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

RUTF
Product Specifications

Odile Caron
Coordinator for food quality assurance
MSF International Office
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 to squeeze out of the sachet: study for quantifiable specification for viscosity
- Appearance: light brown to cream
- Item description
- **Nutritional composition**
- Raw material
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- Documents to provide: Certificate of Analyse
- Presentation of the quality complaints/non conformities
# Nutritional Composition

## Nutritional Information

<table>
<thead>
<tr>
<th>Nutritional Component</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moisture content</td>
<td>2.5% maximum</td>
</tr>
<tr>
<td>Water activity</td>
<td>0.6 maximum</td>
</tr>
<tr>
<td>Energy</td>
<td>520-550 kcal/100 g</td>
</tr>
<tr>
<td>Proteins</td>
<td>10-12% total energy</td>
</tr>
<tr>
<td></td>
<td>12.8-16.2% by weight</td>
</tr>
<tr>
<td>Lipids</td>
<td>45-60% total energy</td>
</tr>
<tr>
<td></td>
<td>25.8-36.3% by weight</td>
</tr>
<tr>
<td>n-6 fatty acids</td>
<td>3-10% total energy</td>
</tr>
<tr>
<td>n-3 fatty acids</td>
<td>0.3-2.5% total energy</td>
</tr>
<tr>
<td>Trans-fatty acids</td>
<td>&lt;3% total fat</td>
</tr>
<tr>
<td>Fibres</td>
<td>&lt;5%</td>
</tr>
</tbody>
</table>

## Minerals (per 100g)

<table>
<thead>
<tr>
<th>Mineral</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>&lt;290 mg</td>
</tr>
<tr>
<td>Potassium</td>
<td>1100-1400 mg</td>
</tr>
<tr>
<td>Calcium</td>
<td>300-600 mg</td>
</tr>
<tr>
<td>Phosphorous (b)</td>
<td>300-600 mg</td>
</tr>
<tr>
<td>Magnesium</td>
<td>80-140 mg</td>
</tr>
<tr>
<td>Iron</td>
<td>10-14 mg</td>
</tr>
<tr>
<td>Zinc</td>
<td>11-14 mg</td>
</tr>
<tr>
<td>Copper</td>
<td>1.4-1.8 mg</td>
</tr>
<tr>
<td>Selenium</td>
<td>20-40 mcg</td>
</tr>
<tr>
<td>Iodine</td>
<td>70-140 mcg</td>
</tr>
</tbody>
</table>

## Vitamins (per 100g)

<table>
<thead>
<tr>
<th>Vitamin</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>vitamin A</td>
<td>0.8-1.2mg RE</td>
</tr>
<tr>
<td>vitamin D</td>
<td>15-20 mcg</td>
</tr>
<tr>
<td>vitamin E</td>
<td>&gt;20 mg</td>
</tr>
<tr>
<td>vitamin K</td>
<td>15-30 mcg</td>
</tr>
<tr>
<td>vitamin B1 (thiamine)</td>
<td>&gt;0.5 mg</td>
</tr>
<tr>
<td>vitamin B2 (riboflavin)</td>
<td>&gt;1.6 mg</td>
</tr>
<tr>
<td>vitamin C</td>
<td>&gt;50 mg</td>
</tr>
<tr>
<td>vitamin B6</td>
<td>&gt;0.6 mg</td>
</tr>
<tr>
<td>vitamin B12</td>
<td>&gt;1.6 mcg</td>
</tr>
<tr>
<td>vitamin B9 (folic acid)</td>
<td>&gt;200 mcg</td>
</tr>
<tr>
<td>vitamin B3 (niacin)</td>
<td>&gt;5 mg</td>
</tr>
<tr>
<td>vitamin B5 (pantoten acid)</td>
<td>&gt;3 mg</td>
</tr>
<tr>
<td>vitamin B7 (biotin)</td>
<td>&gt;60 mcg</td>
</tr>
</tbody>
</table>

(b) Expressed in terms of non-phytate phosphorus
Item description

Nutritional composition

Raw material

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Production process and quality assurance

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Presentation of the quality complaints/non conformities
>>> 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
**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
- Sucrose
- Maltodextrine
- Fructose
- Precooked and/or gelatinised starches
- No honey (risk of Clostridium botulinum toxicity)

=> 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:

<table>
<thead>
<tr>
<th>Estimated absorbed millimoles (sodium + potassium + calcium + magnesium)</th>
<th>-</th>
<th>phosphorus + chloride (minus)</th>
</tr>
</thead>
</table>
>>> Emulsifying agents

<table>
<thead>
<tr>
<th></th>
<th>max 0.5g / 100 grams</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lecithin</td>
<td>max 0.5g / 100 grams</td>
</tr>
<tr>
<td>Mono and diglycerides</td>
<td>max 2g/100g</td>
</tr>
</tbody>
</table>

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;
Packaging and labelling

No addition allowed, except HERE in the supplier zone

RUTF
Ready to Use Therapeutic Food
Aliment Thérapeutique Prêt-à-l'Emploi (ATPE)
For children >6months with Severe Acute Malnutrition
Pour les enfants atteints de Malnutrition Aiguë Sévère

1 sachet = 500 kcal

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, lactosérums 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: 92g
Poids net: 92g

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

Best before:
Date Limite d’Utilisation Optimale:

Lot number:
Numéro de lot:

NOT FOR RE SALE
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
Item description
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Documents to provide: Certificate of Analyse
Presentation of the quality complaints/non conformities
WHO-WFP-UNSSCN-UNICEF, 2007:
Joint statement community-Based Management of SAM

<table>
<thead>
<tr>
<th>Maximum toxin levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aflatoxin level</td>
</tr>
<tr>
<td>Microorganism content</td>
</tr>
<tr>
<td>Coliform test</td>
</tr>
<tr>
<td>Clostridium perfringens</td>
</tr>
<tr>
<td>Yeast</td>
</tr>
<tr>
<td>Moulds</td>
</tr>
<tr>
<td>Pathogenic Staphylococci</td>
</tr>
<tr>
<td>Salmonella</td>
</tr>
<tr>
<td>Listeria</td>
</tr>
</tbody>
</table>
The manufacturer must establish microbiological criteria

*Salmonella* = highest priority


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
The manufacturer must establish microbiological criteria

*Salmonella* = highest priority

Other indicators: Enterobacteriacea (EB)

Other criteria: particular attention to:

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

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

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>n</th>
<th>c</th>
<th>m</th>
<th>M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aflatoxin level</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microorganism content</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coliform test</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clostridium perfringens</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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</tr>
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<td>Salmonella</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Listeria</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Maximum toxin levels:
- Aflatoxin level: 5 ppb maximum
- Microorganism content: 10.00 mg 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

**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

⇒ establish baseline statistics

⇒ monitor process control by reviewing trends

- Use ISO 17025 certified laboratories
- 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
- **Total Aflatoxin**: < 5 ppb

- **Pesticides and heavy metal**

<table>
<thead>
<tr>
<th>Pesticides</th>
<th>Heavy metals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbamates</td>
<td>Arsenic</td>
</tr>
<tr>
<td></td>
<td>&lt;10 ppb</td>
</tr>
<tr>
<td>Organochlorine</td>
<td>Cadmium</td>
</tr>
<tr>
<td></td>
<td>&lt;10 ppb</td>
</tr>
<tr>
<td>Organophosphorous</td>
<td>Lead</td>
</tr>
<tr>
<td></td>
<td>&lt;10 ppb</td>
</tr>
<tr>
<td>Pyrethroid</td>
<td>Mercury</td>
</tr>
<tr>
<td></td>
<td>&lt;10 ppb</td>
</tr>
</tbody>
</table>

**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.

- **Radioactivity**: < 370 bq/kg (Cs 134 & Cs 137)

- **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**
<table>
<thead>
<tr>
<th>Hazard</th>
<th>Potentially in ingredients</th>
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<td>Non-typhoidal <em>Salmonella</em> serovars</td>
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<td>Other Enterobacteriaceae (includes <em>Escherichia coli</em>, <em>Klebsiella</em>, <em>Shigella</em>, <em>Enterobacter</em>, <em>Cronobacter</em>, <em>Citrobacter</em>, and <em>Proteus</em>)</td>
<td>+</td>
<td>+</td>
<td></td>
<td>+</td>
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<td><em>Listeria monocytogenes</em></td>
<td>+</td>
<td>+</td>
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<td>+***</td>
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Item description

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Stability study

Documents to provide: Certificate of Analyse

Presentation of the quality complaints/non conformities
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
- 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
- Item description
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- Documents to provide: Certificate of Analyse
- Presentation of the quality complaints/non conformities
To confirm the product shelf life

- Long term (0, 3, 6, 9, 12, 18, 24 months) at 30±2°C
- Accelerated data at 40±2°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:
  o The product specifications (acceptance criteria)
  o The laboratory(ies) (name, city, country, accredited?)

• Conclusion with:
  o Justification for the shelf life
  o Recommended storage conditions
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Documents to provide: Certificate of Analyse
Presentation of the quality complaints/non conformities
Documents to provide

- Certificate of analysis (for every batch delivered)
  - Nutritional value and nutrient

<table>
<thead>
<tr>
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<th></th>
</tr>
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<tbody>
<tr>
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<td>Fat content</td>
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</tr>
<tr>
<td>Vitamin A³</td>
<td>0.8-1.2mg RE</td>
</tr>
</tbody>
</table>

At least one tracer per premix As per specifications

Representative of the premix
Documents to provide

Guideline update: The management of severe acute malnutrition in infants and children

Why vitamin A on the CoA?

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, 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...
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. Untreated vitamin A deficiency in all children, including severely malnourished children leads to blindness and increased susceptibility to infection and mortality. There is however, evidence from randomized trials of vitamin A toxicity and adverse health outcomes in certain settings.
**Documents to provide**

- Certificate of analysis: microbiology

<table>
<thead>
<tr>
<th>Microorganisms</th>
<th>n</th>
<th>c</th>
<th>m</th>
<th>M</th>
<th>p</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmonella</td>
<td>15</td>
<td>0</td>
<td>0</td>
<td>0/25g</td>
<td>N/A</td>
<td>ISO 6579&lt;sup&gt;10&lt;/sup&gt;</td>
</tr>
<tr>
<td>Enterobacteriaceae (EB at 37°C)</td>
<td>10</td>
<td>2</td>
<td>10/g</td>
<td>100/g</td>
<td>3</td>
<td>ISO 21528-2&lt;sup&gt;11&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

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

**Pooling ≠ composite**

- Authorized for p=2 only
- AND only if validated method

- Forbidden

- p=3

**Stomacher bag**

- Pooling: n=15 research in 375g
- Composite: n=15 research in 25g

**No pooling**

**No composite**
Documents to provide

- Certificate of analysis (every batch delivered)

<table>
<thead>
<tr>
<th>Mycotoxins^12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Aflatoxins</td>
</tr>
</tbody>
</table>

- 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
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
Quality complaints / non conformities

✓ Organoleptic properties:
  o Oil separation
  o RUTF too liquid, RUTF too “hard”
  o Suspectious colour
  o Granular product

✓ Nutritional properties:
  o Vitamin content < specifications
Quality complaints / non conformities

✓ Microbiology
  o Contamination detected by another organisation

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

✓ Documentation
  o Batch number on the documentation not matching
THANKS
FOR YOUR ATTENTION