

Harmonization of lipid-based products by WFP, UNICEF and USAID

UNICEF, WFP and USAID¹, aligned with guidance from WHO and FAO, are harmonizing quality standards, formulations and packaging of Ready-to-Use Therapeutic Food (RUTF), Ready-to-Use Supplementary Food (RUSF) and Medium Quantity Lipid-based Nutrient Supplements (LNS-MQ).

This work entails the following:

- (1) **Nutritional Quality** is ensured by complying with WHO guidelines for nutrient intake from RUTF, for children with SAM, and from RUSF, for children with MAM, and the latest evidence on linear growth.
- (2) **Food Safety requirements** for manufacturing and finished products are in accordance with the latest guidance from WHO and FAO.
- (3) **Harmonization of specifications** across agencies so that programs are using the same standard of products globally.
- (4) **Packaging standardization** in terms of color and type, to facilitate programming and provide greater flexibility to handle pipeline issues.
- (5) **Local production** is facilitated by simplifying requirements for ingredients across the range of LNS products.

The main points achieved to date are the following:

- a. Harmonized product specifications of RUTF, RUSF, LNS-MQ are aligned with FAO/WHO food safety criteria, and WHO nutrient intake targets (for RUTF and RUSF).
- b. Formulations have been improved with minor changes compared to former products.
- c. Dairy is included in all three products to support linear growth and recovery from acute malnutrition: RUSF and LNS-MQ contain 10% milk powder, while RUTF contains 20% milk powder (or the equivalent amount of protein from whey).
- d. Some RUSF and LNS-MQ formulations contain pulses or oil seeds other than peanuts, such as chickpeas / sesame / lentils & rice / almonds. This facilitates use of locally available ingredients and reduces the risk of aflatoxin contamination.
- e. A premix has been designed that can be used for both RUSF and LNS-MQ and the possibility of using it also for RUTF is being looked into.
- f. RUSF and LNS-MQ formulations are the same. RUSF is provided in sachets of 100 g/d and LNS-MQ in 50 g/d. In case of pipeline issues, 2 sachets of LNS-MQ can replace 1 of RUSF, or the other way around.
- g. The 100 g/d of RUSF (approx. 535 kcal, in orange sachet) is appropriate for treatment of MAM. The 50 g/d of LNS-MQ (approx. 265 kcal, in yellow sachet) provides around 1 RNI (recommended nutrient intake [1]) of essential (micro) nutrients for prevention of undernutrition in food insecure circumstances.
- h. RUTF is still provided in sachets of 92 g, providing approx. 500 kcal, in a red sachet.
- i. While the cost per treatment would increase slightly when the same number of now larger sachets of RUSF (100 g instead of 92 g) are provided, the harmonization of specifications across agencies and standardization of formulations across product categories and of packaging improves efficiencies. Overall impact on cost of products and programming therefore appears neutral to positive.

¹ MSF and Tufts University have also been involved in the process.

Further information

A. Quality and nutrient content targets

1. Microbiological criteria

The microbiological criteria for RUSF and RUTF as proposed by FAO and WHO have been included in the specifications for lipid-based products of UNICEF, WFP, USAID and MSF.

2. Clarification on nutrient intake targets as specified by WHO and nutrient content in product specifications

RUTF is formulated according to the joint statement from WHO, UNICEF, WFP and SCN for SAM [2], and RUSF according to the WHO technical note for foods for treating MAM [3]². The nutrient ranges (min-max) that are specified in these guidelines represent the intended nutrient intake and should form the basis for formulating product specifications. Due to variability of nutrient contributions from raw materials and vitamin/mineral premix (10% dosing variation), differences of processing steps among manufacturers, as well as reduction of nutrient content during storage, the min-max range of product specifications, i.e. what the product may contain at any point between production and after 24 mo of storage (at 30°C for 24 mo) is broader than the WHO min-max for targeted nutrient intake.

3. Nutritional aims and use of RUTF, RUSF, LNS-MQ (and LNS-SQ)

RUTF is for treatment of SAM – daily dose in multiples of approx. 500 kcal (92 g sachets), depending on body weight and/or MUAC. RUTF and breastmilk and/or water should be the principle sources of food consumed during treatment. Treatment typically takes 1-2 months.

RUSF is for treatment of MAM – daily dose is typically 1 sachet of approx. 535 kcal (100 g), as a supplement to the regular diet (including breastmilk). Treatment may take 1-3 months. RUSF may also be used in the first phase of an emergency response for groups that cannot chew or need foods of high nutrient density (e.g. young children, older people).

LNS-MQ (medium quantity lipid-based nutrient supplement) is provided to support health, growth and development of young children (6-23 or 6-35 months) when adequate nutrition is lacking such as in a context of severe food insecurity, due to lean season or an emergency situation. Nutritional target: complements the regular diet, with 1 sachet providing 265 kcal/d (50 g) and approximately 1 RNI (recommended nutrient intake, as specified by FAO/WHO) of essential (micro) nutrients. Duration of LNS-MQ consumption depends on the period of exposure to severe food insecurity.

LNS-SQ (small quantity lipid-based nutrient supplement) primarily aims to add essential (micro) nutrients to the diet of older infants and young children (6-23 months) while providing less than 110 kcal/d (20 g). Research on impact of different formulations on growth, health and development outcomes as well as efforts to use the standardized premix (see below) at higher dosage, so that it can contain 1 RNI of micronutrients in 20 g, are ongoing.

² Note: When the WHO technical note was prepared, concurrent twice-yearly distribution of high-dose vitamin A capsules was not taken into account. To reduce the risk of too high vitamin A content, the dose of vitamin A was revised down to the RUTF joint statement min / max ranges.

Considering these uses of the products and nutrient intake targets, it was deemed possible to harmonize the formulations in terms of raw material choices and premix composition.

B. What the harmonization entails

1. Dairy ingredients

Dairy is a nutrient dense ingredient that appears to be important for treatment of acute malnutrition [2, 3, 4, 5] and for linear growth [6, 7]. Dairy has always been an ingredient in RUTF and LNS-MQ, whereas for RUSF some formulations included dairy whereas others contained soy protein isolate.

WHO guidance specifies that 50% of protein in RUTF should be from dairy. For RUSF, the protein quality has been specified (PDCAAS of at least 0.7), which can be achieved with 1/3 of protein from dairy or by including high quality soy products. For LNS-MQ, which is provided to young children and potentially for several months at a time, inclusion of milk powder is desired to support linear growth (prevention of stunting).

Based on this, the harmonized formulation of RUSF and LNS-MQ specifies inclusion of 1/3 of protein from dried skimmed milk, which is equivalent to approx. 10% milk powder in the product. For RUTF, 1/2 of protein should come from dairy, which is equivalent to approx. 20% milk powder, or whey protein concentrate can be used.

This harmonization means that all three lipid-based products include dairy and that by keeping dried skimmed milk in stock, manufacturers can produce any of the three lipid-based products, depending on demand.

2. Other raw materials

While the original lipid-based formulations include peanuts, dried skimmed milk and/or whey protein concentrate and/or soy protein isolate, vegetable oil, sugar, maltodextrin and premix as main ingredients, other raw materials are also being used in lieu of peanuts, including chickpeas, rice-lentil mixture, sesame, almonds, cashews.

Provided that product quality is maintained in terms of nutrition and safety, and that the product is proven to be acceptable to the targeted consumers, adaptation of raw ingredient choice is possible. This enables use of locally produced ingredients, which may reduce cost, take local taste preferences into account and may also lower the risk of aflatoxin contamination, which particularly affects peanuts and corn. Currently, some non-peanut formulations of RUSF and LNS-MQ products are being used, most notably chickpea containing products. Adopting such formulations also for RUTF is being considered.

3. Vitamin & mineral premix

In order to achieve a micronutrient content that is in-line with WHO guidance, addition of a vitamin & mineral premix is required. Taking into consideration the variation of micronutrient content of food ingredients, different manufacturing processes, the desire to maintain required nutrient content throughout shelf life (best stored below 30°C for max 24 months), and the overlapping ranges of target nutrient intake across product categories, a premix has been formulated for use in RUSF and LNS-MQ. Investigations are underway to assess its applicability to RUTF³. Inclusion of this standardized premix should enable most manufacturers to produce

³ Analytical work is being done to assess the range of nutrient levels in finished RUTF product as produced with different combinations of the recommended dairy ingredients and inclusion of the harmonized premix to confirm that nutrient levels remain within desired ranges.

products that remain within the min-max ranges for nutrient content throughout shelf life.

WFP, USAID and UNICEF have included the premix within their agency's specifications for RUSF and LNS-MQ, and USAID also encourages use for RUTF, where feasible. This standardization gives greater flexibility in the supplier base that the agencies share. Each agency manages the product quality compliance of suppliers independently, however the collaboration between agencies facilitates maintaining a high standard of products globally.

4. Supporting local production

Smaller manufacturers in low-middle income countries have smaller capacity for development of new formulations as well as for production. Unpredictability of orders, both in terms of product types and quantities, and long lead times for imported ingredients, such as dairy ingredients and micronutrient premix, are also important challenges. Keeping relatively expensive ingredients in stock without knowing whether they will be used or will have to be discarded because of passing their shelf life date, drives up their prices. Harmonization of specifications and standardization of raw materials (per country/supplier) and of premix across product categories, and possibility to use locally produced ingredients, facilitates timely and more efficient production of ready-to-use products by smaller manufacturers. This is helpful at a time when more and more countries and regions explore possibilities for local production and want this to be done at as low a cost as possible while maintaining quality.

5. Packaging – color coding

To provide clarity for programming across products produced by different manufacturers, standardization of package design and color has been introduced. The color scheme aligns with the four-color MUAC tape: Red for RUTF, Orange for RUSF, Yellow for LNS-MQ, and green is recommended for LNS-SQ (see annex for package examples).

6. Packaging – type and size

All products will be packaged in sachets: 92 g for RUTF, 100 g for RUSF and 50 g for LNS-MQ. Pots for LNS-MQ will no longer be used due to breakage (especially with air drops), food safety issues (dipped into with spoon, finger or stick over the course of several days), and challenges experienced with sealing of the lids. The change to standardized weight for RUSF, i.e. 100 g instead of 92 g of the peanut containing formulation, has been made to ensure the same weight across different product formulations and to facilitate calculations for quantity across the supply chain actors (e.g. 1 MT contains 10,000 sachets, or a 15 kg box contains 150 sachets).

For RUTF, switching over to 100 g is more challenging, because standardized tables specify the number of sachets that should be provided to a child per day depending on the weight gain target, and these have all been set based on a content of 500 kcal per sachet and are used widely. Therefore, RUTF package size is maintained at 92 g.

7. Cost

The standardization of specifications, including the harmonization of raw ingredients and premix used across product categories, means that individual suppliers can spend fewer resources on developing their own formulations, tweaking of premix and elaborate analytical testing of their different products. This allows them to focus their efforts on improving their production process, optimizing the raw materials used, ensuring quality and safety, which has advantages for production capacity and costs.

The expected increase in cost of continuous improvements in quality together with the new requirement of milk in RUSF has been offset by savings from increased efficiencies associated with the specification harmonization. The increase from 92 to 100 g per sachet of RUSF may affect the price of treatment when the same number of sachets is provided, but when treatment takes proportionally less time, it would be cost neutral. In addition, the harmonization of color and package size (note that package size of chickpea RUSF from Pakistan, i.e. AchaMum, has always been 100 g) may result in some programming efficiencies that could mean additional savings.

References

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- [5] Bahwere, P., Balaluka, B., Wells, J. C., Mbiribindi, C. N., Sadler, K., Akomo, P., ... & Collins, S. (2016). Cereals and pulse-based ready-to-use therapeutic food as an alternative to the standard milk-and peanut paste-based formulation for treating severe acute malnutrition: a noninferiority, individually randomized controlled efficacy clinical trial. *The American journal of clinical nutrition*, 103(4), 1145-1161.
- [6] Dror DK, Allen LH. (2011). The importance of milk and other animal-source foods for children in low-income countries. *Food Nutrition Bulletin*; 32: 227-43.
- [7] Hoppe C., Mølgaard C. & Michaelsen K.F. (2006) Cow's milk and linear growth in industrialized and developing countries. *Annual Review of Nutrition* 26, 131–173.

Annex. Examples of product packaging of LNS

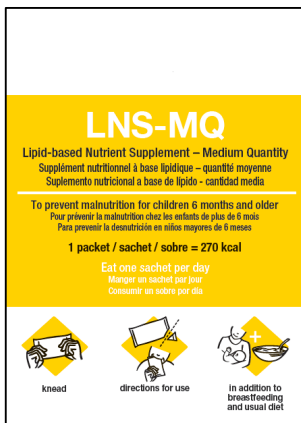
Red for RUTF:



Orange for RUSF:



Yellow for LNS-MQ:



Green for LNS-SQ:

