Therapeutic Milk Market Supply & Outlook

UNICEF Supply Division

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Therapeutic Milk
Market Supply and Outlook – March 2015

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1. Summary

- UNICEF procures therapeutic milk for the inpatient treatment of children with complicated severe acute malnutrition (SAM). Two therapeutic milk formula diets known as F-75 and F-100 are used primarily in emergencies to stabilise a patient's rapid nutritional deterioration and ensure their transition to community-based management of acute malnutrition (CMAM), and ultimately return to normal diet.
- UNICEF therapeutic milk procurement represents 80% of current market share. Despite the decline in F-100 demand since 2003, due to increased Ready-to-Use Therapeutic Food (RUTF) use, UNICEF anticipates demand to increase moderately as a result of a programmatic push to scale-up and expand nutrition programmes and in particular, greater adoption of integrated CMAM practices. However, as therapeutic milk product demand is driven largely by emergencies and dependent on short-term emergency donor funding, country forecast accuracy is limited and subject to wide fluctuation.
- Risk of therapeutic milk contamination (*Cronobacter sakazakii*) and the absence of specific commodity standards in the Codex Alimentarius for therapeutic milk led UNICEF and Médecins Sans Frontières (MSF) to apply the Codex Alimentarius standards for powdered infant formulae to F-75 and F-100. The Codex standards' stringent product sampling and testing plans were introduced as a part of product release criteria.
- Sample testing shows that manufacturers do not consistently achieve end-product vitamin and mineral content accuracy. Manufacturer product preparation instructions and labelling are also not consistent with WHO preparation guidelines. End-product content specifications and preparation instructions are being reviewed to ensure products achieve and retain the desired composition upon consumption.
- UNICEF concluded a therapeutic milk tender during 4Q 2013 and has awarded two suppliers new long-term arrangements (LTAs) for 2014 through 2016, extendable by 12 months.

2. Therapeutic Milk Product and Background

SAM remains a major cause of child mortality. An estimated 19 million children under-five suffer from SAM globally. As an underlying cause, it accounts for an estimated 400,000 child deaths per year, of which most are in Africa and South-East Asia.[1] Severe infectious diseases such as diarrhoea, measles, pneumonia, meningitis and malaria, as well as sudden onset food insecurity, are among the leading causes of SAM.WHO recommends that SAM cases presenting with medical complications such as severe oedema (+++), poor appetite or one or more Integrated Management of Childhood Illness (IMCI) danger signs should receive inpatient treatment.[2] F-75 and F-100 are therapeutic milk formulas for the inpatient management of SAM (Table 1).[3] They stabilise a patient's nutritional deterioration, and ensures their transition to CMAM using RUTF. UNICEF's previous May 2014 RUTF Supply Update and Market Outlook provides general market background on RUTF.

Table 1 WHO SAM Treatment Phases and Duration

Phase	Stabilisation Phase 1	Recovery and Rehabilitation Phase 2
Therapeutic Milk Formula	F-75	F-100
Approximate Duration	Days 1-7	Weeks 2-6

Source: WHO.

[1] World Health Organization, *Guideline Updates on the Management of Severe Acute Malnutrition in Infants and Children*, WHO, Geneva, 2013, p.10.
[2] WHO, *Guideline Updates on the Management of Severe Acute Malnutrition in Infants and Children*, p.3.
[3] World Health Organization, *Guidelines for the Inpatient Treatment of Severely Malnourished Children*, WHO, Geneva, 2003, p.10, p.18.

UNICEF procures therapeutic milk as a standard non-stock item as specified below (Table 2). It is a UNICEF strategic commodity and is included in UNICEF's Emergency Supply List. UNICEF commits to supply the product within 72 hours in emergencies. However, the introduction of stricter microbiological control and quality requirements may constrain supply and increase lead times for delivery.

Table 2 Therapeutic Milk Products Available through UNICEF

Material Number	Product	Packaging
S0000208	F-75	F-75 therapeutic diet, sachet 102.5g / Carton-120
S0000209	F-100	F-100 therapeutic diet, sachet 114g / Carton-90

Source: UNICEF Supply Division.

The F-75 and F-100 refers to product energy density (75 kcal/100ml and 100-110 kcal/100ml respectively). They contain powdered milk, fortified with added vegetable fats, sugar, vitamins and minerals (Table 3). However, UNICEF and manufacturer sampling and testing shows that the accuracy of end-product composition is not consistently achieved due to the existing natural mineral and vitamin content of primary base products. UNICEF is working with WHO and manufacturers to review and define clearer therapeutic milk composition specifications, to ensure that vitamin and mineral content targets are achievable and maintained after product preparation using hot water.

Table 3 WHO F-75 and F-100 Ingredients and Composition[4]

F-75 – Phase 1		F-100 – Phase 2	
Ingredients	**Composition**	**Ingredients**	**Composition**
Powdered milk 25g Sugar 70g Cereal flour 35g Vegetable oil 27g Mineral mix 20ml Vitamin mix 140mg Water to make 1,000ml	Energy 75kcal$_{th}$ (315kJ) Protein 0.9g Lactose 1.3g Potassium 3.6mmol Sodium 0.6mmol Magnesium 0.43mmol Zinc 2.0mg Copper 0.25mg Energy from protein 5% Energy from fat 32% Osmolarity 333mOsmol/l	Powdered milk 80g Sugar 50g Vegetable oil 60g Mineral mix 20ml Vitamin mix 140mg Water to make 1,000ml	Energy 100kcal$_{th}$ (420kJ) Protein 2.9g Lactose 4.2g Potassium 5.9mmol Sodium 1.9mmol Magnesium 0.73mmol Zinc 2.3mg Copper 0.25mg Energy from protein 12% Energy from fat 53% Osmolarity 419mOsmol/l

Source: WHO.

F-75 and F-100 require reconstitution in 500 ml of clean water. Current manufacturer instructions advise preparation to use boiled water, cooled down to room temperature. WHO recommendations advise powdered infant formulae preparation to use water at 70°C, to avoid any potential risk of microbiological contamination.[5] Manufacturer product preparation instructions and labelling are currently not consistent with WHO preparation guidelines. UNICEF is working with manufacturers to confirm if preparation with water at 70°C affects the product's vitamin and mineral levels. Some middle-income countries (e.g. South Africa) are also testing a liquid form of therapeutic milk to address the challenges of product preparation.

Therapeutic milk is supplied in sachets, which are now supplied in smaller sizes than previously produced. Whereas sachets previously produced 2.4 litres of therapeutic milk when reconstituted, the introduction of CMAM, and treatment at a household level, reduced the number of children requiring treatment in centres and the need for such

[4] World Health Organization, *Management of Severe Malnutrition: A Manual for Physicians and Other Senior Health Workers*, WHO, Geneva, 1999, p.13-14.

[5] Food and safety standards referring to powdered infant formulae apply to therapeutic milk, as they are similar products.

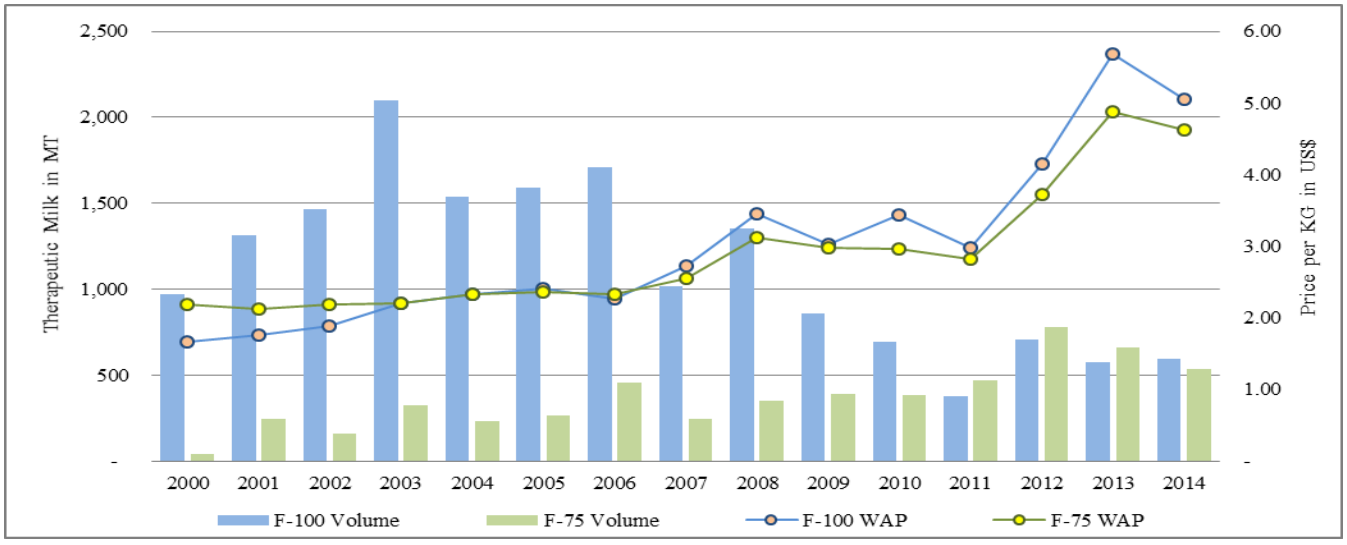
large volumes of therapeutic milk. Reconstituted therapeutic milk is for immediate consumption, or within 24 hours if refrigerated. In order to prevent wastage and avoid preparation errors using scoops to acquire smaller volumes, UNICEF and manufacturers developed a smaller sachet size to produce 600 ml.[6]

Ideally, therapeutic milk production should occur in facilities dedicated to powdered infant formulae production. However, not all UNICEF therapeutic milk suppliers had dedicated production facilities, which increased the risk of micro-organism contamination, including *Cronobacter sakazakii* and *Salmonella*. In response to several incidents of powdered infant formulae contamination, the Food and Agriculture Organization (FAO) published a code of hygienic practices for powdered formulae for infants and young children CAC/RCP 66 - 2008. To establish stricter therapeutic milk production control, UNICEF and MSF applied the sampling plan and release criteria from Codex Alimentarius' standard for powdered infant formulae to F-75 and F-100 product specifications as of 2013.

In emergency and relief situations, WHO recommends babies to be breastfed if possible.[7] Artificial feeding beyond curative therapeutic care in an emergency to address SAM is difficult, hazardous and can lead to increased infant mortality.[8] The promotion and marketing of breast milk substitutes is a concern for UNICEF and WHO.[9] Artificial feeding can undermine the importance of breastfeeding, which is the ideal for infant and young child optimal health, growth and development. UNICEF and WHO recommend that infants are breastfed exclusively for the first 6 months to two years of life. WHO's International Code of Marketing of Breast Milk Substitutes, adopted by the World Health Assembly (WHA) in 1981, regulates the inappropriate sale and promotion of infant foods used to replace breast milk. UNICEF and WHO support and enforce the code through their respective established policies. The International Baby Food Action Network (IBFAN) monitors code implementation and violation. UNICEF reviews the IBFAN reports to ensure that contracted suppliers comply with the code.

3. Demand

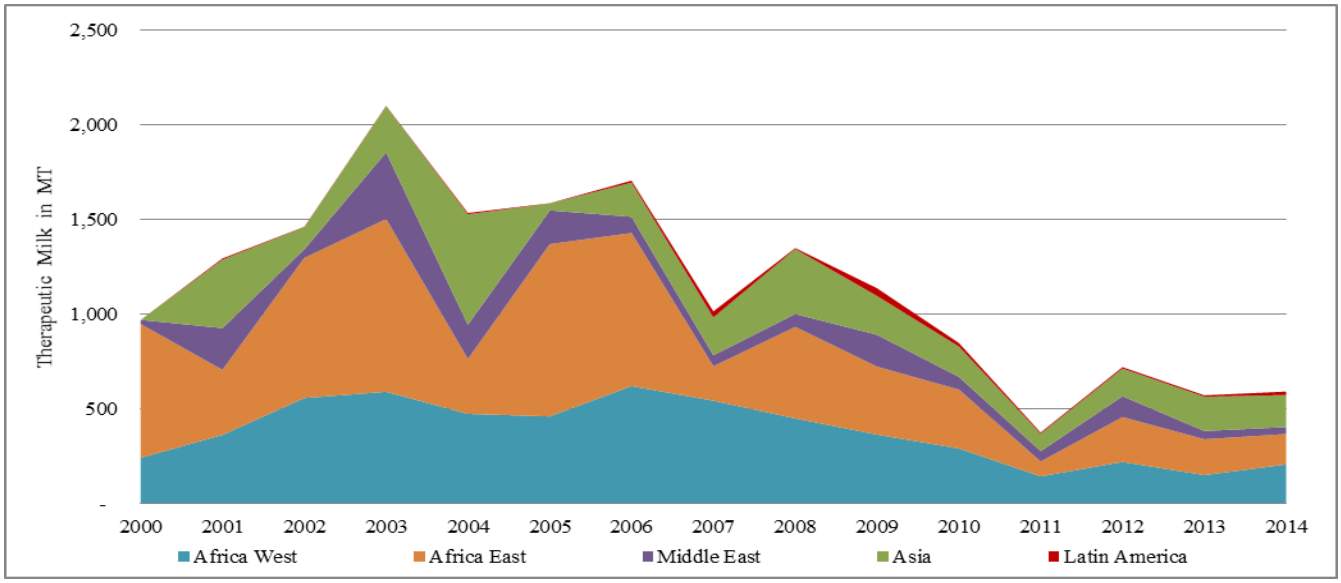
Figure 1 UNICEF Therapeutic Milk Procurement in MT and Annual Weighted Average Prices in US dollars (US$) from 2000 to 2014



Source: UNICEF Supply Division.

[6] UNICEF, *Therapeutic Milk*, Technical Bulletin No.15, UNICEF, Copenhagen, 2010.
[7] World Health Organization, *Infant and Young Child Feeding*, WHO, Geneva, February 2014.
[8] International Baby Food Action Network, *How Breast Feeding Is Undermined*, IBFAN, Geneva, 2014.
[9] UNICEF, *Breastfeeding*, UNICEF, New York, August 2014.

Figure 2 UNICEF F-100 Therapeutic Milk Procurement in MT per Region 2000-2014



Source: UNICEF Supply Division.

From 2000 to 2010, the volume of demand for F-75 therapeutic milk procured through UNICEF has steadily increased, while procurement of F-100 has declined markedly as a result of the introduction of RUTF (Figure 1). Africa accounts for over 60% of F-100 demand, followed by Asia, the Middle East and Latin America (Figure 2). Whereas demand from East Africa varies annually, influenced by crises and natural disasters (droughts, civil war and famine), the demand from West Africa has been consistent in response to chronic food insecurity in the Sahel. The top five countries requesting procurement of F-100 in terms of volume are Burundi, DPR Korea, DR Congo, Ethiopia and Sudan.

The demand for therapeutic milk through UNICEF is difficult to forecast accurately as it is an emergency product. It depends on emergency programming, tight delivery schedules, and the availability of donor funding. Country forecast accuracy ranges from -68% to +54% and between -1,500 MT to +400 MT. However, based on the past two years of actual procurement volumes, UNICEF anticipates demand will moderately increase on account of the programmatic push to scale-up and increase coverage of malnutrition.

4. Supply

Therapeutic milk supply through UNICEF accounts for over ~80% of global market share. UNICEF has currently two LTAs with suppliers (Table 4).

Table 4 Suppliers LTA Information

Supplier	Type of supply	Duration years	Start	End
Hochdorf Nutricare (The Netherlands)	F-75	24 months +12	March 2014	March 2016
	F-100	24 months +12	March 2014	March 2016
Nutriset (France)	F-75	24 months +12	January 2014	February 2016
	F-100	24 months +12	January 2014	February 2016

Source: UNICEF Supply Division.

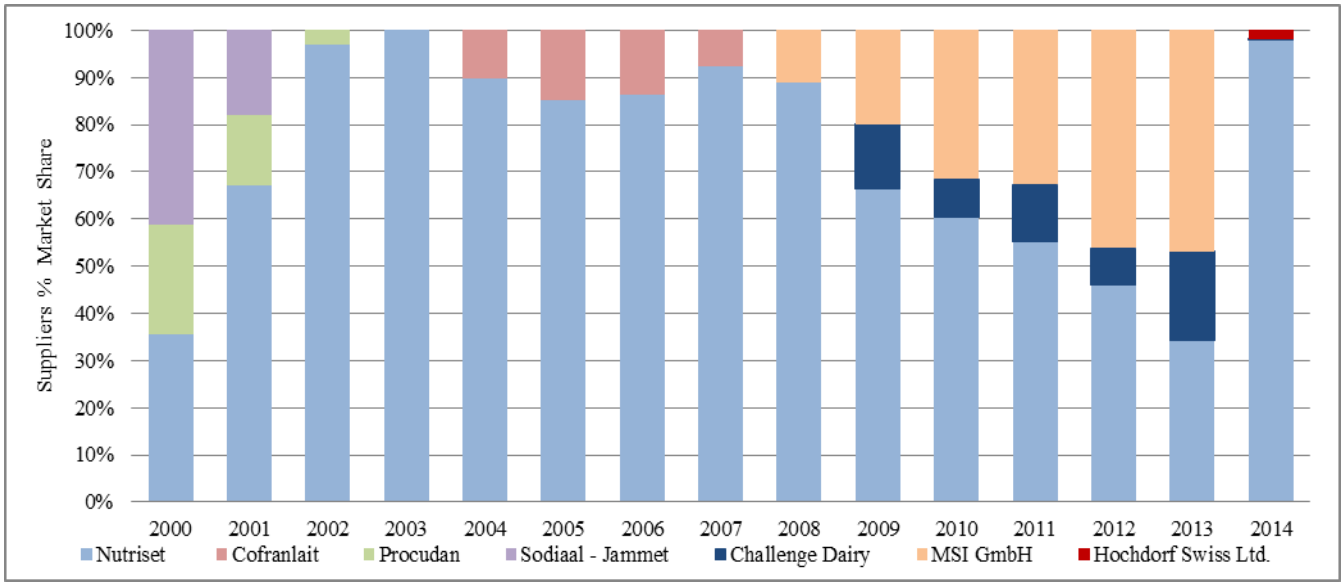
The therapeutic milk market is relatively small compared to that of powdered infant formulae, estimated at $14 billion annually.[10] The standards, codes, regulations and technological requirements for therapeutic milk production may discourage the development and expansion of new market entrants into an already limited market.

In general, UNICEF uses different procurement and tender strategies to motivate additional new market entrants. However, the investment required for product development and production process upgrades challenge potential suppliers in the therapeutic milk market. As a result, one supplier, Nutriset from France, remains the only consistent supplier in the market (Figure 3). UNICEF will continue to encourage new market entrants in order to diversify the market's supplier base. Sources of financing for new and growing manufacturers can be found here.

Supplier performance through UNICEF has been good: 80-90% of orders from 2013 through 2014 met their target arrival dates at destination, even though some suppliers could improve. The introduction of smaller therapeutic milk pack sizes (2011) and increased product testing requirements for microorganism contamination (2012) effected some product lead-times for delivery and pricing.

The weighted average price (WAP) for F-75 and F-100 in 2014 was US$ 4.62 and US$ 5.05 respectively (Figure 1). The WAP trend for therapeutic milk since 2000 steadily increased due to declining volumes. In addition, the price of therapeutic milk is dependent on the market price of its main constituent - Non-fat Dry Milk (NFDM), as well as the price of packaging materials. The market price for NFDM fluctuates substantially (±225%) due to the volatility in demand from large populous Asian countries (China and India). As a result, the NFDM price can range between US$ 400 and US$ 900 per MT. UNICEF anticipates the current WAP to increase further as suppliers acquire dedicated production facilities for therapeutic milk.

Figure 3 Therapeutic Milk Supplier Market Share through UNICEF



Source: UNICEF Supply Division.

5. Issues and Challenges

Table 5 describes the key issues and challenges facing therapeutic milk supply and the possible actions UNICEF will take to address them.

[10] Bandy, Lauren, *Toddler Milk Formula: The Hello Kitty of Packaged Food*, Euromonitor International, London, 14th February, 2014.

Table 5 Major Therapeutic Milk and Supply Challenges

Issues	Considerations
• **Shelf life**: Product shelf life is limited to 24 months, though suppliers' stability data is incomplete.	• Suppliers need to complete their product stability studies and provide the reports to UNICEF. UNICEF will follow up with periodic updates during the LTA period.
• **Storage conditions**: Products are sensitive to storage conditions and require dry conditions below 25°C. Inappropriately stored product gradually turns yellow/brown from white.	• UNICEF updated its Supply Manual in 2014[11] and included revised storage condition instructions. UNICEF country offices are to implement the instructions.
• **Dedicated production facilities**: Suppliers did not have dedicated production facilities, which increased the risk of microorganism contamination.	• UNICEF requires manufacturing sites producing therapeutic milk to comply with Codex standards CAC/RCP 66 - 2008.
• **Product preparation labelling instructions**: Product label instructions are not consistent with WHO guidelines for infant formula preparation, procedures, staff and facility hygiene requirements.	• UNICEF reviews product preparation instructions and labelling to be consistent with WHO preparation guidelines.
• **WHO's International Code of Marketing of Breast Milk Substitute restrictions and violations:** UNICEF is hesitant to contract powdered infant formulae manufacturers that violate the WHO Code. UNICEF has no defined process or minimum criteria in its procurement procedures regarding manufacturer compliance with the WHO Code.	• UNICEF reviews IBFAN's WHO Code violations report, including actions taken by manufacturers named in the last (2014) report, to assess the need for special contracting options or verification requirements. • UNICEF contract provisions will refer to the WHO Code in all future nutrition supply LTAs.

Source: UNICEF Supply Division.

6. Steps Forward

- UNICEF will advocate for therapeutic milk to be included in WHO's Model Essential Medicines List to encourage countries to plan and procure therapeutic milk for their health programmes.
- UNICEF will identify minimum criteria for manufacturer compliance and formalise a process to assess WHO Code violations in relation to procurement procedures. UNICEF contract provisions will refer to the WHO Code in all future nutrition supply LTAs.
- UNICEF will continue to work with WHO and therapeutic milk manufacturers to specify vitamin and mineral content to ensure that manufacturers can meet product specifications.
- UNICEF will continue to work with manufacturers to confirm if preparation with water at 70°C affects the product's vitamin and mineral content and levels.
- UNICEF will investigate therapeutic milk preparation in health facilities as well as prevalent hygienic practices to assess potential contamination risk and options for different product presentations.
- UNICEF will explore the possibility to procure F-75 and F-100 in liquid form for countries challenged with safe reconstitution.

For further questions or additional information, please contact:

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Other UNICEF information notes can be found at: https://www.unicef.org/supply/market-notes-and-updates

[11] UNICEF's Supply Manual is only accessible through UNICEF's intranet.