



UNICEF SD, RUTF pre-bid conference,
12th September 2013



RUTF

Product Specifications

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- ⊕ **Item description**
- ⊕ Nutritional composition
- ⊕ Raw material
- ⊕ Packaging and labelling
- ⊕ Microbiology
- ⊕ Chemical safety
- ⊕ Production process and quality assurance
- ⊕ Stability study
- ⊕ Documents to provide: Certificate of Analyse
- ⊕ Presentation of the quality complaints/non conformities



Item description



- **Ready to use: no cooking/mixing/dilution required**
- **Portable & Portion controlled: max 100g unit**
- **Storage conditions: no refrigeration required**
- **Texture:**
 - **smooth**
 - **uniform paste with small particle size (~~<200 microns~~)**
 - **no grittiness, no lumps**
 - **no oil separation**
 - **easy too squeeze out of the sachet: study for quantifiable specification for viscosity**
- **Appearance: light brown to cream**



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Nutritional composition

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 (<u>pantotenic acid</u>)	>3 mg
vitamin B7 (biotin)	>60 mcg



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Raw material



>>> Milk:

>50% proteins from milk/dairy products

Acceptable sources of dairy protein:

- ✓ **Skimmed milk powder / Full cream milk powder**
- ✓ **Whey protein powder**

Codex STAN 207-1999: Codex Standard for Milk Powders and Cream Powder
Codex STAN 289-1995: Codex Standard for Whey Powders

>>> Peanut or peanut paste

Codex STAN 200–1995: Codex Standard for Peanuts
CAC/RCP 55-2004: Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts.



Raw material



>>> Oil: edible refined vegetable oil

- ✓ Type of oil judiciously chosen
- ✓ Specifications for oil shall be established

Codex STAN 210-1999: Codex Standard for Named Vegetable Oils

>>> Carbohydrates (sweetener): Lactose & glucose polymers

- ✓ Lactose
- ✓ Maltodextrine
- ✓ Precooked and/or gelatinised starches
- ✓ No honey (risk of Clostridium botulinum toxicity)
- ✓ Sucrose
- ✓ Fructose

=> Properly ground (to avoid granulation, oil separation and leakage)

Codex STAN 212-1999: Codex Standard for Sugars



Raw material



>>> *Complex of minerals and vitamins (premix)*

- ✓ **Shall provide from the list of sources of premix authorized by WFP**

DSM Nutritional products / Fortitech, Nicholas Piramal Healthcare Ltd, Hexagon Nutrition, BASF (SternVitamin), GAIN premix facility

- ✓ **CoA provided to the manufacturer for each batch delivered**

- ✓ **Soluble & easily absorbed by patients with SAM.**

- ✓ **Added minerals water-soluble & shall not form insoluble components when mixed together.**

- ✓ **Mineral composition shall not alter the acid-base metabolism of patients with SAM: moderate positive non-metabolisable base sufficient to eliminate the risk of metabolic acidosis:**

Estimated absorbed millimoles (sodium + potassium + calcium + magnesium) - (minus) phosphorus + chloride



Raw material



>>> Emulsifying agents

Lecithin	max 0.5g / 100 grams
Mono and diglycerides	max 2g/100g

Level between 1.5 and 2.0 g/100g can be accepted because there is no adverse effect - all triglyceride oil is decomposed to monoglycerides in the digestion system prior to absorption).

>>> Flavouring

Artificial flavourings not allowed, only natural flavours

>>> Antioxidants

Only natural antioxidants

- **Ascorbyl palmitate**
- **Mixed tocopherols**

BHA and BHT not added as antioxidant



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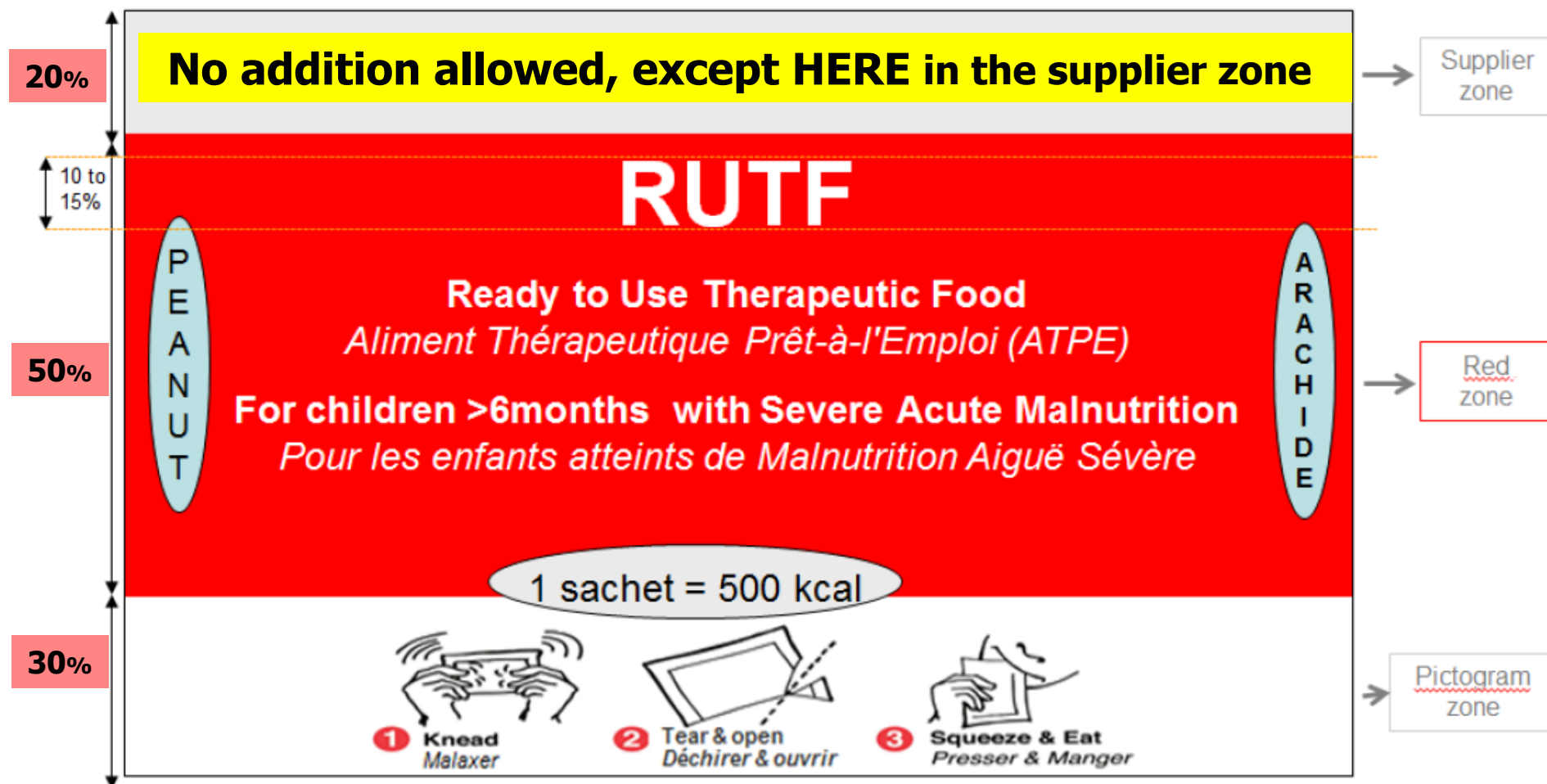


Packaging and labelling



>>> Primary packaging (sachet)

- ✓ <100g only (92 g preferred)
- ✓ No detachable parts that present a choking hazard
- ✓ Packaging materials, inks and glue food-contact approved
- ✓ Ink water and **fat resistant**
- ✓ No transfer from the pouch material (particle, odour, flavour)
- ✓ Requirement for fat – O2 – moisture barrier
- ✓ Pouch free of damage, hermetically sealed
- ✓ Seal free of impression
- ✓ Air and watertightness control implemented during the filling
- ✓ Packaging under nitrogen to protect from oxidation;



Respect of the dimensions (seal area excluded from the zone calculation)

Packaging and labelling

Manufactured by / for
Fabriqué par / pour

Exclusive breastfeeding is recommended up to 6 months of age, with continued breastfeeding along with appropriate complementary foods up to 2 years of age or beyond.

L'allaitement exclusif au sein est recommandé jusqu'à l'âge de 6 mois. De six mois à deux ans, voire plus, l'allaitement doit être complété par une autre alimentation.



- **Ingredients:** sugar, non-hydrogenated vegetable fat (palm, canola), peanut, skim milk powder, whey powder, vitamins & mineral complex, maltodextrin, emulsifier: monoglycerides.

Contains no ingredient of animal origin except dairy products

- **Allergens:** peanuts and dairy

- **To be prescribed and initiated by a trained health and nutrition professional only**

- **Store below 30°C away from direct sunlight**

- **Ingrédients:** sucre, graisse végétale non hydrogénée (palme, colza), arachides, lait écrémé en poudre, lactosérum en poudre, complexe vitamines & minéraux, maltodextrine, émulsifiant: monoglycérides. Ne contient aucun ingrédient d'origine animale, à l'exception des produits laitiers

- **Allergènes:** arachides et produits laitiers

- **Doit être prescrit et initié par un professionnel de santé / nutritionniste qualifié**

- **A conserver en dessous 30°C et à l'abri des rayons du soleil**

Net weight:
Poids net: 92g

Best before:
Date Limite d'Utilisation Optimale:

Lot number:
Numéro de lot:

Consume within 24h of opening
A consommer dans les 24 heures après ouverture

NOT FOR RESALE
NE PAS REVENDRE



Packaging and labelling



>>> *Secondary packaging (carton)*

✓ **Sturdy quality:**

- ECT (Edge Crush test*) > 11kN/m with minimum 60% remaining with 90% humidity at temperature of 40°C
- Able to be stacked to a height of 2.4 m, and resistant to puncturing.

- Plastic bag

✓ **Information printed:**

- Red zone = same information as red zone of sachets
 - Name and address of the manufacturer, packer, distributor, importer, exporter or vendor including the country of origin
 - Storage conditions: product to be stored below X degrees celcius
 - Net weight
 - Numbers of units in a carton,
 - Batch number and best before date
- Minimum 150 sachets per carton**



Packaging and labelling >>> leaflet



- ✓ **Colour code**

- ✓ **Information printed:**
 - **Name and address of the manufacturer incl. the country of origin**
 - **Composition: all ingredients (in order of descending quantities)**
 - **Information of allergens and ingredients of animal origin**
 - **Nutritional values in 100g: energy, proteins, lipids and detailed content of each vitamins and minerals**
 - **Reference to joint statement on management of SAM**
 - **Instructions for use**
 - **Storage instructions**



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WHO-WFP-UNSSCN-UNICEF, 2007:

Joint statement community-Based Management of SAM

Maximum toxin levels

Aflatoxin level	5 ppb maximum
Microorganism content	10,000/g maximum
Coliform test	negative in 1 g
Clostridium perfringens	negative in 1 g
Yeast	maximum 10 in 1 g
Moulds	maximum 50 in 1 g
Pathogenic Staphylococci	negative in 1 g
Salmonella	negative in 125 g
Listeria	negative in 25 g



Microbiology



**The manufacturer must establish
microbiological criteria**

Salmonella = highest priority

CAC/GL 21, 1997, the Principles for the Establishment and Application of Microbiological Criteria for Foods (revision scheduled for 2013).

CAC/GL 63-2007: Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)

"Microbial safety of Ready-to-Use Lipid based Therapeutic and Supplementary Foods - Technical meeting", summary report released on the 6th March 2013, FAO and WHO

Proposed interim purchase specifications for microbiological hazards for lipid based supplementary foods (RUTF and RUSF), final report released on the 6th June 2013, FAO and WHO



Microbiology



The **manufacturer** must establish
microbiological criteria

Salmonella = highest priority

Other indicators: Enterobacteriaceae (EB)

- - -

Other criteria: particular attention to:

***Listeria monocytogenes,
Clostridium botulinum and
mesophilic aerobic bacteria***

Table 1. Identification of potential hazards associated with ready-to-use lipid based therapeutic and supplementary foods

Hazard	Potentially in ingredients	Potentially in processing environment	Potentially will survive processing	Potentially pathogenic at low dose	Potential severity
Mycotoxins*					
Non-typhoidal serovars <i>Salmonella</i>	+	+	+	+	Serious
Other Enterobacteriaceae (includes <i>Escherichia coli</i> , <i>Klebsiella</i> , <i>Shigella</i> , <i>Enterobacter</i> , <i>Cronobacter</i> , <i>Citrobacter</i> , and <i>Proteus</i>)	+	+	+	+	Variable
<i>Clostridium botulinum</i>	+	+	+	+ **	Severe
<i>Listeria monocytogenes</i>	+	+	+	+ ***	Serious
<i>Bacillus cereus</i>	+	+	+	--	Moderate
Enterotoxigenic <i>Staphylococcus aureus</i>	+	+	+	--	Moderate
<i>Clostridium perfringens</i>	+	+	+	--	Moderate

WHO-WFP-UNSSCN-UNICEF, 2007:
Community-based management of SAM

Maximum toxin levels

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Moulds	maximum 50 in 1 g
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Salmonella	negative in 125 g
Listeria	negative in 25 g



Number of units to be taken

The maximum allowable number of defective samples units in a 2-class plan or marginally acceptable sample units in a 3-class plan

The microbiological limit which, in a 2-class plan, separates good quality from defective quality or, in a 3-class plan, separates good quality from marginally acceptable quality

a microbiological limit which, in a 3-class plan, separates marginally acceptable quality from defective quality.



Microbiology



✓ **Ingredient**

✓ **Environment**

✓ **In-line**

✓ **End-product**

&

for *Salmonella* and

Enterobacteriaceae (EB)

⇒ **establish baseline statistics**

⇒ **monitor process control by reviewing trends**

✓ **Use Iso 17025 certified laboratories**



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- **Total Aflatoxin** < 5 ppb

- **Pesticides and heavy metal**

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

CODEX STAN 228-2001: General Methods of Analysis for Contaminants.

CODEX STAN 193-1995: Codex General Standard for Contaminants and Toxins in Food and Feed.

CODEX STAN 229-1993, REV.1-2003: Analysis of Pesticide Residues: Recommended Methods.

- **Radioactivity:** < 370Bq/kg (Cs 134&Cs137)

- **Melamine:** max 1 mg/kg

COMMISSION REGULATION (EU) No 594/2012 of 5 July 2012 amending Regulation (EC)

1881/2006 as regards the maximum levels of the contaminants ochratoxin A, non dioxin-like

PCBs and melamine in foodstuffs

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<i>Clostridium botulinum</i>	+	+	+	+ **	Severe
<i>Listeria monocytogenes</i>	+	+	+	+ ***	Serious
<i>Bacillus cereus</i>	+	+	+	--	Moderate
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- ✓ **Food safety policy in place, complete quality management system based on a HACCP approach**

CAC/RCP 1-1969, Rev. 4-2003: Recommended International Code of Practice. General Principles of Food Hygiene

ISO 22000:2005 (ISO/TS 22004))- Food safety management systems – Requirements for any organization in the food chain

CAC/RCP 66 – 2008: Code of Hygienic Practice for Powdered Formulae for Infants and Young Children

- ✓ **Manufacturer responsible to elaborate an analytical plan, with analysis methods on **Raw material, environment , in-line and RUTF finished product****
- ✓ **Validation of the process (coefficient of variation)**
- ✓ **Traceability**
- ✓ **Batch size <180Mt and 1 week of production**



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=> To confirm the product shelf life

- **Long term (*0, 3, 6, 9, 12, 18, 24 months*) at $30\pm 2^{\circ}\text{C}$**
- **Accelerated data at $40\pm 2^{\circ}\text{C}$ for 6 months may support extrapolation of shelf life (*0, 1, 3, 6 months*)**
- **Long term stability studies at 40°C provide useful information**

⇒ Stability studies must verify:

- **Organoleptic stability: taste, odour, product consistency and behavior (absence of oil separation, absence of oxidation)**
- **Integrity of the packing materials...)**
- **Nutritional value and nutrient stability (maintenance of a level of vitamin and minerals over or within specified levels for at least one water soluble and one fat soluble (vit A) micronutrient).**
- **Demonstrate absence of microbial growth**
- **Integrity of packing material and marking**



Stability study



Report

- **Introduction with detailed description of the product and batch used**
- **Results = summary table including:**
 - **The product specifications (acceptance criteria)**
 - **The laboratory(ies) (name, city, countryn accredited?)**
- **Conclusion with:**
 - **Justification for the shelf life**
 - **Recommended storage conditions**



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Documents to provide

✓ **Certificate of analysis (for every batch delivered)**

- **Nutritional value and nutrient**

Nutritional value and nutrients	
Moisture content	<2.5%
Energy value	520-550 kcal/100g
Protein content	10-12% total energy 12.8-16.2% by weight
Fat content	45-60% total energy 22.8-36.3% by weight
Ash content	3-4% by weight
Vitamin A ^s	0.8-1.2mg RE
At least one tracer ⁹ per premix	As per specifications

→ **Representative of the premix**

✓ Why vitamin A on the CoA?

Guideline update:

The management of severe acute malnutrition in infants and children

4. **Vitamin A supplementation in the treatment of children with severe acute malnutrition**

1. Children with severe acute malnutrition should receive the recommended nutrient intake of vitamin A throughout the treatment period. Children with severe acute malnutrition should daily be provided with about 5 000 IU vitamin A either as an integral part of therapeutic foods or as part of a multivitamin, micronutrient formulation.
2. Children with severe acute malnutrition do not require additional vitamin A if they are receiving F-75, F-100^c or ready-to-use therapeutic foods that comply with WHO specifications (and therefore already contain sufficient vitamin A).
3. Children with severe acute malnutrition should be given a high dose of vitamin A on admission only if they are given therapeutic foods that are not fortified as recommended in WHO specifications and vitamin A is not part of other daily



Documents to provide



✓ **Why vitamin A on the CoA?**

its precursor, carotene, from the diet. Vitamin A is essential to maintain mucosal barriers and for normal humoral and cellular immune responses. In response to infections, inflammatory processes may disrupt vitamin A metabolism and the release of vitamin A from body stores.

In addition to impairing immune responses, vitamin A deficiency causes the epithelial lining to produce less mucous which enables bacterial adherence and thereby the invasion of pathogenic microbes(54). Untreated vitamin A deficiency in all children, including severely malnourished children leads to blindness and increased susceptibility to infection (3) and mortality. There is however, evidence from randomized trials of vitamin A toxicity and adverse health outcomes in certain settings(55).

Documents to provide

✓ Certificate of analysis : microbiology

Microorganisms	n	c	m	M	p	Method
Salmonella	5	0	0/25g	N/A	2	ISO 6579 ¹⁰
Enterobacteriaceae (EB at 30°C)	10	2	10/g	100/g	3	ISO 21528-2 ¹¹

C. sakazakii (UNICEF only) => UNICEF will clarify later

Pooling ≠ composite

**Authorized for p=2 only
AND only if**

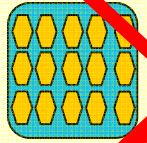
validated method



Stomacher bag

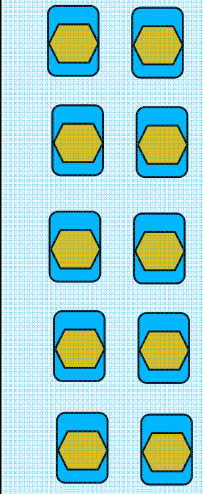
Pooling
n=15 research in 375g

Forbidden



Composite
n=15 research in 25g

p=3



**No pooling
No composite**



Documents to provide



- ✓ **Certificate of analysis (every batch delivered)**

Mycotoxins ¹²	
Total Aflatoxins	<5 ppb max.

- ✓ **Full analysis results (once a year)**

On demand:

- ✓ **Certificate of Origin**
- ✓ **Health certificate**
- ✓ **Certificate of Conformity**
- ✓ **Certificate of non-radioactivity**
- ✓ **If applicable: GMO Free Certificate, Halal certificate**



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Quality complaints / non conformities



✓ **Organoleptic properties:**

- **Oil separation**
- **RUTF too liquid, RUTF too "hard"**
- **Suspecious colour**
- **Granular product**

✓ **Nutritional properties:**

- **Vitamin content < specifications**



Quality complaints / non conformities



✓ **Microbiology**

- **Contamination detected by another organisation**

✓ **Packaging**

- **Wrong Best before date printed on the sachet**
- **Packaging greasy**
- **Leak / bad sealing**
- **No Best Before date / no batch number (has disappeared)**
- **Cartons crashed**
- **Dangerous (can hurt/cut once opened)**

✓ **Documentation**

- **Batch number on the documentation not matching**



THANKS
FOR YOUR ATTENTION