Production of Ready-to-Use Food (RUF): An overview of the steps and challenges involved in the “local” production of RUF

Marie-Pierre Duclercq, Independent Consultant

(Case Studies supplied separately by Samil Industrial Co. and Valid Nutrition)

CMAM Forum Technical Brief, December 2014
Acknowledgments

We would like to thank the following individuals for their very helpful comments and input during the development of this brief: Jan Komrska and Alison Fleet (UNICEF), Odile Caron (MSF), Erwan Chapuis, Thibault Martenot, Mathilde Bridier, Thomas Couaillet and Mamane Zeilani (Nutriset), Omar Taha (Independent), Nicole Henretty, Heidi Reed and Tom Stehl (Edesia), Molly O’Connor (OFW Law), Lynnda Kiess (WFP), Mark Manary and Margo Stoner (Project Peanut Butter), Paul Murphy and Peter Akomo (Valid Nutrition), and Eman Abdalkarim (Samil). We would like to acknowledge especially the significant contribution of the case study authors from Valid Nutrition and Samil.

Thanks to Nicky Dent and Susan Fuller (CMAM Forum) for providing coordination, editing and technical input to the development of the technical brief.

Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACF</td>
<td>Action Contre la Faim</td>
</tr>
<tr>
<td>AUW</td>
<td>Ahfad University for Women</td>
</tr>
<tr>
<td>BPT</td>
<td>Business Profit Tax</td>
</tr>
<tr>
<td>CHAI</td>
<td>Clinton Health Access Initiative (previously known as the Clinton Foundation)</td>
</tr>
<tr>
<td>CID</td>
<td>Commercial Item Descriptions</td>
</tr>
<tr>
<td>CMAM</td>
<td>Community-based Management of Acute Malnutrition</td>
</tr>
<tr>
<td>CS</td>
<td>Cronobacter sakazakii (enterobacterium)</td>
</tr>
<tr>
<td>DFID</td>
<td>(UK) Department for International Development</td>
</tr>
<tr>
<td>ECHO</td>
<td>EU Humanitarian Aid and Civil Protection Department</td>
</tr>
<tr>
<td>EB</td>
<td>Enterobacterium</td>
</tr>
<tr>
<td>FAO</td>
<td>Food and Agriculture Organisation</td>
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<tr>
<td>GMP</td>
<td>Good Manufacturing Practices</td>
</tr>
<tr>
<td>HACCP</td>
<td>Hazard Analysis and Critical Control Points</td>
</tr>
<tr>
<td>ICRC</td>
<td>International Committee of the Red Cross and Red Crescent Societies</td>
</tr>
<tr>
<td>IRD</td>
<td>French Institute of Research (Institut de Recherche et Developpement)</td>
</tr>
<tr>
<td>LNS</td>
<td>Lipid-based Nutrient Supplement</td>
</tr>
<tr>
<td>LRP</td>
<td>Local and Regional Purchasing</td>
</tr>
<tr>
<td>LTA</td>
<td>Long-term Arrangement</td>
</tr>
<tr>
<td>MAM</td>
<td>Moderate Acute Malnutrition</td>
</tr>
<tr>
<td>MSF</td>
<td>Médecins Sans Frontières</td>
</tr>
<tr>
<td>MT</td>
<td>Metric Tonne</td>
</tr>
<tr>
<td>NGO</td>
<td>Non-Governmental Organisations</td>
</tr>
<tr>
<td>PFSCMS</td>
<td>Partners for Supply Chain Management</td>
</tr>
<tr>
<td>PPB</td>
<td>Project Peanut Butter</td>
</tr>
<tr>
<td>QA</td>
<td>Quality Assurance</td>
</tr>
<tr>
<td>RUF</td>
<td>Ready-to-Use Food</td>
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<tr>
<td>RUTF</td>
<td>Ready-to-Use Therapeutic Food</td>
</tr>
<tr>
<td>RUSF</td>
<td>Ready-to-Use Supplementary Food</td>
</tr>
<tr>
<td>SAM</td>
<td>Severe Acute Malnutrition</td>
</tr>
<tr>
<td>SME</td>
<td>Small and Medium-Sized Enterprise</td>
</tr>
<tr>
<td>UNGM</td>
<td>United Nations Global Marketplace</td>
</tr>
<tr>
<td>UNHCR</td>
<td>United Nations High Commissioner for Refugees</td>
</tr>
</tbody>
</table>
Acronyms and definitions:

CMAM - Community-based Management of Acute Malnutrition. CMAM is also known as Integrated Management of Acute Malnutrition (IMAM) or Community-based Therapeutic Care (CTC).

Ready-to-Use Food (RUF) - encompasses any food that is designed to be eaten straight from the packet, without the need for cooking, dilution, or other preparation. RUF is therefore an umbrella term to include the RUTF and RUSF categories defined below.

Ready-to-Use Therapeutic Food (RUTF) - contains all of the energy and nutrients necessary to allow for rapid catch-up growth and is used particularly in the treatment of children from 6 months of age with severe acute malnutrition who have appetite and no medical complications. The majority are lipid-based products based on a paste of peanuts, vegetable fat, sugar, dairy ingredients and micronutrient mix, with low risk of microbiological proliferation and a long shelf-life (e.g. Plumpy’Nut®, Eezeepaste-NUT™). RUTF can also be found in the form of biscuits (e.g. BP-100) where ingredients are compressed into a bar.¹

Ready-to-Use Supplementary Food (RUSF) - are similar in design to RUTF but are meant to provide only part of the daily energy and nutrient requirements. These are commonly in the form of pastes (e.g. Plumpy’Sup™, eeZeeRUSF™) and provide about 500 kcal in doses of 92-100g. RUSF is used in the treatment of moderate acute malnutrition (MAM) and may also be referred to as large quantity LNS (LQ-LNS).

Sometimes referred to as medium-quantity LNS (MQ-LNS),² products can be given in doses of around 50g per day (e.g. Plumpy’Doz™, eeZeeCup TM). These are more likely to be used for blanket targeting of young children (6-23 months) to prevent acute malnutrition.

Products given in doses of around 20g a day (e.g. Enov’Nutributter®), also referred to as small-quantity LNS (SQ-LNS), tend to be used for the prevention of micronutrient deficiencies and promotion of growth in home fortification programmes (especially during the 1000 days from conception to 24 months).

Lipid-based Nutrient Supplement (LNS) - encompasses products in which the majority of energy supplied is derived from fats. These products typically contain varying amounts of vegetable fat, milk powder, ground nuts or soya, sugar and micronutrient mixes. LNS therefore comprise some RUSF (Large Quantity LNS – LQ LNS, MQ, Medium Quantity LNS – MQ-LNS and Small Quantity LNS – SQ-LNS). They are becoming increasingly popular due to their efficacy in promoting growth and cognitive and motor development.³

¹ Production of biscuits or bars will not be covered in this document.
² Occasionally referred to as Ready-to-Use Complementary Food (RUCF)
³ See also International Lipid-based Nutrient Supplement Project (iLNS www.ilins.org). Their objective is to further develop the evidence base for use of LNS to prevent undernutrition in vulnerable populations incl. developing new LNS to enrich local diets.
### Table of Contents

**Acknowledgments** ............................................................................................................. 1  
**Abbreviations** .................................................................................................................... 1  
**Acronyms and definitions:** ................................................................................................. 2  
1 Introduction .......................................................................................................................... 5  

**PART ONE: Overview of Current Situation** ..................................................................... 7  
2 Overview ................................................................................................................................ 7  
2.1 Defining RUTF .................................................................................................................... 7  
2.2 Brief History of Development ............................................................................................ 7  
2.3 Different Scales of Local Production ................................................................................ 8  

3 Product Specification ............................................................................................................. 8  
3.1 Specifications and Codex Alimentarius ............................................................................. 8  
3.2 Nutritional Requirements ................................................................................................... 9  
3.3 Microbiological Testing ...................................................................................................... 9  
3.4 Contaminants .................................................................................................................... 10  

4 Quality Assurance Requirements ......................................................................................... 11  
4.1 Guidance for Low Moisture Foods .................................................................................. 11  
4.2 Traceability ....................................................................................................................... 11  
4.3 Coefficient of Variation and Analytical Plan .................................................................... 11  
4.4 Stability Study and Shelf Life ........................................................................................... 12  
4.5 Labelling of RUF ............................................................................................................... 12  

5 Manufacturing Process ......................................................................................................... 12  

6 Producers’ Validation Process .............................................................................................. 13  

7 Registration of RUTF ........................................................................................................... 13  

8 Procurement of RUTF .......................................................................................................... 14  
8.1 Role of UNICEF ................................................................................................................ 14  
8.2 Role of WFP ...................................................................................................................... 16  
8.3 Role of Other Purchasers .................................................................................................. 16  
8.4 Role of US Governmental Organisations ......................................................................... 16  

9 Setting up a Local Production Facility .................................................................................. 17  
9.1 Feasibility Study .............................................................................................................. 17  
9.2 Initial Set-up Costs ............................................................................................................ 18  

10 Why is Local Production Often More Expensive than Offshore Production? ................ 19  

**PART TWO: Way Ahead** ................................................................................................... 20  
11 Challenges and Recommendations ................................................................................. 20  
11.1 Promoting and Improving Local Agricultural Supply Chain Streams.......................... 20  
11.2 Creating a Specific Legal Status for RUF/Tax Exemptions Locally ................................ 21  
11.3 Raising Awareness to Increase Local Purchasing ............................................................ 22  
11.4 Better Forecasting of Demand and Improving the Supply Chain ................................... 22  
11.5 Improving Access to Finance ......................................................................................... 24  
11.6 Defining International Standards for RUTF and Other RUF ......................................... 24  
11.7 Investing in Laboratories’ Capacities Locally .................................................................. 24  

12 Sustainability of the Local Production Model ................................................................. 25  
12.1 Quality level chosen for RUF products ......................................................................... 25  
12.2 Diversification of product, customer and distribution channel ...................................... 25  
12.3 Improving long-term funding for CMAM scale-up ......................................................... 26  

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diets, investigating efficacy in improving child growth, health and development and improving nutritional status of pregnant and lactating women and their infants. They are also exploring potential delivery systems and their cost-effectiveness.
12.4 Competition with offshore producers.................................................................................27
13 Ongoing Research Related to RUF ......................................................................................27
PART THREE: Case Studies of Local Production Experience ..................................................29
14 Case Studies ..........................................................................................................................29
  14.1 Samil Industrial Co. ...........................................................................................................29
  14.2 Valid Nutrition – Malawi ...................................................................................................31
15 Conclusion ..............................................................................................................................34
References ..................................................................................................................................35

Appendix 1: History of the Cronobacter Sakazakii (CS) Crisis in 2012/2013.................................37
Appendix 2: Sampling Plan........................................................................................................37
Appendix 3: Items Described in RUF Specifications ..................................................................38
Appendix 4: Example of a Manufacturing Flow Diagram of RUF ............................................38
Appendix 5: Validation of New Producers ................................................................................38
  5a UNICEF Validation Procedures (Summary) .......................................................................39
  5b: MSF Procedure for the Validation of Product/Manufacturer (Summary) .........................39
Appendix 6: UNICEF RUTF Paste Supplier Base in 2014..........................................................41
Appendix 7: Partnerships for Local Production .........................................................................42

Tables
Table 1: Evolution of RUTF safety requirements (finished product testing), 2007-2014 .............10

Figures
Figure 1: UNICEF RUTF purchases and number of countries ordering, 2005-2014 ...............15
Figure 2: UNICEF RUTF sourcing in programme and non-programme countries, December 2014 ....15
Figure 3: Average price per MT of RUTF (in USD): local price versus landed cost for sea shipment, July 2014 .........................................................................................................................20
Figure 4: RUTF forecast versus orders since 2009, January 2014 ...........................................23
1 Introduction

Over the past decade Community-based Management of Acute Malnutrition (CMAM) has been adopted by over 60 countries to help treat acute malnutrition in children under five and reduce childhood mortality. A rapid expansion in coverage occurred since CMAM’s initial piloting in 2000, followed by the 2007 Joint Statement on Community-based Management of Severe Acute Malnutrition released by the United Nations Children’s Fund (UNICEF), the World Food Programme (WFP), the World Health Organisation (WHO) and the United Nations Standing Committee on Nutrition (UNSCN). In this document the use of Ready-to-Use Therapeutic Foods (RUTF) was recommended to treat children with severe acute malnutrition (SAM) with appetite and without complications through an outpatient-based approach. Recently a number of similar products known as Ready-to-Use Foods (RUF) or Lipid-based Nutrient Supplements (LNS) have been developed, directed at treating and/or preventing moderate acute malnutrition (MAM) or for preventing micronutrient deficiencies or stunting.

Today, RUF is produced by several private enterprises and not-for-profit organisations, based in Europe, the United States (US), and in a number of developing countries, usually close to where CMAM services are already in place. The term “local producers” is used to refer to food processing companies that manufacture RUF in developing or “programmatic” countries where malnutrition rates are high. They aim at using as many local inputs as possible, but also rely on imported raw materials, expertise and equipment, and often must also outsource services, such as laboratory testing that are not available locally. The local producers can manufacture finished products not only for their own countries, but also for export. While there is no common definition for “production in programmatic countries,” this technical brief will use “local production” to refer to the manufacturing of RUF in the country or region where it will be used and “offshore production” for manufacturing in developed countries. It should be noted that specifications and requirements are the same for both.

In an ideal world, increasing local production of RUF would help reduce the associated supply challenges, costs, lead times on delivery, and stimulate local economies through the transfer of skills and the use of local agricultural products, thereby increasing social impacts and sustainability. Many questions have been raised about the challenges that local factories face and, despite willingness to increase local production of RUF, production levels remain relatively low.

Scope

This technical brief is divided into three sections. Section 1 seeks to provide an overview of the steps involved in production of RUF and quality requirements producers must meet in order to supply product for use in services for treating or preventing malnutrition. Section 2 discusses the identified constraints influencing quality and price, and raises questions about the sustainability of the model of local RUF production as it currently stands. Case studies of common challenges experienced by local producers will complement the first two sections in Part 3.

Whilst this technical brief covers RUF, the majority of experience in local production to date has centred on RUTF products. It will therefore make frequent references to RUTF production, which uses similar manufacturing procedures to other RUF products. The focus is on lipid-based (paste) products only.

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iv Although India and South Africa are counted as a “local producing country” at the current time the main focus is for export.
Why this technical brief?

Information outlining the complexities of local production was identified at the 2011 Addis Ababa “Government experience of scaling up CMAM” conference as an area about which many government officials would like more information:

“Governments also need clear policies on national production of RUTF where feasible, which can lead to new partnerships with manufacturers, tax-dispensations for RUTF production, import exemptions and other cost-reducing measures to make RUTF more affordable and locally or regionally available. . .” Often governments prefer to have production in their own countries or regions rather than importing products, due to both ownership/country involvement and control and sustainability, however their policies often do not facilitate local manufacturing. There is also the perception - currently not the reality - that in-country production will be cheaper.

Many non-governmental organisations (NGOs) – involved in both purchase and use of RUF – have requested greater understanding of production procedures to facilitate local purchase and provide confidence in the quality and control mechanisms for local production, especially following issues related to product quality in 2012 (issues that affected all producers, local and offshore, see Appendix 1). Similarly, donors who fund RUF in both emergency and long-term frameworks would benefit from a wider understanding of the current situation.

A final audience for this technical brief is potential producers, many of whom approach existing producers and purchasers to request information about the steps involved in manufacturing RUF.

NOTE: This is not intended as a guidance document but to provide background information. “Local production” is a rapidly evolving field at the current time and if more details on specifications and manufacturing procedures are required, it is advised to go directly to the online products’ specification or other documents outlined in this brief.
PART ONE: Overview of Current Situation

2 Overview

2.1 Defining RUTF

RUTF is a soft, malleable therapeutic food that can be easily consumed. RUTF does not need to be reconstituted with water and can be safely used at home or at the primary health care level without refrigeration or prior preparation, making it practical for use in environments where resources are limited. RUTF was designed to meet the same nutritional composition as the therapeutic milk F-100, which is typically only consumed by inpatients at the hospital level as it requires reconstitution with clean water and rapid consumption. Prior to the development and use of RUTF, children diagnosed with SAM had no other recourse than to be admitted to hospital as inpatients and treated with therapeutic milk over an extended period (several weeks), with a need for a carer to stay full time. RUTF has changed the way to treat SAM, allowing a home-based treatment.

Currently, RUTF comes in two forms: RUTF paste and RUTF biscuits/bars. The energy-dense micronutrient paste is based on a mixture of peanuts, sugar, vegetable oils, dairy products and a vitamin and mineral premix. The manufacturing process for RUTF paste must ensure that all of the nutritional and chemical properties of the various ingredients are preserved for an extended time without any adverse effects to the quality of the finished product (shelf life of up to 24 months).

2.2 Brief History of Development

Plumpy’Nut® (a brand name owned by Nutriset, a French company) is the most commonly used commercial RUTF available in a peanut paste form, and was the first RUTF to be developed and patented jointly by the French Institute of Research (IRD) and Nutriset, France, in 1996. Since then, almost twenty producers of RUTF exist throughout the world, with an increasing number of producers in developing countries.

In the early 2000s there were a few small-scale attempts to localise production of RUTF, primarily in Africa. These projects were implemented and piloted by several actors, including: Nutriset, Valid International, Project Peanut Butter, and other community-based organisations or international NGOs that sought to establish production units to fulfil their own needs. However insufficient demand hindered project sustainability and most production units were unable to develop to scale. Regardless of the ultimate aim, these small-scale community-based initiatives served to demonstrate some of the potential advantages of in country production as well as some of the difficulties associated with consistently achieving acceptable quality standards. In 2005, local production facilities were scaled-up in Niger, Malawi, and DRC, many with support from Nutriset (within the PlumpyField network).

Nutriset provided a non-exclusive license to Valid Nutrition in 2007, allowing them to produce products legally, without infringing on the established patent. In 2010, Nutriset and the IRD opened access to the patent to any local production of RUTF, subject to certain criteria and payment of a patent usage fee to IRD (Nutriset had chosen not to seek any form of compensation), set at 1% of the turnover earned by the sale of the finished products. The Patent Usage Agreement is an agreement by which Nutriset licences a company or organisation to produce, market, and distribute products covered by the patents co-owned by Nutriset and the IRD. Producers located in developing countries where the Nutriset/IRD patent is in effect (i.e. 25 African countries), and wishing to produce RUTF, can now do so provided their

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vi Biscuits are occasionally mixed with water to make a porridge for younger children. They will not be covered in this document.

vii Now Valid Nutrition – the side of Valid dedicated to product development.
organisational structure meets certain criteria and characteristics. The decision to facilitate access to licenses for local producers was therefore formalised and made accessible online in 2010 and currently there are ten beneficiaries of the Usage Agreement located in six countries; Mali, Sierra Leone, Kenya, Chad, Malawi and Senegal. Nutriset/IRD made the decision to restrict access to these licenses to groups in developed countries, apart from Edesia, a non-profit organisation based in the United States (US) (a member of the PlumpyField network), to preserve and protect local production in developing countries.

2.3 Different Scales of Local Production

Local RUF purchased by UN agencies and NGOs are currently made by Small and Medium-sized Enterprises (SME) and not-for-profit organisations. RUF production occurs in plants of different sizes, some are fully dedicated to RUF production, while others also produce other processed foods. Small-scale local production (manual/handmade production) of RUF still exists, with a few NGOs fulfilling their own needs, but at significant cost and at their own risk. It has proven difficult for these small, community-based facilities to conform to the international quality standards for RUTF, and the cost of finished product will generally always be much higher than larger scale, industrial production.

3 Product Specification

3.1 Specifications and Codex Alimentarius

The first specification for RUTF was proposed in the technical annex of the Joint Statement issued in 2007. Specifications for RUTF have evolved since this, and the local production model has changed accordingly over the years. Local and international producers alike have continuously improved the quality of their products. The main changes in specifications have been in microbiological parameters, as well as packaging and labelling.

The purchasing agencies write their specification for finished products, based on the joint statement, technical knowledge and international guidance (such as codex alimentarius). There is some interagency collaboration (between UNICEF, MSF and WFP) to try to have common specifications. UNICEF and MSF full specifications for RUTF and RUSF are not currently available online but can be provided upon request. Available online are WFP specifications for LNS and Commercial Item Descriptions (CIDs) or specifications for USAID RUTF and RUSF.

However current specifications do not provide an official, international standard for countries to follow and governments have raised questions about what is an appropriate reference for imported or locally produced RUF to facilitate local regulation and encourage allocation of national budgets to these products. A key development, therefore, is that UNICEF has recently requested the Codex Alimentarius Committee to establish standards for RUF for the management of malnourished children:

“development of a codex standard for RUTF and RUSF will prove a reference for manufacturers, purchasers and government regulatory authorities to follow and provide the needed framework for the supply of consistently safe and nutritionally appropriate emergency food aid products across national borders.”

vii “License holders should be companies in the private or the public sector or NGOs with proven track records of manufacturing experience and whose head offices and principal shareholders are based in developing countries” (Nutriset).

viii This will change soon for MSF.

ix While WFP tend to refer to products using the term LNS (small, medium and large-quantity LNS) the generic RUSF term is used in this technical brief for simplicity.
Different codex documents will cover RUF, including nutritional composition (possibly with appropriate minimum and maximum ranges), the hygienic practices for production, and the acceptable contaminant limits (particularly aflatoxins). The discussion paper on the proposal for a standard for RUF is available online, and was presented to the Codex Committee on Nutrition and Foods for Special Dietary Uses at the end of 2014. The President of the 36th session noted that it was premature to decide on the development of a Codex standard or guideline for RUF and requested UNICEF to prepare a revised draft project document, with the support of the Government of Senegal, to be presented at the next session in November 2015 (but RUF will be included in the annex of the Codex on Food Hygiene). When agreement is reached, standards are likely to be agreed and released in around 5 years’ time and would be relevant for existing and new products.

3.2 Nutritional Requirements

**Nutritional requirements for RUTF:**
Most agencies use the nutritional properties specified in the technical annex of the 2007 Joint Statement on Community-based Management of Acute Malnutrition.

**Nutritional requirements for RUSF:**
Table 1 of the Technical note: Supplementary foods for the management of moderate acute malnutrition in infants and children 6–59 months of age, issued by WHO in 2012, describes the nutritional specifications for RUSF (or LNS LQ).

3.3 Microbiological Testing

The microbial specification listed in the 2007 Joint Statement has been superseded by new, more detailed purchasers’ specifications. The Joint Statement required that the product comply with the recommended International Code of Hygienic Practice for Foods for Infants and Children of the Codex Alimentarius Standard CAC/RCP 21-1979. However, in 2008, this was replaced by the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008). This did not detail how these standards should be applied to RUTF and RUSF production and was not adapted to the fat matrix and use of RUF as it was specific to powdered infant formulae. However manufacturing of RUF was required to comply with this code. The composition (low water activity \( a_w \)) and the method of consumption of RUF (ready to eat without reconstitution or preparation) are not likely to introduce the same risks as the consumption of powdered infant formulae. The change in recommended code led to supply chain issues related to *cronobacter sakazakii* detection in 2012 (an enterobacterium (EB) covered under the new specifications - see Appendix 1) and a review of microbiological safety requirements was triggered as a response.

As the effect of this bacterium on malnourished children over 6 months of age was not known, this led to additional and systematic testing of all batches of finished products and a quantity of stock affected by this bacterium was quarantined or destroyed leading to subsequent stock outs for many programmes. In June 2012 UNICEF, in collaboration with WFP and MSF, requested experts from the Food and Agriculture Organisation (FAO) and WHO to review microbiological safety requirements for RUF, followed by an expert meeting held in December 2012. This concluded with an interim specification with specific focus on *Salmonella* and EB. This also highlighted the necessity to have a more stringent sampling plan, as the sampling plans used by manufacturers and purchasers when testing microbiological parameters were not deemed as appropriate.

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\(^{x}\) Covered by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU).

\(^{xi}\) Covered by the Codex Committee on Food Hygiene (CCFH).

\(^{xii}\) Covered by the Codex Committee on Contaminants in Foods (CCCF).
Based on FAO and WHO recommendations, UNICEF, WFP and MSF changed their specifications for microbiological parameters on RUF, and required more stringent microbiological testing plan on samples taken from ingredients, environment and the production line, with the establishment of a dynamic environmental monitoring programme.

Another expert meeting was held in early December 2014 by FAO/WHO, with new recommendations and specifications formalised and available by mid-2015. In the meantime, before they are issued, the specifications described in this technical brief are the “interim specifications” used by UNICEF.

Note: this table should not be taken as a reference as these requirements will shortly change once the WHO/FAO expert meeting recommendations are released in 2015, but are included here to help illustrate the changes in testing that producers were faced with and the more frequent sampling plans required.

Table 1: Evolution of RUTF safety requirements (finished product testing), 2007-2014

<table>
<thead>
<tr>
<th>Sources</th>
<th>Interim safety requirements (UNICEF specifications RUTF paste)</th>
<th>2007 UN Joint Statement on Community-based Management of Severe Acute Malnutrition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microorganism content</td>
<td>&lt;10,000 cfu in 1 g max</td>
<td>&lt;10,000 cfu in 1 g max</td>
</tr>
<tr>
<td>Coliform test</td>
<td>negative in 1 g</td>
<td>negative in 1 g</td>
</tr>
<tr>
<td>Yeast</td>
<td>maximum 10 cfu in 1 g</td>
<td>maximum 10 cfu in 1 g</td>
</tr>
<tr>
<td>Moulds</td>
<td>maximum 50 cfu in 1 g</td>
<td>maximum 50 cfu in 1 g</td>
</tr>
<tr>
<td>Cronobacter sakazakii</td>
<td>maximum 10 cfu in 1 g</td>
<td>Not requested</td>
</tr>
<tr>
<td>Clostridium perfringens</td>
<td>negative in 1 g</td>
<td>negative in 1 g</td>
</tr>
<tr>
<td>Pathogenic staphylococci</td>
<td>negative in 1 g</td>
<td>negative in 1 g</td>
</tr>
<tr>
<td>Salmonella</td>
<td>negative in 25 g (n=25)</td>
<td>negative in 125 g~</td>
</tr>
<tr>
<td>Listeria</td>
<td>negative in 25 g</td>
<td>negative in 25 g</td>
</tr>
<tr>
<td>E. coli</td>
<td>negative in 1 g</td>
<td>Not requested</td>
</tr>
<tr>
<td>Enterobacteriaceae (EB at 30°C)</td>
<td>maximum 10 cfu in 1 g (n=10)</td>
<td>Not requested</td>
</tr>
<tr>
<td>Total aflatoxin</td>
<td>maximum 5 ppb</td>
<td>maximum 5 ppb*</td>
</tr>
</tbody>
</table>

Cfu: colony forming unit  
ISO 17025 certified laboratories shall preferably be used  
~should be 25g not 125g as printed in original document  
*this is 10ppb in a revised version of the joint statement on the WHO website  
Note: WFP and MSF do not require the same number of tests as are listed in this table for product testing. Refer to purchasers’ specifications for more information.

The main change between 2007 and 2014 microbiological requirements was the adding of new tests and the analytical control plan\(^{xiii}\) for Salmonella and EB. In 2007, no sampling plan was requested. From 2013, a 2-class plan with 25 samples and a 3-class plan with 10 samples were requested for Salmonella and EB respectively (see Appendix 2), but again, this will change shortly to take into account FAO and WHO last expert meeting recommendations.

3.4 Contaminants

**Aflatoxins**

Aflatoxins contaminate staple foods, particularly maize and groundnuts, as a result of hot, humid cultivation and storage conditions that promote fungal growth. The risk is particularly high in Africa where the climate conditions allow their growth. To date, the toxicological effect of aflatoxin is widely recognised, with links to various health issues and underweight status in children hypothesised.\(^{14,15}\) Data are still missing to better understand what level of contamination in foods will induce underweight. An evaluation evaluation from the FAO\(^{16}\) also shows that to date, there are still many different levels in food contamination.

that are authorised for total aflatoxin, or aflatoxin B1, or both, according to different countries. Initially, the total aflatoxin limit for RUTF was set at 20 ppb (current maximum level for foods in some countries, including the US), and was later amended to a maximum of 5 ppb in 2007.\textsuperscript{xiv} WFP recently changed the maximum level for RUSF, from 5 ppb to 10 ppb. MSF and UNICEF did not however change their specification for aflatoxin in RUTF. However this upper limit has been questioned as it remains difficult to reach such low levels of contamination in developing countries.

Other contaminants
The current specifications for other contaminants such as pesticides, heavy metals, radioactivity, melamine, are under discussion for a revision.

The specifications also list other items including standards relating to stability/shelf life, packing materials (sachet and carton) and documentation, and presence of contaminants such as heavy metals and melamine. See Appendix 3.

4 Quality Assurance Requirements

4.1 Guidance for Low Moisture Foods
RUF must be manufactured in accordance with the Codex Alimentarius for low moisture foods, ISO 22 000:2005 (Food Safety Management Systems)\textsuperscript{17} and Hazard Analysis and Critical Control Points (HACCP)\textsuperscript{xv} principles: “Food safety is related to the presence of food-borne hazards in food at the point of consumption (intake by the consumer). As the introduction of food safety hazards can occur at any stage of the food chain, adequate control throughout the food chain is essential. Thus, food safety is ensured through the combined efforts of all the parties participating in the food chain..... Hazard analysis is the key to an effective food safety management system, since conducting a hazard analysis assists in organizing the knowledge required to establish an effective combination of control measures.”\textsuperscript{17}

Detailed information about how to exclude moisture from the environment to the extent possible, in order to prevent growth and minimize the likelihood of a pathogen established in the environment, can be found in the draft Codex of low moisture foods. It should be noted that more intensive “environmental screening” using special swabs from high risk areas is becoming increasingly recommended.

4.2 Traceability
A complete traceability system must be in place: for every batch number, the producer must be able to find all the history of the finished products (composition, raw materials used, processing parameters, analytical results, quantity produced and dispatched, customers’ sites receiving deliveries, etc).

4.3 Coefficient of Variation and Analytical Plan
To ensure batches of product are adequately mixed, a method has been proposed by WFP to calculate “the coefficient of variation” to show the concentration of certain minerals (eg. iron or zinc). The value should be as low as possible and always <10. Refer to the WFP site for more information.\textsuperscript{18}

Producers are responsible to elaborate their own analytical plan for the finished product. All analytical test procedures must be described in sufficient detail, including analysis methods. Purchasers follow their own respective control plans to test finished products: for example since 2013, UNICEF established

\textsuperscript{xiv} Although it appeared that in 2011, the maximum aflatoxin level for RUTF was revised to 10 ppb by WHO.

\textsuperscript{xv} HACCP is an internationally recognised and recommended system of food safety management. See \url{http://www.fda.gov/Food/GuidanceRegulation/HACCP/}
compulsory pre-delivery inspections, selecting samples of finished products for testing purposes (salmonella and EB analysis) before allowing the release of shipments. This additional lead time for obtaining results has a significant financial impact due to the immobilisation of finished products awaiting release and thus working capital is tied-up.

4.4 Stability Study and Shelf Life
A stability study should be conducted on the final product (for each formula) in its packaging to confirm shelf life and storage conditions and information is included in purchaser specifications.

4.5 Labelling of RUF
Labelling requirements for RUF have also changed recently. With the increase of producers over recent years, it was not uncommon to find different brands of RUF being distributed within the same operational environment and sometimes to the same affected populations, potentially confusing both communities and the implementing agencies. With the goal of facilitating efficient delivery of CMAM services, UNICEF and MSF worked together on a common design with the objective of ensuring a generic RUTF packaging scheme. Suppliers now have to follow strict labelling guidelines on sachets, with a small “supplier zone” area (less than 20% of the sachet) where they can include their logo and other pertinent information. The current designs – which may well change again – can be found in purchasers’ specifications.

Labelling requirements for RUSF/LNS products will also soon follow suit with different colour schemes and messages to help differentiate between products (red for treatment of SAM, orange for treatment of MAM, yellow for prevention of MAM).

5 Manufacturing Process
This document does not go into detail about the manufacturing process, manufacturing equipment, zoning principles, raw material specifications, raw material sources etc. Some items are listed in section 9.2: “initial set up costs” and more details can be found:
- in the Codex discussion document annexes, including a figure of thermo-processing system for the manufacture of RUF with a “kill-step” of high temperature to reduce minimum pathogen survival.
- in the purchasers’ specifications.

An example of a manufacturing flow diagram of RUF can be found in Appendix 4.

A key point of discussion in RUF production currently is how to eliminate all the bacteria to avoid contaminants in raw materials and environment being transferred to finished product. While some producers are implementing ways to ensure the temperature reached during the RUTF manufacturing process is higher to kill the bacteria (potentially difficult in countries with erratic electricity and high humidity), other producers are concentrating on working with raw materials suppliers and local farmers to improve the quality of the raw materials.

xvi Used by UNICEF in annex of Codex discussion document.
6 Producers’ Validation Process\textsuperscript{xvii}

In the absence of international standards and certifying bodies, UNICEF, MSF, and WFP developed product specifications for RUTF and RUSF and took the responsibility of validating producers according to each agency’s procurement strategy and using the quality assurance documents listed in section 4.\textsuperscript{xviii}

The validation process is the same for local producers as for off shore producers. The three aforementioned agencies work in collaboration and have established agreed-upon minimum references for the audit or inspection of production facilities. The availability of inspectors to visit new potential suppliers was often challenging, but sharing of inspection reports helped facilitate the validation process. However, even though the three agencies agreed to use the same set of criteria for inspection and the same documentation to request primary information from producers (Interagency Manufacturer Quality Questionnaire\textsuperscript{21} and Interagency Product Questionnaire),\textsuperscript{22} each organisation makes its final decision on validation by themselves. UNICEF’s and MSF’s validation procedures are outlined in Appendix 5.

It should be noted that the other organisations that purchase directly from RUF producers (foundations, NGOs, donor agencies, etc.) have adopted UNICEF/WFP/MSF validation as a standard pre-requisite. This reliance on UNICEF, WFP, or MSF endorsement prior to purchasing can be challenging for a new producer trying to enter the market.

7 Registration of RUTF

Registration and legal classification of RUTF vary by country. Depending on the country, RUTF can be registered as a food, medicine\textsuperscript{ix} or an essential supply. The importance of registering RUF as an essential supply/commodity to allow easier integration into national supply (easier clearance of supplies at port, government storage at central medical stores, and government-led distribution and logistics) has been noted in some countries.\textsuperscript{23}

- In Ethiopia, it was initially felt that RUTF should be registered as a drug, but the complexity of this system and the national accreditation process developed for drug manufacturing proved prohibitive; therefore registration as an essential commodity was deemed more practical.
- In Ghana, there is a move to place RUTF on the national medicines list so that it can be included under the free-service programme for children under the age of 5 years, whereby costs are covered/reimbursed by the national health insurance system.
- In Kenya, RUTF is registered as a food.
- In Sierra Leone, RUTF has been placed on the essential drugs list so that CMAM can be included in the free health care initiative.
- In Tanzania, where it is registered as a medicine, RUTF is stored and distributed out of the country’s Central Medical Store.

The decision always needs to consider the local context. It should be noted that complications can arise from classifications that can create parallel distribution systems: in instances where RUTF is registered as a medicine and housed at the Central Medical Store, it may be distributed using different channels relative to RUSF, which would typically be classified as a food commodity and housed separately.

\textsuperscript{xvii} Validation by purchasers, this does not address validation by national authorities.
\textsuperscript{xviii} Codex Alimentarius, ISO 22 000:2005 (Food Safety Management Systems) and HACCP principles.
\textsuperscript{ix} In the Codex document RUF is classified as a food.
It is also important to distinguish registration requirements of locally made RUTF relative to imported RUTF. Locally made RUTF is always endorsed/registered in the country of manufacture by the relevant authorities (e.g. Tanzania Food and Drug Authority or the Federal MoH in Sudan), whereas imported RUTF is not always registered and typically entails the need to secure import authorisation.

8 Procurement of RUTF

8.1 Role of UNICEF

UNICEF remains the world’s major purchaser of RUTF. They report that RUTF production has grown from one producer in 2000 to 18 in 2014 and is expected to continue to rise. Among the RUTF producers (see Appendix 6):

- 11 are located in programmatic countries;
- 3 are based in countries with high malnutrition rates but without significant CMAM programming (two in India, one in South Africa) but mostly involved as of today with export to countries with CMAM;
- 4 are located in Europe and the US, with Nutriset in France still being the major producer and supplier of RUF.

Increasing the number of RUTF producers has been one of UNICEF’s priorities since 2004 as an outcome of the Sahel food emergency resulting in large RUTF orders, and overall increasing demand as more countries are offering CMAM services. Given this new demand, it also became increasingly important for UNICEF to identify new sources of RUTF to avoid any breaks in the supply chain and ensure the continuous implementation of programmes.

UNICEF’s annual RUTF procurement has increased from 6,000 metric tonnes (MT) in 2009 to 34,000 MT in 2013. Procurement in 2013 was sufficient to treat approximately 2.6 million children in 56 countries, covering about 15% of the estimated global caseload of SAM. The value of commodities procured by UNICEF from each producer can be found online in the UNICEF 2013 Supply Annual Report. The forecast for procurement in 2014 was 35,000 MT of RUTF, including 10,500 MT purchased by country offices (i.e. directly purchased from local producers).

Suppliers to UNICEF are chosen based on a competitive bidding process every one or two years. If awarded, a Long Term arrangement (LTA) is signed and includes details on what UNICEF expects the producer to have available in terms of estimated quantities, lead-time, and fixed price; but UNICEF is not obligated to make the forecasted purchases from the approved producer.

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xx These numbers are estimates provided by UNICEF based on their annual Global SAM Update but caution should be taken as they are likely an underestimation given low report rates and based on admissions; on average one box of 13.8 kg is used for a child to recover from an episode of SAM.

xxi Although the RUTF purchased is insufficient to address the global burden of acute malnutrition, the limiting factor is not typically production capacity, but issues such as access to services, coverage and funding. Also, 40% of SAM cases are estimated to be in India – which has not currently adopted a large-scale CMAM model or use RUTF, although small pilots are ongoing.

xxii Finally some 28,000 MT of RUTF was procured in 2014, which is less than planned and a decrease compared to 2013.
A key part of the UNICEF procurement strategy has been, and remains, the support of production in programmatic countries, particularly in Africa, in order to bring the manufacturing closer to the beneficiaries and reduce delivery lead times. UNICEF has publically stated that its objective is to source 50% of RUTF in programmatic countries by 2017. In 2012, procurement of RUTF in programmatic countries by UNICEF country offices reached almost 47% of UNICEF’s total procurement (see figure 2 below). This dropped dramatically to 22% in 2013, largely due to increased quality requirements described earlier. While changes in international standards lead to issues and challenges for all producers, meeting new specifications within a short timeframe poses more challenges to local producers.
8.2 Role of WFP

WFP has also become a major purchaser of RUSF, used for preventative or supplementary programmes for MAM. WFP began purchasing RUSF in 2009, starting with 2,125 MT and increasing to 19,218 MT in 2013. WFP currently has five suppliers validated for international procurement and four suppliers validated for local procurement. Approximately 73% of WFP purchase is from France or the US. In 2013, 72% of children from 6 to 23 months of age in WFP nutrition programmes received either RUF or Super Cereal Plus.

In the past, WFP mainly procured through weekly/monthly bid solicitations. More recently, WFP has started long-term stocking contracts with producers. Currently, WFP typically orders large quantities with a short notice that many local producers are not able to produce in the required timing on such a tight schedule, reducing their ability to supply to WFP.

8.3 Role of Other Purchasers

Whereas UNICEF and WFP remain the main purchasers of RUF, there are a number of other organisations purchasing these products, including the Clinton Health Access Initiative (CHAI) (previously known as the Clinton Foundation), the United Nations High Commissioner for Refugees (UNHCR), the International Committee of the Red Cross and Red Crescent Societies (ICRC), international NGOs such as Médecins Sans Frontières (MSF), Action Contre la Faim (ACF), Concern or Save the Children, as well as US-based stakeholders (e.g. Partners for Supply Chain Management System). More and more importers and distributors (or traders) are also involved in the procurement process and a few governments are directly purchasing RUTF as well, for instance governments in Botswana, Malawi, Zambia and the Kebbi state of Nigeria procure RUTF through UNICEF.

Most of the international NGOs receive the product from donation from UNICEF and WFP. Donations represent 80% of the quantity distributed by MSF.

8.4 Role of US Governmental Organisations

RUTF production in the US has increased significantly since 2008. The US government is a new player in the RUF sector although American food aid policy has long been a very strong influence in the world of international food aid. In 2011, the United States Agency for International Development (USAID) through the Department of Agriculture (USDA) added RUTF and RUSF to their Title II list of commodities approved for use in USAID Food for Peace-funded programmes.

Commodities on the Title II list are required to come from suppliers with facilities based in the US, and using all US-sourced ingredients. These products are donated in-kind to UN agencies (respectively UNICEF for RUTF and WFP for RUSF) and potentially other US NGOs benefiting from title II. US RUF are currently manufactured by three US producers, namely Edesia (part of the PlumpyField network), Mana Nutritive Aid Products Inc. (MANA), and Tabatchnik Fine Foods Inc. USAID strives to cover an estimated 10% of UNICEF and WFP annual procurements, which is typically in the last two to three years around 3,000-5,000 MT per year each. According to UNICEF these donations cover urgent gaps and are used in countries that lack sufficient financing.

Another change to US procurement of food aid in recent years is the authorisation of the USDA Local and Regional Food Aid Procurement Pilot Project. The project was piloted for the first time through authority of the 2008 Farm Bill with the primary purpose to use local and regional procurement (LRP) to

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xxii While WFP tend to refer to products using the term LNS (small, medium and large-quantity LNS) the generic RUSF term is used in this technical brief for simplicity.

xxiv WFP personal communication.
meet urgent food needs due to disasters, and to examine the timeliness and efficiency of procurement in developing countries. In the 2014 Farm Bill, the US Congress made the USDA LRP programme permanent, and allocated funding up to $80 million per year, however the initiative has yet to be funded through appropriations (public funds). The pilot focused on the procurement of raw agricultural commodities, and did not include fortified or processed foods. However, RUF could ultimately be covered by the programme.

9 Setting up a Local Production Facility

9.1 Feasibility Study

“In order for CMAM to gain a footing in a country and begin to expand, a major RUTF benefactor has been required. In most countries this has been UNICEF or the Clinton Foundation. Currently in 73% of countries with CMAM programmes, UNICEF provides 100% of RUTF.” Before setting up a local production facility, a feasibility assessment, including a business plan, is recommended in order to determine viability. Evaluation of the demand through estimating RUF needs, as well as the availability of funding for procurement and CMAM scale-up are all key aspects of the feasibility assessment. There must be interest and involvement from a major purchaser of RUF, typically UNICEF for RUTF and WFP for RUSF. Being the main stakeholders, UNICEF and/or WFP are typically consulted at the initial stage, but NGOs and other agencies active in the field of nutrition, as well as governments, should all be involved in the assessment process. National nutrition policy, current and planned nutrition interventions (Therapeutic and Supplementary Feeding Programmes, support to People Living with HIV/AIDS, etc), existing RUF supply chain mechanisms, and potential challenges should also be studied to ensure a proper understanding of the local and regional contexts.

The economic, political, industrial and logistics environments should also be assessed. Any new potential supplier should be aware of the competition, as local producers often have to compete with international suppliers. A favourable business environment is necessary for a new producer to be competitive and scale up compared to existing producers (see list of RUTF producers in Appendix 6). The following is a non-exhaustive list of key points to cover when evaluating the business climate:

- Political stability and security;
- Banking facilities: access to finance and interest rates, loan rates;
- Tax policy and government schemes to promote investment in country: type and level of taxes applied to imported raw materials and equipment, regional trade agreements, existence of tax dispensation/exemption and duration if any, free zone status and customs clearance formalities;
- Logistics/transportation: infrastructure in country (road networks, airport, sea port, and any seasonal considerations), sea and air routes (local, regional and worldwide), costs of freight and main forwarding agents/carriers;
- Industrial and agricultural sector: availability, quality and cost of raw materials and packaging materials, mapping of potential suppliers and existing supply chains, laboratories’ capacity for product testing and location and existing donors/investors for private investments (agriculture, food businesses).

Quoted during a Government perspectives on scaling up CMAM meeting held in Addis Ababa, 2011.
9.2 Initial Set-up Costs

Several initial investments have to be considered when setting up a local production facility. Over the last few years, the total investment has increased with the rising trend in quality standards. Producers, whether local or international, are upgrading their facilities, and improving their manufacturing processes and controls for review and analysis of raw materials and environmental monitoring. Depending on the country and context it takes about one year, in the best case scenario, to have a plant validated and be able to sell its first products, which means sufficient working capital has to be forecasted to pay expenses in the interim. Some set-up costs to be considered include:

**Premises**: Infrastructure should allow for good manufacturing practices to be followed and a safe environmental monitoring plan: control of hygrometry (atmospheric humidity), pest control, ventilation, etc. Production premises have to be either constructed or renovated, to allow for efficient cleaning and maintenance.

**Purchase of equipment**: The production line is usually composed of hoppers for ingredients, a mixer, grinder(s), and machinery for filling and packing. Addition of thermal processing (such as pasteurisation) is recommended by some purchasers. Equipment must be food-grade (for example for surfaces in contact with the product), and design should allow easy and efficient cleaning. Importation costs, preventive maintenance contracts and supply of spare parts are key elements to consider when choosing equipment.

Additional equipment can also be purchased to process peanuts, such as sorting and roasting equipment. This can be an advantage to better control quality, as peanuts procured locally are often high in aflatoxin, or EB: intervening in the processing and/or supply chain from the beginning will help reduce quality issues with peanuts.

**Laboratory support**: if necessary and possible, local producers often seek to invest in an internal laboratory to obtain results faster for testing aflatoxin, micronutrient tracers (to verify adequate mixing), and some microorganisms in raw materials and the production environment (rapid kits can be used for some analyses). Setting-up an internal laboratory is a large investment, but would allow producers to obtain results faster and, in the medium-term, to reduce the cost of analyses. However, it is necessary to use external accredited laboratories for the analysis of finished products.

**Staff training**: both managers and operators have to be initially trained on manufacturing procedures, quality assurance and control, maintenance of equipment etc. As new requirements are implemented and equipment introduced, this will have a corresponding effect on increasing training and supervision needs.

Set-up costs will of course vary, according to the project size and partner for start-up (see Appendix 7). For an average production project with a capacity of 1000 MT per year of RUF, it can reach approximately 550,000 USD for the machinery alone, without taking into account working capital to start production, and the renovation and/or construction of premises as well the cost of land. The initial set-up costs can easily reach 1.5 million USD, which is about twice the cost of investment relative to 3 years ago.

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xxvi This addition of a “heat-step” is a new process being used by some producers to reduce microbiological contamination risks and subsequent rejection of stock, although it is recommended but not mandatory at the current time.
### Why is Local Production Often More Expensive than Offshore Production?

Historically local production of RUTF has been more expensive than offshore production. This is often misunderstood, because the assumption from many stakeholders is that local production is cheaper due to reduction in costs such as transport, labour and importation tax. The following factors mainly explain why local production is often more expensive:

- **Raw materials often have to be imported in order to conform to quality requirements, or because the volumes of raw materials required for production are not available locally. Peanuts, oils and sugar are the main ingredients that are usually bought locally, but prices are not always competitive with the international market.**

- **Importation tax/duties:** while the UN is exempt from taxes when importing finished products, enabling UNICEF and WFP to import RUTF to programmatic countries at a competitive rate, local producers have often to face import duties on raw materials used to produce RUTF.

- **Transport is a significant driver of higher costs for local producers, especially in landlocked countries with no direct access to a port. Transportation lead times and costs can be problematic inland; the UN has a comparative advantage in instances such as this, as they benefit from lower transport prices given the huge volumes they typically manage. As inland transport can be very unpredictable, raw material inflow has to be well organised to avoid any ruptures in stock that could lead to additional costs being incurred.**

- **Quality control required to ensure product safety is another driver of higher cost in local production when compared to offshore production. As it is difficult to find reliable laboratories in-country or within the sub-region, samples often have to be sent abroad for testing. In addition to the shipping costs, the long lead time for obtaining testing results can have a significant financial impact due to the immobilisation of finished products awaiting release, which increases working capital requirements.**

- **Access to, and the cost of capital is another major differentiator; local bank interest rates are typically much higher in developing countries, access to financing is limited, especially for small and medium companies, and the need for working capital is higher because of significantly longer cash conversion cycles. Inputs take more time to ship to local producers and product release is also longer. While vendors may extend credit to a European or American producer, knowing that a legal infrastructure exists to recuperate their money in case of default, vendors are far less willing to extend credit terms to relatively small food producers from low-income countries. This often translates into local producers having to pay for required inputs up front, weeks before they arrive in country, and months before they can be resold in the form of finished product.**

In such constrained operating contexts, economies of scales will be lower for local producers, and consequently, prices will not decrease as quickly relative to offshore producers. However, in addition to local economic benefit, key advantages to be gained from increasing local production capacity include increased local availability, cultural appreciation and local ownership, the cost-efficiency of supply chain management and reduced delivery time.

**Figure 3** compares the landed price (offshore price plus shipping costs) with local purchase price. RUTF price per carton is available for each producer validated by UNICEF with figures updated regularly. 32 For both international and local producers, an observed decrease of RUTF prices since 2008/2009 and an increase since 2012 can be noted, largely due to the rise in standards outlined above. The increase is more significant for local producers. However this graph does not address the actual landed cost in emergency contexts when offshore RUTF is shipped by air, or overland costs to deliver RUTF to beneficiaries.
In addition, the figure shows the UNICEF calculation of costs, however, it may differ for NGOs (who may not be exempted from taxes) and other purchasing entities, so this should be analysed with care.

Figure 3: Average price per MT of RUTF (in USD): local price versus landed cost for sea shipment, July 2014

Source: UNICEF Supply Division, 2014

PART TWO: Way Ahead

Local production of RUTF started 10 years ago and has been an important step in the fight against malnutrition. It also contributes to development across multiple sectors (economic, social and agricultural) and is important for both emergency and development contexts. Local producers face common challenges that restrict their growth as compared to offshore producers. There are several challenges that could be overcome to further expand local production and make local RUF more available and affordable.

11 Challenges and Recommendations

11.1 Promoting and Improving Local Agricultural Supply Chain Streams

The goal of local producers is to source as many materials as possible locally in order to reduce dependency on imports and associated delays and ultimately maximise impact on local economies and food systems. But to do so, agricultural supply chains must be sufficiently structured; this is rarely the case in low-income countries, and local producers continue to struggle to find consistently high quality raw materials. Even if the quality of local raw materials is deemed sufficient, the prices are often not competitive with international market prices. There is a balance to find between the desire to purchase locally to improve local economies and the need for competitively priced RUF. This problem could be addressed by investing in local supply chains, keeping in mind the long-term benefits associated with the short term cost or investment.

A feasibility study in Ethiopia applied a value chain approach to increasing RUTF production and identified several issues that are common to other agricultural supply chains in developing countries:

- The lack of market information at each stage of the process, from farmers to ingredient suppliers, leaving them unable to respond to market trends;
- Low access to finance for producers requiring essential capital to purchase ingredients, which are often only available seasonally due to lack of adequate storage at farm level;
- The need for improvement in the quality of ingredients, therefore reducing the level of risk of contamination, especially of aflatoxin;
The reality is that investment in agriculture, both by developing country governments and aid donors, has declined since the 1980s xxvii

Actions required to improve local supply chains include the following:
- Governments should play a key role by providing incentives for small farmers through investment in the sector;
- A need to engage more funds and find innovative systems to link agriculture and nutrition; agricultural investment can lead not only to increased production and reduced poverty but also improved nutrition;
- Public private partnerships with NGOs or international organisations that have an expertise in this field should be encouraged; this will help to link farmers to RUF producers, improve yields and quality of raw materials and increase processing of raw ingredients locally.

As regard to imported ingredients, centralised procurement of large quantities could help reduce costs. Pool sourcing for imported raw materials purchase could be organised allowing RUF producers to negotiate prices as a group, and reduce risks linked to market fluctuation (bringing down the cost of the finished product).

### 11.2 Creating a Specific Legal Status for RUF/Tax Exemptions Locally

Some ingredients (milk powder, minerals and vitamins) and packaging materials, equipment and spare parts are not available locally and have to be imported, with often significant duties. It is certainly an area where national governments could improve the competitiveness of local RUF producers by looking at a range of tax exemptions. It is understandable that governments apply protectionism politics to protect their market against cheaper imported goods, but determining a specific legal status like “public health product” for RUF could facilitate such tax exemptions initiatives, facilitate customs clearance and also help countries regulate RUF (as a food, essential commodity, etc.). A certain level of control could be put in place by national governments to ensure any products or commodities imported by producers using such a tax exemption would ultimately be used for the production of RUF and not resold on the local market.

In Burkina Faso, there are incentives to facilitate new business development: a “Code des Investissements” allows new companies to be exempted from tax on machinery and building materials for a period of five years, with one limitation: the list of equipment the producer aims to import over the five year period has to be provided to the national authority at the very beginning of the project and cannot be amended, meaning any plans to increase production capacity or other future developments have to be anticipated well in advance. In other countries free zone status xxviii or bonded stores xxix can also help reduce the amount of taxes for imported materials, sometimes with one limiting condition: a percentage of the production often has to be exported, which can be difficult to handle when the demand in country is already high.

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xxvii Specifically, the share of agriculture in total bilateral and multilateral aid fell from a peak of 22.5% in 1979–1981 to a low of 5.4% in 2003–2005, before increasing to 6%, according to 2009 data from the Development Assistance Committee of the Organisation for Economic Co-operation and Development.

xxviii A free trade zone is a geographic area where goods may be landed, handled, manufactured or reconfigured, and re-exported without the intervention of the customs authorities. Only when the goods are moved to consumers within the country in which the zone is located do they become subject to the prevailing customs duties.

xxix A bonded warehouse is a building or other secured area in which dutiable goods may be stored, manipulated, or undergo manufacturing operations without payment of duty.
11.3 Raising Awareness to Increase Local Purchasing

UN organisations and NGOs are already implementing an approach that takes into account local production in their strategies, but this dynamic should be pursued and developed further. Social responsibility and economic value could, for example, be part of the purchasing policies of procurement actors, promoting long-term sustainable development by favouring food aid products manufactured locally or regionally. Acceptable premium prices in the starting phase could be tolerated, allowing local producers to grow and then the price could be decreased with economies of scale. UNICEF’s willingness to purchase locally, despite higher costs, has been essential for the development of local production capacity. Critics might ask whether the goal is to support local production/local economies or to use funds to purchase larger quantities of RUTF at the lowest cost, but the argument remains, local production is something all parties could benefit from in the long term.

Food aid policies sometimes have a negative impact on local economies by shipping products from developed countries (especially donations and subsidised products), and thereby increasing dependence on imported aid products. However given the smaller capacities of local producers, their capacity may sometimes need to be complemented by imported products from offshore producers to ensure the RUTF supply chain needs are met. Mechanisms could be implemented by humanitarian stakeholders to regulate procurement of RUF and avoid endangering local producers, who have the capacity to respond to demand and should be left to cover the needs of regular programming in their countries. As an example, to date UNICEF has been wisely handling USAID in-kind donations, shipping those donations to cover urgent gaps in countries having a lack of funds to purchase RUF, and/or without any endorsed/validated national production facility or supplier. But there is no guarantee that these principles will continue to be applied and that other purchasers will apply the same mechanism.

11.4 Better Forecasting of Demand and Improving the Supply Chain

Aside from the constraints related to emergency operations which are by definition unforeseeable, better forecasting remains desirable for RUF, particularly for local producers. Unpredictability of demand and strong variations in volume remain a challenge for producers as they often entail difficulties in terms of forecasting, stock management and financial management (longer delivery time to import raw materials relative to offshore producers).

UNICEF considers that supply chain optimisation is a key component to reduce programme costs, the target is now to support 20 supply chain optimisation assessments in country per year, including for nutrition. Following the 2008 nutrition emergency in the Horn of Africa, a study was commissioned by UNICEF to identify RUTF supply chain weaknesses and propose solutions. There were several areas identified where miscommunication or mistrust due to misinformation may be eroding faith in the supply chain. This report served as a first step for UNICEF to improve the RUTF supply chain, including forecasting. The following graph shows that forecasting was indeed improved afterwards, although 2012 and 2013 may have been impacted by the implementation of new quality requirements.
The report also highlighted that the flow of funds is critically important to the functioning of the RUTF supply chain and donor funding schedules may not coincide with the timing of need for RUTF; if funds are not available when needed, the supply chain often works in a reactive mode and introduces inefficiencies and increased costs, for example, having to airlift product deliveries rather than using cheaper modes of transportation such as sea freight. An ideal system would ensure that funding is available ahead of the time of need of product in country without delay, and that funding schedules would be coordinated among donors along with Country Offices.\(^{35}\)

Furthermore, the donor funding schedules, and therefore the purchase orders, may not match with the producers’ capacity: irregular purchase can have a serious impact on local producers’ viability, while large orders may not be able to be fulfilled in the requested delivery period, and therefore may be filled with offshore product. The establishment of long term agreements has certainly helped securing local and international producers, but this concern could be further mitigated through solutions such as pre-positioning buffer stocks of RUF handled by the purchaser or producer, or by creating appropriate buffers of cash/working capital. Such initiatives would allow producers to anticipate and forecast raw material needs, allowing them to contract with raw materials suppliers, therefore obtaining better prices and reducing ultimately the cost of finished product.

Apart from purchasers’ supply chains, local producers also have to improve their own supply chain management processes. They work in challenging environments with a great deal of uncertainty, especially from a logistical perspective, and there is a need to carry out assessments and develop support in this field.

Various other agencies are also conducting detailed assessment into supply chains to assess the critical points where stock is diverted or not replenished. The following are some general findings reported by actors working with CMAM services:\(^{\text{xxx}}\)

- Lack of definition/accountability on roles/responsibilities for supply chain management;
- Poor systems for tracking supply chain performance;
- Leakage of RUF at community level, poor community perceptions/understanding;
- No uniform approach to forecasting, reporting or monitoring RUF supplies across countries;
- Limited capacity and resources at national/sub-national levels;
- Limitations in responsiveness of system in emergencies.

This is an area that requires further attention as lack of stock at sites leads to lack of confidence in the community and higher defaulter rates.\(^{37}\)

\(^{\text{xxx}}\) Personal communication from international NGOs.
11.5 Improving Access to Finance

To date, small and medium enterprises and not-for-profit organisations have been involved in the production of RUF, making it harder to raise capital funds to start up or develop production capacities (when compared to large companies). Most local producers have partnered with international RUF producers and may benefit from financial support in various forms. But for independent local producers who need significant start-up capital and have to finance working capital for a period of an estimated 6 months, access to financing is limited and local bank interest rates are quite often not favourable.

Financing working capital is challenging for local producers and is often the reason for raw material shortages or breaks in production. Local producers often have to first receive payment for an order before they can purchase the ingredients necessary for the next order. That is why late or slow payment by customers has a considerable impact on working capital. Lack of working capital often results in factories running below capacity. It also explains why local producers do not grow as quickly as their offshore counterparts: their priority is first to ensure cash flow is available to have production running continuously before they can invest in increasing capacity. Possible solutions to answer this challenge could include:

- Better forecasting from procurement agencies (as described previously);
- Faster endorsement from purchasers to reduce initial cash flow needs during the start-up phase;
- Prompter payment schedules from purchasers;
- Reduction in pre-delivery quality checks (which can lead to stock already released by producers sitting in warehouses and therefore increases storage and financial costs).

11.6 Defining International Standards for RUTF and Other RUF

It has been suggested that common standards should be set and that RUF production should be regulated by an independent body (i.e. outside of the purchasers and users of the products), therefore providing a reassuring framework, facilitating endorsement of new producers/new products and ensuring consumer protection. RUF will be included in the new codex standards (see earlier), but in the meantime there is also a need for harmonisation of purchasers’ specifications.

There is also a need for more collaboration and discussion between all stakeholders on food safety standards: UN agencies, purchasers, users, consumers, producers, laboratories and national governments or authorities that set standards to protect the health of consumers. Some countries have their own bureau of standards working on defining national standards for RUTF, so standards should be harmonised from the beginning. Producers should also be consulted as they have experience in the development and production of RUF. Exchange between all stakeholders would encourage better understanding of each other’s needs and constraints, and assess feasibility of new norms and appropriate classification before implementation.

In the worst case scenario new requirements could lead to stock-outs, producers becoming unviable or to significant investments that may be challenging to implement. In such cases producers should be given a time period to implement adequate measures and ensure compliance with new specifications. Also, it is essential to consider the end users’ input as they know the reality on the ground and the environment where such products are consumed.

11.7 Investing in Laboratories’ Capacities Locally

The need to build capacities in the area of laboratory testing has become more important with the introduction of new sampling plans and recommended regular environmental monitoring of the factory. The number of analyses required has increased and subsequently training requirements are also greater. Access to an external laboratory for environmental testing is a major challenge for producers in remote or
isolated areas, the lead times often mean they cannot send the sample in time.\textsuperscript{xxxi} Transfer of know-how North-South and South-South could be promoted to develop new analytical laboratories and rapid testing kits, or build capacities of existing ones. Such projects could include purchasers as they also need to perform their own analyses on finished product to guarantee it is consistently safe.\textsuperscript{xxxi}

12 Sustainability of the Local Production Model

The challenges previously described might raise initial scepticism regarding the long-term viability of the local production model, but there are other aspects that local producers should also consider:

12.1 Quality level chosen for RUF products

There is no question or debate about the need to ensure the safety and quality of RUF provided to malnourished children and other vulnerable groups: continuous quality improvement is a must. But there is a need to define a balance and an “acceptable level” for such products, taking into consideration the associated costs and the overall environment in which they are consumed.

The goal of both purchasers and users (e.g. NGOs) alike is to increase local production while decreasing the overall cost of RUF, in order to treat more children and catalyse the scale-up of CMAM programming, but a drop from 47% to 22% purchased from local producers has been noted in 2013. There is surely a compromise to be found or a decision to be made between the desire to foster local production and reduce the cost of RUF at the same time, given the increased quality requirements producers have to adhere to. In a perfect world, all three would be attainable, but as demonstrated by the recent trends outlined in this brief, these changes will not happen overnight. Producers are making significant investments to upgrade manufacturing processes, production facilities and set up internal laboratories in order to improve their quality standards and comply with new specifications.

FAO and WHO are now involved to help establish standards but in recent times several practical questions have been raised by stakeholders: what should be the acceptable quality level for RUF products? How can we ensure that standards practically improve actual safety where these products are being used? Should RUF production be mandated by food or pharmaceutical quality standards? Who should decide what an acceptable risk is for consumers? The current trend in rising standards is already limiting and reducing the use of local ingredients. Without sufficient time, funds and support to upgrade local agricultural supply chains and local transformation of raw ingredients into industrial ingredients, all of them may eventually have to be imported. Therefore the word “local” may be questioned as well as the justification for RUF production to be located in programmatic countries.

12.2 Diversification of product, customer and distribution channel

Offshore and local producers mainly sell RUF to large and institutional purchasers like UNICEF and WFP. This dependency on just a few big customers is risky and quite unusual in business. The success of RUTF has sparked the development of other paste products known as RUSF with manufacturing procedures similar to RUTF production. Some producers have a line of other processed food products besides RUTF, and there is a clear need to expand the customer base by diversifying the range of RUF products and target new end-users/populations.

\textsuperscript{xxxi} Although the development of testing kits may help this, training needs to be considered to ensure kits are used correctly.

\textsuperscript{xxxi} For example a partnership between Hilina (local producer of RUF and PlumpyField member in Ethiopia), Nutriset, and a Dutch accredited food testing lab Nutrilab, lead to the creation of Bless Agri-Food Laboratory in Addis Ababa. This laboratory is able to offer a wide variety of microbiological, chemical and physical analyses on food products, therefore it can carry out analyses on RUF in addition to other agribusinesses in Ethiopia and the sub-region.
It is estimated in 2011 that MAM affects approximately 34 million children under-five while another estimated 165 million children are chronically malnourished, proving a potentially large demand for preventative products. The scale of the problem is far too great to be tackled by the humanitarian sector or public sector alone. New delivery mechanisms, partnerships and business models have to be invented, engaging the private sector even more, bringing them in to the fight against malnutrition. Preventive products that aim to prevent undernutrition among pregnant and lactating women and young children could be distributed through both public channels and private markets, which in turn, will lead to new ways of engagement for public, non-profit and private players. The success of introducing preventative products into the private market will mainly depend on the consumer strategy, a consumer that makes choices and is not considered as a beneficiary in a humanitarian response programme. It will also be dependent on the capacity of stakeholders from diverse origins to work together and on the availability of funds to enhance demand and create innovative distribution models.\(^{39}\)

There is however a great deal of uncertainty as regards to production, demand, regulations, quality standards, and supply chain and marketing strategies for the preventive products. Very few pilot projects and research initiatives have been carried out to date, but difficulties linked to the marketing of such supplements should be anticipated as national and international regulations on the marketing and sales of food products destined for children under 2 years of age are quite restrictive. Cost and demand are among the main concerns: poor families should be able to buy and demand has to be enhanced.

**12.3 Improving long-term funding for CMAM scale-up**

To date, the majority of CMAM funding has come from donor funds, and specifically from emergency budgets, meaning it is largely short term and unpredictable in nature. CMAM programming is therefore subject to a high level of insecurity, making it difficult for governments to be strategic or to actively plan scale-up.\(^3\) The most prominent funder of SAM treatment and provision of RUTF is UNICEF, which in turn receives most of its funding from ECHO/European Commission, DFID (UK Department for International Development), the Japanese government, UNOCHA (the United Nations Office for the Coordination of Humanitarian Affairs and USAID. Since the initial use of RUTF in the early 2000s, UNICEF has succeeded in covering roughly 15% of the estimated global caseload of SAM, so there is still much to do to treat the estimated 17.6 million children with SAM.\(^{40}\) At 10-15 kg of RUTF per treatment, this translates into a need for about 220,000 MT of RUTF and 0.9 billion dollars (this figure does not include costs associated with the scale-up of CMAM programming which needs to be in place before more RUTF can be introduced). This demonstrates the scale of production that may be necessary for SAM treatment alone (see **Figure 1** above, illustrating the increase in procurement of RUTF since 2000).

However, RUTF demand is often driven by the speed of CMAM scale-up; as the availability of guaranteed funds for scale-up is difficult to forecast in the long term, RUTF demand and production capacity are consequently difficult to manage: products may not be able to be delivered if CMAM capacity in country is poor, whereas lack of RUTF may slow down CMAM programming.

Two main challenges to ensure continuous and transparent flow of funds for CMAM scale-up were identified at the 2011 Addis Ababa CMAM conference.\(^3\) The first challenge is to move programming away from donor emergency or short-term funding to development funded programmes with a longer term commitment. The second one is to move away from donor dependency and ensure government ownership, so that governments are directly in charge of the allocation and management of CMAM funds. Greater government ownership remains a difficult challenge precisely because country planning and budgets remain exposed to short-term interventions and their dependency on the provision of RUTF donations which are not guaranteed in the longer term.\(^3\) This is the main reason why many governments would like to have national production to reduce this dependency and ensure sustained CMAM
programming. However, they must be able to absorb the cost of RUTF on a long-term basis (about half of the total costs for CMAM implementation), and will require supply chain support if supplies are to be delivered through a government mechanism. Although there is no demonstrated evidence, it is believed that local production may facilitate implementation and scale-up of CMAM with easier integration of local RUTF into the national supply chain. If, in the end, governments are in charge of managing CMAM funds, it may be easier for them to procure RUTF locally than from offshore producers.

12.4 Competition with offshore producers
A significant challenge for local producers is to compete with offshore producers that operate in more favourable environments and offer cheaper prices.

To date the trend is more for a local production to move toward a regional production and export to neighbouring countries, therefore becoming an international producer. Given the current context with rising standards, this is probably the most competitive and viable model.

While local producers have to compete with producers in France, USA and India, the current Nutriset/IRD patents are currently providing some level of protection. Various scenarios could occur when the patents ends in 2018, xxxiii large multinational companies could start production of RUF, causing offshore prices to decrease more quickly than they did in the last decade. This could put small and medium RUF producers around the world at risk as they do not have the same favourable business conditions as large multinational companies.

13 Ongoing Research Related to RUF
This section lists some of the areas of ongoing research around products. It is not exclusive and more detailed information can be found by referring to the International Lipid-Based Nutrient Supplements (iLiNS) (http://www.ilins.org/ilins-project-research) and CMAM Forum sections on ongoing research (http://www.cmamforum.org/research) and for examples of published studies using different products in Supply Management section (http://www.cmamforum.org/resources#Supply) Some areas of work include:

**Developing alternative RUF recipes and use of linear programming**
The aims of developing new recipes include:
- Reduce costs by using lower cost raw materials that are locally available (e.g. chickpea, sesame, rice, soya, lentils);
- Reduce dependence on expensive imported materials (especially milk powder) by exploring use of protein from vegetable origin such as soy protein and other products;
- Increase acceptability and meet local taste, for example in Asia there is less acceptability of peanut-based RUF and thus a demand for non-peanut-based RUTF;
- Use ingredients that have less risk to microbiological contamination (e.g. other pulses).

Of key importance is not just the optimisation of cost and nutritional profile, but also to ensure adequate bioavailability and that adequate acceptability xxxiv and efficacy trials are conducted. It is key that there is adequate funding for this type of research and development.

Linear programming, an excel-based tool, is a systematic way for users to generate the most cost efficient formulations using a combination of local and imported ingredients which all meet specific requirements laid out by regulatory agencies. Costs and types of locally available food are inputted into a specific

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xxxiii Patent ends in 2021 for some lipid-based products.

xxxiv Acceptability trials have been carried out in DRC, Ethiopia, Ghana, Malawi, India, Pakistan and Vietnam.
programme and generate various options that can then be developed and tested. Use of linear programming is being developed with specific country examples, including by Washington University in St Louis and by Valid Nutrition. It is intended that linear programming tools, when refined, will be made available on an open-access basis via UNICEF and its academic associates. In addition, UNICEF is currently undertaking a review of what local recipes are available.

**Using other products for different populations**
Increasingly RUF is being trialled for different target groups in both a preventative and curative manner. This includes use as follows:
- As part of HIV or tuberculosis treatment and/or as an incentive to maintain drug regimens during the first months;
- For malnourished pregnant and lactating women;
- As a complementary food or to supplement a food basket;
- For prevention of stunting;
- For prevention or treatment of micronutrient deficiencies;
- For management of critically unwell e.g. in recent times use during the ebola crisis.
This increase in range could lead to more opportunities for producers.

**Using additional elements to improve health status**
Work has and is being done adding the following elements to RUFs and measuring whether there are improved outcomes by:
- Adding pre and probiotics;
- Improving fatty acid profile by using high oleic RUTF (monounsaturated fats) or high omega-3 fatty acids;
- Adjusting micronutrient profiles (e.g. zinc) for prevention and treatment.
Again, this could have impact on producers if endorsed as it could mean additional elements to be sourced and added.

**Simplification of protocols: including use of single product for SAM and MAM**
There is recent discussion about streamlining products to give different quantities of the same product to different degrees of malnutrition (MAM, SAM), with the objective to reducing the logistical challenges of managing different supply lines; simplifying protocols for health workers and reducing confusion to communities. Research is ongoing.

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PART THREE: Case Studies of Local Production Experience

14  Case Studies

Two case studies have been provided that give some insight into challenges and successes of local production in Sudan and Malawi.

14.1 Samil Industrial Co.

Written by: Eman Ahmed Abdalkarim, Operations Manager, Samil, Sudan

<table>
<thead>
<tr>
<th>Name</th>
<th>Samil Industrial Co., Khartoum</th>
<th><a href="http://www.samilindustrial.com/">http://www.samilindustrial.com/</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Established</td>
<td>2011, production inaugurated in February 2012</td>
<td></td>
</tr>
<tr>
<td>Partnership / Franchise</td>
<td>Nutriset and Salih Abdelrahman Yagoub Company (the parent company and flagship of Yagoub Group), Sudan. Franchise agreement with Nutriset; as a franchisee, they benefit from usage of Nutriset’s know-how and trademark</td>
<td></td>
</tr>
<tr>
<td>Production Capacity</td>
<td>1,200 MT / year (2012) increased to 3,500 MT / year (2014)</td>
<td></td>
</tr>
<tr>
<td>Product Range</td>
<td>Main product: Plumpy'Nut® (RUTF), recently, Plumpy'Sup™ (RUSF)</td>
<td></td>
</tr>
</tbody>
</table>

Since its establishment, Samil has been providing nutritionally enhanced products for the treatment of acute malnutrition and building nutritional autonomy at a local level. The state-of-the-art factory was set up in order to meet international quality standards.

Financial constraints to local production: The nature of this type of humanitarian business takes a similar path to that of commercial manufacturing businesses in Sudan and therefore is subject to costly taxation; Samil pays a 10% Business Profit Tax. Samil also pays customs charges for each invoice procured internationally: these can rise up to over 60% of the initial value of the invoice, in addition to a 6% charge that is paid towards the clearance of the imported raw materials. Samil also incurs 17% Value Added Tax (VAT) for each product purchased.

In addition to the challenge of high taxation, Samil also faces a major challenge with currency exchange and access to foreign currency. Due to foreign economic sanctions on Sudan, and hence the absence of an international banking system, Samil is often unable to guarantee the flow of cash for the raw materials procured internationally. These financial obstacles have hindered production several times, mainly because over 50% of the raw materials are procured internationally (mainly from Europe) and only 45% (peanut, sugar) are internally sourced. Materials required for production are not always available in Sudan, or are hard to secure locally within the expected quality as all raw materials are carefully selected and prudently produced.

Where products are sourced locally, Samil has faced some challenges in the local supply chains, especially in relation to peanuts. These challenges arise due to a lack of knowledge in scientific food processing technologies. In the early stages of production it was common to find peanuts affected by aflatoxin. The average level of aflatoxin found in peanuts was 120 ppb while the recommended level in food for human consumption is 20 ppb and the UNICEF required level is <5 ppb. Since aflatoxin develops from the very early stages of planting and farming, Samil has worked with farmers to avoid aflatoxin development in the pre-processing stage (harvest, storage, etc.). This has proved a challenging process as convincing local farmers to change their farming habits, particularly when the changes result in increased work, attention, and resources, has not been easy. Nevertheless, Samil has successfully worked with local famers to ensure production of quality peanuts, including improved farming strategies, better storage techniques, enhanced post-harvest processing techniques. Samil has developed a field lab test, which can detect aflatoxin as early as in the first stage of processing.

Since peanuts constitute about 20% of products, Samil has established a fully automated Roasting Unit. As soon as raw peanuts are procured they are tested at the Samil chemical laboratory and once assured to be aflatoxin free they are sorted, roasted, and packed in vacuumed bags. Before the peanuts get released...
for the production of RUTF and RUSF, they undergo a final test to ensure that they are free of Aflatoxin. This processing line of peanuts has been a great success and has enabled the control of many aspects (i.e. aflatoxin levels, peanut grading, colour, quality, etc.).

Samil ensures the maintenance of quality by regularly checking raw materials in storage, maintaining a hygienic environment, and providing regular training for the staff and workers. As part of the PlumpyField network, Samil receives technical assistance and regular review from Nutriset to streamline processes to meet the international high quality standards.

Shortly after the establishment of the factory, Samil opened its internal chemical laboratory with the capacity to measure a few indicators. All microbiological and nutritional analysis, however, continues to be performed in an accredited external lab outside the country. The transportation costs and costs of the required tests are relatively high, but are required to provide evidence that the product is suitable for release for procurement. Samil has begun the process of setting up an internal microbiology laboratory that can perform tests on raw materials, the factory environment and the finished product, with an expected start date of June 2015.

Samil has established relationships with many international humanitarian organisations, such as UNICEF, WFP, and MSF, and from these receives regular orders for procurement of RUTF. Samil also has a strong working relationship with the Federal Ministry of Health (FMOH), who have facilitated procurement of RUTF to other governmental organisations working in the management of acute malnutrition in the various States of Sudan. UNICEF remains Samil’s main client, MSF and ministerial offices procuring several small orders of Plumpy’Nut®. Recently Samil has started the production of Plumpy’Sup™, much of which is expected to be procured by WFP.

Since the establishment of the factory, Samil has been strongly supported by the FMOH. The nutrition department in particular played a significant role in the registration of the product. Moreover, Samil has extended its relation with national NGOs and has established some projects with small organisations (e.g. Majididoon) to meet some national nutritional goals concerning children. Together with the expertise of academics from the faculty of Health Science of Ahfad University for Women (AUW) and with help from Nutriset, Samil is developing a new product for poorer families who are not able to maintain their minimum nutritional intake for their children. Research plays a key role in Samil’s work in collaboration with local NGOs and educational institutions. Samil has also given a grant to AUW to support tuition for 6 masters students who are planning research in the area of nutrition and food technologies.

Samil has succeeded in directly delivering its product to several areas in Sudan, with much shorter lead times; Samil now delivers its product to Fashir, Geneina, Niyalla, and other areas. Samil’s clients are appreciative of this new service, which has become a motivation for Samil to reach even further. To date, Samil has not exported products. Even though Sudan lies in the centre of many countries that require RUTF, it is not always possible to export due to the lack of secure roads or border closure for political reasons or security concerns. Samil’s goal is to reach neighbouring countries and to be able to supply them with a portion of their annual needs of RUTF.
Valid Nutrition have identified a number of benefits to local production and argue that it enables the development of the indigenous food industry, supports the local value chain, especially in agriculture and enables easier and quicker distribution of the food as consumers are closer to the producers. Together with employment, this in turn has a significant positive multiplier effect on economic and social impact. Furthermore, reduced storage time and therefore diminished warehousing costs and food losses, plus better carbon footprint, all add further value.

Production of RUF in Malawi began in 2003 on a very small scale in partnership with a local bakery. Valid International in turn sought approval as a supplier from UNICEF which led to a big shift in the way production was run in order to meet requirements, leading to the set up of Valid Nutrition in 2005. With support from Irish Aid, Gorta and the Department for International Development, the factory has transformed into an industrial plant designed to international standards. The factory currently has an annual capacity of 1,500 MT. It has a well-equipped laboratory for in-house testing of quality control parameters in RUTF production.

Through the experience of setting up local production of RUF in Malawi, Valid Nutrition is able to share some successes and challenges associated with local production.

Valid Nutrition has experienced some frustrations in the market validation/certification process. They recommend clarity on the process of supplier validation and they suggest that as with other industries, this role should be undertaken by an independent regulatory body.

Whereas it is appreciated that quality must be given priority and food safety is paramount, the process of changing and applying new quality standards can be challenging for local producers when the period of transition is not long enough. New standards imply particular consequences for local producers and can add significantly to lead times which can prove very expensive. A solution could be to propose a deadline before implementing a new specification or standard, so that producers have time to work on the implementation (with suppliers, farmers, laboratories as well as securing capital funding when needed). The major challenges are with regard to peanut paste aflatoxin and new EB standards. Valid Nutrition has questioned the reasons behind differing safety levels for aflatoxin standards ranging between 5-10 ppb and stresses that the UNSCN Joint Statement former specification of 10ppb would be helpful and have a more appropriate degree of flexibility for local scenarios without posing any consumer safety risk.

Valid Nutrition favours local sourcing of the ingredients and other materials needed for production with the aim of generating markets for local agriculture and smallholder famers. This sometimes poses challenges with inconsistent quality of raw materials available locally, compared to the choice (and often subsidised alternatives) on offer to European or US producers, particularly in the early stages. Earlier in 2014 in Malawi, production was closed for several weeks due to a lack of good quality peanuts. Valid Nutrition has taken extensive steps to try and overcome the quality issues associated with locally sourced materials by working with farmers and suppliers (see below).

Assessing quality under laboratory conditions is a necessary but costly process. Valid Nutrition has recently been able to install and equip its own laboratory, however customers often require products to be sent to recognised laboratories in Europe or the US. This has a double impact on margin – the actual freight, as well as loss of time and consequent impact on working capital, as well as a longer turn-around for product release.
Cash flow is perhaps one of the most challenging areas in local production. The cost of credit is high (up to 40% interest on an overdraft facility locally). The process from ordering to production to quality checks to supply, invoicing and payment can take several months. Credit arrangements with some raw material suppliers are hard to secure and imported ingredients invariably have to be paid for in advance. The volatile nature of local currency is also challenging.

An example of this can be seen when purchasing imported ingredients; local cash is required at the time of order, the wait for delivery can be up to 15 weeks, followed by a further 10 weeks before material is converted to finished goods, accepted and paid for by the customer. Due to minimum order requirements on materials like milk and packaging, this cycle, which has to be financed – at a cost of 40%+ p.a. at present in Malawi – is very demanding. As such, there are often initial diseconomies of scale for local producers. While Valid Nutrition currently rely on some customers to pay in hard currency the main purchasers pay in local currency.

Initially there was no tax exemption, however, this has now been granted. However this is still a very long process and reclaiming tax can take several months. In some cases VAT refunds can take up to 9 months. Delayed payments and challenges in cash flow have the potential to close factories.

Running costs: The costs involved in the early stages of production are particularly significant. In scaling up, however, the stakes become relatively speaking much higher for a small, local producer, especially if something goes wrong. However, once a local producer can get to scale and establish momentum, these initial hurdles start to diminish, as they are able to secure better terms from international suppliers and financing institutions. Furthermore, for Valid Nutrition, our programme of working with local suppliers (see below), has demonstrably yielded improvements in quality.

To demonstrate the long term financial benefits of successful local production, Valid Nutrition has made some comparisons. This does involve some assumptions and it is acknowledged that this analysis is not exhaustive and is presented purely as indicative of relative economic contributions. Currently freight from Europe or the US averages around $450/MT although it can be much higher for land-locked countries like Malawi. While local producers avoid this cost, they do face other higher costs, especially in the early stages of trying to get to scale. We assume, for the sake of the example, that an offshore producer lands a MT of RUTF in Malawi and the customer pays exactly the same price as for a locally sourced brand – so the cost of freight is being totally absorbed by the offshore producer. The price is taken as being $4,300/MT. Our analysis shows that when the purchase is made from the local producer, over two thirds of the price paid stays either in Malawi or elsewhere in Africa. Conversely, the product bought from the “offshore” producer means that less than 15% stays in Africa. This is just the cash effect and does not include the intangible additional benefits of local sourcing including enhancing skills.

*figures based on current production in Malawi
Capacity building and knowledge transfer: Valid Nutrition is supporting local farmers by promoting increased awareness and action on aflatoxin in peanuts. The National Association of Farmers provides best practices and centralised marketing so that customers get access to commercial quantities. Due to demand for peanut paste created by Valid Nutrition, a company has started production, adding to value locally rather than exporting just raw nuts. The high standards of quality required means that the supplier aims at higher targets – which filters downstream to the farm level.

Linked to the project supporting farmers in quality is a research programme. The farm to mouth evidence-based approach aims to investigate impact on farmers, of capacity building. In addition to an increase in job opportunities, it can also be assumed that there is a degree of capacity building and technology transfer to the local economy by way of staff acquiring skills of food production. In turn, these skills are transferred to other sectors of the manufacturing industry.

Research: Initial findings from this study and analysis compiled over four years can be found at www.validnutrition.org with full results to be published shortly. Valid Nutrition has also been granted funds to establish a new line for production of preventative products which will enhance diversification and hopefully mitigate some of the challenges. The extensive Research and Development programme on new recipes for both RUTF and RUSF is also producing some exciting opportunities that will enhance the competitiveness of local production.

Partnerships: Malawi was one of the first countries to support CMAM: current coverage rates are very impressive and the government sees local production as a priority. Valid Nutrition would also like to acknowledge the support of the government, CHAI Malawi, UNICEF Malawi and UNICEF Supply Division Copenhagen – all of whom have been very helpful and encouraging of the production.

Conclusions: Valid Nutrition has successfully established local production in Malawi. Uniquely in Africa, there is one other independent local producer in the country – Project Peanut Butter, based in Blantyre. It is estimated that 75% of RUTF is now procured locally. We have also demonstrated the positive impact on local farmers in terms of better quality crops and increased business. However there are a number of barriers to the scale up and full success of local production. Many of these can be overcome with commitment from the international community to review processes and make changes.

One of the key challenges is cost of working capital financing and cash flow. Until local producers are able to source raw materials at the quality and price available in Europe or USA, this will continue to be the case. The cost of finance for local producers is significantly higher. Regardless of this, raw material supply and costs can improve over time with the right support. With increased use of other products for MAM and prevention of chronic malnutrition, recent trends show that volumes could be up to ten times bigger, hence the number of farmers impacted becomes very significant.

Valid Nutrition supports the inclusion of ongoing research to be able to demonstrate the impact of local production. Data is needed to answer important outstanding questions and ensure that policy is based on evidence.
15 Conclusion

Local production of RUF has been an important step in the management of malnutrition over the last 10 years. The scale and level of production has considerably progressed, leading to new challenges and opportunities for producers. Significant investments are currently being made in order to comply with new specifications. Clarification about RUF standards and harmonisation of specifications among purchasers are certainly necessary elements that would make the process of scale-up smooth and reassuring for local producers. National governments have a key role to play to support production in their countries by creating a more favourable environment, especially with the shift from donor dependency to government ownership for the management of CMAM. But the international aid community (donors and purchasers) could also be more supportive as national production is more affected by variances in commodity prices on the international market and by changes in quality specifications. In addition, it is important to remember that free market forces, the expiry of the Nutriset’s patent, and other as of yet unforeseen events may also play their part.

While there are many opportunities in the nutrition sector for producers to diversify, the sustainability of the local production model can be classified as fragile with lots of uncertainties concerning the future. Local producers must work on cost-reducing measures to be more competitive with offshore producers, while maintaining quality levels requested. From a development perspective, local production of RUF can contribute to the fight against poverty and malnutrition by supporting local economies and fostering entrepreneurship. It has a positive impact on food security and the strengthening of local food systems. While this model may incur a number of significant short-term costs, advocates for this model see the long-term benefit and the promotion of a more sustainable and ethical model.

Questions and comments may be submitted through the CMAM forum: cmamforum@gmail.com

www.cmamforum.org
References


6. WFP Specifications, including Lipid-based Nutrient Supplement (LNS). http://foodqualityandsafety.wfp.org/specifications


12. The water activity (aw) of a food is the ratio between the vapor pressure of the food itself, when in a completely undisturbed balance with the surrounding air media, and the vapor pressure of distilled water under identical conditions. A water activity of 0.80 means the vapor pressure is 80 percent of that of pure water. Water activity has its most useful application in predicting the growth of bacteria, yeasts and molds. Food can be made safe to store by lowering the aw to a point that will not allow dangerous pathogens such as Clostridium botulinum and Staphylococcus aureus to grow in it. (http://drinc.ucdavis.edu/dairychem4_new.htm)


17. ISO 22000:2005 specifies requirements for a food safety management system where an organization in the food chain needs to demonstrate its ability to control food safety hazards in order to ensure that food is safe at the time of human consumption. It is developed by the International Organisation for Standardisation http://www.iso.org/iso/home/standards/management-standards/iso22000.htm http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=35466


20. Li Ma et al, Thermal inactivation of Salmonella in peanut butter. 2009 J Food Prot 72:1596-1601
29. RUTF Request for Proposal RFP-DAN-2013-501715, September 2013
31. The list of LNS/RUSF products can be found in the WFP specialised nutritious foods factsheet http://documents.wfp.org/stellent/groups/public/documents/communications/wfp255508.pdf. Fortified Blended Food (FFBs), High Energy Biscuits (HEBs) and Micronutrient powders (MNP) are also specialised products used to improve the nutritional intake of vulnerable populations, they are however not detailed in this technical brief.
32. Ready-to-use Therapeutic Food price data, UNICEF supply division, last updated 8 July 2014. This information is available online and updated every 6 months: http://www.unicef.org/supply/index_59716.html
40. Recent World Bank estimation of SAM.
Appendix 1: History of the *Cronobacter Sakazakii* (CS) Crisis in 2012/2013

When the recommended International Code of Hygienic Practice for Foods for Infants and Children of the Codex Alimentarius Standard CAC/RCP 21-1979 was abrogated and replaced in 2008 by the Code of Hygienic Practice for *Powdered Formulae for Infants and Young Children* (CAC/RCP 66-2008), the norms for powdered infant formulae (including *cronobacter sakazakii* CS = absence) were transferred to RUTF in 2009 and RUSF in 2012, without prior assessment of the potential risk of the presence of CS in these specific products (risk assessment had only be carried out in powdered infant formulae).

However reconstituted infant formulae may not introduce the same risks as RUF, as it is not the same matrix and method of use: for example the composition (low water activity $a_w$) and the method of consumption of RUF (eaten directly from the sachet and not reconstituted with water) are very different from powdered infant formulae.

UNICEF introduced the CS requirement gradually, initially requiring producers to confirm absence of CS in milk powder used for manufacturing RUF, followed by introduction of the requirement of CS absence in RUTF. In 2011 a producer alerted UNICEF to the discovery of CS in their finished product and that product was rejected. Later WFP, who had included CS requirement for RUSF in 2012, detected CS in RUSF manufactured by another producer in May 2012. As the effect of this bacterium on malnourished children over 6 months of age was not known, additional and systematic testing were then carried out on all batches of RUSF and RUTF. As the frequency of analyses increased, more and more traces of CS were found in finished products of RUF producers (often below 10 cfu in 1 g). UNICEF discovered that the bacterium was present in the RUTF of all UNICEF approved producers.

Most RUF producers struggled and sometimes had to stop production for a while to ensure the absence of CS. It should be noted that most dairy ingredients producers are not able to guarantee the absence of CS, and that CS is ubiquitous and can be found randomly in almost all raw materials used in the composition of RUF. In addition for the same batch of finished product, results of analyses could be different (absence and presence) depending on the laboratory. RUF being very different to powdered infant formula (lipidic paste instead of powdered milk), the traditional method of analyses used by the laboratories to test CS were not adapted to RUF.

This issue created a supply crisis with several months of stock-outs as affected RUF were quarantined and sometimes destroyed. In the end the acceptable limit of CS moved from a zero tolerance to 10 cfu in 1 g in 2013, a limit that producers are now able to comply with, but this may change again in the future.

*Ref:* Microbial safety of Ready-to-Use Lipid based Therapeutic and Supplementary Foods – Technical meeting, summary report released on the 6th March 2013, FAO and WHO.


Appendix 2: Sampling Plan

<table>
<thead>
<tr>
<th>Microorganisms</th>
<th>n</th>
<th>c</th>
<th>m</th>
<th>M</th>
<th>Class plan</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Enterobacteriaceae</em>†</td>
<td>10</td>
<td>2</td>
<td>10/10g</td>
<td>100/10g</td>
<td>3</td>
</tr>
<tr>
<td><em>Salmonella</em>‡</td>
<td>25</td>
<td>0</td>
<td>0/25g</td>
<td>Not applicable</td>
<td>2</td>
</tr>
</tbody>
</table>

ii. Table 3. Interim microbial criteria from Expert Panel meeting 2012:

Where $n =$ number of sample units to be taken; $c =$ the maximum allowable number of defective sample units in a 2-class plan or marginally acceptable sample units in a 3-class plan; $m =$ a microbiological limit which, in a 2-class plan, separates good quality from defective quality or, in a 3-class plan, separates good quality from marginally acceptable quality; $M =$ a microbiological limit which, in a 3-class plan, separates marginally acceptable quality from defective quality and $p =$ class plan.
Appendix 3: Items Described in RUF Specifications

General Description

Technical Specifications
- Texture
- Flavour and odour
- Colour
- Nutritional composition per 100 g of paste

Shelf Life

Storage Conditions

Raw Material Specifications

Packaging and Labelling Specifications
- Primary packaging, primary labelling, secondary packaging, leaflet

Safety
- Microbiological and toxicological safety
- Mycotoxins
- Chemical safety
- Pesticides and heavy metals
- Radioactivity
- Melamine

Production Process Specifications and Quality Assurance
- Validation of the process and coefficient of variation
- Traceability
- Batch size

Appendix 4: Example of a Manufacturing Flow Diagram of RUF
(from Santini et al17)
Appendix 5: Validation of New Producers

5a UNICEF Validation Procedures (Summary)
- The supplier should complete the Interagency quality manufacturer questionnaire and Interagency food product questionnaire and provide requested documents, as well as samples.
- If needed, the Quality Assurance (QA) division may request more information from the supplier.
- The supplier should mention when it will be ready for an inspection and request that the QA division audit its factory.
- A Good Manufacturing Practices (GMP) inspection by one of the organisations may be scheduled depending on procurement strategy and agenda.
- Following the inspection, the QA division will issue a report with observations and deviations. The producer’s response should provide as much objective evidence as possible for each deviation in order to demonstrate that the deficiency has been addressed. A corrective action plan with deadlines is also required. Depending on the type of deviation (minor/major) and corrective actions plan, the QA division will approve or reject the producer as a recommended supplier to UNICEF.
- Based on UNICEF inspection report, MSF and WFP will contact the supplier and follow their own validation process (analyses of samples, stability study results, etc.). The final decision as to validate suppliers is made independently by each organisation.

4b: MSF Procedure for the Validation of Product/Manufacturer (Summary)
Ref: QA-NFOS-SOP1, date of issue:5/2/2010, revision 15/2/2011

Scope and objectives: This document aims to describe the general procedure for the validation of suppliers of specialised food (ITC codification NFOS) for Médecins Sans Frontières (MSF), and ensures that MSF requirements are met. The objective is to identify and validate product/manufacturer couples that are compliant with the MSF quality standards.

Responsibilities:
- The Medical Directors are final responsible of quality for specialised food used in MSF projects and approve the quality assurance procedures. They delegate the application of procedure to the Coordinator for Quality Assurance of Specialised Food.
- The decision to audit/visit a manufacturing site is the responsibility of the Food Suppliers Selection Group lead by the Coordinator for Specialised Food Quality Assurance.
- The Coordinator for Quality Assurance of Specialised Food and/or external experts and/or UNICEF/WFP quality officers are the key actors for the manufacturer audits and the technical visits. The constitution of the manufacturer assessment dossier is the responsibility of The Coordinator for Quality Assurance of Specialised Food.
- The Coordinator for Quality Assurance of Specialised Food will follow up the product analysis and other requirements for the constitution of the product assessment dossier.
- One pharmacist and one member of the Nutrition working group and the Coordinator for Quality Assurance of Specialised Food will review and evaluate the Supplier Validation Dossier, and decide whether the supplier is validated or not, based on the rating system. In case of difficulty or nonconsensus, the Medical Directors are involved in the decision.
<table>
<thead>
<tr>
<th>Task (process)</th>
<th>Responsible person(s)</th>
<th>Tools (documents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection of Potential Suppliers</td>
<td>NFOS Food Suppliers Selection Group</td>
<td>MIF manufacturer Information File</td>
</tr>
<tr>
<td>Manufacturer Assessment</td>
<td>Coordinator for Quality Assurance of Specialised Food and/or External Experts</td>
<td>Manufacturer Assessment Toolkit (several documents)</td>
</tr>
<tr>
<td>Product Assessment</td>
<td>Coordinator for Quality Assurance of Specialised Food; Collaboration with the Nutrition Working Group</td>
<td>Product Assessment Toolkit (several documents)</td>
</tr>
<tr>
<td>Review and evaluation of the</td>
<td>2 section pharmacists + Coordinator for Quality Assurance of Specialised Food</td>
<td>Rating system &amp; Guide for Dossier review and Evaluation</td>
</tr>
<tr>
<td>Product/Manufacturer dossier</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decision for the validation of</td>
<td>2 section pharmacists + Coordinator for Quality Assurance of Specialised Food. Medical directors if needed</td>
<td>Final decision for the validation of product/manufacturer</td>
</tr>
<tr>
<td>Product/Manufacturer</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

It is the Coordinator for Quality Assurance of Specialised Food’s responsibility:
- To be sure that the current qualification scheme is correctly implemented
- To present the product dossiers to the Medical Directors when needed
- To inform the manufacturers of any decision concerning their products
- To keep the information on the approved couples product/manufacturer at coordination level

**Principles**
- This procedure is based on MSF qualification scheme for international pharmaceutical supply, with some adaptations necessary due to the difference between specialised food and drugs.
- This procedure is open to any manufacturer regardless of the country where it operates. The same procedure applies to any manufacturer, regardless of their location.
- This procedure been exclusively designed for the organization and the decisions taken are only valid for MSF.
## Appendix 6: UNICEF RUTF Paste Supplier Base in 2014

<table>
<thead>
<tr>
<th>Name of supplier</th>
<th>Country</th>
<th>Type of supply</th>
<th>UNICEF procurement started in:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compact Pvt. Ltd</td>
<td>India</td>
<td>International</td>
<td>2010</td>
</tr>
<tr>
<td>Diva nutritional Products (Pty) Ltd</td>
<td>Republic of South Africa</td>
<td>International</td>
<td>2009</td>
</tr>
<tr>
<td>Edesia (PF)</td>
<td>USA</td>
<td>International</td>
<td>2011</td>
</tr>
<tr>
<td>Hilina Enriched Food Processing Center PLC (PF)</td>
<td>Ethiopia</td>
<td>Local</td>
<td>2007</td>
</tr>
<tr>
<td>InnoFaso (PF)</td>
<td>Burkina Faso</td>
<td>Local</td>
<td>2013</td>
</tr>
<tr>
<td>Insta Products Ltd</td>
<td>Kenya</td>
<td>International</td>
<td>2009</td>
</tr>
<tr>
<td>Mana Nutritive Aid Products Inc.</td>
<td>USA</td>
<td>International</td>
<td>2011</td>
</tr>
<tr>
<td>Med and Food for Kids * (PF)</td>
<td>Haiti</td>
<td>Local</td>
<td>2012</td>
</tr>
<tr>
<td>Nutriset SAS</td>
<td>France</td>
<td>International</td>
<td>2000</td>
</tr>
<tr>
<td>Nutrivita Foods Pvt. Ltd (PF)</td>
<td>India</td>
<td>International</td>
<td>2011</td>
</tr>
<tr>
<td>Power Foods (PF)</td>
<td>Tanzania</td>
<td>Local and International</td>
<td>2011</td>
</tr>
<tr>
<td>Project Peanut Butter</td>
<td>Malawi</td>
<td>Local</td>
<td>2009</td>
</tr>
<tr>
<td>Project Peanut Butter</td>
<td>Sierra Leone</td>
<td>Local</td>
<td>2012</td>
</tr>
<tr>
<td>Samil Industry * (PF)</td>
<td>Sudan</td>
<td>Local</td>
<td>2012</td>
</tr>
<tr>
<td>Société JB (PF)</td>
<td>Madagascar</td>
<td>Local and International</td>
<td>2010</td>
</tr>
<tr>
<td>Société de Transformation</td>
<td>Niger</td>
<td>Local</td>
<td>2006</td>
</tr>
<tr>
<td>Alimentaire * (PF)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tabatchnick Fine Foods Inc.</td>
<td>USA</td>
<td>International</td>
<td>2009</td>
</tr>
<tr>
<td>Valid Nutrition</td>
<td>Malawi</td>
<td>Local</td>
<td>2010</td>
</tr>
</tbody>
</table>

*Suppliers that will trial small international supply shipping in 2014 (PF): suppliers that are members of the PlumpyField network (Nutriset’s franchisees)*

### Remarks:

UNICEF anticipates awarding supply arrangements to two new additional suppliers in Asia (Republic of Korea and Pakistan) and actively seeks potential suppliers in programmatically strategic countries like Nigeria, Chad and DRC, or in their proximity. Facilities are being implemented in Nigeria, South Africa and India at the moment. Another supplier (Reco Industries) manufactures RUTF in Uganda, in partnership with USAID. However they do not supply UNICEF and WFP yet.
Appendix 7: Partnerships for Local Production

The technical requirements to achieve the quality standards and the challenges of access to capital to start production have rendered it difficult for independent producers to manage without technical and financial support. Therefore most local production facilities have partnered with experienced producers who offer various types of support and partnership.

To date most local producers are part of the **PlumpyField network**, initiated by **Nutriset** in 2005. The PlumpyField® network includes 8 local producers and one non-profit in the USA. The network employs a franchising model where Nutriset allows each member to benefit from the transfer of technical know-how through a series of in depth trainings, rights to use the Plumpy® brand, continuing assistance and assistance in establishing links with major global buyers. PlumpyField members must meet a detailed set of criteria and guidelines in terms of the manufacturing process, product formulation and use of high quality raw materials and adhere to Nutriset’s brand and graphic guidelines. The model is financed by a compensation system based on an exclusive clause requiring members to source the premix of minerals and vitamins and other ingredients essential to the manufacture and stability of the Plumpy range of products from Nutriset. Further information/contacts: [http://www.plumpyfield.com/](http://www.plumpyfield.com/)

**Diva Nutritional Products Ltd** is a company based in the Republic of South Africa that manufactures specialised foods and supplements for the local and international markets. They are not involved in local production so far but are currently opening a factory in Nigeria. More information/contacts: [http://www.diva.co.za/](http://www.diva.co.za/)

**GC Rieber Compact** is a Norwegian Company that manufactures two types of RUTF (BP-100™ and peanut-based RUTF) and other supplementary foods. In 2009 Compact established Compact India Private Limited and started producing RUF in India. They are now looking at opening a new factory in South Africa. However these two countries manufacture RUF for export only. More information/contacts: [http://www.gcrieber-compact.com](http://www.gcrieber-compact.com)

**Project Peanut Butter (PPB)** is a US non-profit organisation headed by Dr Mark Manary who initially started therapeutic programmes and local production of RUTF in Malawi in the early 2000s. PPB is now producing RUTF in Sierra Leone and will soon open a factory in Ghana. PPB also supports various small-scale production projects across Africa and beyond, in addition to maintaining their own ongoing projects. Further information/contacts: [http://www.projectpeanutbutter.org/](http://www.projectpeanutbutter.org/)

**Valid Nutrition** operates as a social enterprise that produces RUF locally. Valid Nutrition has a factory in Malawi and is identifying partnerships in Ethiopia, Kenya and Nigeria. Further information/contacts: [http://www.validnutrition.org](http://www.validnutrition.org), and [http://www.validinternational.org](http://www.validinternational.org)

Other US-based suppliers **Mana Nutritive Aid Products Inc** (MANA) and **Tabatchnick Find Foods Inc**, have not engaged in local production as of today, despite an earlier attempt by MANA in Rwanda.