2021

MSF
International

MSF QUALIFICATION PROCESS FOR SPECIALISED FOOD

MEDECINS SANS FRONTIERES

1. General principles

The MSF Qualification Process describes the principles and steps used for the approval of Specialised food used in MSF programs. It is based on internationally recognised standards and built on two pillars:

- The manufacturing site GMP assessment
- The product assessment

The MSF Specialised food qualification procedure is open to any manufacturer regardless of the country of operation.

The **norms and standards** used are:

- The CODEX ALIMENTARIUS international food standards, guidelines and codes of practice: for ingredients to be used by the manufacturers, the manufacturing of products, and the finished products (when standard exists).
- The Food Safety System Certification 22000 (FSSC 22000) Scheme that uses international and independent standards such as ISO 22000, ISO 9001, ISO/TS 22003, and technical specifications for sector-specific Pre-Requisite Programs (PRPs), such as ISO/TS 22002.

The **MSF product specifications** summarise the nutritional requirements (for finished product), the quality assurance and quality control requirements for their manufacturing and their release.

2. Steps in the qualification procedure for specialised food

2.1. Preassessment: Screening of technical data sheet and interagency questionnaires

First, the **technical data sheet** of the product is compared with MSF product specifications to check if the product composition is of interest for MSF.

Then, the manufacturer shall complete the **Interagency manufacturer and product questionnaires**. A dedicated questionnaire is used for highly regulated FSMP (Food for Special Medical Purpose, such as enteral nutrition products) manufactured and used in highly regulated countries (HRC). In both cases, special attention will be paid to the supporting documents provided. All the information should be submitted in English. Questionnaires that are not complete will not be considered for evaluation. In this case, the manufacturer will be informed that the questionnaire is incomplete and will be given a deadline to complete it. If the manufacturer is not able to submit the complementary information within the given schedule, the dossier will be rejected.

2.2. GMP Assessment of the manufacturing site

The MSF Coordinator for food Quality Assurance informs the manufacturer whenever a GMP audit is needed.

The **GMP audit** is performed by the MSF Coordinator for food Quality Assurance and/or a recognised auditor from the interagency partnership.

The auditor writes a report including the findings of the audit, and a CAPA (Corrective and Preventive Action Plan) is required. The audit is closed when satisfactory responses are provided to all findings (see step 4: evaluation for details).

2.3. Product assessment

Manufacturers are asked to send samples and submit detailed technical information on the product of interest for MSF: stability study report, certificate of analysis for all nutrients and contaminants as per MSF specifications (annual complete analysis), calculation of the coefficient of variation (for fortified products)... All the information should be submitted in English.

MSF Quality Assurance team performs an organoleptic test and samples are sent to an accredited laboratory for analysis of certain parameters according to the MSF analytical plan for product approval.

2.4. Evaluation of the dossier

A rating is given to ensure impartiality. The following indicators are assessed:

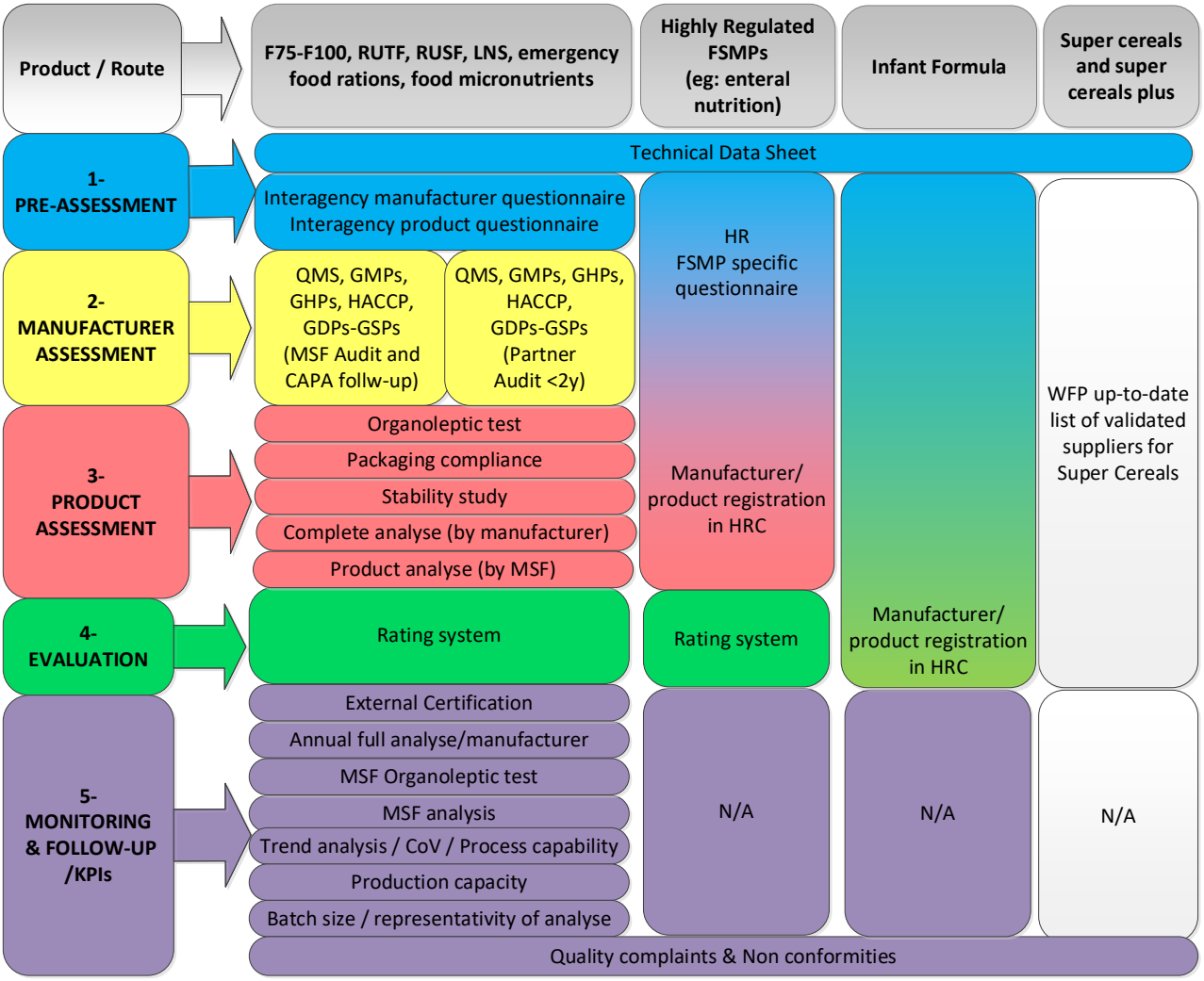
- Manufacturer dossier:
  - Outcome of GMP audit (number of minor, major and critical findings)
  - CAPA: all major and critical findings shall be addressed satisfactory.
- Product dossier:
  - Analyse in accredited laboratory: the rating is based on number of deviations and their intensity
  - Packaging compliance (codex Alimentarius standards and interagency specifications)
  - Stability study report: the rating is based on the stability data, compliance with the interagency requirements for stability study (available upon request) and quality of the report
  - Complete analyses: the manufacturer shall perform complete analyses for all parameters included in MSF Product specifications sheet, including the contaminants. The rating is based on the results and the quality of the report.

For the FSMP manufactured and used in HRC, the evaluation is done based on:

- The response to the Questionnaire for FSMP and all the supporting documents provided
- The registration by the Competent Authority in the country of origin
- A GMP audit might be required
- Samples might be required

Communication of the decision:

- The Coordinator for Food Quality informs the manufacturer in writing when the product is/is not approved by MSF
- If approved, the Product Specification Sheet (PSS) is sent for signature to the manufacturer as an endorsement and commitment to supply MSF with a product according to the agreed specifications
- It is only after the reception of the signed PSS that the product is considered to be "MSF qualified"
- Following the qualification of a product, the commercial negotiation can start with the European Supply Centers.



2.5. Monitoring and follow up

Manufacturer/products approvals are granted for a period of maximum 3 years.

- **The Product Specifications Sheet (PSS) and change declaration:** The MSF PSS is sent to approved manufacturers for endorsement and signature every three years or after each revision. During the period of validity, the manufacturer is asked to advise MSF promptly of any changes in the manufacturing process or specifications of the product. Details of the change are declared in the MSF variation application form provided with the PSS. The implementation of changes is subject to prior formal approval by MSF. If MSF does not accept the proposed change or if its implementation has not been approved beforehand by MSF, the product will be devalidated.

- **Manufacturer dossier**
  - **Periodic re-audits**: Approved manufacturers are audited at least every 3 years, the frequency can be adapted based on a risk assessment (type of product, volumes…).
  - **The questionnaire** is sent every 3 years or when it is revised.
  - The following indicators are monitored by MSF:
    - **External certifications:** approved manufacturers are regularly asked to provide the last up-to-date certificates (FSSC 22000, ISO 22000…).
    - **The production capacity**

- **Product dossier:**
    - **The questionnaire is** sent every 3 years or when it is revised.
    - The following performance indicators are also monitored by MSF:
        - **Complete analyses:** the manufacturer must send at least every 6 months a report with results for all parameters included in MSF Product Specifications Sheet, including the contaminants. Trend analysis of results shall be implemented for nutritional values and nutrients. The rating of this performance indicator is based on the results and the quality of the report.
        - **Coefficient of variation:** Suppliers are asked to provide the calculation of the CoV at least annually.
        - **MSF product re-evaluation:** MSF asks for samples for organoleptic test and analyses a few parameters in an accredited laboratory: the rating is based on number of deviations and their intensity. The frequency depends on the MSF procurement figures.
    - **Stability study:** the manufacturer must send regular updates on the on-going stability studies. The rating of this performance indicator is based on the outcome and the quality of the report.
    - **Heat treatment information** (step in the process and parameters)
    - **Foreign particle detection** capacity (technology used, step in the process and particle size)
    - **Lot (batch) size**
    - **Representativity of the lot in product release testing:** every 3 years, the supplier survey is sent to collect data on testing frequency and representativity of the batch size (number of mixes and quantity) in the testing.

- **Quality complaints**
    - Information on complaints and quality problems, batch recalls are registered and taken into account for maintaining or adapting the status of a product/manufacturer.
    - All critical (eg: salmonella contamination) and major non-conformities are shared at interagency level.

3. CONFIDENTIALITY COMMITMENT

As a principle, all the information communicated to MSF in the context of the qualification process is considered confidential and will be treated as such.

However, manufacturers are reminded that all information contained in the Inter Agency Product Questionnaire may be shared with the UNICEF Supply Division, the World Food Program, Action Contre la Faim / Action Against Hunger, the International Committee of the Red Cross, and USAID.