Quality Assurance
Specialized Food

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Barbara Fernandez
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Amsterdam Procurement Unit

5 operational centres
19 sections
3 international supply centres
Dr Myriam Henkens
International Medical Coordinator

Medicines:
Elodie Jambert

Medical Devices:
Monique Dory

Specialized food:
Odile Caron
Barbara Fernandez

Same global scheme
• Development of the procedure for the validation of product/manufacturer

• Development of detailed product specifications

• Follow up of Quality related questions from the field

=> Collaboration with Unicef and WFP

• Development of procedures and tools for the quality assurance in the field

• Communication/ training
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Procedure for the validation of product/manufacturer
Procedure for the validation of product/manufacturer

Selection of potential suppliers

- No
- Yes

Manufacturer Assessment

Product Assessment

Manufacturer Dossier

Product Dossier
Specialized Food (NFOS) Suppliers Selection Group: determines whether the potential supplies are interesting for MSF.

- List of criteria

  Purchaser
  Operations
  Nutrition WG
  Access
  QA

- Tools: MIF, Interagency Quality questionnaires...
Procedure for the validation of product/manufacturer
2- Manufacturer Assessment = AUDIT

By:

- Coordinator for Quality Assurance of Specialized Food (Odile Caron)
- And/or External consultants
- Collaboration with UNICEF and WFP (same standards reference)
  - The outcome/rating done based on the received report
  - Decision under MSF responsibility according to its own decision mechanism

Tools

- Audit Schedule and check list (make sure that external consultants do same)
- Report (findings: minor / major / critical)
- Corrective actions plan(s) follow-up (all major and critical must be fixed)
Procedure for the validation of product/manufacturer

Selection of potential suppliers

List of criteria

Manufacturer Assessment

Product Assessment

Manufacturer Dossier

Product Dossier

Manufacturer Assessment Toolkit

Product Assessment Toolkit

NFOS Suppliers Selection group

CSFQA and/or External Consultants

Medecins Sans Frontieres
3- Product Assessment

- Interagency product questionnaire

- Product Analysis
  
  - Composition/ Nutritional information (minerals and vitamins)
  - Food safety (microbiology/ mycotoxins)

=> Results compared with: MSF Product Specifications Sheet
   + Manufacturer's results (same lot)

- Stability study
  
  - Composition / Nutritional content + food safety (microbiology)
  - No significant changes during ENTIRE shelf life on 2 representative batches
    - at 30±2°C for the claimed shelf life (real time studies),
    - and at 40°C ±2°C (or 45°C ±2°C) for the claimed shelf life (real time studies)

- Packaging

- New formula: acceptability + efficacy study
4 - Review & Evaluation of the product/manufacturer dossier

By:
1 section pharmacist
+ 1 member of the Nutrition working group
+ Coordinator for Quality Assurance of Specialized Food
<table>
<thead>
<tr>
<th>Rating</th>
<th>Audit: non-conformities</th>
<th>Sample Analyses Results</th>
<th>Stability Study</th>
<th>Packaging and labeling</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>&lt; 10 minor</td>
<td>No deviation</td>
<td>satisfactory at 30°C &amp; 40°C ±2°C for the claimed shelf life</td>
<td>Fully compliant trilingual label (English/French/Spanish)</td>
</tr>
<tr>
<td>B</td>
<td>≤5 major 11 to 20 minor</td>
<td>Composition / nut. values ≤ 2deviation(s) &lt;10% Microbiology/mycotoxins: No deviation</td>
<td>Satisfactory at 30±2°C for the claimed shelf life Extrapolation / accelerated data (40±2°C for 6 months)</td>
<td>Bilingual label (English/French) 1 minor deviation</td>
</tr>
<tr>
<td>C</td>
<td>1 to 5 critical 6 to 15 major ≥21 minor</td>
<td>Composition / nut. values ≥ 3 deviations &lt;10% Microbiology/mycotoxins: No deviation</td>
<td>Data insufficient to cover the proposed shelf life, OR BB date fixed on theoretical studies AND commitment from manufacturer to continue study</td>
<td>English only ≤ 1 major deviation ≥ 2 minor deviations</td>
</tr>
<tr>
<td>D</td>
<td>6 to 9 critical ≥16 major</td>
<td>Composition / nut. values ≥ 3 deviations &gt;10% Microbiology/mycotoxins: 1 deviation</td>
<td>Not satisfactory (e.g. T° not controlled, missing data, different packaging) No commitment to improve/start stability study</td>
<td>≤ 2 major deviations</td>
</tr>
<tr>
<td>E</td>
<td>≥10 critical</td>
<td>Composition / nut. values ≥ 3 deviations &gt;10% Microbiology/mycotoxins: ≥ 2 deviations</td>
<td>Stability data not available</td>
<td>≤1 critical deviation</td>
</tr>
</tbody>
</table>
## 5- Decision

<table>
<thead>
<tr>
<th>Audit reviewer</th>
<th>Product Analyse reviewer</th>
<th>Stability study reviewer</th>
<th>Packaging &amp; labelling reviewer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>A</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>B</td>
<td>□</td>
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</tr>
<tr>
<td>C</td>
<td>□</td>
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<tr>
<td>D</td>
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<tr>
<td>E</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

### Flowchart:

- **Manufacturer/Product Evaluation Summary Sheet**
  - All rating A & B Or 1 C
  - 2 or more C
  - One or more D or E

- **Decision by the 3 reviewers (by consensus)**
  - Approved
  - Not Approved

- Information to the Medical Directors

**Route # M** Possible
Route M possible (Medical Directors decision)

- Time limited decision
- Can be limited to 1 (or more) section(s)
6- Monitoring and follow-up

**Duration of the validation:** 3 years
- Commitment of the supplier by signing the PSS
- Change in the manufacture or specifications of the product must be declared (MSF Variation application form)
- Complete analysis results needed from the supplier at least once a year

**Quality control**
Random samples of products: independent testing (i.e. when organoleptic tests suspicious)

**Quality problems**
Information on complaints, quality problems, batch recalls are registered, investigated and taken into account for maintaining or adapting the status of a product/manufacturer.

**Tools**  Tables (quality complaints follow-up, analysis results...)
● Development of the procedure for the validation of product/manufacturer

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Development of procedures and tools for the quality assurance in the field

Communication/ training
Information about suppliers/products
(Donations / Local purchases)

Quality issues:
- Suspicious product (Storage conditions...)
- Oil separation
- Leaking/empty sachets
- Wrong best before date printed
- Aflatoxins/enterobacter sakazakii/coliforms
Development of the procedure for the validation of product/manufacturer

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Development of procedures and tools for the quality assurance in the field

Communication/ training
Manufacturer / product dossiers (questionnaires + audit reports)

- Quality complaints / questions...

Projects:

- Packaging & labelling (generic name / color code)
- Acceptability / efficacy study
Message to the suppliers

- Sign the commitment (PSS)
- Provide full analyse result (once a year)
- Provide stability study updates

- Communicate in advance in case of change:
  - product composition
  - raw material (vitamin/mineral premix, ...)
  - packaging...

- Avoid any confusion between different products
  - RUTF ≠ RUSF

=> Use the MSF variation application form
Thank you for your attention