

Introducing Updated Packaging and Reconstitution Guidance for Therapeutic Milk

COMMON MESSAGING DOCUMENT 1: 27 July 2017

Issue: Changes are being made to the packaging and reconstitution of therapeutic milk (TM) as part of ongoing efforts to promote quality care and treatment for children with severe acute malnutrition (SAM) through safe preparation of F75 and F100 therapeutic milk. It is important to note that the change in packaging of TM from sachets to tins does not require a change in the protocol for treatment of SAM. There is however a change in the process of reconstituting the dry TM powder into liquid form before provision to the individual with SAM.

Objective of the document: UNICEF is working with other agencies to coordinate the introduction of TM with updated packaging and reconstitution guidance. This document is intended to be a common resource for agencies that are involved in treatment of SAM. It will support communication to governments and partners as part of the process of introducing the TM with updated packaging and reconstitution guidance in third quarter of 2017. This document provides basic information on what improvements have been made, why these improvements have been made, and how these improvements affect current programming to stabilize and treat children with SAM using TM in inpatient settings.

Additional materials will be developed to support the transition process from sachets to tins. This document has been developed by and for technical staff, representing the best available information at the time of finalization.

Key messages

- Therapeutic milk (TM), previously supplied in sachets, will be supplied in tins with scoops from third quarter of 2017.
- Reconstitution of TM in the current sachet packaging has not mitigated the risks of improper dilution nor food safety and contamination risks when lesser amounts than that of the whole sachet of TM powder are required.
- Over the last 10 years, industry standards and best practices have improved. These changes in TM packaging represent greater alignment with these updated standards and best practices.
- As a result in the improvements in production standards, TM will be produced with a lower risk of contamination, and with a better taste and texture, which may also improve compliance.
- The new packaging will result in the longer life of TM once the packaging is opened: 4 weeks for tin as opposed to 24 hours for sachet.
- The change in packaging of TM from sachets to tins does not indicate a change in the protocol for treatment of SAM. There is however a change in the process of reconstituting the dry TM powder into liquid form before provision to the individual with SAM.

What are the specific improvements?

Packaging

In order to ensure the highest level of compliance with international quality standards in packaging and production process, as of July 2017 the following changes in **TM packaging** will be made:

	F75	F00
Current Packaging	102.5 g sachet of F75	114g sachets of F100
New Packaging from mid-2017 onwards	400g tins for F75 + white scoop	400g tins for F100 + blue scoop

The tins, once open, can still be used for four (4) weeks, versus 24 hours for sachets. The sealable tin will also allow for better storage.

Photos of the new packaging in tins



More detailed information on the new packaging (cost, volume, weight, etc.) can be found in Annex 1.

Production Process

Although the composition is still based on WHO's 1999 manual "Management of severe malnutrition: a manual for physicians and other senior health workers"¹, the TM that will now be supplied is less likely to separate once water is added because they are based on milk powders rather than whey powder. All nutrient levels remain the same. The suppliers are using different ingredients (skim milk instead of whey powder) and a different process (spray drying vs blending) to achieve the same nutritional composition which is explained in detail in this document.

Why have improvements been made to packaging of F75 and F100 previously supplied in sachets?

There are two main reasons why the changes in TM are being made:

1. **Minimising Contamination Risk and Incorrect Reconstitution during preparation of TM feeds** - Therapeutic milk (F-75 and F-100) is a commodity used for treatment of children with Severe Acute Malnutrition (SAM) with medical complications in an inpatient setting. Both products require reconstitution with clean water before use and trained health care staff for their administration. **Current F75 and F100 sachet packaging is not mitigating the risks of improper dilution nor food safety and contamination risks when small amounts of TM are required.**

Sachets are designed to be reconstituted in their entirety at one time with 1 sachet + 500 ml of water = around 600 ml of TM. The current smaller sachet packaging was originally put in place to

¹ <http://apps.who.int/iris/bitstream/10665/41999/1/a57361.pdf>

minimize an additional risk of preparing improperly diluted milk when an incorrect amount of water was added to TM powder measured by scoop. However:

- With the introduction of the new smaller sachet packaging in 2010, it has been observed that health workers have continued to use scoops that were not developed for use with TM or spoons, either themselves or have provided these to caregivers to mix up the feeds, greatly increasing the risk of feeds being reconstituted incorrectly. This observation has been repeated in a number of instances and across contexts. For example, while an overall preference for F75 and F100 in sachets was reported in a recent survey in 2016, scoops and other utensils were being used in preparation, as has been noted in other reports from the field. ***Evidence suggest that single use sachets are not being used properly and hence don't fit the purpose of mitigating the risk of incorrect reconstitution and of contamination through improper handling.***
- Previously, for TM produced prior to the updated production standard alignment, 18ml of water were needed per scoop, which are not easy to measure since small sachets were implemented for single use with 500ml of water. Dilution of any amount less than the full sachet is challenging and carries risks, as improper preparation of smaller amounts of TM can lead to hypernatraemic dehydration and osmotic diarrhea on the one hand when not enough water is added, or underfeeding with an overdilute formula on the other hand. There is a high risk of incorrect dilution with the use of scoop and sachet, as the reconstitution protocol is not easy to implement. ***Evidence suggests a high risk of incorrect dilution in use of sachet and scoop.***
- There is an additional risk of contamination of the powder in sachets once opened and not used in entirety. Once opened, the TM powder should be disposed of within 24 hours to prevent contamination, given that there is no effective way to seal the sachet. Repacking or storing opened sachets has been observed. As a result, ***there is an additional food safety risk due to increased contamination risk to TM powder once sachets are opened.***
- Concerns have been raised at times around the use of scoops as a potential contamination source. In the context of appropriate hygienic preparation of TM in line with the WHO's 2007 guideline "Safe preparation, storage and handling of powdered infant formula"², ***scoops can be used hygienically in preparation of TM.*** Scoops are only to be exposed to dry powdered TM and as such should not attain a biofilm to harbour bacteria. In contrast, there is increased risk of bacteria forming in prepared milk that is stored for over 2 hours in the refrigerator and re-used, as the combination of milk powder with water is what allows bacteria formation.

2. Adherence to WHO's 2007 guideline "Safe preparation, storage and handling of powdered infant formula and Codex Code of Hygienic practice for Infant Formula, CAC/RCP 66-2008 to minimise contamination risks - UNICEF and MSF currently collaborate in audits on TM suppliers in order to identify and address quality issues in production. UNICEF has been working with suppliers to increase finished product quality controls and works with suppliers to identify better manufacturing facilities that could fully comply with Codex Code of Hygienic practice for Infant Formula, CAC/RCP 66-2008³, in order to meet quality standards for microbiologic safety limits. UNICEF Supply Division recognized the need to harmonize F75 and F100 product

² http://www.who.int/foodsafety/publications/micro/pif_guidelines.pdf

³ To address several incidents of powdered infant formula contamination by *Cronobacter sakazakii*, FAO published in 2008 Code for hygienic practice for Powdered Infant Formulae (PIF) for Infants and Young Children (CAC/RCP 66 – 2008)³ establishing stricter control of *Cronobacter sakazakii* and *Salmonella*.

specifications with this Code. The new sampling plan and product release criteria were applied both by UNICEF and MSF as of June 2013. ***In 2014 UNICEF specified to suppliers that F75 and F100 must be able to withstand reconstitution with hot water (70 degrees C) which is in compliance with the WHO's 2007 guideline "Safe preparation, storage and handling of powdered infant formula"⁴. With the advent of this formulation, one potential risk of contamination has been reduced as bacteria are killed instantly when in contact with water over 70 degrees C.***

- Current suppliers cannot meet the Codex Code of Hygienic practice for Infant Formula, CAC/RCP 66-2008⁵ standards with sachet packaging, and can only meet these standards with tin packaging. ***Current sachet packaging does not meet Codex standards.***
- ***Packaging in sachets requires more handling during production which increases risk of contamination with Cronobacter sakazakii.*** Packaging TM into sachets requires multiple steps, while in contrast tins can be filled directly, reducing potential exposure to contaminants.
- ***Longer life of TM once the packaging is opened: 4 weeks for tin as opposed to 24 hours for sachet.*** Once sachets were opened, the TM packaged in sachets would need to be used or discarded within 24 hours of opening, but this is not done consistently. In contrast, TM packed in tins can be used for up to 4 weeks from opening before the contents need to be discarded. The new packaging of TM in tins can reduce wastage of TM, in particular for programmes with low number of admissions which would need to prepare less than 600mL of prepared TM per day from the previous sachets.

It is important to note that these changes do not **modify our collective support WHO recommendations on Infant and Young Child Feeding (IYCF) including exclusive breastfeeding for those under 6 months.** Alignment with infant formula manufacturing standards does not mean endorsement of the use of infant formula in place of optimal IYCF recommendations. The 2013 WHO "Guideline Updates on the Management of Severe Acute Malnutrition in Infants and Young Children"⁶ specify in recommendation 8 the prioritization of support for breastfeeding for infants with SAM and without oedema, expressed breastmilk should be given and where this is not possible, commercial (generic) infant formula or F75 or diluted F100 may be given alone or as the supplementary feed together with breastmilk. For infants with SAM and oedema, commercial (generic) infant formula or F75 should be given as a supplement to breastmilk.

How do these improvements affect inpatient treatment programming?

Defining timing for introduction of new packaging

In terms of timing, the introduction of the new packaging of TM will take place from Q3 in 2017, based on available stocks, consumption rates and production capacity. All efforts are being made to prevent breaks in pipeline during the introduction of the new packaging of TM. It is estimated that TM in the previous packaging will be consumed at country level where there are stocks available, and thus it is important that all countries undertake preparatory steps to facilitate introduction of the new packaging.

⁴ http://www.who.int/foodsafety/publications/micro/pif_guidelines.pdf

⁵ To address several incidents of powdered infant formula contamination by *Cronobacter sakazakii*, FAO published in 2008 Code for hygienic practice for Powdered Infant Formulae (PIF) for Infants and Young Children (CAC/RPC 66 – 2008)⁵ establishing stricter control of *Cronobacter sakazakii* and *Salmonella*.

⁶ http://apps.who.int/iris/bitstream/10665/95584/1/9789241506328_eng.pdf

The start date for the introduction will be specific to each country, current stock, foreseen stock outs and ongoing/planned orders.

TM Feed Preparation

Overall, there is a need to continue to promote and reinforce the highest hygiene standards in TM preparation. This includes undertaking refresher training, updating of job aids, and conducting supportive supervision to ensure that all steps outlined in the WHO 2007 guidance are adhered to; all steps - from cleaning milk preparation area to feeding the child - are vital given the immunosuppression of children with SAM⁷. **Water at 70 degrees should be used in preparation of TM.** A thermometer should be used in preparation in order to mitigate the risk of contamination of TM from the hospital environment – as is standard in the WHO 2007 guidance. If a thermometer is not available, it is possible to time 3-5 minutes, which is the average time for boiling water to come down to 70 degrees.

There are a number of issues to be considered in terms of programming that require close monitoring and follow-up when introducing the improved packaging of TM. In contexts where the number of admissions for inpatient care are low, additional supportive supervision and training may be required.

The scoop that is packaged in the tin is the only scoop that should be used with that tin of TM. Regardless of producer and regardless of whether the TM is F75 or F100, volumes of water required per scoop are standard. The sizes of the scoop will however differ between F75 and F100, and the size of the scoop will differ between the F75 and F100 prepared by different suppliers due to differences in specific density of the TM.

Preparation of F75 and F100 when using less than 1 tin	
2 levelled scoops	50ml water
4 levelled scoops	100ml water
8 levelled scoops	200ml water
10 levelled scoops	250ml water
Preparation of the FULL tin of F75	
Entire tin F75	2.2L (2200 ml)
Preparation of the FULL tin of F100	
Entire tin F100	1.850L (1850ml)

Supply Management

Ensuring systematic recording of dates. The date when the product was opened and the date when it must be discarded has to be recorded on the tin and complied with. Once opened, the TM should be discarded after 4 weeks.

Supply forecasting and ordering. Changes in volume of boxes and individual sizes of TM tins will require that supply forecasting and ordering tools be adjusted reflecting the changes. All orders for therapeutic milk should be requested in tins from now on. There is a conversion tool available to support this process.

⁷ http://www.who.int/foodsafety/publications/micro/pif_guidelines.pdf

Storage space. Tins take much more space in cartons than sachets with an estimated +/- 20% storage space needed, requiring close coordination with supply and logistics team to ensure adequate storage space in the warehouses and facilities.

Waste management. The tins should not be re-used in the hospital for storing other products. Please note that tin labels are printed directly on the tin and cannot be removed. Leftover TM supplies from one supplier should not be mixed with the TM from another supplier. Tins are recyclable, however many countries may not always have recycling capacity so creative ideas for recycling will be needed. It is recommended that tins be disposed as per country’s environment regulation in close coordination with responsible authorities and departments.

Equipment Needs

Update list of essential equipment needs for preparation of TM feeds in facilities e.g thermometers.

Information Education Communication (IEC)


A strong distinction needs to be made between TM and infant formula. The labelling for TM packaging highlights this distinction and additional efforts will be made to reflect the distinction of TM and infant formula through labelling. It is very important to emphasize the medical use of the TM for children with SAM and that it is not infant formula.

Training is to be planned and conducted with all personnel involved in inpatient management with special on the job training and follow-up with health personnel directly leading on milk preparation.

Cost and Financing Inpatient Care Programmes

Cost. Comparing with historical cost of TM, there will be about a 30% increase for F75 and about a 40% increase in price for F100 as a result of the new production process. This increase in cost would have occurred whether TM was packaged in sachets or in tins as the main driver of cost is not the packaging but rather the updated production process which better achieves quality and safety standards in comparison to the previous production process.

Annex 1: Summary information on new packaging F75 and F100

Material Number	Item short description	Gross Weight and Volume of each carton	Image
S0000236	<u>F-75 Therap.milk CAN 400g/CAR-24</u> Each canister contains 400g of F-75 Therapeutic milk powder. There are 24 CANs in a Carton	13.7- 14.0 kg 0.0347 m ³	
S0000237	<u>F-100 Therap.milk CAN 400g/CAR-24</u> Each canister contains 400g of F-100 Therapeutic milk powder. There are 24 CANs in a Carton	11.0-13.7 kg 0.0464m ³	