

	TECHNICAL REQUIREMENTS NUTRITIONAL PRODUCTS	Author: A Fleet Revision: ANK, ANS, PSJ Version: 2.0 Date: 16.06.2016
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Background

The technical requirement for nutritional products depends on the product's regulatory classification. Where a product is classified as a food or nutritional supplement, UNICEF is guided mainly by the Codex Alimentarius guidelines for specific food ingredients and for vitamin and mineral food supplements (CAC/GL 55 – 2005). Vitamin and mineral pharmaceutical products (solid dosage format) should follow guidance from a relevant pharmacopoeia (Ph. Eur., BP, USP, IP etc.) in reference to standards for composition, packaging and labeling.

UNICEF Technical Requirements provide a technical guide to suppliers in terms of UNICEF's expectations of quality, safety and efficacy of products and are part of the contractual provisions [long term agreements (LTAs) and Purchase orders (POs)], in addition to UNICEF specifications. Manufacturers and suppliers should provide the required information listed in the Technical requirements for Nutritional Products, in response to UNICEF procurement solicitation, such as Invitation to Bid (ITB), Request for Quotation (RFQ), Request for Proposal (RFP).

Technical Assessment

Suppliers should ensure the relevant sections of the *Interagency Food or Pharmaceutical Product Questionnaires* as well as *Interagency Food or Pharmaceutical Manufacturers Questionnaire* received with the bid document are completed, and all documents listed and required are attached. Please use the *Finished Product Technical Specifications* contained with the bid document as a guide for additional product specific technical requirements.

Quality control

The manufacturer must establish its own finished product specification and clearly state the amount and frequency of testing of each ingredient, microbiological contamination, chemical contamination, and other relevant points to be controlled. By putting this in place the manufacturer can provide documented evidence that its product is manufactured in a consistent quality.

The Certificate of Analysis (CoA) for each batch specifies test results of the representative tracers and the parameters as stated in the individual Product Specifications and is required with every delivery.

In order to verify that the finished product complies with the product specification, unless otherwise specified in the Product Technical Specifications, a complete testing analysis (including all macro, micronutrients, microbiological and other contaminants) of the finished product should be provided for specialized nutritional foods. For products where there is a monograph reference, tests should be compliant to the reference pharmacopoeia monograph.

More frequent testing may also be needed in the startup phase in order to document that the product comply with the finished product specification. For more detailed information on safety requirements please refer to Product Technical Specifications.

Certificate of Analysis (CoA)

A Certificate of Analysis is required for each batch of finished product supplied under purchase orders. CoAs are required to include all active ingredients and microbiological tests unless defined otherwise in the Finished Product Technical Specification.

Manufacturing Standard

The appropriate standards to refer to for raw materials, pre-mixes, ingredients, excipients and the finished products are included in the *Finished Product Technical Specification, Interagency Product questionnaires* and *Interagency Manufacturers Questionnaires*.

The above mentioned questionnaires can be used as tools to prepare for an audit conducted by UNICEF or one of UNICEF's Interagency auditing partners.

Manufacturing site

UNICEF must approve the manufacturing sites (including any contract manufacturers and warehouses used). The manufacturer shall upon request forward a copy of the Manufacturing License for the products issued by its National Regulatory Authority. Site(s) of manufacture of raw material sources, active substances and/or manufacturing Intermediates (e.g. premixes, blends or pastes), as well as any contracted manufacturers or co-packers should be listed in the questionnaires. If available, a GMP certificate shall be submitted with bids. UNICEF must approve any changes in manufacturing sites. Failure to obtain prior approval of changes in manufacturing site may result in termination of the LTA and any pending orders.

Inspection

As UNICEF must approve the site of manufacture, the successful bidder or supplier shall permit UNICEF, or any other representative as may be designated by UNICEF, to have access to the manufacturing facilities of the goods at all reasonable times to inspect the manufacturing site and processes for the production, quality control, quality assurance and packing of the goods. The manufacturer shall provide reasonable assistance to the representative for such appraisal, including copies of any documentation as may be necessary. The inspection may be carried out in conjunction with the National Regulatory Authority.

Pre-delivery Inspections

UNICEF may request that an independent inspector comes to conduct a pre-delivery inspection and collection of products for testing prior to acceptance of delivery. UNICEF reserves the right to reject any products that does not conform to the required specification.

Product composition and/or process changes

UNICEF should be notified and approve of any changes in the formulation, ingredients, excipient sources, finished product specifications and/or major manufacturing process changes that has been included in the original bid submission. (e.g: a change in vitamin and mineral supplier or formula, the addition of a heat step in the product manufacture). Failure to notify UNICEF of product and process changes may result in termination of any LTA and/or pending orders.

Shelf life and storage conditions

Unless specifically authorised in writing by UNICEF, products must be of fresh production e.g., remaining 80% of shelf life at the time of delivery. Shelf life and storage conditions must be confirmed by stability

studies conducted according to the standard specified in the *Interagency Requirements for stability studies for Therapeutic Foods* or International CH/WHO's *Stability testing of active pharmaceutical ingredients and finished pharmaceutical products* attached to the bid document.

Labels and leaflets

The following codex standards on nutrition labeling (Codex STAN 1-1985; Codex STAN 146-1985) should be followed, especially with regards to nutrient declaration, nutrition claim and listing of nutrients. All the packs or containers must be affixed with a clear label, using undeletable ink and able to withstand tropical climates. As a minimum requirement, unless otherwise agreed with UNICEF, all labels and inserts must be printed in English and French and should contain at least the following information: If the product Technical Specification require leaflet, these must also be bilingual and comply to the above international standards.

- Generic name of product (any brand name used must be indicated in the product questionnaire and its suitability assessed and approved by UNICEF as part of the technical evaluation);
- Product description and target recipient group
- A list of the ingredients in descending order of quantities. A detailed list of the active ingredients (vitamin and mineral premix) showing the amount of each present in 100g of finished product.
- Net content
- Manufacturer's name and address;
- Storage conditions (any precautions with respect to excursions outside the prescribed storage requirements should be indicated.);
- Instruction for use in written and pictorial form, and any warnings or precautions that may be necessary.
- Batch number assigned by the manufacturer;
- Manufacturing date in an easily understandable format;
- Best before date in an easily understandable format.

UNICEF should be notified and approve of any changes in labeling of the primary and secondary finished product packaging.

For delivery to UNICEFs warehouse facilities, separate labeling and barcode requirements apply http://www.unicef.org/supply/index_41950.html

Registration of Products

If the receiving country of goods requires that an imported product is registered, UNICEF requires the supplier to arrange the registration and comply with the National regulatory authorities.

Samples

Bidders are required to submit one packaging unit non-returnable samples for technical evaluation if not otherwise stated. Samples will normally be accepted up to one week after the solicitation of the bid. Samples submitted should be in their final status and packaging as intended to be supplied on purchase orders (primary, secondary and tertiary packaging). Labelling and packaging shall be in the format as they would appear at the time of supply; including accessories, pack inserts or similar. Samples must be sent together with the respective Certificate of Analysis.

Sample shall be mailed to:

**UNICEF Supply Division
Medicine and Nutrition Centre
Oceanvej 10-12
DK – 2150 Nordhavn, Copenhagen
Denmark**

All technical documentation should be submitted electronically into a OneDrive folder as specified by UNICEF, separately to financial proposals. Enquiries can be sent to sd.nutritionssupplies@unicef.org. UNICEF's product catalogue can be found here : http://www.unicef.org/supply/index_52843.html