

# Maternal & Child Wasting Products

## Market Diagnostic Assessment

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**RESULTS FOR  
DEVELOPMENT**

# Diagnostic outline

- Project overview
- Market diagnostic
  - Global context
  - Regulatory
  - Demand
  - Finance
  - Supply
- Learnings for MD-RUTF market



# Project overview:

*context & approach*



The Maternal and Child Wasting Management Project used a hypothesis-driven approach to explore market barriers and develop strategic options for the introduction or scale-up of RUTF and LNS products.

## Challenge

- Undernutrition for women and children is a major driver of infant and child morbidity and mortality, with child wasting affecting an estimated 45M children under 5 and contributing to millions of preventable deaths.<sup>1</sup>
- RUTF and lipid-based nutrient supplements (LNS) products have proven potential to save lives and reduce the burden of acute malnutrition.
- **But market access remains low, even for the most mature and well-established wasting products (i.e., RUTFs), and innovative products have an uncertain path to reaching scale.<sup>2</sup>**

## Approach

### Phase 1

Global- and country-level market diagnostic of focal LNS products to identify challenges and enablers to introduce and scale-up access to LNS products

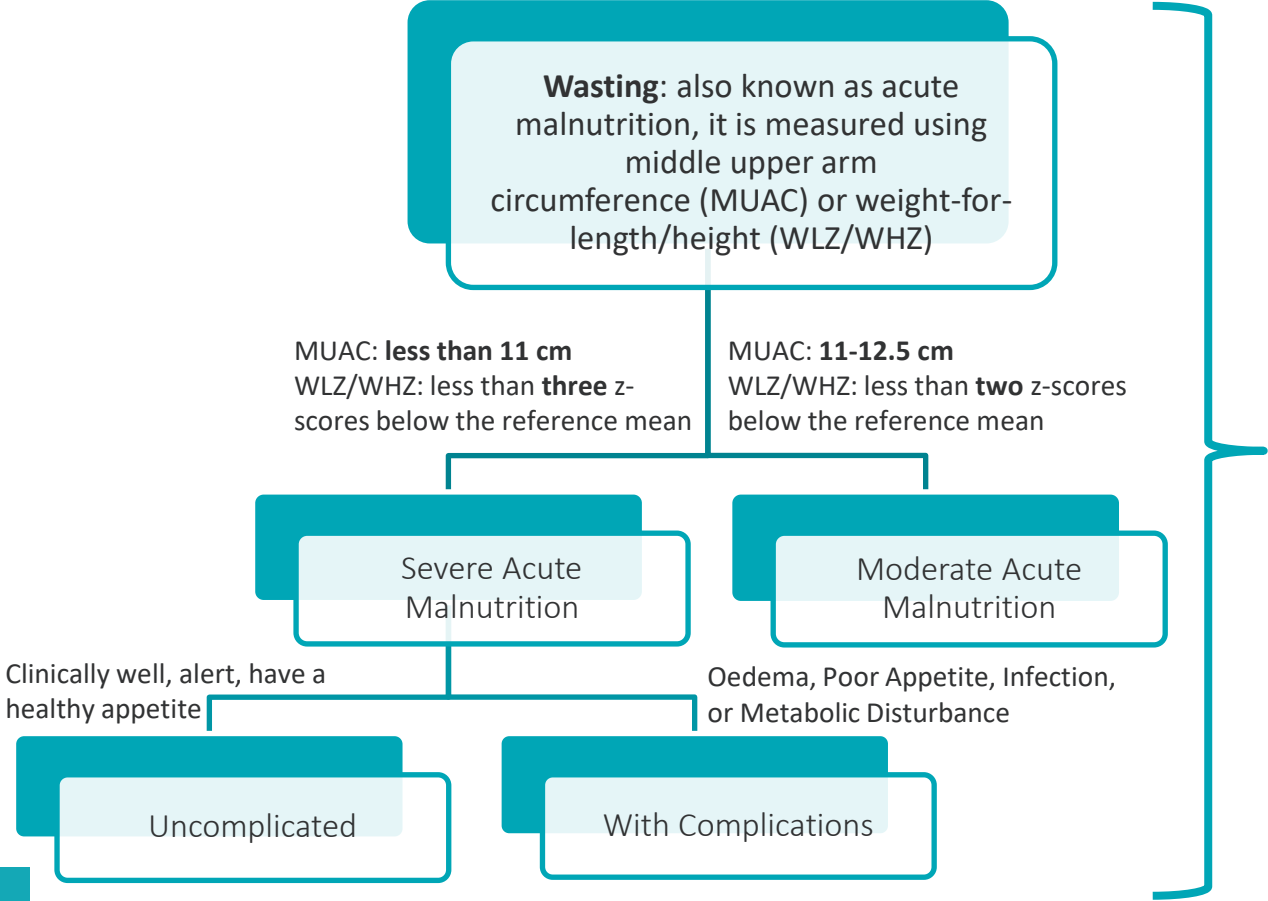
### Phase 2

Co-create strategic market shaping options and harvest "low-hanging fruit" to address the identified market challenges at the global- and country levels



Wasting, or acute malnutrition, is a complex umbrella term for several specific conditions, impacting millions of children under age 5 around the world.

### Flowchart Breakdown of Wasting Criteria

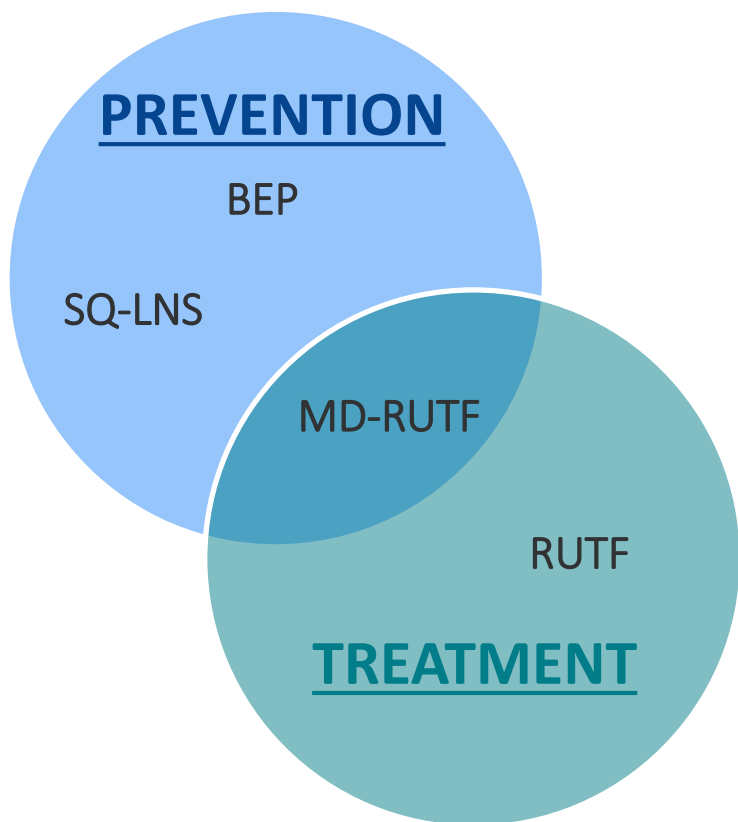


In 2022, an estimated 45 million children under 5 suffered from wasting globally.<sup>2</sup>



Notes: 1) UNICEF. 2007. [Joint Statement on Community-Based Management of Severe Acute Malnutrition](#); 2) UNICEF. 2023. [UNICEF JME Estimates](#);

Specifically, R4D's efforts are focused on 4 wasting products, which vary in terms of recipient and use-case for preventing or treating wasting.



### Balanced Energy Protein (BEP)

**Description:** category of nutritional supplements to address requirements of pregnant and lactating women (*Note: LNS-PLW is a specific formulation*)

**Recipient:** pregnant and lactating women

**Use & Impact:** WHO-recommended during ANC for prevention; in LMICs, estimated 40% reduced risk of low birth weight (LBW), and 29% reduction in small gestational age (SGA) <sup>4,5</sup>



### Small-Quantity LNS (SQ-LNS)

**Description:** lipid-based nutrient supplement delivered in a small packet of paste<sup>6</sup>

**Recipient:** children 6-23 months

**Potential for impact:** WHO-recommended option for prevention; reduced wasting, stunting and underweight rates by 12-14% in children under 2 in LMICs<sup>7</sup>



### Ready-to-Use Therapeutic Food (RUTF)

**Description:** high-energy, nutrient dense paste

**Recipient:** children under 5

**Potential for impact:** WHO-recommended treatment for SAM; reduction in preventable child mortality by treating SAM due to its effectiveness in reducing severe wasting by 26%<sup>4</sup>



### Microbiome-directed RUTF (MD-RUTF)

**Description:** high-energy, nutrient dense paste

**Recipient:** children under 5

**Use & impact:**

- Prevention by reducing SAM relapse post-treatment, which affects up to 37% of children treated for SAM<sup>1</sup>
- Treatment of uncomplicated MAM and SAM at community-level



Sources: 1) ENN. 2020. [Research snapshot](#); 2) Stoubaught et al. 2019. [Relapse after severe acute malnutrition](#); 3) WHO. 2016. [WHO Recommendation for ANC](#); 4) Keats et al. 2021. [Effective interventions to address maternal and child malnutrition: an update of the evidence](#); 5) Lassi et al. 2020. [Impact of dietary interventions during pregnancy on maternal, neonatal and child outcomes in low- and middle-income countries](#); 6) University of California Davis. 2023. SQ-LNS Policy Brief; 7) Dewey et al. 2021. [Small-quantity lipid-based nutrient supplements for prevention of child malnutrition and promotion of healthy development](#);

The wasting products included in our scope are in different phases of market introduction and scale-up; learnings from the more advanced RUTF market can inform introduction and scale-up of more nascent products.

Product pathway

Research & Development

Market Introduction

Market Scale-up

**MD-RUTF**

**No market presence yet.** Novel product formulation identified through pre-clinical models and pilot studies. Research trials currently underway; anticipate at least 2-5 years before market ready.<sup>1</sup>

**BEP**

Multiple BEP products, including the LNS-PLW formulation, exist in the market with limited uptake. Despite the promise of BEP and substantial research invested, **product scale up has been extremely limited.**<sup>2</sup>

**SQ-LNS**

SQ-LNS has proven effectiveness and acceptability but there is a lack of international guidelines, and limited financing and supply; as such **SQ-LNS scale-up within IYCF programs has been very limited.**

**RUTF**

RUTF is an established, effective and generally accepted child wasting treatment product. However, after over 20 years of scale up efforts, market access remains constrained. Only about **1 in 3 wasted children receive treatment.**<sup>2</sup>



Notes: 1) Stakeholder Interview. December 2022; 2) In focus geographies, scale up of BEP has only been identified in Pakistan, and WFP is not currently supporting scale up in other countries; 3) UNICEF. 2022. [No Time To Waste Acceleration Plan](#).

Throughout this project, R4D is utilizing insights from the global-level and in five focus geographies to inform product introduction and scale-up recommendations.

## Global level



Global-level analysis focused on:



Global guidance and quality standards



Global procurer landscape



Global financing trends



Global supplier landscape

## National or sub-national level

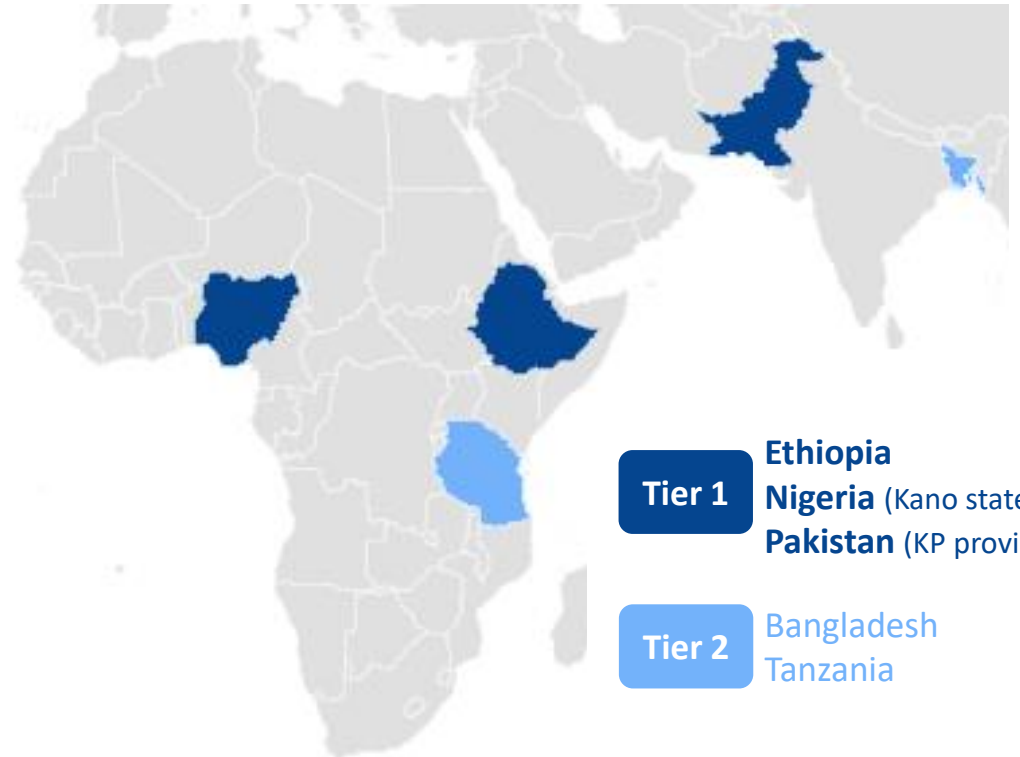


5 focus geographies chosen based on:

Burden of maternal & child undernutrition

Anticipated government buy-in

Current/future local production capacity



**Tier 1** Ethiopia  
Nigeria (Kano state)  
Pakistan (KP province)

**Tier 2** Bangladesh  
Tanzania

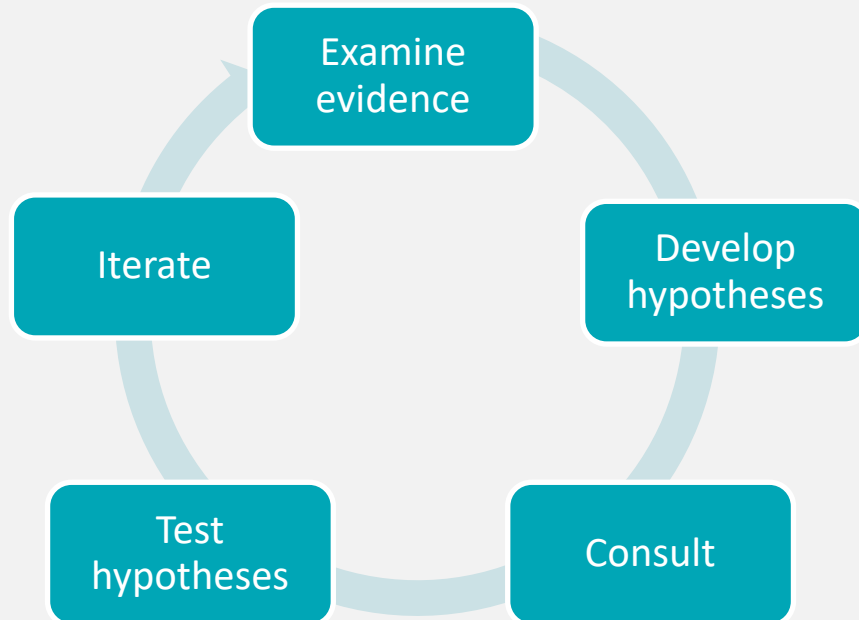


Diversity in geography, institutions, governance and service delivery structures broaden applicability of lessons learned in this project



R4D has been engaging with global and country-level stakeholders in a targeted way -- cultivating relationships to collect data, develop and test hypotheses.

**Our approach:** Hypothesis-driven, iterative co-creation, that blends empirical analysis with stakeholder consultations to identify market bottlenecks across five geographies

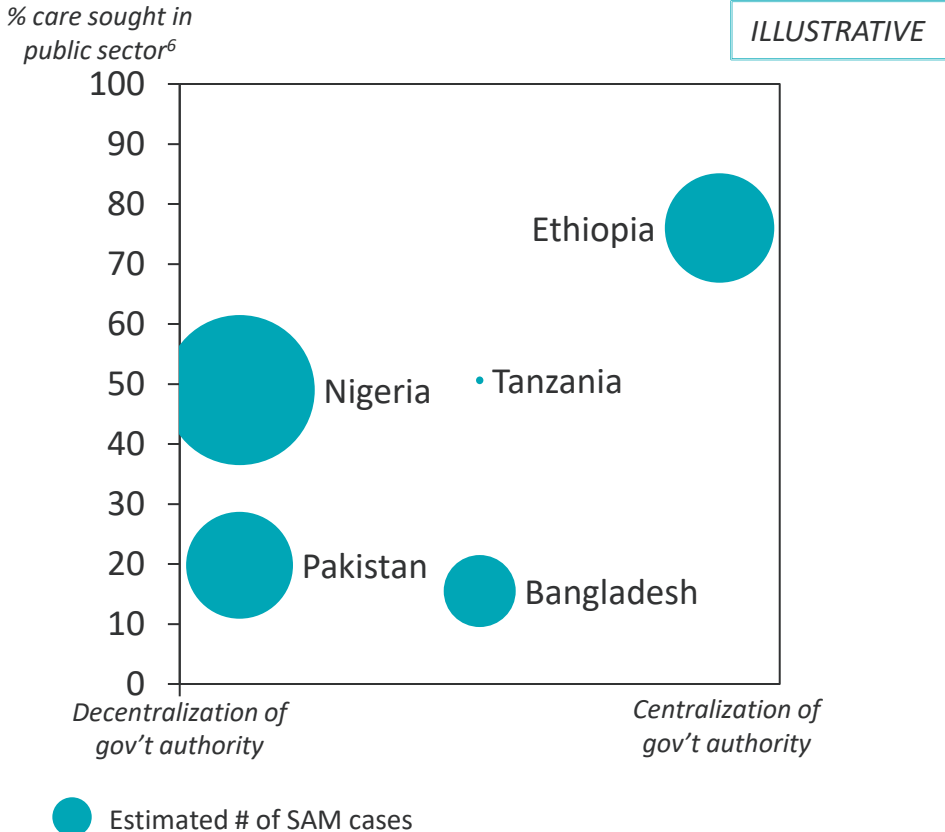


*Illustrative list of global and country stakeholders consulted*



While our insights are generated by comparing country markets, it is important to keep in mind the distinct markets and archetypes that each country represents.

**Focal countries by public sector care seeking, centralization of gov't authority, and estimated SAM cases<sup>1-5</sup>**



**Some country comparison considerations before we dive into the analysis...**

We are comparing countries throughout this presentation in a way that may imply there are a lot of commonalities among them.

**And while there are many commonalities among the market barriers that these countries face, there are key distinctions between the countries as well.** It is unlikely that the same set of market interventions would be successful in each of these countries, as they vary by market size (as shown by each country's estimated # of SAM cases), degree of public sector care seeking, and extent of gov't centralization, as shown on the left.

- Some things to keep in mind throughout the diagnostic:
- Our data collection in Nigeria focused on Kano state, but Kano is not representative of all state archetypes in Nigeria.
  - Similarly, in Pakistan, we've focused on Khyber Pakhtunkhwa (KP) Province, which we know is not representative of the whole country.



Notes: 1) Ethiopia MOH. May 2022. Nutrition Cluster Report; 2. Bangladesh MOH. 2017. Bangladesh Demographic and Health Survey; 3. UNICEF NG. 2023. Presentation 2023; 4) Tanzania MOH. 2018. National Nutrition Survey; 5) WFP Pakistan. 2017. The Economic Consequences Of Undernutrition in Pakistan: An Assessment of Losses; 6) Care seeking of children with symptoms of ARI for whom advice or treatment was sought, children receiving from a public. sector facility

# Market Diagnostic



# Executive Summary – Key Learnings and Reflections

## (1/2)

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- **This analysis explored barriers across REGULATORY, DEMAND, FINANCE, and SUPPLY market domains for RUTF and LNS products (i.e., SQ-LNS, BEP/LNS-PLW, and MD-RUTF). Below are some of our broader reflections on this diagnostic, with specific themes and findings by market domain summarized in the slides that follow.**
- **RUTF provides an essential market-shaping roadmap for all other LNS products:** RUTF provides a detailed, prescriptive market-shaping roadmap for other, more nascent LNS commodities, due to the current maturity of its market.
  - The ways in which RUTF has become a well-known and well-established product **demonstrate the ‘next-step’ market shaping actions required for other, more nascent child wasting commodities.**
  - However, **RUTF does not have all of its market domains optimized**, and addressing the current gaps with RUTF will improve the market for all LNS products.
- **Financing factors constrain RUTF market growth:** While this diagnostic will explore several RUTF market barriers, financing appears to be the largest barrier to increasing RUTF production and uptake, as illustrated by the 2022 funding surge examined in this diagnostic.
  - Countries often need technical assistance or human resources to access match funding and to connect actual RUTF need with quantification, budgeting and fund release year over year.
  - The annual unpredictability of global donation pipeline makes longer-term global supply planning and demand signaling very difficult, which further increases the riskiness of the market for suppliers.
- **Confusion about the role and importance of LNS prevention commodities constrains market growth:** While this diagnostic will detail several market barriers we analyzed, the main barrier to LNS prevention product uptake appears to be regulatory in nature—namely, the lack of global consensus on where these commodities should fit in a country’s nutrition strategy and whether investments in them are more effective and cost-effective than investing in other prevention strategies, coupled with lack of clear guidance for producing and using the products themselves. This is reflected in low focal country awareness of and demand for these products.



# Executive Summary – Key Learnings and Reflections

## (2/2)

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- **Suppliers, both for-profit and non-profit, are generally motivated by their commitment to end malnutrition and are willing to get creative in difficult market conditions to stay operational.** That said, some of the financial and procurement characteristics of this market limit the ability of suppliers to utilize long-term risk mitigation strategies. However, overall, the broad and diverse supply base for RUTF demonstrates the ability of the LNS supply base to expand with the right mix of market signals, investment, and technical assistance.
- **The Child Nutrition Fund (CNF) is a welcome investment that is well-targeted to some of the key market barriers that RUTF and LNS products face, but its success and longevity are not guaranteed.** Concerns that came up in the course of our diagnostic included raising general awareness of CNF, the need for additional advocacy for non-RUTF matching, ensuring countries have necessary support to access match funding, ensuring that countries have a plan or strategy for prioritizing nutrition commodities, monitoring and sharing success stories of the CNF, tailoring the CNF's mechanisms based on feedback and lessons learned, and ensuring the long-term sustainability of funding for the CNF.
- **Governments within focal countries agree on the importance of ending malnutrition, but dynamics of in-country nutrition programming complicate resourcing, planning, and decision-making for nutrition commodities.** For products with nascent markets, these dynamics are compounded and amplified when products don't have clear guidance or for which prioritization, use-case, and/or targeting is not well-understood. Common challenges cited included lack of consensus on nutrition commodity strategy and prioritization, the need for project management capacity across various branches of government, and lacking human resource support for planning, routine activities, and coordinating partners.
- **MD-RUTF continues to be a promising product with an unclear timeline for market introduction. The extent of MD-RUTF's progression to market maturity once it is introduced will be constrained by the maturity of the existing RUTF market:** Continuing to invest in and optimize market domains for RUTF, the most mature product we examined, **will position MD-RUTF to leapfrog existing commodities** when it is introduced, rather than run into challenges we're already aware of for other products. Further, more optimized market domains will benefit all LNS products regardless of the MD-RUTF timeline.





## NEAR TERM NEEDS

- ❖ Well-defined target populations and use-cases for prevention products
- ❖ Standardized product specifications for prevention products
- ❖ Guidance for countries on how to make optimized regulatory decisions for wasting commodities, given the implications of different regulatory classifications

## LONGER TERM NEEDS

- ❖ Clearer regulatory approval pathways for alternative formulations
- ❖ Formal codification of product specifications for prevention products (i.e., CODEX)
- ❖ Stronger global consensus on how countries should evaluate and invest in food-focused interventions and prevention commodities





## NEAR TERM NEEDS

- ❖ Increased awareness of prevention products and their potential benefits at the country level
- ❖ Standardized quantification guidance for treatment commodities generated at global level, and made available to countries to estimate need
- ❖ Stronger global consensus on how investments in wasting prevention should be prioritized, specifically how to prioritize food-based prevention interventions and commodity-based interventions

## LONGER TERM NEEDS

- ❖ Standardized quantification guidance for prevention commodities generated and used
- ❖ Transition to government ownership and coordination of key RUTF and LNS procurement processes





## NEAR TERM NEEDS

- ❖ Increased country awareness of CNF
- ❖ Government ownership and coordination of key nutrition financing and quantification processes
- ❖ Countries more routinely allocate and release domestic funds for wasting commodities

## LONGER TERM NEEDS

- ❖ Securing longer-term future funding pool for CNF
- ❖ RUTF and LNS commodity funding driven more by forecasted need than available funding
- ❖ Pending progress on upstream barriers (e.g., regulatory, prioritization), increased financing for prevention products







## NEAR TERM NEEDS

- ❖ Refinements to CNF APM made based on supplier feedback and challenges experienced
- ❖ Separate global measurement and visualization of prevention commodity supply capacity
- ❖ More transparent and consistent demand signaling for both treatment and prevention products

## LONGER TERM NEEDS

- ❖ Increasing funded demand for prevention products
- ❖ Incentivizing product innovation to allow for more market disruption opportunities



# Regulatory



# Regulatory: Key Themes



## KEY THEMES

1

Guidance on product usage

2

Product and ingredient standardization

3

Incentives to disrupt / create more optimized commodities

4

Product classification at country level



### Treatment Products (RUTF)

**Guidance on use of RUTF is clear, widespread, and largely present at global and country level:** Global guidance on the use of RUTF (i.e., treatment product) is clear and more advanced than it is for prevention commodities, which is also reflected in clearer and more widespread inclusion of RUTF in country EMLs and guidelines. This is not surprising given RUTF's history, use for treatment, and earlier product introduction.

**RUTF specifications and ingredients are standardized:** The development of CODEX guidelines was an important milestone for defining and standardizing ingredient and quality requirements for RUTF. However, the adoption of CODEX also introduced new challenges for market domains.

**RUTF is, in fact, so well-established that barriers to market entry for alternative formulations (AF) are high:** In theory, new CODEX guidelines created a pathway for innovation in AF. However, incentives to innovate are limited and carry significant downside risk for the innovator. Once an AF is developed, there's no clear pathway for regulatory approval or procurement.

**Product classification (i.e., food or medicine) is an important yet context-specific decision at the country level.** RUTF and LNS products – whether for treatment or prevention – can be classified as food or drug products (i.e., medicines) by country regulatory bodies. Depending on the classification, there are important regulatory and market implications related to quality standards, regulatory processes and prioritization, and ultimately cost, though these implications vary by country context. Regardless of classification, focus countries have had to prioritize similar regulatory milestones to achieve current RUTF market dynamics. While these enabling factors were evaluated for RUTFs, we expect they are relevant for LNS prevention products.

### Prevention Products (SQ-LNS, BEP/ LNS-PLW)

**Clear guidance and consensus on use of prevention products is limited:** Prevention products still lack well-defined target populations & use-cases, requiring market actors to make these decisions individually. Guideline ambiguity contributes to market challenges and highlights a larger dilemma: **donors and countries are unsure about how to prioritize prevention products amongst food-focused interventions for wasting prevention.**

**Specifications for prevention products vary:** For prevention products, nothing like CODEX exists currently; in lieu of global guidance, major procurers have developed their own tech specs, which has created inefficiencies for suppliers who wish to supply product to both WFP and UNICEF.

**There is significant potential for product innovation, but within a very nascent market.** The prevention market is nascent enough that disruption is less relevant. Products that could be successful would have to be extremely effective, cost-effective, and/or better bridge dilemma between food-focused interventions and LNS commodities.



Clear global guidance plays an important role in shaping national regulatory landscapes, as we can see when we look at country adoption of WHO's 2013 recommendation for the use of RUTF in SAM treatment.

WHO SAM Management Guidelines (2013) <sup>1</sup>	Ethiopia (2019) <sup>2</sup>	Pakistan (2014) <sup>3</sup>	Nigeria (2016) <sup>4</sup>	Tanzania (2018) <sup>5</sup>	Bangladesh (2017) <sup>6</sup>
<b>Uncomplicated SAM:</b> RUTF recommended for treatment ( <i>inpatient or outpatient</i> )					
<b>Complicated SAM:</b> Child moving to rehabilitation phase, RUTF recommended to transition child from therapeutic milks (F-75/F-100) ( <i>inpatient</i> )					 <i>*guidelines recommend use of therapeutic milks for inpatient care</i>

*\*Note: Some countries (Pakistan, Nigeria, Tanzania) define RUTF dosage by the child's weight, which may result in slightly different dosage than the WHO-recommended 100-135 kcal/kg/day*

**4/5 focus geographies adopted WHO recommendations for the use of RUTF treatment in uncomplicated and complicated SAM cases. This highlights the **relevance and importance of having clear global recommendations for wasting products** for product introduction and scale-up.**



Notes: 1) WHO. 2013. [Updates on the Management of Severe Acute Malnutrition in Infants and Children](#); 2) Ethiopia MOH. 2019. [National Guideline for the Management of Acute Malnutrition in Ethiopia](#); 3) Pakistan MOH. 2014. [Pakistan National Guidelines for the Community-Based Management of Acute Malnutrition](#); 4) Nigeria MOH. 2016. [National Guidelines for Inpatient Management of Severe Acute Malnutrition in infants and Young Children in Nigeria](#); 5) Tanzania MOH. 2018. [Integrated Management of Acute Malnutrition](#); 6) Bangladesh MOH. 2017. [National Guidelines for Facility-based Management of Children with SAM](#);



WHO's 2023 updated guideline provides broader and more specific recommendations on products to treat SAM and MAM; however, recommendations on LNS prevention products remain vague.

The WHO Guideline on Prevention and Management of Wasting and Nutritional Oedema (2023)<sup>1</sup> enhanced the scope and specificity of recommendations ...

... which could positively impact the market and regulatory landscape for treatment products (RUTF) but does not clarify use-cases for LNS prevention products, limiting potential regulatory landscape implications.



- ✓ Establishes preference for LNS products in MAM treatment, which could encourage inclusion of LNS products on country MAM treatment guidelines, and thus increase demand.
- ✓ Re-emphasizes clear guidance on use and appropriate dosage of RUTF for SAM treatment, thus supporting continued demand and scale-up of RUTF.
- ✓ Identifies possible circumstances where SQ-LNS can be used for wasting prevention, and potential criteria which countries could utilize to decide. This may bolster advocacy efforts.
- ✗ However, the wasting prevention guidance does not specifically define the target population, dosage or duration of use for LNS products.



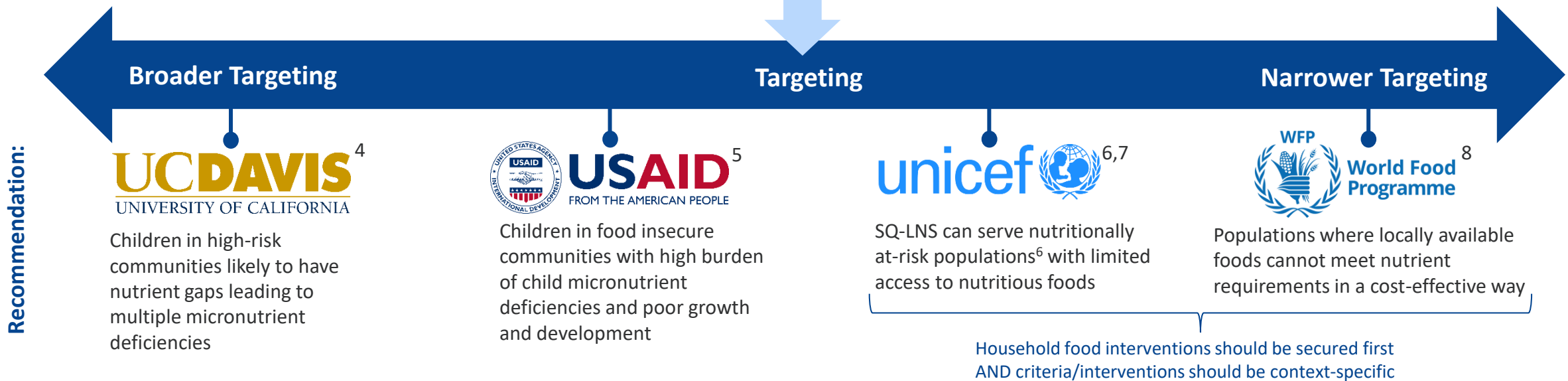
Notes: 1) WHO. 2023. [Guideline on the prevention and management of wasting and nutritional oedema \(acute malnutrition\) in infants and children under 5 years.](#)



In the absence of clear WHO guidance on SQ-LNS use, for example, donors and partners use different targeting criteria to guide funding & procurement decisions.<sup>1</sup>

### WHO recommendation (2023 wasting guidelines)

WHO's updated guidelines on prevention and management of wasting (2023)<sup>2</sup> and their complementary feeding guidelines<sup>3</sup> (2023) state the potential value of SQ-LNS **in areas or during periods of high food insecurity**. In the 2023 wasting guidelines, WHO provides loose ideas about the target population (6-23mo), dosage (100-120kcal/day) and duration of use (12-18mo) but ultimately states, **“the optimal quantity and duration of SFFs [including SQ-LNS] for prevention of wasting and nutritional oedema is unknown based on the available evidence.”**<sup>2</sup>



Notes: 1) These are the perspectives of HQs; opinions and practices can differ between an organization's HQ and country offices. All organizations align on age range for delivery of SQ-LNS to be 6 months – 23/24 months; 2) WHO. 2023. [Guideline on the prevention and management of wasting and nutritional oedema \(acute malnutrition\) in infants and children under 5 years](#); 3) WHO. 2023. [WHO Guideline for complementary feeding of infants and young children 6-23 months of age](#); 4) USAID. 2021. [Lipid-Based Nutrient Supplements: Evidence and Program Guidance](#). USAID Advancing Nutrition Technical Brief; 5) UNICEF. 2023. [Small Supplements for the Prevention of Malnutrition in Early Childhood \(Small Quantity Lipid-based Supplements\): Brief Guidance Note](#). Version 1.0; 6) UNICEF does not define criteria for identifying nutritionally at-risk populations, but they provide the following examples: “e.g., those with a high prevalence of stunting, wasting and anaemia, with an emphasis on contexts with high wasting and treatment relapse rates, mortality and micronutrient deficiencies;” 7) Interview with stakeholder from WFP HQ. Sept 2023.

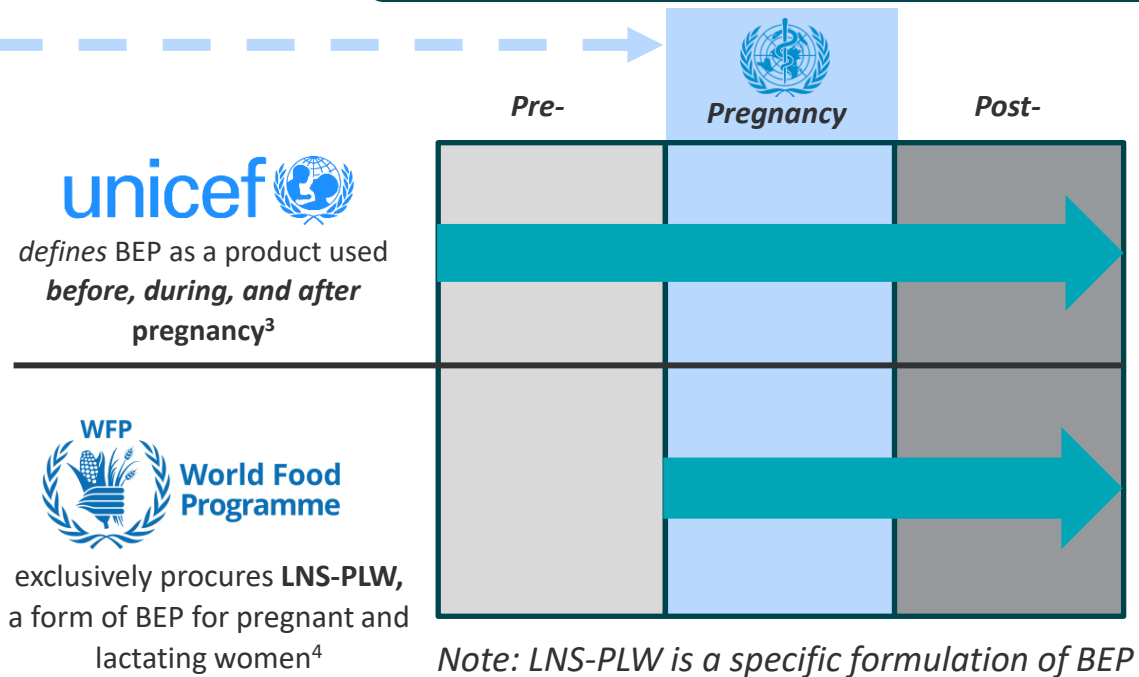
Similarly, global ANC guidelines and recommendations, while clearly recommending BEP, do not provide clear and unified guidance on the product profile, dosage, timing, or duration of use.

**WHO recommendation (2016 ANC guidelines)**

*In undernourished populations, balanced energy and protein (BEP) dietary supplementation is recommended for pregnant women to reduce the risk of stillbirths and SGA neonates.*

- **Context-specific recommendation:** for populations or settings with high prevalence of undernourished pregnant women (e.g., 20% or more underweight women) as determined by low BMI or MUAC.
- Notably, the ANC guidelines on BEP **do not include any references to lactating women or recommendations for a specific product/product profile, dosage or duration of use.**

**Misalignment between WHO recommendation and donor guidelines on timing for the use of BEP:**



Further, BEP’s potential role supporting prevention of child wasting has not been codified in guidelines or policy. BEP is not included in WHO guidelines on the prevention and treatment of wasting, despite evidence on the reduction in small for gestational age (SGA) babies.



Notes: 1) These are the perspectives of HQs; Opinions are practices can differ between an organization’s HQ and country offices; 2) WHO. 2016. [WHO recommendations on antenatal care for a positive pregnancy experience](#); 3) UNICEF. 2022. UNICEF Programming Guidance– Maternal Nutrition: Prevention of malnutrition in women before and during pregnancy and while breastfeeding.; 4)World Food Programme. 2022. Nutrition in Numbers: An overview of WFP nutrition programming in 2021. <https://docs.wfp.org/api/documents/WFP-0000139584/download/>;



For prevention products (SQ-LNS, BEP/LNS-PLW), the lack of global guidance on the target population & use-case contributes to self-reinforcing market challenges.

	Market Challenges	Notes & Examples
	Limited inclusion in country <b>EMLs and treatment guidelines</b>	None of our focus countries currently have <b>SQ-LNS or BEP</b> in their EMLs, though Nigeria is expected to add <b>SQ-LNS</b> in early 2024. Nigeria is also the only focus country with a use-case for <b>SQ-LNS</b> defined in their treatment guidelines. <sup>1</sup>
	<b>Misuse</b> at the provider and patient levels	Without clear guidance, providers may order and prescribe suboptimal products for preventing malnutrition (e.g., using MNP for prevention). <sup>2</sup>
	<b>Donor hesitancy to invest</b> in products without clearly defined target population and use-case	This is particularly problematic for <b>BEP</b> , a newer commodity with very little donor funding.
	<b>Lower awareness</b> of prevention products and thus, lower demand	Awareness of <b>SQ-LNS</b> is low in many countries. <sup>3</sup> In Ethiopia, govt. nutrition program implementers and decision-makers have limited awareness of SQ-LNS and BEP, their use or importance to programs. <sup>4</sup>
	Challenges related to <b>quantification of demand</b> , contributing to insufficient or excessive <b>supply</b>	In the absence of a clear target population for quantifying demand, the Pakistani government used a blanket provision approach – providing <b>BEP</b> to all pregnant women eligible within the BISP social protection program. <sup>5,6</sup>
	Challenges with defining <b>delivery channels</b>	Target population is needed to determine whether <b>BEP</b> is to be delivered through ANC, PHC, and/or postnatal care platforms.

Across all market domains, a lack of guidance about how countries should prioritize funding between prevention and treatment products, and when to use LNS products vs. food for the prevention of malnutrition, is a significant and cyclical challenge.

Notes: 1) Nigeria MOH. 2021. National Guidelines for the Prevention and Control of Micronutrient Deficiencies in Nigeria (MNDC); 2) WHO. 2023. [Guideline on the prevention and management of wasting and nutritional oedema \(acute malnutrition\) in infants and children under 5 years.](#) 3) BMGF Convening. May 25-26, 2022. “Integrating and scaling-up SQ-LNS within coordinated strategies to prevent child malnutrition, improve child survival, and promote healthy development.” Washington, DC; 4) Ethiopia Stakeholders. 2022-2023. 5) Benazir Income Support Programme (Government of Pakistan, 2023), 6) Stakeholder interviews, including with BISP Nashonuma representative.












In addition to inclusion in global treatment guidance, RUTF also benefits from clear CODEX standards on ingredient formulation, though these requirements have created some new challenges for manufacturers in an evolving product landscape.

The 2022 CODEX<sup>1,2</sup> guidelines codified RUTF requirements for ingredients and packaging/labeling...





... which illuminated opportunities for innovation but created and/or failed to address several market challenges.

### New Ingredient Requirements:

-  Introduced protein requirement (PDCAAS)<sup>3</sup> of 0.9 or more
-  Specified 50% of protein source must come from dairy, in addition to seeds, cereals, legumes, and amino acids
-  Increased omega-3, and decreased omega-6 fatty acid requirements
-  Increased vitamin and mineral ranges
-  Introduced roots/cereal/tubers as a new ingredient category

### New Packaging and Labeling Requirements:

Redesigned labeling of the RUTF sachet and carton aligned to categorization of “Foods for Special Medical Purposes”

-  Provides an **official reference** for country-level regulation, as well as quality and safety enforcement, by codifying RUTF standards
-  Provides **clearer innovation pathway** by identifying minimum standards to which alternative formulations must comply
-  **Increased production cost**, primarily due to the protein and fatty acid requirements:
  - 50% of protein must be sourced from powdered milk, one of the most expensive ingredients
  - Fatty acid requirement is typically met by high oleic peanuts, which are not locally grown in Africa and Asia
-  **Complicated sourcing of raw materials**, particularly to meet fatty acid requirements (e.g., import high oleic peanuts, switch to palm oil)<sup>4</sup>

#### Key



Created opportunity



Created challenge



Notes: 1) CODEX. 2022. CODEX Guideline for Ready to Use Therapeutic Food (RUTF); 2) CODEX Alimentarius Commission (CAC) is a joint body of FAO and WHO, that develops international food standards and guidelines; 3) PDCAAS, or Protein digestibility-corrected amino acid score is a metric used to evaluate protein quality for human consumption; 4) Supplier Stakeholder Interviews. 2023;

2022 CODEX guidelines provide a minimum standard for the development of alternative RUTF formulations, with the potential to increase access in the future; however, significant financial and regulatory barriers remain, inhibiting innovation.

### Alternative formulation benefits

- ✓ **Increase cultural acceptability** by using different ingredients which improve taste for local population
- ✓ **Improved cost-effectiveness** of local production by utilizing raw materials which are cheaper and/or do not require importation

### Barriers limiting development<sup>1</sup>

- ✗ **Lack of capital investment** to support manufacturers' R&D efforts; RUTF manufacturers typically experience low profit margins, and thus have limited cash-on-hand
- ✗ **Unclear return on investment (ROI)** given new formulae with improved local taste acceptability and production costs may only be valid in a small segment of the market
- ✗ **Unclear approval process** given global procurers (e.g., UNICEF) currently act as the primary approver/procurer, and have different requirements



Notes: 1) Supplier Stakeholder Interviews. August – November 2023; 2) Hossain et al., 2020. [Acceptability and efficacy of ready-to-use therapeutic food using soy protein isolate in under-5 children suffering from severe acute malnutrition in Bangladesh: a double-blind randomized non-inferiority trial](#). European Journal of Nutrition; 3) Stakeholders anticipate use of local ingredients to be more cost-effective. Research is ongoing to determine cost-effectiveness.



### Spotlight: Sharnali Alternative Formulation Development



In Bangladesh, the International Centre for Diarrhoeal Disease Research, Bangladesh (iccdr,b) developed an RUTF alternative formulation replacing peanuts with rice/lentils (i.e., Sharnali-1) and chickpea (i.e., Sharnali-2). **iccdr,b's alternative formulation development leverages some of the benefits of innovation:**

- ✓ Proven cultural acceptability<sup>2</sup>; anticipated increased cost-effectiveness<sup>3</sup>

**..while also addressing identified barriers:**

- ✓ Local research organization (iccdr,b) funding capital investment; strong ROI, with no other RUTF approved in-country; clear national-level approval process

**But significant challenges persist, and market entry is not guaranteed:**

- ✗ Even in this arguably more enabled environment, the timeline to market introduction is long. An effectiveness trial is now underway; pending positive results, market introduction and scale-up is still several years away.



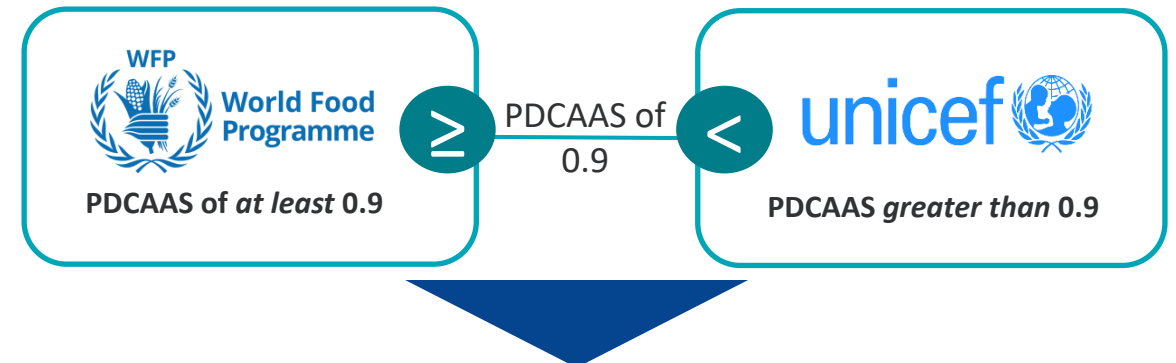
As more nascent products, SQ-LNS and BEP/LNS-PLW do not benefit from clear ingredient and formulation standards, leading to supply challenges that limit scale-up.

## Challenges

- 1 **No independent authority defining ingredient standards**
  - There are no CODEX guidelines for SQ-LNS or BEP/LNS-PLW.
  - In lieu of global guidance, major procurers (e.g., WFP and UNICEF) have developed their own technical specifications and by default, monitor quality assurance according to their specifications.
- 2 **Lack of visibility and harmonization across procurers' formulations**
  - Procurers (e.g., WFP and UNICEF) have slightly different formulations of these products, requiring manufacturers to “change” production lines to meet procurer specifications.<sup>1</sup>

### Example: Misaligned PDCAAS requirements between WFP and UNICEF

- In 2021, **WFP** released technical specifications for LNS-PLW<sup>2</sup>, which required a **PDCAAS of at least 0.9**. In 2022, **UNICEF** released their technical specifications for LNS-PLW<sup>3</sup>, which included a **stricter PDCAAS requirement of greater than 0.9**.



This discrepancy in specifications **negatively impacted several suppliers** that had developed formulations based on the WFP technical specification, which required that they change the proportion of their protein sources and adjust their production lines to supply to UNICEF.<sup>1</sup>

**Suppliers would benefit from more standardized, harmonized and explicitly defined ingredient requirements from the major procurers for prevention products, paving the way for eventual scale-up.**





RUTF and LNS products may be classified as food or medicines by country regulatory bodies; this classification has important regulatory and market implications.

### Market implications for food vs. drug classification<sup>1</sup>:



**Quality standards** are often stricter for medicines than foods, making regulatory processes more complicated.



**Registration** for medicines often costs more than for foods, and foods and medicines may be subject to different **import taxes**, ultimately affecting the **price** of the product.



Medicines may be **prioritized** over foods for forex allocation, availability in medical facilities, etc.
















Stakeholder disagreements about RUTF classification can **impact dossier review timelines**, delaying product approval.



Classification as food may require countries to **build additional warehousing facilities** to separate product storage from pharmaceuticals.

### Example: RUTF classification by federal regulatory bodies in focus countries

Country	Current RUTF classification	Regulatory body	Stakeholder consensus on current classification
Ethiopia <sup>2</sup>	 <b>Food</b> (dietary supplement)	 Ethiopian Food and Drug Authority (EFDA)	
Tanzania <sup>3</sup>	 <b>Food</b> (“High risk food for special nutritional purposes”)	 Tanzania Bureau of Standards (TBS)	 MOH pursuing technical re-evaluation of classification
Nigeria <sup>4</sup>	 <b>Food</b> (dietary supplement)	 National Agency for Food and Drug Administration and Control (NAFDAC)	
Pakistan <sup>5</sup>	 <b>Drug</b> (OTC Therapeutic)	 Drug Regulatory Authority of Pakistan (DRAP)	 WFP encouraging gov’t to pursue food classification
Bangladesh <sup>6</sup>	<b>N/A</b> – not registered	<b>N/A</b> – not registered	

Global guidance on “how” to evaluate the relative costs and benefits of classifying RUTF and LNS products as foods OR medicines would likely be beneficial to countries. Ideally, this guidance would support evaluating the implications – by classification - on quality standards, regulatory processes, financing, and overall prioritization.





Despite varying classifications, countries have prioritized similar regulatory factors for enabling RUTF markets as they exist today, which is instructive when looking ahead to fully enabled country regulatory landscapes for LNS product scale-up.

**Example: Enabling market factors compared across countries with differing classifications for RUTF**

Factors contributing to an enabled market for scale-up

Country	Classification <sup>1</sup>	Included in EML <sup>2</sup>	Included in Guidelines <sup>3</sup>	Regulator reviews dossiers <sup>2</sup>	Gov't procurement policies satisfied <sup>4</sup>	Zero or waived import or sales taxes <sup>5</sup>
Ethiopia	Food	Pending <sup>6</sup>			3/5 required suppliers registered <sup>7</sup>	Waived for UNICEF
Tanzania	Food				2/1 required suppliers registered <sup>8</sup>	Waived for UNICEF
Nigeria (Kano)	Food				1/1 required local supplier registered <sup>9</sup>	Waived for UNICEF
Pakistan	Drug	Pending <sup>6</sup>			1/3 required local suppliers registered <sup>10</sup>	Waived for UNICEF + WFP

sub-national  
level

Regardless of the classification as a food or a drug, countries have prioritized similar regulatory factors to enable current RUTF markets. **This suggests that despite varying classifications, there are similar steps countries can/should prioritize to ensure that their regulatory environments are enabled for RUTF and LNS product scale-up.** This could, for example, be codified in a global good on enabling nutrition regulatory landscapes at the country level.



Notes: 1) See Slide 25 for sources; 2) Government Stakeholder Interviews. 2022-2023; 3) See Slide 17 for sources; 4) Government and Supplier Interviews. 2022-2023; 5) Government and Procurer Interviews. 2022-2023; 6) Ethiopia and Pakistan typically use the WHO EML as their country EML, and we anticipate RUTF will be added during the next revisions of the country-level EMLs; 7) Ethiopia recommends 5 suppliers registered for a competitive government procurement. 8) Tanzania does not require a certain number or certain type of supplier to be registered, just for a supplier to be registered; 9) Nigeria's policy requires a local supplier, which is not limiting because three local suppliers are registered; 10) Pakistan's policy requires three local suppliers, which is limiting because only one is registered.

# Demand



# Demand: Key Themes



1

Primary driver of current demand

2

Product awareness

3

Procurement trends

4

Country-level systems and processes for demand estimation

## Treatment Products (RUTF)

**Available donor funds drive demand for these products more than any other demand factor:** Available funding, rather than other proxies for demand like unmet need or forecasted demand, drives procurement of RUTF and LNS products globally and at the country-level. Global demand for RUTF is significantly higher by volume than global demand for prevention products, which tends to flux based on RUTF demand.

**RUTF awareness is very high:** RUTF is widely known globally and in focal countries as a treatment product for severe wasting. In some focal countries, it was the only product in our assessment that stakeholders were familiar with or had experience with in the context of their health system.

**RUTF procurement is largely led and orchestrated by donors and UNICEF, and is responsive to global emergencies:** Procurement of RUTF is initiated by donors, coordinated by UNICEF, skews heavily toward treatment (RUTF and RUSF) rather than prevention products and is primarily responsive to emergency and humanitarian (vs. development) contexts.

**RUTF quantification is not standardized, and demand estimation and planning is often fragmented at the country level:** In focal countries, parallel and/or multiple systems for the quantification, financing, procurement and distribution of RUTF lead to a fragmented market landscape. There is no standardized quantification methodology for RUTF and LNS commodities, which leads to discrepancies in estimating need. This product class would benefit from standardized quantification guidance.

## Prevention Products (SQ-LNS, BEP/ LNS-PLW)

**Awareness of prevention products in focal countries is low:** Country decision-maker awareness of prevention products is limited and as a result, inhibits demand for these products at the global and country-levels. This limited awareness (and resulting low demand) is related to both the treatment-focused nature of the wasting space as well as larger questions about how to prioritize prevention products amongst food-focused interventions to prevent malnutrition

**Prevention products are not widely procured, especially compared to RUTF:** Prevention products are not widely procured in focal geographies or globally, with the exception of BEP/LNS-PLW in Pakistan.

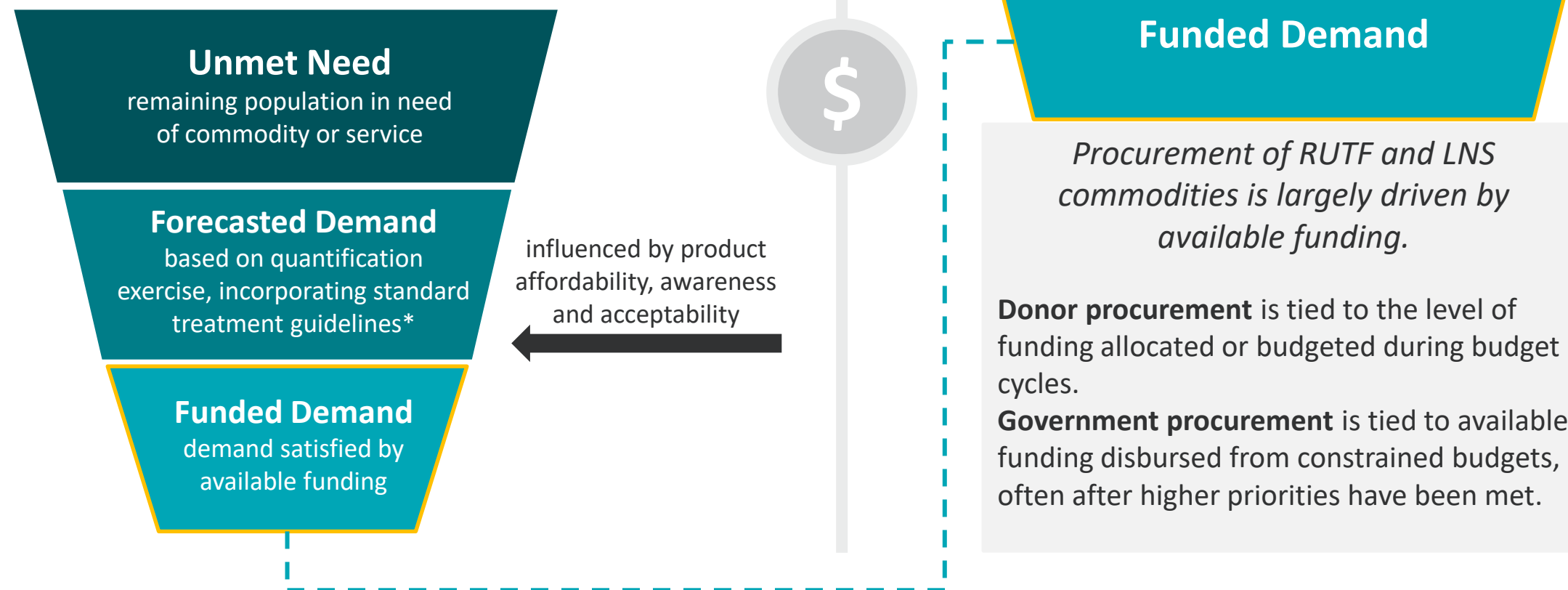
**Limited demand estimation happening for prevention products, but the RUTF market signals what is needed in the future:** For the few focal geographies where prevention products are procured, these systems are similarly fragmented and would benefit from standardized guidance as well.





Available funding, rather than other proxies of demand, drives procurement of RUTF and LNS products globally and at the country-level.

### Working Definitions of Demand<sup>1,2</sup>



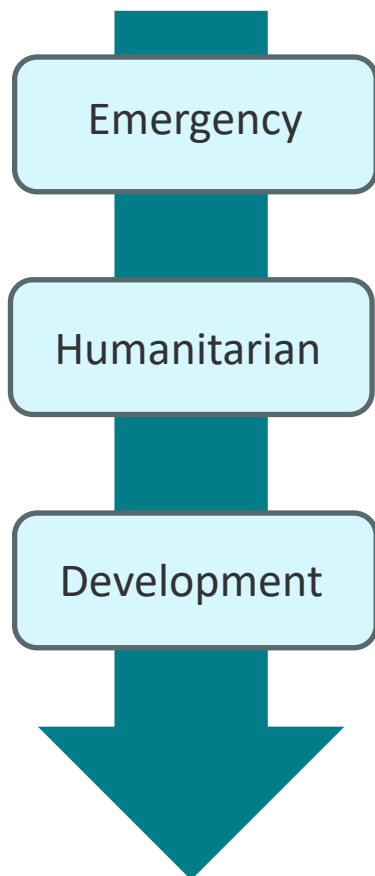
Notes: \*Not available for all LNS products; proxy guidelines should be clearly defined. Demand-related terms and definitions for this diagnostic are described above and incorporate ideas from 1) USAID. 2023. [Discerning Demand: A Guide to Scale-Driven Product Development and Introduction](#); 2) JSI. 2017. [Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement](#).





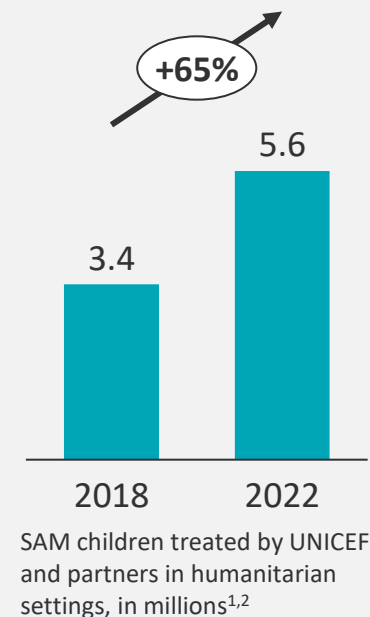
Procurement of RUTF and LNS products is donor-led, treatment-focused and primarily responsive to emergency and humanitarian contexts.

*Current prioritization for global procurement*



## Emergency and Humanitarian-focused Procurement Context

- The increasing need for severe wasting treatment in emergency or humanitarian settings further entrenches the RUTF and LNS market focus on treatment vs. prevention.
- Moreover, RUTF and LNS products are not fully integrated into country health systems and sometimes divorced entirely to donors as part of the emergency and humanitarian response.
- In all focus geographies, donors operate parallel supply chains for RUTF and LNS product procurement and distribution – no matter the procurement context - leading to significant fragmentation.



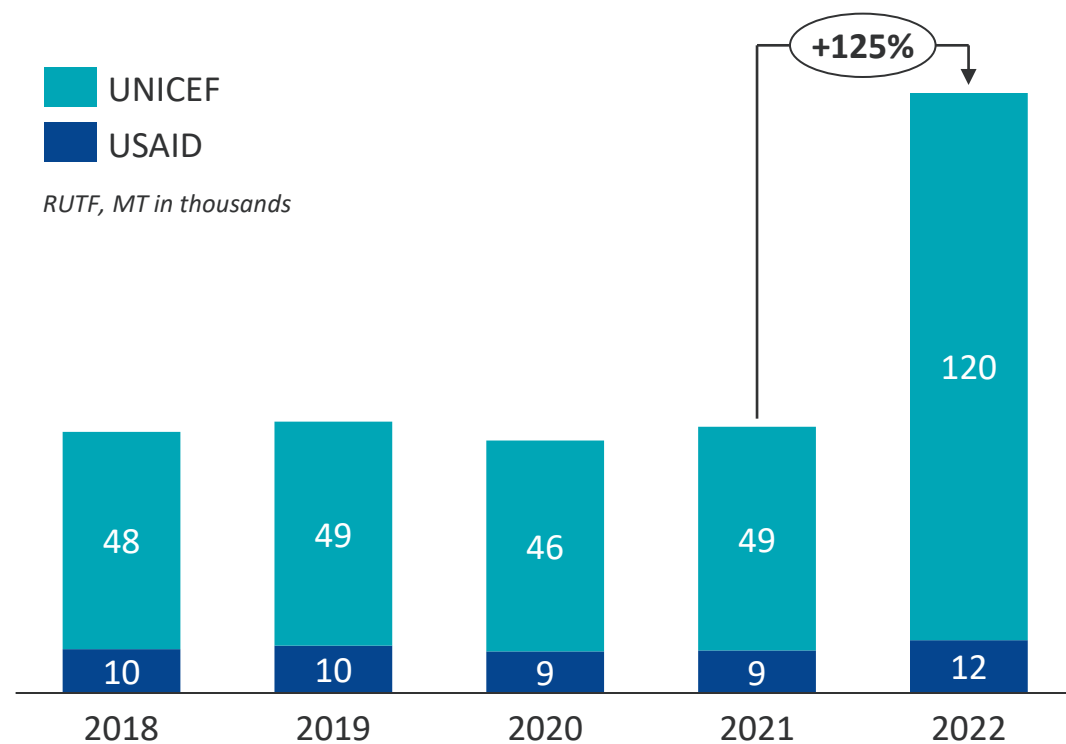
Moving the procurement and distribution of RUTF and LNS products away from the status quo and toward a **government-owned, prevention-focused, development context** will require a paradigm shift.

Notes: 1) UNICEF. 2020. [Global Annual Results Report 2019: Humanitarian Action](#); 2) UNICEF. 2023. [Global Annual Results Report 2022: Humanitarian Action](#).





Globally, procurement volumes of RUTFs were relatively consistent, until a temporary surge in 2022 in response to the global malnutrition crisis.



*Procurement of RUTF by UNICEF and USAID, 2018 – 2022<sup>1-3</sup>*

The surge in RUTF procurement volumes was the result of increased donor funding in response to a conflict and drought-induced global malnutrition crisis.<sup>4</sup>

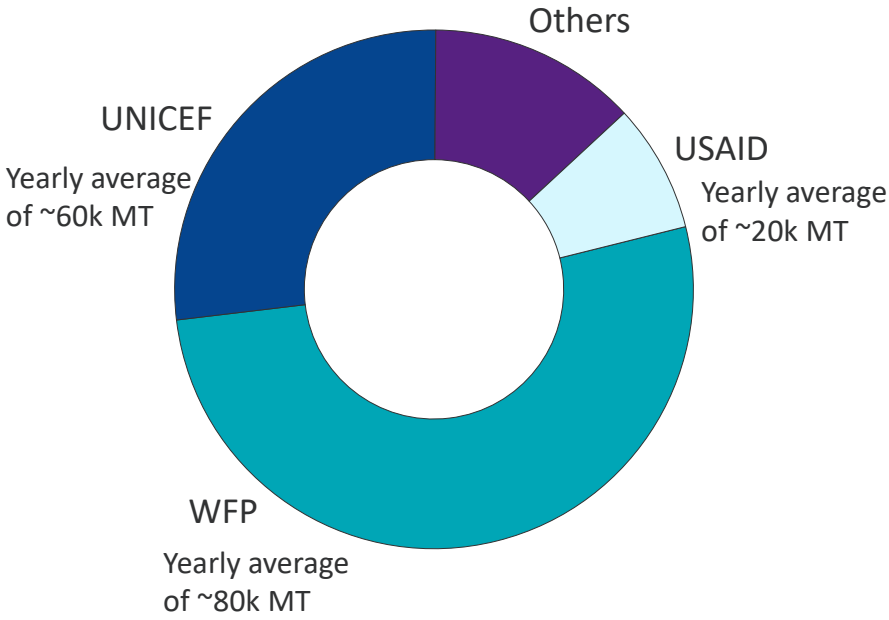
While the funding surge was primarily directed toward RUTF, the product class also experienced an overall increase in procurement: global procurement of RUTF and other LNS commodities increased by 45% between 2020 and 2022 (from 140k to 308k MT).<sup>1,4</sup>

However, the majority of donor commitments from 2022 were for short-term responses, and **the resulting procurement surge is not expected to last beyond 2023.**<sup>5</sup>



Notes: 1) UNICEF. May 2023. [RUTF: Market and Supply Update](#); 2) UNICEF. January 2022. [Procurement update for key nutrition commodities](#); 3) USAID. November 2023. [USAID Procurement Overview](#); 4) UNICEF. March 2021. [RUTF: Market Outlook](#); 4) UNICEF. September 2022. [No Time to Waste Acceleration Plan](#); 5) Stakeholder interviews. July – November 2023.

# UNICEF, USAID and WFP lead procurement of RUTF and LNS products globally.



**Illustrative Mapping of Global Procurement of RUTF and LNS Products by Source, 2017-2022**

**UNICEF** leads procurement of RUTF and SQ-LNS globally, and also procures BEP/LNS-PLW along with small volumes of MQ-LNS and RUSF.

**WFP** leads procurement of RUSF, MQ-LNS and LNS-PLW, and also procures minor volumes of SQ-LNS and RUTF.

**USAID** procures RUTF and RUSF, providing in-kind donations of LNS products to UNICEF and WFP.

**Other procurers**, of RUTF and RUSF primarily, include country governments, Action Against Hunger (AAH), the International Committee of the Red Cross (ICRC), Médecins Sans Frontières (MSF) and other UN agencies.



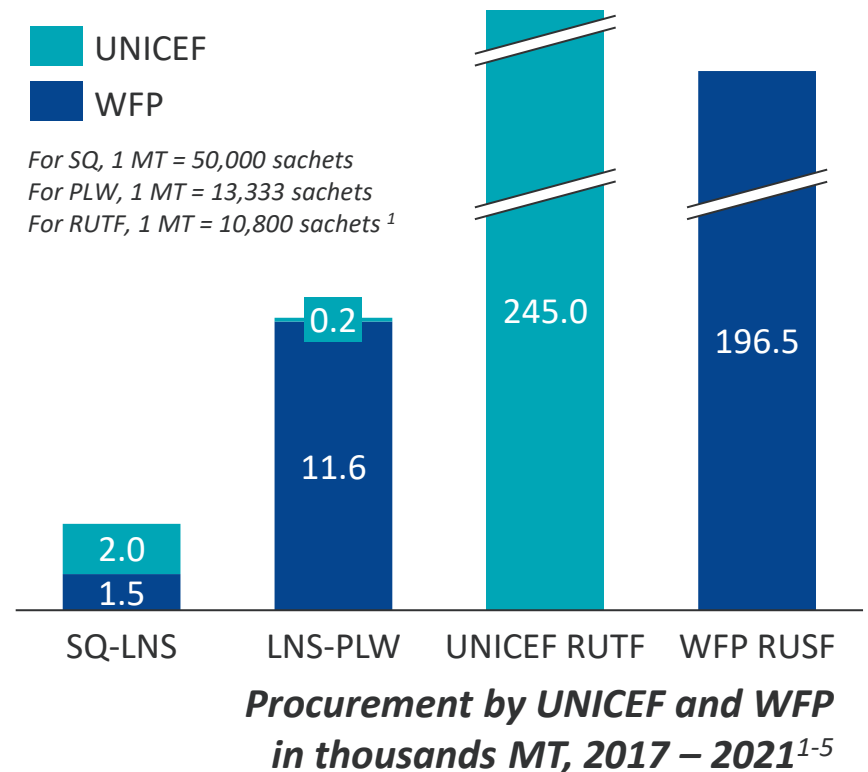
Notes: RUTF and LNS products refers to: RUTF, RUSF, MQ-LNS, SQ-LNS and LNS-PLW/BEP. Estimates of the relative proportions of global procurement sources are based on available procurement data from 2017-2022 (i.e., not all data are available in all years) and published statements on relative proportions between major procurers. Estimate of volumes from other sources derived by comparison to UNICEF volumes as illustrated in the [UNICEF Supply Division Estimate of Global Installed RUTF Production Capacity 2022](#). Other specific sources feeding into this analysis listed on slides 34 and 36.



WFP and UNICEF lead procurement of prevention products (i.e., SQ-LNS, BEP/LNS-PLW), albeit in smaller overall quantities than RUTF.

**UNICEF** is the primary procurer of SQ-LNS but in very small volumes when compared to RUTF. The total volume of SQ-LNS procured is 0.83% of the RUTF volumes over the same period. UNICEF also procures small volumes of LNS-PLW.

**WFP** procures small volumes of SQ-LNS and LNS-PLW. WFP tends to focus on food-based interventions, only using LNS in specific settings. Notably, WFP does lead procurement of other products in the LNS category (e.g., RUSF, MQ-LNS).



**Global procurement skews heavily toward treatment (RUTF & RUSF) versus prevention products.**



Notes: 1) UNICEF. January 2022. [Procurement update for key nutrition commodities](#); [WFP. Specialized Nutritious Foods Sheet](#); 2) UNICEF. June 2018. [UNICEF Market Update for RUTF and other LNS Products](#); 3) UNICEF. November 2023. [UNICEF SD Procurement Overview](#); 4) WFP. September 2019. [SNF Procurement Update](#); 5) WFP. January 2022. [UNICEF Nutrition Supply Forum – WFP Procurement](#)



Global procurement trends are reflected in most focus geographies, with 4/5 country governments procuring treatment but not prevention products.

### Product Procurement in Focus Geographies<sup>1</sup>

Countries	Tx		Px	
	RUTF	SQ-LNS	BEP/LNS-PLW	
Ethiopia	Product is procured	Low-volume of product is available in research or refugee settings	Product is not procured	Product is not procured
Nigeria – Kano	Product is procured by the govt	Product is not procured	Product is not procured	Product is not procured
Pakistan – KP	Product is procured	Product is not procured	Product is not procured	Product is not procured
Tanzania	Product is procured	Product is not procured	Product is not procured	Product is not procured
Bangladesh	Low-volume of product is available in research or refugee settings	Low-volume of product is available in research or refugee settings	Product is not procured	Product is not procured

- Product is procured
- Product is not procured
- Product is procured by the govt
- Low-volume of product is available in research or refugee settings


















































Generally, at the country-level in focal geographies, nutrition experts prefer to use RUTF for SAM treatment—following decades of advocacy, product donation, and procurement. In Bangladesh, nutrition experts are also aware of RUTF though it is absent from the market due to regulatory restrictions.

SQ-LNS and BEP/LNS-PLW, however, are largely absent from country markets, with limited exceptions.



Notes: 1) Stakeholder interviews. January – July 2023. In Ethiopia, UNICEF is conducting pilot research on SQ-LNS in Tigray populations. In Pakistan, a locally branded LNS-PLW called Maamta is provided through the BISP (Benazir Income Support Programme) Nashonuma which is a social protection program. In Bangladesh, RUTF and SQ-LNS only exist in Rohingya refugee camps.

At the country-level, parallel and/or multiple systems for the quantification, financing, procurement and distribution of RUTF\* lead to a fragmented market landscape.

										
Quantification	 unicef	SQ - LNS 	 + 	 + 	 + 	LNS - PLW 	 unicef			
Funder				 DANGOTE FOUNDATION 	 SMOH		 FMOH			
Procurer				 DANGOTE FOUNDATION 	 SMOH					
Distributor				 DANGOTE FOUNDATION 						

\*except where noted

— separate product pathway  
 - - - - - same product with separate pathways

Notes: Countries presented in alphabetical order. ADFIN: Aliko Dangote Foundation Integrated Nutrition; MOH: Ministry of Health; FMOH: Federal Ministry of Health; SMOH: State Ministry of Health; CUAMM: Doctors with Africa CUAMM.

In Bangladesh, RUTF and LNS products are available for refugee populations only. In Ethiopia, the FMOH leads quantification with support from UNICEF. In Nigeria, the SMOH leads quantification with support from UNICEF and both finance, procure and distribute as well; Dangote Foundation (through the ADFIN project) and MSF do not quantify RUTF but rather provide ad hoc funding and procurement. In Pakistan, quantification is led by the FMOH with UNICEF as a technical partner. In Tanzania, the MOH conducts a quantification but does not fund RUTF, while partners fund without quantifications. AAH is no longer procuring RUTF.



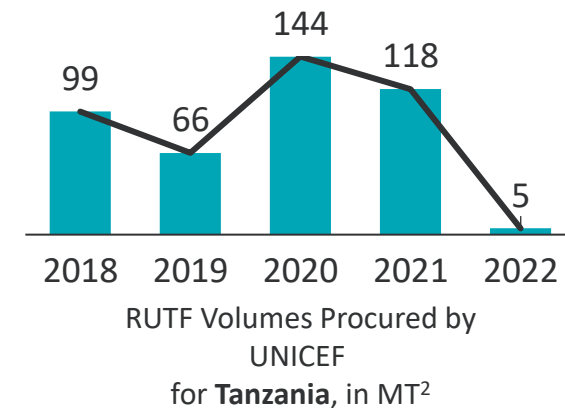
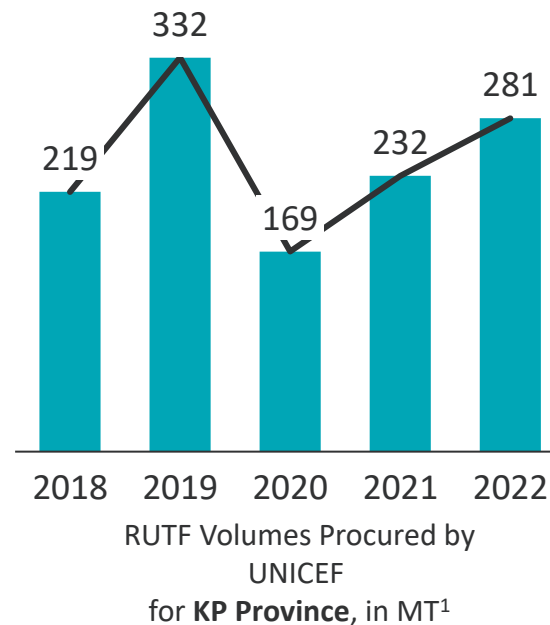


## Despite steady global procurement volumes, volumes of RUTF and other LNS commodities donated at the country-level vary widely from year-to-year.

In many geographies, there is limited or no government procurement of RUTF resulting in **high reliance on donated commodities**.

Yet the **volumes donated to countries vary each year** due to donor prioritization and funding constraints. Volumes are often below forecasted demand and result in consistently high unmet need.

The variability in donated volumes and the lack of visibility into annual donor procurement plans **makes precise supply planning challenging**.



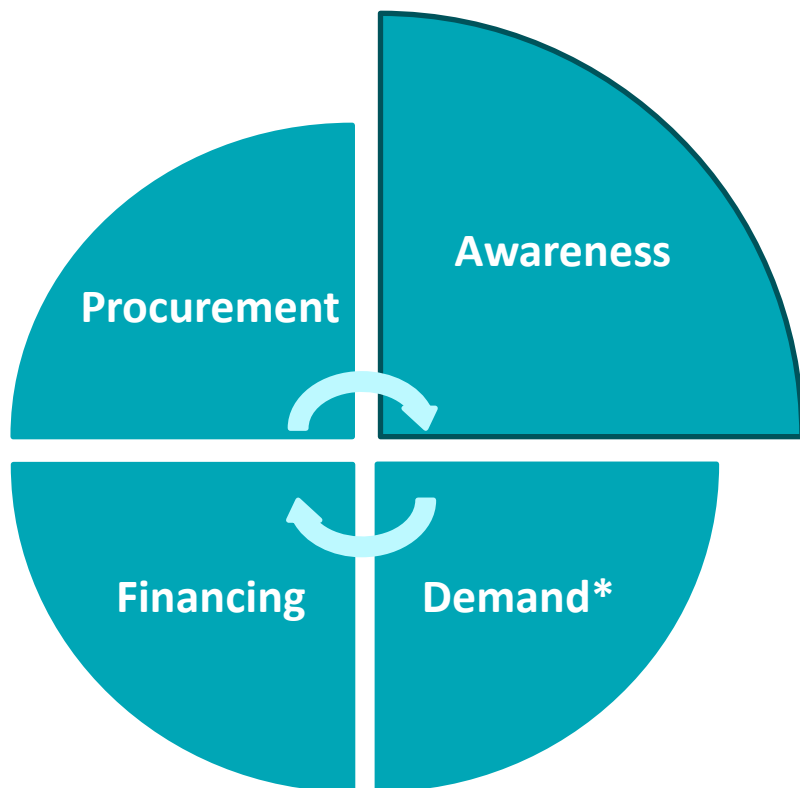
This variation in RUTF volumes at the country level complicates countries' ability to plan for and respond to forecasted demand for treatment products.



Notes: 1) KP Province UNICEF volumes calculated using UNICEF funding values obtained from May – September 2023 stakeholder interviews in KP Province and [UNICEF global average WAP](#) each year; 2) TZ procurement volumes sourced from stakeholder interview with UNICEF TZ. April 2023.



Unlike for RUTF, awareness (a precursor to demand) is limited for LNS prevention products like SQ-LNS and BEP.



Low awareness of LNS prevention products leads to further downstream effects, including low forecasted demand, limited financing and little to no procurement (compared to treatment products, like RUTF).

### Challenges to Awareness of LNS Prevention Products

- **No concerted global push:** RUTF benefitted from global endorsements and large-scale product donation for decades to become widely known and accepted. Prevention products have not received the same attention.
- **Lack of consensus on prioritization:** In general, interventions for the prevention of malnutrition focus on the provision of healthy foods (e.g., via fortified foods). There is limited awareness in our focal geographies of LNS commodities for prevention, and country-level decision-makers are unsure about how to prioritize and/or integrate them into nutrition programming alongside healthy foods.
  - With the exception of SQ-LNS in Nigeria, prevention products are not included in any country-level nutrition guidelines or policies.<sup>1</sup>

Given the treatment-focused nature of LNS markets, prevention products like SQ-LNS and BEP/LNS-PLW will **need dedicated and sustained advocacy**, including product champions within country governments, as well as **formal product introduction** plans to increase awareness and generate demand.

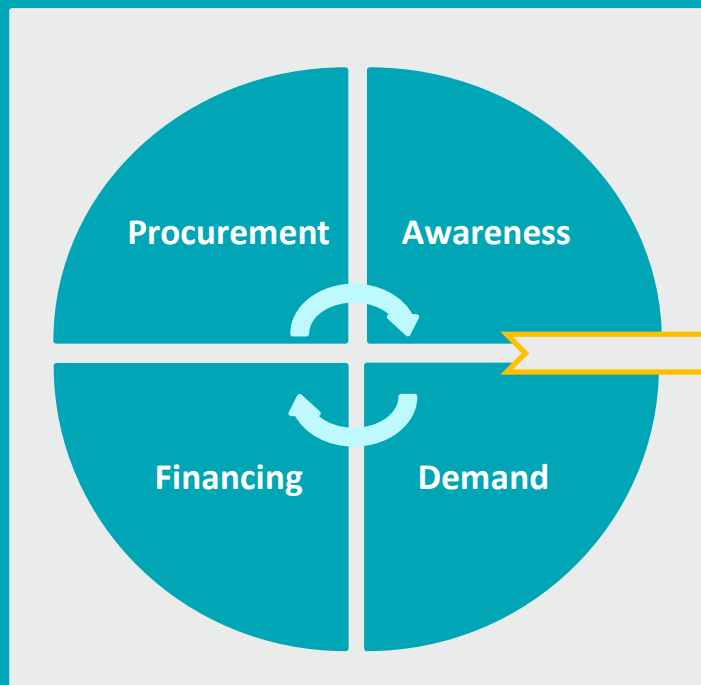


Notes: \*forecasted demand, to inform financing and procurement requirements. 1) Federal Ministry of Health. 2013. [National Guidelines for the Prevention and Control of Micronutrient Deficiencies in Nigeria](#).





Country example spotlight: WFP technical assistance to BISP Nashonuma increased awareness and demand for BEP/LNS-PLW in Pakistan.



### Increasing Awareness and Access to Prevention Products in Pakistan

The Pakistani government secured a World Bank loan specifically to invest in nutrition programming, including through BISP Nashonuma, a conditional cash transfer program that aims to prevent stunting and address chronic malnutrition. WFP provides technical assistance for the implementation of BISP Nashonuma.

WFP's advocacy increased **awareness** of LNS prevention products, including BEP/LNS-PLW. With technical assistance from WFP, the government circumvented the lack of guidance on eligible and dosage for the product and instead quantified **demand** using a blanket provision to all pregnant and lactating women in BISP. With support for **financing** and **procurement**, the government increased BEP/LNS-PLW procurement from 55 MTs in 2021 to 763 MT in 2023 in KP province through BISP Nashonuma.<sup>1,2</sup>



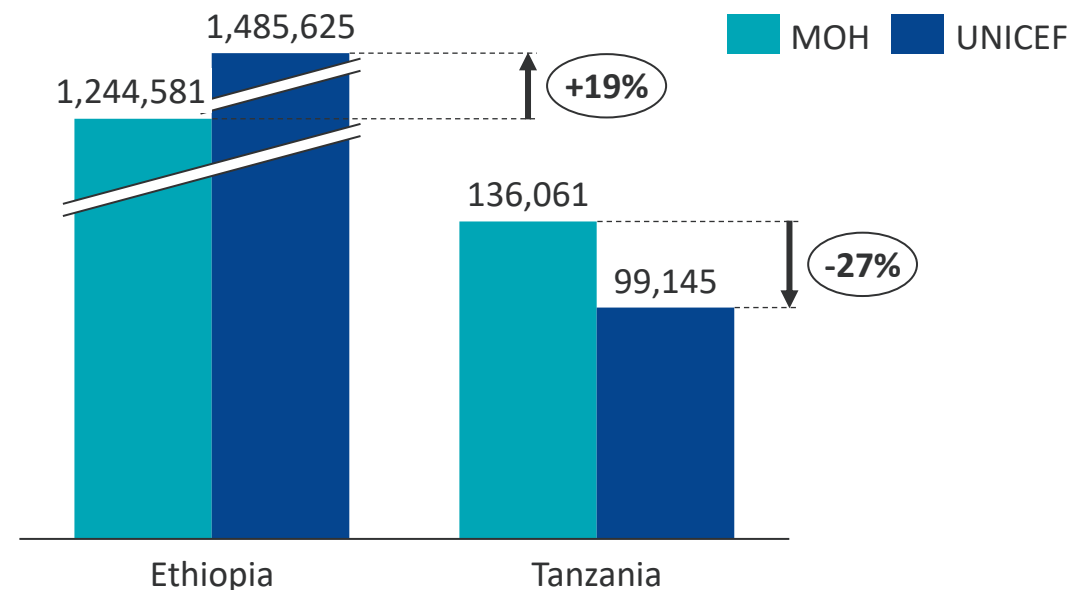


There is no standardized quantification methodology for RUTF and LNS commodities, leading to discrepancies in forecasted demand estimates.

## Gaps in Quantification Processes

The lack of a standardized quantification methodology presents several challenges, including:

- Standardized treatment guidelines (STGs) are a prerequisite for quantification given they form the basis for assumptions around eligibility and dosage.**<sup>1</sup> STGs exist for RUTF and have been adapted, at least in part, in the national guidelines for 4/5 focus geographies. However, STGs do not exist for BEP or SQ-LNS.<sup>2</sup>
- Data sources feeding into quantification processes may be incomplete or suffer from data quality issues.** In Tanzania, the MOH uses a Bottom-Up Quantification (BUQ) methodology based on consumption data. However, RUTF is not fully integrated into the eLMIS so not all facilities are able to report on consumption. Regular stockouts of RUTF may also contribute to underestimation of demand in Tanzania.



*RUTF Demand Estimates in cartons, MOH<sup>3</sup> vs. UNICEF<sup>4</sup> Methodology*

**Demand forecasts among stakeholders can be vastly different for the same intended population when different data sources, assumptions, and quantification methodologies are utilized. This has significant implications for supply planning and funding decisions.**



Notes: 1) JSI. 2017. [Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement](#); 2) WHO. 2023. [Guidelines on the Prevention and Management of Wasting and Nutritional Oedema \(acute malnutrition\) in Infants and Children under 5 Years](#); 3) ET MOH demand estimate for 2022/2023 sourced from June 2023 National Nutrition Program Quantification report. TZ MOH demand estimate for 2023 sourced from March 2023 MSD Supply Planning Workshop; 4) UNICEF demand estimates sourced from UNICEF Ethiopia and Tanzania stakeholder interviews. July - December 2023.



# Spotlight opportunity: RUTF and LNS products would benefit from global quantification guidance to inform processes for forecasting demand, supply planning and financing.

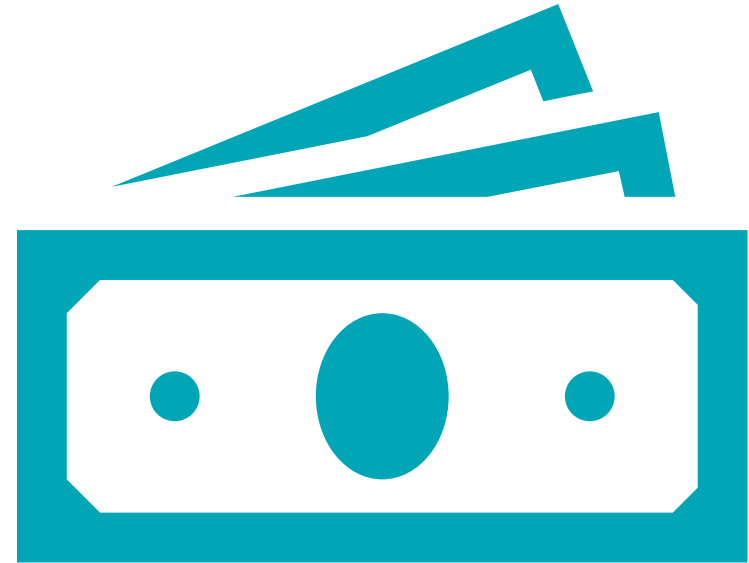


- USAID's MTaPS Supplement for Forecasting Consumption of select RMNCH products<sup>1</sup> offers a standardized methodology for estimating demand based on morbidity, demographic or service data. The supplement provides algorithms, examples, templates and guidance around quantification processes that can be adapted by in-country quantification teams.
- For RUTF and LNS products, **standardized quantification guidance can address common sources of discrepancy**, such as:
  - incorporation of STGs (where available),
  - relevant data sources and appropriate proxies, and
  - how to adjust for complicated and uncomplicated SAM treatment needs.

Quantification guidance for RUTF and LNS products is needed to ensure all procurers have an **established and consistent quantification methodology** to guide their processes of forecasting demand, supply planning and financing.



# Finance





1

Funding source of nutrition commodities

2

Financing sufficiency for country needs

3

Widespread country resource mobilization challenges

4

Innovative financing mechanisms

## Treatment Products (RUTF)

**Donors fund the vast majority of RUTF procured:** In line with procurement trends, RUTF and LNS product financing is primarily donor-enabled within our focus geographies. Donor funding mostly flows toward RUTF of all the commodities in this assessment.

**Current funding for RUTF is insufficient, and country-level financing is low:** Even with significant donor support for RUTF, financing still falls short of need and forecasted demand at both global and country-levels. At the country-level, domestic spending on health is already insufficient; nutrition, and specifically wasting commodities, accounts for only a small portion of health spend, especially when compared to other health programs.

**At country level, achieving consistent resource mobilization for RUTF and LNS commodities has proven challenging:** At the country-level, common financing issues exist, including: 1) RUTF and LNS products are not included (i.e., as line items) and/or prioritized in regular budgeting exercises; 2) funding is fragmented by source, program and delivery channel; and 3) poor coordination of stakeholders who make and execute funding decisions. Furthermore, focus geographies face a variety of roadblocks in mobilizing domestic funding, including lack of inclusion of RUTF and LNS products in guidelines and policies, uncoordinated or fragmented forecasting and budgeting exercises, and budgeted funds not being disbursed on time, in full, or at all.

**The Child Nutrition Fund (CNF) has had some early wins, but requires ongoing monitoring, adjustments, and country TA to ensure its sustained success:** The CNF is an innovative financing mechanism, designed to help scale sustainable policies, programs and supplies to end child wasting. CNF's Match Window has had early success mobilizing funding. Several opportunities for improvement and optimization exist, including raising awareness of fund and eligibility for CNF match and ensuring countries have support they need to access the match. Given early success of the Match Window, there are concerns about sustainability, namely commitments outpacing available funds.

## Prevention Products (SQ-LNS, BEP/ LNS-PLW)

**Funding of prevention products is very limited:** Global funding flows could be generally described as deprioritizing prevention products in favor of RUTF for treatment or food-based interventions for prevention, which is reflected in the regulatory and demand findings of this diagnostic as well.

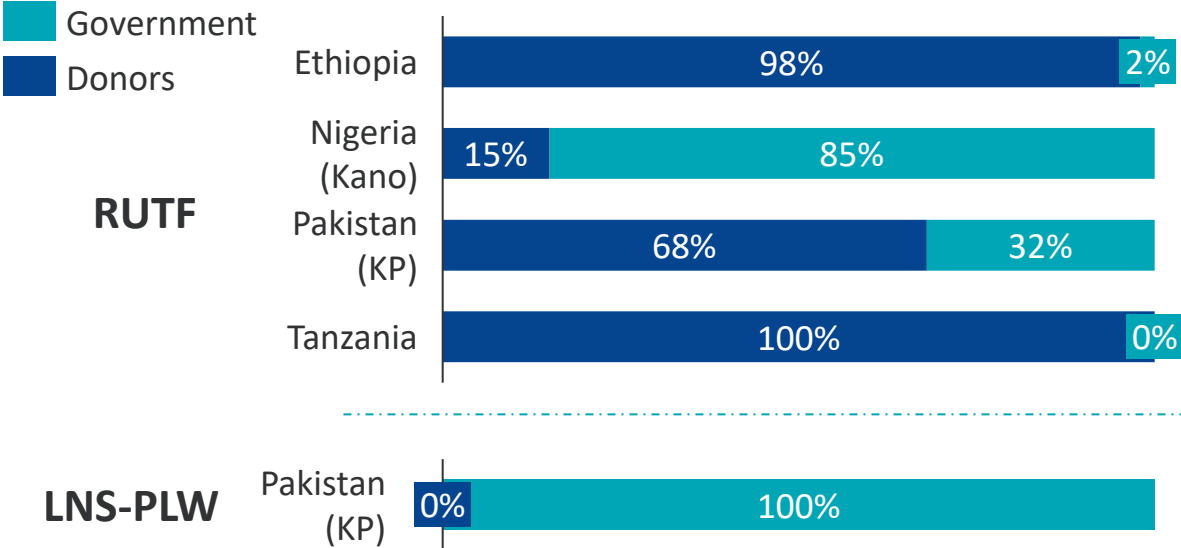
**Funding is low, and funding gap is difficult to estimate given unclear global guidelines and use-cases:** The market for these products is more nascent than RUTF, lacking widespread procurement and even a benchmark for 'sufficiency.'

**The CNF could also help expand access to prevention commodities:** Pending more global consensus on prioritization and use-cases for prevention commodities, the CNF could be utilized to strengthen advocacy and funding for non-RUTF LNS commodities.



In line with procurement trends, RUTF and LNS product financing is primarily donor-driven within our focus geographies.

**RUTF and LNS Funding Sources, 2017 – 2023\***



\***except:** ET<sup>1</sup>: 2020 – 2023 and PK PLW<sup>5</sup>: 2020 -2023. All others<sup>2,3,4</sup>: 2017 – 2023

**When governments mobilize domestic funding, they are utilizing innovative mechanisms:**

- **Ethiopia:** incentivized by the CNF to fund RUTF in 2022, Ethiopia utilized its SDG Pooled Fund, a funding mechanism managed by the MOH.<sup>6</sup>
- **Nigeria (Kano):** first incentivized by UNICEF co-financing for RUTF between 2017-2019, Kano has since used World Bank GFF loans for funding through 2023.<sup>4</sup>
- **Pakistan (KP):** encouraged by WFP and with the support of World Bank loans, the govt dedicated funds for LNS-PLW through the Federal Benazir Income Support Program (BISP Nashonuma).<sup>7</sup>

**Governments’ utilization of innovative mechanisms to mobilize domestic funding suggests partner support and catalytic donor funding could help generate domestic funding for the RUTF and LNS product market.**



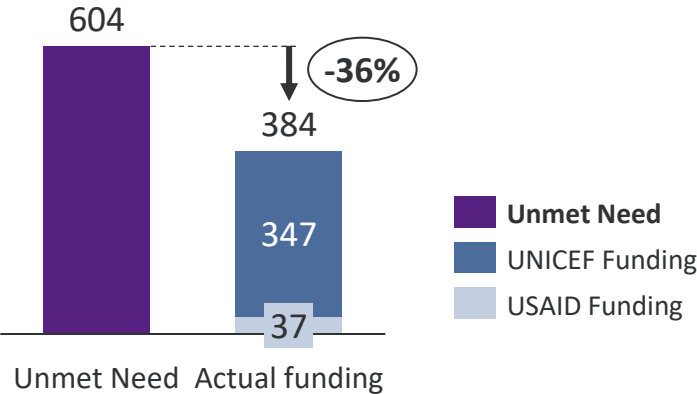
Notes: 1) UNICEF. 2023. UNICEF Ethiopia Service Data; 2) Bangladesh stakeholder interviews. July – November 2023. Note this excludes RUTF and LNS available for refugee populations; 3) Stakeholder interviews in KP Province. May – September 2023; 4) Tanzania RUTF funding calculated using [2022 UNICEF Global WAP](#) and procurement volumes from stakeholder interviews. July – November 2023; 5) Stakeholder interviews in KP Province. May – September 2023; 6) Ethiopia stakeholder interviews. July – November 2023; 7) KP stakeholder interviews. July – November 2023.

Despite significant donor support for RUTF specifically, financing is unable to cover forecasted demand or need--both globally and at the country-levels.

Both at the global-level and in countries, donors provide the bulk of funding for RUTF. However, **significant estimated funding gaps persist, even when donor funding is at its peak** – as was the case during the 2022 funding surge. Thus, **greater resources must be mobilized to meet demand for RUTF and likely other LNS products.**

**Global-level**

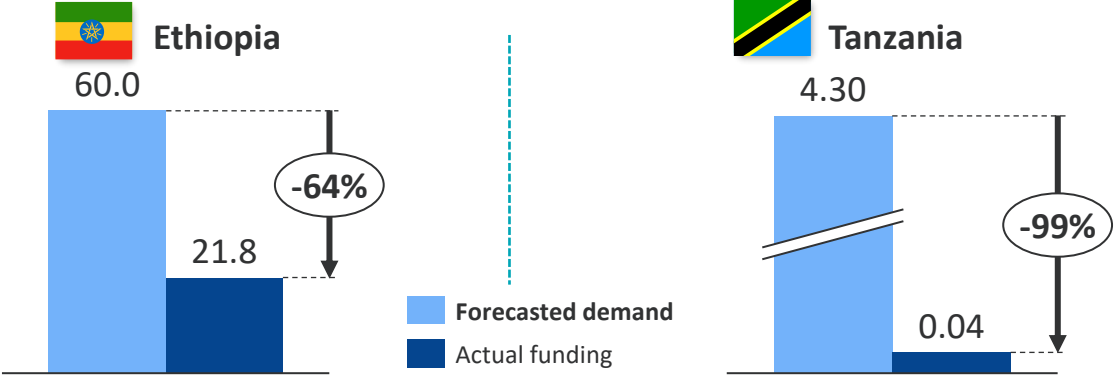
Global RUTF Unmet Need vs. Funding in 2022, in millions USD<sup>1,2,3</sup>



Despite significant investment from the primary global RUTF funders, UNICEF and USAID, an **estimated 36% funding gap persisted globally in 2022.**

**Country-level**

Country-level RUTF Forecasted Demand vs. Funding in 2022, in millions USD<sup>5,6</sup>

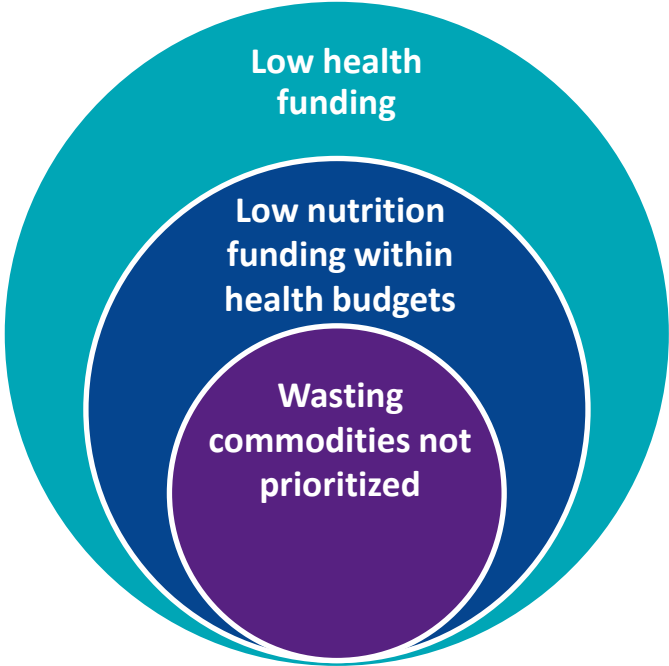


In Ethiopia and Tanzania, **funding gaps of 64%-99% persisted** when comparing forecasted demand to actual funding.<sup>4</sup>



Notes: 1) UNICEF Funding sourced from UNICEF Procurement update for key nutrition commodities (2023); 2) USAID funding calculated using UNICEF 2022 Global Average WAP per carton of \$44.4 and procurement volumes sourced from USAID Nutrition Procurement Update (2023); 3) Using UNICEF 2022 Global Average WAP per carton of \$44.4 to calculate unmet need (all children at risk of wasting, with or without complications, regardless of mortality risk) cost based on: Global number of children (cases) with severe wasting (2021), at 1 carton per case; 4) The Ethiopia MoH computes the RUTF forecast for the entire unmet need while Tanzania computes a more targeted forecast; 5) Actual funding based on UNICEF Ethiopia Service Data sourced from UNICEF ET stakeholder consultations. Forecasted demand based on UNICEF/Ethiopia National Emergency Nutrition Coordination Unit Quantification 2023; 6) Actual funding based on procurement volumes sourced from April 2023 stakeholder interview with UNICEF TZ, and forecasted demand based on UNICEF TZ 2023 quantification volumes sourced from UNICEF TZ stakeholder consultations, calculated using 2022 UNICEF Global WAP

In a landscape where domestic spend on health is already insufficient, nutrition – and specifically wasting commodities – accounts for only a small portion of funding.



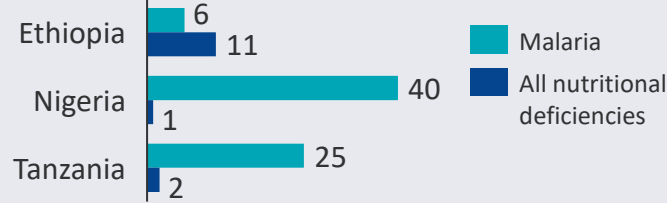
**Low gov't allocation to health funding**

- In high income countries, an average of 14% of GDP is spent on health.<sup>1</sup> For LMICs, the average is 7%.
- **Example:** *Ethiopia*, total annual budget allocated to health is only 5.3% of GDP<sup>2</sup>, well below the 15% target established by African countries.

**Low nutrition funding w/in health**

- There is no recognized benchmark to guide nutrition spending specifically.
- Wasting is attributed to 1 out of 5 under-5 deaths. We compared spend on nutrition interventions to leading causes of under-5 mortality, such as malaria. Nutrition funding is low by comparison.

Average expenditure on a disease/condition as a % of all health expenditure, 2017 - 2020<sup>1</sup>



**Wasting commodities not prioritized**

- Country examples point to low prioritization for wasting commodities, specifically:
- *Tanzania:* National Multisectoral Nutrition Action Plan to 2025/2026 all nutrition activities and commodities are costed for, except RUTF and other LNS commodities.<sup>3</sup>
  - *KP Province, Pakistan:* while wasting commodities have gained priority status in policy documents, it has not translated to procurement. There have been only two development projects that included commodity procurement.<sup>4</sup>



Notes: 1) WHO. Retrieved December 2023. [Global Health Expenditure Database](#). Note: For health expenditure from all funding sources; 2) UNICEF. November 2019. [Analysis of the Ethiopia 2019/20 Federal Budget Proclamation](#); 3) United Republic of Tanzania Prime Minister’s Office. 2021. Tanzania National Multisectoral Nutrition Action Plan 2021/22 – 2025/26; 4) Stakeholder interviews in KP Province. 2022 – 2023.







Furthermore, given nutrition's multi-sectoral nature, funding is often fragmented and poorly coordinated at the country-level, contributing to inefficient use of already limited resources.

## Fragmented funding pathways

Funding is fragmented at the country-level across:

- 1 **Sources:** Example in Pakistan, the National Nutrition Action Plan (May 2021) has not been fully-funded. In response, the government has **parceled out interventions based on fragmented donor support**.<sup>1</sup> 
- 2 **Recipient programs/entities:** Example in Bangladesh, **nutrition investments** (for commodities and service delivery) **can be found in at least 15 ministries/divisions**. Over 90% are on nutrition-sensitive interventions, while the remaining are on nutrition-specific interventions.<sup>2</sup> 
- 3 **Channels:** Across countries, **limited visibility and coordination of humanitarian vs. development** sector funding flows.

## Poor coordination

Country examples provide context to coordination challenges:



### Nigeria (Kano)

- Key decision-makers across nutrition-specific and sensitive programming are **not active within the State Committee on Food and Nutrition (SCFN)** for aligning on or advocating for funding priorities to budget-makers.<sup>3</sup>
- Moreover, there are multiple donors funding RUTF in any given year but there are **no coordinated forecasting exercises** for improved planning and strategic funding decisions.



**Tanzania:** The technical working groups for decision-making between the Pharmaceutical Services Unit (PSU) [on the budget], the Medical Stores Department (MSD) [on procurement] and the Nutrition program are **inactive**. This impedes the funding allocation process.<sup>4</sup>

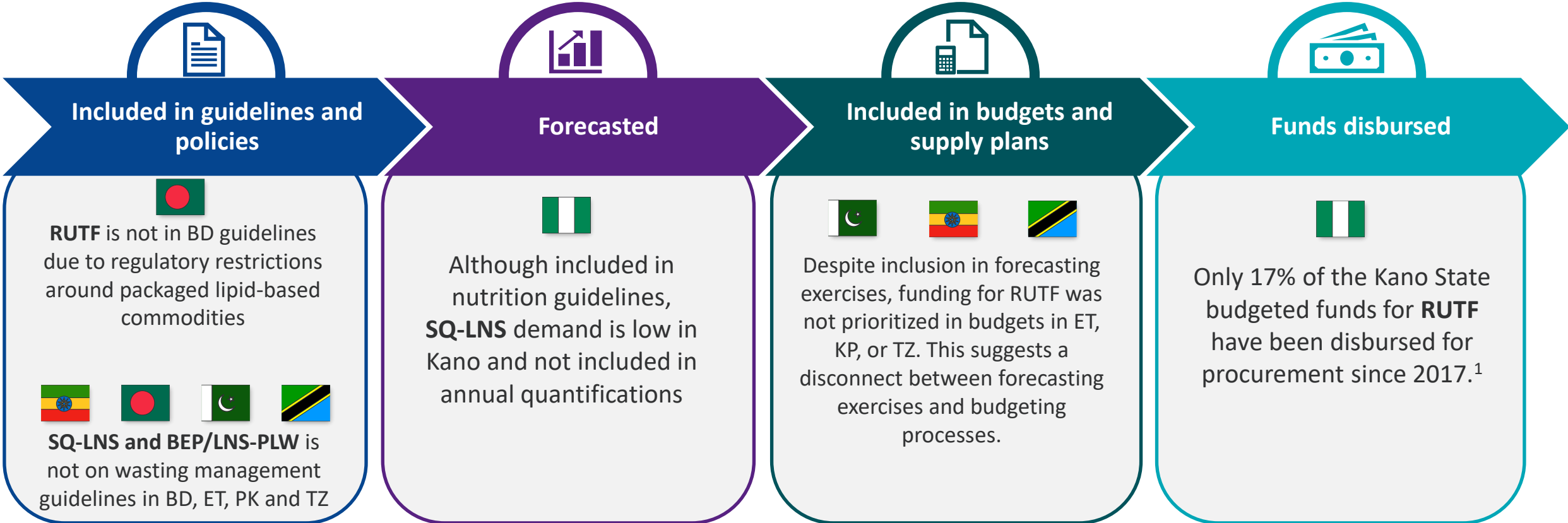
The multi-sectoral nature of nutrition programming means that financing is difficult to coordinate and track across the various funding sources. **Improved coordination mechanisms and utilization of data** for decision-making is needed to make more efficient use of the limited funding resources.



Notes: 1) Stakeholder interviews. July – November 2023; 2) UNICEF & Oxford Policy Management. 2019. [Bangladesh Public Expenditure Review On Nutrition](#); 3) Stakeholder interviews with Kano SMOH. July – November 2023; 4) Stakeholder interviews with Tanzania MOH. July – November 2023.

Throughout the process of domestic resource mobilization, countries need support to identify and advocate for prioritization of funding for child wasting products.

**Typical Domestic Resource Mobilization Flow**

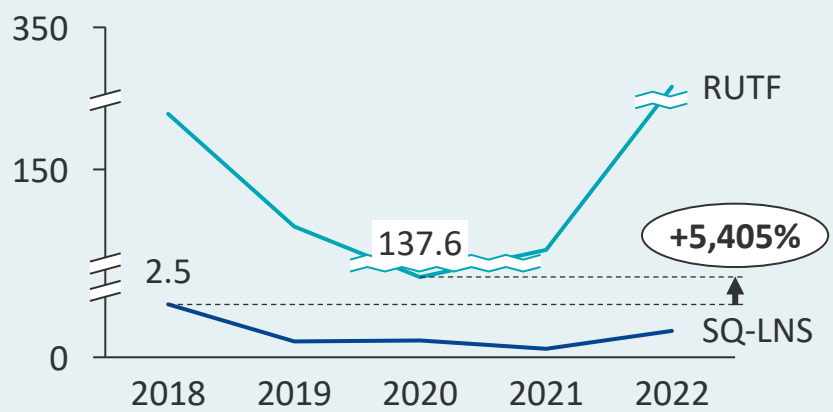


Notes: BD: Bangladesh; ET: Ethiopia; KPK: Khyber Pakhtunkhwa; PK: Pakistan; TZ: Tanzania. 1) Stakeholder interviews with Kano SMOH. July – November 2023.

Funding currently flows to RUTF for treatment or food-based interventions for prevention, suggesting a need for stronger consensus (and then, clearer guidance) on how LNS prevention products should be used and funded.

**Funding for wasting prioritizes treatment commodities, including RUTF, over prevention commodities (SQ-LNS and BEP)**

UNICEF procures the most RUTF and SQ-LNS globally but RUTF has received **several orders of magnitude more funding than its prevention counterpart, SQ-LNS.**

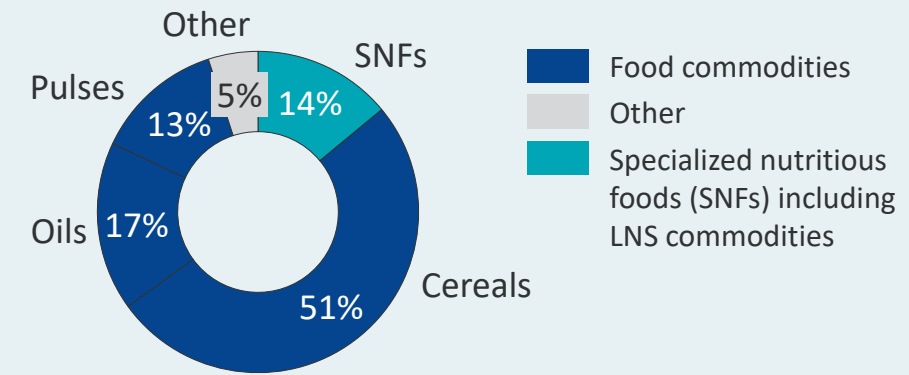


UNICEF Funding Values for RUTF and SQ-LNS in millions USD<sup>1</sup> showing 5-year minimum and maximum funding amounts respectively

**Funding for wasting prevention prioritizes food-based interventions**

Stakeholders are unsure of how to incorporate SQ-LNS and BEP/LNS-PLW alongside healthy diets for SAM prevention.<sup>2</sup> A challenge compounded by the lack of standard dosage and use-case guidelines.

**Funders prioritize nutritious foods and diverse diets** rather than food supplements to prevent wasting.



In 2021, WFP spent \$355 million (14% of all commodity funding) on all SNFs including RUSF, LNS-PLW, SQ-LNS and MQ-LNS.<sup>3</sup>

There is not yet a robust understanding of how to balance commodity funding for both prevention and treatment, and within prevention, how to balance investments in food and LNS prevention commodities. More prescriptive guidance on use-cases and investment prioritization could benefit these products and their markets.



Notes: 1) UNICEF. November 2023. [UNICEF SD Procurement Overview](#); 2) Stakeholder interviews. January – July 2023; 3) WFP. 2022. [WFP Procurement Update](#).

The Child Nutrition Fund (CNF), led by UNICEF, is a new financing mechanism aiming to scale-up allocation of donor and domestic government resources for programs and commodities to prevent, detect, and treat child wasting.



Informally rolled out in 2020, officially launched in November 2023



Aims to mobilize \$3.4B<sup>1</sup> to accelerate the scale-up of sustainable funding, programs and supplies to end child wasting



Develops investment propositions and mobilizes global resources for the prevention, detection and treatment of wasting

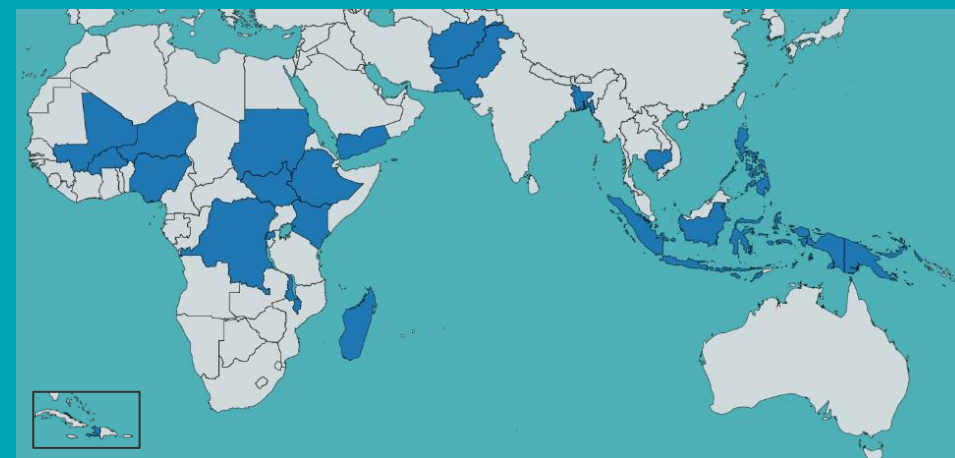


Provides a 1:1 match to governments' investments in RUTF and other nutrition commodities, as well as essential services for wasting management



Offers a range of financing tools such as advance payments and capital for capacity expansions to RUTF and LNS suppliers to support commodity delivery

Designed to support government-led efforts in 23 focus countries with highest numbers of child wasting that have developed operational roadmaps through the UN Global Action Plan on Wasting:



\*Includes Bangladesh, Ethiopia, Nigeria, Pakistan



Notes: 1) The Child Nutrition Fund. Retrieved December 2023. [Child Nutrition Fund: Our ambition](#). 2) UNICEF. November 2023. [The Child Nutrition Fund](#).

The CNF Match Window has demonstrated early success in mobilizing funding for child wasting commodities; increased outreach and advocacy can lead to even greater utilization across countries.

**WHAT IT IS:** Match Window allows countries to access a 1:1 funding match for RUTF and non-RUTF commodity procurement, complemented with additional match funding for programmatic support to deliver and utilize commodities.



**ACHIEVEMENTS:**

**RUTF Envelope**

- **Over \$17M in domestic and donor resources** has been raised for RUTF procurement through matching.<sup>1</sup>
- **Match funding disbursed across 10 countries**, including Ethiopia, Nigeria (1 state), and Pakistan (1 province) of our focus geographies.<sup>1,2</sup>

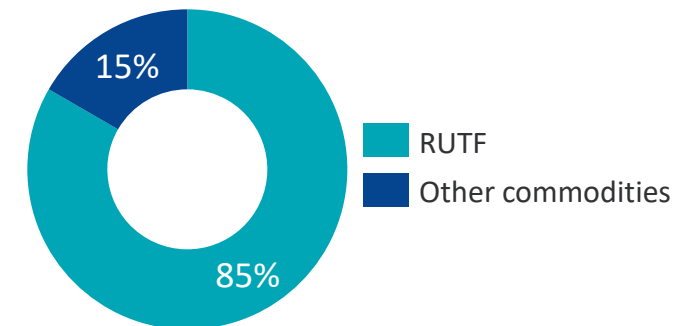
**Non-RUTF Envelope**

- In Pakistan, Punjab province has shown **interest in match funding for MMS**. This is the first and only non-RUTF request the CNF has received.
- **No matched funds** for SQ-LNS or BEP to-date.

**Opportunities for improvement**

1. **Increased country-level outreach** to make more countries aware of the CNF, particularly in decentralized systems such as NG & PK where funding is allocated sub-nationally.
2. **Advocacy and add'l incentives to generate demand for non-RUTF matching** (e.g. co-financing a greater share of the non-RUTF commodity cost).

**Total Match Window Commodity Funding<sup>1</sup>**



Notes: 1) The Child Nutrition Fund. Retrieved December 2023. [Match Window](#); 2) Stakeholder interviews with CNF and UNICEF. December 2022 – November 2023.



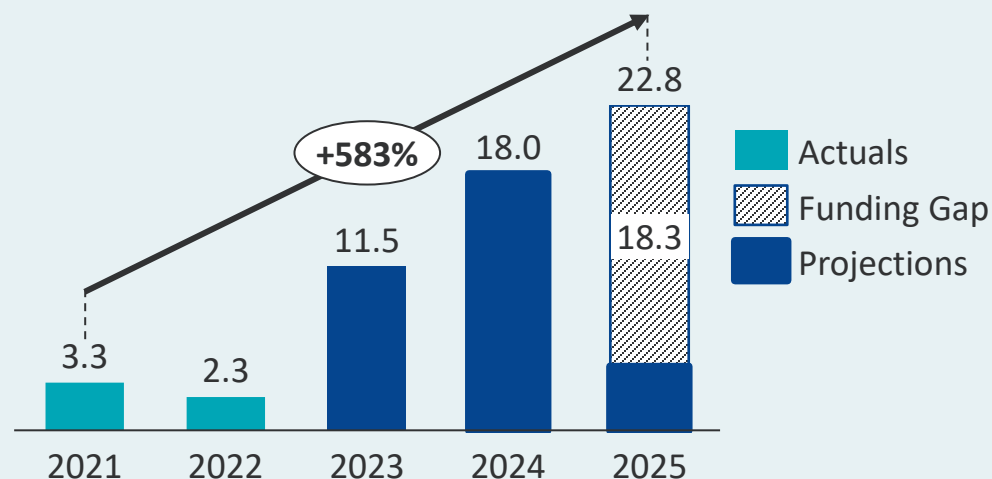
Additionally, the Match Window is successfully incentivizing domestic resource allocation with country interest only expected to grow in coming years; thus, the CNF needs to quickly adapt to keep pace.

The Match Window has achieved significant momentum and proven successful at incentivizing domestic funding for RUTF.

- The Window has catalyzed **repeat matches** from Uganda, Cambodia and Mauritania — with Mauritania nearly doubling its initial 2021 contribution to cover 100% of the RUTF need in 2023.<sup>1</sup>
- The Ethiopia government mobilized domestic resources (\$1.3 million) for the **first time** in 2023 after years of 100% reliance on donor funding.

However, with the growing interest in matching funds, projections outpace the available funding.

The available funding will be exhausted by 2025. The Match Window will need an **additional \$18.3 million** to meet current projections.<sup>1</sup>



Match Window Disbursements and Projections, in millions USD<sup>1</sup>

### Opportunities for Improvement

1. The CNF should enact a **longer-term vision to encourage continued funding** from governments, rather than one-off disbursements. For example, while the Ethiopia match is a step in the right direction, it is a singular investment that covers only 5% of the RUTF budget for 2023 in a context with consistently high unmet need.<sup>2</sup>
2. The CNF needs **transparent monitoring and evaluation metrics** showing how funding is spent and commodities are absorbed by country systems; this could encourage greater donor commitment to match funds.

Notes: 1) The Child Nutrition Fund. Retrieved December 2023. [Match Window](#). Analysis based on reported actuals and projections for RUTF; 2) Analysis based on UNICEF Ethiopia Service Data.

# Supply





1

Health of existing supply base

2

Risk and attractiveness of market

3

Market risk mitigation / support available

## Treatment Products (RUTF)

**The large, diverse RUTF supply base reflects the significant longer-term efforts that have gone into expanding global supply capacity:** The RUTF market has a relatively large and diverse supply base, with a mix of global, regional and local suppliers, and was able to meet the required supply capacity for the 2022 RUTF funding surge.

**Suppliers experience the RUTF market as risky and not generally for the faint of heart or profit-motivated:** RUTF suppliers face a variety of risks, including increasing costs of raw materials and unstable demand, that exacerbate the riskiness of their investments. RUTF is also not a high-margin product, constraining the business models that can viably produce RUTF year after year.

**Technical and financial assistance to some suppliers has been a lifeline—necessary to start up and/or stay in the market:** External financial and technical support can play a substantive role in alleviating many of the risks faced by RUTF suppliers and is sometimes the only way they can stay in the market. The CNF Supplier Financing Facility, and its Advanced Payment Mechanism (APM) in particular, has been successfully leveraged by some suppliers to address key challenges. However, the Supplier Financing Facility is not a panacea, and further tailoring of the APM to meet other manufacturer needs may help further offset risk.

## Prevention Products (SQ-LNS, LNS-PLW)

**Suppliers capable of producing prevention products have increased, but prevention supply capacity is typically only estimated in conjunction with RUTF capacity.** The supply base and capacity for prevention products is not well-understood in aggregate, in part due to limited disaggregation of data between prevention and treatment capacity. There has been a recent increase in the number of suppliers capable of producing SQ-LNS and BEP/LNS-PLW.

**Suppliers are not seeing strong market signals to manufacture prevention products:** There are significant disincentives to actually committing to the production of prevention products, including even tighter profit margins than for RUTF and even poorer demand signaling than for RUTF. Anecdotally, some suppliers are moving forward with plans for the production of prevention products, but it's unclear whether their investments will pay off given low levels of estimated and funded demand.

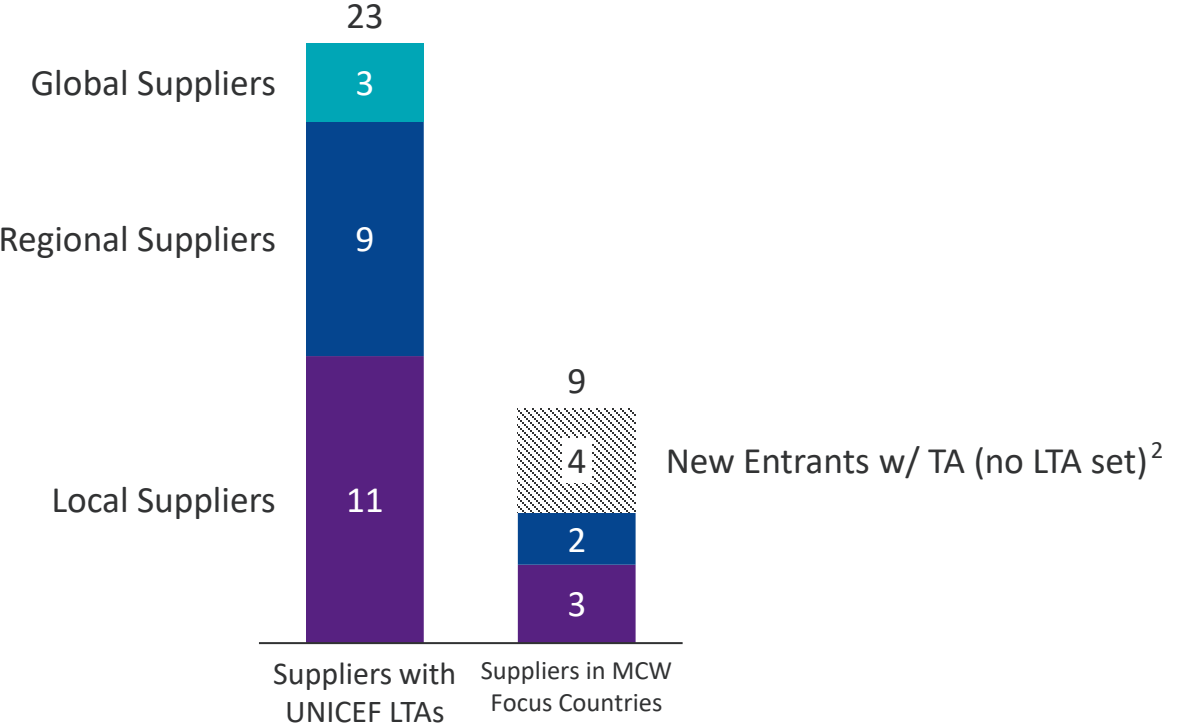
**Broader market incentives to produce prevention products on a large scale are lacking,** but coordinated technical and/or financial assistance could certainly support increased production of prevention products.





RUTF has a diverse supply base with sufficient supply capacity to meet global funded demand.

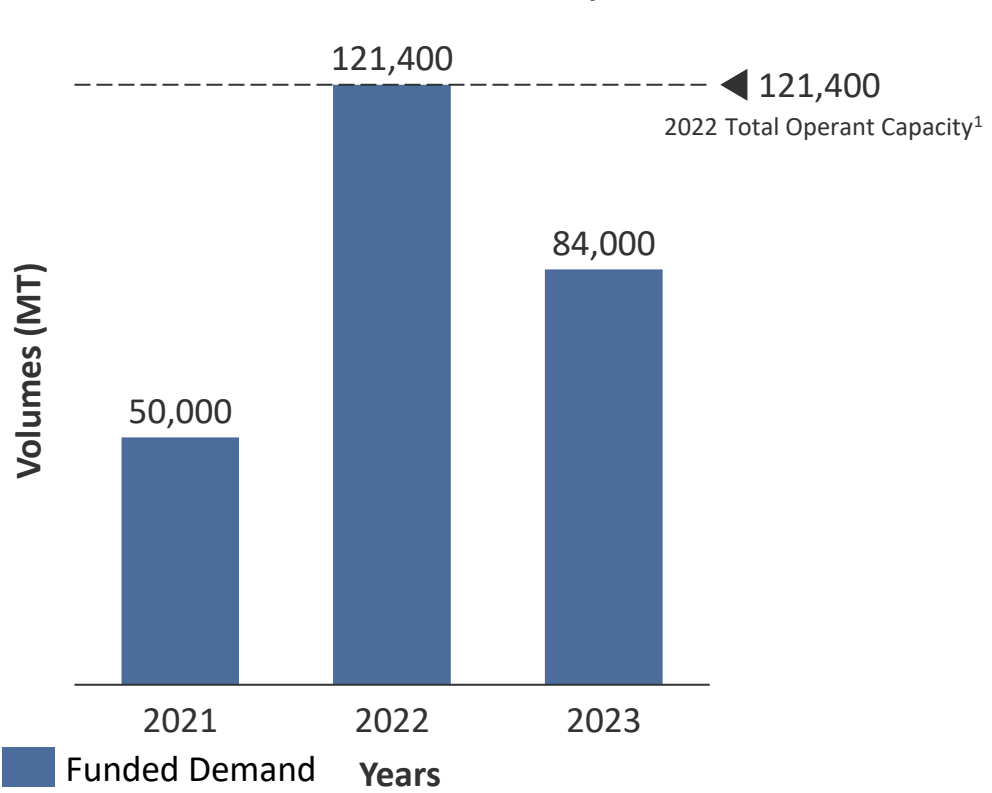
**RUTF Manufacturers for UNICEF, 2023<sup>1</sup>**



Supplier Classification Key	
<b>Global</b>	suppliers based in HICs
<b>Regional</b>	suppliers based in LMICs that aren't UNICEF programmatic countries, or are primarily an exporter
<b>Local</b>	suppliers based in LMICs that are UNICEF programmatic countries and don't primarily export



**Global RUTF Funded Demand, 2021-2023<sup>1,3</sup>**



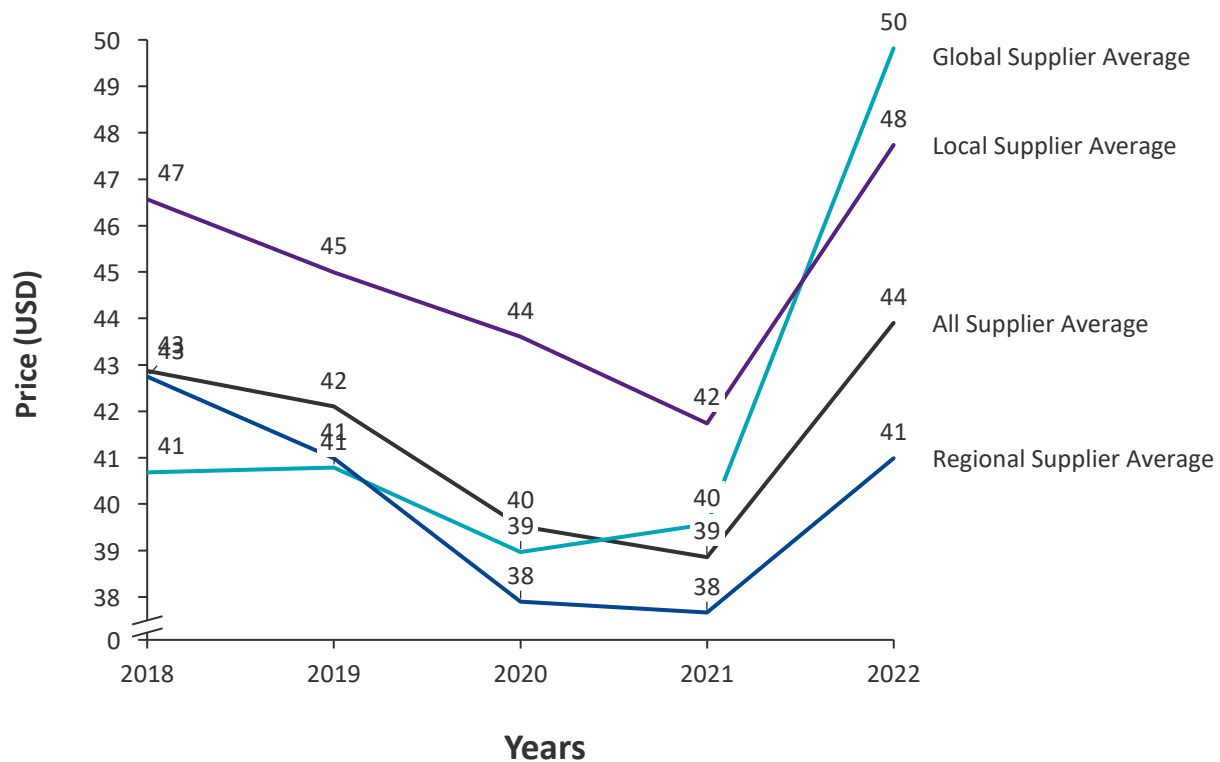
Global funded demand surged massively in 2022, and global supply capacity was able to keep pace and ensure sufficient RUTF available. **However, funded demand and supply capacity, even at its highest levels in 2022, fell short; funded demand only accounted for approximately 64% of unmet need.**<sup>3,4</sup>

Notes: 1) UNICEF. 2023 Market Outlook; 2) Supplier Interviews. 2022-2023; 3) UNICEF Supplier Convening. November 2023. Copenhagen, Denmark; 4) Specific citation can be found on slide 47.



Following a steady decrease in RUTF pricing until 2021, increases in raw materials prices are driving current increases in RUTF prices.

### UNICEF Supply Division Price by Supplier Type<sup>1</sup>



### RUTF Pricing Trends

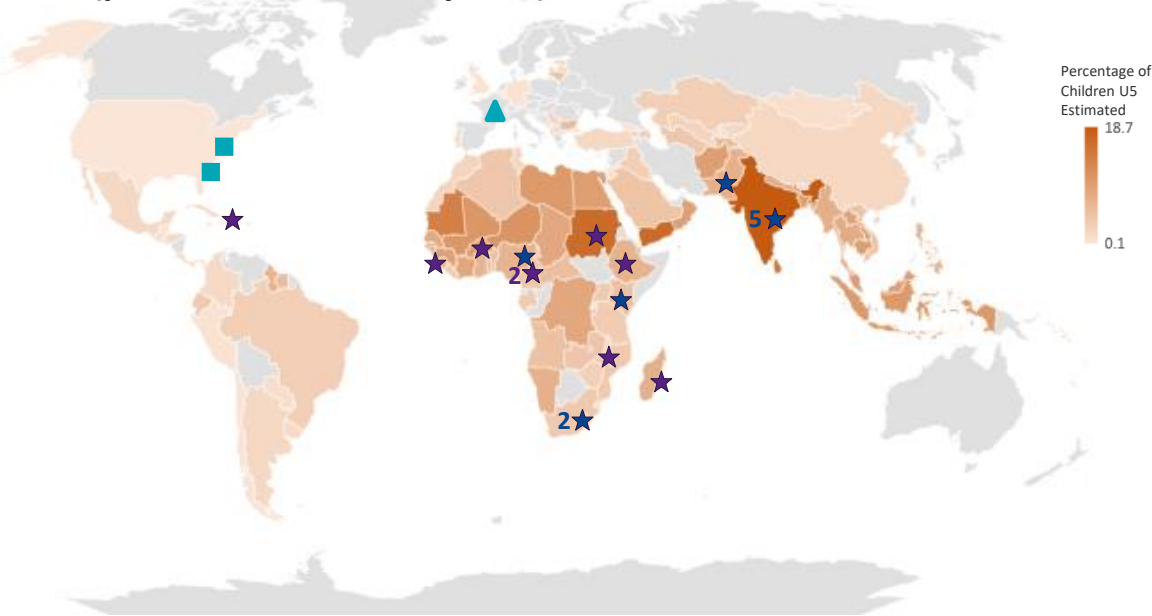
- Until 2022, RUTF price has been steadily decreasing per UNICEF LTAs for global, regional and local manufacturers. **From 2018 to 2021, average price decreased by approximately 9%.<sup>1</sup>**
- In the 2023 Market Outlook, UNICEF cited **competition driving prices down** as well as local and regional manufacturers beginning to achieve economies of scale.<sup>2</sup>
- As of 2022, **prices have started to increase significantly across all regions** – this is driven by increasing raw materials costs, due to both the Ukraine crisis and changing ingredient requirements, including high oleic peanuts.<sup>3</sup>
- UNICEF noted that their ingredient price modeling indicates that **price will likely continue to increase** over the next few years.<sup>2</sup>



Notes: 1) UNICEF. 2023. [RUTF Pricing Data](#); 2) UNICEF. 2023. [RUTF Market Outlook](#); 3) Supplier Stakeholder Conversations, 2022-2023.

# The RUTF supply base for UNICEF is geographically segmented\*, which has both positive and negative implications for the market.

**Percent of Children U5 Suffering from Wasting (per most recent survey data)<sup>1</sup>**



**\*Geographic segmentation** occurs when suppliers divide their market based on location.<sup>2</sup> Although all suppliers can fulfill global RUTF orders, there is active segmentation by procurers who prioritize manufacturers for geographic reasons.

Key <sup>3</sup>	Supplier Type
▲	Non-prioritized global supplier
■	USAID Title II prioritized global supplier
★	UNICEF prioritized regional supplier
★	UNICEF prioritized local supplier

## Pros of Geographic Segmentation

- Geographic segmentation fosters a diverse supply base, and therefore diffused supplier risk– e.g., when DABS closed for several years, or the Samil factory burned down, global supply capacity was not impacted.<sup>3</sup>
- Regional and local supply capacity has become easier to access as supply capacity has developed over the past two decades.<sup>4</sup>
- Local manufacturing is desirable to governments who have expressed an interest in only procuring locally.<sup>3</sup>

## Cons of Geographic Segmentation

- Low-margin businesses need high volumes to succeed<sup>5</sup> but with 23 suppliers, volumes are distributed, limiting market attractiveness.
- Geographic supplier segmentation is strategic if there is a single purchaser and if other criteria, such as price and quality, are considered as well.<sup>2</sup>



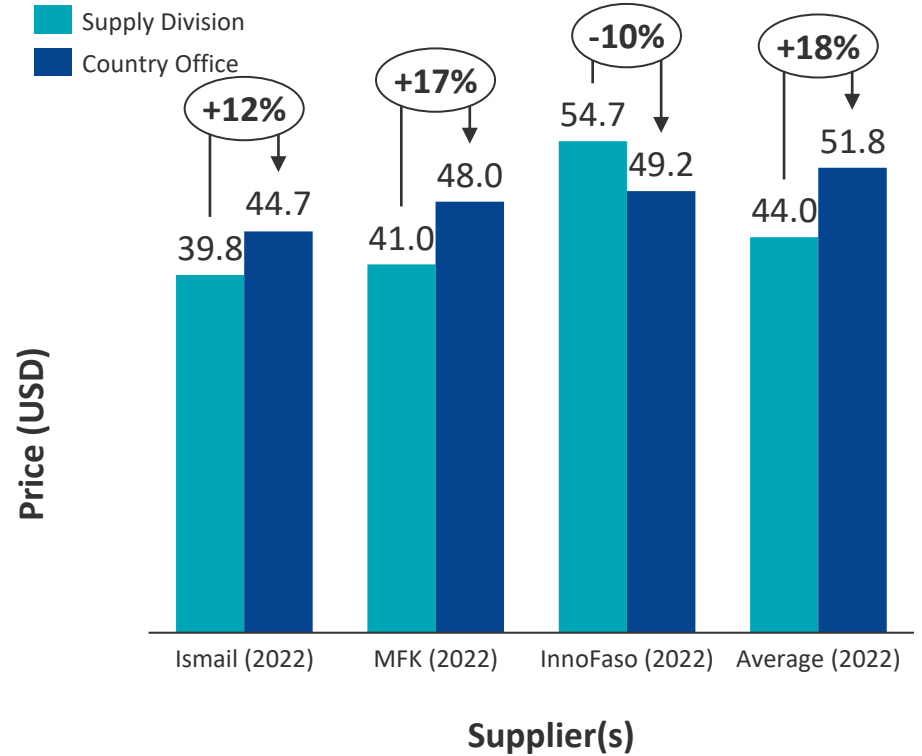
Notes: 1) UNICEF/WHO.WB. 2023. [Joint Child Malnutrition Estimates](#); 2) Rezaei and Ortt. 2012. A Multi-variable Approach to Supplier Segmentation. International Journal of Production Research; 3) Supplier Stakeholder Conversations, 2022-2023; 4) UNICEF. 2023. [RUTF Market Outlook](#); 5) Smith. 2006. Leveraging profitability in low-margin markets. Journal of Product and Brand Management.

The geographic segmentation of the supply base has not created market efficiencies because UNICEF's purchasing is fragmented and doesn't consolidate RUTF volumes, leading to market inefficiencies.

Supplier	2022 SD LTA <sup>1</sup>	2022 CO LTA <sup>1</sup>
Ariel Foods	X	✓
DABS	X	✓
Hilina	X	✓
Ismail	✓	✓
NutriK	X	✓

In programmatic countries where UNICEF procures, the procurement goes through UNICEF Country Office (CO) instead of UNICEF Supply Division (SD). Different suppliers have LTAs with Country Offices or the Supply Division separately. Some suppliers, such as global and regional suppliers, only have LTAs with Supply Division. Local manufacturers have a more mixed set of LTAs, dependent on specific supplier and country dynamics.<sup>2</sup>

RUTF Weighted Average Price for UNICEF Supply Division vs. Country Office<sup>1</sup>

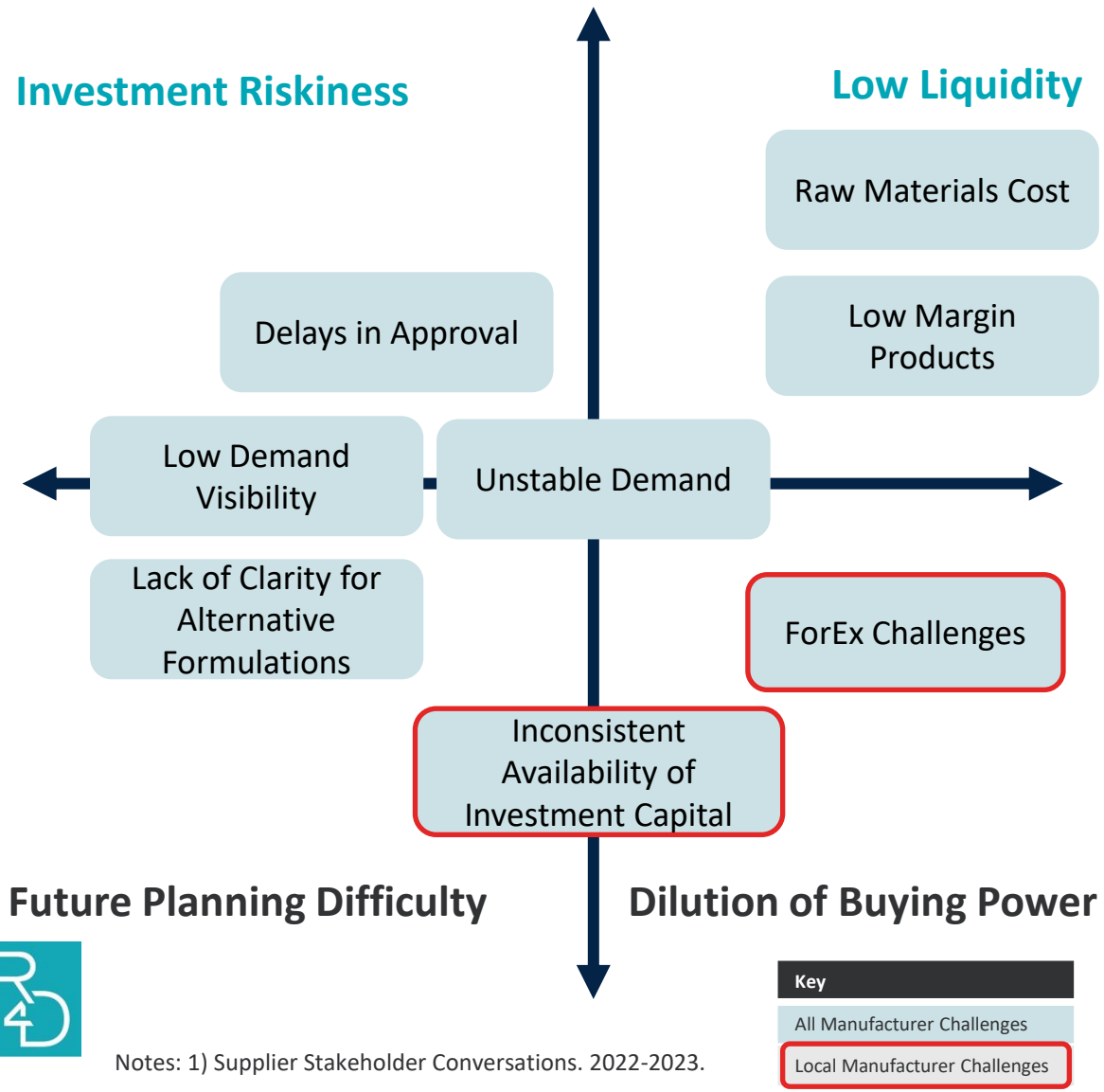


Overall, Country Office procurement price is significantly higher than Supply Division price on average ~\$7.8 USD/18% higher. However, this price differential is not consistent across suppliers, as evident from InnoFaso's SD vs CO 2022 price.



Notes: 1) UNICEF. 2023. [RUTF Pricing Data](#); 2) Supplier Stakeholder Conversations, 2022-2023.

Beyond supplier segmentation, there are many risks facing RUTF suppliers, with a variety of impacts on business viability.



**Impact of Supplier Challenges on Business Viability<sup>1</sup>**

Four different types of impacts on business viability were identified from supplier-described manufacturing challenges; two of them, investment riskiness and low liquidity, were flagged as particular challenges for for-profit supplier models.

Examples Include:

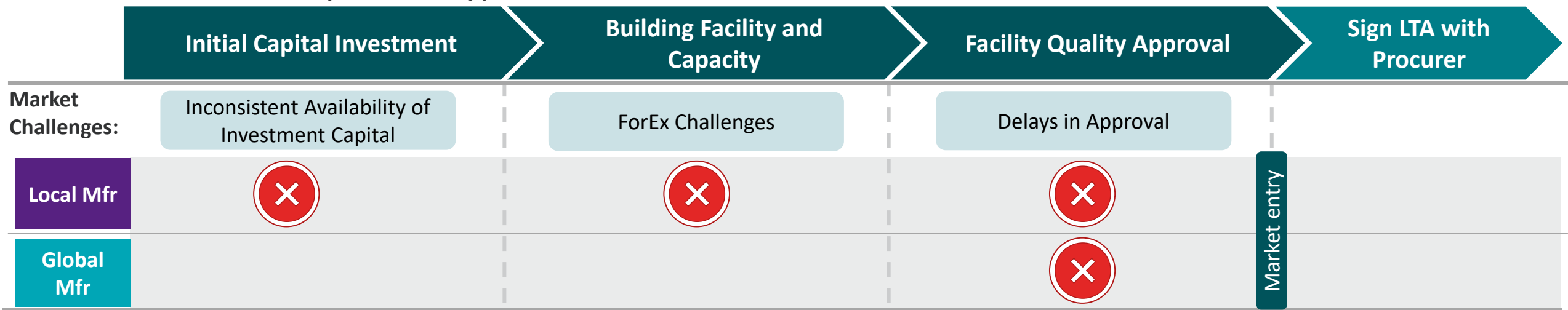
- **Unstable Demand:** causes all four impacts on business viability as it is a central manufacturer challenge (i.e., causes investment riskiness as seen by suppliers investing during the 2022 surge and seeing that demand disappear; causes low liquidity as suppliers have cited inconsistent demand in playing a role in their low cash on hand).
- **ForEx Challenges:** Due to currency fluctuations, some local manufacturers have identified that their buying power is diluted, particularly when it comes to importing.
- **Raw Materials Cost:** Several manufacturers have cited that raw material costs are leaving manufacturers cash-strapped when fulfilling orders, in turn making cost-saving measures such as hedging on ingredients not possible.



Notes: 1) Supplier Stakeholder Conversations. 2022-2023.



New suppliers, especially local manufacturers, often need technical and/or financial assistance to help them get started ...


**Process to stand-up an RUTF supplier:**




**Interventions:**


**Types of Assistance:**

-  Financial
-  Technical

Donors have supported the standup of suppliers, both through financial support and providing technical support for suppliers to build capacity and quality – e.g., CIFF supporting MANA, USAID supporting Emzor Foods. 

Wealthy investors or conglomerates can provide capital with relative ease. 

The Plumpyfield Network provides technical knowledge to help suppliers meet quality standards for key global procurers. 

 = Challenge for this mfr

**Examples of Interventions**

- Donor support
- Plumpyfield
- Wealthy Investor/ Conglomerate



Notes: 1) Supplier and Procurer Stakeholder Conversations, 2022-2023.



...and once established, suppliers still benefit from technical and financial assistance to help mitigate challenges to RUTF manufacturing.


**RUTF Manufacturing Flow:**




Market Challenges:	Delays in Approval	ForEx Challenges	Raw Materials Cost	Low Demand Visibility	Unstable Demand	Low Margin Products
Local Mfr	✗	✗	✗	✗	✗	✗
Global Mfr	✗		✗	✗	✗	✗


**Interventions:**


- Types of Assistance:**
-  Financial
  -  Technical

Sometimes donor support is specifically for the purpose of differentiating the supply base, and if the donor is a procurer, can also ensure an LTA. 

The Plumpyfield Network supports ingredient purchasing for local and regional manufacturers that experience forex challenges. 

Conglomerates can leverage other business lines to circumvent forex and ingredient challenges. 

Donors are addressing raw material costs, such as USAID working with Emzor Foods on peanut processing. 

The CNF Supplier Financing Facility provides advance payments to suppliers as a mechanism to help them overcome payment wait times when suppliers often have low liquidity. 

✗ = Challenge for this mfr

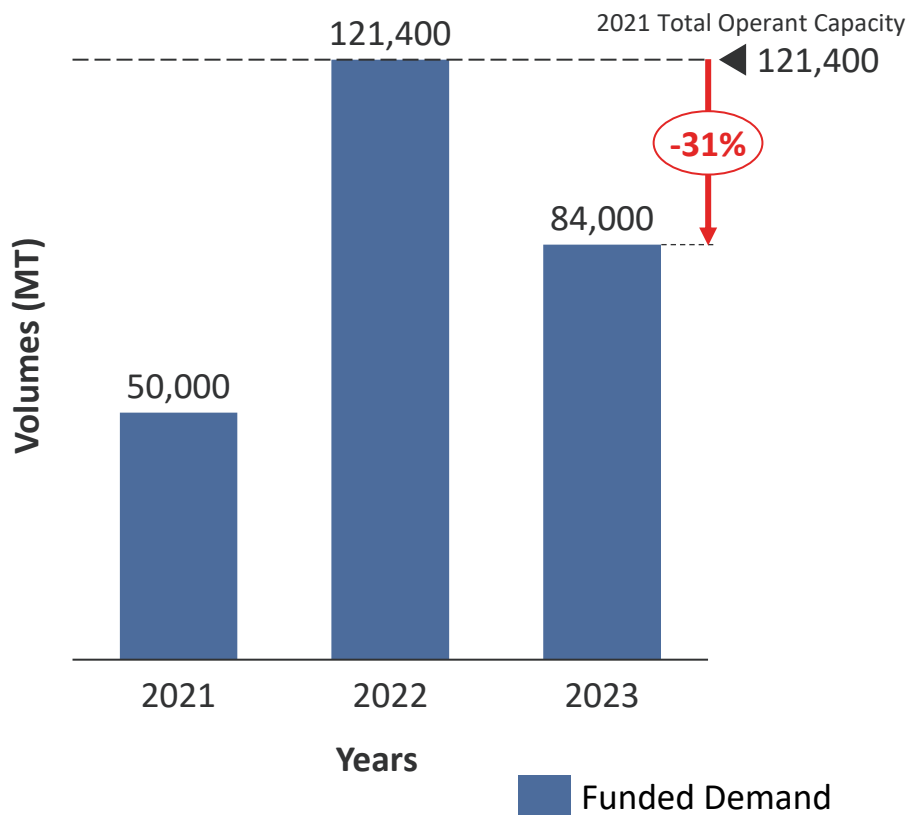
- Examples of Interventions**
- Donor support
  - Plumpyfield
  - Wealthy Investor/ Conglomerate



Notes: 1) Supplier Stakeholder Conversations, 2022-2023.

Ultimately, while the supply base can expand to meet funded demand increases, significant shocks to funded demand are difficult for suppliers to absorb.

Global RUTF Funded Demand, 2021-2023<sup>1,2</sup>



**The Negative Impact of System Shocks**

- RUTF manufacturers are often in precarious or at least unstable positioning due to the previously mentioned industry-specific challenges. A drop of more than 30% in demand for RUTF has serious implications for supplier health and stability.<sup>1,2</sup>
- Several suppliers have identified that while they were able to meet the capacity surge, **they are now experiencing challenges in maintaining their current level of operational capacity, which may lead to layoffs.**<sup>3</sup>
- Furthermore, fewer suppliers are expected to achieve economies of scale in the future due to significantly lower demand, which puts more suppliers at risk of going out of business as RUTF is a low-margin product.<sup>3</sup>
- Several suppliers indicated challenges in securing more orders as of Q4 2023, due to low liquidity.<sup>3</sup>



Notes: 1) UNICEF. 2023. [2023 Market Outlook](#); 2) UNICEF Supplier Convening. November 2023. Copenhagen, Denmark; 3) Supplier Interviews. 2023;





**Spotlight opportunity:** The CNF Supplier Financing Facility has been successfully leveraged early on by suppliers to address key challenges, such as unstable demand and tight profit margins, although more awareness of the mechanism is needed.



The Supplier Financing Facility has been effective in addressing some supplier liquidity challenges...

- The Supplier Financing Facility mainly consists of an Advanced Payment Mechanism (APM), which ensures suppliers can access cash to complete RUTF orders. This is important because many RUTF suppliers have low liquidity, and payment schedules for RUTF can make it difficult for suppliers to purchase ingredients.
- Several suppliers - global, regional and local - identified the APM as particularly useful to help them meet orders during the 2022/2023 RUTF funding surge.<sup>1</sup>

...but awareness is low and the APM does not help suppliers address longer-term cash flow challenges.

- Several suppliers in our focus geographies were not being familiar with the financing facility, which may reflect the recency of the official CNF rollout...but also indicates further work in raising awareness could be beneficial.
- Other suppliers, who were familiar with the mechanism, indicated that the APM was not at a rate or timeline that is significant enough to be beneficial for them, and it may be beneficial to refine current offerings based on supplier feedbacks to improve the mechanism's effectiveness.<sup>2</sup>

Based on supplier-identified challenges, there are different types of interventions that could help bolster supplier sustainability.

Identified Challenges<sup>1</sup>



Unstable Demand is a high priority challenge due to the low-margin nature of RUTF.



Current efforts to improve supplier financing opportunities are not context-specific to the unique challenges facing local manufacturers.



Ingredient prices will continue to increase over the next few years, driving up the price of RUTF and LNS products, no matter the supplier.

Potential Solutions



Solutions such as volume guarantees can improve supplier stability.



Tailoring the APM of the Supplier Financing Facility to more accurately reflect local manufacturer needs, such as payment schedules that reflect supplier capability or context-specific interest rates, would be beneficial.



Supporting suppliers in efforts to either hedge their ingredient purchasing or build sustainable local ingredient sourcing could help manage raw material price risk.

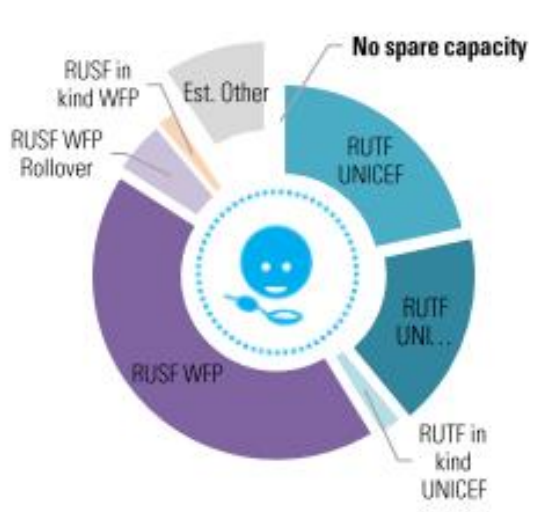
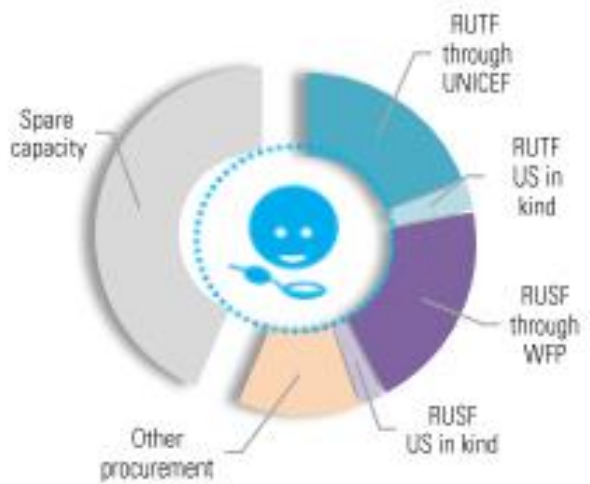


Notes: 1) Supplier Stakeholder Conversations, 2022-2023.

Moving to the more nascent prevention markets, there is not a consistent global understanding of available prevention supply capacity due in part to a lack of prioritization by procurers.

2020 UNICEF LNS Capacity Assessment<sup>1</sup>

2023 UNICEF LNS Capacity Assessment<sup>2</sup>



Prevention products, such as SQ-LNS and BEP/LNS-PLW, were included in the “Other Procurement” category of UNICEF’s RUTF Market Outlooks, which could include other RUTF or RUSF procurement, as recently as 2021 and 2023.

SQ-LNS and LNS-PLW Market Assessment

**The nascent nature of the prevention products market, and its de-prioritization relative to treatment products, has meant that global reporting and assessment for prevention products lacks detail.**

- Suppliers have identified that these products are manufactured on the same product lines as RUTF/RUSF (with some changes depending on product size and formulation), so previous UNICEF assessments have reported on the global lipid product capacity.<sup>3</sup>
- Since most of the production capacity is utilized by RUTF and RUSF, and given the recent demand surge for treatment products, prevention products have not been a focus of market analysis and discussion in the past few years.
- However, in the 2023 Market Outlook, UNICEF did note that during the 2022 funded surge, SQ-LNS capacity was cannibalized to meet the RUTF demand.<sup>2</sup>

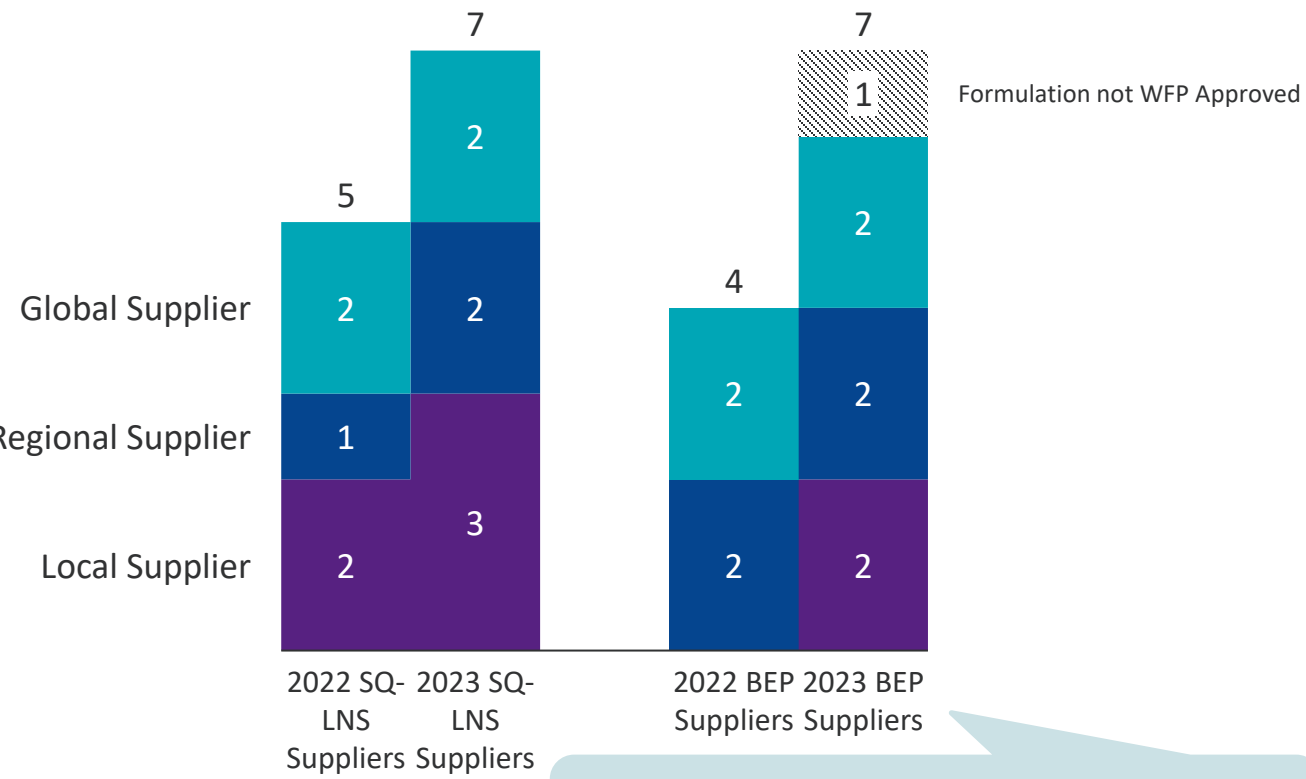


Notes: 1) UNICEF. 2021. [2021 Market Outlook](#); 2) UNICEF. 2023. [2023 Market Outlook](#); 3) Supplier Stakeholder Conversations, 2022-2023.



Fortunately, the number of RUTF suppliers that can supply prevention products has increased substantially in the past year due to signaled interest and relative ease in shifting production lines.

Number of Manufacturers for SQ- LNS and BEP/LNS-PLW, 2023<sup>1,2</sup>



As of 2023, WFP has only ever procured from 2 LNS-PLW suppliers<sup>3</sup>

**SQ-LNS and BEP/LNS-PLW Supplier Trends<sup>1,3</sup>**

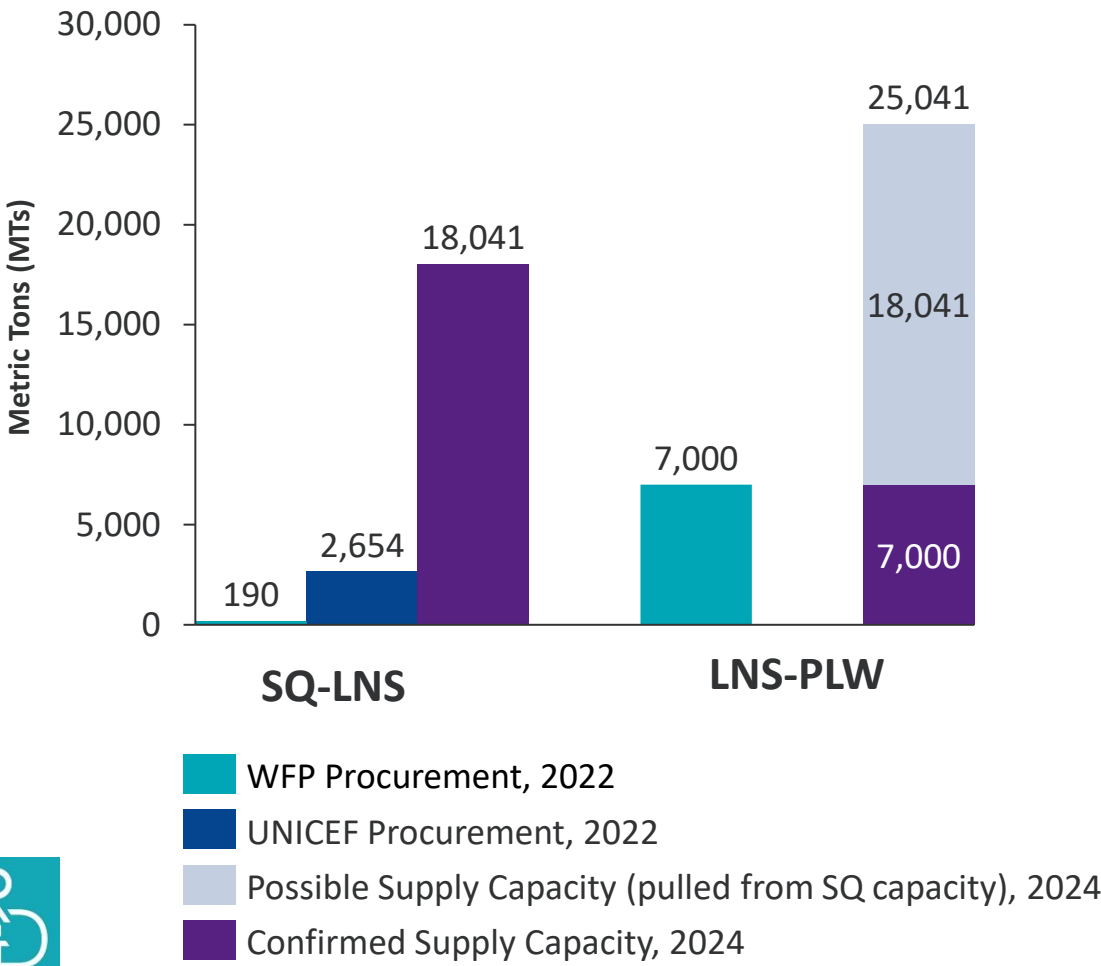
- While there has been an **increase in the number of suppliers capable of producing prevention products** in the past year (from 5 to 7 for SQ-LNS and from 4 to 6 for BEP), there is still **significant uncertainty in the market** which explains the low list of suppliers when compared to more mature markets such as RUTF.
- For BEP, which has even less demand, **WFP only procures from 2 suppliers** and most other manufacturers with BEP products in their portfolio are Plumpyfield members.
- Suppliers have indicated several disincentives to producing of prevention products, including the cost to produce SQ-LNS and BEP (given the fewer grams per sachet requiring the same production lines) and the resulting **tighter profit margins**, compared to RUTF.
- Some suppliers are dedicating more capacity to prevention products moving forward, assuming an increase in demand in 2024.



Notes: 1) Supplier Stakeholder Conversations. 2022-2023. 2) Based on review of supplier sites, including: Nutriset, Edesia, GC Reiber, Nuflower, STA Nigeria, NutriK, InnoFaso, Ismail, MFK, Nutrivita, and MANA; 3) WFP. 2023. [Awarded for Food Tenders](#).

But current demand for SQ-LNS and LNS-PLW remains far below expected capacity, and suppliers must be met with clarified, coordinated demand to support this nascent market.

2022 Funded Demand for Prevention Products vs 2024 Expected Supply Capacity<sup>1,2</sup>



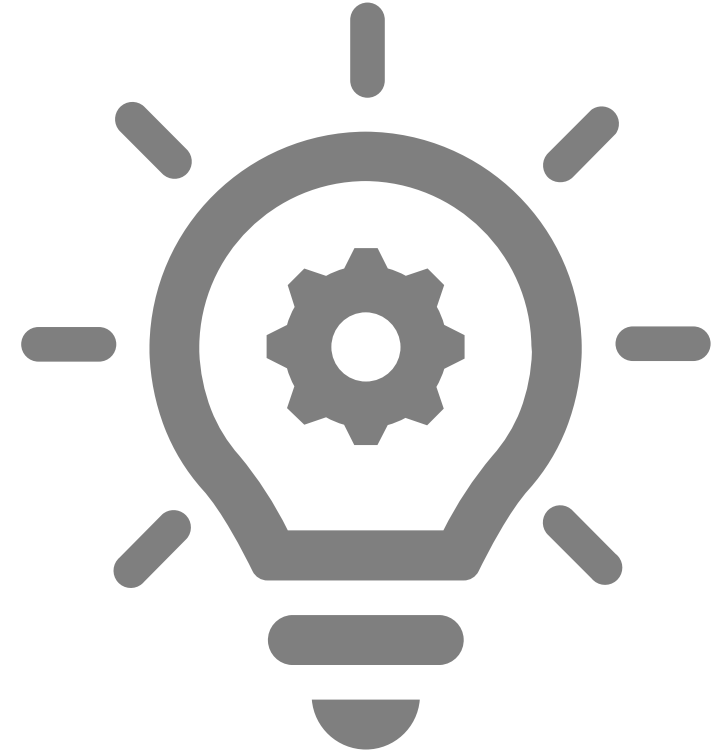
Global SQ-LNS/LNS-PLW Demand vs Supply Capacity<sup>3</sup>

- Several suppliers have indicated that they are heavily investing in prevention product supply capacity for 2024, based on signaled interest from procurers but not yet funded demand.
- One global supplier is building a new facility dedicated entirely to prevention product production, primarily SQ-LNS but with the capacity to expand their LNS-PLW production as well, upon approval of their formulation by key procurers.
- Plumpyfield suppliers have also built their prevention capacity – they have indicated that by 2024 they expect the entire network to have the **capacity to produce 15,000 metric tons of SQ-LNS per year.**
- Comparing 2022 procurement volumes to expected capacity from these suppliers indicates that **unless funded demand significantly increases, suppliers will have set aside capacity for these products that will not be used.**
- Several suppliers have flagged concerns about entering the market due to the even lower margins for prevention product production, and a demand-supply misalignment in **2024 could further dissuade suppliers from production of prevention products.**



Notes: 1) UNICEF Supplier Convening, November 2023, Copenhagen, Denmark; 2) SQ-LNS UNICEF data estimated from graphs shared at the Copenhagen Supplier Convening; 3) Supplier Stakeholder Conversations, 2022-2023.

# MD-RUTF Learnings





1

Many potential benefits/ upsides

2

Relevance of current RUTF/LNS product market

3

Need for market shaping actions during R&D phase

4

Need for near-term RUTF/LNS market-shaping

**MD-RUTF could address several of the challenges highlighted in the diagnostic among the current portfolio of child wasting products.** This includes supply- and demand-side advantages (e.g. reducing costs, simplified case management, reducing SAM relapse).

**Market shaping steps to successfully introduce and scale MD-RUTF are known.**

Lessons learned from current child wasting products should be leveraged to improve MD-RUTF's market introduction and scale-up given (expected) comparable market dynamics. A global-level initiative (similar to RUTF's introduction) appears the most ideal future state for MD-RUTF introduction and scale-up.

**Actions should be taken during MD-RUTF's R&D phase to shape critical market dimensions for its future introduction.**

This includes in the near-term addressing key regulatory, demand, and supply market conditions to build the evidence-base for MD-RUTF's benefits and engage with key stakeholders (e.g., manufacturers, WHO, UNICEF, etc.) in its value chain on its benefits.

**Near-term market shaping investments for RUTF and LNS commodities are a win-win for MD-RUTF and existing products.**

While MD-RUTF is in its R&D phase, continuing to shape the market for existing products will both benefit the current market landscape for child wasting products, as well as bolster the introduction and scale of MD-RUTF if/when introduced.





## NEAR TERM NEEDS

- ❖ Continued investments in market shaping for the current RUTF and LNS markets
- ❖ Strong evidence of MD-RUTF efficacy, coupled with strong engagement with key stakeholders in wasting commodity regulation and procurement
- ❖ Early engagement with manufacturers on feasibility of large-scale production
- ❖ Market assessments of potential ingredients

## LONGER TERM NEEDS

- ❖ (Assuming strong evidence) plans made for product introduction and scale
- ❖ Market shaping TA to support product introduction and scale, and anticipate gaps observed with other child wasting commodities







As an R&D product in the child wasting space, MD-RUTF is expected to address limitations in the current portfolio of child wasting products.

## Expected MD-RUTF's advantages relative to existing child wasting products<sup>1, 2</sup>

### Supply-side

#### Reduces manufacturing cost and end-price

Dairy protein is the largest driver of RUTF costs; MD-RUTF's **reduced dairy protein content should decrease overall production costs.**

#### Greater flexibility for local ingredients

Use of locally available ingredients (chickpeas, lentils and rice) and other protein sources (soybeans) has the potential to **improve sourcing and increase local acceptability.**

### Demand-side

#### Simplifies SAM/MAM management

Can **replace both RUSF and RUTF** for treatment of uncomplicated MAM and SAM.

#### Reduces SAM relapse

MD-RUTF can be **given to children treated for complicated SAM to reduce post-treatment relapse**, which affects up to 37% of children treated for SAM.<sup>3</sup>





Lessons learned from current child wasting products should be leveraged to improve MD-RUTF's market introduction and scale-up given (expected) comparable market dynamics.

### Similar market dynamics between MD-RUTF and child wasting products:





## For successful product introduction a viable future market, immediate interventions in the current R&D phase will shape critical market dimensions.

R&D (next 2-5? years)

	Barriers	Proposed immediate interventions
Regulatory	<ul style="list-style-type: none"> <li>• <b>Evidence required</b> for WHO regulatory changes is dependent on pending efficacy trials</li> <li>• No precedent for a product that replaces both RUSF and RUTF for MAM and SAM treatment; would <b>require WFP and UNICEF buy-in to a single unified treatment protocol</b></li> </ul>	<ul style="list-style-type: none"> <li>✓ <b>Compelling evidence</b> from the results of pending efficacy trials, to support incorporation into WHO guidelines</li> <li>✓ <b>Strong and ongoing advocacy, partnership and meaningful engagement</b> with UNICEF and WFP to address any concerns with the switch to a single unified treatment protocol</li> </ul>
Demand	<ul style="list-style-type: none"> <li>• MD-RUTF currently <b>perceived as “hypothetical”</b> possibility with <b>no clear evidence as to benefits for child wasting</b> prevention and treatment</li> </ul>	<ul style="list-style-type: none"> <li>✓ <b>Communicate R&amp;D progress and emerging findings</b> – particularly among global, regional, and country nutrition stakeholders</li> </ul>
Supply <sup>1</sup>	<ul style="list-style-type: none"> <li>• <b>Concerns about ingredient viability, accessibility and quality</b> <ul style="list-style-type: none"> <li>• E.g., banana powder does not exist widely now and cannot be purchased in bulk, and high moisture food is risky for food safety</li> <li>• E.g., concerns about the starch content and digestibility of lentils and chickpeas</li> </ul> </li> <li>• <b>Unclear cost-effectiveness for manufacturers</b> due to lack of evidence on MD-RUTF manufacturing costs (raw materials, transformation costs, packing, registration, acceptability studies, etc.).</li> </ul>	<ul style="list-style-type: none"> <li>✓ <b>Include manufacturers early in formulation specifications</b> to ensure production-side and pricing factors are considered, particularly to validate cost-reduction and feasibility assumptions</li> <li>✓ Undertake <b>market assessments on the viability, accessibility and acceptability of potential ingredients</b> (e.g., banana powder, other ingredients suggested for SSA)</li> </ul>







Notes: 1) Stakeholder interviews with suppliers. February - November 2023.



Then, we envision market shaping TA across the 4 domains to address similar gaps seen with existing child wasting products.

### Market introduction & scale

Indicative list:

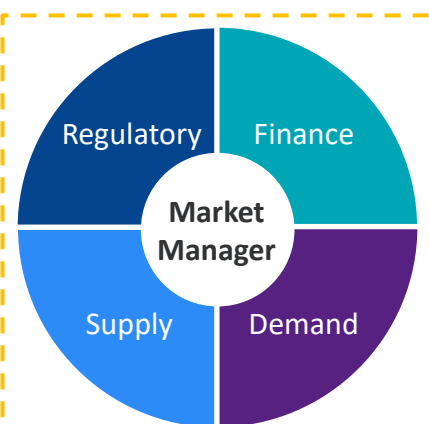
Regulatory 	Demand 	Finance 	Supply 
<ul style="list-style-type: none"> <li>✓ <b>Clear uniformed global guidance</b> detailing MD-RUTF's use-case and prioritization among other products required for child wasting treatment and prevention</li> <li>✓ <b>Specifications for its quality standards and formulations</b> to reduce supply-side fragmentation</li> <li>✓ <b>Country-level TA to align</b> the regulatory environment to global guidelines and recommendations</li> </ul>	<ul style="list-style-type: none"> <li>✓ <b>Catalytic donor-led quantification and procurement</b> in the short-term, with <b>roadmap for long-term country stewardship</b></li> <li>✓ <b>Clear demand signaling</b> with demand-based quantification to inform procurement and financing decision-making</li> <li>✓ <b>Country-level advocacy</b> and if needed, evidence generation.</li> <li>✓ <b>Country-level TWG</b> to increase awareness and demand</li> </ul>	<ul style="list-style-type: none"> <li>✓ <b>ROIs to encourage investment</b> in procurement</li> <li>✓ Donor-led financing, with <b>co-financing agreements</b> in-place to mobilize domestic resources</li> <li>✓ <b>TA to support country-level decision making around prioritizing funding</b> across child wasting products</li> </ul>	<ul style="list-style-type: none"> <li>✓ Invest in developing a robust supply-base by <b>removing some of the "risk" manufacturers will initially take on</b></li> <li>✓ <b>Continue engaging manufacturers early in formulation specifications</b> to ensure production-side and pricing factors are considered, particularly to validate cost-reduction and feasibility assumptions</li> </ul>



Finally, until MD-RUTF is introduced and scaled, continued efforts are needed to shape the market for existing child wasting products to (1) increase access to these essential products, and (2) prepare for MD-RUTF's future entry.

## RUTF market shaping

*Now, ongoing*



*Strategic opportunities*

**Holistic advocacy and market shaping TA to address barriers to scale-up:**

- **Regulatory:** engage with WHO and country regulatory bodies to further institutionalize RUTF in guidelines, and identify gaps that will be relevant to MD-RUTF
- **Financing:** support domestic resourcing for RUTF, which could be channeled toward MD-RUTF in the future
- **Supply:** support a healthy RUTF supplier base, with financial and technical support, that allows them to be more nimble with expansion to AFs and, in the future MD-RUTF
- **Demand:** improve quantification and demand signaling for RUTF (which will then translate to MD-RUTF)

## Opportunities

1

**Immediate:** market shaped for access to RUTF access for child wasting treatment

2

**Longer-term:** easier to build off the RUTF market and make a global “switch” to MD-RUTF in a way that allows MD-RUTF to leapfrog other similar commodities