Nutritional Management of Children with Severe Acute Malnutrition:

Use of Special Therapeutic Foods

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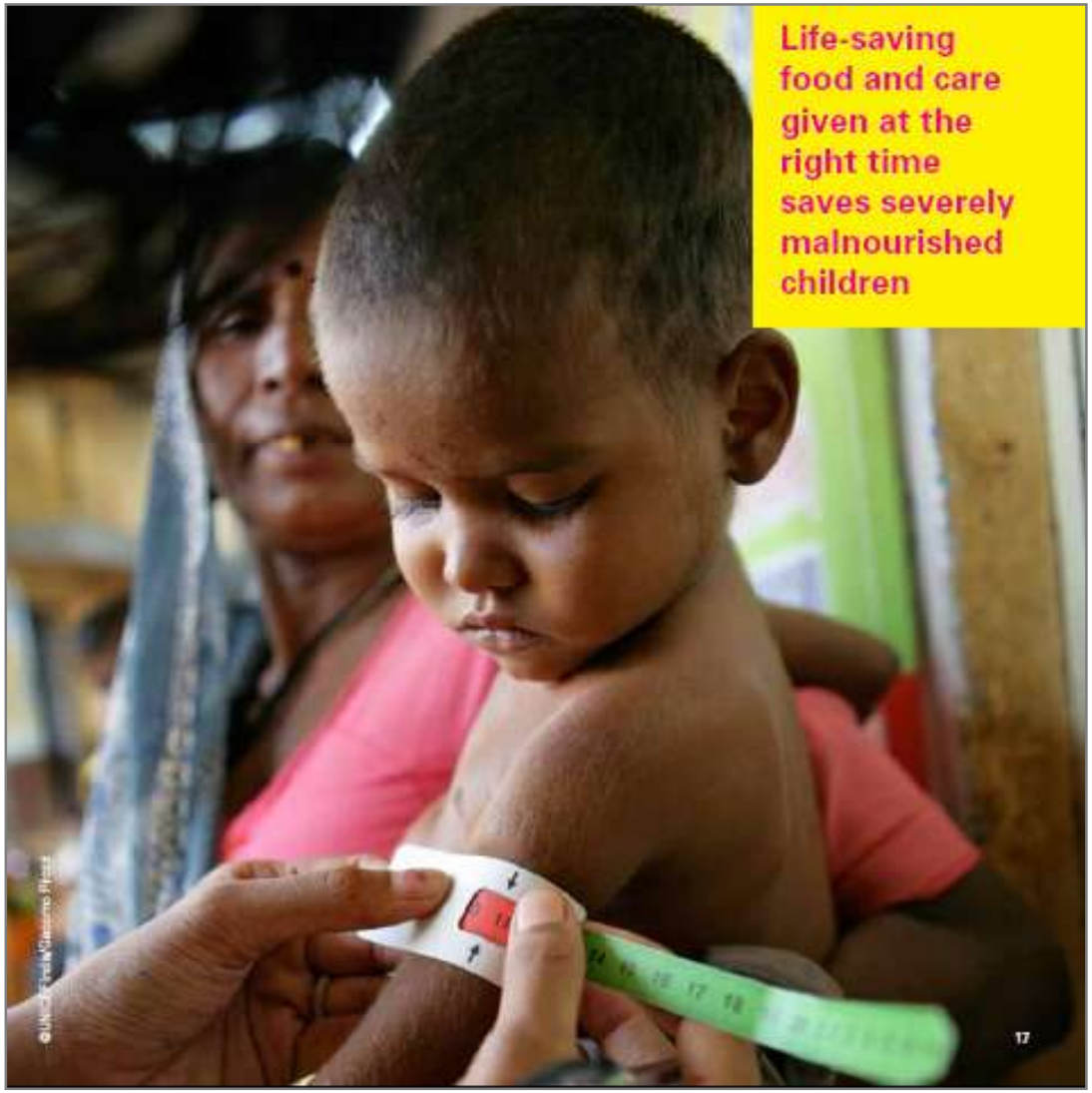
Care and adequate feeding with special therapeutic foods for the severely undernourished can save lives



General Principles of Management

Steps in management of SAM		Stabilization							Rehabilitation						
		Week 1							Weeks						
		1	2	3	4	5	6	7	2	3	4	5	6	7	8
Phase 1															
1	Treat/prevent hypoglycemia														
2	Treat/prevent hypothermia														
3	Treat/prevent dehydration														
4	Correct electrolyte imbalance														
5	Treat/prevent infection														
6A	Correct micronutrient deficiencies														
6B	Provide iron supplements														
7	Start cautious feeding														
Phase 2															
8	Achieve catch-up growth														
9	Provide sensory stimulation and emotional support														
10	Prepare for follow up														

Types of Therapeutic Foods

1. Therapeutic milks
   F-75, F-100
2. Energy-dense micronutrient-enhanced lipid rich pastes
   RUTF (ready-to-use therapeutic food)

Who gets which therapeutic food?

Children with SAM and medical complications admitted to NRCs – Inpatient care

1. Stabilization phase (Phase 1) – F-75
2. Transition and Rehabilitation phase (Phase 2) – F-100 and RUTF

Children with SAM; without medical complications – Outpatient care

1. RUTF

F-75 Therapeutic Milk
Low-protein milk based formula

For children with SAM who are over 6 months of age in Phase 1

- F-75 is NOT a dilute form of F-100; has a completely different nutrient composition
- Designed for patients with severe complicated malnutrition who have impaired liver and kidney function with infection
- Patients should NOT gain weight on F75. The diet allows their biochemical, physiological and immunological function to start to recover
- Provides 75 kcal/100 ml
- Its use is usually limited to the first 3 days after admission to NRC
- Contains milk, sugar, oil, vitamins and minerals in a powder form
- A sachet – 102.5 g to be mixed with 500 ml of boiled water to get 600 ml therapeutic milk;
- 5-6 feeds per day; amount is calculated based on the weight of the child (100-135 kcal/kg body weight/day)
- Conservation: 2 hours at room temperature, and up to 16 hours when refrigerated
- **To be administered under strict medical supervision**

F-100 Therapeutic Milk

For children with SAM who are over 6 months of age in Phase 2

- A child with SAM with an appetite and no major medical complications following F-75 diet can commence treatment with F-100 in the transition and rehabilitation phase (Phase 2)
- F-100 is intended for weight gain and provides 100 kcal/100 ml
- Specially developed for nutritional recovery
- Contains milk, sugar, oil, vitamins and minerals in a powder form
- A sachet – 114 g to be mixed with 500 ml of boiled water to get 600 ml therapeutic milk
- Conservation: 2 hours at room temperature, and up to 16 hours when refrigerated
- **To be administered under strict medical supervision**
- **Children achieving rapid weight gain on F-100 should be changed to RUTF and observed to ensure that they accept the diet before being transferred to an outpatient program**

Nutritional Composition of F-75 and F-100

Constituent	Amount per 100 ml	
	F-75	F-100
Energy	75 $kcal_{th}$ (315 kJ)	100 $kcal_{th}$ (420 kJ)
Protein	0.9 g	2.9 g
Lactose	1.3 g	4.2 g
Potassium	3.6 mmol	5.9 mmol
Sodium	0.6 mmol	1.9 mmol
Magnesium	0.43 mmol	0.73 mmol
Zinc	2.0 mg	2.3 mg
Copper	0.25 mg	0.25 mg
Percentage of energy from:		
protein	5%	12%
fat	32%	53%
Osmolarity	333 mOsmol/l	419 mOsmol/l

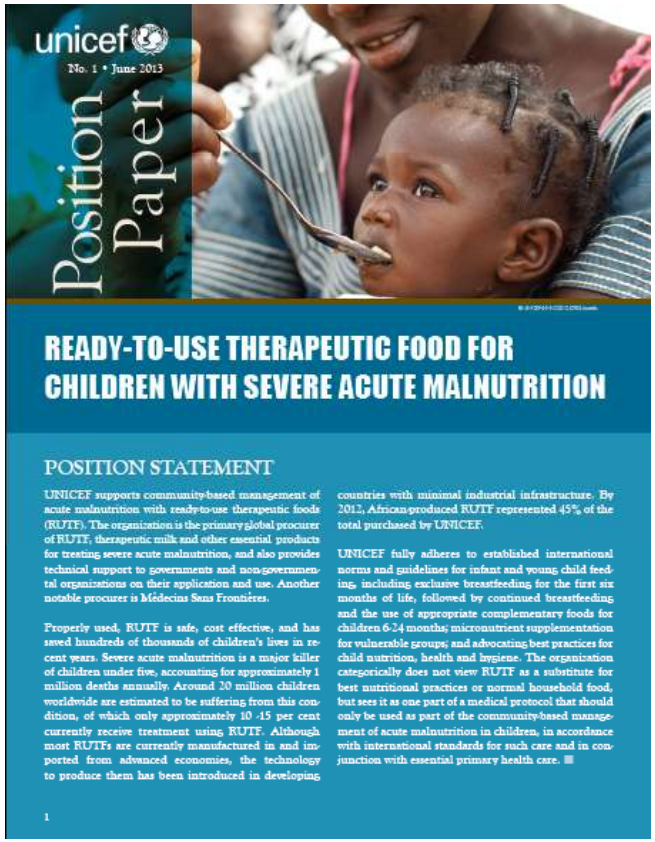
WHO 1999

Ready-to-Use Therapeutic Food (RUTF)

For children with SAM who are over 6 months of age

- Meant for home treatment or outpatient care and nutritional rehabilitation of children with SAM with appetite and without medical complications
- Ready to use: no cooking/mixing/dilution required
- Portable and portion controlled: 92 g sachets
- No refrigeration required
- Smooth texture, uniform paste and easy to squeeze out of sachet
- Light brown to cream in colour
- Provides same amount of calories as F-100

UNICEF's Position on RUTF



UNICEF, 2013

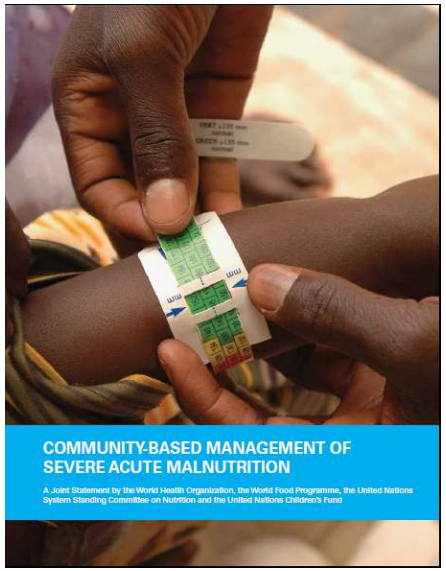
In the absence of international standards, RUTF technical specifications were developed by UNICEF in collaboration with World Food Programme, USAID and MSF.

The advent of RUTF has revolutionized the treatment of children suffering from severe acute malnutrition.

RUTF is a medical treatment that should be employed as part of the community-based management of acute malnutrition in children, in accordance with international guidelines and in conjunction with appropriate medical treatment, essential primary health care and best infant and young child feeding practices.

UNICEF does not use ready-to-use foods for prevention of child undernutrition, and recommends that the prevention of all forms of malnutrition is ideally best undertaken through well established interventions: IYCF, quality health care, WASH, micronutrient supplementation and improving knowledge and practices of families and communities.

RUTF: Finished Product Specifications



WHO, WFP, UN-SCN, UNICEF, 2007

Nutritional information	
Moisture content	2.5% maximum
Water activity	0.6 maximum
Energy	520-550 kcal/100 g
Proteins	10-12% total energy
	12.8-16.2% by weight
Lipids	45-60% total energy
	25.8-36.3% by weight
n-6 fatty acids	3-10% total energy
n-3 fatty acids	0.3-2.5% total energy
Trans-fatty acids	<3% total fat
Fibres	<5%

Minerals (per 100g)	
Sodium	<290 mg
Potassium	1100-1400 mg
Calcium	300-600 mg
Phosphorous [(b)]	300-600 mg
Magnesium	80-140 mg
Iron	10-14 mg
Zinc	11-14 mg
Copper	1.4-1.8 mg
Selenium	20-40 mcg
Iodine	70-140 mcg

[(b)] *Expressed in terms of non-phytate phosphorus*

Vitamins (per 100g)	
vitamin A	0.8-1.2mg RE
vitamin D	15-20 mcg
vitamin E	>20 mg
vitamin K	15-30 mcg
vitamin B1 (thiamine)	>0.5 mg
vitamin B2 (riboflavin)	>1.6 mg
vitamin C	>50 mg
vitamin B6	>0.6 mg
vitamin B12	>1.6 mcg
vitamin B9 (folic acid)	>200 mcg
vitamin B3 (niacin)	>5 mg
vitamin B5 (pantotenic acid)	>3 mg
vitamin B7 (biotin)	>60 mcg

RUTF: Finished Product Specifications

PDCAAS *(a)*	**95% minimum** **100% preferably**

(a) Protein Digestibility-Corrected Amino Acid Score, calculated using the method proposed by FAO/WHO/UNU

- **By calculation**

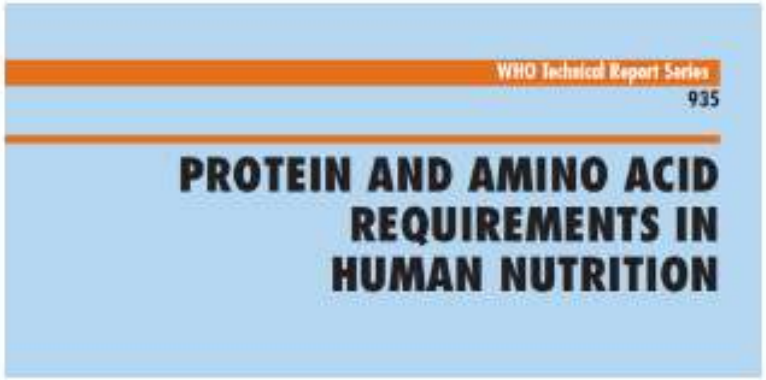


Table 6
Calculation of PDCAAS value for a mixture of wheat, chickpea and milk powder[a]

	Analytical data							Digestible quantities in mixture[b]				
	Weight	Protein	Lysine	Sulfur amino acids	Threonine	Tryptophan	Digestibility	Protein	Lysine	Sulfur amino acids	Threonine	Tryptophan
	(g)	(g/100 g)		(mg/g protein)				(g)			(mg)	
	A	B	C	D	E	F	G	A×B×G/100 = P	P×C	P×D	P×E	P×F
Wheat	400	13	25	35	30	11	0.85	44	1105	1547	1326	486
Chickpea	100	22	70	25	42	13	0.8	15	1232	440	739	229
Milk powder	35	34	80	30	37	12	0.95	11	904	339	418	136
Totals								70	3041	2326	2483	851
Amino acids: mg/g protein (total for each amino acid/total protein)									44	32	34	12
Weighted average digestibility: sum of digestible protein/total protein							0.85					

Age group (years)	Reference patterns: mg/g protein[c]				Amino acid score for indicated amino acid(s) (mg protein per reference pattern)				PDCAAS value: lowest score × digestibility
	Lysine	Sulfur amino acids	Threonine	Tryptophan	Lysine	Sulfur amino acids	Threonine	Tryptophan	
Infants (6–5 years)	57	26	31	8.5	0.78	1.14	1.10	1.39	0.67
Preschool children (1–2 years)	52	25	27	7.4	0.85	1.13	1.26	1.58	0.72
Older children and adolescents (4–18 years)[d]	48	23	25	6.5	0.93	1.39	1.36	1.80	0.79
Adults (>18 years)	45	22	23	6.0	0.99	1.45	1.48	1.94	0.84

[a] Values for protein, amino acid content and digestibility from reference 4.
[b] Protein and amino acids calculated as digestible amounts.
[c] Reference patterns from section 5.
[d] Based on the scoring pattern derived for the 2–18-year age group.

- **Amino acids profile**

RUTF: Raw Material

Milk: >50% proteins from milk/dairy products

Peanuts/ peanut paste

Oil : Edible refined vegetable oil

Carbohydrates (sweetener): Lactose and glucose polymers

Complex of minerals and vitamins (premix): Soluble and easily absorbed by children with SAM

Mineral composition should not alter the acid-base metabolism of children with SAM to eliminate risk of metabolic acidosis

Natural flavourings and anti-oxidants permitted

Emulsifying agents at permissible levels

All raw material to conform to Codex Alimentarius standards

RUTF: Microbiology

The manufacturer must establish microbiological criteria

Salmonella = highest priority

Other indicators:
Enterobacteriaceae

- - -

Other criteria - particular attention to:

Listeria monocytogenes,

Clostridium botulinum and

mesophilic aerobic bacteria

RUTF: Chemical Safety

Total aflatoxins : < 5 ppb

Pesticides and heavy metals:

Pesticides	
Carbamates	<10 ppb
Organochlorine	<10 ppb
Organophosphorous	<10 ppb
Pyrethroid	<10 ppb

Heavy metals	
Arsenic	<0.06 mg/kg
Cadmium	<0.03 mg/kg
Lead	<0.1 mg/kg
Mercury	<0.02 mg/kg

Radioactivity and melamine:
within specified limits indicated by Codex and EU regulation

RUTF: Stability Study

- Confirmation of product shelf life
- Organoleptic stability
- Integrity of packaging material
- Nutritional value and nutrient stability
- Absence of microbial growth

RUTF: Cost

- Rs. 21/ sachet
- Cost per child: 150* sachets × 21 = Rs. 3,150

*for treating one child with SAM over 6-8 weeks

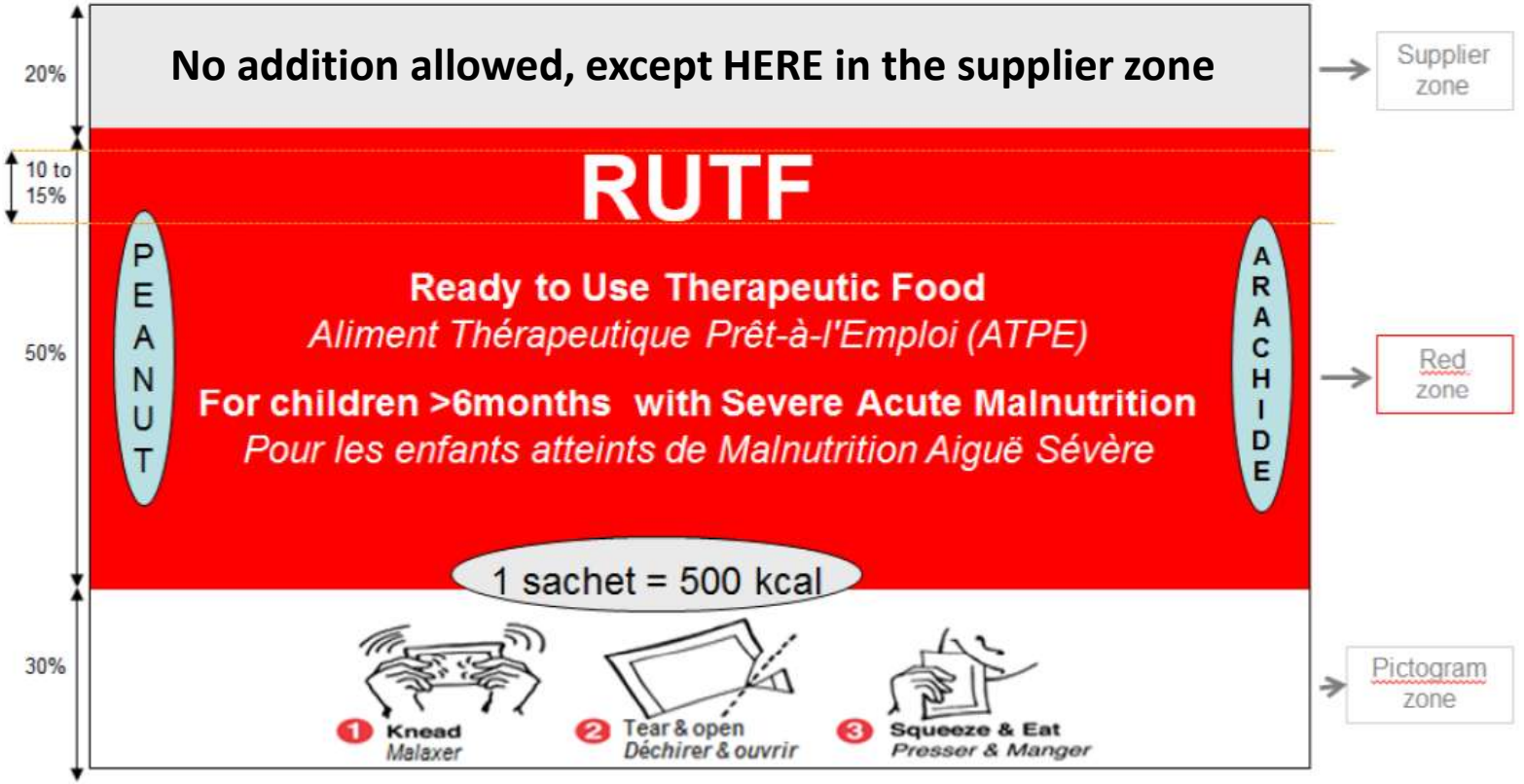
RUTF: Packaging

Primary packaging: 92 g sachet

- ✓No detachable parts to prevent a choking hazard
- ✓Packaging material, inks and glue to be food-contact approved
- ✓Pouch free of damage, hermetically sealed
- ✓Packaging under nitrogen to avoid oxidation
- ✓Air and water tightness control implemented during filling

Secondary package (carton) to contain minimum 150 sachets and a Leaflet with: manufacturer, ingredients, nutritional values per 100 g (energy, protein, lipids and all vitamins and minerals), reference to joint WHO-UNICEF statement on management of SAM, instructions for use and storage.

RUTF: Labelling



In accordance with the General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985)

RUTF: Codex Standard

A draft of the guideline will be presented and discussed in the upcoming 38th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses in December 2016.

RUTF Alternatives

- Increasing demand
- Currently only about 15% children with SAM receive RUTF
- Comparatively high cost
- Locally acceptable ingredients

Why local production?

- Increased acceptability
- Supports community
- May lead to low cost
- Sustainability

RUTF Alternatives

	Current standard formula	Ethiopia	Ghana	Pakistan	India
	Peanut 27g	Oats 1.9g	Maize 12.6g	Maize 5.75g	Oats 5 g
	Milk powder 25g	Peanut 12g	Cocoa 2g	Lentils 12.1g	Peanuts 15 g
	Palm oil 15.8g	Soybeans 6.5g	Soybeans 7.1g	Almonds 10g	Lentils 8 g
	Soybean oil 2.9g	Whey powder 14.4g	Canola oil 14.6g	Canola oil 15.2g	Whey powder 19.95 g
	Sugar 26g	Canola oil 11.5g	Coconut oil 5g	Sunflower oil 8.0g	Coconut oil 21.89 g
		Palm oil 11g	Palm oil 5g	Sugar 24g	Canola oil 1.66 g
		Sugar 25g	Sunflower oil 6.2g	Whey protein 21g	Sugar 18 g
		Whey protein 15.7g	Sugar 25g		Whey protein 7 g
			Whey protein 18.5g		
Ingredient cost (/100g)	$0.230	$0.124	$0.108	$0.145	$0.117

- Two RUTFs did not include peanuts, and all four used alternative dairy proteins
- Cost was about 60% of standard RUTF

Weber et al, 2016

RUTF Alternatives: Nutritional Composition

Nutrient characteristic	WHO specifications	Ethiopia	Ghana	Pakistan	India
Energy (kcal)	520–550	537	592	571	567
Energy (kcal) calculated*	—	553	548	547	567
Lipid (g)	26–36% by weight	34.8	33.4	32.6	36.8
Protein (g)	13–16% by weight	15.4	13.5	13.7	17.6
CHO (g)†	41–58% by weight	44.4	48.2	49.5	41.4
Dairy protein (g)	>50% protein	11.6	9.2	7.4	7.6
Fibre (g)	<5%	1.3	2.2	5	4.3
Calcium (mg)	300–600 mg/100 g	368	128	147	425
Phosphorus (mg)	300–600 mg/100 g	343	188	220	381
n-3% of total energy	0.3–2.5% total energy	2.4	2.4	2.4	0.9
n-6% of total energy	3–10% total energy	9.9	9.9	9.1	6.83
Water content (%)	2.5 max	1.3	1.5	1.1	2.09
pH	—	6.19	6.06	6.07	6.2
Water activity	<0.6	0.19	0.41	0.17	0.52

Acceptability of RUTF Alternatives

- Four 2-arm crossover site-randomized acceptability trials in Ethiopia, Ghana, Pakistan and India
- Fifty children with moderate wasting enrolled in the study from each country
- Ethiopia, Ghana and India : Local RUTF was well tolerated without increased reports of diarrhea or vomiting
- Children consumed similar amounts of both standard and local RUTF
- Future research needed to develop and test many such alternatives to meet the demand for RUTF

Weber et al, 2016

Takeaway

- Good opportunity for alternative RUTF
- Rigorous product development process, and technical specifications need to be followed
- Manufacturing unit to meet the regulatory standards
- All major ingredients to be available at the production location to make local production a viable, cost effective and sustainable option
- Strict international regulatory guidelines need to be adhered to for the product to be accepted by procurement agencies

Acknowledgements

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UNICEF-approved RUTF Suppliers in India

- NutriVita Foods Pvt. Ltd., Warve, Pune (Plumpy Nut)
- Compact India Pvt. Ltd., Gurgaon (eeZeePaste)
- Amul Dairy Cooperative, Anand (Bal Amul)
- Nuflower Foods and Nutrition Pvt. Ltd., Gurgaon (NutriFEEDO)

Thank you!