

CODEX ALIMENTARIUS COMMISSION



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Agenda Item 5

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

Forty-first Session

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REPORT OF THE IN-SESSION WORKING GROUP ON THE PROPOSED DRAFT GUIDELINES FOR READY-TO-USE THERAPEUTIC FOODS

(Prepared by South Africa and Senegal)

Background

The In-session working group met during CCNFSDU41 to further discuss the proposed draft guidelines for RUTF with the following terms of reference:

- To consider the recommendations of the 2019 EWG in document CX/NFSDU 19/41/6 (with specific reference to food additives and the protein quality assessment section)
- To consider the values and outstanding text of the annex on “Nutrition Composition for RUTF”
- Time permitting, to consider also recommendations 5, 6, and 15-20 listed in the Appendix 1 of CX/NFSDU 19/41/6

1. Protein

a. Protein values:

The in-session working group agreed on the proposed values based on the Joint Statement of 2007.

Recommendation 1:

That CCNFSDU agree to the proposed protein values of the Guidelines for RUTF.

Unit	Minimum	Maximum	GUL
g/100g	13	17	-
g/100kcal	2.5	3.0	-

b. Protein Quality Assessment in RUTF

The in session working group looked at the proposed text on protein quality assessment in RUTF and agreed with the below text with some suggested amendments.

Recommendation 2:

That CCNFSDU agree to the proposed text on protein quality assessment in RUTF

Draft Text:

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

Protein quality should be determined using Protein Digestibility Corrected Amino Acid Score (PDCAAS), calculated according to the reference amino acid requirement and scoring patterns related to catch up growth of 10 g/kg/day in the target population which is children 6 to 59 months for RUTF.

For all RUTF formulations, the PDCAAS shall not be less than 90. The PDCAAS shall be calculated using, appropriate digestibility values and the reference amino acid pattern as stipulated in the *Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic foods (2018)*.

High quality protein will be achieved with RUTF formulations containing a minimum of 50% of protein from milk products.

In formulations with lower PDCAAS scores, the quality and/or quantity of protein should be adjusted to achieve the desired value. The addition of limiting amino acids, solely in the L-form, shall be permitted only in amounts necessary to improve the protein quality of the RUTF.

2. Section 5.2.2 Food Additives

The Chair provided some background on the additives sections of the guidelines and highlighted comments received from the eWG members. Two approaches on how best to handle additives and referencing Codex texts in the guidelines were proposed to the In-session working group, which included:

- **The first approach** – to include a table with specific function classes of food additives that would be permitted for use in the formulation of RUTF.
- **The second approach** – to make reference to existing CCNFSDU commodity standards and texts (i.e. CXS 72-1981; CXS 156-1987; CXG 10-1979).

The In-session working group agreed with the first approach, which would avoid further delays in finalising the food additives section of this guideline. Furthermore, the In-session working group agreed on the below text to accompany the revised table on Food Additives.

CCNFSDU agree to the proposed text on Food Additives:

Recommendation 3:

CCNFSDU agree to the draft text and the revised Table A on Food Additives

Draft Text

Only food additives listed in Table A of the guideline are allowed for use in RUTF at the specified maximum use level.

Table A: Food Additives in RUTF Formulation

Functional Class	Food Additive	International Numbering System (INS)	Maximum Use Level
Emulsifier	Mono & diglycerides of fatty acids	471	4000 mg/kg
	Citric and fatty acid esters of glycerol	472c	9000 mg/kg
	Lecithin	322(i)	Up to 5000 mg/kg
Antioxidants	Ascorbyl palmitate	304	1 mg/kg singly or in combination
	Tocopherol concentrate, mixed*	307b	1 mg/kg singly or in combination
	Ascorbic acid	300	GMP
Acidity regulator	Citric acid	330	GMP
Packaging gas	Nitrogen	941	GMP
	Carbon dioxide	290	GMP
Carrier	Silicon dioxide, amorphous	551	10 mg/kg

3. Labelling

The In-session working group re-visited the proposed text on labelling of the RUTF. The Chair reminded the working group that the labelling section should only address specific labelling requirements relevant for RUTF beyond the requirements already established in CXS 180-1991.

The in-session working group agreed to remove proposed texts that were already covered by section 4.4 of CXS 180-1991

Recommendation 4:

That CCNFSDU agree to the draft text on labelling for RUTF Guidelines

Draft text

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), the *General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses* (CXS 146-1985), 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 *General Standard for the Labelling of Prepackaged Foods* (CXS 1 -1985).

Additional Mandatory Labelling Requirements

Provisions of section 4.4 of the Standard for the Labelling and Claims for FSMP (CXS 180-1991) shall apply.

The following statements shall appear on the label of RUTF:

- The product is not to be used for Nasogastric Tube (NG tube) administration.

- The product should be used in conjunction with breastfeeding.
- 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.

4. The annex on “Nutrition Composition for RUTF”

Editorial amendments with regard to the Rounding Issues to the Nutritional Composition for the Proposed Draft Guidelines on RUTF

The 2018 PWG noted some inconsistencies in the rounding off applied to values in the development of the guidelines. The Chairs noted the discrepancies and considered it imperative to apply a systematic approach that would be applied consistently throughout the guidelines. This would align the guidelines with other internationally agreed upon conventional rounding methods. The In-session working group considered the updated values and the outstanding text on the nutritional composition of RUTF.

Recommendation 5:

That CCNFSDU agree to the following values on the nutritional composition of RUTF in the table below.

Table: Nutritional Composition for RUTF**Energy**

Unit	Minimum	Maximum	GUL
kcal/100g	520	550	-

Protein

Unit	Minimum	Maximum	GUL
g/100g	13	17	-
g/100kcal	2.5	3.0	-

Lipids

Unit	Minimum	Maximum	GUL
g/100g	26	37	-
g/100kcal	5	7	-

n-6 Fatty acids

Unit	Minimum	Maximum	GUL
mg/100g	1733	6111	-
mg/100kcal	333	1111	-

n-3 Fatty acids

Unit	Minimum	Maximum	GUL
mg/100g	173	1528	-
mg/100kcal	33	278	-

Vitamin A

Unit	Minimum	Maximum	GUL
mg RE/100g	0.8	1.2	-
mg/ RE/100kcal	0.15	0.23	-
² µg RE/100kcal	145	231	-

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

Vitamin D

Unit	Minimum	Maximum	GUL
³ µg/100 g	15	22	{30}
³ µg/100 kcal	2.7	{3.6} OR { 4.2}	-

³ 1 µg cholecalciferol = 40 IU vitamin D. [Two forms of Vitamin D allowed in RUTF formulation are cholecalciferol (D3) and ergocalciferol (D2).]

Vitamin E

Unit	Minimum	Maximum	GUL
⁴ mg α-TE /100 g	20	-	-
⁴ mg α-TE /100 kcal	3.6	-	-
⁴ 1 mg α-tocopherol = 1 mg RRR-α-tocopherol (d-α-tocopherol)			
⁴ 1 mg RRR-α-tocopherol =2.00 mg <i>all-rac</i> -α-tocopherol (di- α-tocopherol)			

Vitamin K

Unit	Minimum	Maximum	GUL
µg/100 g	15	30	-
µg/100 kcal	2.7	6	-

Vitamin B1

Unit	Minimum	Maximum	GUL
mg/100 g	0.5	-	-
mg/100 kcal	0.09	-	-

Vitamin B2

Unit	Minimum	Maximum	GUL
mg/100 g	1.6	-	-
mg/100 kcal	0.29	-	-

Vitamin C

Unit	Minimum	Maximum	GUL
mg/100 g	50	-	-
mg/100 kcal	9	-	-

Vitamin B6

Unit	Minimum	Maximum	GUL
mg/100 g	0.6	-	-
mg/100 kcal	0.11	-	-

Vitamin B12

Unit	Minimum	Maximum	GUL
µg/100 g	1.6	-	-
µg/100 kcal	0.29	-	-

Folic Acid

Unit	Minimum	Maximum	GUL
⁵ µg/100 g	200	-	-
⁵ µg/100 kcal	36	-	-

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	0.91	-	-

Pantothenic Acid

Unit	Minimum	Maximum	GUL
mg/100 g	3.0	-	-
mg/100 kcal	0.55	-	-

Biotin

Unit	Minimum	Maximum	GUL
µg/100 g	60	-	-
µg/100 kcal	11	-	-

Sodium

Unit	Minimum	Maximum	GUL
mg/100 g	-	290	-
mg/100 kcal	-	56	-

Potassium

Unit	Minimum	Maximum	GUL
mg/100 g	1,100	1,600	-
mg/100 kcal	200	308	-

Calcium

Unit	Minimum	Maximum	GUL
mg/100 g	300	{600} or {785}	-
mg/100 kcal	55	{115} or {151}	-

Phosphorus

Unit	Minimum	Maximum	GUL
mg/100 g	300	{600} or {785}	-
mg/100 kcal	55	{115} or {151}	-

Magnesium

Unit	Minimum	Maximum	GUL
mg/100 g	80	{140} or {235}	-
mg/100 kcal	15	{27} or {45}	-

Iron

Unit	Minimum	Maximum	GUL
mg/100 g	10	14	-
mg/100 kcal	1.8	2.7	-

Zinc

Unit	Minimum	Maximum	GUL
mg/100 g	11	14	-
mg/100 kcal	2.0	2.7	-

Copper

Unit	Minimum	Maximum	GUL
mg/100 g	1.4	1.8	-
mg/100 kcal	0.25	0.35	-

Selenium

Unit	Minimum	Maximum	GUL
µg /100 g	20	40	-
µg /100 kcal	3.6	8	-

Iodine

Unit	Minimum	Maximum	GUL
µg /100 g	70	140	-
µg /100 kcal	13	27	-

Unit	Minimum	Maximum	GUL
Percentage (%)			
[Water activity (aW)]	[0.2]	[0.6]	-