CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 5 **CX/NFSDU 18/40/6**

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

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PROPOSED DRAFT GUIDELINES FOR READY-TO-USE THERAPEUTIC FOODS

ISDI comments on Agenda Item 5 CX/NFSDU 18/40/6

ISDI general comments

A. Suitable Raw Materials and Ingredients

ISDI would like to raise a comment which is out of the scope of the recommendation put forward by the eWG Chair. The comment concerns para 5 “SUITABLE RAW MATERIALS AND INGREDIENTS” in the Proposed Draft Guidelines. The introduction of the paragraph refers to section 3 of the Standard for Labelling of and Claims for Foods for Special Medical Purposes (CXS 180-1991), however, ISDI believes it should be clearly mentioned in the Guidelines that alternative ingredients to peanut in RUTF should be submitted to efficacy studies.

Rationale:

- Use of alternative ingredients to peanut in RUTF may have significant impact on quality, safety and efficacy of the product. Appropriate studies should therefore be conducted at all necessary levels, not only to avoid contaminants but also to guarantee that such products, which may eventually be given to treat children affected by SAM, are as safe, acceptable and efficacious as the now well-established peanut formula.
- Depending on the composition of the untreated plant raw material used, adequate processing steps may have to be selected in order to guarantee its microbiological quality, nutritional quality and the absence of off-flavours.
- All plant raw material processing steps (e.g. roasting, drum drying, extrusion etc.) may contribute to reaching the microbiological specifications. However, the challenge to maintain the high microbiological quality on the long run may be more related to compliance with Good Manufacturing Practices (packaging steps, storage etc.).
- All plant raw material processing steps may not have the same impact on the nutritional quality of these raw materials. For example, roasting will usually help solving the off-tastes and the potential microbiology issues, but will only have a limited impact on the starch gelatinization in cereals, which is a key issue. This should be addressed beforehand, when selecting the plant raw materials and the corresponding processing steps.
- Based on manufactures’ experience, it’s strongly recommended that each raw material envisaged for use in RUTF should be evaluated for their content in:
    - gelatinized starch (considered as easily digestible), for cereals and pulses
    - anti-nutritional factors such as phytates (which can limit iron and zinc absorption) and anti-trypsic factors

More broadly, it should be noted that changing a significant part of the raw materials in RUTF may influence the digestibility and bioavailability of the nutrients, which may impact the efficacy of the finished product. This is all the more critical as these products are to be given to sick, SAM-affected children, whose digestive system is not functioning properly. Therefore, ISDI strongly recommends that any new RUTF formula incorporating alternative ingredients is thoroughly validated through acceptability, efficacy and (if appropriate) effectiveness studies, conducted by independent third parties.

As a consequence, ISDI recommends the addition of the following sentence at the end of the introduction of the para 5.

This section includes cereals, pulses and seeds as possible ingredients to prepare RUTF. These ingredients are not used in most current formulations of RUTF. Any RUTF should be shown to be efficacious in clinical trials before being introduced in programmes.

B. Nutritional Composition for RUTF

ISDI would like to raise a general comment in regard to the calculation of the nutrients in g/100 kcal.

- The minimum "g/100 kcal" should be calculated with: minimum "g/100g" / 5.5
- The maximum "g/100 kcal" should be calculated with: maximum "g/100g" / 5.2

ISDI comments per recommendation

Preamble
Recommendation 1:

That CCNFSDU agree to the following text for the Preamble of the Guidelines for RUTF:

Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients. Children with SAM need efficacious and timely treatment and RUTF is part of the care. RUTF are primarily intended for children with uncomplicated SAM from 6-59 months. Although RUTF may be 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.

These guidelines provide guidance for the production and labelling of 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. 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 varying definitions and nutrient compositions of RUTF. These guidelines should be used in accordance with technical recommendations of the relevant evidence and related Codex texts/documents by WHO, UNICEF and WFP[1]. Governments and other users should ensure adequate provisions are made for competent technical experts for the appropriate use of these guidelines.

[1)] A Joint Statement by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children's Fund. 2007. *Community-Based Management of Severe Acute Malnutrition*; A Joint Statement by the World Health Organization and the United Nations Children's Fund. 2009. *Child growth standards and the identification of severe acute malnutrition in infants and children*, Geneva: World Health Organization; World Health Organisation. 2013. Guideline: *Updates on the management of severe acute malnutrition in infants and children,* Geneva: World Health Organization; World Health Organisation. 2003. ~~*Global Strategy for Infant and Young Child Feeding*, Geneva: World Health Organization; World Health Organisation. 1981. *International code of marketing of breast-milk substitutes,* Geneva: World Health Organization and subsequent relevant WHA Resolutions on infant and young child feeding;~~ *Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions* (CXC 20-1979); Food and Agriculture Organisation and World Health Organisation. 2016. FAO/WHO Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition, Rome: Food and Agriculture Organisation.

ISDI comment

ISDI would like to highlight that RUTFs are not prescribed according to weight and therefore this statement should be removed from the text of the preamble.

As regards to Footnote 1, ISDI notes that the "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 United Nations Children's Fund, 2007" was updated in 2011.
In addition, as RUTF is not breastmilk substitutes, ISDI questions the reference to guidelines included as part of Footnote 1.

Vitamins and Minerals

Recommendation 2:

That CCNFSDU agree to the following texts for the Vitamins and Minerals section

Vitamins and Minerals

[Vitamin and mineral forms used must be soluble and easily absorbed by patients with SAM. Children with SAM have low or absent gastric acid which means that they should not be given inorganic salts of minerals that are insoluble or requiring an acid gastric environment for absorption, in order to avoid metabolic acidosis. It is important that RUTF should have a mineral composition that leads to a moderate excess of non metabolisable base. The non-metabolizable base can be approximated by the formula: estimated absorbed millimoles (sodium + potassium + calcium + magnesium) - (phosphorus + chloride.]

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 (CXG 10-1979). Examples of vitamin and mineral forms for RUTF formulation can be found in the *WHO Management of severe malnutrition: A manual for physicians and other senior health workers (1999).* [The amount of vitamins and minerals added to achieve the target level must be adjusted based on the chemical form and scientific evidence showing adequate stability and bioavailability in the finished product.]

ISDI comment

ISDI supports the recommendation.

Available Carbohydrates
Recommendation 3:

That CCNFSDU agree to the following texts for the Available Carbohydrates section

Available Carbohydrates[2]

The palatability of the RUTF can be increased by the addition of 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*.

[2)] Sucrose, plant starch, maltodextrin, should be the preferred carbohydrates in RUTF. Fructose, glucose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinized starches ~~[gluten-free]~~ by nature may be added. Any carbohydrate added for sweetness should be used sparingly.

ISDI comment

ISDI partially supports the recommendation but would like to explain the various purposes of carbohydrates.

For this reason, ISDI proposes the following rewording of the paragraph:

Available Carbohydrates[2]

Available carbohydrates are added in the formulation to complement other ingredients needed to reach the protein and lipid specifications.

The palatability of the RUTF can be increased by the addition of **sucrose** ~~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*.

[2)] Sucrose, plant starch, maltodextrin, should be the preferred carbohydrates in RUTF. Fructose, glucose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinized starches ~~[gluten-free]~~ by nature may be added. Any ~~carbohydrate~~ **sucrose** added for sweetness should be used sparingly.

Food Additives
Recommendation 4:

It is recommended that:

4.1 CCNFSDU take note and agree with the proposed list of food additives **(Table 1)** and their technological justification that are currently used in RUTF.

4.2 CCNFSDU agree that the electronic working group recommend a proposed list of food additives to the Committee for consideration on their technological justification.

Number	Food Additive	International Numbering System (Number if available)	Functional Class (e.g. color, emulsifier, stabilizer, etc.)	Technological Justification	Approximate Use Level	Maximum Use Level
1.	Mono & diglycerides	471	Emulsifier	Avoid oil separation Improves the binding properties so that it is not necessary to add extra amount of monoglycerides in paste Prevents oil separation without significant influence on meltdown properties Provides stability & maintain viscosity of paste Stabilize crystal lattice at ambient temperature & consequently cool transport is not required	1-2% 1.5% 1.8% 2% 1% 5 g/100 g 1.42g/100g	max 4000 mg/kg of the ready to use food max amount used= 1.65%
2.	Ascorbyl palmitate	304	Antioxidants	Avoid oil oxidation (used in oil only) Antioxidants are important to ensure that the fat is not oxidised		Max 1 mg/100 ml of the product ready for consumption OR max 1 mg/100g of the product ready for consumption OR max 10 mg/kg of the product ready for consumption max amount used = 0.0165%
3.	Tochopherol	307	Antioxidants	Avoid oil oxidation (used in oil only)		Less than 600 ppm
4.	Citric acid	330	Antioxidant	Avoid oil oxidation (used in oil only)	GMP	
5.	Lecithin	322	Emulsifier	Emulsifiers are needed to ensure uniform texture	0.5 g/100 mL (max)	max 5000 mg/kg of the ready to use food
6.	Tocopherols rich extract	306	Antioxidant	Antioxidants are important to ensure that the fat is not oxidised	max amount used = 0.0165%	Tocopherols rich extract
7.	Ascorbic acid	300	Antioxidant	Antioxidants are important to ensure that the fat is not oxidised		GMP
8.	Citric and fatty acid esters of glycerol	472c	Emulsifier	Emulsifying agents acts in such a way that the combined ingredients in the formulation, can be properly reconstituted, thereby creating a stable homogenous end-product.		max 9000 mg/kg of the ready to use food max amount used= 1.65%
9.	Mixed tocopherol concentrate	307 b	Antioxidant	Antioxidants are substances that inhibits oxidation,		Max 1 mg/100 ml of the product ready

				hence counteracting deterioration of the formulation or product allowing it to have an extended shelf life.		for consumption OR max 1 mg/100g of the product ready for consumption OR max 10 mg/kg of the product ready for consumption
10.	Nitrogen	941	Packing Gas	Products are nitrogen flushed before sealing so that oxygen is displaced. This inhibits oxidation and thereby spoilage throughout the product's mentioned shelf life.	GMP	
11.	Carbon dioxin	290	Packing Gas	Products are flushed with carbon dioxin before sealing so that oxygen is displaced. This inhibits oxidation and thereby spoilage throughout the product's mentioned shelf life.	GMP	
12.	Sodium Tri-phosphates	451	Stabiliser	Only additions in oil an fat powders from oil manufacturers.		
13.	Silicium dioxide	551	Free flowing agent			
14.	NATA - 5	N/A	Emulsifier	it maintains a uniform mixture of immiscible phases		Max. Amount Used in RUTF formula: 1%
15.	Grindsted PS - 209 (Composed of Mono-diglyceride & Triglyceride	-2	Emulsifier	To prevent oil separation	0.527%	
16.	Fortium APT 10 (composed of mono & di-glycerides, propylene glycol, mixed tocopherols, and ascorbyl palmitate)		Antioxidant	To inhibit oxidation	0.030 %	
17.	N-ATA 1	-2	Stabiliser	Keeps oil from separating		2.5% 1.28%

ISDI comment

ISDI welcomes the progress made in developing a list of food additives that provide a necessary technical function in RUTF products, based on current use by producers of these products. In the further work on the additives section proposed here, we have included all of the additives in the eWG Table that have an INS number. For those without an identified INS number, we propose to allow for additional input by producers in order to ensure that essential substances are not inadvertently omitted.

ISDI proposes to consider the food additives shown in the Table below, grouped according to functional class, according to CAC/GL 36-1989 (Class Names and the International Numbering System for Food Additives). In addition, the Table provides information on the INS number, the ADI assigned by JECFA, technological justification, proposed use level and Maximum Use Level, and whether the additive was previously endorsed by the CCFA.

For the latter, as a proxy, we provided information on whether the proposed additives are currently authorized in the Infant Formula Standard and Formulas for Special Medical Purposes Intended for Infants (Section A or B) (Codex Stan 72-1981) or the Follow-up Formula Standard (Codex Stan 156-1987). We consider that this

is appropriate given the similar age range for the Guidelines under consideration and the description as "food for special medical purpose" of RUTF. The approach is consistent with information provided in the Codex Procedural Manual (26th Ed) (page 51) pertaining to Elaboration of Codex Standards, Food Additives section, as follows:

"When forwarding a food additive section of a commodity standard for endorsement by the Committee on Food Additives, the Secretariat should prepare a report to the Committee that includes the International System (INS) number, the Acceptable Daily Intake (ADI) assigned by the Joint FAO/WHO Expert Committee on Food Additives, technological justification, proposed level, and whether the additive was previously endorsed by the Codex Committee on Food Additives."

With this background, ISDI proposes the following for further consideration of the Food Additives section of the Proposed Draft Guidelines for Ready-to-Use Therapeutic Foods.

Only the food additives listed in this Section or in the *Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children* (CAC/GL 10-1979) may be present in the foods described in this Guidelines, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food.

Item	Food Additive	International Numbering System (INS)	ADI	Functional Class	Technological Justification	Proposed Use Level	Maximum Use Level	Currently Permitted in STAN 72-1981 or STAN 156-1987 or GL 10-1979
Emulsifiers								
1	Mono & diglycerides	471	17th JECFA (1973) ADI not specified	Emulsifier	Forms or maintains a uniform emulsion of two or more phases in a food (definition GL 36-1989)	1-2% 1.5% 1.8% 2% 1% 5 g/100 g 1.42g/100g 1800mg/kg [1000 to 2000 mg/kg]	4000 mg/kg of RUTF	STAN 72-1981 STAN 156-1987
2	Citric and fatty acid esters of glycerol	472c	Not of concern at proposed use levels 79th JECFA (2014)	Emulsifier	Forms or maintains a uniform emulsion of two or more phases in a food		9000 mg/kg of RUTF	STAN 72-1981
3	Lecithin	322	17th JECFA (1973) ADI not specified	Emulsifier	Forms or maintains a uniform emulsion of two or more phases in a food.		Up to 5000 mg/Kg of RUTFd	STAN 72-1981 STAN 156-1987
Antioxidants								
4	Ascorbyl palmitate	304	17th JECFA (1973) ADI 0 -1.25 mg/kw bw	Antioxidants	Prolongs the shelf-life of foods by protecting against deterioration caused by oxidation.		max 10 mg/kg of RUTF	STAN 72-1981 STAN 156-1987
6	Citric acid	330	17th JECFA (1973) ADI not specified	Antioxidant	Prolongs the shelf-life of foods by protecting against deterioration caused by oxidation.		GMP	STAN 72-1981 STAN 156-1987
7	Tocopherols rich extract	307b	17th JECFA (1973): ADI 0-2 mg/kg for alpha-tocopherol and mixed tocopherols concentrate	Antioxidant	Prolongs the shelf-life of foods by protecting against deterioration caused by oxidation.		10 mg/kg of RUTF	STAN 72-1981 STAN 156-1987
8	Ascorbic acid	300		Antioxidant	Prolongs the shelf-life of foods by protecting		GMP	STAN 156-1987

					against deterioration caused by oxidation.			
Packing Gas								
10	Nitrogen	941	24th JECFA (1980): no ADI necessary	Packing Gas	Products are nitrogen flushed before sealing so that oxygen is displaced. This inhibits oxidation and thereby spoilage throughout the product's mentioned shelf life.		GMP	STAN 72-1981 STAN 156-1987
11	Carbon dioxin	290	29th JECFA (1985): ADI not specified	Packing Gas	Products are flushed with carbon dioxin before sealing so that oxygen is displaced. This inhibits oxidation and thereby spoilage throughout the product's mentioned shelf life.		GMP	STAN 72-1981 STAN 156-1987
Carrier								
12	Sillicon dioxide	551	80th JECFA (2015): ADI not specified	Carrier	Used to dissolve, dilute, disperse or otherwise physically modify a food additive or nutrient without altering its function (and without exerting any technological effect itself) in order to facilitate its handling, application or use of the food additive or nutrient. (Definition GL 36-1989)		10 mg/kg of RUTF	GL 10-1979

The Use of other Matrices in RUTF Formulation
Recommendation 5:

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

The Use of other Matrices in RUTF Formulation

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* (CXS 180-1991).

ISDI comment

ISDI supports this recommendation and would like to add the following text for more clarity.

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* (CXS 180-1991), **particularly regarding their use that 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.**

Nutritional Composition and Quality Factors; Macronutrients; Energy
Recommendation 6:

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

Energy

Draft Text

The energy density of the formulated RUTF should be between 5.2 - to 5.5 kcal per gram. The energy density of 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 Section 8.

Energy Values

Unit	Minimum	Maximum	GUL
Kcal/100g	520	550	-

ISDI comment

ISDI supports this recommendation.

Carbohydrates
Recommendation 7:

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

ISDI comment

ISDI supports this recommendation.

Proteins
Recommendation 8:

That CCNFSDU agree to the proposed protein values in RUTF.

Protein should provide 10%-12% of the total energy.

Unit	Minimum	Maximum	GUL
g/100g	12.8	16.2	-
g/100kcal	2.3	3.1	-

ISDI comment

ISDI does not support the proposed Protein minimum limit of 12.8 g protein/100 g and value of 2.3 g/100kcal.

Justification:

This value is to be compatible with the recommendation which is “protein should provide 10 to 12 % of total energy”.
- If 1 g protein provides 4 kcal and
- The minimum energy is 520 kcal /100g
- 10% of 520 = 52 kcal
- 52 kcal/4 kcal/g = 13 g

The minimum is then 13 g protein/100g. The exact minimum value is 2.36, rounded to 2.4 g/100 g.
2. ISDI does not support the proposed Protein maximum limit of 16.2 g protein/100 g and value of 3.1 g/100 g.

Justification:
This value is to be compatible with the recommendation which is “protein should provide 10 to 12 % of total energy”
- If 1 g protein provides4 kcal and
- The maximum energy is 550 kcal /100g
- 12% of 550 = 66 kcal
- 66 kcal/4 kcal/g = 16.5 g

The maximum is then 16.5 g protein/100g. The exact maximum value is 3.17, rounded to 3.2 g/ 100g.

ISDI suggests the following:

Unit	Minimum	Maximum	GUL
g/100g	13g	16.5g	-
g/kcal	2.4	3.2	-

Protein Quality
Recommendation 9:

That CCNFSDU agree to keeping 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"]

ISDI comment

ISDI supports this recommendation.

Lipids
Recommendation 10:

That CCNFSDU agree to the proposed text on fats/lipids and the proposed minimum and maximum fats/lipids values as follows:
Lipids should provide 45% to 60% of the total energy.

The level of linoleic acid should not be less than 333 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33mg/100kcal. The level of linoleic acid should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.]

Unit	Minimum	Maximum	GUL
g/100g	26	37	-
g/100kcal	5	6.7	-

ISDI comment

ISDI partially supports this recommendation and suggests to widen the range in the last sentence as follows:

The level of linoleic acid should not be less than 333 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33mg/100kcal. The level of linoleic acid should ensure a ratio between linoleic acid and alpha-linolenic acid of between ~~5:1~~ **1:1** and 15:1.

Rationale:
Available evidence suggests that the content of linoleic acid (LA) in current RUTF formulation is too high. This results in poor conversion of alpha linolenic acid (ALA) into DHA. The content of LA in the lower part of the permitted range is preferable.

Having a low LA/ALA ratio does not guarantee a good conversion of ALA to DHA as ALA competes with intermediate metabolites in the final stage of DHA synthesis. The best DHA status at the end of treatment was achieved with an RUTF with a low LA content and a LA/ALA ratio of 1:1..

Reference:
Brenna JT, Akomo P, Bahwere P, Berkley JA, Calder PC, Jones KD, Liu L, Manary M, Trehan I, Briend A. Balancing omega-6 and omega-3 fatty acids in ready-to-use therapeutic foods (RUTF). BMC Med. 2015 May 15;13:117.
Hsieh JC, Liu L, Zeilani M, Ickes S, Trehan I, Maleta K, Craig C, Thakwalakwa C, Singh L, Brenna JT, Manary MJ. High-Oleic Ready-to-Use Therapeutic Food Maintains Docosahexaenoic Acid Status in Severe Malnutrition. J Pediatr Gastroenterol Nutr. 2015 Jul;61(1):138-43.

Essential fatty acids
Recommendation 11:

That CCNFSDU agrees to retaining 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 333 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 33 mg per 100 kcal

ISDI comment

ISDI supports this recommendation but would like to bring to the attention of the eWG Chair that there is a difference between the recommendation and the Annex in the Proposed Draft Guidelines.

In the Annex there is a typo for the line n-6 fatty acids and n-3 fatty acid, regarding the unit and the values in mg/100 kcal. Corrections are shown below:

n-6 Fatty acids

Unit	Minimum	Maximum	GUL
~~g/100g~~ **kcal/100 kcal**	3	10	
mg/100kcal	**333**	**1111**	
mg/100g	**1731.6**	**6111**	

n-3 Fatty acids

Unit	Minimum	Maximum	GUL
~~g/100g~~ **kcal/100 kcal**	0.3	2.5	
mg/100kcal	**33**	**278**	
mg/100g	**172**	**1529**	

Vitamins: Vitamin A
Recommendation 12:

That CCNFSDU agree to the minimum, maximum and associated footnote for vitamin A as follows:

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.

ISDI comment

ISDI supports this recommendation.

Vitamin D; Vitamin D Levels
Recommendation 13:

That CCNFSDU agree to the minimum, maximum/GUL and associated footnote for vitamin D as follows:

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

[3] 1 µg cholecalciferol = 40 IU vitamin D

ISDI comment

ISDI agrees with the proposed minimum of 15 mcg/100g if the maximum accepted limit is [22].

ISDI agrees with the note 3 1 µg cholecalciferol = 40 IU vitamin D with respect to the following clarification required here:

ISDI would like to highlight that according to the conclusion of the paragraph 9.2 of the last proposed draft 2017 eWG Consultation Paper 2 RUTF, "The Chairs also recommend that although the two forms of vitamin D allowed in RUTF formulation, namely cholecalciferol (D3) and ergocalciferol (D2), are already specified in CAC/GL 10-1979, such forms should still be specified in the nutritional composition section to provide further guidance to member states". ISDI support the above cited approach.

Vitamin E
Recommendation 14:

That CCNFSDU agree to the minimum and associated footnote for vitamin E as follows

Unit	Minimum	Maximum	GUL
4mg/100 g	20	-	-
4mg α-TE /100 kcal	4	-	-

[4] 1 mg α-tocopherol = 1 mg RRR-α-tocopherol (d-α-tocopherol)
[4] 1 mg α-tocopherol =2.00 mg *all-rac*-α-tocopherol (dl- α-tocopherol)

ISDI comment

ISDI supports this recommendation and proposes to keep to add α-TE in the first line, and to keep a point number with one decimal in the second line.

Unit	Minimum	Maximum	GUL
4mg **α-TE** / 100 g	20	-	-
4mg α-TE /100 kcal	**3.6**	-	-

Vitamin K; Vitamin B1 Vitamin B2; Vitamin C; Vitamin B6; Vitamin B12; Folic Acid; Niacin; Pantothenic Acid; Biotin
Recommendation 15:

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 as follows:

Vitamin K

Unit	Minimum	Maximum	GUL
µg/100 g	15	30	-
µg/100 kcal	2.9	5.5	-

Vitamin B1

Unit	Minimum	Maximum	GUL
mg/100 g	0.5	-	-
mg/100 kcal	0.1	-	-

Vitamin B2

Unit	Minimum	Maximum	GUL
mg/100 g	1.6	-	-
mg/100 kcal	0.3	-	-

Vitamin C

Unit	Minimum	Maximum	GUL
mg/100 g	50	-	-
mg/100 kcal	9.6	-	-

Vitamin B6

Unit	Minimum	Maximum	GUL
mg/100 g	0.6	-	-
mg/100 kcal	0.12	-	-

Vitamin B12

Unit	Minimum	Maximum	GUL
µg/100 g	1.6	-	-
µg/100 kcal	0.3	-	-

Folic Acid

Unit	Minimum	Maximum	GUL
[5] µg/100 g	200	-	-
[5] µg/100 kcal	38.5	-	-

[5] 1 µg of folic acid = 1.7 µg of Dietary Folate Equivalents (DFE)

Niacin

Unit	Minimum	Maximum	GUL
mg/100 g	5	-	-
mg/100 kcal	0.96	-	-

Pantothenic Acid

Unit	Minimum	Maximum	GUL
mg/100 g	3	-	-
mg/100 kcal	0.6	-	-

Biotin

Unit	Minimum	Maximum	GUL
µg/100 g	60	-	-
µg/100 kcal	11.5	-	-

ISDI comment

ISDI supports this recommendation.

Minerals: Sodium; Potassium; Calcium; Phosphorus; Magnesium; Iron; Zinc; Copper; Selenium; Iodine

Recommendation 16:

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

Sodium

Unit	Minimum	Maximum	GUL
mg/100 g	-	290	-
mg/100 kcal	-	53	-

Potassium

Unit	Minimum	Maximum	GUL
mg/100 g	1,100	1,400	-
mg/100 kcal	212	255	-

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]	-

Iron

Unit	Minimum	Maximum	GUL
mg/100 g	10	14	-
mg/100 kcal	1.9	2.6	-

Zinc

Unit	Minimum	Maximum	GUL
mg/100 g	11	14	-
mg/100 kcal	2	2.6	-

Copper

Unit	Minimum	Maximum	GUL
mg/100 g	1.4	1.8	-
mg/100 kcal	0.27	0.33	-

Selenium

Unit	Minimum	Maximum	GUL
µg /100 g	20	40	-
µg /100 kcal	4	7	-

Iodine

Unit	Minimum	Maximum	GUL
µg /100 g	70	140	-
µg /100 kcal	13.46	25.5	-

ISDI comment

ISDI believes that **no Sodium should be added in the RUTF formulation**. There will be some sodium naturally present in the raw materials used.

In addition, ISDI would like to recommend the following upper limits to take into account the variability of raw materials and manufacturing processes.

Potassium
ISDI does not support the proposed **Potassium** maximum limit value of 1,400 mg/100 g and suggests to increase the limit to **1,600 mg/100 g**.

Copper
ISDI does not support the proposed maximum limit value of 1,8 mg/100 g and suggests to increase the limit to **2 mg/100 g**.

Iodine
ISDI does not support the proposed maximum limit value of 140 µg/100 g and suggests to increase the limit to **160 µg/100 g**.

Additional Nutrients

Recommendation 17:

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.

ISDI comment

ISDI supports this recommendation.

PROCESSING TECHNOLOGIES
Recommendation 18:

That CCNFSDU agree to the proposed text of "Processing Technologies" section of the Guidelines as follows:

In addition to the practices described below, Good Hygiene Practices (General principles of food hygiene CXC 1-1969) should be implemented to avoid cross contamination during the packing and storage of raw materials.

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 may be dehulled as completely as is feasible to reduce the fibre content to acceptable levels and to decrease, and/or if possible, to eliminate phytates, tannins and other phenolic materials, trypsin and

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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 cereals, 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.

[The use of appropriate enzymes may be considered to decrease anti-nutrients in 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 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 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. antimicrobial fumigation) control measures. *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008) and *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007) should be adhered to.

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ISDI comment

ISDI partially supports this recommendation and proposes the following amendment in the introduction.

Processing technologies described below are given as examples of treatment mainly on raw materials.

Any technologies used for raw materials and for RUTF have to be validated according to Guidelines for the Validation of Food Safety Control Measures (CXG 69-2008), to prove that:

- **they do not alter the nutritional value,**
- **they allow reduction of anti-nutritional factors,**
- **they allow to guaranty the microbial quality of the food.**

In addition to the practices described below, Good Hygiene Practices (General principles of food hygiene CXC 1-1969) should be implemented to avoid cross contamination during the packing and storage of raw materials.

GOOD MANUFACTURING PRACTICES AND GOOD HYGIENE PRACTICES
Recommendation 19:

That CCNFSDU agree to the proposed draft text for "good manufacturing practices and good hygiene practices" section as follows:

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

The product should comply with any microbiological criteria established in accordance with the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).

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

ISDI comment

ISDI supports this recommendation.

METHODS OF ANALYSIS AND SAMPLING
Recommendation 20:

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* (CXS 234-1999), *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995), *The Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997), *Code of Hygienic Practice for Low Moisture Foods* (CXC 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* (CXG 54-2004), *Protocol for the Design, Conduct and Interpretation of Method Performance Studies* (CXG 64-1995), and Harmonized IUPAC.

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ISDI comment

ISDI supports this recommendation.

PACKAGING
Recommendation 21:

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.

ISDI comment

ISDI supports this recommendation.

LABELLING
Recommendation 22:

That CCNFSDU agree with the proposed draft text for the "labelling" section of the guidelines as follows:

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* (CXS 180-991), ~~*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* (CXS 146-1985), ~~*Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997)~~ and *Guidelines on Nutrition Labelling* (CXG 2- 1985).

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 Children from 6 to 59 months. 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* (CXS 1 -1985).

Additional Mandatory Labelling Requirements

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.

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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.]

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.

Feeding instructions shall be given; preferably accompanied by graphical presentations.

The time in which the product should be consumed after opening should be clearly indicated.

ISDI comment

ISDI supports the recommendation with the following amendments.

1. ISDI recommends that the following statement should be reworded since RUTF can be consumed at home without medical supervision. This statement as currently worded is inapplicable.

~~"USE UNDER MEDICAL SUPERVISION" shall appear on the label in bold letters in an area separated from the written, printed, or graphic information.~~

ISDI suggests: **To be prescribed by a trained health and nutrition professional only**

2. ISDI recommends that the following statement should be deleted since there is no evidence to support it.

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~~.

3. ISDI recommends removing the word rectal in the following sentence: *The product is not to be used for parenteral, ~~recta~~l or Nasogastric Tube (NG tube) administration. A*

No other type of food mentions such purposes for the product use, as well as there is no evidence on the potential use of RUTF for rectal administration.

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