

The business of RUTF product development and the lack of global certification standards:

World Vision's experience in developing internal guidelines for selection and use of new RUTF suppliers

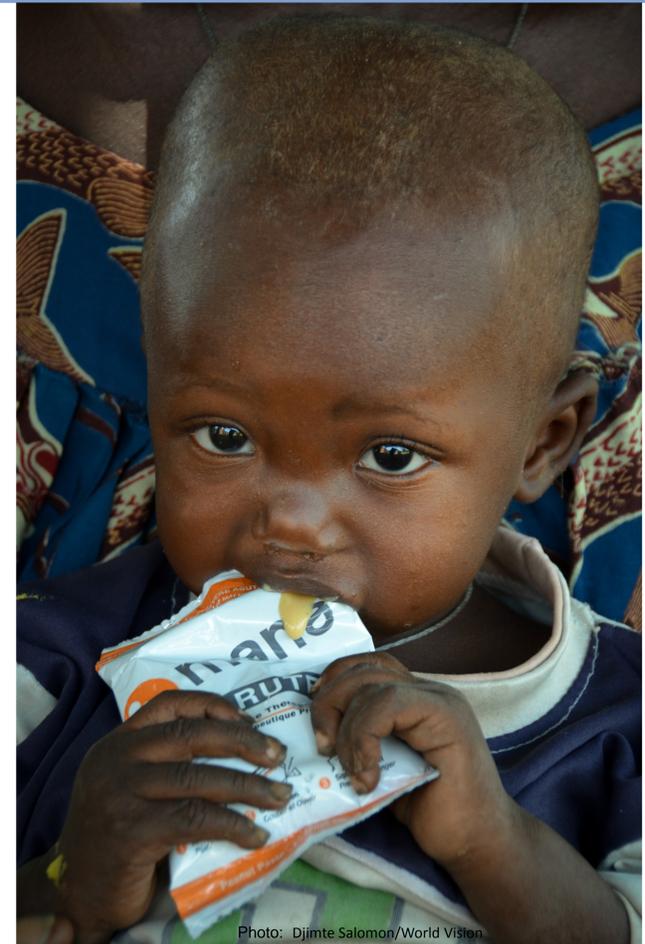
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Background

World Vision (WV) began implementing community-based management of acute malnutrition (CMAM) programming in 2006 and since that time has supported CMAM programmes in 15 countries (Angola, Burundi, Chad, Democratic Republic of Congo (DRC), Ethiopia, Kenya, Mali, Mauritania, Niger, Pakistan, Somalia, South Sudan, Sudan, Zambia and Zimbabwe).

In most of these countries, WV provides support to government-led CMAM programmes through the provision of training, assistance with logistics, supervision, supply of essential medicines and Ready-To-Use Therapeutic Foods (RUTF), where stocks are limited. The majority of RUTF in WV-supported CMAM programmes is procured from UNICEF through the government Ministries of Health (MOH).

To date, WV has not identified the availability of RUTF as the *primary* hindrance to programme implementation. However, both WV and the MOH are reliant on UNICEF for the supply of RUTF and their pipeline is not always reliable. Within the statutory health sector, supply problems have been reported in the MOH-run CMAM programmes in countries such as Ethiopia, Malawi, Sierra Leone, DRC and Zambia. These problems are due to the cost of RUTF, customs delays and weak health sector logistics. To mitigate the effects of an unreliable RUTF supply chain, WV procures RUTF buffer stocks in countries where RUTF shortages are common, either through purchase or in-kind donations from RUTF suppliers.



Steps	Description
1. Checklist of Essential Documents – submitted in full	<ul style="list-style-type: none"> ✓ Manufacturing Standard and Technical Questionnaire for Food Manufacturers ✓ Acceptability Study Documentation ✓ Product Specification and Analytical Tests ✓ Shelf-life and Stability Study Documentation ✓ Certificates of Analyses <ul style="list-style-type: none"> ○ Finished Product ○ Vitamin and Mineral Premix ○ Oil Specification ✓ Other Certificates <ul style="list-style-type: none"> ○ Certificate of origin ○ Health Certificate ○ Halal Certificate ○ Radiation Certificate ○ Melamine free Certificate ○ GMO free certificate ✓ Procedures for controlling Aflatoxin ✓ Labelling Standards ✓ Packaging Standards ✓ Internal Sampling and Testing Plan ✓ Sample(s) for Technical Evaluation ✓ Product Registration
2. Product is RUTF authenticated	RUTF for treatment of children 6-59 months of age with severe acute malnutrition (SAM) and the absence of medical complications. These guidelines do not cover other RUF products
3. Local Level Production Supported and/or Complemented	Where it is feasible and applicable, WV's goal is to actively support national/local level production of RUTF. The Supplier and WV will undertake careful assessments of the settings and ensure that they are not undermining local, national and/or regional efforts in RUTF production.
4. Gaps in WVI RUTF supply chain confirmed	An analysis of the national supply, demand and RUTF distribution logistics must be conducted to confirm any gaps in the existing RUTF supply chain.
5. Human and Financial Investment calculated	WV will conduct an analysis of the human and financial costing required to introduce a newly manufactured RUTF product to the field from a new RUTF supplier

Private sector requests to partner with WV

In recent years, with growing publicity around RUTF and its life-saving benefits, WV was approached by private businesses interested in manufacturing RUTF and supplying it to field programmes. Some businesses were existing food producers, while others were looking to develop this manufacturing capacity as a new venture. While UNICEF certifies RUTF suppliers according to their internal guidelines, there is currently no global mechanism for validating manufacturers.

As WV does not have the expertise in food manufacturing, it was clear that internal guidelines were required to guide decision making within the organisation and ensure that WV exercises due diligence when considering partnerships with producers of RUTF.

Content of Guidelines

Guideline development was led by WV's Nutrition Centre of Expertise, with extensive input provided by UNICEF Supply Division. The guidelines outline a five-step selection process which must be completed in order for a product to be eligible for consideration by WV. A review committee comprised of WV and UNICEF representatives reviews the supporting documentation to determine whether or not a product is suitable for use in WV field programmes.

Conclusion

With wasting affecting an estimated 52 million children under 5 years of age globally,² and the development of community-based protocols for management of severe acute malnutrition using RUTF, the opportunity to scale-up treatment is unprecedented. Introducing new RUTF suppliers will help ensure global supply of RUTF can match treatment demand. However, in the absence of a global certification mechanism for RUTF products, operational agencies are placed in a difficult position of validating new RUTF suppliers. Developing internal guidelines detailing the process and expectations for new suppliers will ensure due diligence is exercised on the part of the operational agency, and provide RUTF to field programmes that is appropriate, safe and acceptable for treatment of severe acute malnutrition.

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² Black RE, Victoria CG, Walker SP, Bhutta ZA, Christian P, de Onis M, Ezzati M, Grantham-McGregor S, Katz J, Martoreli R, Jauy R and the Maternal and Child Nutrition Study Group. Maternal and Child Undernutrition and Overweight in low-income and middle-income countries. The Lancet. 6 June 2013. DOI: 10.1016/S0140-6736(13)60937-X

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