Food Aid Quality Review Phase II Closeout Report

October 2011-February 2016

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For correspondence, contact:

Patrick Webb
Friedman School of Nutrition Science and Policy
Tufts University
150 Harrison Avenue
Boston, MA 02111
patrick.webb@tufts.edu

Acronyms

AMS	Agricultural Marketing Service (USDA)
BMC	Beneficiary's Mother/Caregiver
CIS	Continuous Improvement System
CRD	Commodity Requirement Documents
CRG	Commodity Reference Guide
CSB	Corn Soy Blend
CSB+	Corn Soy Blend Plus/Super Cereal
CSB13	Corn Soy Blend 13
CSB14	Corn Soy Blend 14
FAD	Food Assistance Division (USDA)
FANEP	Food Aid Nutrition Enhancement Program (USDA)
FAQR	Food Aid Quality Review
FAS	Foreign Agricultural Service (USDA)
FBF	Fortified Blended Food
FDA	Food and Drug Administration
FFP	Office of Food for Peace (USAID)
FSA	Farm Service Agency (USDA)
FSMA	Food Safety Modernization Act
FVO	Fortified Vegetable Oil
GH	Global Health (USAID)
GIPSA	Grain Inspection, Packers and Stockyards Administration (USDA)
HEB	High-Energy Biscuit
IGF	Insulin-like Growth Factor
KCCO	Kansas City Commodity Office (USDA)
LNS	Lipid-based Nutrition Supplement
MAM	Moderate Acute Malnutrition
MFFAPP	Micronutrient-Fortified Food Aid Products Pilot Program
MGD	McGovern-Dole FFE
MNP	Micronutrient Powders
MSF	Médecins Sans Frontières
NIFA	National Institute of Food and Agriculture (USDA)
PL 480	Public Law 480 (Agricultural Trade Development and Assistance Act)
PVO	Private Voluntary Organization
REFINE	Research Engagement on Food Innovation for Nutritional Effectiveness
RUF	Ready-to-Use Foods
RUSF	Ready-to-Use Supplementary Food
RUTF	Ready-to-Use Therapeutic Food
R&D	Research and Development
SBCC	Social and Behavior Change Communication
SC+	Super Cereal Plus
SQ	Small Quantity

TOPS	Technical and Operational Performance Support
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
WFP	World Food Programme (United Nations)
WHO	World Health Organization
WPC	Whey Protein Concentrate
WSB	Wheat Soy Blend

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Executive Summary

Tufts University faculty led a worldwide team to carry out a review commissioned by the United States Agency for International Development (USAID)/Office of Food for Peace (FFP) called the Food Aid Quality Review (FAQR) Phase I. Its purpose was to address mounting calls for changes to the specifications of key Title II commodities according to: a) the latest science on nutritional needs of beneficiary populations across the developing world; and b) a growing understanding of the role of specially-formulated commodities in meeting defined nutritional needs.

The findings of FAQR Phase I were published in several forms:

1. A full-length, comprehensive report, Improving the Nutritional Quality of US Food Aid: Recommendations for Changes to Products and Programs
2. A shortened, more policy-focused version of the report, Delivering Improved Nutrition: Recommendations for Changes to US Food Aid Products and Programs
3. Several articles published in a special edition of the Food and Nutrition Bulletin

USAID/FFP accepted the recommendations of Phase I and awarded an extension contract (FAQR Phase II) to Tufts University to help USAID put the recommendations into practice. Key priorities for Phase II included reformulating commodities according to new specifications, generating empirical evidence on the effective programming of such products, and supporting critical interagency harmonization processes with a view to their institutionalization. It is with great satisfaction that the FAQR team reports that ***all* of the 'quick win' recommendations proposed by FAQR Phase I were accomplished during the period of FAQR Phase II implementation**. These included the following:

- Prepare new specifications for adoption by FFP for Fortified Blended Foods (FBFs) in Title II (including but not limited to Corn Soy Blend [CSB]); explore new products beyond existing formulations (new grains or legumes in blends; lipid-based products).
  - ✓ **New specifications have been adopted for 21 food aid products during Phase II; new sorghum-pea blend and lipid-based products have been formulated and tested; Ready-to-Use Foods (RUFs) are now included in Title II's basket of products; new packaging materials and approaches have been explored.**
- Promote new program guidance (decision tools) to facilitate improved matching of products to purposes having nutritional intent.
  - ✓ **Phase I decision trees helped guide USAID partners' adoption and use of RUFs and improved FBFs; field studies were initiated to determine the feasibility and cost-effectiveness of various programming, packaging and product changes in relation to treating or preventing undernutrition. These will help guide programs in their decisions on product choice in relation to program purposes.**
- Revise micronutrient profile of premixes for milled grains; add bulk premix to commodities list for in-country fortification where feasible and cost-effective.
  - ✓ **FFP's micronutrient premixes have been fully revised (updated) for both processed and bulk flour commodities, and fortified rice has been added to the**

list of commodities; FFP is exploring the potential for premix inclusion to Local and Regional Purchase programs.

- Update reference guidance in real time, including the Commodity Reference Guide (CRG).
  - ✓ **The CRG has been updated quarterly. New product fact sheets were written on a rolling basis as new products were introduced.**
- Convene a new Interagency Food Aid Committee to provide a "one-stop shop" for whole-of-government technical actions in food aid (coordination of products, processes) and interface with industry and implementing partners.
  - ✓ **While the name itself was not adopted, a process of structured, regular interagency meetings was established to promote enhanced all-of-government dialogue on food aid issues, greater communication around bottlenecks along the supply chain, and improved understanding of agency-specific needs and constraints. During Phase II, 5 meetings took place among US-based institutions, plus another 9 which included international partners. An agreement was reached by the end of Phase II to establish an informal global working group on product, policy and process harmonization (with UNICEF, World Food Programme (WFP), Médecins Sans Frontières (MSF) and others), as well as a USAID-United States Department of Agriculture (USDA) Task Force focused on cross-agency cooperation and streamlined working practices.**
- Establish public–private partnerships to accelerate development and testing of products.
  - ✓ **The FAQR team has worked closely during Phase II with numerous commodity producers and other entities engaged in the food aid business. These have included work on new product development and shelf-life testing with academic-based entities such as Kansas State University and Massachusetts Institute of Technology, as well as engagement on reformulation, packaging improvements and food safety issues with US companies that produce FBFs and RUFs.**

Of 35 recommendations made by FAQR Phase I, six (mainly around HIV/AIDS food aid products and programming; justification is included in the body of the report) were not incorporated into the FAQR Phase II Scope of Work at initiation in 2011 because other USAID offices were better positioned to deal with those recommendations. Twenty-two of the remaining 29 recommendations have since been completed, three recommendations are ongoing, and four are carried over to the FAQR Phase III contract (covering the period of February 2016 to January 2019). Overall, 100 percent of the recommendations will be completed by the end of FAQR Phase III. These accomplishments are detailed throughout the report, and **Annex 3** provides an update on the status of the recommendations.

In addition to successfully completing all Phase I recommendations that were retained in the scope for Phase II, the FAQR team has held 38 high-level meetings during the second phase, facilitated 6 interactive workshops, disseminated 27 reports, published 11 scientific manuscripts in peer-reviewed journals, presented 4 poster abstracts at international conferences, updated specifications for 21 food aid products, procured over 1500 MT of food aid commodities for field research, developed a website, and collaborated with more than 45 partners. Additional details can be found in **Section IV** and Annex 2**.**

I. Background on Implementing FAQR Phase II

FAQR represents a commitment by USAID and USDA to enhancing the products available to Implementing Partners under Title II of Public Law 480 (PL480), improving quality control and assurance (of products), updating technical guidance and the evidence base for programming, and building interagency support for greater coordination and communication relevant to making food aid policies and procurement practices as supportive as possible of cost-effective programming.

FAQR Phase II (October 2011 to January 2016) built upon work performed under the original FAQR Phase I (April 2009 to September 2011). There was a seamless transition between Phases I and Phase II because of the continued focus on three key areas relevant to enhancing food assistance: 1) Products (development and testing of new or modified nutritionally-enhanced food aid commodities); 2) Programs (the uses of such foods to meet nutritional goals in the context of Title II programs); and 3) Processes (e.g., safety and quality assurance in the supply chain, harmonization of processes among donor agencies, and coordination among agencies within the US Government). Specific areas of concentration included the following:

1. Products

Activities included: i) Development of updated and/or new specifications for FBFs, including the new Corn Soy Blend 14 (CSB14), as well as milled flours, enhanced vegetable oil, micronutrient premixes, and lipid-based RUFs; ii) Laboratory and pilot production testing of new forms of FBF; acceptability (taste) trials; shelf-life studies; and iii) Recommendations for supply chain and related issues.

2. Programs

Activities included strengthening the evidence base for food assistance programming through expert consultations and workshops on key topics (such as protein quality) with representatives of Title II implementing partners and other stakeholders. Multiple activities were undertaken, including a review of the data collected from Title II implementing partners as part of required reporting, and how the data are used and could be better used to inform programming.

Several field studies were initiated during Phase II. In Malawi[1], a study assessed the extent to which beneficiaries can be encouraged to use oil as instructed by implementing partners to prepare CSB porridge for beneficiary children. The study also assessed the impact of packaging changes (providing CSB in 2 kg packages rather than in bulk), in conjunction with behavior change messages, on the correct use of CSB and oil, and on intra- and inter-household sharing.

Research in Burkina Faso is still ongoing and is assessing the effectiveness and cost effectiveness of the new CSB14 (which has three percent whey protein concentrate 80[2] (WPC80) and an updated micronutrient premix), delivered with oil, as compared with alternatives such as lipid-based nutrition supplement (LNS) products and other fortified blended foods (including Corn Soy Blend Plus[3] (CSB+)

[1] Clinical trials information found at: https://clinicaltrials.gov/ct2/show/NCT01873196
[2] Specification found at: http://www.fsa.usda.gov/Internet/FSA_File/ddi2.pdf
[3] Specification found at: https://www.fsa.usda.gov/Internet/FSA_File/csbp2.pdf

and oil and WFP's formulation of Super Cereal Plus[4] (SC+) with skim milk powder and oil incorporated into the matrix), in the prevention of moderate wasting (moderate acute malnutrition, or MAM), the prevention of stunting, and the promotion of adequate growth in children six to 23 months.

A study in Sierra Leone assessed the effectiveness and cost-effectiveness of these same foods in the treatment of MAM in children under age five. Due to the Ebola Virus Disease outbreak, FAQR closed down the treatment study and began scoping new countries to restart this study in a proposed FAQR Phase III.

3. Processes

FAQR II focused on the formation of an Interagency Food Aid Technical Committee as well as implementing regular meetings with major food aid agencies (WFP, UNICEF, USAID, USDA, and others) to address the need for harmonization of food products and related procurement and quality assurance processes used in Title II food aid.

[4] Specification found at: http://documents.wfp.org/stellent/groups/public/documents/manual_guide_proced/wfp262697.pdf

II. FAQR Phase II Outputs: Products, Programs, and Processes

FAQR Phase I put forth 35 recommendations; USAID/FFP accepted the recommendations and awarded an extension contract (FAQR Phase II) to Tufts University to manage the process of bringing the recommendations into practice. The progress implementing these recommendations is detailed in this section based on the three core foci of: 1) Products; 2) Programming; and 3) Processes.

1. *Products*

In FAQR Phase I, a main recommendation was to upgrade the macro and micronutrient content of the CSB provided under Title II programs. Under the USDA nomenclature at the time, the latest version in production and use in Title II and other US Government programs, e.g., McGovern-Dole Food for Education (MGD), was Corn Soy Blend 13[5] (CSB13) (or version 13). The FAQR Phase I proposed upgraded CSB (provisionally named "CSB14"or "CSB version 14") was intended to be the "next generation" CSB product with upgraded micronutrient profile and a dairy component, to meet the latest scientific, food technology, and nutritional requirements recommendations at the time (April 2011).

The *Delivering Improved Nutrition: Recommendations for Changes to US Food Aid Products and Programs* report (1) recommended the US Government food aid basket be upgraded with improved and new products to better meet the nutritional needs of the target groups, primarily children (and mothers)—to prevent or treat MAM in the first 1,000 days (from pregnancy through 23 months)—as well as others who are nutritionally at risk. Recommendations focused on "foods fit for purpose" or "the right food at the right time," taking into account how the products were being programmed and what improvements would be needed based on an upgraded food aid basket. Since the US Government did not have CSB with dairy or any other dairy-FBF, one of the recommendations was to develop and test the effectiveness of a dairy-fortified and upgraded CSB13.

Based on the prices and availability of dairy ingredients in 2011, and the desire to change the macronutrient composition of CSB13 as minimally as possible while upgrading the nutritional quality, it was determined that the addition of three percent of WPC80 would add the most dairy protein at the least cost and the least change in ingredients amounts. This next generation CSB with whey (CSB14) also included an upgraded, more bioavailable micronutrient premix that was adapted to better meet the nutritional needs of the target group. The updated premix complied with the latest World Health Organization (WHO) guidance at the time. The recommendations included developing the CSB14 and testing it in the field, as any new product introduced into food aid needs to have an evidence base regarding its acceptability among food aid consumers and its effectiveness and cost-effectiveness under field conditions in food aid programs.

The steps involved in the research and development (R&D) phase, and in procuring products for the effectiveness trials, are provided in **Annex 5**. In addition, it was recommended to add Ready-to-Use Therapeutic and Supplementary Foods (RUTF and RUSF) to the food aid basket to treat severe acute malnutrition (SAM) and to prevent or treat MAM respectively.

[5] Specification found at: https://www.fsa.usda.gov/Internet/FSA_File/csb13_110507.pdf

Recommendations numbered 1-22 focus on the improved products, with 1-11 focused on updating the macro and micronutrients in CSB and WSB (*Annex 6 *details these updates) and 12-15 focused on upgrading the premix for cereal blends and for milled cereals (*Annex 10 *provides a macro and micronutrient breakdown of the upgrades).

❖ Recommendation 1: The quantity of protein in the FBF should be increased, and WPC should be added.

The updated CSB14 includes three g of WPC80 per 100 g dry product of CSB14. This update increases the protein available and provides essential growth factors derived from an animal source. It was always intended that WPC be tested in terms of its cost-effectiveness, and that some flexibility in the language of specifications be allowed to include 'functionally equivalent' protein sources as appropriate (where WPC is either not easily available or too costly).

To understand the current evidence surrounding protein, a Protein Quality Workshop took place on May 16 and 17, 2012, at Tufts University's Friedman School of Nutrition Science and Policy, supported by the USAID/FFP and co-organized by the Nevin Scrimshaw International Nutrition Foundation. The aim of the workshop was to bring together members of the research, academic, and policy communities in the area of protein and amino acids to discuss the core science and policy implications around protein quality and types of protein in relation to the promotion of child growth, the management of wasting, and maternal nutrition in developing-country settings.

There is increasing focus within the food aid community on the importance of nutrition during the period from six to 24 months in preventing and treating stunting and moderate wasting. Therefore, there is a need to better understand how protein intake during this period affects body composition and to determine the short- and long-term effects of different amounts and qualities of protein intake. Measures of body composition should therefore be included in intervention and in future cohort studies focusing on preventing and treating stunting and moderate malnutrition (2).

Additionally, USAID included dry dairy ingredients (WPC34 and WPC80) as part of the food aid basket; the FAQR Phase II team worked on creating the Commodity Reference Guide Fact Sheet for these products (https://www.usaid.gov/what-we-do/agriculture-and-food-security/food-assistance/resources/whey-protein-concentrate).

❖ Recommendation 2: Increase the fat content.

Some fat derives from the cereal blend, but the expert working group recommended that such products be prepared and served with an appropriate quantity of fortified vegetable oil[6] (FVO). Much of the additional nutritional value offered by lipid products derives from the higher fat, energy density, and energy content per daily dose or ration. The recommended CSB or wheat soy blend[7] (WSB) should be prepared and consumed with FVO at defined volumes (30 g oil per 100 g dry matter, and in increments of that ratio), resulting in higher fat and energy density, meeting essential fatty acid (n-3 and n-6) needs, and increasing fat-soluble micronutrients delivered, all important for management of wasting and for supporting child growth.

This recommendation was tested from July 2013 to July 2014 in a repeat cross-sectional study implemented in Southern Malawi. This study assessed whether, and the extent to which, an increased ration of FVO, delivered with enhanced Social and Behavior Change Communication (SBCC), and in a smaller package that contained messaging and cooking instructions, could influence compliance with the recommended target ratio (30:100) in CSB porridge prepared by beneficiary mothers/caregivers (BMCs). This study was conducted under a MAM treatment program in Southern Malawi.

This study had three main objectives: (I) assess feasibility of the intervention to increase the FVO:CSB ratio in porridge prepared by BMCs, and assess the effectiveness of intervention to achieve that goal; (II) determine the cost and cost-effectiveness of the intervention; and (III) assess potential determinants of effectiveness and cost-effectiveness of the intervention. Caregivers of children in MAM supplementary feeding programs were assigned to three groups across 16 sites: a control group received monthly rations of one L oil, 8 kg CSB in bulk, and standard SBCC; a group receiving 2.6 L oil, 8 kg CSB provided either in bulk (Intervention Group 1) or four 2 kg packages with printed messages (Intervention Group 2); and enhanced SBCC emphasizing the target oil:CSB ratio. Mean oil:CSB ratio in porridge was determined by laboratory analysis of porridge samples.

This Phase II study concluded that *it is possible* to achieve high rates of compliance with recommended FVO:CSB ratio in porridge preparation and to increase the FVO:CSB ratio significantly, even when FVO and CSB are distributed separately. The average amount of oil per 100 g of CSB in Intervention Group 1 was 28, while in Intervention Group 2 it was 25, compared with 12 in the control group (and with only 7 in the intervention group at baseline).

These results are operationally significant for agencies implementing supplementary feeding programs. WFP, among other donors, prioritizes distribution of supplementary foods with FVO already included in the supplement (such as SC+), because of the concern that if oil is provided separately, it will be diverted to other uses and not incorporated into the porridge preparation. This study found that by providing sufficient FVO and strong SBCC, it is possible to get BMCs to prepare porridge with high ratios of FVO:CSB.

[6] Specification found at: http://www.fsa.usda.gov/Assets/USDA-FSA-Public/usdafiles/Comm-Operations/procurement-and-sales/export/pdfs/vo15.pdf
[7] Specification found at: https://www.fsa.usda.gov/Internet/FSA_File/wsb13.pdf

The study found that repackaging CSB in individual, sealed packets with instructional messages did not achieve an additional (greater) compliance with the recommended FVO:CSB ratio than bulk CSB provision. Nonetheless, beneficiaries and program staff noted other advantages of the packets: they are more hygienic than bulk distribution; their distribution at the food distribution points is more efficient and less time-consuming; and some respondents found that receiving packages was more dignified than having to scoop CSB from open tubs.

Also operationally relevant is the result that in this context, neither the FVO nor the repackaged CSB was reportedly sold, despite initial concerns that the more convenient packaging would promote diversion to the market. Analysis of data from market studies will serve to validate these self-reported findings.

These results highlight the importance of assessing cost-effectiveness of program interventions. While the cost per beneficiary was lowest in the Control Group, the cost-effectiveness was more favorable in the Intervention Groups, and specifically most favorable in Intervention Group 1, as the increased cost of repackaging CSB in Intervention Group 2 did not further increase the FVO:CSB ratio nor the proportion of BMCs reaching the target ratio beyond that achieved in Intervention Group 1.

Cost-effectiveness assessment focused on achieving the stated goal of increasing the FVO:CSB ratio and reaching or exceeding the recommended target ratio of 30:100. The study did not assess the impact of the increased ratio on growth outcomes, which, in the case of this study, would be related to recovery from MAM. To justify the recommendation, and to justify an intervention focused on the FVO:CSB ratio, further research would be needed to determine whether achieving this ratio is related to the growth outcomes of interest.

In order to address this research gap, FAQR II initiated cost-effectiveness research on the use of this enhanced FVO:CSB ratio in comparison to other supplementary foods , specifically foods that contain FVO and do not require the beneficiaries to mix FVO with CSB themselves (3). Research focused on the effectiveness and cost-effectiveness of these foods in achieving growth outcomes is being implemented by the FAQR team in Burkina Faso[8] and Sierra Leone.[9] (Details can be found in **Annex 8** and **Annex 9**.)

❖ Recommendation 3: Increase the energy content.

If 100 g of CSB or WSB, for example, is appropriately prepared with 30 g of oil, the energy content increases by roughly two thirds over that of the currently used CSB13 (which is often not prepared with oil at the time of consumption). The research completed in Malawi during FAQR Phase II concluded that it is possible achieve high rates of compliance with recommended 30 g FVO: 100 g CSB ratio in porridge preparation, thus increasing the energy content in a given volume of porridge (3). This is operationally relevant because at the recommended ratio, the porridge prepared with CSB and oil is comparable in fat density to products that are more expensive per dose, such as RUSF.

[8] Clinical Trials information found at: https://clinicaltrials.gov/ct2/show/NCT02071563
[9] Clinical Trials information found at: https://clinicaltrials.gov/ct2/show/NCT02077907

❖ Recommendation 4: Add a flavor enhancer to formulations of CSBs and WSBs.

Based on feedback from an expert panel held during FAQR Phase I, experts agreed that FBFs flavor enhancers were not an issue and that other issues should take priority.

❖ Recommendation 5: Increase the levels of vitamins B_1 (thiamin), B_2 (riboflavin), B_3 (niacin), B_5 (pantothenic acid), B_{12}, D_3, and E in CSBs and WSBs.

In the CSB14 formulation, B_1 levels were not increased because the nutrient goals shifted to target meeting between 55 and 100 percent of the Recommended Nutrient Intake. B_2, B_3, and B_5 were increased; B_5 almost doubled, B_{12} increased. Vitamin E was increased. Vitamin D_3 was not increased in the CSB14 because it was added to FVO. The CSB14 and FVO are intended for programming together, and therefore an increased amount of Vitamin D should still reach the beneficiary. The new CSB14 formulation is currently being produced and assessed in the effectiveness and cost-effectiveness studies in Burkina Faso and Sierra Leone. (Details can be found in **Annex 8** and **Annex 9**.)

❖ Recommendation 6: Maintain vitamin C in CSBs and WSBs at the current level.

Vitamin C levels were increased to make sure adequate levels remained in the product at the time of consumption due to degradation over its shelf life and from the effects of cooking.

❖ Recommendation 7: Reduce levels of vitamin A in CSBs and WSBs.

The vitamin A levels were not reduced during FAQR II, because USAID was working with WFP on harmonization of the CSB family of products (in relation to WFP's Super Cereal products (latest set of WFP specifications: http://foodqualityandsafety.wfp.org/specifications). WFP calls for 1038 mcg vitamin A/100 g of finished product. US specifications have been harmonized with those of WFP and hence set at this level, as WFP does not expect Super Cereal to be consistently programmed with fortified oil.

Table 1below compares the vitamin A content of CSB13, Corn Soy Blend Plus 1(CSBP1)[10], Corn Soy Blend Plus 2 (CSBP2)[11] and WSB15 (2011) and CSB14 and Super Cereal Plus (SCP1, 2014), the CSB/WSB family of FBF product specifications available in the latest set of USDA commodity requirements documents (CRD) (https://www.fsa.usda.gov/programs-and-services/commodity-operations/procurement-and-sales/export/commodity-requirements/index). In fact, CSBP1, CSBP2, Super Cereal Plus (SCP1) and CSB14 all have the same vitamin A content, 1,039 mcg vitamin A/100 g finished product, per their CRD's.

Table 1: Vitamin A levels of fortified blended cereals as per USDA specifications

Commodity Item	Technical Name	Effective Date of Commodity Requirements Document (CRD)	Vitamin A (mcg/100 g)
Corn Soy Blend	CSB13	July 15, 2008	694.46
Corn Soy Blend Plus 2	CSBP2	Sept. 2, 2014	1,038.00

[10] CSBP1 is the active specification used for Corn Soy Blend Plus from October 25, 2012 to September 1, 2014.
[11] CSBP2 is the current specification for Corn Soy Blend Plus starting in September 2, 2014.

Corn Soy Blend Plus 1	CSBP1	Oct. 25, 2012	1,038.00
Corn Soy Whey Blend *for Effectiveness Trials	CSB14	April 18, 2013	1,038.76
Super Cereal Plus	SCP1	March 25, 2014	1,039.80
Wheat Soy Blend	WSB15	March 25, 2011	694.46

Additional Background & Explanation:

FAQR I recommended that the level of vitamin A be reduced in the blended cereals and that the CSB and WSB family of products be programmed with fortified vegetable oil. The recommendation to reduce vitamin A in CSB and WSB was based on the fact that vitamin A, which is a fat-soluble vitamin, is more stable and bioavailable when added to an oil (or lipid based product matrix) than when added in encapsulated form to milled or blended cereal products. Vitamin A is provided through two routes in the food aid basket: in the vitamin/mineral premix of fortified milled and blended cereal products, like corn meal, and CSBs/WSBs including the current CSB Plus (per USDA CSBP2 specification, 2014) and in fortified oil with added vitamin A and D (25,000 mcg vitamin A/100 g finished product, per VO15 specification, 2015). In order to ensure that the recommended amount of vitamin A is delivered to beneficiaries, FAQR I also recommended programming all CSB/WSB products with fortified oil.

A review of the USDA commodity requirements documents (CRD) for the CSB and WSB product family confirms that the FAQR recommended vitamin A decreases were not adopted. During FAQR Phase II, the USAID/USDA CSB products were upgraded (now called CSB Plus – CSBP) in 2012 (CSBP1) then in 2014 (CSBP2) to reflect an upgraded vitamin/mineral premix, but the vitamin A levels remained at 1039 mg/100 g. WSB remained unchanged from 2011 (WSB15); the FAQR II team drafted a specification for upgraded WSB (that would be now called WSB Plus or WSBP) but it has not yet been posted. CSB14 is the FAQR I proposed CSB product with dairy (CSB with dairy in the form of Whey Protein Concentrate 80), designed to prevent and treat moderate acute malnutrition, which is being tested in two FAQR II/III effectiveness trials (Burkina Faso & Sierra Leone). CSB14 was designed with the FAQR I recommended vitamin A levels but due to the harmonization efforts, it also has 1,039 mcg vitamin A/100 g finished product, and it is being programmed with fortified vegetable oil in the trials.

❖ **Recommendation 8: Add vitamin K to the premix for CSBs and WSBs provisionally.**

Vitamin K was added as recommended. Although widespread deficiency of this vitamin is rare, it can occur when the body is unable to absorb nutrients via the intestinal tract due to enteric dysfunction. Deficiency is therefore possible in unsanitary environments and where dietary sources of vitamin K (leafy green vegetables and fruits) are few, as in refugee camps or where markets are disrupted in emergencies. Vitamin K is relatively stable, but is sensitive to light and alkaline conditions. The vitamin suppliers and premix suppliers with whom the FAQR team communicated during Phase I advised that stability studies did not need to be carried out on vitamin K. Therefore, the decision was made not to include it in the shelf-life studies, as there were more critical ingredients for which to measure stability, such as vitamin A.

The value of adding vitamin K should be assessed in field settings. The new CSB14 formulation is currently being produced and assessed in the effectiveness and cost-effectiveness studies in Burkina Faso and Sierra Leone (**Annex 8** and **Annex 9**), though the independent effect of vitamin K will not be assessed.

- **Recommendation 9: Combine two forms of iron, NaFeEDTA and ferrous fumarate, in the CSB and WSB premix to enhance iron absorption.**

Iron forms were combined to increase the rate of absorption. A combination of ferrous fumarate and NaFeEDTA enhances the impact of CSB and WSB by making more iron available to the beneficiary.

- **Recommendation 10: Increase levels of zinc and add potassium in CSB and WSB.**

Zinc levels were increased, and potassium was added as recommended. These two minerals play important roles in child growth, as well as supporting recovery from wasting. Zinc is separately important for enhancing iron absorption and combating diarrheal disease.

- **Recommendation 11: Decrease levels of magnesium, calcium, iodine, and sodium in CSB and WSB.**

Intrinsic levels of micronutrients, including calcium, in the corn and soy vary based on where the corn or soybeans were grown, so the updated vitamin/mineral premix specifications were based on micronutrient level data from manufacturers, taking into account this intrinsic variation in the US. Calcium and magnesium were decreased so as to align with the WFP product specifications. Iodine is more complicated since it is added as iodized salt. Reducing the amount of iodized salt to achieve the desired decrease in sodium would have decreased the iodine level by too much. The iodine content therefore was maintained (i.e. no changes in the specification for iodine levels) and sodium levels were not decreased. Iodine is volatile at the high temperatures in many of the countries where the products are programmed and losses are expected in the product by the time of consumption; therefore decreasing the initial iodine content was not recommended.

Recommendations numbered 12-15 focused on upgrading the premix for cereal blends and for milled cereals.* Annex 10 *provides a macro and micronutrient breakdown of the upgrades.

- **Recommendation 12: Cut levels of vitamin A, vitamin B_1, vitamin B_3, and iron, but increase vitamins D_3 and B_6 in cereal blends and milled cereals.**

Vitamins B_1, and B_3 levels were decreased. B_{12}, B_6. D_3 and zinc were all increased in the the premix. Iron was reduced due to changing the form of the iron to NaFeEDTA, a more bioavailable form of iron. Vitamin A levels were increased to accommodate WFP product specifications.

- **Recommendation 13: Change the form of iron in the cereal blend and premix to NaFeEDTA.**

The iron form was changed to a combination of ferrous fumarate and NaFeEDTA. As in the CSB or WSB reformulation, this was done to enhance bioavailability, which allows for slightly lower levels to be added, thereby containing costs.

- **Recommendation 14: Add zinc and vitamin B_{12} to cereal blends and milled cereals at levels recommended by WHO.**

Zinc and vitamin B_{12} levels were matched with recommendations by WHO.

❖ Recommendation 15: Remove calcium from the premix in cereal blends and milled cereals.

Only B vitamins, vitamin D, iron and zinc are included in the milled cereals (flours) premix. Calcium was never included in the premix for the milled cereals and was reduced in cereal blends (FBF) premix since it is provided as tricalcium phosphate. Tricalcium phosphate is both bulky and costly, causing problems at the point of mixing, and it would require a threefold increase in calcium in the premix to reach target levels of 115 percent of Reference Nutrient Intake—at which point its cost would become prohibitive.

❖ Recommendation 16: Maintain level of vitamin A in oil and add vitamin D in FVO.

Vitamin A was maintained and vitamin D was added to the FVO. Adding vitamin D to the vitamin A FVO took less than six months from completing specifications through a plant production trial. The vitamin D addition was implemented using the same process as the original vitamin A addition in 1998, working with the major oil producer, visiting the plant during trial runs. Additionally, shelf life stability tests were completed on the doubly fortified oil during FAQR Phase II, with no vitamin loss over the accelerated shelf study period (4). The fortification of vegetable oil with vitamin D marks a harmonization success with the WFP specifications for FVO. WFP had been providing vitamin A and D FVO in its food aid basket for several years prior to USAID introducing it in the FFP food aid basket. For further information, please refer to the Commodity Requirement Document (CRD) for FVO15 (5).

❖ Recommendation 17: Lipid-based products should be available for use by Title II implementing partners.

The US Government adopted RUTF for its own programming based on the food aid product already produced and distributed by UNICEF. To create the US specifications for RUSF, FFP worked together with WFP and developed them based on already existing WFP specifications for RUSF and the WHO Technical Note that was posted by WHO in 2012.[12] Creating US specification documents for RUSF involved numerous revisions and adaptations of WFP specifications to conform to US Government regulations or standards as well as common US supplier practices. RUSF took time to incorporate into the US Government food aid basket for a variety of reasons, including harmonization of forms and levels of micronutrients and macronutrient ingredients (there are still a few differences between US Government and WFP specifications, and these are summarized in Table D of the Product Rollout Report (4)). Adding RUSF to the Title II commodity list required finding new suppliers in the United States. Although, RUSF US specifications were posted in FY2014; it took several months for RUSF to get into the pipeline.

Given the similarity in the ingredients, the paste matrix of the RUTF and RUSF being very close in composition, and the relatively minor micronutrient and macronutrient differences when seen from a manufacturing perspective, a unified specification for RUFs comprising both the RUTF and RUSF classes of lipid-based pastes was developed in 2015/2016, with a single micronutrient premix (adopted by USAID, WFP, and UNICEF). Both the RUTF and RUSF specifications had already been developed, taken through a phase-in period, subjected to accelerated shelf-life testing, vetted and purchased for at least a year, and put in prepositioning locations to test the feasibility of US sourced procurement. The FAQR team worked with USAID throughout the process, including the development of the various iterations

[12] http://apps.who.int/iris/bitstream/10665/75836/1/9789241504423_eng.pdf

of the RUSF, RUTF specifications and the harmonization process to develop the unified RUF specifications, as well as the CRG Fact Sheets. See FAQR Phase II Rollout report (4) and Harmonization section of this report for further details on the process of harmonization.

RUSFs are being compared to variations of FBFs in many ongoing trials, including the FAQR research in Burkina Faso and Sierra Leone (**Annex 8** and **Annex 9**).

❖ Recommendation 18: Encourage the development of new cereal-based FBFs.

Corn-soy whey blend (CSB14) and super cereal plus (SC+) were complex to develop because they required introducing a dairy ingredient (non-cereal based ingredient) to a FBF, CSB. Manufacturers that handle dairy ingredients require USDA dairy certification, and at the time, the CSB suppliers produced CSB in milling plants that did not handle dairy ingredients. Out of three suppliers, one declined to participate after assessing the feasibility and cost effectiveness of production. One supplier sought new co-packers to work with who could add dairy ingredient; the other supplier used a different plant within its own company that was certified for the added diary ingredient. Therefore, it took time to establish a reliable supply chain for these products. CSB14 needed to be developed from scratch in order to be procured for the FAQR effectiveness trials, to test the product's impact on nutritional status in a program setting. The process involved prototype development, consumer testing and identification of potential suppliers not in the CSB business. This R&D phase took about 18 months before the product was ready to be procured; however, CSB14 will not be adopted until the results of the effectiveness and cost-effectiveness trials are available. This suggests that it can take up to six years to bring a new evidence-based product to the food aid market, when research on product effectiveness is required.

Other cereal-pulse blends were envisioned as future, more versatile options that could better meet the local tastes and procurement options. Examples include: sorghum-soy blend (or indeed sorghum-pea or other pulse), millet-soy, or other cereal, or even potato-soy (or other pulse) blends. These would offer new choices for programming, potentially including new forms of fortified biscuits for schools or emergency response. As part of the new product development initiatives funded under the USDA Foreign Agricultural Service/Food Assistance Division/McGovern-Dole FFE (FAS/FAD/MGD) pilot project and the USDA National Institute of Food and Agriculture Food Aid/Nutrition Enhancement Program (NIFA/FANEP) project begun in 2011 and 2012, a sorghum-cowpea blend is being developed under a grant with Kansas State University and with Johns Hopkins University for other pulse-staple blends (6). USAID/FFP worked with USDA on the sorghum-cowpea blend concept.

During FAQR Phase II, the Senior Food Technologist and GF&N provided technical assistance to USAID and USDA in the early stage of this effort, in particular, attending Kansas State University meetings, during which the team reviewed plans for field testing and toured the production plant where KSU was producing their prototype products, sampling the products and consulting with USDA's Foreign Agricultural Service Office of Capacity Building and Development (Paul Alberghine) when issues arose.

The FAQR team Senior Food Technologist and GF&N also worked with USAID in the beginning phase of introducing High-Energy Biscuits (HEBs). They reviewed the formulations of WFP's HEB and USAID's emergency food bars (A-28, A-29) to compare and harmonize the USAID/USDA and WFP specifications. The team collaborated with USAID on HEB specifications, including ingredients, micronutrients, processing and microbiological requirements. HEBs have the potential to be used for

'dual-use' programming (emergency and non-emergency) and should be assessed further to understand the cost-effectiveness and shelf-life in order to develop concrete programming guidance. The team also worked on the development of fortified milled rice specifications (see Recommendation 20).

❖ Recommendation 19: Establish public-private partnerships to accelerate development, testing, and implementation of new products.

Input from the industry is critical to ensuring the feasibility and cost-effectiveness of improved products. The appropriate approach would involve a public-private partnership. During FAQR Phase II, the FAQR team served as an independent third party and was able to open up communication which allowed for technical issues between vendors, USDA, and USAID to be addressed and resolved while not compromising the commercial relationship. Relationships between the US Government and suppliers have been strengthened, based on increased communication and meetings among suppliers, USAID food technologists, FFP staff, and other key stakeholders such as Natick Soldier Research, Development & Engineering Center. A meeting took place at the 2012 International Food Aid and Development Conference to enhance public-private partnerships. These meetings need to continue not only during the life of the FAQR program, but also after it is completed. There is still a need to have a mechanism where technical meetings can be held by industry associations, and where USAID and USDA technical staff can come together. For more details, see the Product Rollout Report (4). FAQR has also been supporting the Business Platform for Nutrition Research, which engages the private sector in response to global hunger.

❖ Recommendation 20: Establish a Micronutrient Fortification Program for pursuing innovations in micronutrient delivery.

This recommendation was based on responding to guidance in the 2008 Farm Bill regarding micronutrient fortification. The FAQR team provided technical support in the development of a micronutrient premix for fortification of bulk cereals and point of use individual packets. This work included preparing specifications for bulk and individual premixes in 2012/2013; the product subsequently was not included in the food aid basket.

The FAQR team also provided technical assistance to USDA on fortified milled rice as part of its McGovern Dole Food for Education and Child Nutrition Program (MGD)/ Micronutrient-Fortified Food Aid Products Pilot (MFFAPP) project and research [13]. Two products, a Fortified Poultry-Based Spread (FPBS1) and fortified milled rice (MR25), were recently added to USDA's list in 2015 and 2016 respectively based on results of the MFFAPPP effectiveness trials. USDA plans to add additional products should the evidence suggest effectiveness.

❖ Recommendation 21: Ship micronutrient premix and home fortificant powders as Title II products.

This was not included in the Work Plan for FAQR Phase II as USAID did not see this as a priority for the FAQR team.

[13] A presentation on the MFFAPP research can be found: http://www.powershow.com/view2b/507aa2-M2RkO/Overview_and_Update_of_the_Micronutrient Fortified_Food_Aid_Products_Pilot_MFFAPP_powerpoint_ppt_presentation

2. *Programming*

The programming recommendations target the matching of products to purpose, enhanced operational guidance to implementing partners, and the evidence needed for programming. ***Recommendations numbered 22-29 focus on the improved programming of products.***

❖ Recommendation 22: The capacity for rigorous evaluation of program innovations should be strengthened (i.e. must test new products).

FAQR I recommended increasing the capacity for rigorous evaluation of program innovations. During FAQR II, the Tufts team implemented three field studies to test the program modifications recommended in the FAQR I report. A study in Malawi assessed whether it is possible, by providing sufficient oil and SBCC support, to achieve increased levels of oil in CSB porridge prepared by beneficiary mothers/caregivers, and whether adding SBCC messages to individual packages would improve compliance with the recommendation. Results demonstrated that provision of oil and SBCC significantly improved compliance, and package messaging offered no additional compliance benefit. A report was submitted to USAID (3), and the results are being prepared for publication. These results can inform decisions about programming FBFs with oil given separately vs. incorporated into the food supplement.

An ongoing study in Burkina Faso is assessing the effectiveness and cost-effectiveness of the modified CSB recommended in FAQR I (improved micronutrient profile and added whey protein concentrate, and delivered with oil and SBCC about preparation) in the prevention of stunting and wasting in children six to 23 months of age, compared with the former standard supplement, CSB13 (no longer recommended for children under age two), the WFP product (SC+ with dairy and oil in the mix), and a RUSF. The study includes monthly child measurements as well as interview and observational data from mothers/caregivers to assess how behavioral factors as well as the nutrient composition of the supplement affect the outcomes. Enrollment has been completed, and data collection will be completed in Fiscal Year 2017 (See **Annex 8** for more details). A parallel study assessing the FAQR–recommended supplement in the treatment of MAM in children six to 59 months was implemented in Sierra Leone; the study was suspended before reaching its planned sample size due to the Ebola Virus outbreak, but results based on the limited sample have been analyzed and a report submitted to USAID (7), and the results are being prepared for publication (See **Annex 9** for additional details).

All three studies incorporated an assessment of the supply chain (efficiency of handling, losses, time and labor costs) as well as of the role of project and health sector staff in contributing to the measured outcomes. All studies included cost-effectiveness analysis—assessing the total cost of treatment with each food to achieve the impact. The results of these studies will inform decisions about selection of supplementary foods based on effectiveness and cost-effectiveness.

Prior to implementing field-based research, the Tufts team implemented accelerated shelf-life studies and taste and acceptability trials to ensure the new food met the criteria for inclusion in FFP programming. Reports of these studies were submitted to USAID (4).

These various kinds of studies demonstrate that FFP can commit to implementing preliminary and field tests of program innovations such as the new CSB formulation and the recommendation to increase oil in porridge preparation, and that the results of such studies can be used in programmatic decision-

making. (For example, the added cost of developing printed messaging on CSB packages did not produce any additional benefit with respect to compliance with preparation instructions.) The protocols for these studies are available for others to follow in developing similar assessments. Such studies are costly to implement but can result in a more efficient and cost-effective use of FFP resources in programming, ultimately leading to cost savings.

❖ Recommendation 23: USAID and the office of HIV/AIDS should develop guidance on priority demographics for nutrition support and food assistance.

Although this was not included in the Work Plan for FAQR Phase II, the FAQR team did track the progress made through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the Nutrition Assessment, Counseling, and Support (NACS) approach (8). Food by Prescription was a model established in 2006 in Kenya to address acute malnutrition in people living with HIV (PLHIV), as well as orphans and vulnerable children (OVC), and later scaled up as a national program. The model included nutrition assessment, counseling, and prescription of therapeutic and supplementary food, based on strict anthropometric eligibility criteria. The program resulted in overall net weight gain among pre-antiretroviral therapy (ART) and ART clients, although more ART than pre-ART clients graduated from the services and fewer were lost to follow-up. The Kenya experience— and other findings that specialized food products, in combination with counseling provided to PLHIV who were assessed as malnourished, improved weight gain— signaled the possible benefits of improved nutrition in HIV care and treatment. National HIV programs in more than a dozen countries supported by PEPFAR adopted or adapted the model as a standard of care (9).

❖ Recommendation 24: Better indicators of nutritional need and cutoffs are needed to determine eligibility for food assistance in HIV programming.

This was not included in the Work Plan for FAQR Phase II as USAID did not see it as a priority for the FAQR team, because the Office of HIV/AIDS at USAID was focusing on indicators and cutoffs in HIV programming. PEPFAR distinguishes between (1) therapeutic and supplementary feeding support as a medical intervention for the treatment severe and moderate acute malnutrition (2) food assistance to address household food security. PEPFAR prioritizes (1) for PLHIV and OVC, whereas (2) should be largely addressed by WFP, FFP/Title II and other food assistance programs, irrespective of a positive HIV status. Supplementary feeding support is provided to those beneficiaries with MAM or SAM. Therapeutic and HIV. PEPFAR guidance allows for some food assistance for OVC if not addressed by other food assistance programs. Those receiving supplementary feeding support for treatment of MAM or SAM is a critical component of HIV care and support and is most effectively used when provision is based on established eligibility criteria. Specialized food products, including therapeutic foods (e.g., Plumpy'Nut or other ready-to-use therapeutic foods (RUTFs)), and supplementary foods (e.g., corn-soy blend or other fortified blended flours (FBFs)), are prescribed for a limited duration, typically three to six months, on the basis of clear anthropometric entry and exit eligibility criteria or vulnerability (particularly infants six to 24 months of age). RUTF and FBF are provided, typically monthly, as a take-home ration for the individual patients, not to be shared within the household. Recipients are counseled that they need to consume the RUTF or FBF as "medicine", in addition to their other "meds", especially ARVs, cotrimoxizole, and TB drugs if co-infected (10).

- **Recommendation 25: A strong signal is needed from PEPFAR supporting allocation of funds *for food* in HIV programs.**

This was not included in the Work Plan for FAQR Phase II as the USAID did not see it as a priority for the FAQR team. PEPFAR prioritizes nutrition assessment, counseling and support (NACS) within care for PLHIV and OVC, and within NACS, PEPFAR prioritizes feeding support for treatment of severe and moderate acute malnutrition, while linking with food assistance programs (e.g., WFP & FFP) to address household food security. In the USAID 2014-2025 Multi-Sectoral Nutrition Strategy, there is a clear commitment to an AIDS-Free Generation, Nutrition Assessment, Counseling, and Support (NACS) improves the continuum of health and nutrition care for adults and children by strengthening linkages between facility- and community-based services. NACS was initially developed and implemented with PEPFAR support in more than 16 countries to improve the nutritional status of people living with HIV/AIDS (11). Additionally, in the U.S. Government Global Nutrition Coordination Plan 2016-2021, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the U.S. Government's program to address global HIV and AIDS, focuses on preventing infections, saving lives, and achieving sustainable control of the HIV and AIDS epidemic. The U.S. Government sees an opportunity to increase the scope of NACS for people living with HIV to encompass more fully the complete array of nutrition-specific and nutrition-sensitive programming through a cohesive, unified framework. Through this expansion, coordination with established nutrition service mechanisms will be critical, and U.S. Government agencies can identify their comparative advantage and strategic opportunities to support this system (12).

- **Recommendation 26: Support implementing partners to incorporate data on local consumption and food availability into the design of rations and programs.**

The FAQR team conducted several reviews of calculators available in the design of food aid products (e.g., Nutval–a ration calculator used by the WFP). After review, it was decided that USAID was not yet at a place to develop their own calculator, but they did assist with updating Nutval, since it would be preferable to wait for the new food aid products to be rolled out in order to incorporate end-user feedback. As part of FAQR Phase II, the team participated in the 'Cost of the Diet' tool training implemented by Save UK. The Cost of Diet tool calculates the cost of the cheapest diet that meets the nutritional requirements of families using foods available locally. It can also be used to estimate the proportion of households in a region that are unable to afford a nutritious diet, as well as the size of the gap between current income and the amount of money needed to meet the needs of a household.

- **Recommendation 27: USAID should improve training on needs assessment and on monitoring and evaluation methods and tools with regard to nutrition.**

To improve the processes of program monitoring and evaluation, Tufts implemented a comprehensive assessment of the ways in which data already collected as part of routine reporting, required baseline, midterm, and endline surveys, and awardee-implemented special studies. This activity involved multiple data-gathering workshops and focus groups with stakeholders from the implementing partner and USAID communities, including their Monitoring and Evaluation teams and those responsible for training, as well as Skype/phone interviews with FFP and implementing partner staff overseas.

Tufts also held two dissemination workshops in Washington, DC to share recommendations resulting from the study. The report was submitted to the USAID (13). Recommendations covered preparation and submission of the annual results report and pipeline resource estimate proposal, the awardee

monitoring and evaluation system, knowledge sharing, training and guidance, and the functionality of the FFP Management Information System. A number of the recommendations in the report were in process or have been implemented since the report was completed, as the report was shared widely within FFP. These include the requirement to make all data and reports publicly available through the Development Experience Clearinghouse, having a set of harmonized output indicators for use in all awardees' reporting, and having periodic monitoring and evaluation training workshops conducted by Technical and Operational Performance Support (TOPS). The full set of recommendations is in the report, along with a note on their status as of the end of calendar 2013.

- **Recommendation 28: The USAID should systematically incorporate cost-effectiveness into the evidence base for nutrition programming.**

Each field study implemented in Phase II (the Malawi feasibility study, the Burkina Faso prevention study [**Annex 8**], and the Sierra Leone treatment study [**Annex 9**]) included cost-effectiveness analyses based on detailed protocols for collecting cost data. Protocols include all the costs of the foods and transportation, storage, and distribution as well as the time and money costs to beneficiaries participating in the program. The emphasis on measuring cost-effectiveness, and not only the cost of commodities used in food aid programs, has been a consistent feature of FAQR. Study reports include a detailed description of the methods used for collecting data and calculating cost-effectiveness based on a set of selected outcomes relating to beneficiary behaviors, child growth, and recovery from MAM, and including cost breakdowns (components of program cost) and robustness tests to assess the effect of modifying cost assumptions. The protocols for collecting data, which include financial records as well as direct observations at distribution sites and interviews with staff and beneficiaries, are available for use by other program implementers wishing to conduct cost-effectiveness analysis. In all presentations, the centrality of cost-effectiveness analysis to informed program decisions has been strongly promoted.

As part of FAQR Phase II, Tufts University, in collaboration with University of California, Davis, has developed a comprehensive Microsoft Excel-based projection tool designed to estimate the costs of producing and transporting CSB and RUSF products from their points of production to in-country warehouses from which in-country distribution would occur. The cost-projection tool is intended to enhance the cost-effectiveness of food aid programs aiming to treat or to prevent MAM, in both emergency and non-emergency contexts, but it could also be applicable to other nutrition/health issues, which could be addressed using these products. By allowing groups of in-country planners, nutritionists, and others to jointly set alternative scenarios for a given country, and programming objectives and contexts (e.g., where products are sourced and packaged, the nature and size of the target population, the dosage and duration of the proposed intervention, etc.), the costs of using alternative products to achieve objectives can be explored. Details are in the report titled, **"A Spreadsheet-based Tool for Estimating the Costs of Producing and Delivering Selected Specialized Nutritious Foods."**

- **Recommendation 29: Enhanced guidance should be prepared (such as decision-tree tools) to enable agencies to better select commodities for programming.**

The decision trees were developed by the FAQR Phase II team based on a review of current USAID and other international food aid programming at the time. They look at different programming needs and scenarios and the appropriate food aid products, such as FBFs or RUF, for these situations. The decision trees were used as the basis for the programming section of the CRG Fact Sheets and are posted on the USAID web site, but not in a way that pairs them with the CRG Fact Sheets. The next update of the fact

sheets will incorporate updated decision-tree tools based on the modernized food aid basket and latest food aid programming.

3. *Processes*

As nutrition science develops, there is an increasing need for closer collaboration on a technical level among government agencies to facilitate the development and review of new products, assess quality, and resolve concerns. ***Recommendations numbered 30-35 focus on the improved processes involved in optimizing food aid.***

❖ Recommendation 30: Establish an Interagency Technical Food Aid Committee.

The recommendation to establish coordination across the US Food Aid System has been achieved, despite the lack of traction in establishing a sustainable formal interagency committee as was proposed. Since the FAQR started, there have been five US agency meetings in Washington, DC involving a significant range of US entities, including: USDA (FNS, FSA, FAS/FAD, FAS/Transportation Logistics Branch, Grain Inspection, Packers and Stockyards Administration [GIPSA], Agricultural Research Service , Kansas City Commodity Office [KCCO]), USAID (FFP, Global Health [GH], HIV/AIDS), and the National Institutes of Health.

Participation in these meetings has improved over time in terms of seniority of representation, continuity of engagement (repeat attendance), active involvement in the discussions focused on problem-solving, and willingness to think about issues going beyond their own immediate responsibility. Outcomes of the increased commitment among agencies to tackle immediate and chronic problems relating to publication of specifications, procurement approaches, supply chain management, quality control issues, product development and more include the following:

- Much improved information sharing among US agencies involved in various aspects of the food aid agenda;
- Collaboration (to avoid duplication of efforts) in field testing of new products; and
- A much smoother and faster translation of technical specifications into CRDs, which supported the upgrading of 21 products based on FAQR's technical recommendations.

Attempts have been made over time to find ways to institutionalize the interagency engagement. Proposals have included: a) inclusion of formal language in the 2012 Farm Bill which would establish such a body; b) elaboration of the roles of the Food Aid Consultative Group; c) potential reactivation of a USDA-chaired technical committee on food aid matters that was abolished in the 1980s; and d) developing funding lines in annual agency appropriations to support a rotating agency chairing of an informal group. None of these has found traction, so the FAQR continues to host and chair such meetings; this will continue for the duration of the FAQR activity. It is hoped that the vocal expressions of the value of such interagency meetings to improved functioning of the food aid system will, at some point, translate into a more formal mechanism to continue these meetings, with the associated commitment of resources.

An additional benefit of the interagency meetings has been a series of nine US-global agency meetings (starting with WFP, then adding UNICEF, MSF, and engagement with the Food and Agriculture Organization of the United Nations and Codex). These have been aimed at harmonizing approaches to product specification (premix as well as macronutrient composition), packaging and labeling, standardization of product usage in the field, food safety standards, and exploration of joint-audits and novel product development. These have also been hugely successful in promoting common lipid-based

products (a single RUF versus multiple variants), greater consensus on micronutrient premix specifications, collaboration on standardizing food safety protocols, and discussions on improved packaging and transportation. Collaboration among FFP, the FAQR team, WFP and other parties in field research has been successfully implemented in multiple developing countries. A mechanism for enhanced communication on research gaps and recent findings was established jointly by FAQR and WFP with FFP support: the Research Engagement on Food Innovation for Nutritional Effectiveness (REFINE) website is proving to be the 'go-to' website for food aid agencies and researchers to explore what aspects of the food aid agenda remain poorly evidence-based.

- **Recommendation 31: Establish a formal product review and approval process.**

USAID/USDA Interagency Meetings started as a venue for formal information reporting from different agencies, but over the years has progressed to create technical working groups that tackle issues related to the food aid basket. As working relationships between USAID and USDA strengthened, one interagency priority was for agencies to work toward a unified way to respond to new product inquiries from potential suppliers. USDA created a template, a letter for interested suppliers, and is starting to develop a formal process for an application, review, and approval process jointly with the USAID and USDA. Formalization of the process is ongoing, but progress includes the formation of an interagency committee with members from the USAID-FFP (food technologist, nutrition advisor) and from the USDA (Food and Nutrition Service and FAS), which reviews products.

- **Recommendation 32: Establish performance-based specifications (i.e., basic nutritional profiles of final products) for nutritionally-enhanced products.**

The recommendation to establish performance-based specifications for nutritionally-enhanced products allows food aid products to be more in line with commercial specifications which provide a nutritional profile to meet in the finished product. The specifications developed under FAQR Phase II were all based on consultation with nutrition experts and food technologists. On the supplier side, there were no issues related to making the changes because there were no technical challenges aside from adding whey powder to the FBF-type products. (When whey is added as an ingredient, production plants are required to be USDA dairy-certified.) All other changes were straightforward to implement, and now all of the products have agreement on the supplier side. Suppliers and US agencies recognize that performance-based specifications are more commercial-industry friendly. While USDA has not yet adopted specifications that are entirely performance-based, specifications related to micronutrients content do outline the appropriate levels required for final products, with a table detailing macro and micronutrient content requirements per 100 grams of finished product. A new specification template was developed by USAID/FFP for the latest nutritional products. FFP could work with USDA to adopt this template for their next generation of commodity requirements/ specifications.

- **Recommendation 33: Develop a planning model which would better predict demand for FBFs and support longer vendor contracts for value-added commodities.**

The FAQR team did not develop a tool that would better predict demand for FBFs and support longer-term contracts. The team developed the recommendation to revise the procurement system to allow for 12- to 18-month contracts based on a fixed volume rather than batch-by-batch tenders and prepositioning of emergency stockpiles of FBFs for rapid deployment, which would permit more

predictable contracts. The team also consulted with USAID on methods to better predict demand based upon historical cost data.

❖ Recommendation 34; Design and implement a comprehensive food aid quality assurance strategy and plan of action.

As part of the Product Rollout Report, the FAQR team developed a Continuous Improvement System (CIS) as a comprehensive food aid quality assurance strategy. The CIS focuses on Specifications revision and harmonization, Interagency Institutionalization, Supplier/Vendor feedback and communication, Food Safety Modernization Act (FSMA) implementation, customer/end user feedback, and programming guidance. More background on the CIS can be found in the Product Rollout Report (14). The CIS follows, with proposed implementers for each aspect of the CIS included in parentheses.

1. Review and revise specifications for all products on an annual basis. (USAID- FFP, GH, USDA-Farm Service Agency [FSA], Agricultural Marketing Service [AMS], FAS)
    - Incorporate new and updated nutrition and food technology science advances into revised Specifications.
    - New product introductions: communicate with suppliers and solicit feedback on new product specifications for each Specification update until Specification is finalized.
2. Continue to solicit Supplier/Vendor feedback on a regular basis. (USAID- FFP)
    - Hold Suppliers/Vendors Advisory Group meeting on an annual basis.
    - Increase the functions of the Food Aid Consultative Group to include Supplier/Vendor feedback.
    - Create online feedback form (anonymous if requested) for Suppliers to suggest discussion topics for meetings and/or provide timely feedback as issues arise.
3. Communicate with Suppliers that they must continuously update their own quality system to meet FSMA requirements (quality assurance, quality control, process control, and food safety). (USAID-FFP, USDA-AMS, Food and Drug Administration [FDA]).
    - Actors within USAID and USDA must be made aware as well, through interagency meetings and FDA involvement.
4. Hold Customer/End User annual meetings to request feedback on:
    - Products that have been rolled out, from food aid end users/consumers and private voluntary organizations (PVOs). (USAID)
    - Emergency and non-emergency product uses, needs, projected demand for procurement. (USAID)
5. Create and distribute food aid product usage information. (USAID: FFP, GH)
    - Review existing product usage information and distribution methods.
    - Develop a tool to extract and update PVO product usage information.
6. Continue institutionalization of the interagency processes. (USAID/FFP, USDA)
7. Harmonize product specifications across US agencies and international organizations. (USAID-FPP, GH, USDA: FSA, AMS, FAS)

❖ Recommendation 35: Update the Commodities Reference Guide (CRG) and establish a process for regular updating and communication.

The CRG was introduced in 1988 with two sections: Part 1 on Commodities, including Commodity Fact Sheets on many, but not all, approved Title II commodities; and Part 2 on Programming. New templates were developed, with USAID, in the beginning of FAQR Phase II (2011-2012). The new templates includes commodity background information (key nutrition facts, where/by whom it is commonly consumed, product information/varieties), logistical information influencing the choice of commodity (packaging, storage and preparation considerations), nutrition information and/or links to the USDA Nutrient Database and Shelf Life/Best if Used By Date. While programming instruction was originally included, for the most part it is no longer included in Commodity Fact Sheets (CFS) due to other groups performing this function. However, CFS do include brief programming guidance based on the 2011 FAQR Report decision trees.

CRG Updates: after approval of the new template, old Fact Sheets were converted into the new template. Nutritional values for commodities were calculated, and content related to commodities was researched and added to CFSs. Now, CFs are updated quarterly, and new product CFS are developed on a rolling basis as new products come up the line. CFS updates include reviewing all content and sources, fixing broken links, and adding updated sources and information from CRDs as new ones go into effect.

Discussions are ongoing to revamp this process further, developing a Food Product page on the FFP website which would include products procured directly by USAID such as RUFs and HEBs and updated fact sheets. The identification of needs will be part of FAQR III landscape analysis.

III. Future Priorities

The United States Agency for International Development's (USAID) Office of Food for Peace awarded the ***Food Aid Quality Review Phase III*** contract to Tufts University's Friedman School of Nutrition Science and Policy for the period covering February 1, 2016 to January 31, 2019 with two option years. The Food Aid Quality Review (FAQR) seeks to provide USAID and its partners with actionable recommendations on ways to improve nutrition among vulnerable people for whom the direct distribution of food aid can make a significant impact. The first phases of FAQR involved reviews of nutrition science; FAQR Phase I recommendations were published in *Improving the Nutritional Quality of US Food Aid: Recommendations for Changes to Products and Programs*. This report led to FAQR Phase II's focus on reformulating Fortified Blended Foods (FBFs), the inclusion of lipid-based products in FFP's commodity list, and testing new products under field conditions.

FAQR Phase III will conclude Phase II activities, while also responding to additional (new) FFP priorities. FAQR Phase III will focus on generating links between research on food product formulation with recommendations on cost-effective programming and policy-level action among national and multilateral institutions engaged in food assistance. Tufts will work closely with several key domestic and international collaborators, the United States Agency for International Development (USAID), the United States Department of Agriculture (USDA), and with United Nations (UN) partners, all of whom are committed to strengthening the evidence base for use of specialized food products for targeted nutrition goals.

Phase III Priority areas include:

1. researching the effectiveness and cost effectiveness of new food products;
2. studying improved packaging and delivery approaches to enhance logistics, while maintaining product quality;
3. organizing consultative and expert meetings synthesizing state-of-the-art evidence on food-based nutrition delivery;
4. defining and disseminating improved field tools for calculating the cost-effectiveness;
5. exploring food technology innovation in food product processing;
6. enhancing supply chain oversight;
7. establishing stronger and more user-friendly food quality assurance; and
8. facilitating institutional harmonization and enhanced processes.

FAQR III continues to be framed by: **1) Products, 2) Programming, and 3) Processes**:

Products

Tufts will examine such mission-critical issues as: how food matrices affect bioavailability of nutrients and digestibility of products; the potential for thermal/non-thermal processing technologies to improve food matrices; potential roles for existing products that are rarely used today, as well as new products (which may include fortificant powders) and novel packaging technologies to improve resistance to infestation, shelf life, and efficiency of handling; dual-use products for emergency response; completion of the data

collection, analysis, and reporting on field studies that assess the effectiveness and cost-effectiveness of various newly formulated food products.

Programming

Tufts will focus on program cost-effectiveness of various intervention designs. This will include strategy development for pre-positioned special nutrition products, guidance on options for deployment of specialized products, elaboration of a strategy for responding to food needs in the initial stages of a sudden onset emergency, and dissemination of cost calculation tools. It will also generate improved technical guidance, share details on research protocols used in testing new food aid products in the field, and further harmonize product specifications.

Processes

FAQR III will provide recommendations on institutional and industry processes for capacity building, including the institutionalization and strengthening of interagency technical collaborations, mechanisms to ensure greater policy and product harmonization (domestically and internationally), providing recommendations for enhanced supply chain oversight, establishing stronger and more user-friendly quality assurance feedback loops, as well as promoting food safety and quality standards that can also be applied to local and regional food procurement.

IV. Summary of FAQR Phase II Accomplishments

A team led by Tufts University faculty carried out a review commissioned by the United States Agency for International Development (USAID)/Office of Food for Peace (FFP) called the Food Aid Quality Review (FAQR) Phase I. Its purpose was to address mounting calls for changes to the specifications of key Title II commodities according to: a) the latest science on nutritional needs of beneficiary populations across the developing world; and b) a growing understanding of the role of specially-formulated commodities in meeting defined nutritional needs.

The findings of FAQR Phase I were published in several forms:

1. A full-length, comprehensive report, Improving the Nutritional Quality of US Food Aid: Recommendations for Changes to Products and Programs
2. A shortened, more policy-focused version of the report, Delivering Improved Nutrition: Recommendations for Changes to US Food Aid Products and Programs
3. Several articles published in a special edition of the *Food and Nutrition Bulletin*

USAID/FFP accepted the recommendations and subsequently awarded an extension (FAQR Phase II) for Tufts to help USAID put those recommendations into practice. It is with great satisfaction that the FAQR team highlights the following accomplishments as a result of the Phase II work:

Food Aid Products

- ✓ Twenty-one food aid products have been updated/upgraded:
  - Eight commodities have new micronutrient specifications (All-Purpose Wheat Flour, Bread Flour, Bulgur, Soy Fortified Bulgur, Cornmeal, Corn Soy Blend Plus, Soy Fortified Cornmeal, Fortified Vegetable Oil).
  - Eight products were developed/adopted and now have specifications (Dried Dairy Ingredients, Whey Protein Concentrate (WPC)34 and WPC80, High Energy Biscuits, Fortified Milled Rice, Ready-to-Use Nutritional Food (RUF), Ready-to-Use Supplementary Food (RUSF), Ready-to-Use Therapeutic Food (RUTF), Super Cereal Plus.
  - Milled Rice specifications were updated.
  - Four products are under development, with draft specifications written.
- ✓ Macronutrients were updated in Fortified Blended Foods (FBFs):
  - Energy and fat content in FBF porridge increased through recommendation to prepare with more oil. Field trial demonstrated feasibility. Now adopted.
- ✓ Micronutrients were updated in CSB and WSB:
  - B_2, B_3, and B_5, Zinc and Vitamin E were *increased*. Vitamin C was *increased*.
  - Vitamin K and potassium were *added*.
  - Ferrous fumarate is now combined with NaFeEDTA to enhance iron bioavailability.
  - Calcium and magnesium *decreased* to align with World Food Programme (WFP) specifications.
- ✓ Micronutrient premix for cereal blends and milled cereals was also upgraded:
  - Vitamins B_1, and B_3 levels were *decreased.*
  - B_6, D_3 and zinc were all *added*.

- Iron was *reduced* due to adoption of NaFeEDTA. This reduction does not alter the amount of iron uptake by the end user, as NaFeEDTA enhances iron bioavailability.
- Vitamin A was *increased* to align with WFP specifications.

✓ New sorghum-pea blend and lipid-based products were formulated and are now being field-tested.
✓ Ready-to-Use Foods (RUFs) are now included in Title II's basket of products.
✓ Smaller FBF bags were proposed and are in the process of being adopted in programming.
✓ Protein quantity in FBF was *increased* via dry dairy ingredients (WPC34 and WPC80).
✓ The Commodity Reference Guide (CRG) is now being updated quarterly. New product fact sheets are written on a rolling basis.
✓ Accelerated shelf-life studies were completed on FBFs and RUSF. The results indicate degradation of vitamin A in FBFs which provides evidence to improve packaging or shelf-life to maintain vitamin A. A solution is programming FBFs with FVO to ensure vitamin A needs are met.

Programming

✓ Building the evidence-base:
  - Demonstrated value of smaller FBF bags: streamlines distribution process, enhances dignity for recipient, potentially reduces food contamination.
  - Demonstrated that social and behavioral change communication (SBCC) given along with vegetable oil improves compliance in FBF preparation.
  - Demonstrated feasibility of having beneficiaries add more oil to FBF preparation.
  - Demonstrated value of focusing on *cost-effectiveness,* not just commodity price.

✓ With FFP and WFP, the FAQR team established a website to share information on planned/ongoing operations and other field research relevant to food aid operations called REFINE (Research Engagement on Food Innovation for Nutritional Effectiveness) which allows agencies and researchers to identify knowledge gaps in food aid research.
✓ There are ongoing field trials will respond to demand for evidence of what works in relation to management of MAM, prevention of stunting, body mass, and value-chain costs.

Enhancing Processes

✓ Hosted five US government-wide meetings in Washington, DC involving USDA (FNS, FSA, FAS/FAD, FAS/Transportation Logistics Branch, Grain Inspection, Packers and Stockyards Administration [GIPSA], Agricultural Research Service, Kansas City Commodity Office [KCCO]), USAID (FFP, Global Health [GH], HIV/AIDS), and the NIH.
  - Improved communication among key US agencies involved in the food aid agenda; collaboration (to avoid duplication of efforts) in testing new products and programming approaches.
  - Technical working groups established to focus on resolving inter-agency issues.

✓ Ongoing work on template, guidance, and procurement process enhancements.
✓ Hosted nine global harmonization meetings (USAID, WFP, UNICEF, MSF, and engagement with FAO).
  - Formation of a technical inter-agency group which has adopted a formal Terms of Reference and working agenda, with FAQR team acting as secretariat.
  - Successful multi-agency harmonization of product specifications (premix as well as macronutrient composition), packaging and labeling.

- Standardization of product usage guidance for field implementers.
- Moves towards joint audits and common food safety standards.
- Moves toward promoting single RUF versus multiple variants, consensus on micronutrient specifications, adoption of standard size of packaging, bulk packaging and improved packaging materials.
- Common approach to advocating for RUF specifications with CODEX.

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Annex 1. Food Aid Quality Review Acknowledgements

The Food Aid Quality Review would like to acknowledge contributing research staff, consultants and partners:

Principal Investigators

Patrick Webb, PhD
Principal Investigator (PI), Lead Author
Alexander McFarlane Professor of Nutrition
Friedman School of Nutrition
Tufts University

Beatrice Roger, PhD
Co-Principal Investigator, Lead Author
Professor, FPAN Program Director
Friedman School of Nutrition
Tufts University

Research Staff and Consultants (domestic)

Irwin Rosenberg, MD
Science Research Specialist
Professor
Friedman School of Nutrition
Tufts University

Ken Chui, PhD
Biostatistician
Assistant Professor
Friedman School of Nutrition
Tufts University

Shelley Walton
Project Manager
Friedman School of Nutrition
Tufts University

Jocelyn Boiteau
Project Administrator
Friedman School of Nutrition
Tufts University

Elizabeth Ignowski
Research Coordinator
Tufts University

Stephen Vosti, PhD
Consultant
Costing Specialist

Quentin Johnson
Consultant
Food Technologist

Devika Suri
Consultant
Data Manager

Breanne Langlois
Data Analyst
Friedman School of Nutrition
Tufts University

Lauren Wilner
Data Analyst
Friedman School of Nutrition
Tufts University

Simone Passarelli
Data Analyst
Friedman School of Nutrition
Tufts University

Kristine Caiafa
Research Assistant
Friedman School of Nutrition
Tufts University

Harley Stokes
Research Assistant
Friedman School of Nutrition
Tufts University

Research Staff and Consultants (Burkina Faso)

Ilana Cliffer
Field Research Director
Friedman School of Nutrition
Tufts University

Adéline Kologo
Consultant
Field Research Assistant

Nadira Saleh
Consultant
SBCC and Acceptability Test Research Assistant

Research Staff and Consultants (Malawi)

Gray Maganga
Senior Research Coordinator
Friedman School of Nutrition
Tufts University

Ishmael Nkosi
Consultant
Field Research Assistant

Research Staff and Consultants (Sierra Leone)

Jamie Green
Field Research Director
Friedman School of Nutrition
Tufts University

Subcontracting Partners

Global Food & Nutrition
Nina Schlossman, President
Leah Koeppel, Program and Research Coordinator
Lauren Wood, Program and Research Coordinator
Nicole Coglianese, Program and Research Coordinator

ACDI/VOCA
Robert Rosengren, Senior Technical Director
Dylan Butler, Project Coordinator
Elise Solario, Project Coordinator
Régis Terrien, Deputy Chief of Party

Save the Children, USA
Beatrice Sheuermann, Program Manager
Suzanne Berkey, Senior Director

Institut de Recherche en Sciences de la Santé (IRSS)
Laetitia Ouedraogo, Co-Investigator
Seni Kouanda, Co-investigator
Hermann Lanou, Co-Investigator
Augustin Zeba, Co-Investigator
IRSS

University of Malawi, Center for Social Research
Alister Munthali, Co-investigator

Washington University in St. Louis
Mark Manary, Co-Investigator
Bethany Marron, Clinical Research Manager
Amanda Maust, Clinical Research Manager
Ellen Murray, Project Coordinator
Elizabeth Cimo, Data Analyst

International Nutrition Foundation (INF)
Memuna Sawi, Co-investigator, Njala University
Nicole Lescarbeau, Grant and Accounting Manager

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Annex 2. Summary of FAQR Phase II Accomplishments

2.1 Meetings (38)

Meeting	Purpose
International Interagency Harmonization (9)	The purpose of International Interagency Harmonization meetings (USAID, WFP, UNICEF) is to discuss areas of potential harmonization among agencies programming food aid with nutritional goals and reached agreement on a commitment to advance harmonization as well as the process for continued collaboration. Meetings focus on the harmonization of issues in relation to: a) product specifications and formulations; b) quality assurance and control requirements; c) packaging; d) policy processes around the review of new or changed products; and e) problem resolution/common approaches to supplier review and approval.
US Interagency (USAID/USDA) (5)	The US Interagency (USAID/USDA) meetings focus on enhancing communications and technical dialogue among US partners involved in food aid.
FAQR Team Meetings (12)	The FAQR team held team meetings to discuss FAQR activities and deliverables in each of the three main areas: products, programming and processes, and to outline next steps.
Meetings at Kansas City (2)	The FAQR team **visited Kansas State University (KSU) and KCCO** on January 31 to February 1, 2012 to meet with stakeholders and visit a CSB production facility, share methodology and projected timetable for completing draft updated of CRD documents. The FAQR team visited KCCO/Procurement Support Branch on May 2, 2013. FAQR team members and a WFP representative participated in meetings with teams from GIPSA Federal Grain Inspection Service (FGIS) laboratories and USDA KCCO/Procurement Support Branch.
International Food Aid & Development Conference (IFADC)	The FAQR team attended the **International Food Aid & Development Conference (IFADC)** held from May 7-9, 2012. THE IFDAC allowed the team to stay informed on new development in U.S. Government programs with similar nutrition and food security objectives. The FAQR team convened an **IFADC side meeting with industry** stakeholders on May 8, 2012 as part of the ongoing consultation with industry and other Title II stakeholders. The FAQR team also convened an **IFADC side meeting with PVOs** on May 9, 2012 to seek input on defining the future process of engagement and consultation.

International Atomic Energy Agency (IAEA) Symposium	The FAQR team attended the **International Atomic Energy Agency (IAEA) Symposium** "Understanding Moderate Malnutrition in Children for Effective Interventions" held on May 26-28, 2014. Dr. Beatrice Rogers presented at the IAEA symposium, "Maximizing Potential for Impact: Measuring and Addressing Issues of Supplement Sharing and Diversion in MAM Programs," based in part on preliminary results from the first round of data collected in Malawi. Dr. Patrick Webb also presented at IAEA, "What works in managing MAM? Evidence from recent systematic reviews and remaining knowledge gaps."
Experimental Biology (2)	The FAQR team presented a poster at **Experimental Biology 2013**: *Systematic Review and Meta-Analysis of Food-Based Interventions for Recovery from Moderate Acute Malnutrition.* The FAQR team presented two posters at **Experimental Biology 2015**: *The Price of Oil: Assessing Behavior Change Communication & Increased Oil Ration on improving Oil Use in Food Aid Preparation for Children Malawi*[14] and *Comparison of Four Supplementary Foods in Treating Moderate Acute Malnutrition in Sierra Leone: an Ebola-truncated Effectiveness Study*[15].
Global Technical Meeting: Long-Term Consequences of Chronic Undernutrition in Early Life	Dr. Patrick Webb moderated the jointly hosted by UNICEF, Emory and Tufts Universities' Global Technical Meeting. The purpose of this meeting was to learn about current research on stunting.
FAQR Team Retreat	The primary purpose of the FAQR team retreat, May 6-8, 2013, was to finalize preparations for the three upcoming FAQR field studies and to finalize and move forward on FAQR Phase II deliverables. This served as a platform for the entire FAQR team to review aspects of Phase II in person and converge on next steps.
Malawi Dissemination Meetings (2)	The FAQR Field Research Coordinator in Malawi, Gray Maganga, held **Field Exit Meetings** in December 2014 with CRS, USAID mission, and PVOs (Africare, Save the Children and Project Concern International) to discuss preliminary study results, date use and publications, and field exit plan and process. The meetings provided an opportunity to answer questions on the recommended ratio of distributing and preparing CSB and FVO. Maganga also met with the Ministry of Health (MOH), Nation Health Science Research Center

[14] Found at: http://foodaidquality.pbworks.com/w/file/105591195/FINAL%20MALAWI%20EB%20POSTER%20FOR%20SUBMISSION%2024%20MAR%2015.pdf

[15] Found at: http://foodaidquality.pbworks.com/w/file/105591171/FINAL%20SALONE%20EB%20POSTER%20FOR%20SUBMISSION-%2024MAR15.pdf

	(NHSRC), and local partners to review the study process, share preliminary results and discuss the use of data. Participants provided feedback on the study process during these meetings. The FAQR team held the Malawi Dissemination of Results[16] on May 27-28, 2015 in Washington, DC. The FAQR team presented the Malawi research results at the USAID, and collaborated with TOPS to host a meeting for the PVO community, with a breakout group session following the presentation of results.
Protein Quality Briefing	The FAQR team held a **Protein Quality Briefing** on July 11, 2012 in Washington, DC, to share conclusions from the Protein Quality Workshop, discuss future research and policy/program implications, and provide a forum for further input from industry stakeholders.
International Union of Nutritional Sciences (IUNS)Committee International Congress on Nutrition (ICN)	The FAQR team attended the 2013 **International Congress on Nutrition** held in Granada, Spain from September 15-20, 2013. Specifically, the team attended sessions relating to stunting, treatment and prevention of MAM and SAM, biomarkers of growth, measurements for assessing malnutrition, food aid products, and processes and programs. The FAQR team, WFP, and Nevin Scrimshaw International Nutrition Foundation, with support from USAID/FFP, organized the **REFINE Launch Event, ICN Satellite Symposium** held on September 15, 2013. The symposium, titled "What Works in Prevention and Treatment of Moderate Acute Malnutrition: A Systematic Review of Meta-Analyses," brought together members of the research, academic, and policy communities working on interventions for the treatment of prevention of acute malnutrition. Presenters discussed the current findings of three recent systematic reviews on food aid for treatment or prevention of MAM, compared and contrasted the systematic reviews, and identified policy and program implications and areas in which future research is needed. The symposium also marked the launch of the REFINE. The FAQR team presented a poster: *Systematic Review and Meta-Analysis of Food-Based Interventions for Recovery from Moderate Acute Malnutrition*

[16] Found at: http://foodaidquality.pbworks.com/w/file/97725258/FAQR%20Malawi%20Study%20Results.pdf

2.2 Workshops (6)

Workshop	Purpose
Protein Quality Workshop	The FAQR team held a **Protein Quality Workshop** on May 16-17, 2012 at Tufts University, Boston, MA to determine the state of the science and evidence about protein quality and sources in relation to the needs of nutritionally-vulnerable groups. The workshop consisted of four scientific sessions plus a fifth session to summarize findings and to identify future research needs.
FAQR Workshop at the East Africa Regional Knowledge Sharing Meeting	The FAQR team organized a **workshop at the East Africa Regional Knowledge Sharing Meeting** in Addis Ababa, Ethiopia held on June 11-13, 2012. The workshop focused on uses of Title II reporting requirements, and sought input from those directly involved in program implementation that collection, report and make use of the information provided in the various reports. The goal of the session was to determine the burden, accuracy and usefulness of data collected, and to obtain recommendations for ensuring data are used to inform and improve program design.
Uses of Data Stakeholder Workshops (2)	The FAQR team and TOPS held a **Uses of Data Stakeholder Workshop** on October 16, 2012. The purpose of the workshop was to get PCO perspectives on the usefulness, burden, and accuracy of Title II data collection and reporting and to identify ways in which data use could be improved to inform program design. The FAQR team held a second **Uses of Data Stakeholder Workshop on** July 12, 2013 with FFP stakeholders, followed by a coordination meeting with TOPS to review workshop recommendations.
SQ-LNS and MNP Workshops (2)	The FAQR team participated in working groups to plan the USAID-sponsored **Micronutrient Powder (MNP) and Small Quantity-LNS (SQ-LNS)** consultations in Washington, DC held on October 14-16, 2015 and October 19-20, 2015. The aim of the consultation was to summarize, review and analyze from operationalizing MNP and SQ-LNS in programmatic settings.

2.3 Reports (27)[17]

- Quarterly Technical Reports to USAID (18): October 2011-January 2016
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2.4 Publications (11)

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2.5 Scientific Poster Abstracts (4)

2.5.1 Systematic Review and Meta-Analysis of Food-based Interventions for Recovery from moderate Acute Malnutrition (Presented at EB 2013)

Suri D[1]; Moorthy D[2]; Rosenberg I[1,3]
[1]Nevin Scrimshaw International Nutrition Foundation, Boston, MA, US
[2] Tufts Medical Center, Boston, MA, US
[3] Tufts University, Friedman School of Nutrition Science and Policy, Boston, MA, US

Background and Objective: The rationale of this systematic review was to examine the comparative effectiveness of lipid-based nutrient supplements (LNS) versus fortified blended foods (FBF) in the treatment of moderate acute malnutrition (MAM).
Data Sources: All published articles identified though MEDLINE® and Cochrane Central Register of Controlled Trials, from inception to July 2012.
Study Selection: Reviewers independently selected eligible comparative studies of children under age five with MAM. Interventions were broadly categorized as FBF or LNS.
Results: Thirty-four out of 12,453 screened articles were accepted. Interventions ranged from eight to 16 weeks. Meta-analysis of five studies showed a 10% less recovery rate from MAM in children treated with FBF as compared with LNS (RR=0.9, 95% CI 0.8,1.01; 79.6% LNS vs 77.5% FBF). This indicates that for every 48 children who were treated with FBF rather than LNS, one less child recovered from moderate malnutrition. Weight gain was significantly higher in children treated with LNS but change in length was not significantly higher in children treated with FBF.
Conclusions: LNS is associated with a higher rate of recovery from MAM when compared with FBF. The studies on children with MAM are heterogeneous leading to dilution of comparative effect. The clinical relevance of outcomes as well as cost-effectiveness needs to be taken into consideration when interpreting the results.

2.5.2 The Price of Oil: Assessing Behavior Change Communication & Increased Oil Ration on improving Oil Use in Food Aid Preparation for Children Malawi (Presented at EB 2015)

Lauren Wilner[1], Devika Suri[1], Gray Maganga[1], Breanne Langlois[1], Shelley Marcus[1], Jocelyn Boiteau[1], Patrick Webb[1] and Beatrice Rogers[1].
[1]Friedman School, Tufts University, Boston, United States.

Objective: As part of USAID's Food Aid Quality Review, a study evaluated the effectiveness of providing an additional oil ration in tandem with social behavior change communication (SBCC) to an existing supplementation program to increase the oil content and reduce sharing of porridge prepared for children under age five with moderate acute malnutrition in Malawi.
Methods: Mothers/caretakers (BMCs) of beneficiary children in the program were randomly selected at 12 intervention and four control food distribution points (FDPs) for participation in interviews and to provide samples of their porridge for analysis. The two intervention groups each received a monthly ration of 2.6 L fortified vegetable oil (FVO), 8 kg Corn Soy Blend (CSB) and SBCC. Controls received a standard ration of 1 L oil, 8 kg CSB and no messaging. The proportion of BMCs receiving messaging about porridge preparation, as well as about ingredient use, storage, and purposes was analyzed. Community health workers (CHWs) and BMCs from all three groups were compared in order to understand the flow of communication, and the perception of SBCC messaging on behalf of those communicating the messages (CHWs), and those receiving the messages (BMCs).
Results: There were 235 BMCs in the intervention and 160 in the control groups. On average, BMCs in the intervention groups were instructed to use higher ratios of FVO:CSB (37:100 in intervention group 1, 41:100 in intervention group 2, and 24:100 in the control group), which correlated with higher lab values in the intervention groups than the control for the FVO:CSB ratio (28:100, 25:100, and 12:100 respectively).
Conclusion: While the success of this intervention is attributable to the combination of increased FVO ration, as well as SBCC, the differential SBCC among the groups indicates the importance of SBCC in promoting specific behaviors.

2.5.3 Comparison of four supplementary foods in treating moderate acute malnutrition in Sierra Leone: an Ebola-truncated effectiveness study (Presented at EB 2015)

Bethany Marron[2], Jamie Green[1], Lauren Jayson[1], Devika Suri[1], Shelley Marcus[1], Jocelyn Boiteau[1], Mark Manary[2], Patrick Webb[1] and Beatrice Rogers[1].
[1]Friedman School of Nutrition, Tufts University, Boston, US
[2]Washington University, St. Louis, MO

Objective: A prospective cluster randomized control trial, supported by WFP and USAID, compared the effectiveness of four supplementary foods in the treatment of moderate acute malnutrition (MAM) in children six to 59 months of age in normal programmatic settings in Sierra Leone.
Methods: Twenty clinics in Kenema District were randomly assigned to one of four treatment foods: Super Cereal (SC) plus fortified vegetable oil (FVO) and sugar (acting as the comparison group), Super Cereal Plus (SC+), Corn Soy Blend 14 (CSB14) plus FVO, and Plumpy'Sup (PS). Children aged six to 59 months with MAM (MUAC > 11.0 cm and < 12.5 cm) were enrolled in the clinic-based supplementary feeding programs, receiving a food ration every two weeks for 12 weeks or until recovered from MAM (determined by MUAC ≥ 12.5 cm). Beneficiaries' anthropometric data were collected during each clinic visit including MUAC, height, and weight.
Results: The study was terminated early due to the Ebola outbreak and our sample size was reduced from 5,000 to 1,153 children who enrolled in and completed the study. Out of these, recovery rates were 61% in the SC plus FVO group (comparison), 56% in the CSB14 group, 57% in the PS group, and 63% in the SC+ group. There were no significant differences in recovery rates, SAM, or failure to respond between each study arm and the SC comparison group; death rates were significantly higher in SC+ compared with SC (0.9% vs 3.2%, p=0.046).
Conclusion: We found no significant difference in MAM recovery rates among the four supplementary foods. However, due to our limited sample size the power to detect a significant difference was reduced.

2.5.4 Systematic Review and Meta-Analysis of Food-based Interventions for Recovery from Moderate Acute Malnutrition (Presented at ICN 2013)

Suri D[1]; Moorthy D[2]; Rosenberg I[1,3]
[1]Nevin Scrimshaw International Nutrition Foundation, Boston, MA, US
[2] Tufts Medical Center, Boston, MA, US
[3] Tufts University, Friedman School of Nutrition Science and Policy, Boston, MA, US

Background and Objectives: The rationale of this systematic review was to examine the comparative effectiveness of lipid-based nutrient supplements (LNS) versus fortified blended foods (FBF) in treatment of moderate acute malnutrition (MAM), and effects on growth in young children.
Data Sources: All published articles identified though MEDLINE®, and the Cochrane Central Register of Controlled Trials, from inception to July 2012.
Study Selection: Reviewers independently selected studies on the basis of predetermined eligibility criteria, considering any comparative studies of children under age five with MAM. Interventions were broadly categorized as FBF or LNS. Outcomes of interest included recovery from MAM, weight and length gain.
Data Extraction: Article information was extracted using a standardized protocol into predesigned forms and reviewed for accuracy.
Results: Thirty-four out of 12,453 screened articles were accepted, after a two-step process of double independent abstract and full text screening. Interventions ranged from eight to 16 weeks. Meta-analysis of five studies showed a 10% lesser recovery rate from MAM in children treated with FBF as compared with LNS (RR=0.9, 95% CI 0.8,1.01.; 79.6% LNS vs 77.5% FBF). This indicates that for every 48 children who are treated with FBF rather than LNS, one child will not recover from moderate acute malnutrition. Weight gain was significantly higher in children treated with LNS (SMD = -0.21; 95%CI -0.31,-0.1; n=4 studies). The change in length was higher in children treated with FBF (SMD=-0.02; 95%CI -0.1-0.06; n=4 studies) but this difference was not significant.
Conclusions: LNS is associated with a higher rate of recovery from MAM and a larger weight gain when compared with FBF. The studies on children with MAM are heterogeneous leading to dilution of comparative effect. The clinical relevance of outcomes and differences between treatments with LNS vs FBF, as well as cost-effectiveness need to be taken into consideration when interpreting the results.
Key Words: moderate acute malnutrition (MAM), LNS, FBF, therapeutic foods, children, systematic review

2.6 Food Aid Commodities

The FAQR team procured food aid commodities for the Prevention Study in Burkina Faso (CSB14, SC+, and RUSF) and the Treatment Study in Sierra Leone (CSB14). The FAQR team solicited competitive Terms of Reference bids, reviewed supplier responses, and selected suppliers to each of the commodities. FAQR coordinated with field staff, implementing partners, and commodity suppliers to establish commodity production and shipment schedules. The FAQR team worked with the suppliers and freight forwarders to schedule overseas commodity shipments. To determine production and shipping schedules, the FAQR team took into consideration in-country warehouse capacity, rate of food distribution and warehouse drawdown, and the timelines for production (availability of suppliers to procure the raw materials and produce the commodity), transcontinental shipment, customs clearance, and inland transportation. With each production, the FAQR team reviewed and approved Certificates of Analyses prior to shipment. The FAQR implementing partners assisted in customs clearance and in-country transport of the products.

2.6.1 Commodity Procurement for Prevention Study in Burkina Faso

	Shipment 1	**Shipment 2**	**Shipment 3**	**Shipment 4**	**Shipment 5**	**Shipment 6**	**Total**
CSB14 (MT)	**103.7**	**89.0**	**103.3**	**86.1**	**68.9**	**0**	**451.0**
SC+ (MT)	**142.8**	**120.0**	**126.3**	**59.03**	**52.0**	**65**	**574.1**
RUSF (MT)	**129.3**	**143.0**	**26.8**	**93.7**	**53.7**	**27**	**473.5**

***Note that the other study foods were procured by ACDI/VOCA: CSB+ and FVO**

2.6.2 Commodity Procurement for Treatment Study in Sierra Leone

	Shipment 1	**Shipment 2**
CSB14 (MT)	**8**	**6**

***Note that the other study foods were procured by WFP or donated: SC+, SC, FVO, Sugar, RUSF**

2.7 Web Communications

- **Foodaidquality.pbworks.com**
  - Workspace users: 710
- **REFINEnutrition.org**
  - Studies tracked: 60 (ongoing or recently completed)
  - Publications in REFINE library: 178
  - Update newsletters (started November 2014): 8

- Total @REFINEnutrition tweets (started July 2015): 61

2.8 Collaborators (45)

Products (14)	• United States Agency for International Development (USAID) • United States Department of Agriculture (USDA) • Global Food & Nutrition Inc. • Quican Inc. (Quentin Johnson, consultant) • Covance Laboratory • Kansas State University • Kansas City Commodity Operations • Bunge North America • Didion Milling • Cal Western Packaging Corporation • Challenge Dairy Products • Edesia • Federal Grain Inspection Service • Harvard University

Programming (29)	• Technical and Operational Performance Support (TOPS)
	• Nevin Scrimshaw International Nutrition Foundation (INF)
	• University of California, Davis (Stephen Vosti, consultant)
	• Ministry of Health, Malawi
	• University of Malawi, Centre for Social Research
	• Catholic Relief Services (CRS) Malawi
	  o Wellness and Agriculture for Life Advancement (WALA) program
	  o Africare
	  o Total Land Care (TLC)
	  o World Vision International (WVI)
	  o Project Concern International (PCI)
	• University of Malawi, Chancellor College (CHANCO) laboratory
	• Pakachere Institute of Health and Development Communication (PIHDC)
	• Ministry of Health, Burkina Faso
	• Institut de Recherche en Sciences de Santé (IRSS)
	• ACDI/VOCA
	• Save the Children
	• Institut de Recherche en Sciences Appliquées et Technologies (IRSAT), Burkina Faso
	• National Public Health Laboratory (LNSP), Burkina Faso
	• Sierra Leone Ministry of Health and Sanitation
	• Washington University in St. Louis
	• Project Peanut Butter
	• Njala University in Sierra Leone
	• Didion Milling
	• Challenge Dairy
	• Edesia
	• Starship International
	• Fettig & Donalty, Inc.
	• Food and Nutrition Technical Assistance III Project (FHI360/FANTA III)

Processes (6)	• World Food Programme (WFP) • United Nations Children's Fund (UNICEF) • United States Department of Agriculture (USDA) • Médecins Sans Frontières (MSF) • Emory University • Natick Laboratories

Annex 3. Summary Table with Phase I Recommendations and Status

FAQR Phase I Recommendations		
Rec. #	**Recommendation**	**Status**
A. Upgrade the Macronutrient Composition of CSB		
1	The quantity of protein should be increased, and whey protein concentrate (WPC) should be added.	Completed-FY13
2	Increase the fat content.	Completed-FY13
3	Increase the energy content.	Completed-FY13
4	Add a flavor enhancer to formulations of FBFs.	Removed from Phase II Deliverables
B. Upgrade the Micronutrient Composition of CSB		
5	Increase the levels of vitamins B_1 (thiamin), B_2 (riboflavin), B_3 (niacin), B_5 (pantothenic acid), B_{12}, D_3, and E.	Completed-FY13
6	Maintain vitamin C at the current level.	Completed-FY13
7	Reduce levels of vitamin A.	Completed-FY13
8	Add vitamin K to the premix provisionally.	Completed-FY13
9	Combine two forms of iron, NaFeEDTA and ferrous fumarate, in the premix to enhance iron absorption.	Completed-FY13
10	Increase levels of zinc and add potassium.	Completed-FY13
11	Decrease levels of magnesium, calcium, iodine, and sodium.	Completed-FY13
C. Upgrade the Premix for Cereal Blends and for Milled Cereals		
12	Cut levels of vitamin A, vitamin B_1, vitamin B_3, and iron, but increase vitamins D_3 and B_6.	Completed-FY13
13	Change the form of iron in the premix to NaFeEDTA.	Completed-FY13
14	Add zinc and vitamin B_{12} at levels recommended by WHO.	Completed-FY13
15	Remove calcium from the premix.	Completed-FY13
D. Upgrade the Micronutrient Composition of Fortified Vegetable Oil		
16	Maintain level of vitamin A in oil and add vitamin D.	Completed-FY13
E. Introduction of New Products		
17	Lipid-based products should be available for use by Title II implementing partners.	Completed-FY14
18	Encourage the development of new cereal-based FBFs.	Ongoing throughout the life of FAQR
19	Establish public–private partnerships to accelerate development, testing, and implementation of new products.	Ongoing throughout the life of FAQR
20	Establish a Micronutrient Fortification Program for pursuing innovations in micronutrient delivery.	Removed from Phase II Deliverables
21	Ship micronutrient premix and home fortificant powders as Title II products.	Removed from Phase II Deliverables
F. Current Programming Approaches		
22	The capacity for rigorous evaluation of program innovations should be strengthened.	Ongoing throughout the life of FAQR
23	USAID and the office of HIV/AIDS should develop guidance on priority demographics for nutrition support and food assistance.	Removed from Phase II Deliverables
24	Better indicators of nutritional need and cutoffs are needed to determine eligibility for food assistance in HIV programming.	Removed from Phase II Deliverables
25	A strong signal is needed from PEPFAR supporting allocation of funds *for food* in HIV programs.	Removed from Phase II Deliverables
G. Enhancing Programming Guidance to Implementing Partners		
26	Support implementing partners to incorporate data on local consumption and food availability into the design of rations and programs.	Completed- FY14

FAQR Phase I Recommendations		
Rec. #	**Recommendation**	**Status**
27	USAID should improve training on needs assessment and on monitoring and evaluation methods and tools with regard to nutrition.	Completed-FY14
28	USAID should systematically incorporate cost-effectiveness into the evidence base for nutrition programming.	In progress-Expected Completion FY19
29	Enhanced guidance should be prepared (such as decision tree tools) to enable agencies to better select commodities for programming.	Completed-FY14
H. Enhanced Coordination Across the US Food Aid System		
30	Establish an Interagency Food Aid Committee.	Completed-FY12
I. New Product Introduction and Modification		
31	Establish a formal product review and approval process.	In progress-Expected Completion FY17
32	Establish performance-based specifications (i.e., basic nutritional profiles of final products) for nutritionally-enhanced products.	Completed-FY14
33	Develop a planning model which would better predict demand for FBFs and support longer vendor contracts for value-added commodities.	In progress-Expected Completion FY16
J. Quality Assurance		
34	Design and implement a comprehensive food aid quality assurance strategy and plan of action.	In progress-Expected Completion FY17
35	Update the Commodities Reference Guide (CRG) and establish a process for regular updating and communication.	Completed FY14 (Commodity Fact Sheets)

Annex 4. Export Commodities Upgraded or Developed During FAQR Phase II, with Commodity Requirement Documents (CRDs)

	Export Commodity Item	Technical Name	Effective Date	Upgrades During FAQR Phase II	Commodity Reference Guide Fact Sheet Status	CRD Link
1. 2.	All Purpose Wheat Flour Bread Flour	WFBF7	Jul 25, 2012	1: current version	-updated	http://www.fsa.usda.gov/Assets/USDA-FSA-Public/usdafiles/Comm-Operations/pdf/wfbf7.pdf
3. 4.	Bulgur Soy-Fortified Bulgur	BWSF15	Aug 6, 2015	3: current version, BWSF14 (1), BWSF15 (1)	-updated	http://www.fsa.usda.gov/Assets/USDA-FSA-Public/usdafiles/Comm-Operations/procurement-and-sales/export/pdfs/bwsf15.pdf
5.	Cornmeal	CM6	Aug 6, 2015	3: current version, CM5 (1), CM6 (1)	-updated	http://www.fsa.usda.gov/Assets/USDA-FSA-Public/usdafiles/Comm-Operations/procurement-and-sales/export/pdfs/cm6.pdf
6.	Corn Soy Blend Plus	CSBP2	Sept 2, 2014	4: current version, CSB1 (2), CSB2 (1)	-updated	http://www.fsa.usda.gov/Assets/USDA-FSA-Public/usdafiles/Comm-Operations/procurement-and-sales/export/pdfs/csbp2.pdf
7. 8.	Dried Dairy Ingredients: WPC34 WPC80	DDI2	Nov 27, 2013	1: current version	-updated	http://www.fsa.usda.gov/Assets/USDA-FSA-Public/usdafiles/Comm-Operations/procurement-and-sales/export/pdfs/ddi2.pdf
9.	High Energy Biscuits	HEB1	May 13, 2015	1: current version	- under development	http://www.fsa.usda.gov/Assets/USDA-FSA-Public/usdafiles/Comm-Operations/pdf/Highenergybiscuit.pdf
10. 11.	Milled Rice Fortified	MR23 MR25	Jul 8, 2014 Feb 3, 2016	1: MR23 2: current version,	-updated - under	https://www.fsa.usda.gov/Assets/USDA-FSA-Public/usdafiles/Comm-Operations/pdf/mr23_090513.pdf https://www.fsa.usda.gov/Assets/U

	Milled Rice			MR24 (1)	development	SDA-FSA-Public/usdafiles/Comm-Operations/pdf/MR25A.pdf
12.	Ready-to-Use Nutritional Food (RUF)	RUF	Dec 21, 2015	1: current version	-under development	http://www.fsa.usda.gov/Assets/USDA-FSA-Public/usdafiles/Comm-Operations/pdf/ruf.pdf
13.	Ready-to-Use Supplementary Food (RUSF)	RUSF	Aug 18, 2015	2: current version, RUSF1	-updated	http://www.fsa.usda.gov/Assets/USDA-FSA-Public/usdafiles/Comm-Operations/pdf/rusf1.pdf
14.	Ready-To-Use Therapeutic Food (RUTF)	RUTF	May 22, 2012	1: current version	-updated	http://www.fsa.usda.gov/Assets/USDA-FSA-Public/usdafiles/Comm-Operations/pdf/rutf2.pdf
15.	Soy Fortified Cornmeal	SFCM4	Aug 6, 2015	4: current version, SFCM3 (1), SFCM4 (2)	-updated	http://www.fsa.usda.gov/Assets/USDA-FSA-Public/usdafiles/Comm-Operations/pdf/sfcm4.pdf
16.	Super Cereal Plus	SCP1	Mar 26, 2014	1: current version	-updated	http://www.fsa.usda.gov/Assets/USDA-FSA-Public/usdafiles/Comm-Operations/pdf/scp1.pdf
17.	Vegetable Oil Products	VO15	Aug 5, 2015	3: current version, VO13 (1), VO14 (1)	-updated	http://www.fsa.usda.gov/Assets/USDA-FSA-Public/usdafiles/Comm-Operations/procurement-and-sales/export/pdfs/vo15.pdf
Commodities Under Development						
18.	Rice Soy Blend Plus/Supercereal Rice	-	draft	draft specifications: December, 2014	-	-
19.	Supercereal Plus-Rice	-	draft	draft specifications: December, 2014	-	-
20.	Wheat Soy Blend Plus/Supercereal- Wheat	-	draft	draft specifications: December, 2014	-	-
21.	Supercereal Plus- Wheat	-	draft	draft specifications: December, 2014	-	-

Annex 5. Case Study of Corn Soy Whey Blend (CSWB/CSB14) for Effectiveness Trials in Sierra Leone and Burkina Faso: The US Food Assistance Supply Chain on a Small Scale

- **Develop product specifications**
  - Base specifications on CSB13, updated with micronutrient and macronutrient recommendations from FAQR Phase I; integrate with WHO Technical Note (July 2012) and input from WFP
  - Harmonize specifications based on new iterations of CSB Plus and USAID specifications during two year period
- **Identify suppliers and source new product samples in the US**
  - Identify more than one supplier for product
  - Develop Terms of Reference (TOR) to procure product samples and request prototypes from three suppliers
- **Conduct consumer taste tests**
  - Global Food and Nutrition conducted taste panels in Boston, Washington DC, and Liberia
  - Tufts conducted taste testing in Malawi and Burkina Faso as part of the trials there
  - Determine which samples met organoleptic criteria and consumer preference; all of them did
- **Study feasibility of recommendations**
  - Tufts conducted a study in Malawi to test programming, packaging and messaging recommendations, in specific the recommendation to prepare CSWB with fortified vegetable oil in correct proportions (50 g CSWB to 15 g oil for children under 24 months; 100g CSWB to 30 g vegoil to mothers) in order to ensure the recommended nutrient consumption
- **Procure product for effectiveness trials (6 months)**
  - Develop and issue Terms of Reference (TOR), Request for Proposals (RFP) and evaluation criteria
  - Send out to all the suppliers identified
  - Evaluate bids–understand lead time required for new products and nature of start up production
  - Procure products; work with freight forwarder and NGO partner to make shipping and delivery arrangements for the first tranche of product to get to the field in time for start of messaging/packaging trials (Malawi) effectiveness trials (Burkina Faso; Sierra Leone)
  - Work with NGO and local authorities to obtain approval for importation of any new commodities
  - Work with NGO on repackaging, storage conditions, handling, distribution to beneficiaries, and preparation
- **Conduct accelerated shelf life and stability testing (26 weeks testing; 6 weeks report/presentations)**
  - Source products; identify and seek bids from certified third part laboratories (3) specializing in shelf life and stability testing in the US
  - Select and make arrangements with laboratory
  - Develop protocol for accelerated shelf life tests
  - Receive, manage and tabulate results
  - Develop report on results
    - Recommendations to incorporate these tests in all future new products based on what was learned about product parameters, premix, testing
- **Conduct effectiveness and cost-effectiveness trials (3-4 years)**
  - Build the evidence base for incorporating CSWB into USG food aid basket
    - Identify partners
    - Develop study protocols
    - Recruit study subjects; randomize treatment groups
    - Collect data
    - Analyze data

Annex 6. Nutritional Content of CSB14 compared to CSB13

		CSB13	CSB14
Nutrient	**unit**	**100 g**	**100 g**
Kcals	Kcals	386.1	380
Protein (g)	g	15.9	14
Fat (g)	g	8.7	6
Mineral			
Calcium	mg	650	362
Copper	mg	0.403	_
Iodine	mg	0.06	0.04
Iron	mg	10.56	6.5
Magnesium	mg	167.95	_
Manganese	mg	0.815	_
Phosphorus	mg	522	280
Potassium	mg	563	140
Selenium	mg	0.021	_
Sodium	mg	326.31	_
Zinc	mg	5.94	5
Vitamin			
Vit A	mcg	819	1038.76
Vit B1 Thiamin	mg	0.61	0.2
Vit B2 Riboflavin	mg	0.481	1.4
Vit B3 Niacin	mg	6.291	8
Vit B5 Pantothenic Acid	mg	3.285	1.6
Vit B6	mg	0.532	1
Vit B9 Folic Acid	mcg	247.4	110
Vit B12	mcg	1.32	2
Vit C	mg	40.2	90
Vit D3	mcg	4.95	11.04
Vit E	mg	0.98	8.3
Vit K	mcg	0.9	30

Annex 7. Nutritional Content of Fortified Vegetable Oil

Oil	Fortification per 100g		Total (Intrinsic+ Fortificant)	
	Intrinsic (100g)	Recommended Level	Fortificant Form	100g
Water (g)	0	0.0		0
Energy (kcal)	884	0.0		884
Protein (g)	0	0.0		0
Total Lipid (fat) (g)	100	0.0		100
Carbohydrate	0	0.0		0
Sugars, total (g)	0	0.0		0
Minerals				
Calcium (mg)	0	0.0		0
Iron (mg Ferrous Fumerate)	0.05	0.0		0.05
Iron (mg EDTA)	0	0.0		0
Iron, total (mg)	0	0.0		0.05
Magnesium (mg)	0	0.0		0
Phosphorous (mg)	0	0.0		0
Potassium (mg)	0	0.0		0
Sodium (mg)	0	0.0		0
Zinc (mg)	0.01	0.0		0.01
Vitamins				
Vitamin C, total ascorbic acid (mg)	0	0.0		0
Thiamin (mg)	0	0.0		0
Riboflavin (mg)	0	0.0		0
Niacin (mg)	0	0.0		0
Vitamin B6 (mg)	0	0.0		0
Folate, DFE (µg)	0	0.0		0
Vitamin B12 (µg)	0	0.0		0
Vitamin A (IU)	0	6,000.00-7,500.00	Retinol palmitate	6,000.00-7,500.00
Vitamin E (alpha-tocopherol) (mg)	8.18			8.18
Vitamin D (IU)	0	1,600.00-2,300.00	D3 as cholecalciferol	1,700.00-2,100.00
Vitamin K (phylloquinone) (µg)	183.9	0.0		183.9
Lipids				
Fatty acids, total saturated (g)	15.65	0.0		15.65
Fatty acids, total monosaturated (g)	22.783	0.0		22.78
Fatty acids, total polyunsaturated (g)	57.74	0.0		57.74
Cholesterol (mg)	0	0.0		0

Annex 8. Burkina Faso: Effectiveness and Cost-Effectiveness Study on Prevention of MAM and Stunting

Background

Tufts University completed a review of Title II commodities and their uses under the Food Aid Quality Review (FAQR) in October 2011 (see www.foodaidquality.pbworks.com for more information). The FAQR report recommended improvements in the formulation of existing Fortified Blended Food (FBF) products used in Title II programming by including a dairy ingredient, improving the micronutrient premix and preparing CSB consistently with fortified vegetable oil in the recommended ratio of 30 g oil to 100 g CSB. The FAQR Report also recommended strengthening the evidence base for innovations in products and programming and testing the effectiveness and cost-effectiveness of any recommended program or commodity modifications.

Tufts University is collaborating with ACDI/VOCA and Save the Children in Burkina Faso, District of Sanmatenga to conduct an assessment of the effectiveness, cost, and cost-effectiveness of these recommended changes to CSB. Institut de Recherche en Sciences de la Santé (**IRSS**) is working with Tufts University to carry out data collection. The study compares isocaloric amounts of the 4 foods:

1) Corn Soy Blend 14 (CSB14), with whey protein concentrate and enhanced micronutrient profile, prepared with fortified vegetable oil (FVO)
2) Ready-to Use Supplementary Food 1(RUSF1), a generic Lipid-Based Nutrient Supplement (LNS) product aligned with WHO recommendations for treatment and prevention of moderate acute malnutrition
3) Supercereal Plus (CSB++/SC+), the FBF used by WFP, which has an enhanced nutrient profile, dairy ingredient (non-fat dry milk), and oil already embedded into the CSB
4) Supercereal (CSB+/SC) prepared with FVO

Type of Study

Prospective, cluster-randomized, effectiveness trial

Problem to be Studied

Prevention of moderate acute malnutrition (MAM) and stunting in children.

Objective

To test the relative effectiveness and cost-effectiveness of four supplementary foods in the prevention of MAM and stunting in normal programmatic settings.

Study Design

The study is cluster-randomized collecting information on participating children. We assigned Food Distribution Points to one of the four arms. Enrollment of children was done on a rolling basis, from August 2014-June 2015. We enrolled children continuously until the required sample size was reached. The study is an effectiveness trial, meaning that we will study the programs' operation and the beneficiary households' compliance with recommendations regarding preparation and consumption of the supplementary food.

Prevention of MAM and Stunting

The comparison is based on the preventive model: distribution of the food supplement to at-risk children six to 23 months. All study arms deliver the same services to children and their households, except for the difference in the food supplement and the messages that go along with that particular supplement. The subjects in this study are children six to 23 months of age whose mothers are enrolled in the supplementary feeding program operated by Save the Children, coordinated by ACDI/VOCA in the District of Sanmatenga. ACDI/VOCA and Save the Children are responsible for delivering and distributing the food supplements. IRSS, along with the Tufts University team, are responsible for screening and enrolling children into the supplementary feeding program, and collecting data. The total number of children is approximately 6,000 (1,500 per arm).

The study follows children from the age of six months (when distribution of the food supplement intended for children's consumption is initiated) to 24 months. We follow up with children monthly up to four months post intervention to assess their growth and health status.

The study collects data on effectiveness and cost-effectiveness through growth measurements, individual interviews, focus group discussions, and observations. The study also collects water samples and CSB porridge samples to further validate results.

Primary outcomes to be measured are incidence of acute malnutrition and incidence of stunting. Secondary outcomes include rate of recovery, time to recovery, compliance with recommended methods of preparation and allocation of the food supplement.

Cost-effectiveness will assess differences among the four study arms in cost per case of MAM, per case of stunting, and per case of linear growth faltering averted (that is, relative to the intervention with the highest rates).

IRSS is conducting anthropometric measurements, individual interviews, focus group discussions, and observations. Tufts University worked with IRSS to train enumerators in data collection (qualitative and quantitative) and data analysis. Tufts University also trained enumerators to measure length, weight, and MUAC of children enrolled in the research study. These skills are valuable assets in any future nutrition and maternal and child health research activities. Tufts works collaboratively with the IRSS senior researchers on the design and implementation of the study.

Annex 9. Sierra Leone: Effectiveness and Cost-Effectiveness Study on Treatment of MAM

Background

The study sought to determine the relative effectiveness and cost effectiveness of four supplementary foods in the treatment of moderate acute malnutrition (MAM) in normal programmatic settings in Sierra Leone. The results of this study will guide decisions about what commodities to use in supplementary feeding programs in particular contexts and populations, and what factors need to be addressed to ensure maximum effectiveness in the treatment of moderate malnutrition.

Tufts University completed a review of USAID Title II food aid commodities and their uses under the Food Aid Quality Review (FAQR) in October 2011 (see www.foodaidquality.pbworks.com) for more information). The FAQR report recommended improvements in the formulation of existing Fortified Blended Food (FBF) products used in Title II programming. Specifically it was recommended to modify current Corn Soy Blend (CSB) to include a dairy ingredient and an upgrade of the micronutrient premix as well as to prepare CSB consistently with fortified vegetable oil in the recommended ratio of 30 g oil to 100 g CSB. The FAQR Report also recommended strengthening the evidence base for innovations in products and programming and testing the effectiveness and cost-effectiveness of any recommended program or commodity modifications.

Tufts University was partnering with Washington University in St. Louis, School of Medicine, Project Peanut Butter, Sierra Leone Ministry of Health and Sanitation Nutrition Department, World Food Programme (WFP), and the United States Agency for International Development (USAID) to conduct an assessment of the effectiveness, cost, and cost-effectiveness of these recommended changes to CSB. Study participants received one of four test foods varying in energy and nutrient density as well as amounts provided. The four foods were:

1. Super Cereal Plus (SC+) at 800 kcal/d, 215 g/d
2. Super Cereal (SC) and oil and sugar at 998 kcal/d – 200 g SC and 20 g oil and 20 g sugar, per day
3. Corn Soy Blend 14 (CSB14) and oil at 978 kcal/day – 150 g CSB14 and 45 g oil, per day
4. Plumpy'Sup – 500 kcal/d, 92 g/d

Type of Study

This was a prospective, randomised, controlled study of the effectiveness of various approaches to managing moderate child wasting. This study was not a clinical trial.

Study Design

Twenty (20) PHUs were selected in the Kenema District. These 20 PHUs and the villages they serve were used as the study sites to test the effectiveness of four supplementary foods in the treatment of MAM in normal programmatic settings. The 20 PHUs were grouped into four to represent each food or arm of the study. The study is targeting 5,000 children in total: 1,250 children per arm.

Children were enrolled and graduated based on mid-upper arm circumference (MUAC); weight and height were recorded as well and available for final analysis. Locations (communities, clinics) were assigned to one of the four arms (that is, commodities to be tested).

Treatment of MAM

The comparison was based on a targeted food delivery to children six to 59 months who are screened for MAM. Supplementary food rations were delivered for 12 weeks from enrollment (diagnosis with MAM). Children were monitored for relapse after discharge.

The primary outcome measures are recovery from MAM (achieving MUAC ≥ 12.5 cm by 12 weeks) once or failure (death, development of severe acute malnutrition, transfer to hospital for inpatient care, failure to recover from MAM by 12 weeks, default). Secondary outcome measures include rates of weight, height, and MUAC gain, time to graduation, and adverse effects from the supplementary foods. Cost-effectiveness will assess differences among the four study arms in cost per case of MAM managed.

Ebola Virus Disease Outbreak

The onset of Ebola in Kenema District starting in June 2014 necessitated changes to the research protocol, which affected measurement and food distribution as well as patient follow-up and household data collection. The team suspended data collection in July 2014, and cancelled all research activities in October 2014. Tufts University and Washington University will analyze the data which was collected, with a reduced sample size, before the study cancellation.

Annex 10. Nutritional Content of Milled and Blended Cereal Premix

Fortification of milled and blended cereals (premix composition)				
Nutrient	**Previous Title II Fortification Level**	**FAQR Phase I Recommended Level**	**FAQR Phase II Progress: Achieved Recommended Fortificant Level and Form**	**FAQR Phase I Recommended Fortificant Form**
	mg/100 g	mg/100 g		
Vitamin A	0.66	0.11	*	Vitamin A palmitate 250 (spray dried)
Vitamin B_1 (thiamin)	0.638	0.4	Yes ✔	Thiamin mononitrate
Vitamin B_2 (riboflavin)	0.396	0.4	Yes ✔	Riboflavin
Vitamin B_3 (niacin)	5.28	4	Yes ✔	Niacinamide
Vitamin B_6		0.4	Yes ✔	Pyridoxine hydrochloride
Vitamin B_9 (folic acid)	0.154	0.154	Yes ✔	Folic acid
Vitamin B_{12}		0.011	Yes ✔	Vitamin B_{12} 0.1% (water soluble)
Vitamin D_3		0.002	Yes ✔	Vitamin D_3 100,000 IU/g
Iron (EDTA)		4	Yes ✔	NaFeEDTA
Iron (Ferrous fumarate)	4.4			
Zinc		2.4	Yes ✔	Zinc oxide
Note: Iron levels were aligned with WFP specifications. * See text for explanation for why recommended levels were or were not achieved.				