

## Quality Assurance Requirements for Food by Prescription

### Background

HIV/AIDS contributes to malnutrition by reducing food intake and nutrient absorption. Malnutrition can exacerbate the impacts of HIV/AIDS by weakening the immune system, increasing susceptibility to opportunistic infections (OI) and reducing treatment effectiveness.

Food by Prescription (FBP) is a program approach that provides food and nutrition interventions as part of clinical HIV care and treatment. These specialized foods are provided as a take-home ration designed to be consumed by individual patients. Food is packaged in daily doses and recipients are counseled on the importance of consuming the food themselves, similar to their medications. SCMS purchases two kinds of specialized food products: Ready-to-use-Therapeutic- Food (RUTF) and supplementary foods like Fortified-Blended-Flour (FBF).

RUTFs are designed for the management of severe acute malnutrition and are high energy, fortified, ready-to-eat foods that are soft or crushable and easy for young children to eat without preparation. Supplementary foods are designed to supplement existing diets and are used primarily to manage moderate or mild malnutrition or prevent malnutrition.

For information on product specifications, see [Frequently asked questions – Specialized Food Products](#).

### New Suppliers

New suppliers are required to complete a Request for Information (RFI) to provide information on product specification (composition, packaging), competitive price, supply capacity, lead time, and registrations in destination countries, QA/QC systems, etc. The SCMS QA unit will work with the procurement unit to qualify suppliers of FBP products. Potential suppliers must meet the following criteria before the procurement unit can recommend them for a quality assurance review:

- The supplier must produce a product based on specifications from a client and be able to meet all specification requirements.
- The supplier must have the production capacity to meet anticipated demand.
- The supplier must have the financial resources and capacity to fulfill the value of the orders required.
- The supplier must provide the procurement unit with all the required documentation.
- The supplier should be in a location such that it can respond to client needs.

The QA unit will prioritize investigation of those suppliers whose product meets current client requests. If needed (e.g. if the list of potential suppliers in a country exceeds the capacity of QA to perform audits, or if suppliers are not responsive), SCMS procurement unit will schedule a site-visit with the manufacturer to assess the business opportunities, collect required documents and screen for general quality assurance factors including: SOPs and HACCP plan, visually clean production facility, non-porous surfaces in the production area, and adequate pest control. A short list of recommended suppliers will then be provided to the QA unit.

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#### SCMS Project Team

## **Quality Assurance Requirements**

Patients with HIV/AIDS are at an increased risk to food-borne illness due to their weakened immune systems. They require additional micronutrients to bolster their immune system to ward off illness, like those contracted from food. When conducting quality assurance assessments of products and suppliers, SCMS seeks to reduce the risk of microbiological contamination and ensure products meet label claim for micronutrient content.

The QA process for approving suppliers includes all or some of the following activities, depending on the product category: document review, initial sample analysis and routine sampling, site visit/audit, approval, incident reporting, and re-evaluation. The following discussion describes these activities in detail.

### **1. Documentation Review**

All FBP suppliers are required to submit to SCMS the following documents:

- Current National License for Food Manufacturing issued by the local authorities
- Inspection Certificate
- Product Specifications
- Copy of Master Labeling
- Health Certificate
- Certificate of Origin
- Certificate of Good Manufacturing Practice (GMP)
- Copies of last two most recent inspection reports
- Technical and Product Information

Preferred but not required documents include:

- Certificate of Compliance (Codex Alimentarius – Recommended International Code of Hygienic Practice for Food; ISO 22000:2005; HACCP)
- Certificate of Genetically Modified Organisms (GMO)

### **2. Product Sample**

During the supplier approval process, an initial sample must be submitted together with the appropriate production information to be analyzed in accordance with product specifications.

After manufacturer approval, samples will be collected and analyzed as per frequency established in the SCMS sampling policy for FBP products. Samples may be requested at any point along the supply chain. The number of units collected will be dependent on the lot size of the commodity. Routine sampling frequencies may be adjusted based on inspection reports or evaluated trends.

#### **Ready-to-use therapeutic foods:**

Samples of product (minimum 500 gr) are required for testing analysis. The RUTF sample will be tested against the following specifications published in the 2007 WHO/WFP/UN-SCN/UNICEF Joint Statement on Community-Based Management of Severe Acute Malnutrition.

**Table 1: Limit of Microorganisms in RUTF**

<b>Maximum Toxin Levels</b>	
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
Molds	Maximum 50 in 1 g
Pathogenic Staphylococci	Negative in 1 g
Salmonella	Negative in 125 g
Listeria	Negative in 25 g
Enterobacter sakazakii*	Negative in 10 g

\* Testing on the milk component is acceptable.

**Table 2: Micronutrient Quality Standards in RUTF**

<b>Quality Criteria</b>	<b>Limits</b>
Moisture Content	2.5% maximum
Energy	520-550 Kcal/100g
Protein	10% - 12% total energy
Lipids	45% - 60% total energy
Sodium	290 mg/100 g maximum
Potassium**	1100-1400 mg/100 g
Calcium	300-600/100 g
Phosphorus	300-600 mg/100 g
Magnesium	80-140 mg/100 g
Iron**	10-14 mg /100 g
Zinc	11-14 mg/100 g
Copper	1.4 – 1.8 mg/100 g
Selenium	20-40 µg
Iodine	70-140 µg/100 g
Vitamin A**	0.8 to 1.1 mg/100 g
Vitamin D	15-20 µg/100 g
Vitamin E	20 mg/100 g minimum
Vitamin K	15-30 µg/100 g
Vitamin B1	0.5 mg/100 g minimum
Vitamin B2	1.6 mg/100 g minimum
Vitamin C**	50 mg/100 g minimum
Vitamin B6	0.6 mg/100 g minimum
Vitamin B12	1.6 µg/100 g minimum
Folic Acid	200 µg/100 g minimum
Niacin	5 mg/100 g minimum
Pantothenic acid	5 mg/100 g minimum
Biotin	60 µg/100 g minimum
n-6 fatty acids	3%-10% of total energy
n-3 fatty acids	0.3%-2.5% of total energy

\*\* Examples given. One or more vitamin and mineral should be selected as a tracer to show homogeneity of each blend/batch.

The RUTF should also meet the following criteria:

- Low fiber content
- Compactness and ease of transport and storage
- Precooked (if possible in the form of pastes or drinks) so that clients can consume them directly without preparation or cooking
- Safety for all age group over 6 months
- Shelf life of at least 12 months.

**Fortified Blended Flours:**

FBF products should meet the following minimum criteria:

- Pre-cooked composite flour
- Fortified with multiple micronutrients at least using the WFP pre-mix prescription
- Additional oil, sugar for energy density
- At least 400 Kcal/100
- National hygienic (microbial) conditions, especially for aflatoxins

Specifically, FBF ingredients should meet the following specifications:

- Maize or wheat
- Soy (if possible, the soy should be dehulled in order to reduce phyate, fiber and contaminant content)
- Sugar
- Vegetable oil (preferably rapeseed (canola) or soybean oil as these have healthier fatty acid profiles than most other vegetable oils available)
- Whey protein concentrate (WPC) 80% or skim milk powder (if costs permit)
- Micronutrient premix to meet the micronutrient levels listed below, after accounting for the endogenous levels in the ingredients

The FBF sample will be tested against the 2010 World Food Programme (WFP) “Technical Specifications for the manufacture of: Corn Soya Blend for Older Children and Adults – CSB Plus.” These specifications are based on WHO recommendations for FBF for children, but with reductions in certain nutrients to avoid too high an intake with the FBF is consumed in combination with RUTF.

***Table 3: Limit of microorganisms in FBF***

<b><i>Maximum Toxin Level</i></b>	
Aflatoxin level	20 ppb (B1, B2, G1, G2)
Mesophyllic aerobic bacteria	100,000 cfu per g
Coliforms	100 cfu per g
Salmonella	0 cfu per g
Escherichia Coli	<10 cfu per g
Staphylococcus	<10cfu per g
Bacillus cereus	50 cfu per g
Yeasts and molds	1,000 cfu per g
Pb	20 ppb
Cd	100 ppb

**Table 4: Micronutrient Quality Standards in FBF**

<b><i>Vitamin/Mineral FBF-V-10</i></b>	<b><i>Target</i></b>
Moisture content	10% maximum
Energy	380 Kcal minimum
Protein	14% (N x 6.25) minimum
Fat	6.0 % minimum
Crude fiber	5.0% maximum
Vitamin A	1,664 IU
Thiamine	0.128 mg
Riboflavin	0.448 mg
Niacin	4.8 mg
Pantothenic acid	6.7 mg
Vitamin B6	1.7 mg
Folate	60 mcg
Vitamin B12	2 mcg
Vitamin C	100 mcg
Vitamin D	4 mcg
Vitamin E	8.3 mcg
Vitamin K	100 mcg
Iron (a)	4 mg
Iron (b)	2.5 mg
Zinc	5 mg
Iodine	40 mcg
Carrier	qs
<b><i>Other Minerals</i></b>	
Potassium	400 mg
Phosphorus	200 mg
+ Calcium	130 mg

**Additional Fortified Blended Flour Characteristics:**

The permitted variation in premix content is -10 to +15% for added vitamins and +/- 10% for added minerals. Variable levels of micronutrients (i.e. iron, zinc, etc.) naturally present in maize and soya may lead to variable amounts of micronutrients in the finished product.

Aflatoxins – Aflatoxins are naturally occurring mycotoxins and are toxic. Under favorable conditions of temperature and humidity, certain fungi grow on certain foods including peanuts and maize. The WFP Technical Specifications for CSB limits the permitted level of aflatoxin to 20 ppb (B1, B2, G1, G2). The US Food and Drug Administration (US FDA) limits aflatoxin limits present in food to < 5 ppb.

Particle Size - Uniform fine texture with the following particle distribution:

- 95% must pass through a 600 microns sieve
- 100% must pass through a 1,000 microns sieve

Organoleptic – product must have a pleasant smell and palatable taste.

Cooking Time – product must be suitable for young children and adults after cooking at a simmering point for a minimum of five minutes and a maximum of ten minutes.

Shelf Life – product must retain above qualities for at least 12 months from date of manufacture when stored dry at ambient temperatures prevalent in the country of destination.

Peroxide value – maximum 10 meq/kg fat.

Dispersiveness – product must be free from lumping or balling when mixed with water of ambient temperature.

Consistency/Viscosity of porridge – Bostwick test: min 55 mm per 30 sec at 45°C and at the proposed preparation dosage (i.e. 40g of product plus 250g water after cooking at simmering point for five minutes).

Anti-nutrients – the urease index of FBF should be between 0.01 and 0.2 pH units.

Heavy metals – Maximum lead (Pb) level is 20 ppb and maximum cadmium (Cd) level is 100 ppb.

### **3. Site Inspections**

Inspections of manufacturing sites for potential suppliers must be conducted if:

- a.) Manufacturing site has not been inspected within the last two years by a SCMS (USAID) recognized entity (i.e. UNICEF and MSF)
- b.) Manufacturing site has been inspected within the last two years but was found to be non-compliant with the Codex Alimentarius General Principles of Food Hygiene and ISO 22000:2005

If inspections have been conducted by UNICEF or MSF within the last two years and no major adverse observations were recorded, the inspection requirements may be waived by SCMS QA.

If an inspection is required, a qualified member of the SCMS Quality Assurance Unit conduct the site inspection according to the Codex Alimentarius General Principles of Food Hygiene, ISO 22000:2005 and the World Food Programme site-inspection checklist. Samples may also be collected for analysis at the time of inspection. In general, site inspections will consist of a review of:

- Quality management systems
- Personnel
- Equipment
- Documentation
- Production
- Quality Control

### **4. Supplier Approval**

SCMS Quality Assurance will review the supplier's documentation, sample analysis results and site inspection report and then advise the Procurement Unit of approvals and/or rejections based on the guidelines outlined herein. The recommendation will be formally documented and the manufacturer will be added to the approved suppliers list.

The approved suppliers list is posted on the [USAID Supply Chain Management Systems](#) website under 'Additional Resources'.

**5. Supplier Re-evaluation**

Approved suppliers will be re-evaluated every two years unless product quality issues are reported or suspected wherein re-evaluation may commence sooner than the two year review period. Product quality issues which may initiate an early re-evaluation include: notification of deviations, complaints, recalls, or failing test results. Early re-evaluation may also occur if major changes occur at the approved manufacturing site, such as plant relocation.

**6. Complaint Monitoring**

Any complaints concerning FBP products will be thoroughly investigated as per SCMS product quality assurance procedures.