Increasing access to RUTFs

Scoping solutions to address market barriers: final readout of recommendations

March 2022

RESULTS FOR DEVELOPMENT

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- **Summary of key findings and recommended actions by stakeholder**
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Project background and context setting

Acknowledgement

This work was conducted independently by a team at Results for Development Institute (R4D) led by Jack Clift under the general direction of Cammie Lee with managerial and technical contributions from Chia-Ying Lin, Rachel Huynh, Yodi Tesfaye, Pili Mmbaga, Fantaye Teka, Brooke Detweiler and Augustin Flory. The team additionally benefited from discussions with R4D colleagues Mary D'Alimonte, Albertha Nyaku and Paul Wilson.

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The opinions expressed in this deck are solely the responsibility of the individual R4D authors listed above and should not be interpreted to reflect the opinions and beliefs of CIFF or ECF. This deck is accompanied by a 2-page policy brief focused on priority actions to increase access to RUTF globally. Additional outputs related specifically to findings and recommendations in Ethiopia and Tanzania are forthcoming.

Strengthening Systems for the Treatment of Acute Malnutrition (SSTAM) Project studies key market barriers and opportunities to increase access to RUTF

*SSTAM is an 18-month project funded by **Children's Investment Fund Foundation (CIFF)** and **Eleanor Crook Foundation (ECF) to identify key market barriers** that inhibit access to RUTFs, and **scope opportunities** to address priority bottlenecks. The project also assesses challenges **globally** with a **country focus on Ethiopia and Tanzania**.*

The Challenge

- Wasting is one of the largest mortality drivers for children U5, contributing to up to 2M deaths annually
- Urgent action is needed to achieve the WHA target by 2025 to reduce and maintain childhood wasting to less than 5%
- In 2019, 47M children were affected by wasting, of which 14.3M were severely wasted
- RUTF is a highly cost-effective treatment for SAM. However, funding for RUTFs only manages to cover roughly 25% of the potential need

Market Analysis Framework…

…identified 4 Opportunity Areas

- **Financing**
- **Alternative Formulations**
- **Demand, Procurement, Supply Base**
- **Regulatory**

Source: UNICEF WHO WBG Joint Child Malnutrition Estimates 2020

Recall: Based on assessment of market health for RUTFs, our comprehensive work emphasizes what can be done to address **AVAILABILITY** of life-saving RUTFs

RUTF Market Outcome Assessment

Our priority

Availability
Critical need to (sustainably) raise availability as less than 1/3 of SAM children access RUTF

Affordability
Affordability is not a patient-level barrier in current model; *but* cost affects procurement (→***availability***)

Awareness
Product well established. Some awareness gaps; but low appetite to address when product is unavailable

Appropriate Design
Standard RUTF is effective, simple to use; but not fully tailored to local taste

Assured Quality
Not a major issue for the current, highly centralized/standardized RUTF market

With the emphasis on **increasing availability of RUTF**, highest impact actions are identified as…

- **Action #1:** Prioritize sustaining and increasing funding for RUTF – from all sources, including donor, domestic & co-financing
- **Action #2:** Increase focus on procuring from suppliers who provide best combination of price, performance and supply security
- **Action #3:** Actively shape the emerging market of alternative formulations (AFs) to a highly curated set of cost-effective recipes; and invest in the needed evidence generation
- **Action #4:** Progressively strengthen local capacity, supply chains, and integrated systems needed for future RUTF markets

Summary of key findings and recommendations

Summary of key takeaways

1

Increasing total **FINANCING** for RUTF is the largest opportunity we see for increasing overall market availability. Efforts to **sustain/increase donor financing** for RUTF should be an immediate priority given the potential to have the greatest impact on availability in the short term, and several donors have shown that substantial increases are possible. Efforts to **mobilize domestic resources** should be pursued as a part of a longer-term, more sustainable financing strategy. Both sources can be leveraged through **joint financing / co-financing approaches.**

If there is limited bandwidth and attention for solving the challenges on RUTF, we believe financing should be the #1 priority for short-term and long-term impact

Summary of key takeaways

1. Increasing total **FINANCING** for RUTF is the largest opportunity we see for increasing overall market availability. Efforts to **sustain/increase donor financing** for RUTF should be an immediate priority given the potential to have the greatest impact on availability in the short term, and several donors have shown that substantial increases are possible. Efforts to **mobilize domestic resources** should be pursued as a part of a longer-term, more sustainable financing strategy. Both sources can be leveraged through **joint financing / co-financing approaches.**

2. **ALTERNATIVE FORMULATIONS** present a medium-term opportunity for improved overall cost-effectiveness through products with **modest price reduction or improvement in efficacy**. They are not a silver bullet; achieving maximum benefit will require **careful market shaping**. Maximizing cost savings relies on not further fragmenting the supply base; maximizing benefits will need strong efforts to replace less effective products in countries with more effective ones. Both efforts can be supported with accelerated **evidence generation.**

3. Given the central role of UNICEF, the **DEMAND/PROCUREMENT and SUPPLY BASE** questions are largely intertwined; there may be some **small remaining gains** to be made in efficient supply and price reduction, particularly if 'local production' is considered a means to an end rather than an end in itself, and product is **not procured from high cost producers**. More efficient usage and reduced leakage should be further investigated within countries, particularly as country ownership for management and deployment of RUTFs grows

If financing is already receiving due attention, several other market shaping approaches have potential for modest short-term impact and long-term sustainability

Summary of key takeaways

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4. Possible actions related to **REGULATION and QUALITY ASSURANCE** are potentially important for the long term, even if they are unlikely to have a major short term impact on availability and affordability of RUTF. **Enhanced clarity and faith in regulatory processes** can better enable long-term innovation, and **strengthened national systems/frameworks** for RUTF will be increasingly needed if the market becomes less centralized around UNICEF procurement in the future.

Regulation and Quality Assurance changes can influence long term outcomes, and will require increasing attention if the market moves to more local ownership

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In addition: there is a cross-cutting tension between efforts to accelerate local ownership, and ongoing systems of centralization and standardization. Further consensus is needed on **how RUTF will be financed, produced and procured sustainably**, what the **timeline** should be for transition (and what will facilitate it); and what **tradeoffs** are entailed. If move to full domestic ownership of SAM treatment will take place over an extended period, transitioning responsibility for the commodities specifically could be an immediate priority, a medium-term ambition, or the last step in full integration.

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Summary of recommended actions by stakeholders

Summary of key actions

	Immediate term actions		Longer term actions	
	Actions	**Potential Stakeholder Contributions *(draft)***	**Actions**	**Potential Stakeholder Contributions *(draft)***
Financing	**(Advocate to) increase donor funding for RUTF in line with growth from exemplar donors such as US and UK[1]**, with coordinated action to influence aid budgets for nutrition, and to support country-led efforts to mobilize resources from a range of external sources	• **Global advocates** to lobby donor HQs & parliamentarians • **Local advocates** to lobby for coordinated planning with donors at country level • **Donors** at HQ to prioritize wasting treatment; at country level to work on coordinated plans (with government and across donors) • **Governments** to develop costed plans incl RUTF and coordinate with donor partners	**Domestic resource mobilization:** • **Prioritization and reallocation of domestic resources within existing health budgets / revolving funds** • Inclusion of RUTF in national benefits package • *Ring-fencing/earmarking funding for RUTF or broader set of nutrition products*	• **Local advocates** to lobby national and/or local government and/or facilities (depending on where authority sits) to allocate funds to RUTF *and* to disburse them in timely fashion • **National and local governments** (as appropriate) to allocate domestic resources against quantified need for RUTF and/or include RUTF within revolving funds • **Governments** to support RUTF's inclusion in relevant national policies to facilitate its addition to national benefits package • **Donors** to support technical assistance for fiscal space analysis, costing and capacity-building for government • ***National governments*** *to consider establishing the legal framework that allows ring-fencing of health/nutrition funds*
	Explore, refine and expand co-financing arrangements *(e.g., UNICEF Match Fund, GFF, Power of Nutrition)*	• **UNICEF** to monitor uptake of match fund, share findings externally and consider refinement; and fundraise for it • **GFF** and **Power of Nutrition** (with **World Bank** partners) to raise wasting treatment and RUTF as an option for funding in country dialog • **Governments** to consider including RUTF in investment case for GFF / Power of Nutrition • **Donors** to consider country-level matching/co-financing		
Alternative Formulations	**Invest in evidence generation** to accelerate approval of AFs & differentiate between AFs	• **Donors** to invest in evidence generation on effectiveness of AFs across relevant outcomes, and across settings • **Academia/Implementers** to execute trials • **Governments** and other stakeholders to support evidence at national level	**Consolidate market around only the very best AFs**	• **UNICEF and other procurers** to decide on a tightly limited set of AFs to procure, to balance attractive characteristics / regional preferences with low fragmentation • **Donors** to consolidate support only to priority products or development of superior products
	Increase focus on cost-effectiveness in decisions on approving and scaling AFs	• **UNICEF** to explicitly prioritize cost-effectiveness in uptake/procurement decisions • **Academia** and other partners to generate high quality cost data & cost-effectiveness analyses • **Donors** to support research, include CE in own decisions on supporting AFs, and attach CE conditions to their funding for UN procurement • **WHO** to reconsider stance on disregarding CE when product is inferior by some metrics	*Support demand generation for AFs in the future after approval*	• ***Donors*** *and* ***academia/implementers*** *to support/execute national acceptability trials* • ***Advocates*** *to lobby government decision-makers on uptake of superior AFs* • ***UNICEF*** *and other partners to include option of switching to AFs in government discussions* • ***Donors, UNICEF*** *and others to provide incentives to switch where appropriate*

1. Note: UK/US have been leaders in increasing wasting funding, with an average 28% year-on-year growth from 2015 to 2019. However given overall aid cuts in UK, significant growth is not expected from the UK in the near term; efforts are needed just to sustain UK funding, and grow other sources.

High priority actions
Lower priority actions

Summary of key actions

	Immediate term actions		Longer term actions	
	Actions	**Potential Stakeholder Contributions *(draft)***	**Actions**	**Potential Stakeholder Contributions *(draft)***
Demand, Procurement, Supply Base	**Procure from suppliers producing at greater scale and lower cost,** potentially with more of a consolidated regional focus	• **UNICEF** to shift procurement mix to higher scale/lower cost producers • **Donors** to provide conditions on their procurement support to move to higher scale/lower cost producers • (Regional) **Suppliers** to invest in scale and export capability	**Strengthen national level capacity to manage RUTF and support national efforts to investigate and address supply-chain leakage**	• **Donors and Governments** to consider policies and investments in national supply chain infrastructure that facilitate the integration and/or further optimization of RUTF supply chain and improve facility-level management of RUTF • **Donors to fund research** to investigate the scope of RUTF supply-chain leakage, and as appropriate, to consider investments to improve product traceability
			Procurers to continue to explore whether new contracting terms, financing, and/or order predictability options might allow suppliers to cut costs	• ***UNICEF** to periodically solicit suggestions from suppliers and other stakeholders on options for support that could allow cost reduction. UNICEF (or 3rd party) then to evaluate promising options, report out and consider implementing* • ***Suppliers** and others to recommend options to UNICEF*
	(Advocate to) reduce or eliminate tariffs when importing RUTF ingredients or exporting products to neighboring countries	• **Advocates** to lobby government to reduce tariffs on ingredients for critical nutrition/health products • **Regional Economic Communities** to advocate for regional reductions in relevant tariffs and trade barriers • **Governments** to reduce tariffs	*Consider case-by-case whether investments in establishing an accredited lab that can test, certify and inspect agri-food items, or technical assistance, provide positive returns*	• ***Donors** to fund / **academia or implementers** to execute cost-benefit analysis to determine in which scenarios investments to increase national laboratory capacity to perform agri-food QA provide positive returns*
Regulation	**Continue to build clarity and buy-in for standards and processes governing product approval and uptake**	• **WHO** to lead collaborative processes to discuss and refine primary vs secondary outcomes for RUTF; and continue efforts to ensure expectations are clear on processes and that they are then seen to be followed through • **Academia and other technical partners** to participate in collaborative processes • **Civil society** to work with WHO and the broader community to ensure processes are seen by all as clear and fair	**National stakeholders to consider (at relevant time) where national regulatory framework changes are needed for long term**	• **Government** to assess tradeoffs and define appropriate classification for RUTF and consider inclusion of RUTF in national EMLs or an alternative priority list; review and consider updates for RUTF supplier registration requirements, build internal capacity on assessing RUTF manufacturers • **Donors/implementers** to support TA for adapting (upcoming) CODEX RUTF guideline to create national guidance; and registering suppliers
			Monitor any issues created by current QA architecture and investigate desirability of alternative approaches for this product class at global, regional or national levels	• **Advocates, implementors and suppliers** to raise issues of current QA structure, quantify negative impacts and suggest alternative options for consideration • **UNICEF/WHO** and broader stakeholders including national **governments** to consider/evaluate alternative QA options and propose an approach to implementing any superior options • **Donors/implementers** to provide TA to develop national quality standards for RUTF

High priority actions *Lower priority actions*

Recommendations and findings by topic

Financing

Recommendations

Filling the financing gap for RUTF is the largest opportunity for increasing overall market availability. Domestic leadership and oversight is critical to coordinated financing at national level; sustaining and increasing donor support for country-led wasting efforts must be a high priority in the short term until sufficient resources can be mobilized domestically.

A Immediate attention should be given to **increasing/sustaining donor funding for RUTF** as the highest impact opportunity to increase RUTF availability in the short-term. Donor contributions have high impact on resource availability in the current landscape and some donors have shown it is possible to substantially increase wasting spending in the span of a few years. Efforts are needed sustain those gains while helping countries to leverage additional (ideally long-term, on-budget) external resources in support of national plans to address wasting.

B Despite current low levels of domestic financing for RUTF and challenges in meeting commitments, **increasing domestic contribution to RUTF/wasting is an important long-term goal** to achieve programmatic sustainability, and also may increase the chances of donor support in solidarity. To support DRM, we recommend **tailored advocacy to prioritize RUTF within existing budgets/financing mechanisms for essential health commodities,** at the appropriate level. For contexts with limited fiscal space to contribute to RUTF, efforts to increase **government ownership of external resources (e.g., strengthening resource tracking, pursuing on-budget aid)** can be an important step to increase the sustainability of the funding flows for RUTF.

C As an important opportunity to simultaneously **increase both donor and domestic funding** for RUTF, **co-financing arrangements should be explored and refined over time**, so that countries with different levels of fiscal space are able to take advantage. Co-financing can be explored through country-level stakeholder coordination, or via global mechanisms such as the UNICEF RUTF match fund or the Power of Nutrition/GFF.

Immediate term actions	Longer term actions
A **(Advocate to) increase donor funding for RUTF in line with growth from exemplar donors such as US and UK**[1], with coordinated action to influence aid budgets for nutrition, and to support country-led efforts to mobilize resources from a range of external sources	B **Domestic resource mobilization:** • **Prioritization and reallocation of domestic resources within existing health budgets/revolving funds** • **Inclusion of RUTF in national benefits package** • Consider pros and cons of ring-fencing/earmarking funding for RUTF or broader set of nutrition products
C **Explore, refine and expand co-financing arrangements** *(e.g., UNICEF Match Fund, GFF, Power of Nutrition)*	

Bold = priority actions

1. Note: Given overall aid cuts in UK, significant growth is not expected from the UK in the near term; efforts are needed just to sustain UK funding, and grow other sources.

Financing

Key findings informing our recommendations

Key facts

1. **Insufficient funding to meet the need**
Current financing only covers 25% of children who need treatment. While broad investments needed for wasting have been estimated to cost $9.1B over 2015-2025, at current prices ~$400M would be required in RUTF costs alone to raise coverage to 90% for a single year.

2. **Donors contribute a majority of RUTF financing, with fairly heavy reliance on humanitarian funds**
Donors contribution is estimated at about 80%-90% of total RUTF funding, while RUTF financing is especially reliant on short-term, off budget humanitarian funds, which complicates planning and can undermine efforts towards greater government ownership.

3. **Donors have shown a clear ability to step up financing for wasting, led by the US and UK**
ODA for wasting grew to ~$507M in 2019 from ~258M in 2015, driven in large part by a 28% average growth rate in wasting funding from the US and UK. However, it remains **unclear how COVID-19 will impact funding for wasting in the long term**, and the overall reduction in the UK's aid budget is also a concern.

4. **Current domestic financing is low, and historically has struggled to grow despite high ambition on all sides**
Based on latest large scale WHO data, there was **no evidence of overall growth in domestic funding for wasting between 2015 and 2018**. While there is global interest in greater domestic financing, fiscal space is limited. **At country level, there have been strong commitments, but these have often not translated into an actual increase in resources.** There is some perception that wasting is a humanitarian issue that donors can lead, a perception that may be reinforced when humanitarian aid is disbursed 'off-budget' and not channeled through government budgets, coordination mechanisms, or pooled funds.

5. **Joint donor-domestic financing approaches provide an avenue for increasing donor and domestic resources, and have not yet been fully utilized or optimized**
Leveraging existing innovative financing platforms: the Power of Nutrition has adopted a new strategy that broadens its focus to include all forms of malnutrition, creating greater opportunity for RUTF financing; opportunities for RUTF financing within the Global Financing Facility (GFF) have not been fully utilized
New mechanisms: UNICEF is piloting a simple match fund concept which allows countries to take advantage of a 1:1 match. If this concept demonstrates initial success, this may expand and evolve over time and attract a wider range of participants.

Alternative Formulations

Recommendations

ALTERNATIVE FORMULATIONS present a medium-term opportunity for improved overall cost-effectiveness through products with modest price reduction or improvement in efficacy. They are not a silver bullet; achieving maximum benefit will require careful market shaping.

A While some aspects of AF regulation have been contentious *(see Regulation section),* approval and uptake of promising AFs is limited by the current evidence base. **Accelerating evidence generation** for some of the most promising AFs can accelerate market entry/impact

B Cost efficiencies to date have largely been achieved through increased scale. Generally**, there are some modest theoretical price benefits** from introduction of AFs with **substitution of less expensive ingredients**, but these could be largely offset if the products are not produced at optimal scale **due to market fragmentation**. **Therefore, we would recommend efforts to consolidate around a subset of 'winning' formulations to supply the full market; and discourage over proliferation of non-superior options**

C Additional **emphasis is needed on cost-effectiveness** in addition to cost savings; while cost savings may be modest stakeholders should also be looking to incentivize better products, whether on **improved recovery rates** in the short term or on metrics suggesting better underlying health improvements for the long term. **Maximizing the benefits would need a strong push to transition to better products once available**

	Immediate term actions	Longer term actions
A	**Invest in evidence generation** to accelerate approval of AFs & differentiate between AFs	B **Consolidate market around only best AFs**
C	**Increase focus on cost-effectiveness** in decisions on scaling AFs	Support demand generation for AFs in the future after approval

Bold = priority actions

Alternative Formulations

Key findings informing our recommendations

Key facts

1. **Individual studies of AFs have shown promise but not yet enough to convince decision-makers**
While questions have been raised about process for approving non-dairy formulations of RUTF (see Regulation section), there are limitations in the evidence base. While alternative formulations with increased efficacy, and formulations with reduced cost, have shown promise in limited trials, there is not yet enough to convince decision-makers to approve/procure at scale.

2. **Price reduction opportunities are fairly modest through cheaper ingredients**
Current evidence for cost reduction have <7% savings through replacement of peanut with cheaper ingredients. Higher savings may be possible with formulations replacing milk but these are still controversial from an effectiveness perspective.

3. **With low margins and fairly fixed recipes, recent price improvements likely came from scale**
Price improvements from 2007-2011 coincided with increased competition in the market, moving from 1 supplier to 14 competitors producing the original formulation. With no increase in supplier numbers between 2011 – 2017, as average volumes per supplier have increased by ~150% there has been a further decline in average price of 17%; however, with as many as 35 alternative formulations being submitted for consideration in the latest 2018 tender, there is risk of further fragmentation. This could lead to suboptimal outcomes, with excessive complexity on the procurement and supply planning, and potential reversals of previous gains to scale.

4. **Lack of emphasis on cost-effectiveness**
Key actors in this space place restrictions in place that could prevent approval / adoption of more cost-effective AFs. WHO have stated that they will not consider cost-effectiveness of alternative RUTFs that do not reach the same efficacy as standard RUTF; in this case, a much cheaper product that could save lives through higher coverage would be ruled out. As procurers, UNICEF have signaled they are only interested in products that are cheaper than standard formulation RUTF; this would preclude procuring more cost-effective products that are slightly more expensive than standard RUTF but significantly more effective on short- or long-term outcomes.

3

Demand, Procurement, Supply Base

Recommendations

With UNICEF's role, the DEMAND, PROCUREMENT and SUPPLY BASE questions are largely intertwined; there may be some small gains to be made in efficient supply and price reduction, particularly if 'local production' is considered a means to an end rather than an end in itself.

A The supply base is heavily shaped by UNICEF, and does not fully optimize for availability and affordability of RUTF. We estimate that existing financial resources could increase RUTF volumes by 3% or more if UNICEF chose to **procure more from suppliers producing at greater scale and lower cost.** We find many arguments for local production to be overstated, and expect that most benefits could be more achieved **with focus on regional suppliers**

B In general, there may be **small opportunities for more efficient production** and **cost reduction**; however, it remains debatable whether investments in these would have a positive return. A possible exception is the **reduction or elimination of tariffs when importing ingredients or exporting products to neighboring countries**

C As country ownership grows, **efforts in strengthening capacity are needed to better forecast demand and ensure inventory data visibility** for better management of RUTF. To address **supply chain leakage** within countries, we believe that **more investigation is needed** to design solutions, and **integration into national health supply chains has also been proposed as one approach**. But the value of that approach will vary from country to country given differing strengths of existing supply chains

	Immediate term actions		Longer term actions
A	**Procure from suppliers producing at greater scale and lower cost, potentially with more of a consolidated regional focus**	C	**Strengthen national level capacity to manage RUTF and support national efforts to investigate and address supply-chain leakage**
B	**(Advocate to) reduce or eliminate tariffs when importing RUTF ingredients or exporting products to neighboring countries**		Continue to explore whether new contracting terms, financing, and/or order predictability options might allow suppliers to cut costs
			Consider case-by-case whether investments in establishing quality labs, or technical assistance, provide positive returns

Bold = priority actions

Demand, Procurement, Supply Base

Key findings informing our recommendations

Key facts

1. **Current supply base is fragmented and includes some small-scale players with higher prices**
While majority of supply comes from competitively priced suppliers, there are some producers selling at lower scale and higher prices. For this reason the average WAP is above the international WAP. Removing high-cost producers could reduce the market average price by 3% or more.

2. **Local production might not achieve expected benefits that would justify a higher price in procurement**
Currently, many local producers are heavily reliant on imported ingredients, greatly limiting hoped-for benefits of local production, such as reduced carbon footprint, improved lead times, greater robustness to supply disruption, or stimulation of local economy. Evidence is mixed on whether local production would inspire domestic financing.

3. **Price reduction opportunities from production efficiencies appear modest, and may not justify costs involved**
A few ideas have been explored with experts to **improve production efficiencies**, such as via volume guarantees, addressing challenges with access to capital, quicker or advanced payment, or Forex availability. While potentially beneficial to suppliers, partners including UNICEF have not yet assessed any idea to have sufficient ROI to be taken on. Experts have also suggested reassessing the stringent input and output requirements from the procurer; but opinions vary whether the current requirements are appropriately safety conscious, or inappropriately risk averse and costly.

4. **Removing or reducing tariffs for imported ingredients is more promising for competitiveness**
Tax rates on imported goods could account for 6-35% of total input costs while imported RUTFs typically enjoy a reduced tax or tax-exempt status (at least theoretically). As local manufacturers rely heavily on imported ingredients for RUTF, reducing tariffs would allow them to be more cost competitive (though also reducing government revenue)

5. **Potential to bring major commercial food companies into the market is low**
Some have hoped that attracting large food companies to the RUTF market could bring scale, technology and greater production efficiencies. However, food companies have expressed concerns with limited market size, low margins and complexities of the RUTF market as a commercial venture. There may still be potential for technical assistance or capital investments in production capacity via CSR programs.

6. **Extent of (and solutions for) supply chain leakage are not well understood**
Leakage in the supply chain is often mentioned anecdotally, but very little hard data is available (particularly) for recent years. Some informants believe that data may exist in confidential internal reports but is not shared publicly out of a concern that this would undermine resource mobilization efforts. Integrating RUTF into health inventory management systems has been shown in some settings to reduce loss at lower levels of the system. Local production has been posited as an opportunity to for clinics to pick up directly from manufacturer to reduce upstream loss.

Regulation

Recommendations

Our proposed actions related to REGULATION and QUALITY ASSURANCE are potentially important for a long term, sustainable, country-driven market - even if they are unlikely to have a major short-term impact on availability and affordability of RUTF.

A Product innovation for RUTFs may be enhanced by **greater clarity, consensus and trust/buy-in for the regulatory standards and processes** governing product approval and uptake for new products. Greater clarity, consensus and trust/buy-in would allow more efficient targeting of innovation efforts and improve the environment for investments.

B With UNICEF and NGOs procuring majority of RUTFs, **national regulatory framework updates** are likely not a major short-term binding constraint; however, country stakeholders should **look at where changes are needed** to move towards a more localized approach in the long run (e.g. classification as food/meds and supplier registration requirements). Adding RUTF to relevant lists of essential products may also be beneficial in some countries.

C In the long run, **independent quality assurance mechanisms will need to continue to evolve** from the current model that depends heavily on UNICEF (and is therefore influenced by UNICEF's procurement priorities). In the short run this is not a major market challenge, but if the market evolves towards a wider set of procurers including more national governments, appropriate QA at local, regional or global level will be increasingly important; potentially for not only RUTF but for a broader set of food/nutrition products.

	Immediate term actions	Longer term actions
A	**Continue to build clarity and buy-in for standards and processes governing product approval and uptake,** e.g. through collaborative processes to discuss and refine primary vs secondary outcomes for RUTF; continuing effort to ensure expectations are clear on processes and that they are then seen to be followed through	B **National stakeholders to consider (at relevant time) where national regulatory framework changes are needed for long term** C **Monitor any issues created by current QA architecture and investigate desirability of alternative approaches for this product class at global, regional or national levels**

Bold = priority actions

Regulation

Key findings informing our recommendations

Key facts

1 **Challenges around appropriate outcomes and prioritizing them**

While there is broad consensus that recovering from SAM and reducing mortality are the key goals for RUTF, there is not universal approval for the full set of outcomes used in recent assessments. Some experts argue that RUTF efficacy should be judged primarily on recovery and mortality, with other outcomes considered as purely secondary; but recent practice seems to indicate that RUTFs must meet/exceed results on a broader set of outcomes including rate of weight gain (which is not universally accepted as appropriate). Some argue more attention should be paid to relapse and cognitive impacts, but these are not measured in most trials.

2 **Perceived inconsistencies in WHO evidence review has raised concerns with process**

Some informants have raised concerns about the fairness of WHO processes, and suggested that this undermines willingness of investors to support the market. As a recent example, in a recent review of RUTF with <50% protein from milk, WHO's announcements created an expectation that effectiveness, preference/acceptability and cost-effectiveness would all be examined. However, cost-effectiveness was not reviewed, with some informants publicly disputing the explanations given for this decision by WHO. To the extent there is loss of confidence in the process, this may make investing in the space less attractive.

3 **National regulatory systems have not had to prioritize RUTF in the past**

With the majority of RUTF being procured by UNICEF and other donors, countries still need to build a regulatory framework for RUTF. As countries take on more of a role in managing, deploying, funding and/or procuring RUTF, some short-term regulatory updates need to be considered, such as supplier registration, quality assurance, and inclusion in an essential product list (EML or other, as appropriate) that may be a prerequisite for domestic resource mobilization or inclusion in national supply management systems

4 **Concerns have been raised on UNICEF's de facto role as QA leader for the market**

The market current largely relies on UNICEF for Quality Assurance of RUTF suppliers, but UNICEF is not independent - it has its own procurement priorities and may not choose to inspect suppliers from whom they do not plan to procure, which could create a barrier to entry in the broader market. This regulatory set up may not be a major binding constraint today (in itself, being quality assured will be of limited benefit to a supplier today if UNICEF is not procuring from them), but would be more distorting in the future if there is more diversified procurement. WHO Prequalification is a possible option, but has not been used for RUTF in the past and is considered burdensome for smaller providers.

5 **While Nutriset patent may have been a market constraint in the past, this should no longer be an issue**

Nutriset's patent is cited as a contributor to past lack of competition, but appears now to have expired

Deeper dive by section

Financing

Recommendations

Filling the financing gap for RUTF is the largest opportunity for increasing overall market availability. Domestic leadership and oversight is critical to coordinated financing at national level; sustaining and increasing donor support for country-led wasting efforts must be a high priority in the short term until sufficient resources can be mobilized domestically.

A Immediate attention should be given to **increasing/sustaining donor funding for RUTF** as the highest impact opportunity to increase RUTF availability in the short-term. Donor contributions have high impact on resource availability in the current landscape and some donors have shown it is possible to substantially increase wasting spending in the span of a few years. Efforts are needed sustain those gains while helping countries to leverage additional (ideally long-term, on-budget) external resources in support of national plans to address wasting.

B Despite current low levels of domestic financing for RUTF and challenges in meeting commitments, **increasing domestic contribution to RUTF/wasting is an important long-term goal** to achieve programmatic sustainability, and also may increase the chances of donor support in solidarity. To support DRM, we recommend **tailored advocacy to prioritize RUTF within existing budgets/financing mechanisms for essential health commodities,** at the appropriate level. For contexts with limited fiscal space to contribute to RUTF, efforts to increase **government ownership of external resources (e.g., strengthening resource tracking, pursuing on-budget aid)** can be an important step to increase the sustainability of the funding flows for RUTF.

C As an important opportunity to simultaneously **increase both donor and domestic funding** for RUTF, **co-financing arrangements should be explored and refined over time**, so that countries with different levels of fiscal space are able to take advantage. Co-financing can be explored through country-level stakeholder coordination, or via global mechanisms such as the UNICEF RUTF match fund or the Power of Nutrition/GFF.

Immediate term actions	Longer term actions
A **(Advocate to) increase donor funding for RUTF in line with growth from exemplar donors such as US and UK**[1], with coordinated action to influence aid budgets for nutrition, and to support country-led efforts to mobilize resources from a range of external sources	B **Domestic resource mobilization:** • **Prioritization and reallocation of domestic resources within existing health budgets/revolving funds** • **Inclusion of RUTF in national benefits package** • Consider pros and cons of ring-fencing/earmarking funding for RUTF or broader set of nutrition products
C **Explore, refine and expand co-financing arrangements** *(e.g., UNICEF Match Fund, GFF, Power of Nutrition)*	

Bold = priority actions

1. Note: Given overall aid cuts in UK, significant growth is not expected from the UK in the near term; efforts are needed just to sustain UK funding, and grow other sources.

Financing

Key findings informing our recommendations

Key facts

1. **Insufficient funding to meet the need**
Current financing only covers 25% of children who need treatment. While broad investments needed for wasting have been estimated to cost $9.1B over 2015-2025, at current prices ~$400M would be required in RUTF costs alone to raise coverage to 90% for a single year.

2. **Donors contribute a majority of RUTF financing, with fairly heavy reliance on humanitarian funds**
Donors contribution is estimated at about 80%-90% of total RUTF funding, while RUTF financing is especially reliant on short-term, off budget humanitarian funds, which complicates planning and can undermine efforts towards greater government ownership.

3. **Donors have shown a clear ability to step up financing for wasting, led by the US and UK**
ODA for wasting grew to ~$507M in 2019 from ~258M in 2015, driven in large part by a 28% average growth rate in wasting funding from the US and UK. However, it remains **unclear how COVID-19 will impact funding for wasting in the long term**, and the overall reduction in the UK's aid budget is also a concern.

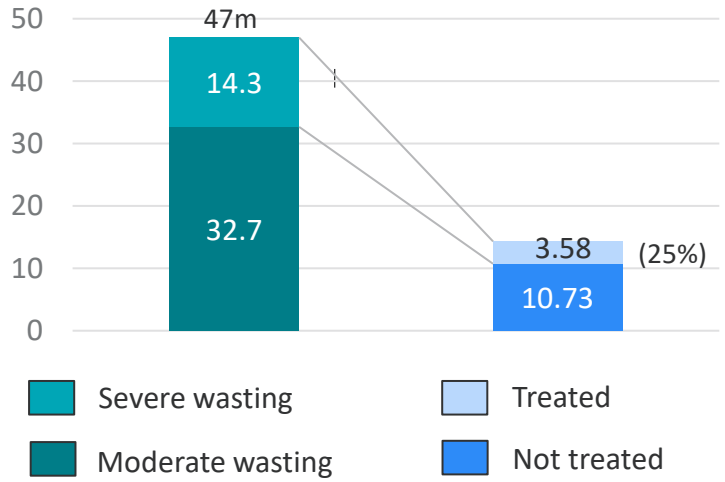
4. **Current domestic financing is low, and historically has struggled to grow despite high ambition on all sides**
Based on latest large scale WHO data, there was **no evidence of overall growth in domestic funding for wasting between 2015 and 2018**. While there is global interest in greater domestic financing, fiscal space is limited. **At country level, there have been strong commitments, but these have often not translated into an actual increase in resources.** There is some perception that wasting is a humanitarian issue that donors can lead, a perception that may be reinforced when humanitarian aid is disbursed 'off-budget' and not channeled through government budgets, coordination mechanisms, or pooled funds.

5. **Joint donor-domestic financing approaches provide an avenue for increasing donor and domestic resources, and have not yet been fully utilized or optimized**
Leveraging existing innovative financing platforms: the Power of Nutrition has adopted a new strategy that broadens its focus to include all forms of malnutrition, creating greater opportunity for RUTF financing; opportunities for RUTF financing within the Global Financing Facility (GFF) have not been fully utilized
New mechanisms: UNICEF is piloting a simple match fund concept which allows countries to take advantage of a 1:1 match. If this concept demonstrates initial success, this may expand and evolve over time to provide more nuanced terms that can attract a wide range of participants.

The large unmet need for wasting treatment, including RUTF, requires substantial investment if scaled-up coverage is to be achieved.

75% of severely wasted children receive no treatment

Millions of children, 2020 estimates



- Out of the estimated 14.3 million severely wasted children, only ~3.5 million receive treatment
- **An additional ~US $400M[1] for RUTF alone** would be required to raise treatment from 25% to 90%, on top of estimated $175-200M currently spent

Sources: Estimate based on UNICEF 2020 combined WAP $41.01/carton; UNICEF et al. "Levels and trends in child malnutrition: Key Findings of the 2020 Edition of the Joint Child Malnutrition Estimates"

Pre-Covid, add'l l $9.1B needed to increase wasting coverage to 90%

10-yr incremental financing needs for wasting treatment is $9.1B to scale up coverage to 90% children in low and middle income countries

- $8.1 billion would be required for direct service provision with additional $971M invested in capacity strengthening; developing policies, protocol, and guidelines; M&E of treatment programs
- Cost estimate based on 2015 data to reach 90% coverage, with assumptions on assumed cost efficiencies in RUTF and other treatment costs by 2020

Sources: WBG, "An Investment Framework for the Treatment of Severe Wasting"

With Covid impact, more needed to support disrupted services

- 30% reduction in essential nutrition services (w/ disruptions reaching 75% to 100% in some countries during lockdown)
- By 2022, estimates suggest a **20% increase in wasting cases** translating to ~9 million additional children in need of acute malnutrition services[1]
- An additional **$1.2B** per year is required to scale-up nutrition interventions needed to mitigate the effects of the pandemic[2]

1. UNICEF. No time to waste: Improving diets, services and practices for the prevention, early detection and treatment of wasting in early childhood. New York: UNICEF, 2021.
2. Osendarp, S., Akuoku, J.K., Black, R.E. *et al.* The COVID-19 crisis will exacerbate maternal and child undernutrition and child mortality in low- and middle-income countries. *Nat Food* **2,** 476–484 (2021). https://doi.org/10.1038/s43016-021-00319-4

In 2019, more than half of wasting funding came from humanitarian sources

>60% of funding channeled through UN agencies, with less than 3% direct to recipient governments

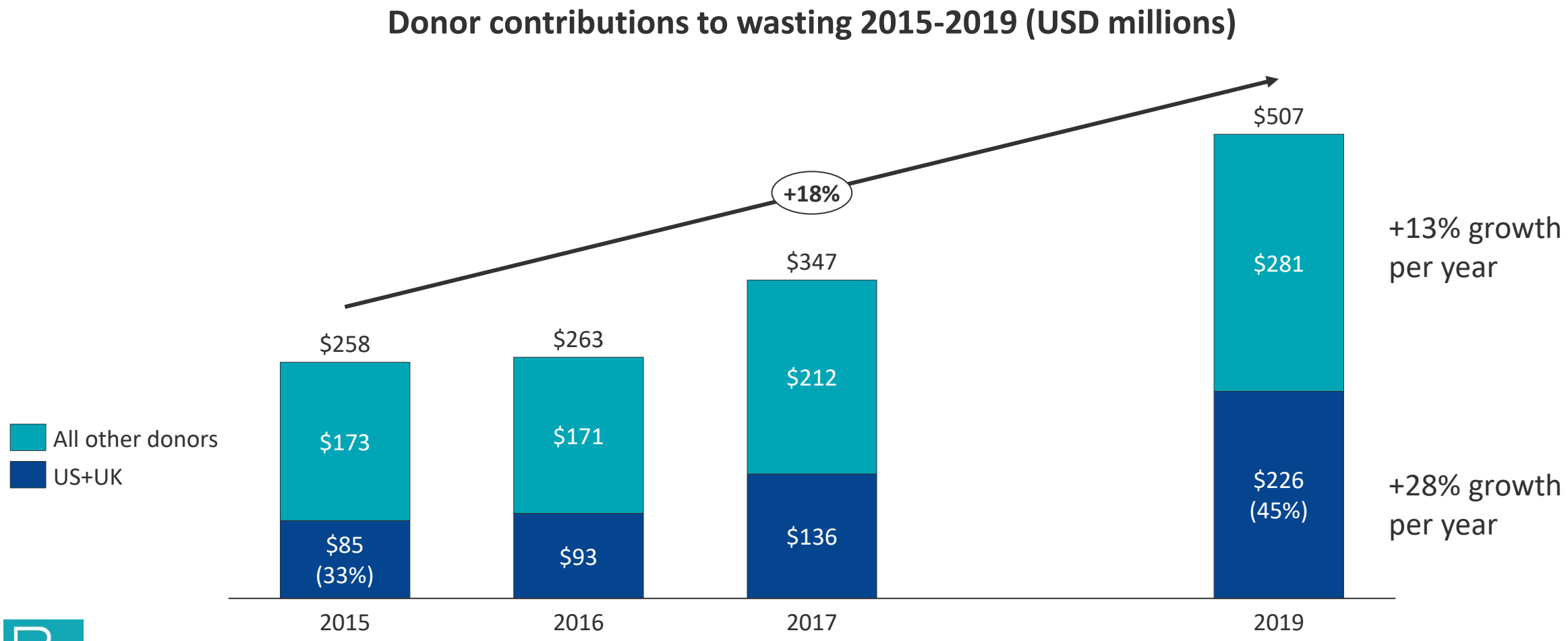
Key Notes

While donors contribute an estimated 80%-90% of the entire RUTF funding, 54.5% of the donor funding is from short-term, unpredictable humanitarian resources.

Moreover, out of the small amount of wasting funding that is channeled via recipient governments, only ~5% came from humanitarian sources. This suggests that a reliance on humanitarian resources is likely to hamper development of local systems and capacity.

Source: R4D analysis using OECD CRS Database

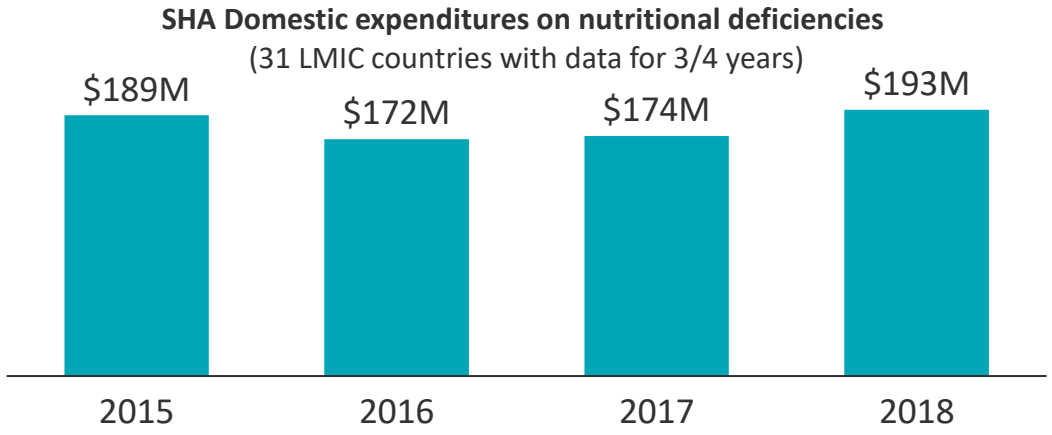
US and UK have led the way in increasing ODA for **wasting interventions** with 28% annual growth



Source: R4D reanalysis of OECD CRS data processed under R4D Aid for Nutrition project

With promising financial *commitments* to wasting, domestic allocations and expenditures for wasting remain constrained

Related domestic spend in LIC/LMIC (2015-18)



Indicators of relevant domestic financing

Domestic budgets

- The 2018 Global Nutrition Report reported a small uptick in government budget *allocations* for nutrition-specific programs (and larger growth for nutrition-sensitive programs), using data collated by the SUN Movement Secretariat for 25 countries
- However, it has not yet been possible to match these allocations against actual *expenditures* in most countries, and some major SUN countries are not represented in this data

Domestic resource mobilization efforts

There have been some promising commitments to increase domestic contribution to wasting programs as whole, with some commitments for RUTF specifically, but this has often not translated into increased allocations:

- ***Burkina Faso:*** In 2018, the government added RUTF to the budget, was paying for 20% of costs with plans to increase until the COVID pandemic and funds were reallocated
- ***Ethiopia/Tanzania:*** strong financial commitments have not yet translated to strong spending on RUTF *[see next slide]*

Sources: Top chart is R4D analysis of WHO System of Health Accounts data from 2015-2018 (data pulled Oct 9, 2021);; 2018 Global Nutrition Report.

DRM Considerations: Health and Nutrition Financing Snapshot

Benchmark	Ethiopia	Tanzania
15%	8.8% (2017)	6.7% (2019)
Abuja Declaration: 15% of Govt budgets should be allocated to health	% of Govt Budgets Allocated to health	
$60	$24.23 (2018)	$36.82 (2018)
Estimated per capita health expenditure required in low-income countries to provide essential health interventions	Per capita health expenditure	
~$6	$3.7	$0.50
Additional country commitment per child U5 required to achieve WHA targets on nutrition	Commitment per child U5 for nutrition-specific interventions	

*Government commitments to National Nutrition Budgets in **Ethiopia** and **Tanzania** have not translated to expenditure. While increasing DRM for RUTF is a long-term goal for achieving greater financial sustainability, progress should be pursued incrementally with realistic targets.*

Est Annual Cost of Procured RUTF **Ethiopia: US$~40m** **Tanzania: <US$300,000**

National Commitment: *ET and TZ have committed to fund **45%** and **30%** respectively of their National Nutrition budgets*

- UNICEF CO is encouraging Ethiopia to assume 10% of the cost of RUTF by 2025, **to date, no funds have been allocated.**
- A review of TZ's National Multisectoral Nutrition Action Plan (NMNAP) in 2016 found that the GoT only mobilized **3%** of the total budget, and **96%** of IMAM interventions were funded by donors.

Local Commitment: Fiscal decision-making is devolving to local levels in ET and TZ. In 2017 over 60% of public health expenditure was administered at the regional level in ET and 100% of the Government of Tanzania's budget contribution for IMAM was from local government sources.

To ensure that RUTF/IMAM is prioritized AND funded, the following can be considered where appropriate at both national and local levels:

- **Advocacy to increase fiscal space for health (and nutrition)** through the prioritization of health sector spending in government budgets.
- **Identification of reliable domestic funding sources:** Unpredictable financing resulting from off-budget donor support, non-release and delays in distribution of funds hampers effective planning and implementation. **Governments** should support RUTF's inclusion in relevant national policies to facilitate its addition to national benefits package, as well as continuing to advocate for donors to provide more on-budget support channeled through national systems.
- **Financial capacity building** and use of multi-year budgeting tools to provide more visibility and predictability.

Innovative and joint financing options are increasingly available to support RUTF, but more can be done to optimize their use

	Characteristics of financing mechanisms	Challenges and opportunities
Global Financing Facility (GFF)	• Founded in 2015, the GFF is a multi-stakeholder global partnership that supports the scale up of evidence-based investments for reproductive maternal newborn and child health and nutrition. • **Investment cases** are developed at country level to help align all stakeholders around priority interventions and mobilize resources, with domestic resources, external aid and private sector contributions complemented by funding from the World Bank and the GFF Trust Fund. • SAM treatment with RUTF is an evidence-based intervention that could be included in investment cases and GFF has often been cited as a potential financing source.	➢ Some countries have included wasting treatment as a priority intervention in their investment cases, but **few have allocated funds for treatment and even fewer have expended funds for RUTF** and other nutrition commodities. ➢ Lack of prioritization may be driven in part by the perceived cost of the intervention and by a belief that RUTF will continue to be funded from separate humanitarian sources, and therefore should not be prioritized for other sources. ➢ Inclusion of RUTF in the investment case does not mean that RUTF will be funded by GFF itself, but raises the chance of it being prioritized for resources from some source, as part of a country-led financing effort.
Power of Nutrition (PON)	• Also founded in 2015, the PON is an innovative financing platform for pooling and leveraging resources across sectors to address malnutrition. This has typically featured 4x leverage (3:1 match) for private donations, as a donation is matched by PON core partner funds, and then matched again by the implementing organization. • At founding, PON focused on 11 high impact interventions identified in the Lancet series 2008/2013, including management & prevention of acute malnutrition. Historically, the PON has had more emphasis on addressing stunting than wasting, with country eligibility determined on the basis of stunting burden.	➢ Despite the stunting emphasis, a number of country programs have included wasting treatment; at the same time, some high burden countries have not included it. ➢ The PON is adopting a new strategy that includes addressing all forms of malnutrition through a multi-sectoral approach. It will be up to governments to prioritize SAM treatment in discussions. ➢ The PON model typically has focused on the 3:1 match for private donors. More recently they have piloted allowing governments to get that match on domestic resources, which could be an opportunity for countries in future to multiply their investments.
UNICEF Nutrition Match Fund	• UNICEF, with support from FCDO and others, are currently piloting a 1:1 match fund for RUTF to incentivize domestic contribution as well as the capacity of governments to plan for and finance the product. • The match fund includes technical assistance and access to pre-financing through UNICEF's Vaccine Independence Initiative (VII).	➢ Depending on the lessons of the pilot phase, it would be worth exploring ways to optimize impact, e.g, monitoring domestic funding and assessing ways to continue incentivizing domestic contributions for countries with tighter fiscal space.

Alternative Formulations

Recommendations

ALTERNATIVE FORMULATIONS present a medium-term opportunity for improved overall cost-effectiveness through products with modest price reduction or improvement in efficacy. They are not a silver bullet; achieving maximum benefit will require careful market shaping.

A While some aspects of AF regulation have been contentious *(see Regulation section),* approval and uptake of promising AFs is limited by the current evidence base. **Accelerating evidence generation** for some of the most promising AFs can accelerate market entry/impact

B Cost efficiencies to date have largely been achieved through increased scale. Generally**, there are some modest theoretical price benefits** from introduction of AFs with **substitution of less expensive ingredients**, but these could be largely offset if the products are not produced at optimal scale **due to market fragmentation**. **Therefore, we would recommend efforts to consolidate around a subset of 'winning' formulations to supply the full market; and discourage over proliferation of non-superior options**

C Additional **emphasis is needed on cost-effectiveness** in addition to cost savings; while cost savings may be modest stakeholders should also be looking to incentivize better products, whether on **improved recovery rates** in the short term or on metrics suggesting better underlying health improvements for the long term. **Maximizing the benefits would need a strong push to transition to better products once available**

	Immediate term actions	Longer term actions
A	**Invest in evidence generation** to accelerate approval of AFs & differentiate between AFs	B **Consolidate market around only best AFs**
C	**Increase focus on cost-effectiveness** in decisions on scaling AFs	Support demand generation for AFs in the future after approval

Bold = priority actions

Alternative Formulations

Key findings informing our recommendations

Key facts

1. **Individual studies of AFs have shown promise but not yet enough to convince decision-makers**
While questions have been raised about process for approving non-dairy formulations of RUTF (see Regulation section), there are limitations in the evidence base. While alternative formulations with increased efficacy, and formulations with reduced cost, have shown promise in limited trials, there is not yet enough to convince decision-makers to approve/procure at scale.

2. **Price reduction opportunities are fairly modest through cheaper ingredients**
Current evidence for cost reduction have <7% savings through replacement of peanut with cheaper ingredients. Higher savings may be possible with formulations replacing milk but these are still controversial from an effectiveness perspective.

3. **With low margins and fairly fixed recipes, recent price improvements likely came from scale**
Price improvements from 2007-2011 coincided with increased competition in the market, moving from 1 supplier to 14 competitors producing the original formulation. With no increase in supplier numbers between 2011 – 2017, as average volumes per supplier have increased by ~150% there has been a further decline in average price of 17%; however, with as many as 35 alternative formulations being submitted for consideration in the latest 2018 tender, there is risk of further fragmentation. This could lead to suboptimal outcomes, with excessive complexity on the procurement and supply planning, and potential reversals of previous gains to scale.

4. **Lack of emphasis on cost-effectiveness**
Key actors in this space place restrictions in place that could prevent approval / adoption of more cost-effective AFs. WHO have stated that they will not consider cost-effectiveness of alternative RUTFs that do not reach the same efficacy as standard RUTF; in this case, a much cheaper product that could save lives through higher coverage would be ruled out. As procurers, UNICEF have signaled they are only interested in products that are cheaper than standard formulation RUTF; this would preclude procuring more cost-effective products that are slightly more expensive than standard RUTF but significantly more effective on short- or long-term outcomes.

Some alternative formulations have shown promise in effectiveness, while others are showing opportunities for lower cost, but this is not yet sufficient for decision-makers

Some formulations promise superior effectiveness…

Example: Oat-based RUTF

Produced by Project Peanut Butter (PPB), this formulation contains oats and milk, with reduced peanut and sugar.

A recently published randomized control trial suggests a potential **10% improvement in recovery rate** as well as gain in mortality and rates of weight gain, in the study setting of Sierra Leone.[1,2]

If these results are verified, scaling up oat-based RUTF could save many lives compared with standard RUTF. However, these promising results have not yet been replicated or shown to apply in other settings.

Some formulations promise substantial cost savings…

Example: Soya-maize-sorghum (SMS) RUTF

Data provided by Valid Nutrition argues that the SMS formulation can save them **20-30% in cost**, mainly in reduced ingredient costs, but also in working capital demands related to importing products to Malawi.[3] Valid also argue that the SMS formulation can be considered non-inferior to standard RUTF in efficacy based on their most recent trial in Malawi.

However, WHO has not yet approved the use of non-dairy RUTF, and argues more and broader evidence is needed of non-inferiority. Similarly, the cost saving potential has not been fully validated outside of the Malawi environment.

While substantial investments have been made in alternative formulation R&D, the evidence base is not yet robust enough for decision-makers to scale-up (/approve) any recipes that are claiming strong gains in efficacy or cost

Source: 1. Stakeholder interview 2. Hendrixson et al, Treatment of SAM with oat or standard RUTF (2020) 3. Paper on Cost Effectiveness of SMS-RUTF (2020), **Valid** claims that they save **28.5%** in overall cost of ingredients, translating into reductions of **20 – 30%** in final product cost; others have argued that this analysis is not generalizable

Price reduction opportunities for alternative formulations are fairly modest through cheaper ingredients that replace dairy and peanuts

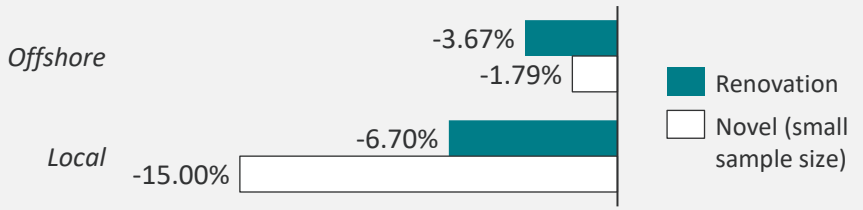
WHO's 2021 RUTF Guideline on dairy protein content in RUTF noted that no published trials have answered questions about cost-effectiveness; while UNICEF's data based on recent price revision of offers shows potential price reduction between 1.79% and 15% below standard RUTF.[1,2] The large bulk of bids were for renovation products, with <7% savings, lower for offshore producers.

Renovation category – cereals, legumes or grains as partial or full replacement to peanuts in the standard formulation, in addition to 50% proteins sourced from dairy. These products are compliant with 2007 UN Joint Statement, enabling UNICEF to procure.

Novel category – combination of cereals, legumes or grains in addition to added **amino acids** and/or possibly different levels of the **vitamins and minerals.**

Innovation category – combination of cereals, legumes, grains and **different sources of animal proteins** – such as fish, egg or insect proteins.

% price reduction offered by UNICEF RUTF suppliers (median)[2]



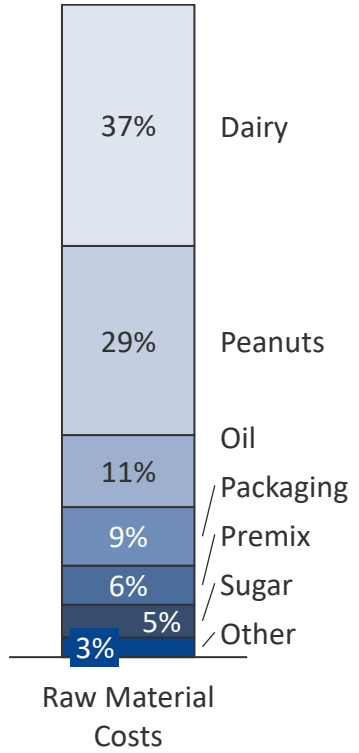
UNICEF explained in the WHO consultation meeting that locally produced alternative formulations show larger cost reduction potential because the local standard RUTF are on average more expensive

UNICEF data between 2015 – 2018 estimates that **RUTF ingredients** account **74%** of the total costs (incl raw material, production and profit)[1]

Reducing milk and peanut content could reduce the largest ingredient expense, though there is limited data on this for production at scale.

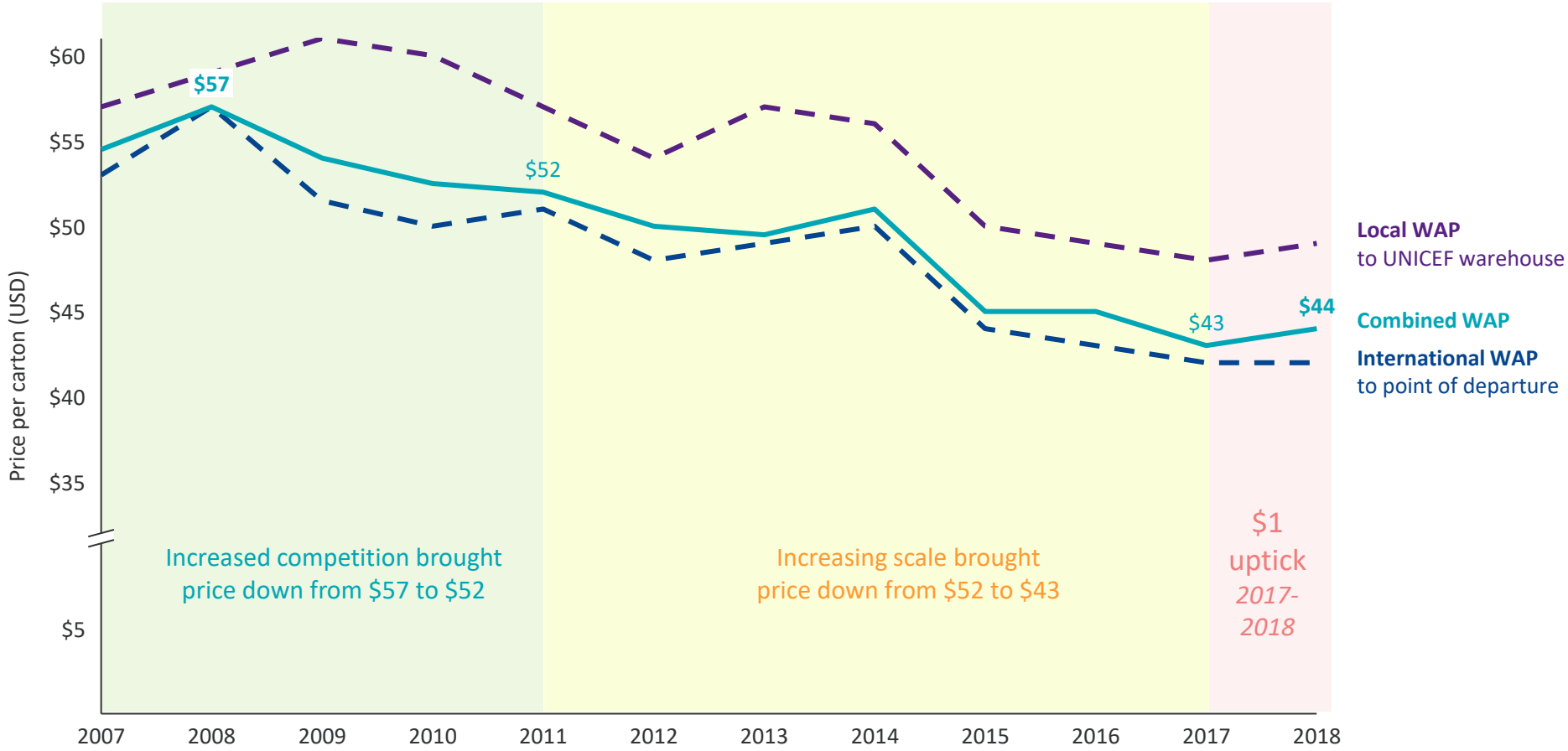
Initial supplier offers on renovation products (*left*) show small price reductions, with those **local suppliers who face high prices for high quality peanuts** standing to benefit most.

Saving potential could be higher for novel products (which are not yet approved by WHO), but fewer data points are available on the cost impact, and are controversial.



Source: 1. WHO guideline on dairy proteins in RUTF (2021) 2. Cost data shared by UNICEF in 2021 November WHO Technical Consultation meeting 3. **Valid** argue that they save **28.5%** in overall cost of ingredients, translating into reductions of **20 – 30%** in final product cost (Paper on Cost Effectiveness of SMS-RUTF, Valid, 2020) and that this is a higher cost savings even than the 15% price reduction offered to UNICEF; others have argued that this analysis of cost savings is not generalizable to a larger market impact, and there has not been the same 'revealed preference' cost data through specific tender bids for novel categories as for renovation.

With fairly fixed recipes, price gains have come via competition in first instance; with margins low, remaining gains seem to come from scale



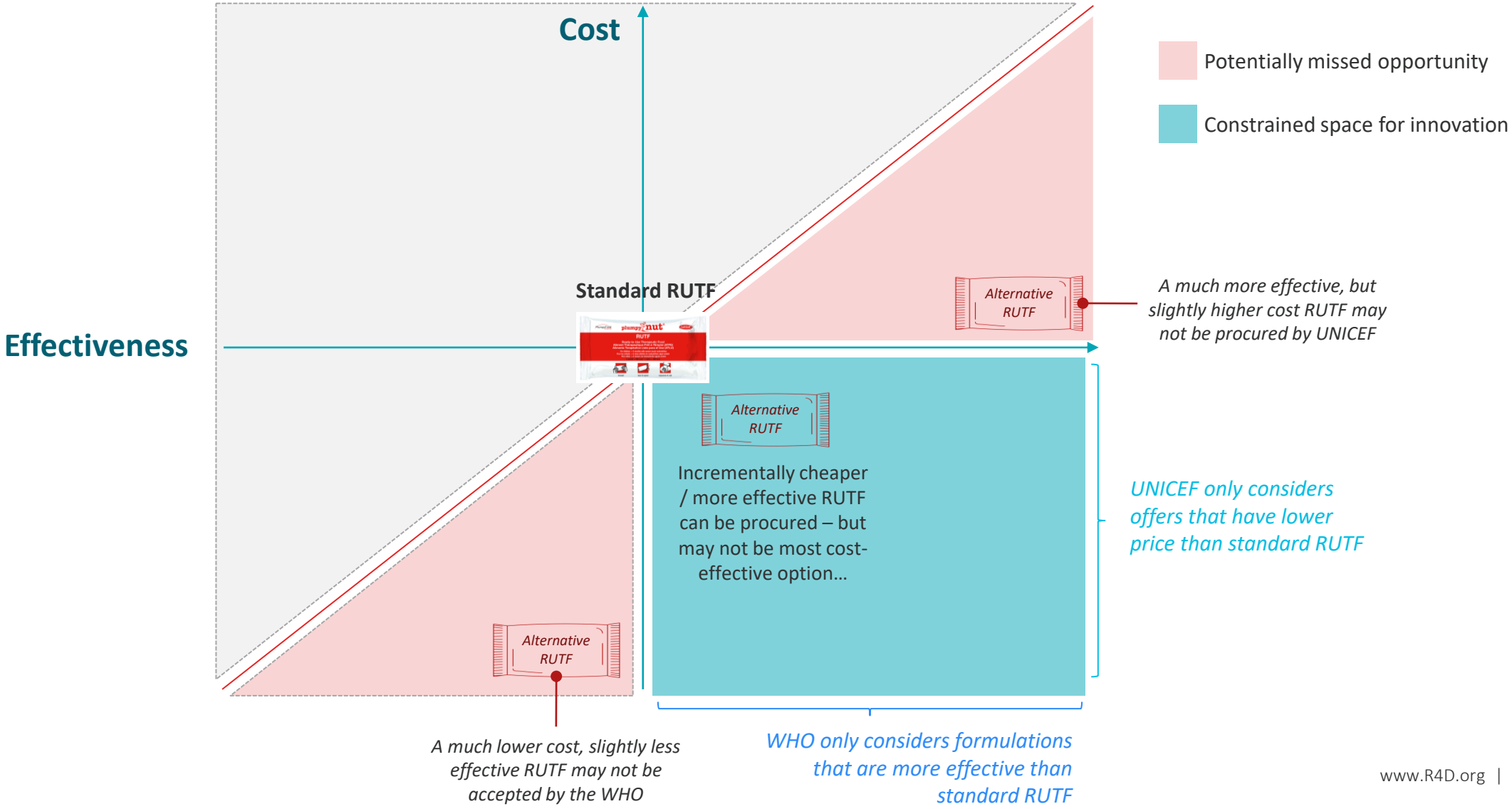
	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
# of Suppliers	1	2	8	6	14	14	11	13	12	11	11	12
Avg thousand MT/supplier	4.6	5.4	1.0	3.4	1.9	2.1	3.1	2.4	2.8	3	4.8	4

Note: Estimates inclusive of both country office and offshore LTAs; suppliers awarded in both agreements only counted once
Source: UNICEF SD, Market Update for RUTF and other LNS products ppt at pre-tender consultation (June 2018); published prices

As more alternative formulations become available, there may be fragmentation on the production, tendering and supply management of RUTF

	Fragmentation Risks	Mitigating Factors
Supply	Alternative formulations may lead to further supply-side fragmentation, challenges for production at scale when **supplying multiple products.**	This may be mitigated if suppliers continue to offer only one RUTF product and replace the standard recipe with the alternative one.
Demand	For UNICEF or other donors, there will be **more complicated tendering and management** of products that considers different country preferences and where different formulations are no longer considered fungible.	Mitigating options can include not deferring to local preferences. However, as UNICEF procurement already tolerates some fragmentation and higher prices for local producers in select markets, the impact of product variation may be less than in a more pure pooled procurement model.
Financing	In many countries, RUTF have relied on a single source of financing (typically donors channeled via UNICEF). Unlike with supply and demand, financing is **not likely to be more fragmented by AFs** unless in a given geography there are multiple funders of RUTFs and they take firm stances on supporting different alternative formulations.	Fragmentation can be avoided if stakeholders globally agree to support a subset of recipes interchangeably, or so long as all RUTF funders in a given country are willing to coalesce on a single product to finance.

WHO approval and UNICEF procurement policies for RUTF substantially narrow the space for innovation, and could disqualify some cost-effective options



3

Demand, Procurement, Supply Base

Recommendations

With UNICEF's role, the DEMAND, PROCUREMENT and SUPPLY BASE questions are largely intertwined; there may be some small gains to be made in efficient supply and price reduction, particularly if 'local production' is considered a means to an end rather than an end in itself.

A The supply base is heavily shaped by UNICEF, and does not fully optimize for availability and affordability of RUTF. We estimate that existing financial resources could increase RUTF volumes by 3% or more if UNICEF chose to **procure more from suppliers producing at greater scale and lower cost.** We find many arguments for local production to be overstated, and expect that most benefits could be more achieved **with focus on regional suppliers**

B In general, there may be **small opportunities for more efficient production** and **cost reduction**; however, it remains debatable whether investments in these would have a positive return. A possible exception is the **reduction or elimination of tariffs when importing ingredients or exporting products to neighboring countries**

C As country ownership grows, **efforts in strengthening capacity are needed to better forecast demand and ensure inventory data visibility** for better management of RUTF. To address **supply chain leakage** within countries, we believe that **more investigation is needed** to design solutions, and **integration into national health supply chains has also been proposed as one approach**. But the value of that approach will vary from country to country given differing strengths of existing supply chains

	Immediate term actions		Longer term actions
A	**Procure from suppliers producing at greater scale and lower cost, potentially with more of a consolidated regional focus**	C	**Strengthen national level capacity to manage RUTF and support national efforts to investigate and address supply-chain leakage**
B	**(Advocate to) reduce or eliminate tariffs when importing RUTF ingredients or exporting products to neighboring countries**		Continue to explore whether new contracting terms, financing, and/or order predictability options might allow suppliers to cut costs
			Consider case-by-case whether investments in establishing quality labs, or technical assistance, provide positive returns

Bold = priority actions

Demand, Procurement, Supply Base

Key findings informing our recommendations

Key facts

1. **Current supply base is fragmented and includes some small-scale players with higher prices**
While majority of supply comes from competitively priced suppliers, there are some producers selling at lower scale and higher prices. For this reason the average WAP is above the international WAP. Removing high-cost producers could reduce the market average price by 3% or more.

2. **Local production might not achieve expected benefits that would justify a higher price in procurement**
Currently, many local producers are heavily reliant on imported ingredients, greatly limiting hoped-for benefits of local production, such as reduced carbon footprint, improved lead times, greater robustness to supply disruption, or stimulation of local economy. Evidence is mixed on whether local production would inspire domestic financing.

3. **Price reduction opportunities from production efficiencies appear modest, and may not justify costs involved**
A few ideas have been explored with experts to **improve production efficiencies**, such as via volume guarantees, addressing challenges with access to capital, quicker or advanced payment, or Forex availability. While potentially beneficial to suppliers, partners including UNICEF have not yet assessed any idea to have sufficient ROI to be taken on. Experts have also suggested reassessing the stringent input and output requirements from the procurer; but opinions vary whether the current requirements are appropriately safety conscious, or inappropriately risk averse and costly.

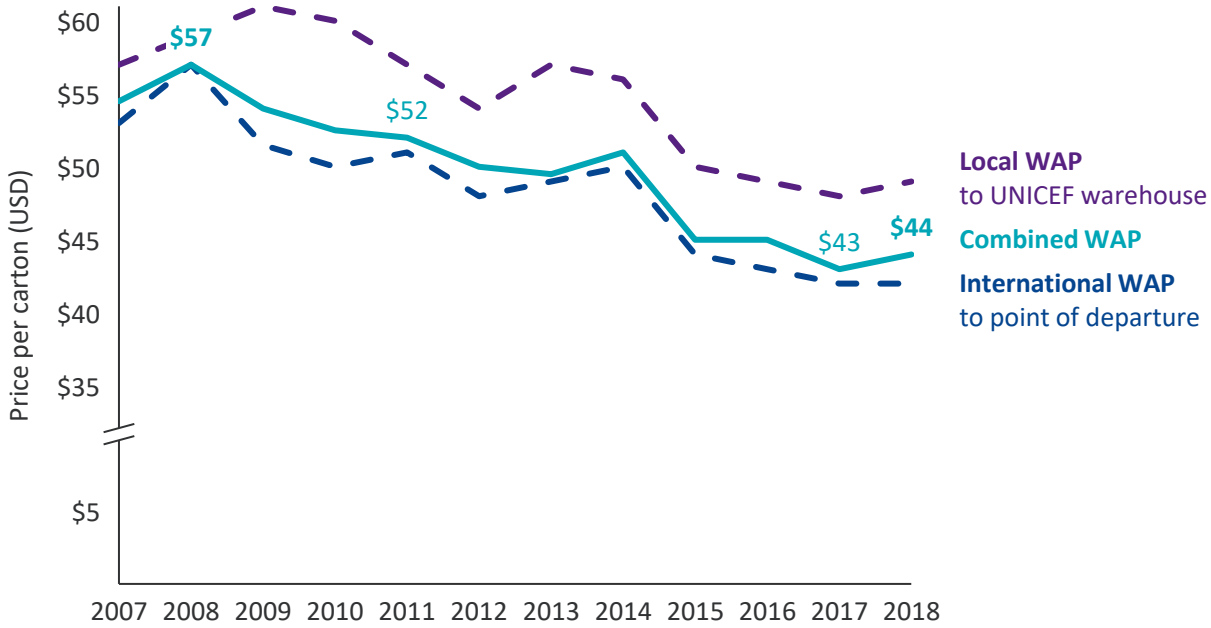
4. **Removing or reducing tariffs for imported ingredients is more promising for competitiveness**
Tax rates on imported goods could account for 6-35% of total input costs while imported RUTFs typically enjoy a reduced tax or tax-exempt status (at least theoretically). As local manufacturers rely heavily on imported ingredients for RUTF, reducing tariffs would allow them to be more cost competitive (though also reducing government revenue)

5. **Potential to bring major commercial food companies into the market is low**
Some have hoped that attracting large food companies to the RUTF market could bring scale, technology and greater production efficiencies. However, food companies have expressed concerns with limited market size, low margins and complexities of the RUTF market as a commercial venture. There may still be potential for technical assistance or capital investments in production capacity via CSR programs.

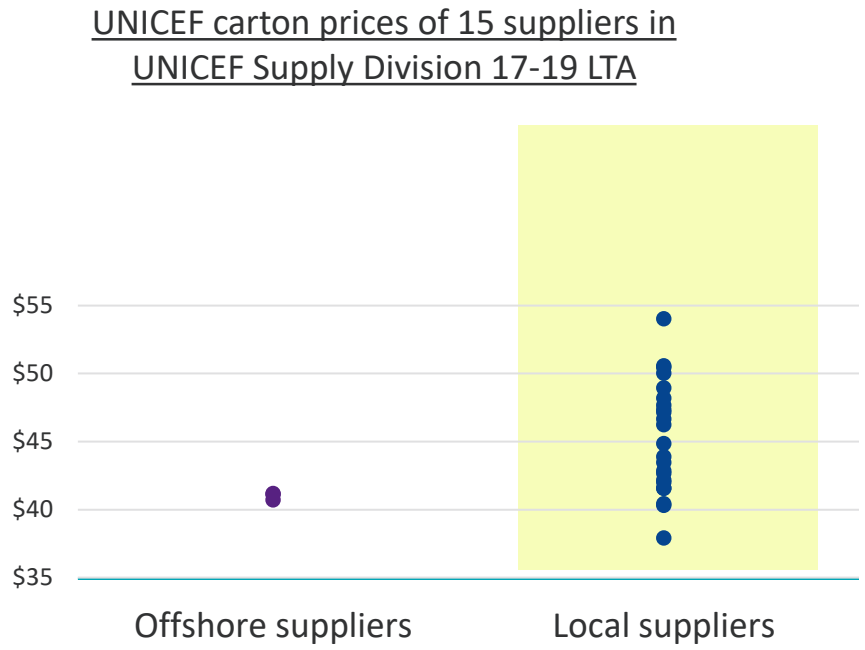
6. **Extent of (and solutions for) supply chain leakage are not well understood**
Leakage in the supply chain is often mentioned anecdotally, but very little hard data is available (particularly) for recent years. Some informants believe that data may exist in confidential internal reports but is not shared publicly out of a concern that this would undermine resource mobilization efforts. Integrating RUTF into health inventory management systems has been shown in some settings to reduce loss at lower levels of the system. Local production has been posited as an opportunity to for clinics to pick up directly from manufacturer to reduce upstream loss.

Despite many local suppliers having competitive prices, range of high-cost suppliers keep Local WAP significantly above International WAP

UNICEF local Weighted Average Price has remained higher than International WAP…



…reflecting the much wider spread of local supplier prices in awarded LTAs

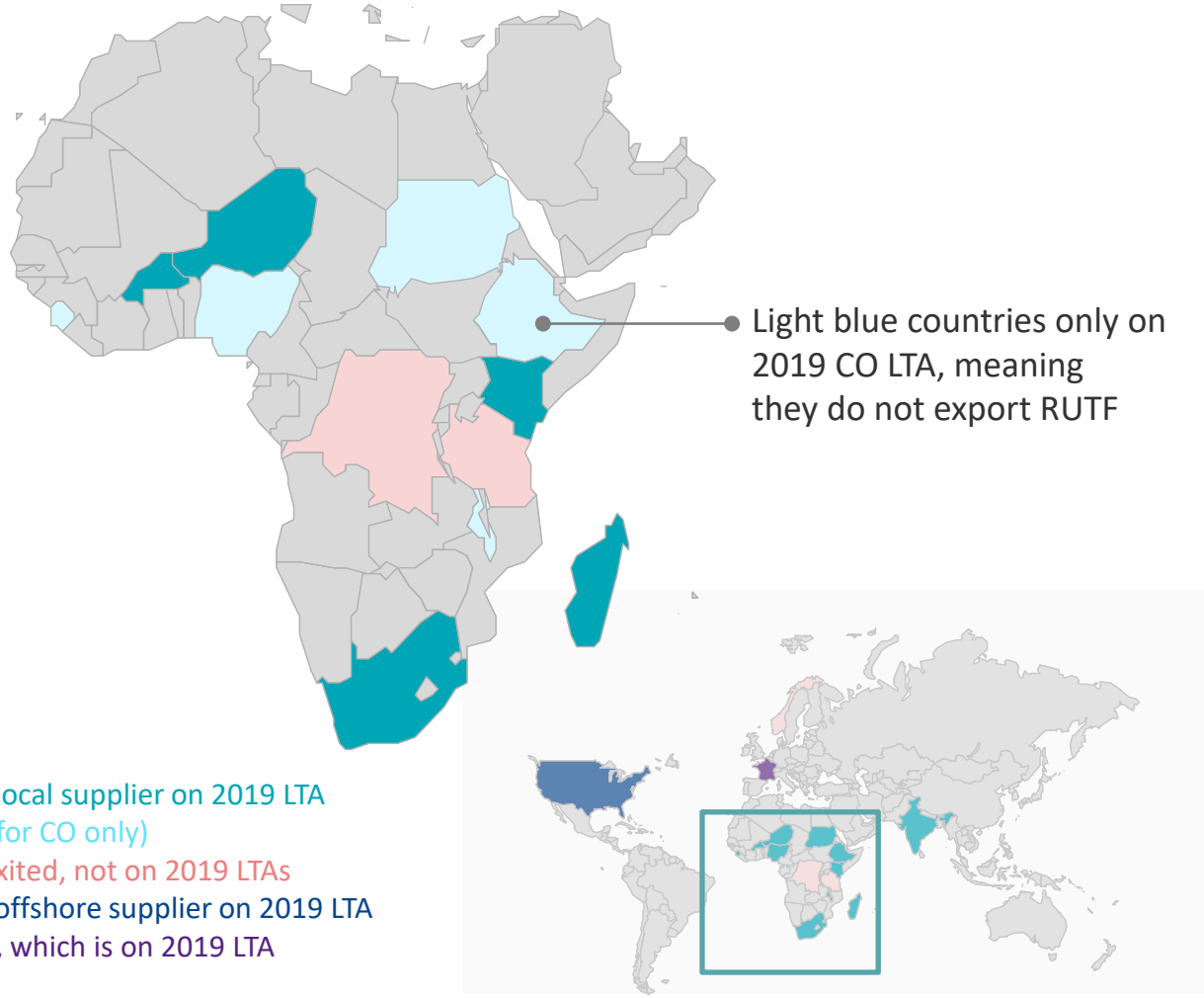


Note: Estimates inclusive of both country office and offshore LTAs; suppliers awarded in both agreements only counted once
Source: UNICEF SD, Market Update for RUTF and other LNS products ppt at pre-tender consultation (June 2018); published prices

Capacity aside, the geographic footprint of the African supply base is not optimized to meet RUTF demands via regional export

Focus: African supplier footprint

- "These manufacturers popped up by themselves in the beginning. Clearly the **original aim was to put suppliers in high burden countries** where **donor financing is available** for buying product; secondly, there should be **capacity to export into the surrounding countries** (infrastructure, roads, etc) – ideally not a land-locked country as they depend on the import of raw materials. We definitely would not have these manufacturers in many of the places we have them now." – Expert interview
- 5 of 10 African countries with a supplier on the 2019 LTA are only on the CO LTA, which suggests that few are used for regional export
- Aside from being landlocked and lacking shipping capacity, many countries also lack broader enabling environments for business, such as affordable financing, export processing zones, and favorable taxes

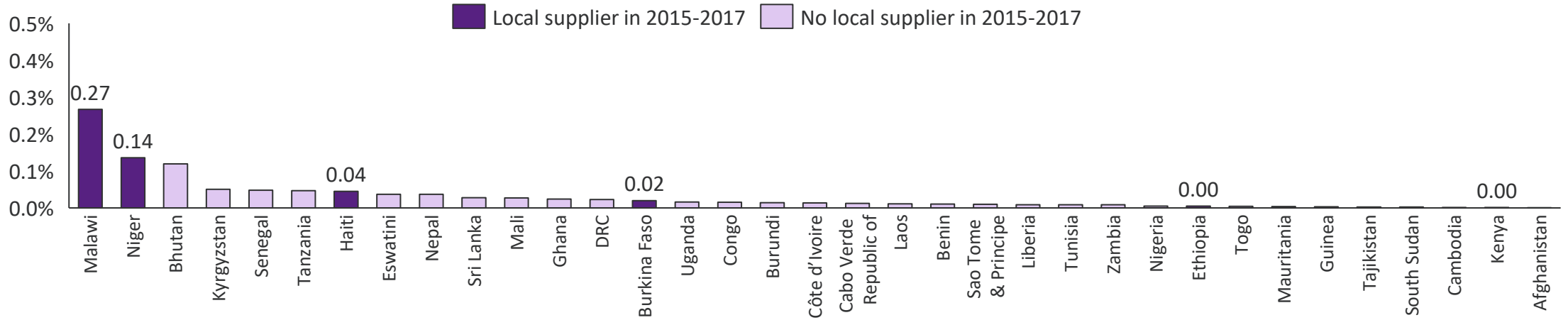


Benefits presented for local supply are difficult to value, may warrant scrutiny on case-by-case basis

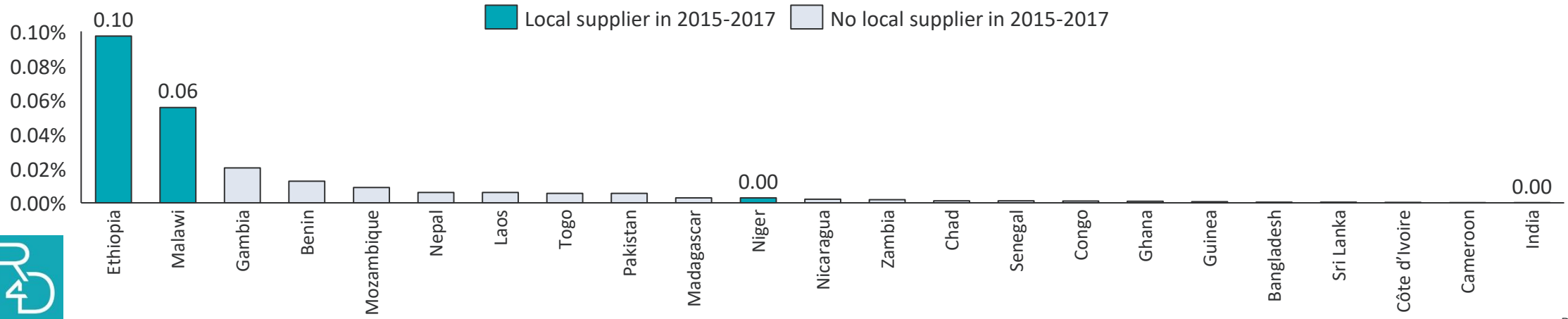
Supporting rationale for local supply	Open questions on impact
1 **Improve local availability, quicker action in emergencies**	▪ Limited evidence on emergency response that can be attributed to local suppliers ▪ While locally produced product saves time in transit from factory to final destination, this may be more than offset by time from order to production being completed. Local suppliers not likely to have large buffer stock of products (or ingredients) on hand.
2 **Lower shipping, reduced carbon footprint**	▪ Due to lack of local infrastructure and high-quality requirements, some local suppliers are still required to import multiple inputs globally, as well as ship to laboratories for quality control. Total carbon footprint for local supply (including carbon footprint associated with importing ingredients, electricity use in production, etc) may be higher rather than lower in many cases.
3 **Contribution to local economy**	▪ Economic contribution from production is unlikely to be substantial, particularly in countries where majority of inputs are imported. Labor cost is small percentage of overall product value, and if ingredients are imported none of the ingredient value is retained in local economy. ▪ Unclear how to assess benefits of contributing to local economy in one country vs another (if the counterfactual option is import from another country in the region rather than from HIC).
4 **Local product may meet local tastes and improve acceptability / uptake / adherence**	▪ Current formulation has been highly standardized, not customized for local taste. ▪ Acceptability of product generally not a major issue in Africa, so limited room for improving acceptability by local producers in Africa.
5 **Inspires domestic financing, government commitment**	▪ ***Difficult to evaluate, but seems strongest argument.*** Some correlation between local supply and measures of domestic financial support for nutrition, but doesn't necessarily imply causality in that direction. ▪ Likely varies by country, in which case support for expensive local company could be withdrawn if government does not make financial contribution to procurement.

While causality could flow both ways, some positive correlation between local supplier presence & domestic nutrition funding metrics

Countries ranked by average domestic government expenditure on nutrition deficiency as % of GDP (2015-17)



Countries ranked by total ODA loan spend on basic nutrition as a % of total ODA loans (2015-17)



Top chart source: WHO System of Health Accounts data from 2015-2017
Bottom chart source: OECD Creditor Reporting System (CRS) data from 2015-2017

Note: it is not possible in these data sources to disaggregate spending specifically on RUTF/wasting at country level; these trends therefore require further validation

Local Production: Experiences from Tanzania and Ethiopia

Local production models may be reliant on ongoing support from Governments, RUTF funders and partners (i.e., UNICEF) to maintain viability

Enabling and Inhibiting Factors

	Power Foods, TANZANIA	Hilina Enriched Foods, ETHIOPIA
Overview	▪ In 2010, Power Foods, a small-scale food producer specializing in fortified flour began producing RUTF after an initial infusion of capital. Despite this, the unsustainable business model, questions about quality, coupled with lack of support from GoT and other partners eventually led to the company's exit in 2014.	▪ Hilina began manufacturing RUTF and RUSF in 2006/2007 as a Nutriset franchisee and remains Ethiopia's sole producer with production targeted for the local market. The company doesn't operate at full capacity and faces challenges with market competitiveness, losing previous held contracts with USAID due to the high cost of production. Has relied on UNICEF's willingness to pay a modest premium for local supply.
Business environment A	▪ **Export tax exemption** Despite the enthusiasm for local production for the local market, all of the RUTF produced in Tanzania was earmarked for export to benefit from export tax exemption ▪ **Limited IMAM service coverage** in Tanzania limited demand for the product. ▪ **Limited support from Govt and external partners**	▪ **Price preference** UNICEF's 10% preference for local suppliers (landed cost) and Hilina's lead time advantage on modest size orders helped the company win tenders despite higher prices. ▪ (*previously in place)* **Import tax exemption** on raw materials for RUTF[1] ▪ **Unpredictable demand:** 95% of their product is for UNICEF and WFP; the emergency nature of orders and limited demand communication from their client inhibits efficient production planning for RUTF
Regulatory environment B	▪ **Registration as a medicine** allowed for RUTF inclusion in the EML and distribution through pharmacies reportedly reducing misuse ▪ **Stringent quality requirements** ~75% of raw material inputs were imported and sourced inefficiently from multiple suppliers leading to higher costs	▪ **Local, accredited food lab** Bless Agri, based in Addis Ababa, ensures quality product is released to the market; its proximity to Hilina facilitates faster turnaround time for results ▪ **Stringent quality requirements** ~90% of the raw materials (e.g., peanut, milk, palm oil and packaging materials) are imported
Access to capital C	▪ **Seed start-up capital**: Power Foods received a $1M grant from a private donor to help launch local RUTF production	▪ **Inadequate access to capital and high interest rates** pose challenges to overall production planning and the timely sourcing of raw materials ▪ **Forex shortage** Shortage of forex to import raw material

Teal text= enabling factor; **Red text**=inhibiting factor

1. Import taxes are being reestablished for these raw materials in Ethiopia to protect local producers

Key Considerations for Local Production

According to UNICEF, there is sufficient manufacturing capacity to meet globally funded demand for RUTF. Therefore, local production should be considered carefully by countries and potential producers, as the current largest funder (UNICEF) expects that in this maturing market, local suppliers should be price competitive (landed cost) with large off-shore producers. This might not always be feasible through small-scale production or when the business environment is not an enabling one. Conversely, local production is more likely to be successful where economies of scale are more achievable-- if the supplier can supply more than 1 market and/or produce a broader set of products. On a country by country basis, some of the points below should be considered where relevant and deemed beneficial.

Business environment A

Assess the market viability: estimate demand, availability of financing for procurement, interest from a major purchaser

Include (time-bound) preferences for local manufacturers in international and national procurement policies, to support startup phase and allow supplier a reasonable time to reach competitive standard

Reduce/eliminate tariffs for raw material import or export of finished product to neighboring countries. *Tax rates on imported goods can account for 6-35% of total input costs[1] while imported RUTFs are typically tax-exempt*

Regulatory environment B

Improve national nutritional product quality testing capacity. *Many LPs must ship samples overseas for quality testing due to limited capacity of national laboratories leading to delays and extra costs.*

Support local input producers to reach required quality standards. *While stringent input regulations are likely to remain in place, RUTF producers may be able to switch from imported to local inputs if quality is raised (likely only if this is line with a broader agriculture strategy)*

Access to capital C

Provide access to seed capital at favorable rates to reflect social value of RUTF production

External procurers to consider advance payment for RUTF in hard cash to overcome forex, working capital and order predictability challenges, enabling LPs to more efficiently plan production and procurement of raw materials

Source:1. Segre, J. et al. Local versus offshore production of ready-to-use therapeutic foods and small quantity lipid-based nutrient supplements

There may be small opportunities for more efficient production and cost reduction; however, it remains debatable whether investments in these would have a positive return

A few cost reduction ideas besides local production and alternative formulations have been mentioned…

- Volume guarantees
- Access to capital
- Quicker or advanced payment
- Forex availability
- Market shaping for ingredients (e.g. milk or premix)

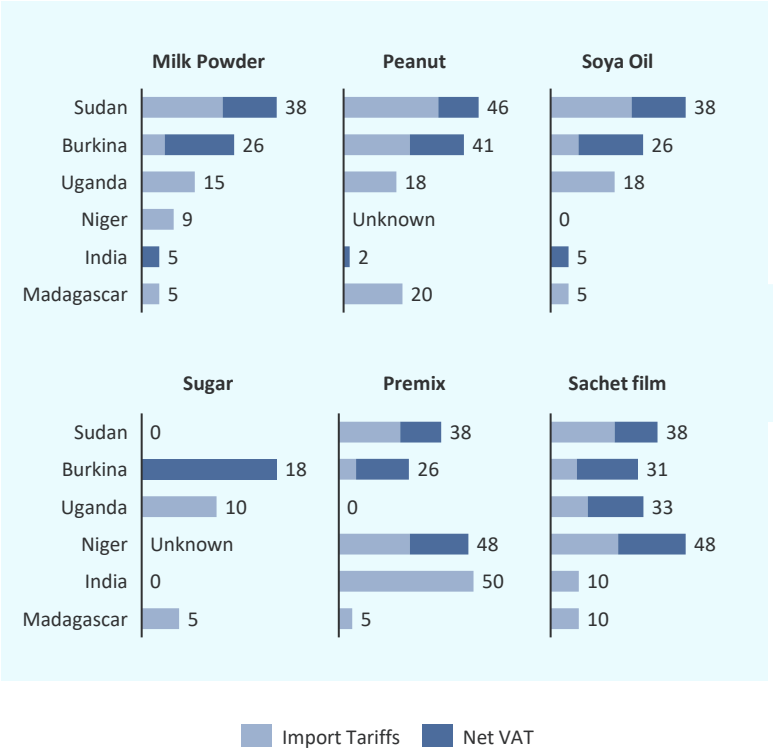
However, internal ROI and other assessment of impacts have not (yet) shown sufficient return to justify required investments

Reduction or elimination of tariffs for imported ingredients might be promising…

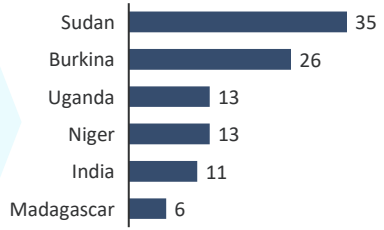
- UNICEF can import RUTF free of import duties and value added tax (VAT)
- However, local manufacturers rely heavily on imported ingredients, with the VAT, the tax rates could account for **6-35%** of total input costs

> Tax exemptions from both import duties and VAT would encourage local production to be more cost competitive[1]

Approximate taxes (%) by input and country[2]



Approximate total taxes if all inputs are imported (as % of total input costs)



Source: 1. Segrè et al, Local versus offshore production of ready-to-use therapeutic foods and small quantity lipid-based nutrient supplements (2017) 2. Plumpy'Field Network Approximations – tax rates are theoretical and can be specific to a given country. Formulation data from based on Beesabathuni & Natchu, 2010

While international food companies may be able make a CSR contribution, it is unlikely that they will bring their muscle to the market in a commercial venture

Potential advantages of working with food companies…

- Scale up of production/savings from economies of scale
- Improved production efficiencies
- Technology

However, food companies have generally expressed concerns due to[1] …

- Limited market size
- Low profit margins (5.5%)[2]
- Complexities of the RUTF market as a commercial venture

Alternative opportunities for contributions by food companies

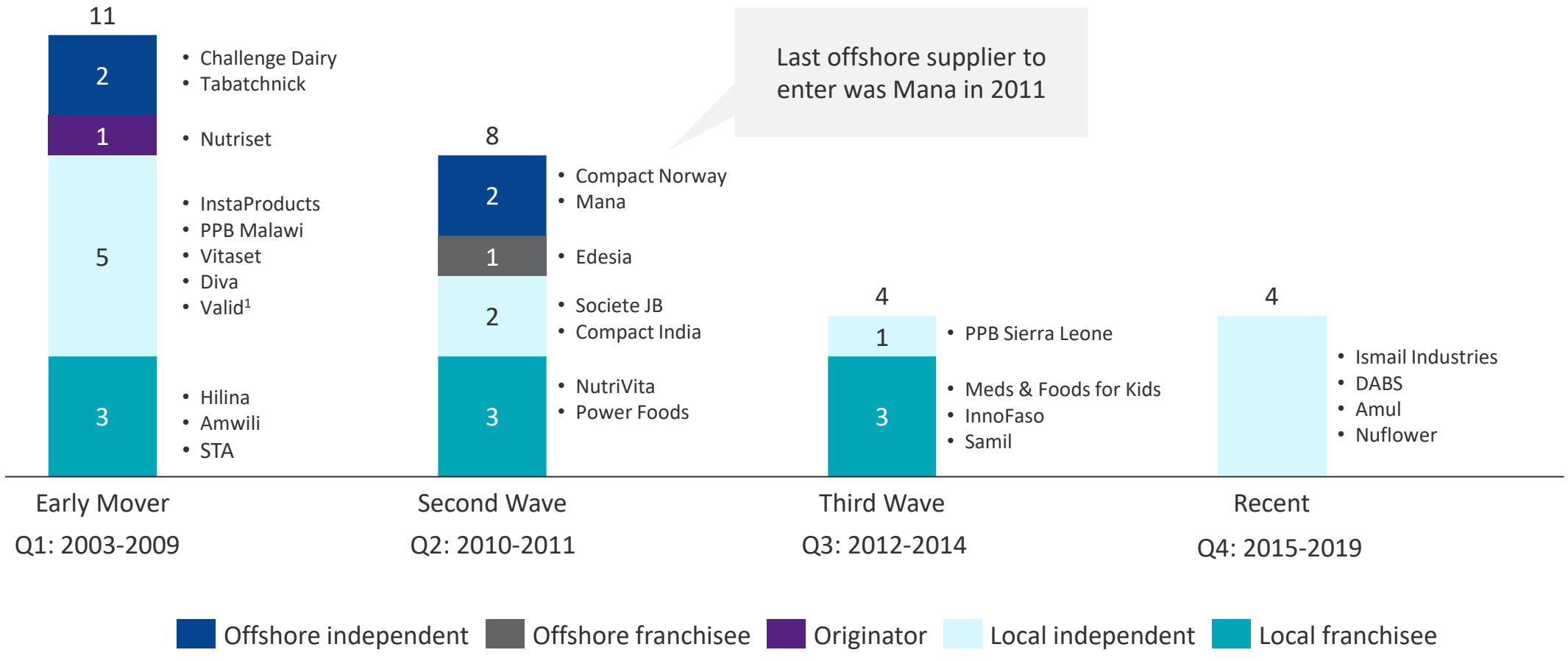
Despite limited interest for food companies to enter market as a commercial venture, partners have shared some examples of potential alternative contributions…

- Partnerships in setting up the factory
- Direct donations of RUTF
- Other **technical assistance** or **capital investments** in production capacity via CSR programs:
  - Running part of the value chain in production
  - Supporting local manufacturers in sourcing, production or distribution

Source: 1. Stakeholder interviews 2. UNICEF presentation at 2021 Nov WHO Technical Consultation

Limited market entry from new players is consistent with a view that RUTF is not an enticing market

All suppliers by market entry timing (proxied by earliest of first UNICEF offshore/CO LTA won, 2003-2019)



Note: Grouped by quartile of all LTA suppliers' first year awarded

1. Valid Nutrition was founded in 2005 but did not win an offshore LTA until 2015, CO LTA in 2010

Despite significant data limitations on stock-outs, diverse sources suggest supply chain leakage is a contributing factor for RUTF shortages

Stockout data from 9 UNICEF Bottleneck Analyses[1]

Year	Country	% HF with stockouts	Root causes of stock out cited
2014	**Malawi**	64%	Forecasting, inventory management, ownership
2014	**Tanzania**	85%	Capacity
2016	**Pakistan**	12%	Funding, inventory management
2017	**Afghanistan**	36%	Capacity, distribution, ownership
2017	**Burkina Faso**	4%	Funding, inventory management, misuse
2018	**Chad**	82%	Inventory management, misuse
2018	**Mauritania**	6%	*Not seen as a bottleneck*
2019	**Somalia**	44%	Capacity, forecasting, inventory management
2019	**Philippines**	23%	Capacity, distribution, inventory management

Heard from key informants and studies[2]

ENN 2020 RUTF Scoping Study

"A rapid assessment among another five INGOs active in CMAM programming in multiple countries found all experienced significant RUTF shortages in 2018."

"Most agencies do not routinely gather data on stockouts; it has become 'the norm'. Facilities and INGOs are rarely alerted to impending stockouts."

Global experts

"Nobody talks about the leakage. It's just one of those things that's hidden, not reported - up to 20% disappears. Stock-outs are a massive problem for NGOs - massive."

"Half of surveyed stakeholders in our SAM/MAM mapping in East and West Africa reported problems with the RUTF/RUSF supply chain." (Brown et al, 2019)

1. UNICEF Bottleneck Analyses (BNAs) 2014-2019 2. Stakeholder interviews and ENN 2020 RUTF Scoping Study

While more investigation is needed to address supply chain leakage, likely causes include fragmented ownership, lack of accountability, and limited national supply chain capacity

Ownership across the supply chain	Central Storage	Distribution to District	District Storage	Distribution to Health Facility	Health Facility Storage	Distribution to Last Mile
Niger	*UNICEF*	*UNICEF*	*NGO*	*NGO*	*NGO*	*NGO*
Nigeria	*UNICEF*	*UNICEF*	*Private Sector*	*NGO*	*NGO*	*NGO*
Kenya	*Private Sector*	*Private Sector*	*Govt*	*Govt*	*Govt*	*Govt*
Cameroon	*UNICEF*	*UNICEF*	*UNICEF*	*UNICEF*	*Govt*	*Govt*

	Unique features of RUTF supply chain…	***…lead to weaknesses that have impact on availability***
Storage	RUTF is a bulky, high volume product that attracts pests and requires large storage capacity	➢ Limited storage capacity constrains ability to maintain adequate buffer stock ➢ Poor storage can lead to leakage and product damage
Perception	RUTF seen as an expensive, complicated product to be managed by partners and remain separate from other medicines and health products	➢ Limited accountability among and between different stakeholders ➢ Unclear management structure for monitoring and reporting
Inventory management	RUTF is often managed outside of national supply LMIS and by nutrition staff lacking adequate logistics and stock training	➢ Mismanagement, stockouts, leakage, underreporting ➢ Stockout data is limited, but a review of 9 country BNAs found stockouts to be a common barrier, with stockouts ranging from 6-85%

Regulation

Recommendations

Our proposed actions related to REGULATION and QUALITY ASSURANCE are potentially important for a long term, sustainable, country-driven market - even if they are unlikely to have a major short-term impact on availability and affordability of RUTF.

A Product innovation for RUTFs may be enhanced by **greater clarity, consensus and trust/buy-in for the regulatory standards and processes** governing product approval and uptake for new products. Greater clarity, consensus and trust/buy-in would allow more efficient targeting of innovation efforts and improve the environment for investments.

B With UNICEF and NGOs procuring majority of RUTFs, **national regulatory framework updates** are likely not a major short-term binding constraint; however, country stakeholders should **look at where changes are needed** to move towards a more localized approach in the long run (e.g. classification as food/meds and supplier registration requirements). Adding RUTF to relevant lists of essential products may also be beneficial in some countries.

C In the long run, **independent quality assurance mechanisms will need to continue to evolve** from the current model that depends heavily on UNICEF (and is therefore influenced by UNICEF's procurement priorities). In the short run this is not a major market challenge, but if the market evolves towards a wider set of procurers including more national governments, appropriate QA at local, regional or global level will be increasingly important; potentially for not only RUTF but for a broader set of food/nutrition products.

	Immediate term actions	Longer term actions
A	**Continue to build clarity and buy-in for standards and processes governing product approval and uptake,** e.g. through collaborative processes to discuss and refine primary vs secondary outcomes for RUTF; continuing effort to ensure expectations are clear on processes and that they are then seen to be followed through	B **National stakeholders to consider (at relevant time) where national regulatory framework changes are needed for long term** C **Monitor any issues created by current QA architecture and investigate desirability of alternative approaches for this product class at global, regional or national levels**

Bold = priority actions

Regulation

Key findings informing our recommendations

Key facts

1 **Challenges around appropriate outcomes and prioritizing them**

While there is broad consensus that recovering from SAM and reducing mortality are the key goals for RUTF, there is not universal approval for the full set of outcomes used in recent assessments. Some experts argue that RUTF efficacy should be judged primarily on recovery and mortality, with other outcomes considered as purely secondary; but recent practice seems to indicate that RUTFs must meet/exceed results on a broader set of outcomes including rate of weight gain (which is not universally accepted as appropriate). Some argue more attention should be paid to relapse and cognitive impacts, but these are not measured in most trials.

2 **Perceived inconsistencies in WHO evidence review has raised concerns with process**

Some informants have raised concerns about the fairness of WHO processes, and suggested that this undermines willingness of investors to support the market. As a recent example, in a recent review of RUTF with <50% protein from milk, WHO's announcements created an expectation that effectiveness, preference/acceptability and cost-effectiveness would all be examined. However, cost-effectiveness was not reviewed, with some informants publicly disputing the explanations given for this decision by WHO. To the extent there is loss of confidence in the process, this may make investing in the space less attractive.

3 **National regulatory systems have not had to prioritize RUTF in the past**

With the majority of RUTF being procured by UNICEF and other donors, countries still need to build a regulatory framework for RUTF. As countries take on more of a role in managing, deploying, funding and/or procuring RUTF, some short-term regulatory updates need to be considered, such as supplier registration, quality assurance, and inclusion in an essential product list (EML or other, as appropriate) that may be a prerequisite for domestic resource mobilization or inclusion in national supply management systems

4 **Concerns have been raised on UNICEF's de facto role as QA leader for the market**

The market current largely relies on UNICEF for Quality Assurance of RUTF suppliers, but UNICEF is not independent - it has its own procurement priorities and may not choose to inspect suppliers from whom they do not plan to procure, which could create a barrier to entry in the broader market. This regulatory set up may not be a major binding constraint today (in itself, being quality assured will be of limited benefit to a supplier today if UNICEF is not procuring from them), but would be more distorting in the future if there is more diversified procurement. WHO Prequalification is a possible option, but has not been used for RUTF in the past and is considered burdensome for smaller providers.

5 **While Nutriset patent may have been a market constraint in the past, this should no longer be an issue**

Nutriset's patent is cited as a contributor to past lack of competition, but appears now to have expired

Lack of consensus around appropriate outcomes and prioritization between them has resulted in different outcomes measured across studies and affects buy-in for WHO's recent assessment

Possible Outcomes

Covered in WHO's recent assessment of dairy content[1]	Weight Gain	Rate of weight gain until recovery
	Recovery	Percentage of children cured; time to recovery; sustained recovery
	Mortality	Percentage of children who died
	Relapse	Percentage of children who re-enrolled after being cured
	Anthropometry	Weight-for-height or -length; MUAC; Weight-for-age; Height- or length-for-age
	Cognitive Development	

Key Notes

- Some experts believe that **weight gain** is a proxy, not a health outcome. While **"rate of weight gain"** was measured by all 6 studies WHO assessed, there's also argument around **"weight gain"** being potentially more important than "rate of weight gain"
- **Recovery rates** were measured in 4 out of 6 studies WHO assessed, while none had included **sustained recovery**, which is increasingly important
- Despite being included in WHO's interested outcome, none of the studies had covered **relapse**
- There are some concerns that current trials and tools are not designed to capture the full impact on child development (e.g. **cognitive development**) or underlying physiology (e.g. **gut microbiome**)
- **Other outcomes:** Valid's soya-maize-sorghum (SMS) formulation claims to **treat anemia and restore iron in the body**. However, there is potentially interaction between iron restoration and slower rate of weight gain, which leads to superiority in anemia treatment but inferiority in weight gain in their studies[2]

Source: 1. WHO guideline on dairy proteins in RUTF (2021) 2. Valid, Paper on Cost Effectiveness of SMS-RUTF (2020)

Perceived inconsistencies in WHO evidence review for reduced dairy content has raised concerns with process, which may make investments in RUTF less attractive

WHO called for proposals to compare standard RUTF and AFs with <50% dairy content in terms of …

1. Efficacy, effectiveness, and safety
2. Values and preferences (cultural, religious, etc), inter/intra-household sharing, acceptability, adherence, equity, feasibility, accessibility, and sustainability
3. Cost of production (ingredients, quality control), cost per death averted, cost per DALY averted, as well as the cost-effectiveness in different settings

However, only **effectiveness and preference** studies were examined, and the WHO claimed that **there was no published trials** for cost-effectiveness.

INSIDE DEVELOPMENT | FUTURE OF FOOD SYSTEMS

Despite pressure, WHO review keeps status quo malnutrition treatment

By *Teresa Welsh* // *19 March 2021*

Global Health | Research | Agriculture & Rural Development | WHO

A ready-to-use therapeutic food packet. Photo by: Mulugeta Ayene / UNICEF Ethiopia / CC BY-NC-ND

As the World Health Organization prepares to release a review of its guidelines for ready-to-use therapeutic foods, disputes over existing research, data, and metrics in determining the effectiveness of alternative RUTF formulas threaten to prevent progress in increasing treatment for severe acute malnutrition, or SAM, which kills an estimated 1 million children under 5 each year.

> *Cost is important, but it's also the effectiveness which is important. So there's no point in having a cheap product … if it's not effective in terms of recovery of children.*
>
> — WHO[2]

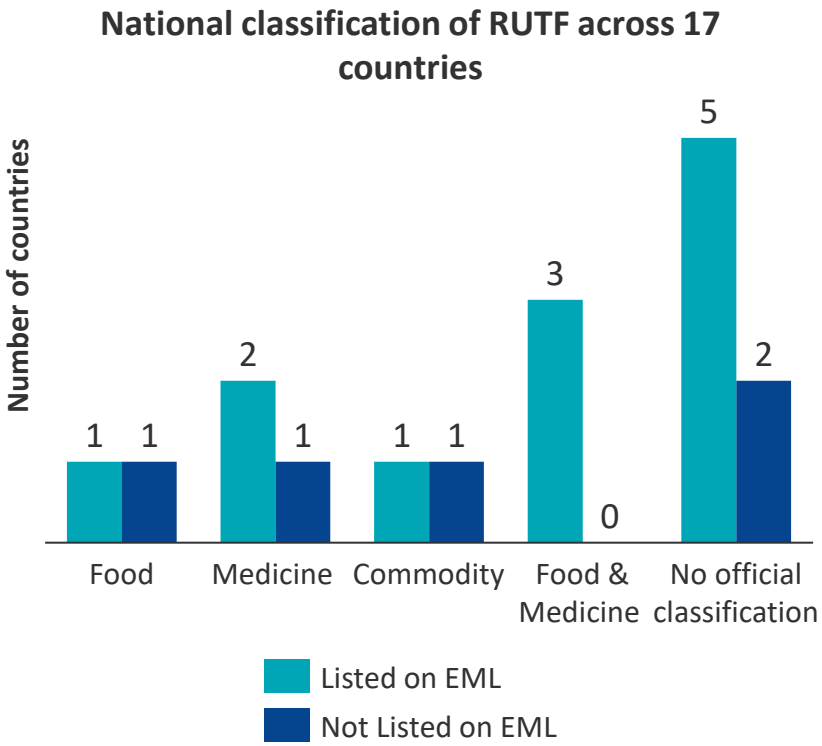
> *It is an absolute scandal…that the WHO has organised a review process that has not enabled a fair and accurate assessment of SMS-RUTF… this will fuel skepticism about the aid community and set back any chance of meaningful investment from the private sector*— Alternative RUTF producer[3]

To the extent that controversy reduces confidence in market rules/raises market risk profile, investment could suffer

Source: 1. WHO guideline on dairy proteins in RUTF (2021) 2. Devex, Despite pressure, WHO review keeps status quo malnutrition treatment (2021) 3. Valid Nutrition, Paper on Cost Effectiveness of SMS-RUTF (2020)

As countries take on more of a role in managing, deploying, funding and/or procuring RUTF, some short-term regulatory updates need to be considered…

National regulatory changes to consider…	Implications
Classification of RUTF as medicine or food	▪ RUTF should be recognized and prioritized as an essential nutrition commodity, however the appropriate classification is dependent on context ▪ The national classification can determine whether RUTF is included in the national supply chain or LMIS
Inclusion in the Essential Product List	▪ Inclusion of RUTF on the EML does not automatically translate to improved market outcomes and needs to be met with sufficient political will; in contexts with weak health systems inclusion on the EML may have little impact ▪ EML inclusion can be an important first step to integrate RUTF into the national supply chain/LMIS
National supply chain management system	▪ Integration of RUTF into the national supply chain management system could potentially increase national ownership, but the readiness of the national supply chain must be considered
Supplier registration requirements	▪ Country governments may need to strengthen/adapt their existing drug supplier registration and/or quality assurance system as they take on ownership in procurement of RUTF



Source: 1. Chatelet et al, Process and impact of integration of RUTF in national EML (2019) 2. ACF, RUTF and the WHO EML (2018)

In absence of supplier accreditation, procurers effectively run QA for the market – with UNICEF being the largest, most influential regulator

On UNICEF as de-facto regulator

- UNICEF readily acknowledges its intended role is not that of a regulator
- However, a long-standing patent and broader void in regulatory ownership has inhibited development of product specifications, which further inhibited development of broader standards and prequalification mechanisms
- As a result, UNICEF de-facto must invest in developing and publishing their own specifications to enable and procure high-quality supply[1]
- Given the insufficient formal regulation, and that UNICEF has neither the mandate nor capacity to prequalify product and suppliers globally, this is an area of broader market risk, and a potential barrier to entry

Outcomes	Potential issues sourced from interviews, reports
Affordability	**Right-sizing specification stringency to maintain quality** • Some have found UNICEF's technical specifications to be too tight (especially for aflatoxin levels), and inspections too frequent (qualified suppliers may be tested on both inputs and outputs) • Codex's ongoing work should provide more guidance on these technical specification
Availability	**UNICEF QA theoretically creates a barrier to entry for new suppliers (though this may not be a very binding constraint in practice)** • Some other procurers reportedly use UNICEF prequalification as a global standard (like WHO PQ) before considering procuring from them • Though UNICEF does publish specifications to invite suppliers to tender, there are some concerns that UNICEF is not as transparent or communicative about their assessments/rationale for prequalification as they could be • As UNICEF has neither the mandate nor capacity to prequalify product and suppliers globally, this may shut out certain suppliers from gaining necessary prequalification to compete. In particular, producers who are not a priority within UNICEF's procurement strategy are unlikely to be receive inspection quickly (or potentially ever). • However: as UNICEF's *procurement* is critical for a producer to play a major market role, UNICEF's QA role plays at most an incremental barrier to entry; an independently QA'ed producer from whom UNICEF did not want to procure would by definition have limited impact on the market.

> ***"UNICEF is not a normative organization and we do not want to be seen as one"***
>
> - UNICEF Requirements for RUTF Manufacturers presentation (2010)

1. UNICEF's pre-contract assessment includes: QA Center approves manufacturing sites; assessment of local regulatory environment, factor in prior UNICEF experience; regular GMP inspection by UNICEF (15% fail rate from 2003-2010); similar process for sub-contractor approval. Ongoing assessment includes: Pre-delivery inspections, review of packing list, receive Certificate of Analysis, random batch analysis (includes microbiological and analytical testing, aflatoxin testing)

Nutriset's patent has restricted competition on the original formulation and compounds the lack of guidance on alternatives, further inhibiting access globally

Ongoing implications of patent today

Global confusion on state of patent, shifting liability

- Still, the patent apparently prevents suppliers from importing their RUTF into countries where Nutriset has an *active* patent
- Existing efforts (as well as speculation) suggest it has long expired globally – if not in 2020
- Despite that, and in absence of a definitive call by Nutriset or regulators, UNICEF Supply Division is looking to suppliers to inform import restrictions on their product, and is placing the risk on suppliers for any legal liability
- There is even confusion around what the patent covers – for instance, one expert consulted believes Nutriset would still consider an alternative formulation a violation of the patent based on how they have defined it

Current market shape is partly a reflection of how Nutriset has used its patent rights – impacting key market outcomes, affordability & availability

- Assuming the patent applies only to original formulation, and with insufficient guidance on alternatives, the market has been (and still is) effectively stuck with an originator formulation that this patent has controlled for ~20 years now
- Besides Nutriset supplying their own RUTF product, the only paths to purchase the single globally approved RUTF formulation is through *local suppliers* that are either in the Nutriset franchise network or paying a reportedly substantial patent usage agreement fee – clearly not optimal to maximizing affordability and availability compared to a free market
- Global ambiguity around the patent (scope, expiry, resolution to past lawsuits) and no clear arbiter slows activity, investment in a market already encumbered by regulatory challenges

Heard from stakeholders

UNICEF SD

*"We asked **suppliers to self-regulate** and inform which jurisdictions apply – many didn't suggest anything, but a few did. We'll abide by that until [next tender]."*

*"The **patent holder has to tell us**. UNICEF doesn't have specialized lawyers on this."*

Suppliers

*"We **pay a substantial amount** for a patent user agreement every year to sell more freely to certain countries."*

"[Nutriset] will do whatever they can to extend it indefinitely. In 2007, [we] were in court with evidence – [they] withdrew and went home, which was telling."

Global NGOs

*"We've talked to patent lawyers – it **definitely completely expired in 2018** but Nutriset is still enforcing it."*

*"So much **contradictory information** on this… There are **19 burdened countries that cannot import anything besides Nutriset**."*

Still, it is widely accepted that the patent will fully lift in all distribution countries by 2021

Note: Nutriset's original PlumpyNut product was subject to various patent applications from 1998 and was patented in US in 2002; in 2005, Nutriset created their PlumpyField network for suppliers in program countries with a majority local stake – extending franchisees rights to use the patented formulation; in 2010, Nutriset published an online patent usage agreement (for a fee) for other suppliers in program countries to use it