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Therapeutic Milk: Market & Supply Update

UNICEF Supply Division

April 2018

Therapeutic Milk Market and Supply Update – April 2018

This update provides information on therapeutic milk supply for the period 2018-2019. It highlights new product packaging in metal canisters allowing for a longer shelf life, preparation in smaller quantities, less waste, reduced contamination risks, and alignment with Codex Alimentarius standards for hygienic practices for powdered infant formula.

1. Summary

- Therapeutic milk formula F-75 and F-100 are strategic products used by UNICEF and partners to support nutritional feeding programmes aimed at decreasing under-five child mortality from severe acute malnutrition (SAM).
- UNICEF procures F-75 and F-100 for the inpatient treatment of children with complicated SAM primarily in emergencies. Health workers use F-75 and F-100 for inpatient care to stabilize a patient's nutritional deterioration, and to ensure their transition to community-based management of acute malnutrition (CMAM), and return to normal diet.
- Over the last few years, nutrition programmes use less F-75 and F-100 in favour of ready-to-use therapeutic food (RUTF), which does not require mixing with water and enables home treatment through CMAM. However, UNICEF continues to regard F-75 and F-100 as strategic products that are essential for the inpatient treatment of SAM with complications.
- UNICEF, in collaboration with the World Health Organization (WHO) and partners, have improved the standards and quality of service delivery for children with SAM by driving improvements in processing and packaging F-75 and F-100. Manufacturers now package F-75 and F-100 in canisters instead of sachets. Canisters reduce the risk of contamination during production; extend product shelf life; and allow health workers to use the product for a longer period after opening. In addition, manufacturers replaced the product's main dairy ingredient of whey powder with milk powder to give products a milkier texture with less separation when added to water.
- Therapeutic milk procurement through UNICEF represents an 80% share of the global market. Despite the decline in procurement in favour of RUTF, UNICEF anticipates the demand for therapeutic milk to increase moderately as a result of the continued scale-up and expansion of integrated CMAM. However, forecast accuracy remains a challenge given the emergency nature of the programmes using these products and their dependence on donor funding.
- In 2017, UNICEF awarded long-term arrangements (LTAs) to two suppliers through 2018 and 2019, with a possible extension for further 12 months.

2. Background

In 2016, the total number of deaths in children under-five worldwide reached 5.6 million. Even though it represents a drop of 56% since 1990,¹ WHO estimates approximately 45% of all under-five deaths are related to aspects of malnutrition and its various forms.² This represents the loss of approximately 2.5 million children a year, mostly from low- and middle-income countries (LICs and MICs) across Africa and Asia.³ Malnourished children, particularly those suffering from SAM,

¹ World Health Organization, [Children: Reducing Mortality](#), WHO, October 2017.

² World Health Organization, [Malnutrition](#), WHO, Geneva, May 2017.

³ UNICEF, World Bank Group, World Health Organization, [Joint Child Malnutrition Estimates – Key Findings of the 2017 Edition](#), UNICEF, New York, May 2017, p. 3.

have a higher risk of mortality from common childhood diseases such as diarrhoea, malaria, and pneumonia. The interaction between malnutrition and infection can also create potentially lethal cycles of deteriorating illness and nutritional status.

In 2016, UNICEF, WHO, and the World Bank Group estimated there were approximately 52 million children under-five suffering from wasting, of which 17 million suffered from its severe form, SAM.⁴ Poor nutrition during a child’s first one thousand days of life can also lead to stunting, which is irreversible, and affects cognitive ability, reducing school and work performance.⁵

In 2015, world leaders at the United Nations (UN) Sustainable Development Summit adopted the Sustainable Development Goals (SDGs) including targets that tackle malnutrition. Targets 2.1. and 2.2. seek to ensure access to safe, nutritious, and sufficient food all year round, and end all forms of malnutrition, respectively, and target 3.2. seeks to end all preventable deaths of children under-five by 2030.⁶

2.1. Therapeutic Milk Products

UNICEF procures therapeutic milk as strategic, standard products (Table 1). F-75 and F-100 are powdered milk diet products with added vegetable fats, carbohydrates, and fortified with 13 vitamins and 10 minerals. They provide the special dietary requirements for young children and infants above six months of age with SAM. F-75 and F-100 refer to their respective energy density characteristics of 75kcal/100ml and 100-110kcal/100ml, respectively. As these products are essential relief items required for UNICEF emergency response, UNICEF includes them in its Emergency Supply List (ESL).⁷ These products have a limited shelf life, and so they are not stocked at UNICEF’s warehouse in Copenhagen, but rather produced on order and shipped directly from suppliers.

Table 1 Therapeutic Milk Products Available through UNICEF

Material Number	Product	Packaging
S0000236	F-75	F-75 Therapeutic milk CAN 400g/CAR-24
S0000237	F-100	F-100 Therapeutic milk CAN 400g/CAR-24
S0000208	F-75	F-75 Therapeutic diet, sachet, 102.5g/CAR-120
S0000209	F-100	F-100 Therapeutic diet, sachet, 114g/CAR-90

Source: UNICEF Supply Division

Trained health workers use F-75 and F-100 for inpatient care to treat children with SAM who have medical complications, which include severe oedema, poor appetite, or one or more integrated management of childhood illness (IMCI) danger signs. WHO’s treatment protocol recommends health workers use F-75 during the first phase of inpatient stabilization and F-100 during the second phase of nutritional recovery and rehabilitation, until interventions stabilize a patient’s nutritional deterioration (Table 2).⁸

⁴ Ibid., p. 2.

⁵ UNICEF, *Malnutrition, Current Status and Progress*, UNICEF, Geneva, December 2017.

⁶ United Nations, *Sustainable Development Goal 3, Ensure Healthy Lives and Promote Well-being for All at All Ages*, UN, New York, 2015.

⁷ UNICEF, *List of Approved Emergency Items: Emergency Supply List, UNICEF*, Copenhagen, September 2017.

⁸ World Health Organization, *Updates on the Management of Severe Acute Malnutrition in Infants and Children*, WHO, Geneva, 2013.

Table 2 WHO SAM Treatment Phases and Duration

Phase	Stabilization - Phase 1	Rehabilitation - Phase 2
Approximate phase duration	Days 1-7	Weeks 2-6
Required therapeutic milk formula	F-75	F-100

Source: World Health Organization

As patients start to regain sufficient appetite, they transition to CMAM and RUTF. Following the introduction of CMAM programmes, scale up, and use of RUTF in countries, the use of F-100 has been reduced to about 4 days from 2-6 weeks. UNICEF provides a detailed market update highlighting [RUTF market and supply availability](#).⁹

2.2. Product Composition and Packaging

Manufacturers re-designed the sachets used for F-75 and F-100 to allow health workers to reconstitute the entire contents at one time in 500ml of water, to make approximately 600ml of therapeutic milk. However, observers noted that end-users were often inconsistent in following the label's instructions in preparing therapeutic milk. For example, health workers used scoops or spoons not developed or designed for use with therapeutic milk, making it difficult to ensure a correct dosing. In addition, once opened, health workers left the remaining milk powder open and exposed it to the risks of contamination, as they could not effectively reseal the sachets. A recent joint UNICEF-Médecins Sans Frontières (MSF) audit of a potential therapeutic milk manufacturer noted that sachets have a higher risk of microbial contamination during production compared to canisters. Industry sources also confirmed that canisters are the powdered infant formula (PIF) industry's standard packaging. Over the last 10 years, industry standards and best practices in both the production of specialized milks, and the instructions given for inpatient setting preparations, have adapted to better address the risks of food safety.

As such, in collaboration with WHO and partners, UNICEF sought to improve the standards and quality of service delivery for children with SAM with improvements to F-75 and F-100 processing and packaging. UNICEF now also supplies F-75 and F-100 in new 400g metal canisters with a plastic lid and scoop.¹⁰ They were specifically developed to allow the preparation of smaller amounts of therapeutic milk (as little as 28ml), should only a small number of patients need treatment (Table 3),¹¹ together with the option to gradually phase out using sachets. The new resealable packaging allows therapeutic milk once opened to have a longer shelf life, increasing it from 24 hours to four weeks, compared to sachets, resulting in less wastage. Canisters also reduce the risk of contamination during production, storage, and usage.

Table 3 Packaging and Pack Size

Material Nb.	Short description	Carton Gross Weight / Volume	Image
S0000236	<ul style="list-style-type: none"> Canister contains 400g of F-75 therapeutic milk powder and scoop. Each carton contains 24 canisters. 	<ul style="list-style-type: none"> 13.7-14.0 kg 0.035-0.046 m³ 	
S0000237	<ul style="list-style-type: none"> Canister contains 400g of F-100 therapeutic milk powder and a scoop. Each carton contains 24 canisters. 	<ul style="list-style-type: none"> 13.7-14.0 kg 0.035-0.046 m³ 	

Source: UNICEF Supply Division

⁹ UNICEF, [Ready-to-Use Therapeutic Food: Current Outlook](#), UNICEF, Copenhagen, February 2017.

¹⁰ F-75 comes with a white branded scoop; and F-100 comes with a blue branded scoop.

¹¹ UNICEF, [Product Update for Therapeutic Milk F-75 and F-100, Technical Bulletin, No.23](#), UNICEF, Copenhagen, August 2017.

Manufacturers also improved products by replacing whey powder as the main dairy ingredient with milk powder, to provide a milkier texture with less separation once health workers mix it with water. Even though all product nutrient levels remain unchanged, the improvements to therapeutic milk products procured through UNICEF represent greater alignment with the Food and Agriculture Organization's (FAO) Code of Hygienic Practice for Powdered Formulae for Infants and Young Children ([CAC/RCP 66 2008](#));¹² FAO and WHO's [Safe Preparation, Storage, and Handling of Powdered Infant Formula Guidelines](#);¹³ as well as industry best practices.

2.3. Product Use

WHO recommends health workers prepare therapeutic milk with boiled, safe drinking water that has been left to cool for a minimum 3-5 minutes (so that the water temperature is no cooler than 70°C).¹⁴ Health workers should leave the prepared therapeutic milk to cool to feeding temperature before giving it to patients.

In emergency and relief situations, WHO recommends babies to be breastfed if possible. Artificial feeding beyond curative therapeutic care in an emergency to address SAM is difficult, hazardous, and can lead to increased infant mortality. UNICEF and WHO are concerned about the promotion and marketing of breast milk substitutes, as artificial feeding can undermine the importance of breastfeeding, which is *the ideal* for optimal infant and young child health, growth, and development. UNICEF and WHO recommend that infants are breastfed exclusively for the first 6 months to two years of life. The World Health Assembly's (WHA) [International Code of Marketing of Breast Milk Substitutes \(IBMF\)](#), adopted 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. Current Market Situation

3.1. Changes in Demand and Forecast

The demand for therapeutic milk through UNICEF is difficult to accurately forecast as funding unpredictability affects country forecast accuracy. As it is an emergency product, actual demand depends on emergency programming, schedules, and donor funding.

UNICEF procurement of F-75 and F-100 reached 2,400 MT in 2003, and gradually declined to level off at around 1,000-1,200 MT annually as a result of the successful introduction of RUTF, and the implementation of CMAM programmes after 2007 (Figure 1).¹⁵ Consequently, the relative share of F-75 and F-100 procurement volumes also changed over time. While F-100 originally represented over 80–90% of total therapeutic milk demand, its share gradually reduced to below 50% in 2011. Even children suffering from SAM with complications, requiring treatment with F-100, now stay for shorter periods of time in hospitals, as caregivers manage the final stages of recovery with RUTF at home. On the other hand, the concurrent increase in F-75 demand reflects integrated SAM management programmes and geographical expansion, as country programmes

¹² Food and Agriculture Organization, [Code of Hygienic Practice for Powdered Formulae for Infants and Young Children CAC/RCP 66 2008](#), FAO, Rome, 2015.

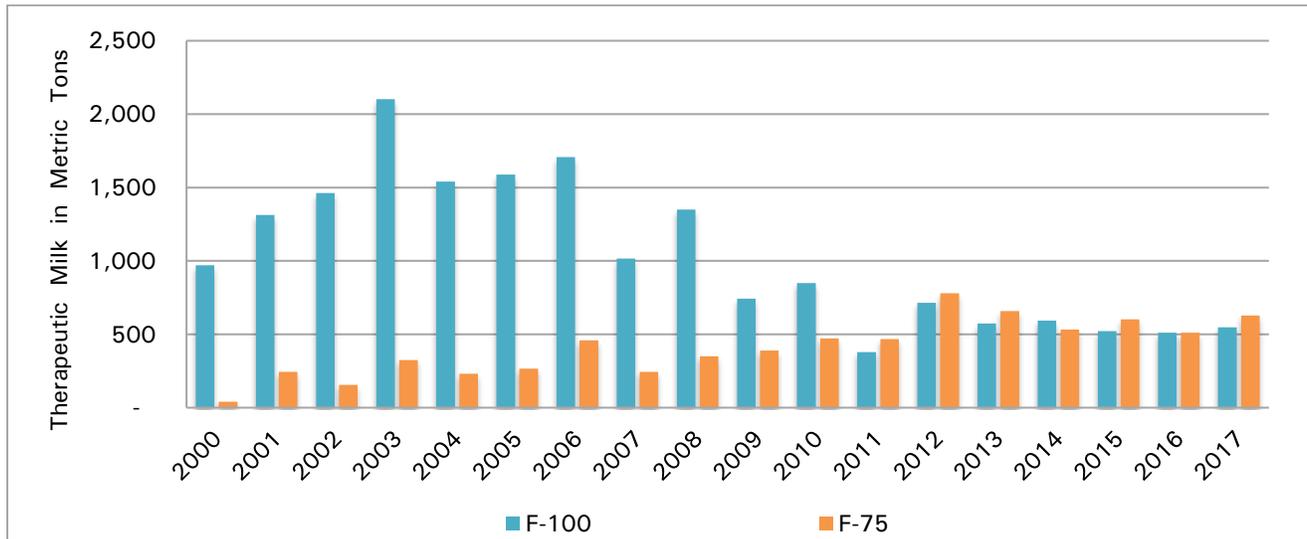
¹³ Food and Agriculture Organization, World Health Organization, [Safe Preparation, Storage, and Handling of Powdered Infant Formula Guidelines](#), WHO, Geneva, 2007.

¹⁴ Ibid., p. 9.

¹⁵ UNICEF, the UN Standing Committee on Nutrition, WHO, The World Food Programme, [Joint Statement on Community-Based Management of Severe Acute Malnutrition](#), UNICEF, Geneva, May 2007.

include more inpatient facilities. UNICEF anticipates therapeutic milk demand will increase moderately, due to ongoing integrated CMAM scale-up and expansion. However, as CMAM expansion and beneficiary numbers in several countries level out, UNICEF anticipates the trend in demand will stabilize at a slightly higher level, unless there is additional funding and investment by governments. UNICEF does not anticipate the introduction of canisters, replacing sachets, to affect total procurement volumes.

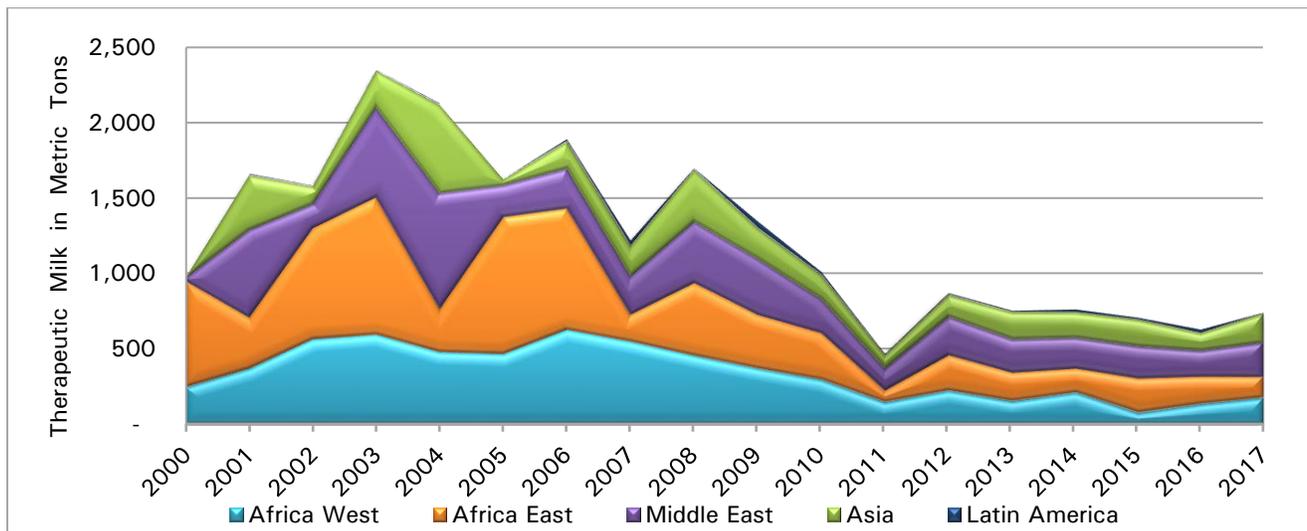
Figure 1 UNICEF Therapeutic Milk Procurement 2000 – 2017



Source: UNICEF Supply Division

Africa accounted for most of UNICEF’s F-100 demand in 2017 (42%), followed by the Middle East (31%), and Asia (26%) (Figure 2). Whereas demand from East Africa varies annually, and is influenced by regular cycles of crisis and natural disasters (droughts, conflicts, and famine), demand from West Africa has been consistent due to chronic food insecurity in the Sahel. Afghanistan, Angola, DPR Korea, Ethiopia, Nigeria, and Yemen are the countries that had the largest demand for F-100 in 2017.

Figure 2 UNICEF F-100 Therapeutic Milk Procurement per Region 2000 – 2017



Source: UNICEF Supply Division

3.2. Supply

The market for therapeutic milk accounts for approximately USD 6-8 million annually, and is modest when compared to the global market for PIF, worth an estimated USD 41 billion annually.¹⁶ However, within the therapeutic milk market UNICEF’s procurement constitutes an 80% market share. The International Committee of the Red Cross (ICRC), MSF, WHO, and other non-governmental organizations (NGOs) procure the remainder.

Ideally, therapeutic milk production should occur in facilities with dedicated PIF production. In the past, not all UNICEF therapeutic milk suppliers had dedicated production facilities, which increased the risk of microbiological contamination, including from *Cronobacter sakazakii* and *Salmonella*. In response to several incidents of PIF contamination, FAO published a Code of Hygienic Practices for Powdered Formula for Infants and Young Children (CAC/RCP 66-2008).¹⁷ To establish stricter therapeutic milk production control, UNICEF applied the Codex Alimentarius’ standard for PIF to F-75 and F-100 product specifications, sampling plan, and release criteria as of 2013.

In 2017, UNICEF concluded its therapeutic milk tender targeting suppliers with dedicated PIF-standard manufacturing capacity. UNICEF awarded LTAs to two suppliers that meet the Codex’ standards for hygienic production of infant milk formulas (Table 4). Knowing that therapeutic milk is a high-risk product considering the vulnerable nature of the beneficiaries requiring it, UNICEF is planning to award an LTA to a third manufacturer to ensure continuous supply availability and mitigate any risks that could disrupt therapeutic milk supply.

Table 4 UNICEF Supplier Long-Term Arrangement

Supplier	Product	LTA start date	LTA end date
Nutriset, France	F-75 Therapeutic milk, CAN, 400g	04/07/17	03/07/19
	F-100 Therapeutic milk, CAN, 400g	04/07/17	03/07/19
Aspen Pharmacare, South Africa	F-75 Therapeutic milk, CAN, 400g/CAR-24	08/09/17	07/09/18
	F-100 Therapeutic milk, CAN, 400g/CAR-24	08/09/17	07/09/18
	F-75 therapeutic diet, sachet, 102.5g/CAR-120	08/09/17	07/09/18
	F-100 therapeutic diet, sachet, 114g/CAR-90	08/09/17	07/09/18

Source: UNICEF Supply Division.

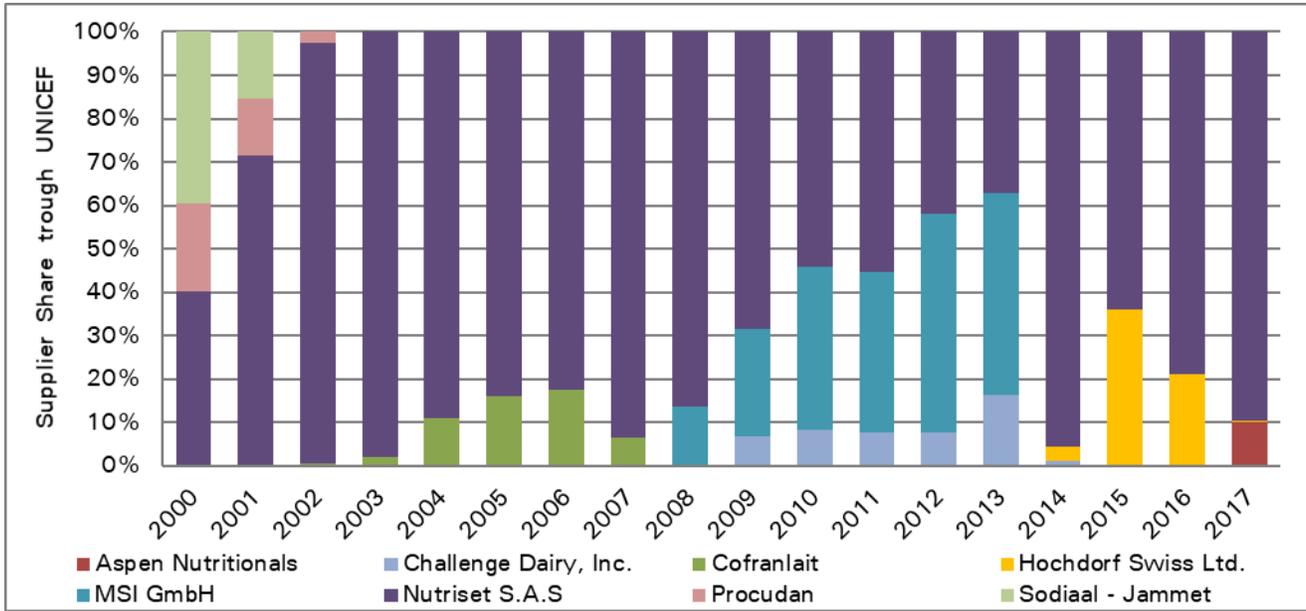
UNICEF does not stock therapeutic milk at its warehouse in Copenhagen due to its limited shelf life. Rather, manufacturers deliver directly to consignees. The minimum order is for one carton containing 24 canisters. Purchase orders can take 30 to 90 days to deliver on account of processing, production, sampling/testing, and shipment. Supplier performance through UNICEF has been good, with most orders averaging 83%-93% of their target arrival dates at destination, even though suppliers can further improve performance.

Supplier interest in manufacturing therapeutic milk continues to evolve over time. It is a relatively small and highly specialized market, requiring regular investment in product development and upgrades to production processes to comply with FAO’s Codex Alimentarius standards, which poses a challenge to many potential suppliers. Figure 3 provides an overview of the different therapeutic milk suppliers through UNICEF from 2000 through 2017.

¹⁶ Lauren Bandy, [Toddler Milk Formula: The Hello Kitty of Packaged Food](#), Euromonitor International, London, February 2014.

¹⁷ FAO, [Code of Hygienic Practice for Powdered Formulae for Infants and Young Children CAC/RCP 66 2008](#).

Figure 3 Therapeutic Milk Procurement Share in Volume through UNICEF 2010–2017

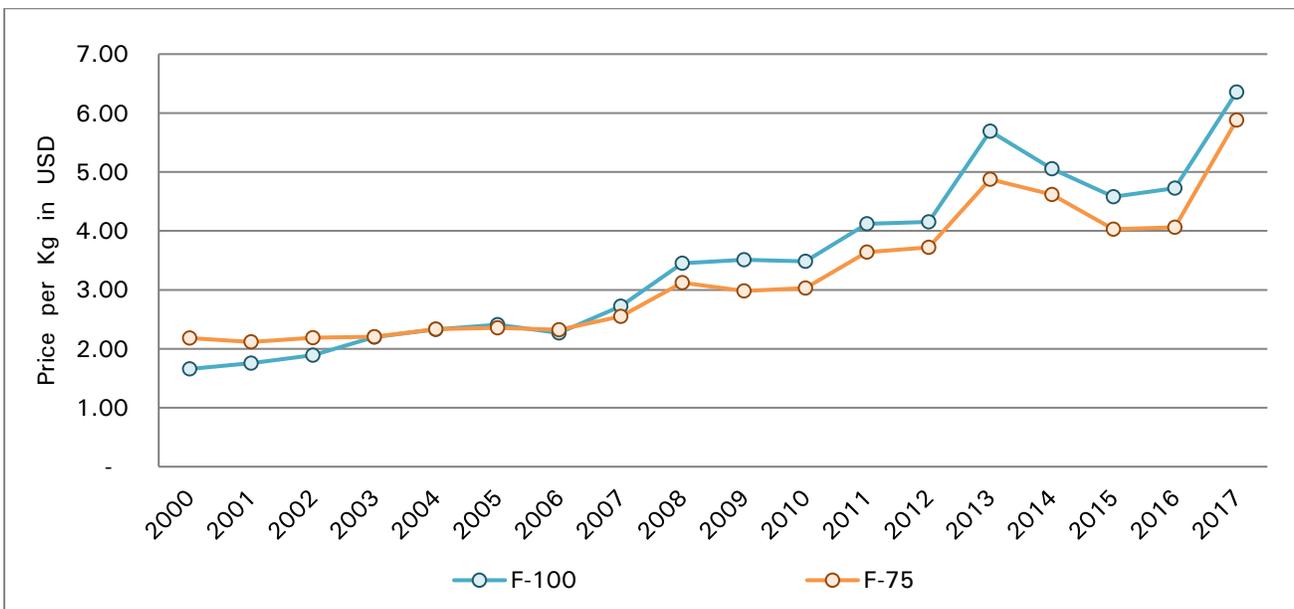


Source- UNICEF Supply Division

3.3. Pricing

Figure 4 describes the weighted average price (WAP) trend for therapeutic milk since 2000. The price of therapeutic milk is heavily dependent on several factors, including the price of milk powder, which fluctuates significantly according to shifts in global supply and demand; as well as packaging materials; USD-EUR foreign exchange rate fluctuations; and the relative profit margins for infant formula, which uses the same manufacturing capacity as therapeutic milk.

Figure 4 Therapeutic Milk Weighted Average Price 2000 - 2017



Source: UNICEF Supply Division

The reduction in size of therapeutic milk sachets, introduced in 2011, increased the finished product's pricing by about 30%. The recent replacement of sachets by metal canisters with scoops, combined with improved quality requirements, significantly increased prices further in 2017 by 30-40% (Figure 4). The price increase reflects mostly the higher quality production requirements as well as the use of higher quality production systems. The systems are different from those used to produce sachets in previous tenders, and used to produce therapeutic milk in canisters. They are the industry standard and their use for therapeutic milk is in competition with producing higher value infant formula products.

For current indicative prices please consult [UNICEF's Supply Catalogue](#).^{18, 19}

4. Issues and Challenges

The market for therapeutic milk faces a number of key issues and challenges (Table 5), for which UNICEF identifies a number of possible actions to address them.

Table 5 Major Therapeutic Milk Market and Supply Chain Challenges – Continued overleaf

Issues / Challenges	Actions / Considerations
<ul style="list-style-type: none"> It is difficult to define the ideal size of a single use sachet; the associated risks with incorrect measuring; as well as additional waste. The use of sachets present a higher risk of microbial contamination. 	<ul style="list-style-type: none"> UNICEF introduced canisters with measuring scoops to ensure products are fit for purpose. The new packaging option will gradually replace sachets.
<ul style="list-style-type: none"> Occurrence of microbial contamination and other quality issues result in product unavailability or recalls. 	<ul style="list-style-type: none"> UNICEF will only procure from manufacturers that have dedicated PIF production facilities, and award LTAs to at least three suppliers to mitigate any disruption to supply availability. UNICEF will ensure early detection through supplier- and UNICEF-initiated sampling and testing protocols. UNICEF is replacing sachets with canisters to reduce the risk of contamination, and align with PIF industry standard packaging.
<ul style="list-style-type: none"> Some suppliers do not have dedicated therapeutic milk production facilities, which can increase the risk of microbiological contamination. 	<ul style="list-style-type: none"> UNICEF now requires manufacturers producing therapeutic milk to comply with Codex standards CAC/RCP 66 - 2008. UNICEF is expanding its supplier base with sufficient manufacturers having their own purpose-built PIF production facilities to ensure demand can be met.
<ul style="list-style-type: none"> Products have a limited 24-month shelf life, as stability data from suppliers is incomplete. 	<ul style="list-style-type: none"> UNICEF will follow up with suppliers the need to complete their products' stability studies during their LTA period.
<ul style="list-style-type: none"> Products are sensitive to storage conditions and require dry conditions maintained below 25°C. Products stored inappropriately gradually turn yellow/brown from white. 	<ul style="list-style-type: none"> UNICEF recommends country offices to implement optimal storage instructions as specified in UNICEF's Supply Manual, and support partners to assure warehouses and health facilities have proper storage conditions. UNICEF projects will set and apply the required standards and specifications for temperature controlled transport. UNICEF developed and is disseminating a guidance document for in-country nutrition product transport and storage, taking into account applicable regulations and best practices.
<ul style="list-style-type: none"> Unable to respond timely to emergency requests due suppliers not having minimum stock levels held at their premises. 	<ul style="list-style-type: none"> UNICEF will include in tender documents and LTAs the requirement for suppliers to hold a minimum buffer stock level ready for dispatch within 48 hours of a procurement order.

¹⁸ UNICEF, [Supplies and Logistics](#), UNICEF, Copenhagen, 2017.

¹⁹ UNICEF's Supply Catalogue contains specifications for over 2,000 products that respond to the needs of children and their families. It is designed to assist UNICEF supply staff to identify the most appropriate supplies for country programmes, and assist country offices with their supply planning, delivery, and monitoring.

Issues / Challenges	Actions / Considerations
<ul style="list-style-type: none"> Users report products have a bitter taste and phase separation issues (product formula “separating” when mixed). 	<ul style="list-style-type: none"> The size of buffer stock will be based on UNICEF’s analysis of emergency requests. UNICEF will encourage product recipe improvements, replacing whey powder with milk powder, as well as the correct use of emulsifier, leading products to have a creamier taste, more homogeneity, and less bitter. UNICEF will ensure milk powder inclusion does not change the formula’s lactose level, which remains below the levels normally present in breast milk.

Source: UNICEF Supply Division

5. Steps Forward

- To ensure that UNICEF can meet any demand, and alternative product sources are available to mitigate any risk to supply availability, UNICEF will continue to expand its supplier base with sufficient manufacturers that have dedicated purpose-built PIF production facilities.
- UNICEF will ensure that awarded manufacturers adhere to strict manufacturing and product quality and specification requirements.
- UNICEF will ensure products are fit for purpose through the introduction of canisters, as a new packaging option (while phasing out requirements for the current sachets), as they are more hygienic, protect milk powder from the risks of degradation, and are the industry’s standard packaging for infant formula.
- UNICEF will ensure a timely response to emergency requests through availability of minimum quantities of quality-approved therapeutic milk produced and held at supplier premises.
- UNICEF will explore the possibility to procure F-75 and F-100 in liquid form, or as a dual-pouch product, for countries challenged in being able to ensure the product’s safe reconstitution. These products could offer a solution in situations where resources are limited (e.g. during hospital night shifts, and in emergencies), where access to inpatient care is constrained or where safe water is not easily or readily available.
- UNICEF, and partners, will continue to invest in communication and training programmes for end-users in the field in how to prepare therapeutic milk appropriately. UNICEF and partners, produced video guidance for the safe preparation of F-75 and F-100 in Arabic, English, and French, accessible [here](#).²⁰

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Other UNICEF information notes are found at: http://www.unicef.org/supply/index_54214.html

²⁰ UNICEF, [Safe Preparation of Therapeutic Milks F-75 and F-100, UNICEF](#), Copenhagen, January 2018.