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Food Aid Quality Review Phase II

Accelerated Shelf Life Studies: Methods and Results Relating to New and Upgraded Food Aid Products

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Acronyms

AOAC	Association of Official Analytical Chemists (now AOAC International)
CRD	Commodity Requirements Document
CSBP	Corn Soy Blend *Plus*
CSWB	Corn-Soy Whey Blend
FAQR	Food Aid Quality Review
FBF	Fortified Blended Food
FFP	Office of Food for Peace
ICP	Inductively Coupled Plasma
R&D	Research and development
RUSF	Ready-to-Use Supplementary Food
SC *Plus*	Super Cereal *Plus*
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
WFP	World Food Programme
WPC80	Whey Protein Concentrate 80 percent
UNICEF	United Nations Children's Fund

A. Executive Summary

This report presents the results of a series of accelerated shelf life and stability studies of new and upgraded food aid products. The studies were conducted on behalf of the United States Agency for International Development's (USAID) Food for Peace Office (FFP) as part of Phase II of the Food Aid Quality Review (FAQR) (USAID Contract AFP-C-00-09-00016-00). The aim of the activity was to exercise due diligence during food aid product development. The tests were conducted to determine the vitamin and mineral stability and integrity of new and upgraded products produced in the United States and included in food aid effectiveness trials that began in 2014.

The accelerated shelf life series was carried out on Corn-Soy Whey Blend (CSWB), Super Cereal *Plus* (SC *Plus*), Corn Soy Blend *Plus* (CSBP), Ready-to-Use Supplementary Food (RUSF) and Fortified Vegetable Oil. Four were already in the USAID food aid pipeline and one was newly developed based on FAQR Phase I recommendations. Products were manufactured and packaged according to technical specifications current at the time of production. The samples were analyzed for vitamin content (vitamins A and C), mineral content (iron, calcium and phosphorus), peroxide levels and organoleptic properties (product appearance, odor and taste and packaging appearance). Testing followed standard methods certified by the Association of Official Analytical Chemists (now AOAC International) and commonly used by the North American food industry and the United States Department of Agriculture (USDA) Official Testing laboratories. All products were stored under controlled temperature and humidity conditions, namely 40 degrees Centigrade (104 degrees Fahrenheit) and 75 percent. Relative Humidity for a period of 26 weeks to mimic 26 months in real time. The products were sampled and tested seven times.

Results

Vitamin A levels in all fortified blended foods (FBFs) degraded substantially during testing, as might be expected in these blended cereals, but remained very stable in RUSF and fortified vegetable oil, both lipid-based products. Product packaging of the RUSF (small size and strong material) and the oil (opaque steel can) may have protected the vitamin A from degradation that comes with exposure to light and humidity.

Peroxide levels remained below the maximum permitted in the FBFs compared to specifications, but reached and exceeded the maximum permitted in vegetable oil by week six (equivalent to six months storage).

Organoleptic characteristics: FBFs all developed a slight grainy odor over the course of their shelf lives. Three of the four showed sparse black flecks at various points that were likely due to dark germ color and heat processing of the raw material (corn). RUSF odor, appearance, texture and packaging remained stable and normal. Appearance, taste and packaging

characteristics of fortified vegetable oil remained unchanged despite an increase in peroxide values during the shelf life study period; a slight "oily" odor developed at week six but was not noted in the tests at the end of the study.

Mineral levels varied among the FBFs, mostly as expected, due partially to intrinsic differences in product ingredients. These findings highlight the role that that intrinsic values play in establishing specifications.

Vitamin C (endline only) levels were uniformly low in all FBFs but within the normal range in the RUSF.

Recommendations

Overall Recommendation: Incorporate accelerated shelf life testing into USAID food aid product Research and Development

> **Recommendation 1:** Conduct accelerated shelf life/stability testing on all new products and existing products that may have major modifications or updates, e.g., new ingredients or changing nutrient levels and forms in FBFs.
>
> **Recommendation 2:** Develop standard protocols; add minerals (weeks 0 and 26) and vitamin A and C (all points).
>
> **Recommendation 3:** Harmonize shelf life protocols and conditions wherever possible among aid organizations working on product development. As part of this process, share data and results from all new product studies for more effective transparency regardless of origin and source.

Overall Recommendation: Seek ways to optimize vitamin A delivery in the USAID food aid basket

> **Recommendation 4:** Challenge Vitamin A suppliers to develop methods of improving vitamin A stability in dry premixes for inclusion in FBF production.
>
> **Recommendation 5:** Assess new packaging material to reduce degradation of vitamin A and other vitamins.
>
> **Recommendation 6:** Conduct further research to determine the most appropriate delivery mechanism for vitamin A in the food aid basket, considering various factors including its susceptibility to degradation in FBFs, cost and programmatic implication.

B. Introduction

The Food Aid Quality Review (FAQR) Phase I recommended an improvement to United States (US) food aid products, including the introduction of new specifications and new products (Webb et al, 2011). The new products included: 1) Corn Soy Whey Blend (CSWB), a fortified blended food (FBF) with an improved micronutrient premix (compared to previously used FBFs) and added whey protein, currently being assessed in field-based effectiveness trials before being formally introduced into the food aid pipeline; 2) Corn Soy Blend *Plus* (CSBP), an FBF similar to that used by the World Food Programme (WFP) with an upgraded micronutrient premix compared to prior CSB versions; 3) Super Cereal *Plus* (SC *Plus*), a corn-soy FBF with a dairy component, similar to that used by WFP with added dairy protein in the form of nonfat dry milk or whey protein concentrate (80 percent), oil, sugar and an upgraded micronutrient premix; 4) Ready-to-Use Supplementary Food (RUSF), a micronutrient-fortified lipid (peanut)-based paste and 5) vegetable oil doubly fortified with vitamins A and D.

Part of product research and development (R&D) included working with new manufacturers in the US to become suppliers of these products to the US Government. One critical step of due diligence in the R&D process is shelf life testing to understand the behavior of the product over time, in terms of stability of its ingredients and nutrients as well as the integrity of its sensory characteristics. Shelf life testing is costly as it measures the product parameters in real time and includes storage costs during the entire time period, 26 months for example. Accelerated shelf life testing, costing a fraction of the price, is done under extreme conditions of temperature and humidity, reducing the time to 26 weeks, with one week representing one month of real time testing.[1,2]

This accelerated shelf life study was conducted in support of the United States Agency for International Development's (USAID)/Food for Peace Office (FFP) funded FAQR effectiveness trials in Burkina Faso[3] and Sierra Leone[4] comparing the effectiveness of these products or product combinations (CSBP and fortified vegetable oil are programmed together) in preventing moderate wasting and stunting and treating moderate wasting, respectively.[5] All products for

[1] FAO Agris http://agris.fao.org/agris-search/search.do?recordID=US8629267

[2] MOCON http://www.mocon.com/pdf/webinars/PackageIntegrity/ShelfLifeStudies-BasicsConceptsPrinciples.pdf The author clearly shows that if you change the temperature of the accelerated storage study you can use an equation to determine the equivalency of weeks = years at ambient temperature

[3] Burkina Faso Study listed on ClinicalTrials.gov, Identifier: NCT02071563

[4] Sierra Leone Study listed on ClinicalTrials.gov Identifier: NCT01785680

[5] All products tested in this study are used in the Burkina Faso trial. In Sierra Leone, only the CSWB from US supplier B is used; the remaining products are sourced by the WFP.

this accelerated shelf and stability study were procured during summer 2013, coinciding with the start of the effectiveness trials. See Appendix 1 for an overview of the products and study.

The study fits within the larger context of food industry product development, which commonly involves shelf life and stability studies in product development stages to ensure integrity of the product over time. In this context, new specialized food aid products will undergo such testing going forward. Given the special constraints faced in Food for Peace food aid delivery (extreme heat, humidity, extended supply chain conditions and long delivery times), the pace of new product development and efforts to harmonize with the WFP, United Nations Children's Fund (UNICEF) and other food aid agencies, shelf life and stability testing becomes ever more important.

C. Study Design/Methods

Purpose of Study

- The primary purpose was to exercise due diligence during the food product development process for new USAID/FFP products and to conform to good manufacturing practices as carried out in the food industry at large.
- The secondary purpose was to determine the stability of key attributes over the course of the shelf life of the US-sourced products being used in the FAQR effectiveness trials.

Methods

This study follows the standard conventions of accelerated shelf life studies as outlined below with testing methodology explained in the Appendix 2. It is important to use the same internal or contract laboratory through the time series so all testing was conducted by Covance Laboratories of Madison, Wisconsin. The tested products were sourced simultaneously with those used in the effectiveness trials using the same product specifications, giving the potential to improve understanding of the results of the effectiveness trials.

1. Testing

Products were identified (see subsection "Selection of Products" below) and suppliers sent product samples directly to Covance Laboratories, which stored the products and conducted the tests according to the protocol (see subsection "Parameters tested"). Covance submitted a Certificate of Analysis with test values for each of the six products at each time point. The data were reviewed and entered into a database at Global Food and Nutrition Inc to monitor trendlines and compile results.

2. Storage Conditions

Samples of all products were stored in laboratory conditions set at 40 degrees Celsius (or 104 degrees Fahrenheit) and 75 percent humidity, a standard of accelerated life studies. Changes over one week in these conditions are designed to mimic those encountered during one month in the supply chain; the full testing period is designed to simulate 26 months or approximately two years of product life under real conditions.

3. Testing Intervals

Testing was conducted at seven times during the studies, on a rolling basis according to when they had been received and the studies initiated. Testing times were: at baseline, week 3, week 6, week 9, week 13, week 19 and week 26. These times ensure compliance with general design principles of ICH Stability Testing of New Drug Substances and Products Q1A (R2), Feb. 6, 2003, which specify that testing intervals should be designed to cover the entire shelf life under consideration and include sufficient intervals to interpret the stability of the analyte (e.g., specific vitamin or mineral). Intervals are generally uniform, with fewer data points collected in the latter half of a study, since the rate of change typically levels off.

Products Tested

The products tested are those used in the FAQR Phase II effectiveness trials and were specified and requested as part of Tufts University's procurement of the products for the trials. Fortified vegetable oil was sourced directly from the producer since this product was already in the USAID pipeline. The products tested included the following (photos in Figure 1):

- **CSWB**
  - Corn-soy fortified FBF with an improved micronutrient premix (compared to previously used FBFs) and added whey protein concentrate (80 percent) (WPC80)
  - Packaged in 25-kg bags, eight bags were needed for the study
  - Products from two US suppliers (Supplier A and B) were tested
  - Specification: developed for Effectiveness trials, based on FAQR Phase I recommended CSWB product (FAQR Request for Product, 2013)

- **SC *Plus***
  - Corn-soy FBF with added dairy in the form of non-fat dry milk of WPC80, oil and sugar and an updated micronutrient premix
  - Packaged in 1.22-kg bags, 16 bags were needed for the study
  - Product from one US supplier was tested
  - Specification: Draft USDA Commodity Requirements Document (CRD) (USDA, 2013)

- **CSBP**
  - Corn-soy FBF with an improved micronutrient premix, first version
  - Packaged in 25-kg bags, eight bags were needed for the study
  - Product from one US supplier was tested
  - Specification: USDA Commodity Requirement Document for CSBP1 (USDA, 2013)

- **RUSF**
  - Micronutrient-fortified lipid (peanut)-based paste
  - Packaged in 92-g sachets, 24 sachets were needed for the study
  - Product from one supplier was tested
  - Specification: USDA CRD for RUSF1 (USDA, 2013)

- **Vegetable Oil Fortified with Vitamins A and D**
  - Vegetable oil fortified with vitamins A and D
  - Packaged in 4-L steel cans, eight cans were needed for the study
  - Product from one US supplier was tested
  - Specification: USDA CRD for fortified vegetable oil (USDA, 2012) Figure 1. Products Tested

CSWB and CSBP

SC *Plus*

RUSF

Fortified Vegetable Oil

Timeline of Study

Products entered into the study on a rolling basis, as they became available. The study timeline was as follows:

Date	Activity
Summer 2013	Samples requested by Tufts in Requests for Proposals for CSWBs, CSBP, SC *Plus* and RUSF
Fall 2013	CSWB samples received; testing initiated
Winter 2013	CSBP, SC *Plus* and RUSF samples received; testing initiated
Spring 2014	Fortified vegetable oil samples received; testing initiated; CSWB testing completed
Summer 2014	CSBP, SC *Plus*, RUSF testing completed
Fall 2014	Fortified vegetable oil testing completed

Parameters Tested

The products were analyzed for: stability of vitamin A, peroxide value and organoleptic (sensory and packaging) properties; a baseline and endline analysis of calcium, iron, potassium and a one-time analysis of vitamin C. The analyses of vitamin A, vitamin C, calcium, iron, potassium and peroxide followed the AOAC official methods. The organoleptic testing was carried out using a test procedure accepted by the North American Food Industry as standard. For detailed explanations of each test, see Appendix 2. Parameters and test times are provided in Table 1.

Table 1. Parameters and Test Times

	Initial	Week 3	Week 6	Week 9	Week 13	Week 19	Week 26
Vitamin A	X	X	X	X	X	X	X
Peroxide	X	X	X	X	X	X	X
Organoleptic Analysis	X	X	X	X	X	X	X
Minerals (Calcium, Iron and Potassium)	X						X
Vitamin C							X

1. Vitamin A (all products)

Rationale: Vitamin A, as a sensitive and labile micronutrient, has traditionally been the biomarker in food fortification. When vitamin A levels are stable, vitamin D levels are likely stable as well. Vitamin A is measurable in oil, compared to vitamin D whose concentration is low and less accurate to measure.

The study measured vitamin A at all seven time points to tests the stability of this key indicator. Target and permitted range varies for each product (see Table 2).

2. Peroxide (all products)

Rationale: Peroxide is an indicator of rancidity, which is a common quality issue in fortified food products in the field. Peroxide tests are typically used in conjunction with other tests to determine the level of degradation and eating quality of foods over their expected shelf life. In this study the complementary test was the organoleptic analysis (detailed in section 3 below)

The study measured peroxide at all seven time points as an indicator of rancidity. Peroxide in the products should not exceed 10 meq/kg fat, except for fortified vegetable oil with maximum 1meq/kg fat.

3. Organoleptic analysis (all products)

Rationale: Organoleptic, or sensory, characteristics can change over time, especially in the types of field conditions and extended delivery times that food aid products encounter. These tests are important to assessment of consumer acceptability as well as packaging integrity.

The study conducted organoleptic analysis at all seven time points to ensure product quality by visual observation of product appearance (color, texture/consistency), packaging appearance and product odor. For fortified vegetable oil, analysis also included assessment of taste.

4. Calcium, Iron and Potassium (CSWB, CSBP and SC *Plus* and RUSF) – Baseline & Endline

Rationale: Although calcium, iron and potassium levels were not expected to change, testing for these micronutrients at the beginning and end of shelf life were included to confirm that the correct amounts were present.

The study measured the mineral content at baseline and endline to ensure the correct level of key minerals and that the amount of mineral premix was added correctly. Target and permitted range varies for each product (see Table 3).

5. Vitamin C (CSWB, CSBP and SC *Plus* and RUSF) – Endline only

The vitamin C test was added based on stakeholder feedback after the USAID-WFP harmonization meeting in Rome in January 2014.The study therefore measured vitamin C content at endline only for all products except for fortified vegetable oil which does not contain vitamin C (see Table 1). Adding Vitamin C (since Vitamin A was already included) to the accelerated shelf life study protocol was done in anticipation of harmonized shelf life study protocols going forward since WFP includes both vitamins A and C in their shelf life studies. Target and permitted ranges for each product are provided in Table 3.

Table 2. Parameters, Targets and Permitted Range (Measured at Each Interval)

Parameters		CSWB	SC *Plus*	CSBP	RUSF	Fortified Vegetable Oil
Vitamin A (mcg/100g)	**Target**	1039	1038	1038	1200	n/a
	[Range]	[935-1143]	[880-1300]	[880-1300]	[900-1500]	[1800-2250]
Peroxide (meq/kg fat)		Max 10	Max 10	Max 10	Max 10	Max 1
Organoleptic Analysis		**All products:** The product should be free from foreign materials and substances, is not hazardous to health, does not contain excessive moisture, is free from insect damage and fungal contamination				
	Appearance	Fine yellow powder; aberrations noted	Yellow powder; aberrations noted	Fine yellow powder; aberrations noted	Thick light brown paste; consistency noted	Clear light yellow liquid; viscosity noted
	Packaging	Brown bag; problems noted	Silver bag; problems noted	Brown bag; problems noted	White sachet; problems noted	Steel can; problems noted
	Odor	Any odor noted	Any odor noted	Any odor noted	Any odor noted	Any odor noted
	Taste	-	-	-	-	No taste detected

Table 3. Minerals & Vitamin C: Parameters, Targets and Permitted Range

Parameters		CSWB	SC *Plus*	CSBP	RUSF	Fortified Vegetable Oil
Minerals (baseline & endline)						
Calcium	Target	428	452	512	600	n/a
[mg/100 g]	[Range]	[355-470]	[420-630]	[461-589]	[540-660]	
Iron	Target	9.2	11.8	11.8	10	n/a
[mg/100 g]	[Range]	[8.3-10.2]	[6.5-13.5]	[6.5-13.5]	[9-11]	
Potassium	Target	780	810	724	770	n/a
[mg/100 g]	[Range]	[681-880]	[650-970]	[652-833]	[693-844]	
Vitamin C	Target	90	90	90	100	n/a
(endline only)						
(mg/100 g)	[Range]	[81-103]	[81-103]	[81-103]	[75-125]	

D. Results

CSWB

Vitamin A: Both CSWB products yielded similar and parallel results. Initially, vitamin A content in both CSWB products was near the lower limit of the permitted range of the specifications (see Figure 2). The vitamin A content deteriorated over time; both products' vitamin A content dropped below the permitted range starting at the sixth week.

Peroxide: The peroxide content was more varied over time, but the values were all well below the maximum limit (see Figure 3).

Organoleptic characteristics: Results of the organoleptic evaluations were as expected except for a mild grainy odor in Supplier A's product and some black flecks in Supplier B's product in the last two weeks of testing (see Table 4).

Other micronutrients: Calcium and iron remained at the normal level between baseline and endline sampling for both products. Potassium was below the recommended range at both time points for both products. Vitamin C was below the recommended range at the end of the study (see Table 5).

Figure 2. Vitamin A Results for CSWB

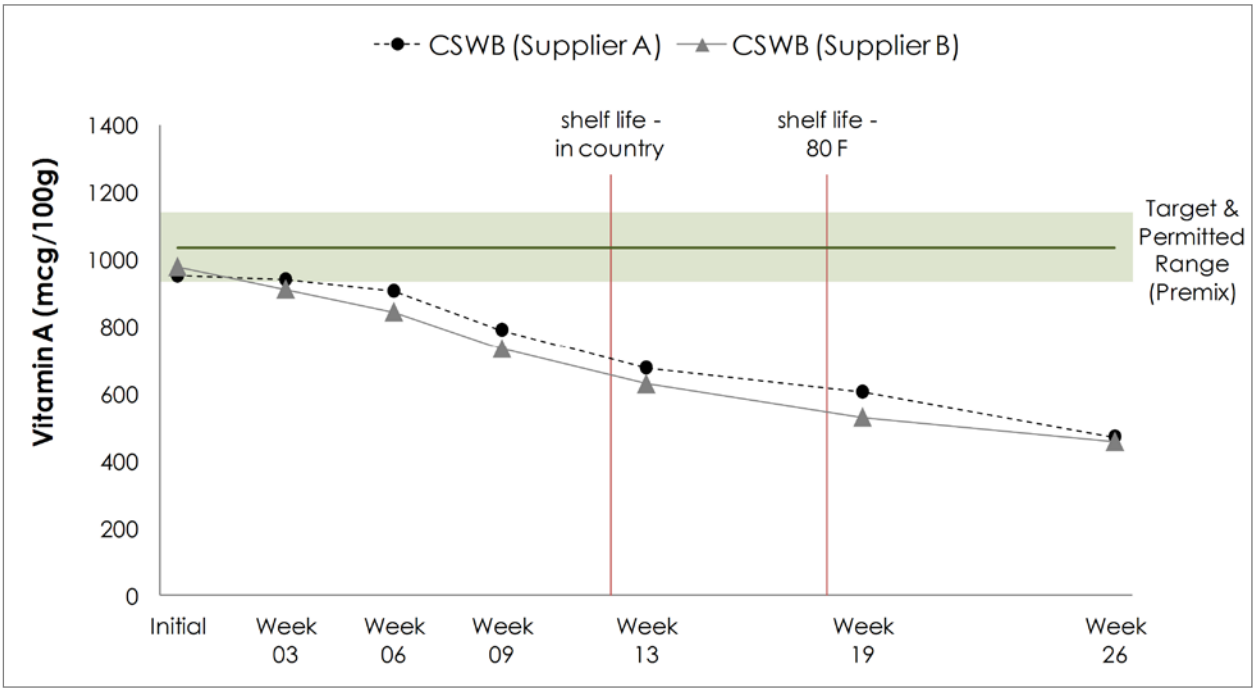

Figure 3. Peroxide Results for CSWB

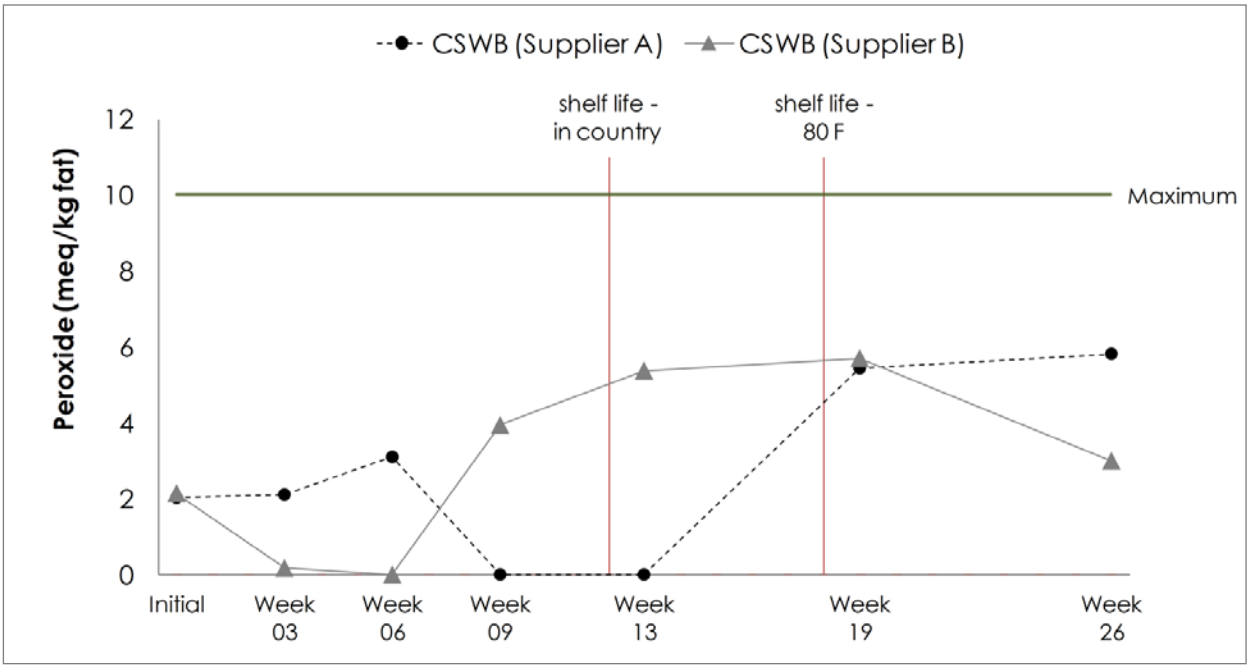

Table 4. Organoleptic Results for CSWB

	Supplier A							Supplier B						
	Initial	Week 03	Week 06	Week 09	Week 13	Week 19	Week 26	Initial	Week 03	Week 06	Week 09	Week 13	Week 19	Week 26
Appearance	Normal							Normal					Few black flecks	
Odor	Normal					Mild grainy odor		Normal						
Packaging	Normal							Normal						

Table 5. Mineral and Vitamin C Results for CSWB and Comparison to Accepted Ranges

	Baseline	Endline	Baseline	Endline
Calcium (mg/100g)	Normal (431)	Normal (419)	Normal (409)	Normal (431)
Iron (mg/100g)	Normal (9.5)	Normal (9.0)	Normal (8.35)	Normal (9.83)
Potassium (mg/100g)	Below (631)	Below (638)	Below (597)	Below (637)
Vitamin C (mg/100g)	n/a	Below (41.8)	n/a	Below (59.5)

SC *Plus* and CSBP

Vitamin A: Vitamin A follows the same trend as the CSWB, which would be expected from a corn soy blend product. Vitamin A in CSBP began below the permitted range and dropped continuously throughout the period to less than half of it original amount. Vitamin A in SC *Plus* began at the lower end of the acceptable range and in week three fell below acceptable levels and in week six deteriorated below the permitted range. It continued to drop at a steady rate for the rest of the trial, ending at week 26 with only two-thirds of the original vitamin A content (see Figure 4).

Peroxide: CSBP peroxide levels remained low through week nine, and then steadily increased to approach the maximum acceptable level by week 26, although it stayed slightly below the threshold. Peroxide levels remained low in the SC *Plus* to endline (see Figure 5).

Organoleptic characteristics: At week nine, both products developed a slightly grainy odor. At week six, some black flecks were found in the CSBP and in week 19, similar flecks were found in the SC *Plus* (see Table 6). Discussions with the vendor of the products advised that the black specks were due to dark tips on the germ end of the corn kernel. The organoleptic results did not display off-flavors that would have been prominent with high peroxide levels. No issues were noted with packaging.

Other micronutrients: In CSBP, calcium was higher than the acceptable range at baseline and endline and iron levels were normal at both time points. Potassium was in the normal range at baseline but slightly above recommended levels at endline. Vitamin C was below the acceptable level at week 26. In SC *Plus*, calcium, iron and potassium were all in the normal range at both testing times, while vitamin C was below accepted levels at endline (see Table 7).

Figure 4. Vitamin A Results for SC *Plus* and CSBP

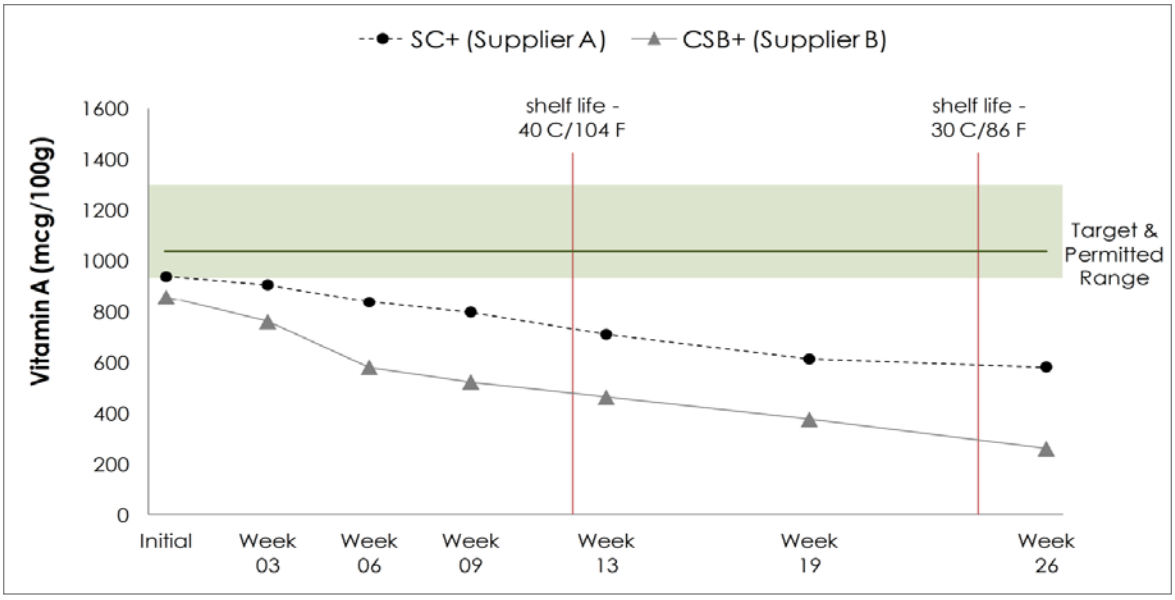

Figure 5. Peroxide Results for SC *Plus* and CSBP

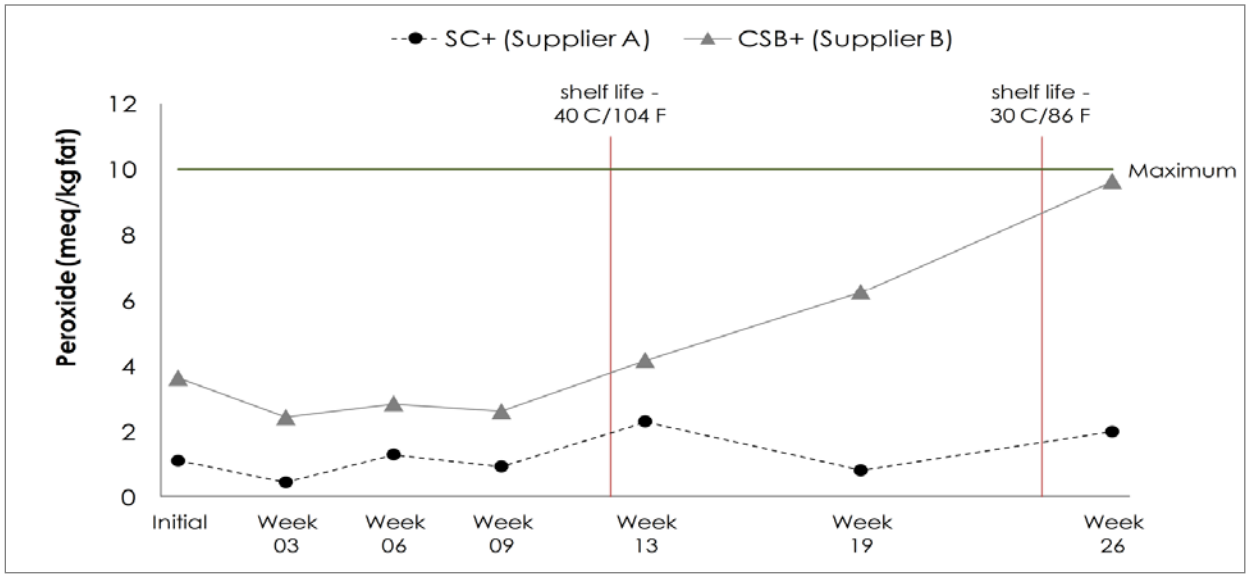

Table 6.Organoleptic Results for CSBP and SC Plus

	CSBP							SC *Plus*						
	Initial	**Week 03**	**Week 06**	**Week 09**	**Week 13**	**Week 19**	**Week 26**	**Initial**	**Week 03**	**Week 06**	**Week 09**	**Week 13**	**Week 19**	**Week 26**
Appearance	Normal		Few black flecks					Normal					Few black flecks	
Odor	Normal			Slight grainy odor				Normal			Slight grainy odor			
Packaging	Normal							Normal						

Table 7. Mineral and Vitamin C Results for SC Plus and CSBP Compared to Accepted Ranges

	SC *Plus*		CSBP	
	Baseline	**Baseline**	**Endline**	**Endline**
Calcium (mg/100g)	Normal (628)	Above (1130)	Above (1220)	Normal (570)
Iron (mg/100g)	Normal (8.9)	Normal (11.5)	Normal (12.2)	Normal (8.38)
Potassium (mg/100g)	Normal (745)	Normal (776)	Slightly Above (842)	Normal (724)
Vitamin C (mg/100g)	n/a	n/a	Below (38.2)	Below (47.3)

Ready to Use Supplementary Food (RUSF)

Vitamin A: Except for a spike in week three, vitamin A remained within the recommended range. The spike was just above maximum and still within the allowable margin of error for analysis (see Figure 6).

Peroxide*:* The levels of peroxide remained uniformly low throughout the trial (see Figure 7).

Organoleptic Characteristics: The product retained its appearance, packaging and odor without any changes over the 26 weeks (see Table 8).

Other micronutrients: Tests for calcium, iron, potassium and vitamin C were conducted only at endline for RUSF. Calcium and vitamin C levels were within the permitted range, while potassium and iron were just above the permitted range (see Table 9).

Figure 6. Vitamin A Results for RUSF

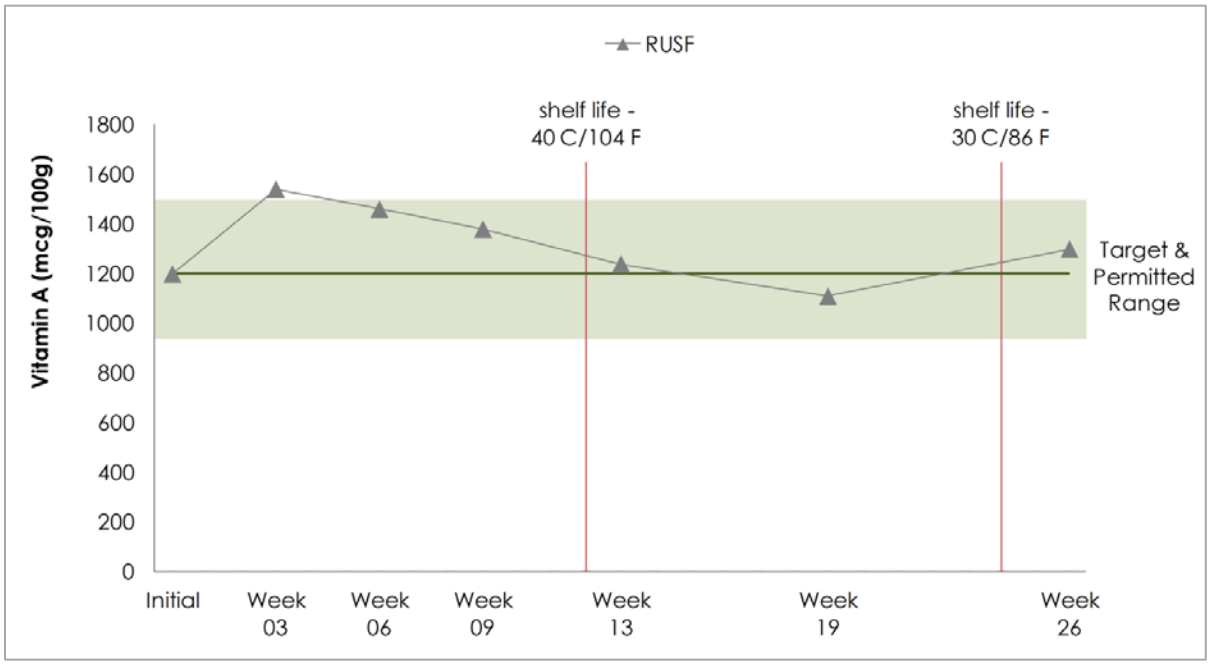

Figure 7. Peroxide Results for RUSF

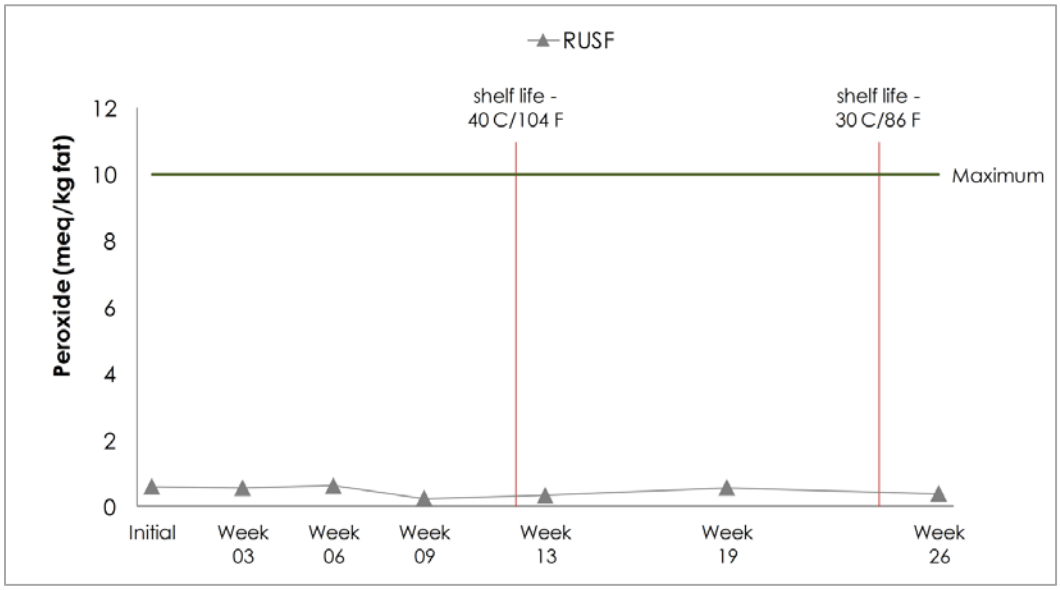

Table 8. Organoleptic Results for RUSF

	Initial	Week 03	Week 06	Week 09	Week 13	Week 19	Week 26
Appearance	Normal						
Odor	Normal						
Packaging	Normal						

Table 9. Mineral and Vitamin C Results for RUSF

	Baseline	Endline
Calcium (mg/100g)	**n/a**	**Normal (570)**
Potassium (mg/100g)	**n/a**	**Slightly above (846)**
Iron (mg/100g)	**n/a**	**Slightly above (11.2)**
Vitamin C (mg/100g)	**n/a**	**Normal (120)**

Fortified Vegetable Oil

Vitamin A: Vitamin A remained relatively stable, but slightly above the permitted range.

Peroxide: Peroxide levels climbed above the maximum starting at week six, with the greatest rate of change between week six and week nine when it started leveling off. Peroxide levels stayed relatively consistent after week nine but remained well above the allowed limit.

Organoleptic Characteristics: There were no changes in organoleptic characteristics aside from a slight oil odor detected at week six which remained through the duration of the study.

Micronutrient: n/a (no fortification besides A & D)

Figure 8. Vitamin A Results for Fortified Vegetable Oil

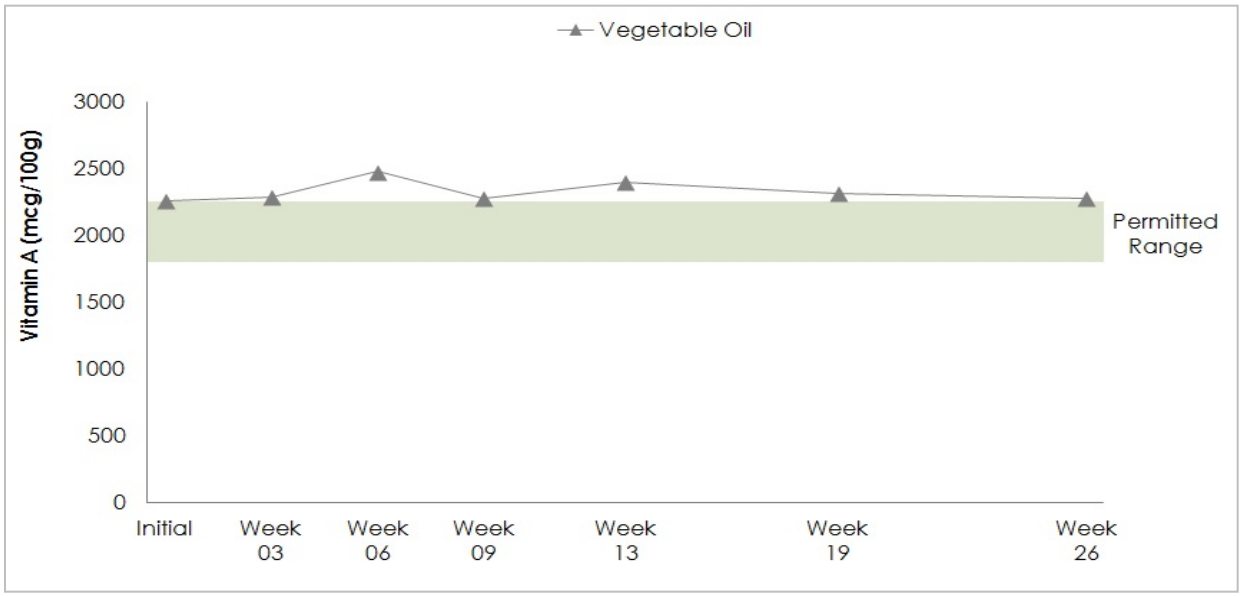

Figure 9. Peroxide Results for Fortified Vegetable Oil

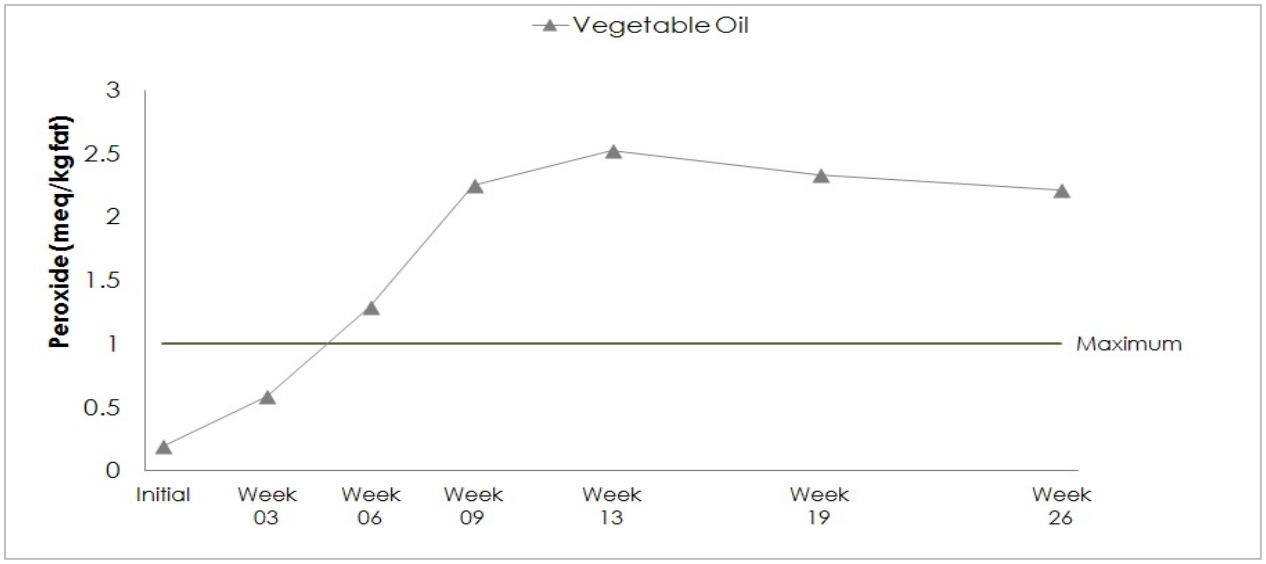

Table 10. Organoleptic Results for Fortified Vegetable Oil

	Initial	Week 03	Week 06	Week 09	Week 13	Week 19	Week 26
Appearance	Normal						
Odor	Normal		Slight Oil Odor				
Taste	Normal						
Packaging	Normal						

E. Discussion

Vitamin A

Vitamin A levels in all FBFs (both CSWBs, CSBP and SC *Plus*) degraded substantially over the course of the 26 weeks of testing. Of the four FBF products, the stability of vitamin A was highest in SC *Plus,* with vitamin A twice as much loss in CSBP and 1.5 times in CSWB compared to SC *Plus*. This may be due to the packaging, which differed from the others in its size (1.22-kg vs. 25-kg bags) and material (multi-layer, heat sealed plastic vs. multi-wall paper).

SC *Plus* is the only FBF with added vegetable oil in its composition, which might have protected the fat-soluble vitamin A in this product.

The loss of vitamin A in all the FBFs has significant consequences for programming costs and impact for recipients. The financial cost of losses in the range of 50 – 65 percent for vitamin A is more than or equal to twice the original cost of vitamin A addition at the point of manufacture. The nutritional cost is a loss of vitamin A activity which is sub-optimal for addressing malnutrition of consumers in the field. Despite specifications requiring the most stable form of fortified vitamin A, all FBFs continue to be highly susceptible to degradation. This finding is not new; the issue originally was raised by SUSTAIN during their evaluation of US food aid quality in 1999. Recommendations to improve the stability of dry vitamin A compounds have not resulted in significant progress (SUSTAIN, 1999, 2001). FAQR Phase I addressed the issue and recommended that vitamin A fortification would be more cost-effective if it were provided in fortified vegetable oil than in FBFs and suggested product modifications as well as the programming of FBFs together with fortified oil in order to optimize vitamin A bioavailability in food aid programming. Feasibility and effectiveness of these recommendations are being tested in the field based effectiveness trials and should inform optimization of next generation products and programming.

In contrast to the group of FBFs, vitamin A levels remained very stable in RUSF and fortified vegetable oil, both lipid-rich products. The packaging of the products – the RUSF's small sachet size and strong material and the fortified vegetable oil's opaque steel can— also may have played a role in protecting the vitamin A from sunlight in these products.

In order to deliver acceptable levels of vitamin A to target populations through FBFs, the quantity of vitamin A in the premix would have to be almost doubled – which would have significant cost implications and implications with respect to approaching reaching the upper limits of recommended consumption. Therefore, shifting delivery of vitamin A to the oil and the lipid-based RUSF products would ensure greater stability and cost-effectiveness. This would also require programmatic changes to ensure that the fortified oil is delivered with the FBF, with the pipeline remaining intact and synchronous.

Peroxide

Peroxide values are measured to give an indication of expected shelf life of foods. Typically, they are measured in combination with free fatty acid levels or organoleptic testing. Peroxide levels in the FBFs remained below the maximum levels permitted in specifications. Although peroxide levels neared the maximum in the case of CSBP by week 26, there were no organoleptic indicators of rancidity. Peroxide levels in the RUSF were very low and stable over the 26 weeks – again, perhaps a result of the small package size and material.

Peroxide levels climbed above the maximum permitted in current specifications for fortified vegetable oil by week six. However there were no organoleptic indicators of rancidity in the vegetable oil through the length of the study. Vegetable oil rancidity has not been a major source of complaints from the field. Therefore maximum level should not be changed at this point.

Organoleptic Characteristics

No major organoleptic issues were noted with regards to product appearance, odor or packaging. All four FBFs developed a slight grainy odor over the course of their shelf lives and three of the four showed sparse black flecks at various points. Conversations with suppliers indicated that the flecks may have been a result of the method of heat processing the corn. According to the suppliers this can occur from the cooking of some of the bran particles in the corn meal toward the end of a production run. They advised that they are not evenly distributed during the whole of the production run.

Micronutrients

Mineral levels in the FBF products varied, mostly as expected, due partially to intrinsic differences in product ingredients – namely, soy and corn - sourced from all over the US. One consistent result, however, was low potassium levels in both CSWBs at baseline and endline. This may be due to incorrect assumptions about potassium levels in whey protein concentrate that were made when drafting specifications. Similarly, high level of potassium in CSBP and SC *Plus* might also be attributable to intrinsic nutrient levels. These findings highlight the role that intrinsic values play in establishing specifications and the importance of including these minerals in the accelerated shelf life protocols going forward. Mineral testing was not initially conducted on RUSF, based on the assumption that mineral degradation would be limited in the lipid-matrix, but should be considered in future accelerated shelf life studies at baseline and endline.

A potential limitation of the study is the inability to compare vitamin C levels over the course of the study. Vitamin C was added to the protocol after an international meeting in January 2014 with WFP in which vitamin C was selected as a useful marker for shelf life studies;

however, this meeting took place after all products except fortified vegetable oil had completed baseline testing. Vitamin C (as with vitamin A) was within the acceptable range in the RUSF, compared to the FBFs in which vitamin C levels were uniformly low at endline. This is likely due to the type of packaging used and the lipid based matrix of the food providing additional protection from potential degradation due to moisture and oxygen. These results may suggest looking at the use of the more stable encapsulated vitamin C. Vitamin C testing should be considered to be included throughout future shelf life studies.

F. Laboratory & Analysis Costs

The price of conducting accelerated shelf life testing of these new USAID products in a certified third party laboratory is a small investment that should be built into the cost of bringing food aid products on line in order to create more effective products consistent with the desired nutrient profiles. Laboratory costs including testing, storage and maintenance, for all six products is under $18 thousand (an average of less than $3 thousand per product) (see Table 11). The cost of CSBP testing was higher than for CSWB due to increased storage price at the time that CSBP was added (when the lab was nearing full storage capacity). It should be noted that the cost of tracking, monitoring, interpreting and reporting on the results is not included and would need to be factored in.

Table 11. Cost Breakdown: Laboratory Storage, Testing and Reporting

Product tested	Cost
CSWB (2 products, $2,810 each)	$ 5,620.00
CSBP	$ 3,710.00
SC *Plus*	$ 2,510.00
RUSF	$ 2,256.00
Fortified Vegetable Oil	$ 2,460.00
Additional endline tests	$ 909.00
Total Study Cost	**$ 17,465.00**

G. Conclusions & Recommendations

Accelerated shelf life studies are industry standard for new product development and should be adopted as due diligence and become standard for all new or upgraded food aid products. The price of accelerated shelf life studies conducted by a recognized/certified third party laboratory seems reasonable and the price needs to be built into the cost of bringing new and upgraded products on line. The use of new types of ingredients and modifications in micronutrient levels, types and forms (vitamins and minerals) can have an impact on both shelf life duration and organoleptic properties of the FBFs through the supply chain from production through distribution. Delivering vitamin A (and possibly other labile nutrients like vitamin C) remains a challenge in terms of the optimal and most cost-effective means of delivery in the food aid basket today and should continue to be addressed going forward. That said, no changes to nutrient levels of the products tested should be made solely based on the results of these accelerated shelf life studies. Proposed changes to specific products should be addressed through ongoing product improvement processes and harmonization discussions. In addition, they should be revisited once results from the FAQR effectiveness trials are available.

The findings this study point to two overall recommendations and five specific recommendations:

Overall Recommendation: **Incorporate accelerated shelf life testing into USAID food aid product R&D**

Recommendation 1: Conduct accelerated shelf life/stability testing on all new products and existing products that may have major modifications or updates, such as adding new ingredients or changing nutrient levels and forms in FBFs.

Recommendation 2: Develop standard protocols to include mineral testing at both baseline and endline and vitamin A and C at all points.

Recommendation 3: Harmonize shelf life protocols and conditions wherever possible among aid organizations working on product development. As part of this process, share data and results from all new product studies for more effective transparency regardless of origin and source.

Overall Recommendation: Seek ways to optimize vitamin A delivery in the USAID food aid basket

Recommendation 4: Challenge vitamin A suppliers to develop methods of improving vitamin A stability in dry premixes for inclusion in FBF production.

Recommendation 5: Assess new types of packaging material to reduce degradation of vitamin A and other vitamins.

Recommendation 6: Conduct further research to determine the most appropriate delivery mechanism for vitamin A in the food aid basket, considering various factors including its susceptibility to degradation in FBFs, cost and programmatic implications.

H. References

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Appendices

Appendix 1: Accelerated Shelf Life Studies Overview

Product	Producer	Trial Country	Tests	Amount	Status
Corn Soy Whey Blend **CSWB**	Supplier A	Burkina Faso	Accelerated Stability study analyzing organoleptic, stability, vitamin A and peroxide values	8 25-kg bags	Completed
			One time analysis of K, Ca and Fe	10 g	Completed
	Supplier B	Sierra-Leone	Accelerated Stability study analyzing organoleptic, stability, vitamin A and peroxide values	8 25-kg bags	Completed
			One time analysis of K, Ca and Fe	10 g	Completed
Ready to Use Supplementary Food **RUSF**	Supplier C	Burkina Faso	Accelerated stability testing analyzing organoleptic, peroxide value and vitamin A	24 Sachets	Completed
Super Cereal *Plus* **SC *Plus***	Supplier B	Burkina Faso	Accelerated Stability study analyzing organoleptic, stability, vitamin A and peroxide values	16 1.5-kg bags	Completed
			One time analysis of K, Ca and Fe	10 g	Completed
Corn Soy Blend *Plus* **CSBP**	Supplier A	Burkina Faso	Accelerated Stability study analyzing organoleptic, stability, vitamin A and peroxide values	8 25-kg bags	Completed
			One time analysis of K, Ca and Fe	10 g	Completed
Fortified Vegetable Oil	Supplier D	USAID programs	Accelerated stability study analyzing vitamin A values	8 4-L cans	Completed through week 13

Appendix 2: Detailed Test Protocols

1. Vitamin A as Retinol

Vitamin A has been used as one of the biomarkers for determining that the micronutrient premix has been added at the correct amount as specified in the in the USDA CRDs for CSBP2 (2013) and vegetable oil VO15 (2012) and the specifications for the CSWB and SC *Plus* in the FAQR RFPs:

- **Conducted a**t t=0, 3 weeks, 6 weeks, 9 weeks, 13 weeks, 19 weeks and 26 weeks
- **Analytical Method:** Vitamin A by HPLC or UHPLC
- **Mnemonic:** V ALC, AFD1
- **Scope:** This method is applicable to the determination of retinol in foods, food products, infant formulas, premixes, pharmaceuticals, pet foods, feeds and other matrices at the supervisor's discretion. The method measures all-trans and 13-cis retinol isomers. It does not include contributions of vitamin A activity from pro-vitamin A carotenoids.
- **Principle:** The sample is saponified to break down fat and release the vitamins. The digest is extracted with an organic solvent. Vitamin A is measured directly as all-trans retinol and 13- cis retinol by ultra or high performance liquid chromatography (UHPLC or HPLC).
- **Limit of Quantitation:** The limit of quantitation is 1 IU/g, but can vary with sample size according to the following calculation:

$$\mathrm{LOQ} = \frac{\text{Low Standard } \left({}^{\mathrm{mg}}/_{\mathrm{mL}}\right) \times \text{Sample Volume (mL)}}{\text{Sample Weight (g)} \times 0.3 \left({}^{\mathrm{mg}}/_{\mathrm{IU}}\right)}$$

- **Precision:** The data that support the precision (measurement uncertainty) accuracy for this assay are on file in the Food Nutritional Chemistry and Food Safety department's central files.
- **Sample Required:** 30 g
- **Method References:** Official Methods of Analysis of AOAC International, Current Ed., Methods 992.04, 992.06 and 2001.13, AOAC INTERNATI0NAL, Gaithersburg, MD, USA (Modified).

2. Peroxide Value

Peroxide values reflect product rancidity and the products' shelf life:

- Conducted at t=0, 3 weeks, 6 weeks, 9 weeks, 13 weeks, 19 weeks and 26 weeks
- **Analyte:** Peroxide Value
- **Mnemonic:** PVFF
- **Scope:** This method is applicable to all normal fats and oils and extracted fats and oils. This method is highly empirical and any variation in procedure may result in variation in results.

- **Principle:** This method determines all substances, in terms of milli-equivalents of peroxide per kilogram of sample, that oxidize potassium iodide under the conditions of the test. These are assumed to be peroxides or other similar products of fat oxidation.
- **Sample Required:** 15 g
- **Method References:**
  - American Oil Chemists' Society, 'Cd 8-53 Peroxide Value Acetic Acid- Chloroform Method' (modified), Official Methods and Recommended Practices of AOCS, Fifth Ed., American Oil Chemists' Society, Champaign, IL (2003).
  - United States Pharmacopeia, 34th Rev., <401> Fats & Fixed Oils, USP Convention, Inc., p. 153, Rockville, MD (2011).
  - *Official Methods of Analysis of AOAC INTERNATIONAL* (2000) 17th Ed., AOAC INTERNATIONAL, Gaithersburg, MD, USA, Official Method 983.23. (Modified)

3. Organoleptic Analysis

The study conducts organoleptic analysis at all 7 time points to ensure product quality by looking at product appearance, packaging appearance and product odor. For fortified vegetable oil, analysis also includes description of taste.

- Method References**:** Covance internal SOP designed to supplement the United States Pharmacopeia, 25th edition, page 2363, USP Convention, Inc., Rockville, MD, 20002.
- Visual examination of the package and its contents, with general descriptions of the color and form. Specific notes are made on what may be considered defects such as packaging damage, separation, non-uniform material form, etc. Likewise the odor of the product is recorded with common descriptors. Unless otherwise agreed to, evaluation is by 1 analyst.

4. Mineral Analysis (for Fortified Blended Foods only: CSWB, CSBP and SC *Plus*)

The purpose of this testing is to verify that the minerals (Calcium, Iron and Potassium) were added to the fortified blended foods in the correct range as specified in the USDA CRDs for CSBP2 (2013) and the specifications for the CSWB and SC *Plus* in the FAQR RFPs. In addition, the premix used for vitamins also contains iron and testing for iron confirms that the premix was added at the correct addition rate:

- **Conducted at t=0** for Calcium, Iron and Potassium
- **Analyte:** Inductively Coupled Plasma (ICP) Spectrometry
- **Mnemonics:** ICPL, ICPN, ICPS, ICP3, ICP_S
- **Scope:** This method is applicable to the determination of up to 20 elements in virtually all matrices.
- **Principle:** The sample can be either dry ashed, wet ashed, or read directly. If dry ashed, the sample is placed in a muffle furnace set to maintain 500 o Celsius until ashing is

complete. The resulting ash is treated with concentrated hydrochloric acid, dried and redissolved in hydrochloric acid solution. If wet ashed, the sample is digested on a hot plate with nitric acid, hydrochloric acid and/or hydrogen peroxide. The amount of each element is determined with an ICP spectrometer by comparing the emission of the unknown sample against the emission of each element from standard solutions

- **Limit of Quantitation:** Element and sample dependent
- **Precision:** On a cereal matrix most RSDs are <5.00 percent
- **Sample Required:** 10 g**.**
- **Method References:** *Official Methods of Analysis of AOAC INTERNATIONAL,* Current Ed., Methods 984.27 and 985.01, AOAC INTERNATIONAL, Gaithersburg, MD, USA, (Modified).

5. Vitamin C

The study measured the vitamin C content at endline to ensure the right amount of premix was added correctly. This test was added following a discussion in January 2014 Harmonization meeting. Target and permitted range varies for each product.

- **Conducted at t=26**
- **Analyte:** Vitamin C
- **Mnemonics:** VCF
- **Scope:** This method is applicable for most foods and feeds. It measures both ascorbic acid and erythorbic acid if present.
- **Principle:** The vitamin C in the sample is extracted, oxidized and reacted with o-phenylenediamine to produce a fluorescent compound. The vitamin C content is determined by comparing the sample extract fluorescence to the fluorescence of known standards.
- **Limit of Quantitation:** Most matrices - 1 mg/100 g
- **Precision:** On a cereal sample matrix the RSD is 7.33 percent
- **Sample Required:** 8 g
- **Method References:** *Official Methods of Analysis of AOAC INTERNATIONAL, 18th Ed., Method 967.22, AOAC INTERNATIONAL, Gaithersburg, MD, USA, (2005). (Modified)*