UNICEF Technical Requirements for RUTF Products

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Consultation with RUTF Suppliers
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Product description

- RUTF is high energy fortified food suitable for children with Severe Acute Malnutrition (SAM). The product contains peanut/milk paste, oil, sugar, milk powder and micronutrient premix.
- Nutritionally equivalent to F100 milk.
- RUTF is consumed directly without prior dilution or cooking.
RUTF characteristic

- Smooth, homogenous texture. Oil should not separate. Pleasant sweet flavour.
- Low moisture content (<2.5%), which produces a low water activity that prevents the growth of pathogenic micro-organism during storage.
- Can be given safely for home consumption.
RUTF nutritional composition (1)

• The nutritional composition of RUTF is given including the upper and lower limits of each component, as defined in the UNICEF/WFP/WHO/SCN Joint Statement.

• The value for each nutrient should be expressed in g, mg or mcg per 100 g of product.
RUTF nutritional composition (2)

Protein, lipid and fatty acids contents are expressed as a % of total energy provided by 100 g of product

- **Energy**: 520 - 550 kcal
- **Proteins**: 10% - 12%
- **Lipids**: 45% - 60%
- **n-6 fatty acids**: 3% - 10%
- **n-3 fatty acids**: 0.3% - 2.5%

Note: At least half of the proteins contained in RUTF should come from milk/dairy products (skimmed milk powder, whey protein powder).
## RUTF nutritional composition (3)

<table>
<thead>
<tr>
<th>Vitamins and minerals in RUTF</th>
<th>Chemical forms recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A</td>
<td>Retinyl acetate</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>Cholecalciferol (D3)</td>
</tr>
<tr>
<td>Vitamin E</td>
<td>DL-alpha-tocopherol acetate</td>
</tr>
<tr>
<td>Vitamin K</td>
<td>Phylloquinone 5%</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>L-ascorbic acid</td>
</tr>
<tr>
<td>Vitamin B1</td>
<td>Thiamine hydrochloride</td>
</tr>
<tr>
<td>Vitamin B3</td>
<td>Niacinamide</td>
</tr>
<tr>
<td>Vitamin B6</td>
<td>Pyridoxine hydrochloride</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>Cyanocobalamin (0.1%)</td>
</tr>
<tr>
<td>Iron</td>
<td>Encapsulated ferrous sulfate or fumarate</td>
</tr>
<tr>
<td>Folic acid</td>
<td>Pteroyl monoglutamic acid</td>
</tr>
<tr>
<td>Zinc</td>
<td>Zinc gluconate, sulfate or oxide</td>
</tr>
<tr>
<td>Copper</td>
<td>Encapsulated copper sulfate</td>
</tr>
</tbody>
</table>

Source: Chaparro CM, Dewery KG., Maternal and Child Nutrition (2010), 6 (Suppl.1), pp 1-69
## Product Composition

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Reference Standard</th>
<th>UNICEF requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peanuts</td>
<td>Codex STAN 200 - 1995 Codex Standard for Peanuts. CAC/RCP 55-2004 Codex Al - Code of Practice for the Prevention and Reduction of Aflatoxin Contamination</td>
<td>Specify if roasted peanuts are used.</td>
</tr>
<tr>
<td>Sugar</td>
<td>Food Chemical Codex</td>
<td>Honey is not permitted --&gt; risk of Clostridium Botulinum toxicity.</td>
</tr>
<tr>
<td>Oil</td>
<td>Codex STAN 210 - 1999 Codex Alimentarius Volume 8: Codex Standard for Named Vegetable Oils</td>
<td>The following vegetable oil can be used: palm oil, rapeseed oil, soy bean and sunflower oils.</td>
</tr>
<tr>
<td>Premix</td>
<td>Food Chemical Codex</td>
<td>The chemical forms of all vitamins and minerals added must be specified.</td>
</tr>
<tr>
<td>Emulsifiers</td>
<td>Codex STAN 073-1981</td>
<td>The following emulsifiers can be used: lecithin (max 0.5g/100g); mono and di-glycerides (max 0.15g/100g).</td>
</tr>
</tbody>
</table>
Product Quality (1)
Analytical plan

The RUTF manufacturer is responsible to elaborate an analytical plan of RUTF raw materials and finished product. All analytical test procedures must be described in sufficient details, including microbiological methods.
Product Quality (2)
CoA of raw materials

- Certificates of Analysis of raw materials must be provided to UNICEF.
- Specification and test results of the vitamin and mineral premix should be provided by the premix supplier.
- Specifications and test results of the oil used should be provided by the oil supplier.
- Any change of raw material sources -> UNICEF must be informed.
Product Quality (3)
CoA of finished product

• **Complete** batch analysis of the finished product should be provided at least once a year.

• **CoA for each batch** of finished product should provide test results of representative (tracer) compounds in the finished product such as Zinc, Potassium, Iron, Vitamin A, Vitamin C.
Product Safety (1)
Microbiological

Product safety is confirmed by certificate with the following tests:

- Aflatoxin (5 ppb max)
- Micro organisms (10,000 in 1 g max)
- Coli (neg. in 1 g)
- Clostridium perfringens (neg. in 1 g)
- Yeast (max 10 in 1 g)
- Moulds (max 50 in 1 g)
- Pathogenic Staphylococci (neg. in 1 g)
- Salmonella (neg. in 125 g)
- Listeria (neg. in 25 g)
- Chronobacter Sakazakii (neg. in 10 g)

Must be provided for each batch
Product Safety (2)

Chemical

- RUTF must not contain any substance originating from micro-organisms or any other poisonous or deleterious substances (e.g. anti nutritional factors, heavy metals, pesticides) in amounts that may represent a hazard to health.
- Pesticides and radioactivity should be checked in finished product.
- GMO free and Melamine free certificates might be requested by certain countries specifically.
Product shelf life
Stability studies

• Stability studies need to be conducted on the final product to confirm the product shelf life (2 years).

• Stability studies should be conducted as following:
  Accelerated stability study: 40 Celsius degree, 75% humidity. Test the sample at 1, 3, 6 months.
  Long term stability study: 30 Celsius degrees, 65% humidity. Test the sample at 3, 6, 9, 12, 18 and 24 months.

If recipe changes, new stability studies must be provided
Product Efficacy and Acceptability

• Efficacy studies should be conducted for products not using the Joint Statement formulation.

• Acceptability studies should be done on malnourished children in typical beneficiary countries, using products of various ages: 3 months, 6 months and 12 months life.
Labelling

The following information should be clearly printed out on the label (in English and French)

• Product generic name: Ready to Use Therapeutic Food (RUTF)
• Statement "RUTF for Children with Severe Acute Malnutrition"
• Raw materials should be listed in order of descending quantities
• Clear pictorial instructions
• Manufacturing date
• Best before date
• Batch/lot number
• Storage conditions

A leaflet should be included in each carton with detail nutritional composition of the product, including composition of the mineral and vitamin premix.
Packaging

• Finished product should be packed in 92g sachets placed in a carton containing 150 sachets.

• Primary packaging material should be recognized as safe for food packaging and should protect the product during the assigned shelf life. Sachets should be hermetically sealed to prevent any leakage.

• The secondary packaging must be of a sturdy export quality in order to provide protection of the goods for carriage by air, sea and/or road to the final destinations (including remote locations under adverse climatic conditions).
Summary (1)

The following documents should be submitted:

• Technical Questionnaire for Food Manufacturers and a copy of Manufacturing License.

• Finished product specification detailing composition of vitamin and mineral premix used and registration status of product in UNICEF programmatic countries.

• Analytical test procedures adopted, including biological and microbiological methods. All test procedures should be validated. Results of the validation studies, comments on the choice of routine tests, and standards must be provided.
Summary (2)

- Stability study confirming assigned product shelf life.
- CoA of raw materials (peanut, sugar, milk, vitamin and mineral premix).
- CoA of oil used -> type of oil -> n-3:n-6 ratio.
- CoA of finished product + nutritional composition and microbiological tests (including aflatoxin levels).
Summary (3)

- CoA confirming absence of Cronobacter Sakazakii in Milk Powder.
- Certificate of origin, Health certificate, Halal certificate, Radiation certificate, Melamine free and GMO free certificates.
- Label layout.
- Explanation on measures put in place to control aflatoxin.
- Internal sampling and testing plan.
Our Final Goal

Provide **effective** and **safe** RUTF products to SAM children.
Thank You!