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Technical Requirements for Specialized Nutrition Food Products

1. Background

UNICEF Technical Requirements document serves as a technical guide for suppliers and manufacturers, outlining UNICEF's expectations regarding the quality, safety, and efficacy of products. These requirements are part of the contractual framework—alongside product specifications—in Long-Term Agreements (LTAs) and Purchase Orders (POs). Suppliers must submit the relevant information specified in the Technical Requirements for Nutritional Food Products when responding to procurement solicitations such as Invitations to Bid (ITBs), Requests for Quotations (RFQs), or Requests for Proposals (RFPs). Version 3.0 of the Technical Requirements applies to the products listed in Annex 1.

The applicable requirements vary depending on the product's regulatory classification. For products classified as food, food for special medical or dietary purposes, or nutritional supplements, UNICEF observes Codex Alimentarius texts (standards, guidelines, code of practice, and other guidance) for food raw materials and vitamin and/or mineral supplementation.

2. Technical Assessment and Approval Process of Products for Long term Agreements (LTA)

The quality and safety of nutritional products are primarily evaluated through a technical review of product dossiers, analysis of submitted product samples, and audits of manufacturers based on Good Hygienic Practice (GHP) and Good Manufacturing Practice (GMP) standards. Once UNICEF programmatic demand is established, relevant products and sourcing details are incorporated into product specifications. Products are then assessed for compliance with both the *Technical Requirements for Specialized Nutrition Food Products* and the corresponding product specifications. These documents define key

parameters such as the target population, intended use, composition, shelf life, raw material standards, processing criteria, quality assurance measures, and analytical testing requirements. A simplified flow diagram of product evaluation process is illustrated in figure 1.

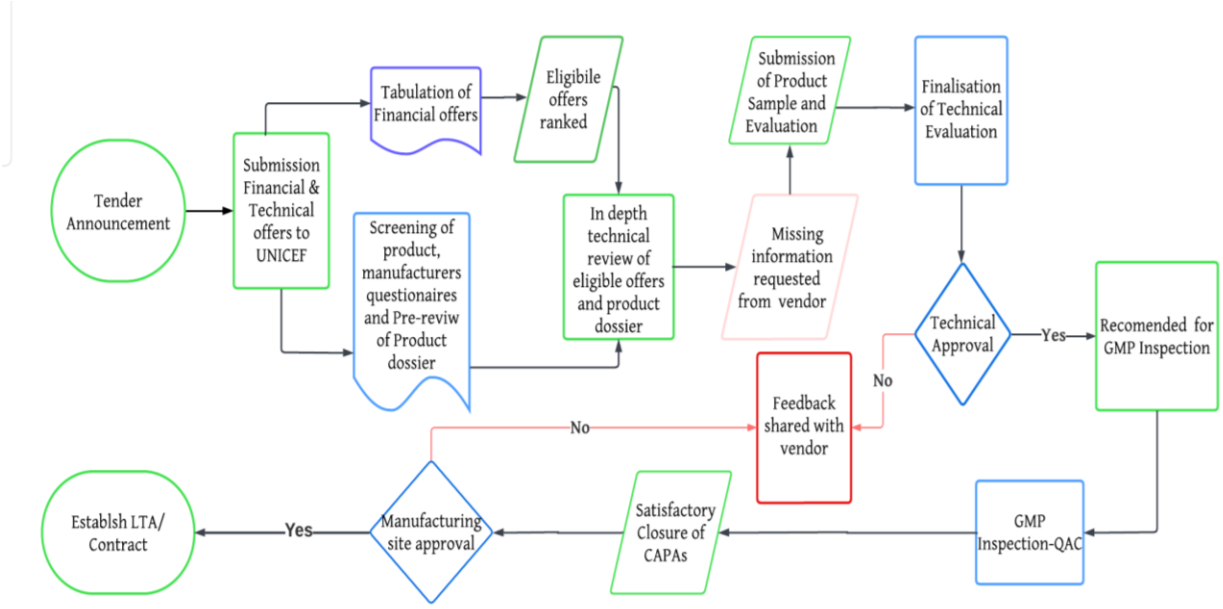

Figure 1: A simplified process of product evaluation and approval for establishment of Long-Term Agreement (LTA)

UNICEF screens and assesses compliance with the specification and technical requirements based on the responses provided by manufacturers in the relevant sections of the *Interagency Food or Pharmaceutical Product Questionnaires* as well as *Interagency Food or Pharmaceutical Manufacturers Questionnaire* as part of a solicitation process.

A filled and signed *Interagency specialized food product questionnaire* (ISFPQ) must be provided for each product submitted by the manufacturer in their bid. The submitted questionnaire provides detailed information about the product and the controls implemented to prevent the finished products from physical, chemical and microbiological risks. The information provided must include (1) product specification, (2) list of ingredients, (3) product safety, (4) packaging and labeling, (5) logistic information, (6) regulatory information, (7) production processes, (8) quality assurance, (9) quality control processes, (10) stability (shelf life) testing and storage conditions of the product of interest.

A filled-in *Interagency specialized food manufacturer quality questionnaire* (ISFMQQ) must also be signed and submitted together with the ISFPQ. The submitted ISFMQQ provides manufacturer information about five areas of the manufacturer: (1) Company Information (2) Quality Management system (3) Good Manufacturing Practice (GMP) and Good Hygienic Practice (GHP) (4) Quality Control and (5) Storage and Transport.

The above-mentioned questionnaires can be used as tools to prepare for an inspection conducted by UNICEF or one of UNICEF's Interagency partners[1].

3. Technical Assessment and Approval Process of Products for Ad-hoc, emergency or limited procurement

The selection of products for emergencies or ad-hoc procurement requires sufficient justification of need from program countries. Products not listed in the UNICEF Supply Catalogue may still be considered for one-time, limited-volume purchases through a simplified evaluation process. In such cases, manufacturers and suppliers must submit adequate technical documentation demonstrating the product's quality, safety, and efficacy. Products offered under these conditions must include detailed product specifications that align with relevant Codex Alimentarius guidelines and/or other applicable international standards, where available. Additionally, products should be sourced from manufacturers that have been pre-qualified by UNICEF, a partner agency, or a recognized stringent regulatory authority.

The Specialized nutritional food products which UNICEF Supply Division does not purchase under LTAs but as required by emergency situations and Ad-hoc requirements by partners and countries may follow a simplified process of product evaluation (Figure 2).

If a manufacturer and product are qualified through this process, particularly if the assessment is based on EU regulations or conducted by trusted interagency partners such as Médecins Sans Frontières (MSF) or the World Food Program (WFP)—this qualification may also support consideration for inclusion in a Long-Term Agreement (LTA). UNICEF will establish a risk based onsite GMP inspection of the manufacturing site which is qualified on the ground of ad-hoc or emergency need.

[1] Interagency partners involved in audits are World Food Programme (WFP), Médecins Sans Frontières (MSF) and the US Department of Agriculture.

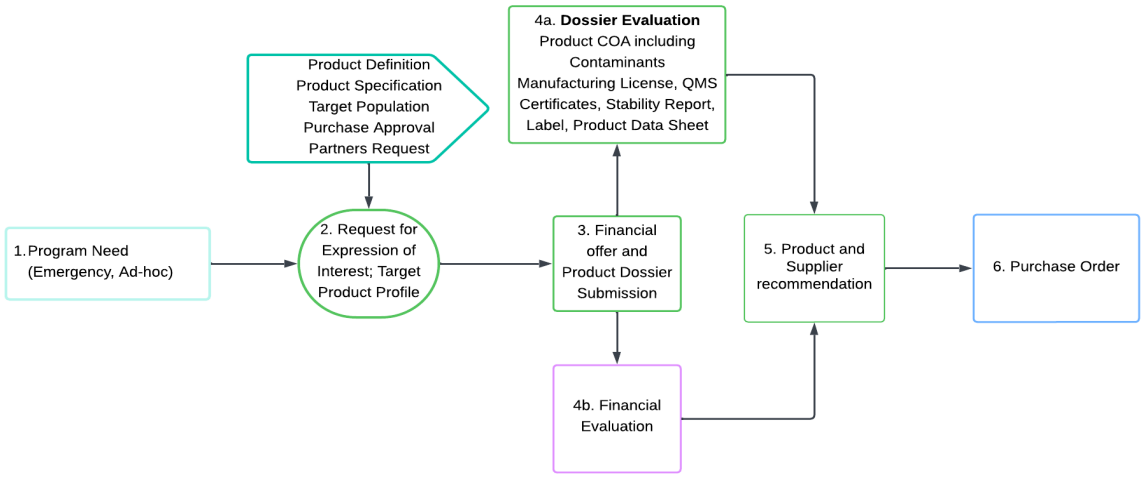

Figure 2: A simplified process of product evaluation and approval for emergency and Ad hoc purchase

4. Ingredients and Raw Materials

High-quality nutritional products begin with the use of high-quality raw materials and ingredients. UNICEF evaluates ingredients, processing aids, additives, and other excipients based on internationally recognized standards, including those set by Codex Alimentarius, the Food Chemicals Codex (FCC), and USP pharmacopoeial monographs (particularly for Micronutrient Powders).

Manufacturers are required to develop ingredient specifications in alignment with these international standards, as referenced in UNICEF product specifications. Furthermore, manufacturers must validate their ingredient suppliers to ensure compliance with these established specifications and quality benchmarks.

For specialized nutritional products, the selection of vitamin and mineral premixes must ensure appropriate levels of purity, potency, quality, and safety. These premixes should be sourced from suppliers that can demonstrate consistent quality and purity, and that conduct contaminant and impurity testing in accordance with USP, FCC, or other relevant pharmacopeial standards.

In many cases, ingredients require preprocessing before they can be incorporated into the final formulation. For any new type or source of raw material, manufacturers must conduct a comprehensive risk assessment covering the entire supply chain. This includes

implementing appropriate sampling and testing procedures before the ingredient is used in production.

5. Quality by Design Principles and Manufacturer Start-up

The formulation of new nutritional products must incorporate quality standards from the initial design stage through to processing and finished product release. Manufacturers developing new products are expected to follow a stepwise approach—from laboratory-scale (benchtop) development to industrial-scale production—and must fully document the quality assurance processes involved in this scale-up. During these activities, manufacturers should identify and establish the product's critical quality attributes and ensure they are consistently met through defined process parameters. These activities must be translated to corresponding HACCP plan, prerequisite programs (PRPs) and standard operating procedures (SOPs).

Each manufacturer is required to establish a finished product specification. This must clearly outline the type, amount, and frequency of testing for each ingredient, including monitoring for microbiological and chemical contamination and other critical control points. This approach ensures consistent product quality and provides documented evidence of compliance.

During the startup phase of production, more frequent testing may be necessary to demonstrate compliance with the finished product specification. A validated startup procedure and increased quality control measures are expected during start up and re-initiation of production.

For more detailed safety and quality requirements, please refer to the relevant product technical specifications.

6. Certificate of Analysis (CoA) for LTA recommendation and batch release

A complete CoA is required for recommendation of the product for LTA or contract. Unless otherwise stated, a complete analysis of the finished product must be included in the CoA—covering macronutrients, micronutrients, microbiological and chemical contaminants, and any other relevant parameters. The required frequency of full CoA testing will be defined in the product specifications or solicitation documents.

Manufacturers with LTAs should include a full CoA in as part of their annual quality control program.

A release Certificate of Analysis (CoA) as per the product specification is required for each batch of finished products supplied under purchase orders. It should include test results for key parameters and representative tracers as specified in the individual product specifications.

For products that fall under a pharmacopeial monograph, manufacturers must ensure that each batch-specific CoA meets both their own finished product specification and UNICEF's requirements.

7. Manufacturing Process

Manufacturers of specialized nutritional products must perform risk assessments of the manufacturing process. Manufacturers are requested to submit a Hazard Analysis and Critical Control Point (HACCP) plan and a flow diagram of the manufacturing process and controls of critical steps, tests and process parameters for each product submitted for evaluation.

Manufacturers are required to validate their process with established process control parameters in at least one commercial batch and keep an ongoing record of the trend during production. The manufacturing process is considered fully qualified once trending of established physical, chemical and microbiological parameters is established and found within established specifications from multiple batches. The parameters selected for trending must be the critical parameters such as product color, consistency, taste, tracers (for example Iron, Vitamin C), and total plate count (TPC), Enterobacteriaceae, & Salmonella. Any new supplier is recommended to perform trending of their data from multiple batches. Ongoing data collection and application of statistical process control is recommended to establish monitoring of processes and to validate selected parameters.

8. Manufacturing Site

UNICEF must approve the manufacturing sites (including any contract manufacturers and warehouses used). The manufacturer shall 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. The available quality management system certificate (e.g., FSSC 22000 or equivalent certificates), food quality and safety certificates, GMP or any relevant certificates shall be included in the submitted dossier.

9. Change of Manufacturing Site or Technical Transfer

UNICEF must approve any changes in manufacturing sites or new site additions for an approved product. Where a new ingredient supplier or new processing is introduced, change control procedures apply. Advance notification of a change in a manufacturing site to UNICEF will enable adequate re-inspection to be planned with minimal disruption to supply. Failure to obtain prior approval of changes in manufacturing sites may result in termination of the LTA and any pending orders.

10. 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 conduct an inspection. The inspection will include an audit of the quality management system of the company, manufacturing site design and flow of personnel, materials and air flow, environmental monitoring, processes for the production and its monitoring, quality assurance and quality control procedures, cleaning procedures, waste management, packing, storage and warehousing of ingredients, intermediate and finished products

To strengthen manufacturers' performance, monitoring the inspection may be carried out in conjunction with the National Regulatory Authority and UNICEF's partner organizations, e.g., members of the Interagency Working Group (IAWG) for Specialized nutritional Foods.

11. Pre-delivery Inspections

UNICEF may request that an independent inspector conduct a pre-delivery inspection and collection of products for testing prior to acceptance of delivery. UNICEF provides guidance and product specifications to the inspection agency to perform inspection and collection of samples before sending the sample to UNICEF's contracted third party laboratory. UNICEF reserves the right to reject any products that do not conform to the required specification.

12. Product Composition and/or Process Changes

UNICEF must be notified and obtain an approval changes in the formulation, ingredients, excipient/additives/processing aids and their sources, finished product specifications and/or major manufacturing process changes that have been included in the supply agreement. Major changes include but are not limited to changes in vitamin and mineral supplier or formula, excipient carrier, raw material source, or packaging. Changes in production processes include but are not limited to the addition of thermal treatment and installation of new equipment. The list of major changes included in Table 1 is just an example and must not be considered as the final list for the product concerned. Manufacturers are required to introduce a new change in a plan manner and perform risk assessment of the change. Further, manufacturers must provide sufficient justification that the proposed changes will not impact on the quality and safety of the finished product. Failure to sufficiently justify or notify UNICEF of product and process changes may result in termination of any supply agreement, LTA and/or pending orders.

Examples of major changes in specialized nutrition products manufacturing					
Product	Change in source of ingredients and origin	Production Process	New machinery and significant change in processing parameters	Packaging	Change in primary packaging composition
	Change of major (bulk) ingredients by >10% of the formulation		Use of different processes e.g., heat treatment in LNS, granulation and coating in active ingredients		Change in primary packaging supplier
	Change of formulation which alters significantly physical properties including organoleptic properties		Change in critical process parameters		Change in container closure system
	Change of additives and processing aids e.g. stabilizer quantity in LNS products		New line, Zoning		

Table 1: Examples of major changes in nutrition products. This is a non-exhaustive list and may vary depending on the product and the manufacturer.

13. Shelf Life and Storage Conditions

Unless specifically authorised in writing by UNICEF, products must be of fresh production e.g., with 80% of self-life remaining at the time of delivery. For specialized nutritious food, shelf life and storage conditions must be confirmed by stability studies conducted according to the standard specified in the *Interagency stability study requirements for nutritional products*. For vitamin and mineral supplements such as MNPs, stability requirements follow the International Council for Harmonization of Technical Requirements for Pharmaceutical for Human use (ICH) CH or World health Organization (WHO) *Stability testing of active pharmaceutical ingredients and finished pharmaceutical products* attached to the bid document.

14. Packaging

Packaging of nutritional products includes primary packaging and secondary packaging. UNICEF requires primary packaging used is made of food grade packaging material. The barrier properties for gas, water and light should be able to withstand until the end of the shelf life of the product. Manufacturers are required to have a packaging process control established to produce products with the right size, weight, strength and sealing properties. Packaging, which is not in direct contact with food, is considered as secondary packaging and should be of good quality to protect the movement during land and sea transport, pressure of stacking and pressure difference of air transport. UNICEF's product specifications include primary and secondary packaging requirements.

15. Product Label and Label Claims

UNICEF product specifications include labelling requirements. The following Codex standards on nutrition labeling (Codex STAN 1-1985; Codex STAN 146-1985) should be followed, with regards to nutrient declaration, nutrition claim and listing of nutrients unless otherwise specified in the UNICEF product specification. UNICEF recommends that the nutrients values stated in nutritional table shall apply average values as per Codex (CXG 2-1985 Guidelines on nutrition labeling and CODEX STAN 180-1991). The values presented in the nutritional table are the supplier's responsibility and cannot be lower than the minimum values, as per UNICEF specifications, at the end of the shelf -life. All the packs or containers must be affixed with a clear label, using indelible ink, which is able to withstand tropical climates.

UNICEF must be notified and get approval of any changes in labeling of the primary and secondary packaging of the finished product.
For delivery to UNICEFs warehouse facilities, separate labeling and barcode requirements apply, in line with *UNICEF's requirement for packing, packaging and labelling-technical specifications and fees.*

16. Dangerous Goods

UNICEF requires that dangerous goods are identified as such and an appropriate UN number, packing group and IATA classification are included in a submitted material safety data sheet (MSDS). MSDS is required with each shipment of dangerous goods.

17. Sustainable Procurement

Suppliers and manufacturers should consider all aspects of sustainable procurement, with special emphasis on environmental, social, and economic aspects. Suppliers must fill in the corresponding form on United Nations General Marketplace (UNGM) and any annex to UNICEF tender documents related to sustainability. UNGM Sustainable procurement indicators Sustainable Procurement Indicators (ungm.org).

Technical evaluation will include the implementation of ISO14001 – Environmental management, specifically the manufacturer's practices with regards to waste management, chemicals and environmental impact. Those suppliers not having an ISO 14001 must demonstrate that they are working towards implementing measures to comply with Science Based Targets.

In line with sustainable procurement efforts and to eliminate waste, vendors are asked to consider eliminating nonfunctional secondary/tertiary packaging without compromising the integrity of the finished products, while still ensuring that sufficient product information to end users is available together with the product. Where applicable, vendors are expected to use sustainable packaging that complies with recognized sustainability standards.

See UNICEF Sustainable procurement procedure. *Sustainable procurement procedure | UNICEF Supply Division*

18. Registration of Products

If the destination country for the goods requires that a product is registered, UNICEF requires the supplier to arrange the registration and comply with the National regulatory authorities' document requests. Submission of documentation for registration of products is part of the technical submission for evaluation and may be required for specific national regulatory bodies.

19. Samples

A product sample will be requested from suppliers who have submitted sufficient product documentation during a tender. Bidders are typically required to submit one packaging unit of non-returnable samples within a specified timeframe for evaluation.

Samples submitted must ideally 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 as well any customs clearance documentation required for Denmark.

20. Labelling for samples

Suppliers must check the importation requirements for food. We recommend that the samples are labelled as "sample for testing purpose only" and "no commercial value".

Sample shall be mailed to: UNICEF Supply Division
Medicine and Nutrition Centre, Oceanvej 10-12
DK – 2150 Nordhavn, Copenhagen
Denmark

21. Submission of Product Dossier

All technical documentation must be submitted electronically into a SharePoint folder as specified by UNICEF, separate to financial proposals. UNICEF provides unique access to a SharePoint folder to each supplier making technical submissions in a bidding process. Suppliers and manufacturers are required to follow the instructions provided in the bidding documents for requesting access to the SharePoint folder. All technical documents are

required to be uploaded to the provided folder for any successful product evaluation. The required documents to be submitted can be found in the relevant questionnaires, the product specifications or in the tender documents.

Enquiries and requests for access to the SharePoint folder can be sent to sd.nutritionsupplies@unicef.org.

UNICEF's product catalogue can be found here: Nutrition - All Products

Annex 1

<table>
<tr><th colspan="4">List of Specialized Nutrition Products</th></tr>
<tr><td rowspan="9">Therapeutic Foods</td><td>Ready-to-Use Therapeutic Foods (RUTF)</td><td rowspan="4">Lipid based nutritional Supplement (LNS)</td><td>Small Quantity-Lipid based Nutritional Supplement (LNS-SQ)</td></tr>
<tr><td>Therapeutic milk -F-75 and F-100</td><td>Lipid based Nutritional Supplement - medium Quantity (LNS-MQ)</td></tr>
<tr><td>Ready-to-Use Therapeutic Foods- Biscuits (RUTF-Biscuits)</td><td>Ready-to-Use Supplementary Foods (RUSF)</td></tr>
<tr><td>Ready to use therapeutic milk-F-75</td><td>Lipid based nutritional supplement for Pregnant and breastfeeding women and girl (LNS-PBWG)</td></tr>
<tr><td>Ready to use therapeutic foods-Soy (RUTF-Soy)</td><td rowspan="3">Fortified Foods</td><td rowspan="2">Fortified Biscuits</td></tr>
<tr><td>Ready-to-use therapeutic foods-Chickpea (RUTF-Chickpea)</td></tr>
<tr><td>RUTF Innovation</td><td>Emergency Ration-BP-5</td></tr>
<tr><td>RUTF Renovation</td><td rowspan="4">Food Fortification and supplement</td><td rowspan="2">Multiple nutrients powder-15 components</td></tr>
<tr><td>RUTF Novel</td></tr>
<tr><td rowspan="3">Complementary Processed Foods</td><td rowspan="2">Super cereal with Sugar (Super cereal +)- Corn soy based (CSB+)</td><td>Multiple nutrients powder-5 components</td></tr>
<tr><td>Food fortification (Iron, calcium, Iodine)</td></tr>
<tr><td>Super cereal with milk powder (Super cereal ++) - Corn soy + milk powder based (CSB++)</td><td>Therapeutic complex of minerals and vitamins (CMV)</td></tr>
<tr><td colspan="2">Complementary foods for infants and children</td><td colspan="2">Food for inherited metabolic disorders and allergies</td></tr>
<tr><td rowspan="2">Infant Formula</td><td rowspan="2">Ready to use Infant formula (RUIF)</td><td colspan="2">Food for special dietary purposes</td></tr>
<tr><td rowspan="2">Powdered Infant formula</td><td colspan="2" rowspan="2">Other Emergency Foods for children</td></tr>
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