World Vision
health and nutrition

Guidelines for the Selection and Use of New Ready-to-use-Therapeutic Food (RUTF) Products in World Vision Programmes

World Vision/UNICEF
2014

Healthy children for a healthy world

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List of Acronyms

AI	Active Ingredients
cGMP	Current Good Manufacturing Practice(s)
CMAM	Community-based Management of Acute Malnutrition
FDA	Food and Drug Administration
FPMG	WV Food Programming and Management Group
GIK	Gifts in Kind
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practice(s)
HACCP	Hazard Analysis Critical Control Point
IMRAD	Structure for original research article for scientific journal **i**ntroduction, **m**ethods, **r**esults, **a**nd **d**iscussion
ISO	International Standards Organization
MOH	Ministry of Health
MT	Metric tonne
NCoE	Nutrition Centre of Expertise
NGO	Non-governmental organization
RUF	Ready-to-use Food
RUTF	Ready-to-use Therapeutic Food
SAM	Severe Acute Malnutrition
UN	United Nations
UNICEF	United Nations Children Fund
WASH	Water, Sanitation and Hygiene
WHO	World Health Organization
WV	World Vision
WVI	World Vision International

1. Introduction

1.1 Background

World Vision (WV) began implementing programmes with Ready-to-Use Therapeutic Foods (RUTFs) during the Niger Food Crisis in 2005. Shortly thereafter, the World Health Organization (WHO) endorsed the Community-based Management of Acute Malnutrition (CMAM) methodology as a proven and effective model for the treatment of Severe Acute Malnutrition (SAM). To date, WV is implementing CMAM programmes in 12 different countries worldwide. In turn, a significant number of children under 5 years suffering from SAM have been treated with RUTFs.

To ensure children suffering from SAM are treated with the highest quality of programming in each country, all of WV's programmes are implemented alongside a comprehensive CMAM capacity building package of activities. Each technical assistance activity is led by a qualified internal and/or external[1] CMAM Advisor and it takes place at critical stages of the CMAM implementation process, in collaboration with local Ministries of Health. The delivery of assistance for all staff prioritises a strong practical element; including ongoing coaching and mentoring at the decentralised distribution sites and/or within the communities. This training equips staff with the skills and tools required to effectively treat SAM with RUTFs in a variety of contexts[2] and appropriately monitor and evaluate their programmes to ensure that targets are being reached.

Effective treatment of SAM requires a reliable and efficient supply chain for RUTF. To date, WV has not identified the availability of RUTF as the *primary* hindrance to programme implementation. However, both WV and the Ministry of Health (MOH) are reliant on UNICEF for the supply of RUTF and their pipeline is not always reliable. Within the statutory health sector, supply problems have been reported in the MOH-run CMAM programmes in countries such as Ethiopia, Malawi, Sierra Leone, and Zambia. These problems are due to the cost of RUTF, custom delays and weak health sector logistics. To mitigate the effects of an unreliable RUTF supply chain, National Offices budget for a buffer stock of RUTF at the onset of their programme design.

The first commercially available RUTF was manufactured in the 1990s by the French firm, Nutriset, under the commercial name Plumpy'nut® (containing peanuts, milk powder, sugar oil and vitamin and mineral mix); however, with the rapid expansion of CMAM programmes it became clear new sources were needed to cover increasing demand. Nutriset developed networks of franchisees in programmatic countries producing Plumpy'nut® under their license. However even this additional capacity could not satisfy ever growing demand. UNICEF advocated with food manufacturers to start production of generic RUTF. Currently, there are about 22 UNICEF-approved RUTF manufacturers. They all produce peanut-based RUTF. In addition there is ongoing research of various ingredients to develop alternative RUTF recipes with the objective to reduce the cost of product as well as accommodate various palates (mainly for Asian countries). These alternative RUTF products are not yet used in programmatic settings. World Vision will closely follow the development of new RUTF recipes and when new

[1] WVI Nutrition Centre of Expertise partners with Valid International via a Global Memorandum of Understanding whereby Valid International provides technical support to World Vision in the implementation of CMAM.
[2] WV CMAM programmes use RUTFs for the treatment of SAM in HIV and non-HIV contexts

recipes are found to be effective and safe for the treatment of SAM, these guidelines will be revised to include such products for use in WV CMAM programming.

Funding for capacity building, implementation and management costs associated with CMAM programmes continue to be the limiting factors associated with programme expansion and scale-up. However, as the global demand for RUTF increases, WV will consider diversifying its supplier base to ensure that the needs are met based on what is currently being forecasted. An internal review and analysis will be done in consideration of the complexity of the issues surrounding introduction of RUTF products manufactured by new suppliers and the associated costs (e.g. WV staff time) required to introduce a new product to the field.

In the face of the increasing demand for RUTF and businesses approaching WV for the use of their RUTF products in the field, WV needs to exercise due diligence when considering partnerships with producers of RUTF products from a new source. As a child-focused organisation, WV takes seriously any potential risk of harm to the lives of the children that WV is treating from distributing inappropriate product through WV programmes. Accordingly, the World Vision International (WVI) Nutrition Centre of Expertise (NCoE) has developed the following internal procedures and guidelines which will govern the use of such products in the organisation.

2. Purpose of document

This document serves as a guideline for the selection and use of RUTF products from new suppliers in WV programmes. It is intended for both off-shore RUTF companies and companies located in countries where RUTF is being used. The technical evaluation criteria applied for products manufactured locally are the same for the off-shore supply. If existing RUTF companies have already exercised due diligence, involving a technical evaluation of products and an assessment of the manufacturing facilities, WV will not duplicate the efforts that have already been accomplished. Where due diligence has already been completed, WV will request copies of the existing documentation that supports the approval of new products.

3. Selection process

3.1 Successful submissions

WV will deem a product eligible for consideration of use of RUTF from a new supplier in WV programmes, when the review committee[3] considers that:

- All of the essential documents have been completed and submitted in full (Section 3.2.1)
- The introduction of this new product supports the contextual and financial conditions (Sections 3.2.2, 3.2.3, 3.2.4, 3.2.5)
- All of the essential documents and supporting information meet the outlined standards (See Section 3.0)

[3] The combined WV/UNICEF review committee will comprise 1) WVI Nutrition Centre of Expertise; 2) WVI Gifts in Kind; 3) UNICEF Food Technologist/Quality Assurance Specialist/Manufacturing Facilities Expert; 5) WV Support Office(s) and National Office(s) affiliated with new RUTF product and 6) WVI Global Supply Chain – Procurement Staff

3.2 Overview of process for WVI's use of new RUTFs

3.2.1 Checklist: Essential documents submitted in full

For suppliers to be eligible for consideration of using their RUTF products in WV programmes, all of the following documents and standards must be completed and submitted to the Nutrition Centre of Expertise (NCoE):

- ✓ Manufacturing Standard and Technical Questionnaire for Food Manufacturers
- ✓ Acceptability Study Documentation[4]
- ✓ Product Specification and Analytical Tests
- ✓ Shelf-life and Stability Study Documentation
- ✓ Certificates of Analyses
    - Finished Product
    - Vitamin and Mineral Premix
    - Oil Specification
- ✓ Other Certificates
    - Certificate of origin
    - Health Certificate
    - Halal Certificate
    - Radiation Certificate
    - Melamine free Certificate
    - GMO free certificate
- ✓ Procedures for controlling Aflatoxin
- ✓ Labelling Standards
- ✓ Packaging Standards
- ✓ Internal Sampling and Testing Plan
- ✓ Sample(s) for Technical Evaluation
- ✓ Product Registration

3.2.2 Product is RUTF authenticated

Currently, there is a growing variety of Ready-to-Use Foods (RUFs) on the market. They are packaged into different products, targeting beneficiaries in a variety of humanitarian contexts. To date, WV has primarily used the product labeled "Ready-to-Use-Therapeutic Foods (RUTFs)" for treatment of children 6-59 months of age with severe acute malnutrition (SAM)[5] and the absence of medical complications. Within WV and other implementing contexts, the successes of RUTFs have been seen in conjunction with the implementation of a highly effective programme model of home-based therapy for the treatment of SAM, namely Community-based Management of Acute Malnutrition (CMAM). Although WV remains actively

[4] Effectiveness data is not required as long as RUTF products have the same recipe outlined in ANNEX 2

[5] F100 and F75 are therapeutic milk products for children with severe acute malnutrition and presenting with medical complications. The formulation of RUTF was derived from F-100 and uses the same ingredients with the addition of peanut butter. *Briend A. Treatment of Severe Malnutrition with a Therapeutic Spread. Field Exchange, 1997; 2: 15.*

engaged and receptive to emerging research on different RUF products, the following WV internal procedures and guidelines are specifically referenced to the development of RUTFs for the sole purpose of treating SAM.

3.2.3 Local level production supported and/or complemented

Where it is feasible and applicable, WV's goal is to actively support national/local level production of RUTF, thereby supporting local farmers, local profits and the national economy. Purchase decisions will not just be based on price alone but they will consider the whole developmental aspects of local production. The goal of local production is to bring the product closer to the beneficiary and thereby facilitate the transfer of CMAM programme management from NGO/UN agencies to National Governments. A reliance on imported products makes this transfer more difficult. By agreeing to partner with different RUTF companies and thereby supporting the importation of this product, the Supplier and WV will undertake careful assessments of the settings[6] and ensure that they are not undermining local, national and/or regional efforts in RUTF production.

3.2.4 Gaps in WVI RUTF supply chain confirmed

WV currently receives most of the RUTF for CMAM programmes through donations from UNICEF. WV does purchase small quantities directly from suppliers to cover for potential stock-outs, thereby minimising programme disruptions. UNICEF currently supplies RUTF to over 40 countries, inclusive of all of the 12 countries where WV currently has CMAM programming. For the majority of WV CMAM programmes, a shortage of RUTF is *not* the limiting factor in the expansion of WV CMAM programmes. An analysis of the National supply, demand and RUTF distribution logistics must be conducted to confirm any gaps in the existing RUTF supply chain, for which the introduction of RUTF products suppliers and logistical support could benefit WV CMAM programmes.

3.2.5 Human and financial investment calculated

To date, operational funds for CMAM i.e. staffing and technical support is the key limiting factor in WV CMAM programmes. Introducing a RUTF product from a new RUTF supplier to the field is a rigorous process, when the regulatory measures as outlined in these guidelines have not yet been undertaken. Additional WV staff time (international and national) and associated costs are required for the development, purchasing and shipping of a new RUTF product. It is for this reason that WV will conduct an analysis of the human and financial costing required to introduce a newly manufactured RUTF product to the field from a new RUTF supplier, under the direction of these guidelines. Furthermore, the total cost of developing and introducing a new RUTF product from a new RUTF supplier will be balanced against its inaugural costs and market value over time, as well as, the cost of existing RUTF product purchase and shipping.

[6] In settings where RUTF production and distribution is difficult (ex. civil war) and settings where local production cannot meet surges in demand (e.g. refugee crisis), regional or international production will be required to meet surges in demand and the specific need.

4. Is your product eligible for WV/UNICEF selection and use in WV programmes? Supporting information and documents for food manufacturers

4.1 Technical questionnaire for food manufacturers[7]

The Technical Questionnaire for Food Manufacturers (ANNEX 1) covers the following:

4.1.1 Company information (including any Affiliates)[8]

Compliance with Law: Company, including its Affiliates, shall be in compliance with all applicable laws and regulations (such as labour, employment, health and safety, etc.) and not engage in any child labour per the General Contract.

4.1.2 Quality system

Products must be manufactured in accordance with the Codex Alimentarius and the Code of Practice for Food Premix Operations (Pan American Health Organization (FCH/NU/66)). Other Quality Management Systems (QMS) and food safety approaches such as ISO 22000, GMP and HACCP (e.g. Annex 5 on the U.S. Department of Health and Human Services, Public Health Service, and FDA 199 Food Code) are highly recommended. Where the product is manufactured and regulated as a pharmaceutical or by a pharmaceutical company, this should be in compliance with current Good Manufacturing Practices (cGMP) according to WHO guidelines (Technical Report Series 908). (Ref: WHO Geneva, 2004. Quality Assurance of Pharmaceuticals. A compendium of guidelines and related materials. Volume 2, updated edition). (http://www.who.int/medicines/organization/qsm/activities/qualityassurance/gmp/gmpcover.html)

As WV and/or UNICEF must approve the site of manufacture, the Supplier shall permit WV and/or UNICEF, or any other representative as may be designated by WV and/or 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 should provide reasonable assistance to the representative for such appraisal, including copies of any documentation as may be necessary. WV and/or UNICEF reserve the right to reject any material that does not conform to the required specification. The inspection papers are required from the National Regulatory Authority.

4.1.3 Manufacturing site/location

The physical site where any aspect of manufacture occurs must be stated, including production, sterilisation, packaging and quality control and other manufacturing activity performed at each site. WV and/or UNICEF must approve the site of manufacture and the manufacturer should upon request forward a copy of the

[7] UNICEF Manufacturing Standards, 2010

[8] Any company and/or affiliate presenting with a conflict of interest for WV (e.g. companies breaching Code of Marketing of Breast-milk Substitutes) will be screened at this stage of the product questionnaire but much earlier on in the process.

Manufacturing License for the products issued by its National Regulatory Authority. WV and/or UNICEF must approve any changes in manufacturing site or location. Failure to obtain prior approval of changes in manufacturing site may result in termination of an agreement and any pending orders as per the General Contract.

All contract manufacturers must be indicated for review and approval by WV and/or UNICEF. The site of contract manufacture and the name of the contract manufacturer must be approved by WV and/or UNICEF. Change of contract manufacturer requires prior approval from WV and/or UNICEF.

4.1.4 Audit

A request for consent for WV and/or UNICEF to undertake an audit of the manufacturing site is required. See Annex 1 for consent.

4.2 Active ingredient(s) and excipients

Chemical forms of vitamins and minerals should be described. Vitamin and mineral premix used for the finished product should be supplied by accredited and internationally validated premix companies. Where relevant monographs exist, Active Ingredients (AI(s)) and excipients should comply with a relevant official and internationally recognised compendium. In cases where AI(s) are not described in an official pharmacopoeia/compendium, a copy of the Supplier's certificate of analysis, a description of the tests and limits for results for the AI and excipients are needed. A confirmatory certificate of analysis from the Supplier should be available at least for the duration of the shelf life of all batches of finished products in which the AI and excipients are used. WV and/or UNICEF should be notified and approve of any changes in AI sources, routes of synthesis and/or specifications. Failure to do so may result in termination of any agreement and/or pending orders. Site(s) of manufacture of active substances and/or manufacturing intermediates (e.g. granulates) as well as any alternative manufacturers should be listed. If available, a GMP certificate should be submitted to WV.

4.3 Acceptability studies[9]

Prior to introducing RUTF from a new supplier to a field programme, evidence of product acceptability must be demonstrated. WV and/or UNICEF must ensure that malnourished children find the taste and texture of the new product acceptable. Organising an acceptability study requires significant effort on the part of WV and/or UNICEF. The Supplier should perform acceptability studies independently, preferably in multiple countries, and inform WV and/or UNICEF of the results in a scientifically sound report[10].

Note: If conducting an independent acceptability studies is not feasible, additional funding to cover WV costs for this exercise must be provided by the Supplier.

[9] UNICEF Product Specification Standards, 2010

[10] Report should be written in **IMRAD** format with the following sections: **I**ntroduction, **M**ethods, **R**esults, **A**nd **D**iscussion. See http://writing.wisc.edu/Handbook/ScienceReport.html for more details.

4.4 Product specification and analytical test procedures[11]

The finished product specification details the composition of vitamin and mineral premix used and the registration status of the product in programmatic countries. Products offered must be as specified in the general item description and any specific requirements indicated and manufactured in accordance with recognised international standards (found in ANNEX 2).

The international standards include:

1. The Recommended International Code of Hygienic Practice for Foods for Infants and Children of the Codex Alimentarius Standard CAC/RCP 21-1979 (available at http://www.codexalimentarius.net/download/standards/297/CXP_021e.pdf).
2. All added mineral salts and vitamins should be on the Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children of the Codex Alimentarius Standard CAC/GL 10-1979 (available at http://www.codexalimentarius.net/download/standards/300/CXG_010e.pdf).
3. The added minerals should be water-soluble and should not form insoluble components when mixed together. The food should have a mineral composition that will not alter the acid base metabolism of children with severe acute malnutrition. In particular, it should have a moderate positive non-metabolisable base sufficient to eliminate the risk of metabolic acidosis. The non-metabolisable base can be approximated by the formula: estimated absorbed millimoles (sodium + potassium + calcium + magnesium) - (phosphorus + chloride).

   The standard of the raw materials used in manufacture of the finished product should indicate the relevant official compendia (Ph. Eur. USP, BP, as well as any information on analytical limits or in-house test methods).

   All analytical test procedures must be described in sufficient detail, including biological and microbiological methods, where relevant, to enable the procedures to be repeated if necessary. All test procedures should be validated. Results of the validation studies, comments on the choice of routine tests, and standards must be provided.

4.5 Shelf-life and Stability study[12]

Unless specifically authorised in writing by WV and/or UNICEF, products must be of fresh production, e.g. less than four months old at the time of delivery. Products offered should have an assigned shelf life of minimum two years, except those whose shelf life is normally less. Stability Studies must confirm assigned shelf life duly concluded and signed. The studies must be done in the storage conditions recommended on the label and verify the following:

1. Organoleptic stability—in terms of taste, odour, product consistency and behaviour.
2. Nutrient stability—maintenance of a level of vitamins and minerals over or within specified levels for at least one water soluble and one fat soluble micronutrient every six months.
3. Demonstrate absence of microbiological growth.

[11] UNICEF Product Specification Standards, 2010
[12] UNICEF Product Specification Standard, 2010

4. Stability of oils and fatty acids in RUTF product—verify absence of oxidation.
5. Integrity of packing materials.

For details on how to conduct stability study refer to WHO guidelines on Stability testing of active pharmaceutical ingredients and finished pharmaceutical products http://www.who.int/medicines/publications/pharmprep/pdf_trs953.pdf

4.6 Certificate of analyses[13]

The following authenticated documents must be provided by an accredited company or individual as a means of certifying the purity of the products being exported. See Annex 3 for further specifications.

4.6.1 Finished product and batch analysis

The complete certificate of analysis of finished product (for technical evaluation purposes) must specify the nutritional composition (including chemical forms of all minerals and vitamins) and microbiological tests (including aflatoxin levels) for at least one batch.

A complete batch analysis of the product depending on the production capacity and WV order frequency should be provided under the following guidelines:

- Once a year for a total annual production of less than 1,000 MT
- Every six months for an annual production between 1,000 MT–2,000 MT
- Every three months for an annual production between 2,000 MT–12,000 MT
- Every month for an annual production above 12,000 MT

Pesticides, radioactivity and heavy metal contamination should be checked in the finished product once a year. However, WV can require more frequent testing.

More frequent testing may also be needed in the start-up phase in order to document that the product complies with the finished product specification. New producers should submit complete analysis every three months. Once reliability has been established the frequency of testing can be decreased to every six months.

4.6.2 Vitamin and mineral premix

This must be issued by the Premix manufacturer.

[13] UNICEF Product Specification Standard, 2010

4.6.3 *Oil specification*

The type of oil and n-3: n-6 ration must be specified.

4.6.4 *Absence of* Cronobacter Sakazakii *in finished product*

The certificate of analysis must confirm the absence of *Cronobacter Sakazakii* in finished product.

4.7 Other certificates[14]

Some countries may require some of the below mentioned certificates or other regulatory documents to be issued by the authorities in the country of origin. WV and/or UNICEF will notify the vendor of the additional certifications required.

4.7.1 *Certificate of origin*

This certificate must state the country where the RUTF is made.

4.7.2 *Health certificate*

This certificate must confirm that the sanitary requirements of country of origin have been complied with/product is suitable for human consumption.

4.7.3 *Halal certificate*

This certificate must confirm that all products are permissible under Islamic law. All ingredients and finished product are edible by Muslims.

4.7.4 *Radiation certificate*

This certificate must certify that foods have not been exposed to radioactivity.

4.7.5 *Melamine-free certificate*

This certificate must certify that foods do not contain traces of melamine.

4.7.6 *GMO-free certificate*

This certificate must certify that finished product do not contain genetically modified organisms (GMOs)

4.8 Controlling Aflatoxin[15]

A written explanation on measures put in place to control aflatoxin must be provided. Aflatoxin testing should be carried out for all batches of product supplied to WV. Requirements for further testing will be determined by a Quality Assurance Specialist and stipulated in each purchase order thereafter.

[14] UNICEF Product Specification Standard, 2010
[15] UNICEF Product Specification Standard, 2010

4.9 Labelling[16]

The following codex standards on nutrition labeling (Codex STAN 1-1985; Codex STAN 146-1985, and guideline: CAG/GL2 – 1985 – Rev – 1993) 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. **As a minimum requirement, all labels and inserts must be printed in English and French[17]**, preferably by lithography direct on container, self-adhesive labels, pharmaceutical defiberised paper (80mg/kvm), film or UV coated for protection against humidity. Should supplier use paper labels or another product suitable for foil packages and lids, these must be affixed to prevent detachment in tropical climates and should be printed in undeletable ink, in black on white. WV should be notified and approve of any changes in labelling of the primary and secondary finished product packaging.

The label should contain at least the following information:

- ✓ Generic name of product in English "**Ready to Use Therapeutic Food**" and in French "**Aliment Thérapeutique Prêts à l'Emploi**" (Any brand name used must be indicated in the product questionnaire and its suitability assessed and approved by WVI as part of the technical evaluation);
- ✓ Clear statement in English "**RUTF for children with Severe Acute Malnutrition**" and in French "**ATPE pour les enfants atteints de malnutrition aiguë sévère**";
- ✓ 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 in100g of finished product should be provided in a leaflet and not on a product label;
- ✓ 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 in English and French or other language (as specified);
- ✓ Batch Number assigned by the manufacturer;
- ✓ Manufacturing date;
- ✓ Best before date in an easily understandable format.
- ✓ No WV logo on the label.

[16] UNICEF Product Specification Standards, 2010
[17] Where necessary, labels requiring additional languages (e.g. Arabic, local languages) should be provided through printed leaflets to be included within each carton.

4.10 Packaging[18]

Evidence and documentation of the following criteria below must be provided to WV:

1. The finished product should be packed in 92g sachets/pouches placed in a carton containing 150 sachets[19]/pouches. Each carton should contain detailed leaflet specifying nutritional composition of the product including list of all minerals and vitamins.
2. Primary packaging material used should be generally recognised as safe for food packaging and should protect adequately product during the assigned shelf life and sachet/pouch seal should prevent any leakage.
3. The secondary packing is of a sturdy export quality, of virgin base materials and of a commercial standard that will provide adequate protection of the goods for carriage by air, sea and/or road to final destinations worldwide, including remote locations under adverse climatic and storage conditions, and high humidity, i.e. not less than 17kN edge crush resistance with minimum 60% remaining with 90% humidity at a temperature of 40◦C (tropical conditions);
4. The packaging unit is strong, able to be stacked to a height of four pallets as static storage and two pallets during transport, and resistant to puncturing;
5. All wood packaging, including pallets and boxes, utilised in any shipment, have undergone the treatment, marking and documentation required to meet the specifications described in ISPM No. 15: Guidelines for Regulating Wood Packaging Material in International Trade, available at www.ipcc.int;
6. Pallets manufactured from other materials than solid wood are NOT acceptable (such as wood chip, plastic, MDF board, ply wood or carton). Pallets must have three (3) longitudinal bottom deck lead boards, feet are NOT acceptable. For more information on WV Palletisation Standards, go to Chapter 7 of the Food Resource Manual found on the following link: http://www.wvifood.org/foodmanual/
7. Deliveries to any destination are packed and/or palletised in the most cost-effective way to minimise freight costs.

4.11 Internal sampling and testing plan[20]

Evidence and documentation of an internal sampling and testing plan must be provided to WVI.

4.12 Sample(s) for technical evaluation[21]

- Reference sample(s) of product(s) as intended to be supplied to WV for technical evaluation (1 carton).

[18] UNICEF Product Specification Standards, 2010
[19] WV encourages suppliers to start RUTF production directly in sachets. WV management of large order of RUTF packed in pots is not possible. Authorization of potted products will be done will be done on case-by-case basis.
[20] UNICEF Documents and Samples Standards, 2010
[21] UNICEF Documents and Samples Standards, 2010

4.13 Product registration[22]

The Supplier will be required to register product with the national authorities in WV programmatic countries in order to facilitate import and use of product.

5. Legal guidelines[23]

5.1 General Contract

The Supplier and the Manufacturer are responsible to fulfill all the terms and conditions in the General Contract.

5.2 Intellectual Property Infringement

The Supplier and Manufacturer warrant that the use or supply by WV of the goods sold under the Purchase Order does not infringe any patent, design, trade name or trademark. In addition the Supplier will, pursuant to this warrant, indemnify, defend and hold WV harmless from any actions or claims brought against WV pertaining to the alleged infringement of a patent, design, trade-name or trademark arising in connection with the goods sold under the applicable Purchase Order.

5.3 Payment in case of patent infringement

The Supplier and the Manufacturer will cover total cost of Goods to WV pursuant Purchase orders received during the term of future agreements in the event these are confiscated by the Authorities in the country of the final destination due to infringement of patent, design, trade-mark or trade-name.

6. WVI Nutrition Centre of Expertise contact

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loria_kulathungam@worldvision.ca
nutrition@wvi.org

Telephone: 905.565.6200 ext 3396 or 3867

All documents should be sent to:

Dr. Carolyn MacDonald, WVI Nutrition Director and Nutrition Centre of Expertise Lead
1 World Drive, Mississauga, Ontario CANADA L5T 2Y4

[22] UNICEF Product Specifications Standard, 2010
[23] UNICEF General Terms and Conditions of Contract, 2010

ANNEX 1

Technical Questionnaire for Food Manufacturers

To be completed and returned to World Vision International, Nutrition Centre of Expertise, 1 World Drive, Mississauga, ON, CANADA, L5T 2Y4, attn. Dr. Carolyn MacDonald with all requested documents attached.

1. GENERAL INFORMATION

Name, address, telephone, telefax, Internet address of the company:

2. AFFILIATES

If the company is owned by another company, or belongs to a group of companies, please indicate your position within the structure:

3. QUALITY SYSTEM

3.1. Good manufacturing practice

Indicate the standards (Codex Alimentarius, ISO, HACCP or other) with which the company complies and attach a copy of the quality compliance certificates:

3.2. Manufacturing authorisation for food products

Please indicate if you are licensed to manufacture food by a National Authority and attach a copy of the Authorisation:

3.3. Inspection – is an audit included in here.

Date of last inspection by the National Authority (if applicable):

Please attach a copy of the last inspection report (with an English translation) if it can be made available for review by WV and/or UNICEF on a confidential basis.

Have other Authorities / Organisations inspected the company?

Please attach a copy of the last inspection report if it can be made available for review by WV on a confidential basis.

3.4. Personnel

Please indicate the name and the education of the following key staff:

Managing director:

Production Manager:

Quality Control Manager:

Number of personnel in total:

Number of personnel in production:

Number of personnel in quality control:

4. MANUFACTURING

4.1. Manufacturing site

Please state all addresses at which manufacturing of food products take place, and indicate which year the factory was built:

4.2. Ventilation system

Please indicate whether the manufacturing areas are equipped with controlled ventilation systems

Yes No

4.3. Quality Control

Chemical laboratory in-house contracted out

Microbiological laboratory in-house contracted out

4.4. Contract manufacture

Please indicate if you undertake contract manufacture for other companies:

Yes No

Do you subcontract to other companies?

Yes No

If yes, please list products and/or services:

4.5. Complaints / Recalls

Do you have a complaint / recall procedure

Yes No

Please indicate significant product complaints and any recalls the last three years:

4.6. Research and development activities

Please indicate the type of activities and annual investment

4.7. Production capacity

State annual production capacity in current calendar year in MT.

_____

Is production capacity based on one or more shifts?

_____

State foreseen annual production capacity in current calendar year in MT.

_____

5. AUDIT

Can a representative designated by World Vision and/or UNICEF perform an audit of the Manufacturing site?

For new companies:

When will your manufacturing site be ready for a representative designated by World Vision and/or UNICEF perform an audit?

6. OTHER INFORMATION

Contact person:

Add any other information:

I hereby certify that the information given in this questionnaire and the attachments is correct

Date and signature:

ANNEX 2

Product Specifications[24]

Item Name:
Ready-to-Use Therapeutic Food (RUTF) - Therapeutic spread 92g sachets/CAR-150

General Description:

Ready-to-use therapeutic food is high energy, fortified food, suitable for the treatment of children with severe acute malnutrition. This food should be soft or crushable and should be easy for young children to eat without any preparation, preferably packed for a one-time/daily consumption basis, to minimise between-feeds contamination.

Texture

The RUTF should have a smooth homogeneous finish and should be free of lumps; the oil should not separate and be free of a gritty, grainy, and sandy texture.

Flavour and odour

The RUTF should have a pleasing sweet, clean dairy flavour and odour. The product should be free from foreign odours and flavours such as, but not limited to, burnt, scorched, rancid, malted, sour, or stale.

Colour

The RUTF should have yellow, light brown to brown colour. The product should not have a dull, grey tinge, or other abnormal cast. The finished product should show no evidence of excessive heating (materially darkened or scorched).

Foreign material

The RUTF should be clean, sound, wholesome, and free from evidence of rodent or insect infestation.

Stability

The emulsion of the product should be stable at temperatures ranging from -15° to 49°C with no evidence of separation throughout the shelf life of the product.

[24] UNICEF Product Specification Standards, 2010

Technical Specifications:

Nutritional composition per 100g of food:

Energy	520 - 550 Kcal
Proteins	10% - 12% of total energy

(At least half of the proteins contained in the foods should be derived from milk products.)

Lipids	45% - 60% of total energy
- n-6 fatty acids	3% - 10% of total energy
- n-3 fatty acids	0.3% - 2.5% of total energy

Minerals

- Sodium	290 mg maximum
- Potassium	1100 - 1400 mg
- Calcium	300 - 600 mg
- Phosphorus (excluding phytate)	300 - 600 mg
- Magnesium	80 - 140 mg
- Iron	10 - 14 mg
- Zinc	11 - 14 mg
- Copper	1.4 - 1.8 mg
- Selenium	20 - 40 µg
- Iodine	70 - 140 µg

Vitamins

- Vitamin A	0.8-1.2 mg
- Vitamin D	15-20 µg
- Vitamin E	> 20 mg
- Vitamin K	15-30 µg
- Vitamin B1	> 0.5 mg
- Vitamin B2	> 1.6 mg
- Vitamin C	> 50 mg
- Vitamin B6	> 0.6 mg
- Vitamin B12	> 1.6 µg
- Folic acid	> 200 µg
- Niacin	> 5.0 mg
- Pantothenic acid	> 3.0 mg
- Biotin	> 60 µg

Moisture content	2.5% maximum

Guidance on chemical forms of vitamins and minerals

Mineral/Vitamin	Mineral/Vitamin forms		
	Preferred	**Can be used**	**Not suitable**
Iron	Ferrous sulphate	Ferrous fumarate	Ferric pyrophosphate
	NaFe EDTA	Coated ferrous fumarate Coated ferrous sulphate Ferrous gluconate	Elemental iron
Zinc	Zinc sulphate	Zinc oxide	Zinc acetate Zinc citrate
Copper	Copper sulphate		Copper oxide
Iodine **Potassium**	Potassium iodide Potassium chloride		Potassium iodate Potassium phosphate
Magnesium	Magnesium sulphate	Magnesium citrate Magnesium gluconate	
Calcium **Phosphorus**	Dicalcium phosphate	Tricalcium phosphate	Calcium carbonate Monocalcium phosphate
Maganese	Maganese sulphate	Manganese Gluconate	
Selenium	Sodium selenite Sodium selenate		
Vitamin A	Dry retinyl acetate Dry retinyl palmitate		
Vitamin D	Dry cholecalciferol D3 sd		
Vitamin E	Dry DL-α tocopherol acetate 50%		
Vitamin K	Dry phylloquinone 5%		
Vitamin B1	Thiamine mononitrate Thiamine hydrochloride		
Vitamin B2	Riboflavin		
Vitamin B6	Pyridoxine hydrochloride		
Niacin B3	Niacinamide		
Folic Acid B9	Pteroyl monoglutamic acid		
Vitamin B12	Cyanocobalamin 0.1% sd	Cyanocobalamin 1% sd	
Vitamin C	L-Ascorbic acid fine powder	Sodium ascorbate	
Panthothenic acid B5	Calcium d-panthothenate		
Biotin B7	Biotin		

Special requirements:

1. Safety:

The food should be free from objectionable matter. It must not contain any substance originating from micro-organisms or any other poisonous or deleterious substances, including anti nutritional factors, heavy metals or pesticides in amounts that may represent a hazard to health, and with limits as detailed below:

- Aflatoxin level — 5 ppb maximum
- Salmonella — negative in 25g
- Enterobacteriaceae — below 10 cfu in 1 g

Maximum acceptable level for lead contamination is < 0.1 mg/kg (finished product).

ANNEX 3

Analytical Requirements

Unless otherwise specified in the future Purchase Orders the analytical and microbiological requirements for each batch of supplied RUTF should be as follows:

Test	Tolerance
Energy	520-550 kilocalories/100g
Protein	10-12 % of kilocalories/100g
Lipids	45-60% of kilocalories/100g
- n-6 fatty acids	3% - 10% of total energy
- n-3 fatty acids	0.3% - 2.5% of total energy
Water activity (A_w)	Less than 0.60
Micro-organism content	Maximum 10,000 CFU (Colony Forming Units) in 1g
Aflatoxin	Maximum 5 ppb (parts per billion)[25]
Salmonella	Negative in 25g (to be tested in 25 samples)
Enetrobacteriaceae below 100cfu - acceptable)	Below 10cfu in 1g (to be tested in 10 samples, 2 samples

Certificate of analysis:

The Certificate of Analysis for each batch of product should provide test results of representative tracer in the finished product for at least one mineral and one vitamin like:

Vitamin A	Not more than 125.0 per cent and not less than 75.0 per cent as stated on label
Vitamin B_1	Not more than 125.0 per cent and not less than 75.0 per cent as stated on label
Vitamin C	Not more than 125.0 per cent and not less than 75.0 per cent as stated on label
Iron	Not more than stated on label
Zinc	Not more than stated on label

Batch analysis frequency plan:

A complete batch analysis of the product depending on the production capacity and WV order frequency should be provided under the following guidelines:

- Once a year for a total annual production of less than 1,000 MT
- Every six months for an annual production between 1,000 MT–2,000 MT
- Every three months for an annual production between 2,000 MT–12,000 MT
- Every month for an annual production above 12,000 MT

Pesticides, radioactivity and heavy metal contamination should be checked in the finished product once a year. However, WV can require more frequent testing.

More frequent testing may also be needed in the start-up phase in order to document that the product comply with the finished product specification. New producers should submit complete analysis every three months. Once reliability has been established the frequency of testing can be decreased to every six months.

World Vision
health and nutrition

FOR FURTHER INFORMATION, PLEASE CONTACT:

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