promotional claims should be made for these mandatory ingredients.**
Proposed text for comments Fats and oils can be incorporated in adequate quantities as technologically feasible for the purpose of increasing the energy density of the product. 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 products.

6. Cereals

Cereals
Question 6: **Please provide comments on the draft text and provide justification for your comments** **IACFO wishes to add:** while retaining maximum nutrient value.
Proposed text for comments All milled cereals suitable for human consumption may be used provided that they are processed in such a way as to reduce the fibre content, when necessary, and to decrease and, if possible, to eliminate anti-nutrients 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, while retaining maximum nutrient value.

7. Vitamins and Minerals

Vitamins and Minerals

Question 7:

Please provide comments on the draft text and provide justification for your comments

Added industrial non-food-based micronutrients have a lower absorption level than food-based and breastmilk-based vitamins and minerals. Some industrial micronutrients such as added iron can increase risk of diarrheal disease and malaria. This can exacerbate the symptoms of SAM. Hence caution and sound scientific principles must be applied in the fortification of RUTFs. Gut damage is a serious SAM symptom and industrial nutrients can negatively affect the already damaged gut lining.

Proposed text for Comments

All added vitamins and minerals must be in line with the Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979).

Vitamin and mineral forms used must be soluble and easily absorbed by patients with SAM. The added minerals should be water-soluble and should not form insoluble components when mixed together. The product should have a mineral composition that will not alter the acid base metabolism of children with severe acute malnutrition.

8. Digestible Carbohydrates

Digestible Carbohydrates

Question 8

Please provide comments on the draft text and provide justification for your comments

The addition of simple carbohydrate in the form of sugars must be limited to the WHO recommendations that added sugars should be limited to no more than 5% of total energy. Sugars such as fructose and corn syrups should be prohibited because of their possible adverse effects which may be exacerbated by the condition of SAM.

Draft text for Comments

Energy density and the palatability of the RUTF products can be increased by the addition of appropriate digestible carbohydrates. Digestible carbohydrates must adhere to the relevant Codex Alimentarius texts.

Particular attention should be given to the sugar particle size, which if not properly ground, can cause oil separation from the RUTF pastes.

Honey should not be used in RUTF products.

9. Food Additives and Flavours

Food Additives and Flavours

Question 9.1

Do you agree that RUTF products should fall under Food Category 13.3 of the General Standard for

Food Additives (CODEX STAN 192-1995).

If Yes, please provide the justification for your answer.

Question 9.2

If No, please propose an alternative food category from the existing categories in GSFA or new food category.

NO. IACFO does not agree. Foods for older infants and young children should not include food additives and flavours. These are primarily for aesthetic and cosmetic purposes and expose the vulnerable gut of a child suffering from SAM to unnecessary chemicals, many of which have detrimental effects and can prolong rehabilitation. Exposing infants to unnecessary chemicals at such an early age adds to the life long chemical burden.

Question 9.3

From the list of additives allowed in the Food Category No. 13.3 (reflected in Table 1 above), are there any additives that are not justified or should be excluded in the formulation of RUTF products. Please indicate a specific additive and the justification for your response.

See above

Question 9.4

Are there any additives that are currently used in the formulation of RUTF products that are not included in the list in Table 1?

or those that should be considered based on the
Same as above

Question 9.5

Are there any other additives that should be considered for use in RUTF, based on the raw materials and ingredients that could be used in the formulation of RUTFs in future?

Same as above

The presence of additives in the finished RUTF products as a result of carry-over

The Chairs proposes the following texts for handling additives in the finished RUTF products as a result of carry-over.

Question 9.6

Please provide comments on the proposed text:

Only the food additives referred to in the standard may be present in the RUTF products, as a result of carry-over from raw material or other ingredients (including food additives) used to produce the food, subject to the following conditions:

a. The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and

b. The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw material or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General

Standard for Food Additives (CODEX STAN 192-1995).

IACFO disagrees with this statement and proposes that the RUTF products be manufactured without added flavourings and food additives.

10. The Use of Other Matrices in RUTF

The Use of other Matrices in RUTF Formulation

Question 10:

Please provide comments on the draft text and provide justification for your comments

IACFO does not agree. All formulations must be based on sound independent scientific evidence to demonstrate their effectiveness in the treatment of SAM when compared to other formulations and high energy and nutrient family foods.

While considering new formulation with other ingredients in accordance with the general principles mentioned in the *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-1991) several scientific studies have reported that use of formulation with other ingredients are less effective in terms of recovery rates in comparison to standard, peanut and milk (25%) based formulation.

An equivalence non-blinded cluster randomized controlled trial from Zambia has found that the effectiveness of a milk-free soy-maize-sorghum-based RUTF (SMS-RUTF) with 25% milk content in standard peanut-based RUTF (P-RUTF) in treatment of children with SAM is not equal, recovery rates being lower in children who received SMS-RUTF.[4]

A randomized, double blind, clinical, quasi-effectiveness trial from Malawi has concluded that treating children with SAM with 10% milk (plus Soy) RUTF is less effective compared with treatment with the standard 25% milk RUTF. Recovery among children receiving 25% milk RUTF was greater than children receiving 10% milk RUTF, 64% compared with 57% after 4 wk, and 84% compared with 81% after 8 wk ($P < 0.001$). Children receiving 25% milk RUTF also had higher rates of weight and height gain compared with children receiving 10% milk RUTF.[5]

Proposed text for comments

New formulations of RUTF with other ingredients may be used if they are formulated in accordance with Section 3 of the *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-1991).

[4] Irena AH, Bahwere P, Owino VO, Diop EI, Bachmann MO, Mbwili-Muleya C, Dibari F, Sadler K, Collins S. Comparison of the effectiveness of a milk-free soy-maize-sorghum-based ready-to-use therapeutic food to standard ready-to-use therapeutic food with 25% milk in nutrition management of severely acutely malnourished Zambian children: an equivalence non-blinded cluster randomized controlled trial. Matern Child Nutr. 2015 Dec;11 Suppl 4:105-19. https://www.ncbi.nlm.nih.gov/pubmed/23782554

[5] Oakley E, Reinking J, Sandige H, Trehan I, Kennedy G, Maleta K, Manary M. A ready-to-use therapeutic food containing 10% milk is less effective than one with 25% milk in the treatment of severely malnourished children. J Nutr. 2010 Dec;140(12):2248-52. https://www.ncbi.nlm.nih.gov/pubmed/?term=A+Ready-To-Use+Therapeutic+Food+Containing+10%25+Milk+Is+Less+Effective+Than+One+with+25%25+Milk+in+the+Treatment+of+Severely+Malnourished+Children

Macronutrients

11. Energy

Energy			
Unit	**Minimum**	**Maximum**	**GUL**
Kcal/100g	520	550	

Question 11.1

Do you agree with these energy values?

Yes **No**

Question 11.2

If not please provide alternative values and the scientific justification to support your preferred values.

The additional energy required will depend on the amount of breastmilk the older infant and young child is receiving.

Question 11.3

Please provide comments on the proposed text for the guidelines

IACFO does not agree with the proposed text. If these are guidelines based on the best available and independent evidence then why the sudden abandoning of the guidelines to allow additional fats and added sugars just to increase the enrgy value??

Proposed Text to be Included in the Guideline

~~The energy density of the RUTF can be increased 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.~~

The energy density of the formulated RUTF should be at least 5.2 - to 5.5 per gram.

12. Carbohydrates

Carbohydrates
Question 12.1
Is a minimum available carbohydrates required in RUTF products?
YES
Question 12.2
If you support a limit for total available carbohydrates, should a maximum level or GUL be established?

YES

Question 12.3

If you support establishing a minimum available carbohydrates level, provide the proposed levels and give justification for your proposals.

The appropriate balance bewteen fats, CHOs and proteins as per sound scientific evidence should determine the maximum and the minimum levels of CHOs.

13. Protein

Protein
Protein should provide 10%-12% of the total energy ("at least 50% of protein is provided by milk products")
Question 13.1 Do you agree with the current range of 10-12% of protein contribution to total energy? **Yes** ~~**No**~~ **Please provide justification for your answer.**
Question 13.2 Do you agree with the amended statement in brackets? "at least 50% of protein is provided by milk products". **Yes** ~~**No**~~ **Please provide justification for your answer.**

Unit	**Minimum**	**Maximum**	**GUL**
g/100g	[13g]	-	

Question 13.3

Do you agree with these proposed values?

Yes ~~**No**~~

If not please provide alternative values and the scientific justification to support your preferred values.

14. Fats/Lipids

Fats/Lipids
Fats/Lipids should provide 45%-60% of the total energy
Question 14.1

Do you agree with the current range of 45% - 60% of fat contribution to total energy?

~~Yes~~ No

Please provide justification for your answer.

WHO recommends a level of fats no more that 30% of total energy.

Unit	Minimum	Maximum	GUL
g/100g	[30g]	-	

Question 14.2

Do you agree with these proposed values?

Yes **No**

If not please provide alternative values and the scientific justification to support your preferred values.

Question 14.2

Is there a need to include a minimum/maximum level ~~or GUL, or not specified~~, for fats in RUTFS? Please provide justification for your answer.

15. Essential Fatty Acids

Fatty Acid	Codex Stan 72-1981 (Infant Formula)	CAC/GL 9-1991 (Formulated Complementary Foods)	Codex Stan 156-1987 (Follow-up formula, revision in progress, agreement on LA levels at Step 4)	EFSA, 2014. (Essential composition of infant and follow-on formula)	RUTF Nutritional Composition
Linoleic Acid	300 mg/100 kcal (~2.7% E)	333 mg/100 kcal (~3.0% E)	300 mg/100 kcal (2.7% E) or 500 mg/100 kcal (4% E)	500-1200 mg/100 kcal (~4-9.6%E)	3-10% of total energy
Alpha-linolenic acid	50 mg/100 kcal (0.5% E)	Not specified	50 mg/100 kcal (0.5% E)	50 mg/100 kcal (0.5% E)	0.3-2.5% of total energy

Essential Fatty Acids

Based on the evidence provided, as well as the recommendations on essential fatty acids from different Codex texts and EFSA **(Refer to Table above),** please provide comment (with justification) whether the current RUTF nutritional composition on essential fatty acids should remain or changed to align with other existing Codex text. Please specify your recommended values with scientific justification.

IACFO agrees with the EFSA recommendation.

16. Vitamins

16.1 Vitamin A

Vitamin A			
Unit	**Minimum**	**Maximum**	**GUL**
mg RE/100g	0.8	1.1	

Question 16.1.1

Do you agree with these current values?

~~**Yes**~~ **No**

If not please provide alternative values and the scientific justification to support your preferred values.

Current values are too high. Recommended Dietary Allowances (RDAs) for Vitamin A for children 6 months to 8 years are 300-500 mcg RE according to the National institutes of Health, US department of health and human services.[6] Vitamin A values should not exceed these levels as high levels can cause serious adverse effects.

Setting of Maximum or GUL

Question 16.1.2

Is there a need to include a maximum level or GUL, or not specified, for Vitamin A? Please provide justification for your answer.

Question 16.1.3

Do you agree that beta-carotene should not contribute to the vitamin A requirements in RUTF products?

When there is adequate protein in the child's diet the beta-carotene contributes to the vitamin A requirements.

16.2 Vitamin D

Vitamin D			
Unit	**Minimum**	**Maximum**	**GUL**
µg/100 g	15	20	

Question 16.2.1

Do you agree with these current values?

~~**Yes**~~ **No**

If not please provide alternative values and the scientific justification to support your preferred values.

Proposed maximum levels of Vitamin D are very high. Recommended Dietary Allowances

[6] https://ods.od.nih.gov/factsheets/VitaminA-HealthProfessional/#h2

(RDAs) for Vitamin D for children from birth to 13 years is 15 mcg according to the National institutes of Health, US department of health and human services.[7] Maximum Vitamin A values should not exceed these levels as high levels can cause serious side effects.

Setting of Maximum or GUL

Question 16.2.2

Is there a need to include a maximum level ~~or GUL, or not specified?~~ Please provide justification for your answer.

16.3 Vitamin E

Vitamin E			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100g	20	-	

Question 16.3.1

Do you agree with these current values?

~~**Yes**~~ **No**

If not please provide alternative values and the scientific justification to support your preferred values.

The proposed minimum level of Vitamin E is very high. Recommended Dietary Allowances (RDAs) for Vitamin E for children from birth to 13 years is 4 - 7 mg according to the National institutes of Health, US department of health and human services.[8] Vitamin E values should not exceed these levels as high levels can cause serious adverse effects.

Setting of Maximum or GUL

Question 16.3.2

Is there a need to include a maximum level ~~or GUL, or not specified~~? Please provide justification for your answer.

16.4 Vitamin K

Vitamin K			
Unit	**Minimum**	**Maximum**	**GUL**
µg/100 g	15	30	

QUESTION 16.4.1

[7] https://ods.od.nih.gov/factsheets/VitaminD-HealthProfessional/
[8] https://ods.od.nih.gov/factsheets/VitaminE-HealthProfessional/

Do you agree with these current values

~~Yes~~ No

If not please provide alternative values and the scientific justification to support your preferred values.

The proposed minimum and maximum values for Vitamin K are very high for infants. Recommended Adequate Intakes for Vitamin K for infants (0-12 months) is 2 – 2.5 mcg according to the National institutes of Health, US department of health and human services.[9] Vitamin K values should not exceed these levels as high levels can cause serious adverse effects.

Setting of Maximum or GUL

QUESTION 16.4.2

Is there a need to include a maximum level ~~or GUL, or not specified~~? Please provide justification for your answer.

16.5 Vitamin B1

Vitamin B1			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100g	**0.5**	**-**	

Question 16.5.1

Do you agree with these current values?

Yes ~~No~~

If not please provide alternative values and the scientific justification to support your preferred values.

Setting of Maximum or GUL

Question 16.5.2

Is there a need to include a maximum level ~~or GUL, or not specified~~? Please provide justification for your answer.

16.6 Vitamin B2

Vitamin B2			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100g	1.6	-	

Vitamin 16.6.1

Do you agree with these current values

~~Yes~~ No

[9] https://ods.od.nih.gov/factsheets/VitaminK-HealthProfessional/

If not please provide alternative values and the scientific justification to support your preferred values.

The proposed minimum values for Vitamin B2 are very high for children. Recommended Dietary Allowances (RDAs) for Vitamin B2 (Riboflavin) for children 0 - 8 years according to the National institutes of Health, US department of health and human services are 0.3 – 0.6 mg.[10] Vitamin B2 values should not exceed these levels.

Vitamin 16.6.2

Setting of Maximum or GUL

Is there a need to include a maximum level or GUL, or not specified, for Vitamin A? Please provide justification for your answer.

16.7 Vitamin C

Vitamin C			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100g	50	-	

Question 16.7.1

Do you agree with these current values?

~~**Yes**~~ **No**

If not please provide alternative values and the scientific justification to support your preferred values.

The proposed values for Vitamin C are high for children. Recommended Dietary Allowances (RDAs) for Vitamin C for children 0 - 8 years according to the National institutes of Health, US department of health and human services are 25-40 mg.[11] Vitamin C values should not exceed these levels.

Setting of Maximum or GUL

Question 16.7.2

Is there a need to include a maximum level ~~or GUL, or not specified~~? Please provide justification for your answer.

16.8 Vitamin B6

Vitamin B6			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100g	0.6	-	

Question 16.8.1

Do you agree with these current values?

[10] https://ods.od.nih.gov/factsheets/Riboflavin-HealthProfessional/
[11] https://ods.od.nih.gov/factsheets/Riboflavin-HealthProfessional/

~~Yes~~ **No**

If not please provide alternative values and the scientific justification to support your preferred values.

The proposed minimum values for Vitamin B6 are high for children between 0-3 years. Recommended Dietary Allowances (RDAs) for Vitamin B6 for children 0 - 3 years according to the National institutes of Health, US department of health and human services are 0.1 – 0.5 mg.[12] Vitamin B6 values should not exceed these levels.

Setting of Maximum or GUL

Question 16.8.2

Is there a need to include a maximum level ~~or GUL, or not specified~~? Please provide justification for your answer.

16.9 Vitamin B12

Vitamin B12			
Unit	**Minimum**	**Maximum**	**GUL**
µg/100 g	**1.6**	-	

Question 16.9.1

Do you agree with these current values?

~~Yes~~ **No**

If not please provide alternative values and the scientific justification to support your preferred values.

The proposed minimum value for Vitamin B12 is high for children between 0-8 years. Recommended Dietary Allowances (RDAs) for Vitamin 12 for children 0 - 8 years according to the National institutes of Health, US department of health and human services are 0.4 – 1.2 mcg.[13] Vitamin B12 values should not exceed these levels.

Setting of Maximum or GUL

Question 16.9.2

Is there a need to include a maximum level ~~or GUL, or not specified~~? Please provide justification for your answer.

16.10 Folic Acid

Folic Acid			
Unit	**Minimum**	**Maximum**	**GUL**
µg/100 g	200	-	

Question 16.10.1

[12] https://ods.od.nih.gov/factsheets/VitaminB6-HealthProfessional/
[13] https://ods.od.nih.gov/factsheets/VitaminB12-HealthProfessional/

Do you agree with these current values?

~~Yes~~ No

If not please provide alternative values and the scientific justification to support your preferred values.

The proposed minimum value for Folic Acid is high for children between 0-3 years. Recommended Dietary Allowances (RDAs) for Vitamin 12 for children 0 - 3 years according to the National institutes of Health, US department of health and human services are 65 – 150 mcg DFE.[14] Folic Acid values should not exceed these levels.

Setting of Maximum or GUL

Question 16.10.2

Is there a need to include a maximum level ~~or GUL, or not specified~~? Please provide justification for your answer.

16.11 Niacin

Niacin			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100g	5	-	

Question 16.11.1

Question Do you agree with these current values?

Yes ~~No~~

If not please provide alternative values and the scientific justification to support your preferred values.

Setting of Maximum or GUL

Question 16.11.2

Is there a need to include a maximum level ~~or GUL, or not specified~~? Please provide justification for your answer.

16.12 Pantothenic Acid

Pantothenic Acid			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100g	3	-	

Question 16.12.1

Do you agree with these current values?

Yes ~~No~~

If not please provide alternative values and the scientific justification to support your

[14] https://ods.od.nih.gov/factsheets/Folate-HealthProfessional/

preferred values.
Setting of Maximum or GUL **Question 16.12.2** Is there a need to include a maximum level ~~or GUL, or not specified~~? Please provide justification for your answer.

16.13 Biotin

Biotin			
Unit	**Minimum**	**Maximum**	**GUL**
µg/100 g	60	-	
Question 16.13.1 Do you agree with these current values? **Yes** **~~No~~** If not please provide alternative values and the scientific justification to support your preferred values.			
Setting of Maximum or GUL **Question 16.13.2** Is there a need to include a maximum level ~~or GUL, or not specified~~? Please provide justification for your answer.			

17. MINERALS

17.1 Sodium

Sodium			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	**290**	-	
Question 17.1.1 Do you agree with these current values? **Yes** **~~No~~** If not please provide alternative values and the scientific justification to support your preferred values.			
Setting of Maximum or GUL **Question 17.1.2** Is there a need to include a maximum level ~~or GUL, or not specified?~~ Please provide justification for your answer. Yes, a maximum level for sodium should be included. WHO recommends a reduction in			

sodium intake to control blood pressure in children. The recommended maximum level of intake of 2 g/day sodium in adults should be adjusted downward based on the energy requirements of children relative to those of adults.[15]

17.2 Potassium

Potassium			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	1,100	1,400	

Question 17.2.1

Do you agree with these current values?

Yes ~~**No**~~

If not please provide alternative values and the scientific justification to support your preferred values.

Setting of Maximum or GUL

Question 17.2.2

Is there a need to include a maximum level ~~or GUL, or not specified~~? Please provide justification for your answer.

17.3 Calcium

Calcium			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	300	600	

Question 17.3.1

Do you agree with these current values?

Yes ~~**No**~~

If not please provide alternative values and the scientific justification to support your preferred values.

Setting of Maximum or GUL

Question 17.3.2

Is there a need to include a maximum level or GUL, or not specified? Please provide justification for your answer.

17.4 Phosphorus

[15] http://www.who.int/nutrition/publications/guidelines/sodium_intake_printversion.pdf

Phosphorus			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	300	600	

Question 17.4.1

Do you agree with these current values?

Yes ~~No~~

If not please provide alternative values and the scientific justification to support your preferred values.

Setting of Maximum or GUL

Question 17.4.2

Is there a need to include a maximum level ~~or GUL, or not specified?~~ Please provide justification for your answer.

17.5 Magnesium

Magnesium			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	80	140	

Question 17.5.1

Do you agree with these current values?

Yes ~~No~~

If not please provide alternative values and the scientific justification to support your preferred values.

Setting of Maximum or GUL

Question 17.5.2

Is there a need to include a maximum level or ~~GUL, or not specified~~? Please provide justification for your answer.

17.6 Iron

Iron			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	10	14	

Question 17.6.1

Do you agree with these current values?

Yes ~~**No**~~ If not please provide alternative values and the scientific justification to support your preferred values.
Setting of Maximum or GUL **Question 17.6.2** Is there a need to include a maximum level ~~or GUL, or not specified~~? Please provide justification for your answer.

17.7 Zinc

Zinc			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	11	14	
Question 17.7.1 Do you agree with these current values? **Yes** ~~**No**~~ If not please provide alternative values and the scientific justification to support your preferred values.			
Setting of Maximum or GUL **Question 17.7.2** Is there a need to include a maximum level ~~or GUL, or not specified~~? Please provide justification for your answer.			

17.8 Copper

Copper			
Unit	**Minimum**	**Maximum**	**GUL**
mg/100 g	1.4	1.8	
Question 17.8.1 **Do you agree with these current values?** **Yes** ~~**No**~~ If not please provide alternative values and the scientific justification to support your preferred values.			
Setting of Maximum or GUL			

Question 17.8.2

Is there a need to include a maximum level ~~or GUL, or not specified~~? Please provide justification for your answer.

17.9 Selenium

Selenium			
Unit	**Minimum**	**Maximum**	**GUL**
µg/100 g	20	40	

Question 17.9.1

Do you agree with these current values?

Yes ~~**No**~~

If not please provide alternative values and the scientific justification to support your preferred values.

Setting of Maximum or GUL

Question 17.9.2

Is there a need to include a maximum level ~~or GUL, or not specified~~? Please provide justification for your answer.

17.10 Iodine

Iodine			
Unit	**Minimum**	**Maximum**	**GUL**
µg/100 g	70	140	

Question 17.10.1

Do you agree with these current values?

Yes ~~**No**~~

If not please provide alternative values and the scientific justification to support your preferred values.

Setting of Maximum or GUL

Question 17.10.2

Is there a need to include a maximum level ~~or GUL, or not specified~~? Please provide justification for your answer.

18. Additional Nutrients

Additional Nutrients

Question 18.1

Are there any nutrients that should be taken into consideration in the formulation of RUTF?

~~Yes~~ **No**

Please provide details (including the proposed values) and the scientific justification to support the addition of the additional nutrients.

Optional ingredients or nutrients should not be permitted.

IACFO is concerned that the global trade of products can result in unsuitable and culturally inappropriate foods being fed to young children. IACFO strongly supports the use of locally sourced ingredients, and believes that national authorities are best placed to ensure the safety and appropriateness of products.

There should be routine pre-determined schedules of surveilance of the impact of ingredients to monitor side effects and ensure safety.

19. Contaminants

Contaminants
Question 19.1 Please provide comments on the draft text and provide justification for your comments.
Draft text for Comments It is recommended that the products covered by the provisions of these guidelines be prepared and handled in accordance 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. **a. Pesticides Residues** The products should be prepared with special care under good manufacturing practices, so that residues of those pesticides which may be required in the production, storage or processing of the raw materials or the finished food ingredients do not remain, or, if technically unavoidable, are reduced to the maximum extent possible. These measures should take into account the specific nature of the products concerned and the specific population group for which they are intended. **b. Other Contaminants** The product should not contain contaminants or other undesirable substances (e.g. biologically active substances) in amounts which may represent a hazard 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.

20. Technologies for and Effect for Processing

Technologies for and Effect for Processing
Question 20.1 Please provide comments on the draft text and provide justification for your comments.
Draft text for Comments **1. Preliminary Treatment of Raw Materials** Cereals, legumes, pulses and oilseeds should first be treated to obtain wholesome and clean raw materials of good quality. Such treatments include, but are not limited to: • **Cleaning or washing**: to eliminate dirt, damaged grains, foreign grains and noxious seeds, insects and insect excreta and any adhering material. • **Dehulling**: when necessary, pulses, legumes, oilseeds and certain cereals such as oats, barley, sorghum, millet and teff should be dehulled as completely as is feasible to reduce the fibre content to acceptable levels and to decrease, and if possible, to eliminate phytates, tannins and other phenolic materials, trypsin and chymotrypsin inhibitors which can lower the protein digestibility and amino acid bioavailability and mineral absorption**.** • **Degermination:**where necessary and appropriate, degermination of wheat, corn, soy and other crops should be considered in order to reduce the phytate content. **2.Milling** • Milling or grinding of suitable raw materials should be carried out in such a way as to minimize the loss of nutritional value and to avoid undesirable changes in the technological properties of the ingredients. • Dry raw materials may be milled together, if technologically feasible, or mixed after milling or grinding. • Formulations containing milled cereals, legumes, pulses and/or oilseeds that have not been otherwise processed require adequate boiling to gelatinize the starch portions and/or eliminate anti-nutritional factors present in legumes and pulses. Boiling improves the digestibility and absorption of nutrients. • The bulkiness of foods from food formulations containing dry ingredients obtained by milling of the raw materials can be reduced by adding, during the formulation, adequate amounts of enzymes such as alpha-amylase which, during the slow heating to boiling, predigest partially the starch and reduce the amount of water needed for the preparation of the food. **3.Toasting** • Toasting (dry heating) enhances the flavour and the taste of the food through dextrinization of starch. It also improves digestibility and contributes to reducing the bulkiness of the formulated food. Moreover, it reduces microorganisms and enzyme activity and destroys insects, thus improving keeping qualities. • Protein damage due to the Maillard reaction may occur in the presence of reducing carbohydrates. The toasting process should therefore be carefully controlled. • Pulses as well as oilseeds such as soya beans, groundnuts and sesame seeds can be toasted as whole grains directly or after soaking. • Toasted raw materials can be milled or ground for use as ingredients.

4. Sprouting, Malting and Fermentation

- Cereals and pulses can be induced to germinate by soaking or humidifying. It is necessary, however, to ensure that growth of mycotoxin producing microorganisms does not occur. The action of natural amylases contained in the grains results in the pre-digestion of the starchy portion of the grain (dextrinization) thus reducing the bulk of the food when prepared for feeding and, ultimately, increasing the nutrient density of the food. Sprouting, malting and fermentation can induce hydrolysis of phytates and decrease its inhibitory effect on mineral absorption, and may improve B vitamin content.
- During the germination process, the seed coat of the grain splits and can be removed by washing. The malted raw material is milled or ground after drying.

5. Other Processing Technologies

Whenever feasible, RUTF products or their raw materials should be treated with a validated microbial reduction treatment in order to inactivate pathogens such as *Salmonella*, noting that some pathogens have increased heat resistance characteristics at reduced water activities in food matrices.

Commonly used microbial reduction treatments for low-moisture foods 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. Where foods are irradiated, refer to the *Code of Practice for Radiation Processing of Food* (CAC/RCP 19-1979) and the *General Standard for Irradiated Foods* (CODEX STAN 1 06-1983).

Question 20.2

Are there any other additional technologies for processing that should be considered under this section?

21. Good Manufacturing Practices and Good Hygiene Practices

Good Manufacturing Practices and Good Hygiene Practices

Question 21.1

Please provide comments on the draft text and provide justification for your comments.

Draft text for Comments

It is recommended that the products covered by the provisions of this guideline be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CAC/RCP 1-1969), and *Code of Hygienic Practice for Low-Moisture Foods* (CAC/RCP 75-2015).

The product should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

The ingredients and final product should be prepared, packed and held under sanitary conditions and should comply with relevant Codex texts.

22. Methods of Analysis and Sampling

Methods of Analysis and Sampling
Question 22.1 Please provide comments on the draft text and provide justification for your comments.
Draft text for Comments 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.

23. Packaging

Packaging
Question 23.1 Please provide comments on the draft text and provide justification for your comments. IACFO agrees
Draft text for Comments It is recommended that Ready to Use Therapeutic Foods for children from 6 to 59 months be packed in containers which will safeguard the hygienic and other qualities of the food. The containers, including 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.

24. Packaging of RUTF into Single-Use Sachets

Packaging of RUTF into single-use sachets
Question 24.1 The current weight of 92 grams of each RUTF sachet was established by calculating the calories needed over the average treatment period of a SAM child for recovery. Is there a need to consider single-use sachets to minimize the risk of contamination for the RUTF products at home? **Yes** ~~**No**~~ Please provide the justification for your answer. Since the products are used for older infants the caloric needs beyond breastmilk is approximately 200 kcal between six to 9 months and slightly higher (300 to 400 kcal) between 9 and 12 months. This is especially important since the product needs to be consumed within 24 hours after opening of the package.

25. Labelling

Labelling

Question 25.1

Please provide comments on the draft text and provide justification for your comments.

Please add at the end of the paragraph: and the International Code of Markeing of Breastmilk Substitutes and subsequent relevant WHA resolutions on labelling and claims, including the *WHO Guidance on ending inappropriate markeing of foods for infants and young children.*

Draft text for Comments

It is recommended that the labelling of Ready to Use Therapeutic Foods for children from 6 to 59 months be Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-991), Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985), the Codex General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses (CODEX STAN 146-1985) and the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997).

The Name of the Food

The name of the food to be declared on the label shall indicate that the food is a Ready To Use Therapeutic Food for the treatment of children from 6 to 59 months suffering from SAM. The appropriate designation indicating the true nature of the food should be in accordance with national legislation. The age from which the product is recommended for use shall appear in close proximity to the name of the food.

List of Ingredients

The list of ingredients shall be declared in accordance with Section 4.2 of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1 -1985).

Declaration of Nutritive Value

The declaration of energy and nutrients on the label or in labelling shall contain the following information expressed per 100 grammes 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 and kilojoules;

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

(c) the amounts of essential and non-essential amino acids and/or essential fatty acids, expressed in metric units.

(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 following statements shall appear on the label of the RUTF products:

- "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~~ **treatment** 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 administration.
- A statement indicating whether the product is or is not intended as the sole source of nutrition.

Instructions for use

- The label should indicate clearly from which age the product is recommended for use. This age shall not be less than six months for any product.
- Directions as to the preparation and use of the food shall be given; preferably accompanied by graphical presentations.
- The age apropriate serving sizes must be indicated.
- The suggested number of feedings per day should be indicated.

26. Additional Requirements

Additional Requirements

Proposed statements and text for Comments

- RUTF products are not breastmilk substitutes and shall not be presented as such. The label must not make a comparison to breastmilk, or suggest that the product is nearly equivalent or superior to breastmilk;
- Labels must not include any image, text or other representation that may undermine or discourage breastfeeding
- The products should carry no health, nutrition or other promotional claims nor any idealising text or pictures or representation that might suggest use for infants under the age of 6 months (including references to milestones and stages)
- Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months.
- The product should be consumed within 24 hours after opening.
- The shelf-life of the product is [24 months].
- The products must not be cross branded with any breastmilk substitute. The packaging design, labelling and materials must be different from those used for breast-milk substitutes so that they cannot be used in a way that also promotes breast-milk substitutes (for example, different colour schemes, designs, names, slogans and mascots other than company name and logo should be used).
- The product must not convey an endorsement or anything that may be construed as an endorsement by a professional or other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.

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Question 26.1

Do you agree with the proposed statements to be included under the Additional Requirements for labelling purposes?

Yes **No**

Including the additions and deletions proposed.

Question 26.2

Please provide comments on the draft text and provide justification for your comments

See answer to Question 2 referring to the new EU legislation banning health and nutrition claims on FSMPs.

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