U.S. DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service
Commodity Procurement Program

International Commodity
Procurement Division
1400 Independence Ave., SW, Room
3522-S, STOP 0239
Washington, DC 20250-0239

USAID/USDA COMMODITY REQUIREMENTS

RUF2
READY-TO-USE NUTRITIONAL FOOD

FOR USE IN
INTERNATIONAL FOOD ASSISTANCE PROGRAMS

Effective Date: July 14, 2021

Document Revision History: This RUF2 commodity requirements document supersedes the RUF commodity requirements document, dated December 21, 2015.

RUF
READY-TO-USE NUTRITIONAL FOOD

FOR USE IN
INTERNATIONAL FOOD ASSISTANCE PROGRAMS

Table of Contents

1. PRODUCT DESCRIPTION

Ready-to-use nutritional food (RUF) is intended for children aged 6 months and above, aiming at prevention of acute malnutrition, treatment of moderate acute malnutrition (MAM) or treatment of severe acute malnutrition (SAM) in any cultural setting. RUF is packaged in flexible packaging in the form of paste suitable for use by the Federal Government, humanitarian agencies, and non-governmental organizations. RUF may be used in climatic extremes from the arctic to tropical zones. Depending on the dose and quantity, RUF may be either used as supplementary food (in large quantity as RUSF or medium quantity as LNS-MQ –Lipid-based Nutritional Supplement in Medium Quantities) or as a sole source of food when using the ready to use therapeutic formulation (or RUTF). RUF provides adequate energy, protein, fat, vitamins, and minerals to effectively prevent MAM or treat SAM. The RUF will be used by multiple ethnic and cultural groups. No alcohol, animal products other than dairy products, nor any known allergens except peanuts, soy, tree nuts, and dairy products shall be used in the manufacture of these items.

RUF is generally made with oil seeds, tree nuts, pulses, cereals, sugar, dairy protein, vegetable oils, vitamins, and minerals. Applicable food safety and quality standards include, but are not limitedto:

1. Compliance with the US Food and Drug Administration (FDA) Regulations including the Food Safety Modernization Act
2. Guidelines on Formulated Supplementary Foods for Older Infants and Young Children, CAC/GL 08-1991 of the Codex Alimentarius (Except nutrients requirements in the annex of the guidelines)
3. General principles for addition of essential nutrients to foods: CAC/GL 09-1987 (amended 1991), of the Codex Alimentarius
4. Recommended International Code of Practice. General Principles of Food Hygiene CAC/RCP 1-1969, Rev. 4-2003
5. ISO 22000:2018: Food safety management systems
6. Code of Hygienic Practices for low-moisture Foods. CAC/RCP 75-2015. Adopted in 2015.

2. FORMULATION

Table 2.1. Nutritional requirements for *Ready-to-use Nutritional Food,* in a per 100g on finished product basis[1]

Nutrient	Unit	(RUSF, LNS-MQ)		RUTF		Annotations
		Min[2] (Qty)	Max (Qty)	Min[3] (Qty)	Max (Qty)	
Energy	Kcal	510	560	520	550	Using 535 kcal average
Protein[4]	%	11	16	12.8	16.2	By weight
Fat[5]	%	26	36	26	36	By weight
ω-3 fatty acids	g	0.30	1.80	0.2	1.5	ω6/ω3 must be <10:1
ω-6 fatty acids	g	2.6	6.1	1.8	6	Total PUFA must be <20%
Micronutrients						**Single MN Premix**
Retinol (Vit A)	µg	700	1600	800	1600	1400[6]
Thiamin (Vit B1)	mg	1.0		0.5		1.5
Riboflavin (Vit B2)	mg	2.1		1.6		2.6
Nicotinamide (Vit B3)	mg	13		5		16
Pantothenic Acid (Vit B5)	mg	4.0		3		4.9
Pyridoxine (Vit B6)	mg	1.8		0.6		2.2
Biotin (Vit B7)	µg	60		60		65
Folate (Vit B9) - DFE	µg	340		200		300
Cobalamine (Vit B12)	µg	2.7		1.6		2.9
Ascorbate (Vit C)	mg	60		50		90
Cholecalciferiol (Vit D)	µg	15	20	15	20	18
Tocopherol Acetate (Vit E)	mg	16		20		20
Phytomenadione (Vit K)	µg	27		15	30	27
Calcium (Ca)	mg	535	750	300	600	413
Copper (Cu)	mg	1.4	1.9	1.4	1.8	1.2
Iodine (I)	µg	100	140	70	140	110
Iron (Fe)	mg	10	14	10	14	10
Magnesium (Mg)[7]	mg	150	225	80	140	100

[1] This nutritional profile is expected in finished product at time of consumption (**Tc**), assuming an average **Tc** of eighteen (18) months. Values in % are weight-based. This table should also be used as reference for nutritional labeling on packaging, accordingly as it corresponds to RUTF, RUSF or LNS-MQ

[2] These values are minimum levels expected at consumption and target thresholds to declare on labels.

[3] These values are minimum levels expected at consumption and target thresholds to declare on labels.

[4] At least 50% of protein must derive from dairy sources in RUTF and 33% (in the form of dairy skim milk) in RUSF and LNS-MQ. These requirements result in approximately 20% weight-based of dairy protein in RUTF and 10% weight-based SDM in RUSF and LNS-MQ. Calculation is based on a factor of 4 kcal/ gram of protein. For recommended 10-12% of kcal in 100 grams/535 kcal of product, it would equate to 13-16 grams of protein per pouch. For variation in packages sizes, e.g. 50 grams sachets, corresponding calculations should be made.

[5] Fat and omega fatty acids targets are based on WHO technical note requirement for 520 and 550kcal/100g food. Trans fatty acid must be under 3% of total energy.

[6] See Table 2.2

[7] The range 80-140 Mg is only taking into account added Mg in premix, not accounting for contributions from raw ingredients

Nutrient	Unit	(RUSF, LNS-MQ)		RUTF		Annotations
		Min[2] (Qty)	Max (Qty)	Min[3] (Qty)	Max (Qty)	
Manganese (Mn)	mg	1.2	2.4			1.0
Phosphorus (P)	mg	450	750	300	600	319
Potassium (K)	mg	900	1400	1100	1400	350
Selenium (Se)	µg	20	40	20	40	15
Sodium (Na)	mg	0	270	0	290	0
Zinc (Zn)	mg	11	14.0	11	14	11

Table 2.2. Single micronutrient premix and recommended chemical forms and sources.

Nutrients	Unit	Recommended nutrient sources (/alternative options)[8]	Micronutrients added per 100g RUF +/-10%[9]
Retinol (Vit A)[10]	mcg	Dry Vitamin A Palmitate / Dry Vitamin A Acetate	1400[11]
Thiamin (Vit B1)	mg	Thiamine mononitrate / Thiamine hydrochloride	1.5
Riboflavin (Vit B2)	mg	Riboflavin	2.6
Niacin (Vit B3)	mg	Niacinamide	16
Pantothenic Acid (Vit B5)	mg	Calcium d-Pantothenate	4.9
Pyridoxine (Vit B6)	mg	Pyridoxine hydrochloride	2.2
Biotin (Vit B7)	mcg	Biotin (1% trituration)	65
Folic acid (Vit B9)	mcg	Folic acid food grade	300[12]
Cobalamine (Vit B12)	mcg	Vitamin B12 (0.1 sd)	2.9
Ascorbate (Vit C)	mg	Ascorbic acid fine powder	90[13]
Cholecalciferiol (Vit D)	mcg	Dry Vitamin D3 (sd)	18
Tocopherol Acetate (Vit E)	mg	Dry Vitamin E acetate (50% DL-alpha-tocopherol)	20
Phytomenadione (Vit K)	mcg	Dry Vitamin K (5%)	27
Calcium (Ca)	mg	Di-Calcium Phosphate anhydrous/tricalcium phosphate	413[14]

[8] These are preferred chemical forms. There might be other options possible, which supplier may opt to use in consultation with contracting agency, as long as it does not impact dosing and functionality.
[9] Levels of micronutrients in the premix are based on GAIN studies on micronutrient retention in lipid-based nutrient supplements, available knowledge on expected nutrient contribution of the various raw ingredients and variability calculation throughout processing and shelf life to allow the different formulas match nutritional targets at time of consumption as recommended by WHO for SAM and MAM.
[10] Beadlet or spray dried form can be used assuming there is no carryover of antioxidants not approved in codex.
[11] This is the recommended amount if there is no process loss. If process losses have been demonstrated by a study appropriate over dosage should be applied to ensure that analytical target is reached
[12] This is equivalent to 500 mcg Dietary Folate Equivalent
[13] This is the recommended amount if there is no process loss. If process losses have been demonstrated by a study appropriate over dosage should be applied to ensure that analytical target is reached
[14] This is equivalent to 1.4% Di-calcium phosphate: In final product Ca/P ratio should be 1-1.5, including raw material and 30% of P from plant sources

Nutrients	Unit	Recommended nutrient sources (/alternative options)[8]	Micronutrients added per 100g RUF +/-10%[9]
Copper (Cu)	mg	Copper sulphate anhydrous/ copper gluconate	1.2
Iodine (I)	mcg	Potassium iodide (10% trituration)	110
Iron (Fe)	mg	2.5 mg from NaFeEDTA + 7.5 mg, which can be from Ferrous sulphate monohydrate, dried / ferrous sulfate / ferrous fumarate, encapsulated or not	10
Magnesium (Mg)	mg	Magnesium sulphate monohydrate / magnesium citrate or gluconate	100
Manganese (Mn)	mg	Manganese sulphate monohydrate	1.0
Phosphorus (P)	mg	Di-Calcium Phosphate anhydrous / tricalcium phosphate	319[15]
Potassium (K)	mg	350 mg potassium chloride + 500 mg tri potassium citrate or potassium phosphate	350[16]
Selenium (Se)	mcg	Sodium selenite / sodium selenate	15
Zinc (Zn)	mg	Zinc sulfate anhydrous	11

Micronutrient premixes shall be procured from a GAIN-approved premix facility. https://gpf.gainhealth.org/suppliers/current-suppliers. Micronutrient premixes shall be delivered to the processor with a complete Certificate of Analysis (COA) as well as a Proof of Purchase of premixes. Micronutrient premixes shall be stored in a dry, cool, and clean place where the temperature is a maximum of 25°C.

3. PROCESS AND PRODUCT DESCRIPTION

RUFs are generally processed using milled roasted peanuts, other nuts, pulses or oil seeds, blended with vegetable oils, dairy protein, minerals and vitamin premix through a batch-type blending step, under a high temperature (between 75 and 130°C) enclosed system. Processing may include a scraped surface heat exchanger (SSHE) with adequate residence time as pasteurization or kill step, specific for high viscosity product so it would not generate severe fouling during processing. Product is hot-filled and ideally rapidly cooled down. The product shall be a thick, homogeneous paste. The flavor shall be typical of the product and ingredients, without off- flavors or flavors attributable to the vitamins and minerals. The paste shall not show evidence of oilseparation and shall be as smooth as possible, with minimal granulation so as to not elicit chewing.Color, taste, and appearance shall be typical for the products and not show evidence over processing.

[15] This is equivalent to 1.4% Di-calcium phosphate: In final product Ca/P ratio should be 1-1.5, including raw material and 30% of P from plant sources

[16] This is equivalent to 0.5 % of potassium chloride. Higher milk powder content in RUTF formula adds additional potassium, calcium and phosphorus to the formulation, which account for higher K levels at consumption time.

4. ANALYTICAL REQUIREMENTS

Table 4.1. Nutritional analytical values per 100 grams of finished product

No.	Parameter	Units	(RUSF, LNS-MQ)		RUTF		Reference Methods (AOAC)[17]
			Min	Max	Min	Max	
Main Composition							
1	Protein (by weight)	%	11[18]	16	13[19]	16	988.05, 992.15
2	Fat (total)	%	26[20]	36	26	36	996.06, 991.36, 950.54
3	Water Activity	-	0.2	0.5	0.2	0.5	978.18
Vitamins and Minerals (expressed in a per 535 kcal/100 grams of product**)**							
4	Vitamin A (retinol isomers)	mcg	700	1600	800	1600	2001.13, 2011.11, or 2011.13
5	Vitamin C	mg	60	220	50		984.26, 967.21
6	Iron	mg	10	14	10	14	985.35, 984.27, or 999.10

Table 4.2. Microbiological release criteria, contaminants, and reference methods in the finished product

Microbiological Test[21]	IC/SU	n	c	m	M	Report Unit	Ref. Methods
Enterobacteriaceae	*I/10*	*10*	*2*	*10*	*100*	*/g*	*AOAC 975.55; AOAC 2003.01*
Salmonella[22]	*C/10*	*10*	*0*	*0*	*0*	*Absent/25 g*	*2004.03, 2003.09, 2011.03, or BAM, Ch. 5*
Aflatoxin B1, B2, G1 and G2. (ppb)	*Max 10 ppb*						*AACC 45-16; 990.33, 991.31, 998.03, or 999.07*

Annotations:
IC: Whether the testing sample is individual (I) or composite (c)
SU: Sample Units
n: Number of sub-samples to be examined
c: Maximum Number of acceptable sample units between m and M
m: maximum of cfc of the organism per gram (or ppb) that may be accepted
M: Maximum allowable number of microorganism (cfu) per gram in any one sub-sample. Any sub-sample with a number above M causes the rejection of the lot under consideration.

3-Monochloroprane-1-2- diol Esters (3-MCPDEs) and Glycidyl Esters (GEs): Testing is not mandatory for lot release, but supplier monitoring is required and should be based on a HACCP-based risk analysis. Suppliers are to work with the USG contracting officer and food technologists to outline an appropriate monitoring plan.

[17] Other comparable, equivalent and validated methods if cost effectiveness is demonstrated
[18] 33% of protein must derive from dairy skim milk. Calculation is based on a factor of 4 kcal/ grams of protein. This requirement results in approximately 10% weight-based of skim milk powder in RUSF and LNS-MQ.
[19] 50% of protein must derive from dairy. Calculation is based on a factor of 4 kcal/ grams of protein. For recommended 10-12% of kcal in 100 grams/535 kcal of product, it would equate to 13-16 grams of protein per pouch. For variation in packages sizes, e.g. 50 grams sachets, corresponding calculations should be made.
[20] To convert calories to grams of fat, in order to estimate fat in weight percentage, a factor of 1g of fat = 9 calories has been assumed
[21] Based on WHO/FAO Expert recommendation of 11 December 2014 on the microbial safety of lipid-based ready to use foods (RUF).
[22] These sampling criteria assume that the facility has stringent preventive food safety and quality programs which must include a validated **HACCP** system, along with corresponding prerequisite programs, as well as a Pathogen and Environmental Monitoring Program (**PEM**) and **microbiology zoning** demarcation and policy.

5. QUALITY ASSURANCE

5.1. Start-up. Suppliers shall go through normal start-up process, as a preparatory or first production run in which the supplier develops and documents baseline data on composition, micronutrient levels, microbiology, operator training, grading table (sensory analysis) and all calibrations necessary before running at full capacity. Important elements to assess during start-up include implementation and validation of HACCP plans, pathogen and environmental monitoring procedures (PEM), microbiology zoning policies, sanitation program and any applicable food safety and quality guideline referenced in the product description section in this document. Suppliers may be required to submit samples of preliminary production for USG for organoleptic/sensory acceptability. (The solicitation can indicate whether submittal of samples to USG for acceptability is required.)

5.2. Inspections and audits. Prior to any award, suppliers should have demonstrated sound quality and food safety programs, through written quality programs and a letter expressing its commitment to the highest quality and food safety standards through the provision of appropriate supplier's Certificates of Analysis (CoAs). Bidders should provide this information, or attest to it, as part of their bid package. USG usually carries out comprehensive audits annually, as well as unannounced routine inspections. Suppliers are expected to have and use a system for ensuring delivery of conforming product.

5.3. Sampling and testing. Comprehensive testing including all the parameters in Table 2.1 and Table 4.2 shall be carried out during start up and annually thereafter. Sampling frequency and lot size shall be defined based on daily volume produced. For daily production equal or greater than 100MT, a day of production is recommended as a lot size; if daily production is less than 100MT then a week of production is recommended as lot size. For higher daily production volumes, 100MT is recommended as the inspection lot size.

For ongoing monitoring testing, on a daily basis and reported in a per lot basis, parameters in Table 4.1 will be monitored for nutritional compliance and parameters in Table 4.2 for microbiological and contaminant compliance. Both microbiological and nutritional testing for ongoing monitoring purpose must be carried out by an ISO-17025 accredited laboratory and reported on CoAs. CoAs must be provided for each lot for USG acceptance of product. Suppliers must have an effective and reliable system for verifying that conforming product is being produced and delivered. Suppliers will be required to provide documentation of system results for each lot offered for delivery, (e.g., results of verification inspections of finished product, analytical test results, sensory and grading table data, etc.). Suppliers' documentation for each lot must demonstrate the lot's conformance using a system that applies criteria equal to or tighter than those listed in Paragraph 5.4 below. USG verification testing for parameters in Tables 4.1 and 4.2 will be performed on all inspection lots offered. Samples will be selected by supplier and submitted to USG laboratory for verification testing.

5.4. Sensory and grading table assessment. Conformance of finished product shall be assessed using the last version of ANSI/ASQC Z1.4 standard, using lot size as defined for manufacture, with inspection level of S-3, single sampling plan, and with AQL for critical defects

of 0.1%, for major, 1.5% and for minor, 4%. Table 5.1 indicates most common defects. Supplier's system shall establish and apply thresholds of acceptability for grading table defects.

Table 5.1. Most common reasons for nonconformance and their classification

Parameters	Measurements (Lot is non-conforming if these parameters are not met)	Methods
Texture	*Product should be smooth enough so that it would not stimulate chewing; product should show no oil separation*	*Supplier must develop grading table evaluation with corresponding SOP, and subjected to auditing; comparability to accepted standard*
Granulation	*Granulation measurement using particular sizing is advised for start-ups but not required. Granulation should allow smooth texture, too coarse a granule can contribute to oil phase separation.*	*Product should be free of gritty, grainy, and sandy texture; comparability to accepted standard.*
Flavor	*Product should have flavor typical of the product and ingredients, without off-flavors or flavors attributable to the vitamins and minerals.*	*Organoleptic evaluation; comparability to accepted standard.*

Finished product and packaging defects[23]			
Defect Categories			***Defect Description***
Critical[24]	***Major[25]***	***Minor[26]***	
X			*Tear, hole, or open seals.*
X			*Aberrations[27] in pouch material or seals resulting from sealing, pouch fabrication, hot filling or heat processing that reduce the effective closure seal width to less than 1.6 mm (1/16 in) for heat seals and 1mm for ultrasonically produced seals.*
	X		*Seal width not as specified*
	X		*Not sealed as specified*
	X		*Required labeling or marking missing, incorrect, illegible, or that smudges*
	X		*Presence of entrapped matter (for example, product residue) that reduces the effective closure seal to less than 1.6 mm (1/16 in) wide for heat seals and 1mm for ultrasonically produced seals.*
	X		*Distance between inside edge of tear notch or serrations and inside edge of seal is less than 4.7625 mm (3/16 in) with minimum seal width of 2.5 mm (0.10 in).*
		X	*Tear notch or serrations missing*
		X	*Tear notch or serrations not located as specified*
		X	*Depth of tear notch or serrations not adequate to facilitate opening pouch*
		X	*Excess pouch material at edges exceeds 4.7625 mm (3/16 in)*
	X		*Pouch has foreign odor*
	X		*Any evidence of loss of headspace indicating potential leakage*

[23] Any evidence of insect or rodent infestation shall be cause for rejection of the lot.

[24] A critical defect is a defect that judgment and experience indicate would result in hazardous or unsafe conditions for individuals using the item.

[25] A major defect is a defect, other than critical, that is likely to result in failure, or to reduce materially the usability of the unit of product for its intended purpose.

[26] A minor defect is a defect that is not likely to reduce materially the usability of the unit of product for its intended purpose or is a departure from established standards having little bearing on the effective use or operation of the unit.

[27] Aberrations in pouch material or heat seals include: a) Major fold-over wrinkles or severe wrinkles, extending into heat seal area and reducing effective seal width to less than 1.6 mm (1/16 in) for heat seals or 1mm for ultrasonically produced seals; or b) Severe wrinkles in the body of the pouch along the inside edges of the heat seals.

6. PACKED PRODUCT REQUIREMENTS

6.1 ***Primary Packaging****. The product shall be packaged in hermetically sealed flexible packaging material. Seal integrity and overall pouch integrity shall be adequate to withstand rough handling typical of international distribution channels. The manufacturer shall state target seal width (not less than 1/10" or 2.5mm) and include a tear notch or serrated edge(s) to facilitate opening. Packaging dimensions shall be as indicated in contract requirements. The pouch material shall be capable of being fabricated into pouches, with material generally recognized as safe (GRAS) for use with food in accordance with 21 CFR Parts 170-199. Film should possess the following permeability characteristics:*

Description	Measurement Unit	Method
O_2 Permeability (23 ºC – 50% RH)	*0.06 cc/100 ins²/day*	*ASTM D 3985*
WV Permeability (38ºC – 90% RH)	*0.05 gm/100 ins²day*	ASTM F 372

6.2 Secondary packaging. Shipping containers or cases have approximate dimensions of 8.68 in. height x 16 in. length x 13.25 ins width. Cases will be a regular slotted container constructed of a minimum 450 lb. burst test, double wall corrugated fiberboard. In order to fill at least 90% of the cubic capacity of a 20-foot intermodal container, appropriate stacking has to be made (i.e. Prepare pallets with four layers of cases for double pallet high stacking in containers).

7. LABELING REQUIREMENTS

7.1. Primary packaging shall have the following markings: Name of the product, USAID's logo, ingredient list, net content, batch/lot number, date of manufacture, best used before date, storage instructions, name of manufacturer, address, and country of origin, and any other additional markings as per contractual agreement.

7.2. Secondary packaging shall have the following markings: Name of the product, USAID's logo, batch/lot number, date of manufacture, best used before date, name of manufacturer, address, and country of origin, and any additional markings as per contractual agreement.

7.3. Suppliers are required to print QR codes on primary and/or secondary packaging per traceability guidelines.

7.4. Target groups, color coding and use: Nutritional pastes or spreads produced under this specification are intended for the management of malnutrition and nutrient deficiencies and may include Ready to Use Therapeutic Foods (RUTF) for Severely Acute Malnutrition (SAM) treatment, Ready to Use Supplementary Foods (RUSF in 100g, normally 150 pouches per carton) for MAM treatment and LNS-LQ and MQ for MAM prevention (50g, normally 300 50g pouches or 15 kg net weight cartons). From a programming standpoint, a color-coding denomination shall be applied to facilitate differentiation of use. The following color-coding denominations have been adopted, asper the intended purpose of the product.

RUF Type	Net weight (g)	Protein (%)	Color	Purpose
RUTF lipid based	92	13-16	Red	SAM treatment
RUSF/LNS LQ	100	11-16	Orange	MAM treatment
LNS MQ	50	11-16	Yellow	SAM/MAM prevention

Front and back of sachets should be of the particular color corresponded for its purpose and the specific hue for each color (e.g., Yellow Pantone 109, Orange Pantone 151, Red PMS 485).

8. SHELF LIFE, SHIPPING AND STORAGE

The product shall have a shelf life of at least twenty-four (24) months when stored up to 30°C at 75% relative humidity. Suppliers should provide accelerated shelf life studies and maintain retain samples at least for thirty (30) months. Food safety and quality guidelines must be implemented at distribution sites such as PVOs warehouses, hospitals, refugee camps, etc. In particular, there must be a well-defined pest control policy and continuous Good Hygiene Practices (GHP) training to personnel handling the product at the end of the food chain.

9. PREPARATION AND CONSUMPTION

RUF does not need to be prepared in any way prior to consumption, making it practical for use where cooking fuel and facilities are limiting constraints. Since RUF has high lipid content, and there might be a slight oil separation, gentle kneading of the pouches is recommended prior to opening.