



SHARING SCIENCE & TECHNOLOGY TO AID IN THE IMPROVEMENT OF NUTRITION

Results Report on the Vitamin C Pilot Program

CONTRIBUTING AUTHORS

Françoise Chomé
Peter Ranum

PUBLICATION DATE

1997

PUBLICATION BY

SUSTAIN, Washington D.C.
www.sustaintech.org



MISSION

The mission of SUSTAIN is to share science and technology to improve nutrition in developing countries. We do this by engaging industry, the scientific research community and governments in collaborative efforts to enhance the nutritive quality of food staples and by encouraging technologic innovation.

ORIGINS

SUSTAIN originated as a volunteer-based initiative to share food technology expertise with developing countries. SUSTAIN's early programs supported developing country food industries striving to improve product quality, food safety, packaging and marketing. SUSTAIN volunteers, drawn largely from U.S. food industries, provided requesting food companies with hands-on expertise to achieve these goals.

In the mid 1990's, SUSTAIN began to devote significant program attention to addressing the nutritional challenges of vulnerable populations. Our appreciation of the critical role micronutrients play in health and survival, particularly for infants, children, and women of childbearing age, led us to target applications of food science and technology to the pervasive problem of micronutrient deficiencies in developing countries.

BUILDING PARTNERSHIPS TO IMPROVE NUTRITION

In 1999, SUSTAIN launched operations as a 501(c)(3) non-profit organization whose goal remains technology sharing to improve global nutrition. SUSTAIN works as a catalyst organization, building partnerships across industry, the scientific and public health communities and government to improve the quality of food, and thus the quality of life for people in developing countries. SUSTAIN also sponsors research and encourages industry's development of innovative technologies in support of nutritional enhancements.

WWW.SUSTAINTECH.ORG

TABLE OF CONTENTS

Table of Contents	ii
List of Tables	iv
List of Abbreviations	v
Acknowledgments	vi
Executive Summary.....	vii
I. Objective.....	1
II. Background.....	2
III. The Operational Component.....	4
A. Special Vitamin Premix	4
B. Special Procurement of Commodities	4
C. Country Site Selection.....	5
IV. Monitoring and Evaluation Component	7
A. Methodology	7
1. Determination of Vitamin C Uniformity in the Commodities at Plant Sites.....	7
2. Determination of Vitamin C Stability from Manufacture to Points of Distribution.....	10
3. Determination of Within-Bag Variability of Delivered Commodities	13
4. Determination of Vitamin C Retention During Food Preparation.....	13
5. Analytical Methods	16
B. Results and Discussion	18
1. Uniformity of Vitamin C in the Commodities at Plant Sites.....	18
2. Stability of Vitamin C from Manufacture to Points of Distribution.....	23
3. Within Bag Variability of Delivered Commodities	25
4. Vitamin C Retention During Food Preparation.....	25
5. Analysis of Vitamin C Cost	31
V. Additional Information Requested by the Committee on International Nutrition	34
References.....	49
VI. Appendices.....	51

- A** Composition and specification of Wheat Soy Blend (WSB) and Corn Soy Blend (CSB)
- B** Advisory panel, statistical subgroup, and other people consulted
- C** Specifications and laboratory analysis of vitamin fortification premix in CSB/WSB
- D** Schedule of WSB and CSB pilot procurements from production to distribution
- E** Cooked food storage temperature history
- F** Effect of frozen storage on vitamin C content in CSB/WSB samples
- G** Flow charts of production processes for plants A through E
- H** Analytical data on CSB/WSB samples taken from plants A through E
- I** Control charts of vitamin C content in samples taken from plants A through E
- J** Histogram analysis of vitamin C content in samples taken from plants A through E
- K** Letter to USAID (specifications for a special production of CSB with high vitamin C level)
- L** Analytical data on CSB/WSB samples taken from Haiti and India
- M** Within-bag variability at distribution point
- N** Analytical data on cooked CSB/WSB samples taken from Haiti and Tanzania
- O** USDA letter
- P** Information on possible alternative CSB/WSB bags

LIST OF TABLES

Table 1. Summary of Plants and Production Runs Sampled.....	8
Table 2. Minimum Number of Samples that Needed to be Collected at Distribution Sites.....	11
Table 3. Sampling Sites to Study Vitamin C Stability from the Point of Manufacture to the Point of Distribution	13
Table 4. Summary of Sample Sizes	15
Table 5. Summary of Vitamin C Results From Production Plants	21
Table 6. Retention of Vitamin C in Dry Commodities	24
Table 7. Summary of Food Preparation Samples Collected in Selected Countries.....	25
Table 8. Summary of Vitamin C Content of the WSB and CSB After Cooking	29
Table 9. Reported Cases of Anemia In Refugee Populations	36
Table 10. Reported Scurvy Outbreaks in the Greater Horn of Africa: Somalia, Sudan, Ethiopia, and Kenya.....	39
Table 11. Additional Costs of Adding 50 mg/100g more Vitamin C to CSB/WSB	43
Table 12. Costs of Stabilized Vitamin C Products for CSB/WSB Fortified at 40 mg/100g	44
Table 13. Cost of Different Forms of Iron.....	46
Table 14. Possible Consequences of Added Cost from Higher Vitamin C Level	47
Table 15. List of Data Files.....	48

LIST OF ABBREVIATIONS

ADRA	Adventist Development and Relief Agency
AOAC	Association of Analytical Chemists
BHA	butylated hydroxyanisole
BHR	Bureau of Humanitarian Response
BHT	butylated hydroxytoluene
CARE	Cooperative for American Relief Everywhere
CDC	Centers for Disease Control
CIN	Committee on International Nutrition
COV	coefficient of variation
C _p	production capability
C _{pk}	production capability index
CRS	Catholic Relief Services
CSB	corn soy blend
FDA	Food Drug Administration
FFP	Office of Food for Peace
FGIS	Federal Grain Inspection Service, also called Grain Inspection, Packers and Stockyards Administration
HPLC	high performance (pressure) liquid chromatograph
IOM	Institute of Medicine
MCH	maternal child health
MT	metric ton
NAS	National Academy of Sciences
OCF	other child feeding
PVO	private voluntary organization
PL 480	Public Law 480
RDI	recommended daily intake
TCP	tricalcium phosphate
SUSTAIN	Sharing United States Technology to Aid in the Improvement of Nutrition
UNHCR	United Nations High Commissioner for Refugees
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
WFP	World Food Programme
WSB	wheat soy blend

ACKNOWLEDGMENTS

The authors wish to express their sincere appreciation to Dr. Sam Kahn and Dr. Tom Marchione for their valuable comments, suggestions, and guidance over the course of the Vitamin C Pilot Program. The authors would also like to thank the advisory panel and subgroup members (listed in Appendix B) for their dedication to this study and for their valuable expertise. Staff members at SUSTAIN and numerous other people deserve our appreciation (see Appendix B), but the list is too long for this page. Each of their contributions was extremely important, and contributed to the overall success of the Vitamin C Pilot Program.

EXECUTIVE SUMMARY

This report contains the results of the USAID Vitamin C Pilot Program for use by USAID in consultation with the National Academy of Sciences to determine appropriate vitamin C fortification levels in food commodities used in U.S. food aid programs.

The Vitamin C Pilot Program, initiated in March 1996, was designed to produce, provide, and evaluate food aid commodities with increased levels of vitamin C fortification. Using standard procedures, USAID's Food for Peace program procured two commodities for the pilot program. These commodities, corn soy blend (CSB) and wheat soy blend (WSB), were provided to Tanzania and Haiti at higher levels of vitamin C. SUSTAIN provided technical advice and monitored and evaluated the results of the program.

The report details the following monitoring results:

- 1. The uniformity of vitamin C distribution in the products at five plant sites.** Vitamin C distribution at each plant site varied from plant to plant and within any given production run. The variability was particularly evident in CSB, which is produced by a continuous process. WSB, while produced in much more limited quantities, is processed by a batch system and showed more uniformity. The ability of the different plants to control the amount and variation of vitamin C added to the commodities was dependent on the type of processing equipment, plant design, and quality control procedures used in each plant.
- 2. The stability of vitamin C from point of production to distribution of CSB shipped to India and of WSB shipped to Haiti.** The time involved for shipping, transport, and storage (nine months for Haiti and five months for India) resulted in very little loss of vitamin C. The WSB with the conventional level of added vitamin C that was sent to Haiti showed a small (13%) but significant ($P < .01$) loss of vitamin C. The WSB with the high level of added vitamin C and the CSB sent to India showed no significant ($P > .05$) change in vitamin C.¹
- 3. The variation of vitamin C distribution within bags after shipping and handling to Haiti and Tanzania.** Within-bag variation was tested after shipping and handling by sampling bags at two recipient sites from the top, middle, and bottom of the bag. There was variation among samples taken from the three bag locations but the variability was consistent throughout the bag, indicating that there was no systematic stratification or concentration of the vitamin within one part of the bag.
- 4. The stability and presence of vitamin C after food preparation by recipients in a regular program in Haiti and an emergency program in Tanzania.** Retention of vitamin C added at conventional levels was between 17 and 32% in CSB gruel samples and was 27% in WSB gruel samples. Gruel samples containing 14% CSB or WSB are the

¹ The pilot CSB procurement sent to Tanzania could not be tested for vitamin C because the distribution of added micronutrients in this pilot procurement was not uniform. Therefore, it was deemed impractical for purposes of means comparisons; consequently, a procurement of conventional CSB shipped to India was substituted.

most common foods prepared from these commodities, accounting for 62% of the 39 prepared food samples collected. CSB and WSB containing low levels (below 24 mg/100g) of vitamin C lose nearly all of the vitamin C during cooking. Conversely, the higher vitamin C levels allowed cooked food to retain some vitamin C at the time of consumption. The retention at high levels of added vitamin C was 56% in CSB gruel and 32% in WSB gruel. In the refugee camps in Tanzania, the next most common food made from CSB was “ugali,” which contains 40% CSB. It showed an average vitamin C retention after cooking from 36 to 74% for ugali prepared with CSB containing high levels of vitamin C. In Haiti, the second most cooked dish made from WSB contained 80% WSB. This dish showed a mean vitamin C retention of 18% with WSB containing the conventional level of vitamin C and a mean retention of 33% with WSB containing the high level of vitamin C.

- 5. A projection of the increased cost to the Food for Peace Program of increased levels of vitamin C.** The current price of the ethyl cellulose coated vitamin C used in conventional CSB and WSB (40mg/100g) is \$9/kg or \$3.69/MT of fortified CSB or WSB. The price of vitamin C fluctuates and is currently quite low compared to past years, when the cost was twice as high. If the ethyl cellulose coated vitamin C level of the commodities was increased from its present level of 40 mg/100g of commodity to 90 mg/100g, the cost would increase by \$6.33/MT. Part of this cost increase can be attributed to having to use a more dilute vitamin premix, resulting in higher storage and shipping expenses.

These results are fully detailed in samples and analyses shown in the appendices.

The report also presents supplemental information requested by the Committee on International Nutrition of the National Academy of Sciences. Reports of scurvy outbreaks have been confined, except in rare occasions, to refugee populations in East Africa where refugees are largely dependent on food aid. SUSTAIN's literature search did not identify cases of scurvy that were attributed to food aid in regular development programs.

General rations containing inadequate vitamin C, combined with a lack of diversity of food sources, have been named as the primary factors for outbreaks of scurvy in displaced and famine-affected populations. Other characteristics are lack of ability to cultivate or trade for other food sources, remoteness and inaccessibility, cultural factors affecting food acceptance, and age and physiological status (pregnancy and lactation) of individuals in these situations. Many authors recommend 6 to 10 mg of vitamin C a day as a minimum requirement to prevent clinical manifestation of scurvy. The amount of vitamin C provided by CSB or WSB, containing 40 mg/100g of vitamin C at the point of consumption, when provided at a ration of 30 grams of CSB or WSB per day, would be 3.6 mg/day given a 30% cooking retention.

Until 1994, fortified cereal blends such as CSB and WSB were only occasionally provided in the general ration to refugees in East Africa when high prevalence of scurvy was determined. Most reported outbreaks of scurvy occurred before 1990. Fortified blended foods are now more routinely provided in emergency food aid program.

Use of vitamin C tablets was not found to be a practical method for preventing vitamin C deficiency in refugee populations.

Based on current production, increasing the level of vitamin C in all CSB and WSB produced to 90 mg/100g while keeping the current budget constant would reduce the tonnage produced by 4,662 metric tons and reduce the number of persons that could be fed a ration of 30 grams per day for a year by 425,797.

This report also includes information on alternative bagging, use of antioxidants, alternative forms of vitamin C, and iron fortification. Alternative forms of packaging are under consideration by the U.S. Department of Agriculture (USDA). USDA's primary interest in evaluating alternative packaging materials is to improve the strength of the bag rather than improving the micronutrient protection. Improved vitamin C protection does not appear necessary: this study showed relatively low levels of vitamin C degradation after shipping, handling, and storage.

A discussion of alternate forms of iron that might reduce the oxidation of vitamin C is also included in this report. However, this report also notes that further testing would be needed to determine the feasibility, acceptability, and cost of incorporating these other sources of iron into CSB and WSB.

The form of vitamin C currently used in CSB and WSB contains 97.5% ascorbic acid with a 2.5% ethyl cellulose coating. There are alternative forms of vitamin C now available with coatings of different types and thickness. These may provide better protection during food preparation than the current product, but no studies have been done to determine that. There are also other chemical forms of vitamin C with improved heat stability that are used in aquaculture, but none have been approved for human feeding.

I. OBJECTIVE

This activity provided technical information to the U.S. Agency for International Development (USAID) Vitamin C Pilot Program, which was designed to produce, provide, and evaluate food aid commodities that are fortified with increased levels of vitamin C. SUSTAIN specified the premix, recommended the pilot production quantity, and advised on field site selection. SUSTAIN also monitored and evaluated product quality, production costs, and vitamin C stability from the point of manufacture to the point of distribution and consumption. Two vitamin C fortified commodities used in the USAID Food for Peace Program were evaluated: corn soy blend (CSB) and wheat soy blend (WSB). This report presents results for use by USAID and the Committee on International Nutrition (CIN), Institute of Medicine of the National Academy of Sciences (NAS), to determine whether vitamin C levels in U.S. food aid commodities need to be increased.

II. BACKGROUND

Corn soy blend (CSB) and wheat soy blend (WSB) products are highly nutritious, low-cost, fortified foods that are used to deliver a wide array of macro- and micronutrients in the P.L. 480, Title II, Food for Peace Program. In fiscal year 1996 (October 1995 through September 1996), 238,300 metric tons (MT) of CSB and 11,310 MT of WSB were programmed for development activities and emergency activities such as refugee camp food distribution (USAID Annual Food Assistance Report, 1996). These blended cereal-based foods are partially precooked, which allows them to be easily incorporated into a number of different food preparations by recipients.

CSB and WSB are fortified with six essential minerals and eleven vitamins. This fortification accounts for 13% of the product cost. Like other P.L. 480 commodities, CSB and WSB are procured for USAID by the U.S. Department of Agriculture (USDA) Export Operations Division/Farm Service Agency. Currently there are seven different commercial companies approved by USDA to produce these commodities.

According to USDA guidelines, commodities must be produced in the United States under inspection by the USDA Grain Inspection, Packers and Stockyards Administration/Federal Grain Inspection Service (FGIS). An FGIS representative is present during commodity production and takes samples for analysis. Chemical and physical tests are run on these samples to determine compliance with specifications for the finished CSB/WSB. These routine tests include some nutritional analyses (protein, fat, moisture content, crude fiber), but they do not include tests for any of the added vitamins or minerals. Vitamin levels are not included in final product specifications. USDA composition specifications for CSB and WSB are contained in Appendix A.

CSB and WSB have vitamin C added in the ratio of 40 mg for every 100 g of commodity. The form of vitamin C currently used contains 97.5% ascorbic acid with a 2.5% ethyl cellulose coating. In September 1995, the U.S. Senate and House Appropriations Committees recommended that a pilot program be established to provide commodities with a 90 mg/100g fortification level (Foreign Operations, Export Financing, and Related Programs Appropriations Bill, 1996, S.Rpt. 104–143).

The operational component for the Vitamin C Pilot Program was implemented by the USAID Food for Peace Office in the Bureau of Humanitarian Response. It involved procuring, producing, and providing CSB with high and conventional levels of vitamin C to refugee camps in Tanzania and providing WSB with conventional and high levels of vitamin C to development programs in Haiti, using the usual program procedures for P.L. 480 Title II food aid.

The monitoring and evaluation component of the Vitamin C Pilot Program was conducted by SUSTAIN under a cooperative agreement with USAID. SUSTAIN, through the USAID Global Bureau's Office of Health and Nutrition in cooperation with the Program, Planning, and Evaluation office for the Bureau of Humanitarian Response (BHR), monitored the

uniformity, stability and physical availability of vitamin C in the commodities from three selected country programs. In cooperation with the World Food Program (WFP), private voluntary organizations (PVOs), and USAID missions, SUSTAIN collected dry commodity samples in three countries. SUSTAIN also collected information about the local food preparation of the commodities and cooked samples in two countries, and determined vitamin C retention after cooking by testing samples of prepared food collected at recipient sites in these two countries.

The protocol for this activity was reviewed by an Advisory Panel of experts drawn from government, food relief agencies, and the food industry (Appendix B). These experts are knowledgeable in the fortification, stability, and testing of vitamins in these types of foods. This Advisory Panel met twice: once on April 18, 1996, to review the call forward request and sampling strategy, and again on May 17, 1996, to review the protocol. A statistical subgroup of the Advisory Panel, made up of statisticians and quality control experts of the food industry, advised on statistical matters and interpretation of the results (Appendix B). They met on May 3, 1996, to review the statistical plan of the study and to recommend the number of samples to be collected, and again on April 25, 1997, to discuss the statistical analysis of the results. Recommendations and suggestions from these meetings have been incorporated into this report. A protocol was designed and submitted to the Committee of International Nutrition (CIN) of the Institute of Medicine, National Academy of Science. Agreement on the protocol and recommendations by the CIN were presented to USAID in December 1996.

III. THE OPERATIONAL COMPONENT

SUSTAIN advised the USAID Office of Food for Peace (FFP) in the Bureau for Humanitarian Response on the means to implement a pilot program that would closely represent ordinary food aid operations from procurement through distribution at field sites. This involved:

1. specifying the vitamin premix with higher levels of vitamin C;
2. recommending the quantities of enhanced and conventional commodities to be procured; and
3. consulting on the field programs to be selected.

A. Special Vitamin Premix

The vitamin premix used for CSB and WSB are commercial products made by either Watson Foods or ADM Paniplus. There are two types: one premix contains the antioxidants butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT), and the other does not. The latter is used during some processes when the antioxidants are added to the oil. The USDA specifications on this premix and a breakdown of the composition are shown in Appendix C, Table C-1. A special premix for adding the higher level of vitamin C was designed (the composition is shown in Appendix C, Table C-2). A batch of this product was prepared by Watson Foods and used by two plants for their special production. Because of the higher level of vitamin C, this premix has to be made at a 3 lbs/ton addition rate instead of the 2 lbs/ton addition rate specified with the current conventional level of vitamin C.

B. Special Procurement of Commodities

SUSTAIN requested the Commodity and Procurement Division of USAID/BHR/FFP to order 500 metric tons (MT) of CSB and 240 MT of WSB with the higher vitamin C level and the same quantities of CSB and WSB with the conventional level of vitamin C. These pilot quantities were recommended by the statistical subgroup of the Advisory Panel as sufficient quantity to constitute a valid pilot test. The production time for both quantities was 2.5 days of production at the CSB and WSB plants. The statistical subgroup determined that collecting 48 samples during this time frame was more than adequate to determine uniformity of vitamin distribution within the commodities according to SUSTAIN's criteria to assess a minimum 20% drop in vitamin content and the expected variation under normal commercial commodity production. All subsequent sampling was conducted using this same time frame of collecting 48 samples during 2 to 3 days of commodity production.

Special markings were printed on the side of the CSB and WSB bags. This was suggested by collaborating agencies in the field to help find the bags and distinguish them from the routine production runs of these two commodities. Therefore, the WSB and CSB logos were printed in blue (instead of the usual red) for the batches with conventional vitamin C levels. For the

commodities with the higher level of vitamin C, an additional blue bar was printed on the bag next to the logo. SUSTAIN informed the collaborating agencies that it was important that these commodities receive the same transportation, storage, and distribution treatment as any other P.L. 480 commodities.

The contracts for production of the pilot procurements were awarded to the lowest bidder using standard procurement procedures. At that time, two plants (referred to in this report as Plant A and Plant B) were being awarded contracts for the production of two pilots procurements. From June 24 to 28, 1996, Plant A, the winning bidder for CSB, produced 500 MT of CSB with high vitamin C followed by 500 MT of CSB with the conventional level of vitamin C. Half of each type was sent to refugee camps in Western Tanzania to meet emergency needs of that time. From July 8 to 12, 1996, Plant B, the winning bidder for WSB, made 240 MT of WSB with conventional fortification followed by 240 MT of WSB with high vitamin C. All of this production was sent to Haiti.

C. Country Site Selection

A third task for SUSTAIN was to work in conjunction with FFP to determine the target country sites for the pilot program.

Criteria for Choice of Recipient Country Sites

The countries chosen by the Office of Food for Peace and SUSTAIN for this pilot program were Haiti, a regular development program, for WSB and Tanzania, an emergency food aid distribution program, for CSB. These sites were chosen according to the following criteria:

1. One site needed to be in a country where CSB was used in the feeding program and the other site needed to be in a country where WSB was used.
2. One feeding program needed to be in an emergency context and the other needed to be in a development context.
3. At least one country food aid program needed to be chosen where scurvy had been reported in past camp feeding situations and one program needed to be where significant iron deficiency has been reported.

Other criteria considered were:

1. Interest in the Vitamin C Pilot Program by local country, PVOs, and USAID.
2. Logistical assistance available in the country to SUSTAIN during sampling.

Haiti

There were three PVOs distributing food aid in Haiti (ADRA, CARE, and CRS). SUSTAIN worked with ADRA (Adventist Development and Relief Agency) because it was the only PVO that had WSB on their remaining allocation for Haiti for fiscal year (FY) 1996 and could

include the pilot procurement in their program. Also, USAID/Haiti was willing to collaborate with SUSTAIN.

Tanzania

In Tanzania, SUSTAIN worked with the World Food Programme (WFP), the United Nations High Commissioner for Refugees (UNHCR), and the USAID mission. A total of 350 MT of the CSB pilot procurement was distributed in the Ngara region of Western Tanzania, where several refugee camps were located. The rest of the special procurement was allocated to other areas of Tanzania, mainly in the Kigoma region.

India

The pilot production run sampled at Plant A that was sent to Tanzania did not contain sufficiently uniform distribution of vitamin C to allow for an efficient test of stability in shipping. Therefore, after the production of conventional CSB at another plant, Plant C, was determined sufficiently uniform to allow determination of vitamin C stability during shipping, and in consultation with USAID, SUSTAIN tracked down the procurement produced at Plant C. This production of CSB had been shipped to Cochin in southwest India. The WFP office and USAID/India helped SUSTAIN locate and sample this procurement, which was distributed in a preschool feeding program.

IV. MONITORING AND EVALUATION COMPONENT

A. Methodology

SUSTAIN managed the monitoring, evaluation, and quality control component of the pilot program. This involved four principal tasks:

1. determining the uniformity of vitamin C in the commodities during production;
2. determining the stability of the added vitamin C from the point of manufacture to the point of distribution;
3. estimating the variability of vitamin C distribution within bag; and
4. determining the stability of the added vitamin C during normal food preparations and estimating how much vitamin C would actually be contributed to the recipients' diets from normal rations of these commodities.

1. Determination of Vitamin C Uniformity in the Commodities at Plant Sites

CSB/WSB Production Tested

After the initial sampling results indicated uniformity problems in the fortification of CSB, it was the consensus among USAID and the SUSTAIN Vitamin C Advisory Panel that each of the seven CSB/WSB plants that are being awarded production contracts should be sampled to assess the extent of the uniformity problem.

Four of the six U.S. plants producing CSB and one of the two WSB plants were sampled. One CSB plant and one WSB plant were not in production during the sampling period. A conventional vitamin C level production run and a high vitamin C production run were sampled in Plants A and B, as summarized in Table 1.

Table 1. Summary of Plants and Production Runs Sampled

Plant	Commodity	Fortification Level of Vitamin C	Production Process	Bag Marking
A	CSB	Conventional	Continuous	Solid blue diamond
		High	Continuous	Solid blue diamond with bar
B	WSB	Conventional	Batch	Solid blue hexagon
		High	Batch	Solid blue hexagon with bar
C	CSB	Conventional	Continuous	Normal red diamond
D	CSB	Conventional	Continuous	Normal red diamond
E	CSB	Conventional	Continuous	Normal red diamond

Criteria for Accepting a Production Run for Study of Stability in Shipping

The test results on the special production were sent to members of the Advisory Panel and the statistical subgroup of the Advisory Panel to recommend whether the pilot production batch was worthy of continued study based on the following criteria:

1. That the production was in control by normal standards of statistical quality control as applied by the U.S. food industry.
2. That the variance in production was small enough to detect a 20% drop in ascorbic acid content with a 95% confidence level.

The experts concluded that the special production of CSB by Plant A failed to meet either criteria and that the special production of WSB by Plant B met both criteria. It was the consensus between USAID and the SUSTAIN Vitamin C Advisory Panel that additional CSB/WSB plants should be sampled to assess the extent of the uniformity problem. They also agreed that the special production of CSB by Plant A, scheduled to be sent to Tanzania, did not contain a sufficiently uniform distribution of vitamin C to allow for an efficient test of stability in shipping.

Method of Sampling of CSB and WSB at Production Sites

Based on the recommendations from the statistical subgroup, 48 samples of each run were collected. The sample collection was spread out evenly over a 2 to 3 day production run. Ten of these samples were duplicated for use as blind analytical checks. All CSB and WSB samples taken at the mill were tested within 10 days after sampling for vitamin C, and within the following two weeks for niacin.

Except for adding the special high vitamin C premix, the plant was instructed not to alter or slow down the production of the commodity in any way that would make it different from a normal production run. Arrangements were made through USDA and Protein Grain Product International to sample the production according to the following procedures:

1. The company to be sampled and the responsible FGIS field office were contacted to confirm arrangements on sampling procedures, times, and materials.
2. A SUSTAIN representative visited the production site to review the sampling procedure with plant and FGIS employees.
3. With assistance from FGIS inspectors and plant quality control (QC) staff, SUSTAIN collected 48 samples from each production run over a 2 to 3 day period. Samples of commodities with both conventional and high vitamin C levels were collected by removing a filled bag from the line, scooping a sample from the top of the bag, and putting the sample into an eight ounce black plastic container with a tight snap-on lid. Each container was labeled with the date, time, and sample number. The sampled bags were labeled with the same information, given a distinctive colored mark on the sides and bottom, and returned to the production line. During other standard production runs, the bags were sampled in the same manner but were not labeled or given a special marking. This allowed many of the samples to be taken without removing the bags from the line.
4. Duplicate samples were made by removing bags from the line, mixing the top portion of the product with a scoop, and filling two sample cups. The duplicates were given different sample numbers and dummy times so that they could not be identified as duplicates by the analytical laboratory.
5. As time allowed, additional bags of the special production were sampled and the bags labeled. These samples were sent to frozen storage in Kansas City, Missouri, to be tested later only if the bag could be found and sampled at the recipient site. Two full bags were taken from each production run, sampled, sealed, labeled, and sent to frozen storage for eventual use in food preparation studies.
6. Samples of the vitamin premix being used were taken each day from the premix feeder.
7. With help from plant personnel, SUSTAIN diagrammed the production method used and recorded the following information:
 - ♦ Times of personnel shift changes.
 - ♦ Manufacturer and lot numbers of vitamin and mineral mixes used.
 - ♦ Production rates (bags/hour) every hour.
 - ♦ Temperature and weather conditions (every day).
 - ♦ Any special circumstances or events (e.g., chokes, accidents).
 - ♦ Any process control readings and test results that the plant offered to make available and the check weights on the five basic ingredients and time/date taken, if available. Only one plant provided this information.

2. Determination of Vitamin C Stability from Manufacture to Points of Distribution

Method for Determining Stability

The stability of the added vitamin C was assessed by the following independent methods.

Comparison of Mean Levels

This method compared the mean and the variation of the vitamin content in both the CSB and the WSB products at production to the mean and the variation of the micronutrient content in the same lot of product just prior to being used in food preparation in the recipient country. The Student's T test and confidence interval were used to determine whether the means were statistically different from each other and if so, whether they were statistically different by more than 20%. This range was considered by the Advisory Panel to be the measurable difference in vitamin content that can be accepted taking into account analytical and sampling error.

Comparison of Paired Samples in Specially Marked Bags

Once the specially marked, sampled bags were located in the field and sampled, the vitamin C content was compared to the vitamin C content found in those same bags during production. The Student's T test and confidence interval were employed to determine whether the paired values were statistically different from zero and whether they were statistically different by more than 20%.

Using Niacin as a Marker of Vitamin Fortification

During normal production, niacin is added to WSB and CSB as part of the vitamin premix. Niacin is considered a highly stable vitamin and is not likely to show a decrease during storage and transport. Since these commodities are fortified with a uniform premix having a set niacin to vitamin C ratio, a change in that ratio would reflect a loss of vitamin C, assuming no loss of niacin. The ratio between vitamin C and *added* niacin in conventional CSB is $364/45 = 8.1$. A ratio below that of vitamin C to total niacin minus the natural niacin found in the field samples of conventional level CSB would indicate a loss of vitamin C. In this case, a ratio of 6.5 would indicate a 20% drop in vitamin C. With the high level of vitamin C, a ratio below 14.5 is required to show a 20% drop or more.

Sampling Dry Products at Recipient Country Sites

Sampling trips were made to Haiti, Tanzania, and India. The trips were arranged after obtaining confirmation from the responsible food distributing agency (ADRA or WFP) in the recipient country that bags with the sought for contract number had arrived at the final distribution sites. No attempt was made to alter or expedite the normal distribution of the

commodity. The schedule of the distribution of the commodities in Haiti and Tanzania are contained in Appendix D. A detailed distribution schedule was not available for India, as the commodity was tracked down only after the procurement was delivered to the distribution site.

A statistical software program was used to determine how many commodity samples needed to be taken from the field in order to detect a 20% decrease in vitamin C (Table 2).

Table 2. Minimum Number of Samples that Needed to be Collected at Distribution Sites

Commodity/Level of Vitamin C	Country of Distribution	Number of Samples	Comments
WSB/conventional	Haiti	10	
WSB/high	Haiti	14	
CSB/conventional	Tanzania	150	did not meet criteria
WSB/high	Tanzania	124	did not meet criteria
CSB/conventional	India	16	

Sampling method

In each country, samples were collected by laying the bag flat on the floor or ground and cutting the bag at the top, or middle, or bottom with a razor blade. A single sample of about 100g was extracted from the bag, and in most cases the position of the cut in the bag was noted. The sample was put into sampling cups with either screw-top lids or snap-seal lids. SUSTAIN brought the samples back to the United States for analysis within two weeks of collection. Until delivered to the laboratory, the sampling containers were stored in several layers of sealed plastic bags placed in cardboard boxes.

Haiti

The procurement specially produced by Plant B in early July with the conventional (240 MT) and enhanced (240 MT) levels of vitamin C was unloaded in the ADRA warehouse in mid-October 1996. A total of 19,103 bags were delivered. Distribution to the food distribution centers of this procurement started in early December (Appendix D, Table D-2). For each batch, several bags were sampled at production and specially labeled (63 bags of the high vitamin C, 68 bags of the conventional vitamin C). To allow SUSTAIN to track down the specially marked bags, ADRA was asked to deliver five of the specially labeled bags to ten pre-selected feeding centers during their normal three-month distribution cycle.

The selection of the feeding centers was based on the type of food distribution program and their location (urban versus rural). There were three types of feeding programs run by ADRA, but WSB was distributed through only two of them: the Maternal Child Health

(MCH) and Other Child Feeding (OCF) programs. The locations selected were: 1) a primary MCH and a primary OCF in an urban area, and 2) two primary MCH centers and one primary OCF center in a rural area. In addition to these five locations, secondary centers in close proximity to the primary centers were selected to ensure there was a matching pair of centers in each of the five distribution areas. In each of the five locations, the primary centers received WSB with the conventional level of vitamin C level and the secondary centers received WSB with the high level of vitamin C.

Distribution to the selected centers began in late January 1996, and the sampling took place in the centers in March 1997. Typically, a center receives three months' worth of commodities at a time and the commodities are distributed to the recipients twice a month. The commodities are consumed during the two to three weeks between distributions.

Tanzania

The special procurement of CSB produced in Plant A from June 24 to 28, 1996, was sent to the refugee camps in western Tanzania and was distributed in December 1996 (Appendix D, Table D-1). Logistics and internal transport of food commodities were handled by the World Food Programme, and distribution at the distribution sites was under the management of UNHCR.

The field sampling of the special procurement of CSB was revised after analysis of the production samples. The Advisory Panel recommended against sampling this procurement in the field because the production was not in control and failed to meet SUSTAIN's acceptance criteria. USAID project officer concurred on this initial recommendation; however, on advice from the Committee on International Nutrition of the National Academy of Sciences (December 1996) and USAID, SUSTAIN attempted to reinstate part of the sampling plan in Tanzania. After consulting with WFP and USAID/Tanzania and reviewing the availability of the special production that was sent to Tanzania, SUSTAIN determined that it would be feasible to gather prepared food samples of the special CSB procurement from the refugee camps in Tanzania. In Tanzania, SUSTAIN's focus was on observing food preparation practices and sampling CSB (from the remaining special procurement) just prior to and after cooking. SUSTAIN sampled eight bags from the special procurement.

In addition, SUSTAIN sampled seven bags from another CSB procurement, which was produced at Plant D in April 1996.

India

To test the stability of vitamin C during shipping, SUSTAIN identified another conventional procurement, one destined for India. The production was sampled in early October 1996 and met the criteria of being in control and having an acceptable variability to be able to detect a 20% drop in ascorbic acid.

Four lots (136 MT/lot) of this conventional procurement were being distributed in the Cochin region. Most of the bags sampled came from two lots only. Sampling was done at six

different schools and at two different warehouses serving the area. The warehouses were privately run under contract to WFP. The bags found in the schools were kept in school pantries. The schools, which each teach from 12 to 40 children, received CSB several times a month. The CSB was provided to the schools for their school lunch program and it was served once a day

Table 3. Sampling Sites to Study Vitamin C Stability from the Point of Manufacture to the Point of Distribution

Country Site	Type	Product	Producer	Sample Date (Production)	Sample Date (Distribution)	Time Interval Between Sampling (in months)
Tanzania	Refugee	CSB	Plant A	Jun 96	Jan 97	7
Haiti	Development	WSB	Plant B	Jul 96	Mar 97	9
India	Development	CSB	Plant C	Oct 96	Mar 97	5

3. Determination of Within-Bag Variability of Delivered Commodities

Within-bag variation after shipping and storage was determined by collecting samples from 13 bags of CSB in Tanzania and 9 bags of WSB in Haiti. A single sample of approximately 100g each was extracted from three different positions of the bag: the top third of the bag (position “a”), the middle third (position “b”), and the bottom third (position “c”). Each sample was analyzed separately.

4. Determination of Vitamin C Retention During Food Preparation

Purpose and Objectives

Vitamin C is susceptible to destruction by oxidation in the presence of moisture, especially when combined with heat, alkali, dissolved copper, or iron. Various cooking methods accelerate vitamin loss. Because fortified commodities such as CSB and WSB are cooked by the food aid program beneficiaries, instructions are given on how to prepare the commodities. No studies, however, have reported how these commodities are actually prepared by the beneficiaries, so the vitamin loss occurring during the preparation of these commodities was not known. Therefore, the purpose of the food preparation data collection component of this study is to determine the extent to which vitamins are lost during typical preparations of two food aid commodities: WSB and CSB. The objectives were:

1. To document the food preparation methods used by food aid beneficiaries in two programs: one in a development situation and one in a refugee situation.

2. To sample the typical food preparations of WSB and CSB from several beneficiary households for vitamin C analysis.

CSB sampling took place in refugee camps in Tanzania and WSB sampling occurred in impoverished areas in Haiti. In both locations, food preparations were made with WSB and CSB with both conventional and high vitamin C levels that was taken from the special procurement.

Materials and Methods

The equipment used in sampling CSB and WSB included plastic bags, cooler (Igloo), ice packs, 4-ounce containers for samples, spoons, pH paper, portable scale, camera, thermometers, recording thermometers. With the assistance of the agencies distributing the food aid commodities (ADRA in Haiti, WFP in the refugee camps in Tanzania), SUSTAIN made appointments to meet with beneficiaries who use WSB or CSB regularly. Appointments took place at the recipients' homes. Community leaders (MCH centers workers in Haiti, "street" social workers in the refugee camps) asked several mothers if they would volunteer for the study. The only requirement was that they would be available for cooking with the appropriate ingredients at the time of the appointment. Preliminary observations had shown that in Haiti the most commonly prepared WSB dishes were gruel and a vegetable broth with dumplings; in the Tanzanian refugee camps the most commonly prepared CSB dishes were gruel and *ugali*, a Swahili word referring to a stiff porridge traditionally prepared with fermented cassava. The mothers selected for the study were free to choose the type of dish that they wanted to cook.

Distribution of Extra Rations

At the sampling appointments, SUSTAIN met with the mothers and gave them each an extra ration of the commodity taken from the special procurement bags, which were sampled just prior to cooking. The extra rations were identical in quantity to their regular rations (one- to two-weeks' worth of commodity). Typically, the ration is consumed within two or three weeks after distribution. This is true for the beneficiaries in Haiti and in Tanzania. For each commodity, the mothers were divided into two groups: one which cooked the commodity with the higher level of vitamin C and one which cooked the commodity with the conventional level of vitamin C.

Food Preparation

During food preparation, ingredients and weights, cooking procedures, cooking times and temperatures, and pH measurements were recorded. The length of time that the WSB or CSB commodities were placed in a water solution prior to cooking was also recorded. SUSTAIN noted the type and nature of utensils and the type of fuel used to cook the food. Critical parts of the preparation were also photographed to record the procedure.

Sampling

In both Haiti and Tanzania, mothers usually serve the food immediately after cooking. As soon as the food was ready, SUSTAIN collected a representative sample of the cooked food in a 4-ounce container, which was closed tightly and put in a cooler with frozen ice packs. Within eight hours of collection, the cups were transferred to a freezer. Freezer temperatures were measured to ensure that the samples were kept frozen at all times. SUSTAIN brought the frozen samples back to the United States in a cooler with ice packs and put them in a freezer until they were picked up by Lancaster Laboratories for analysis. A thermometer that recorded the temperature every 30 minutes was put with the samples to verify that the samples were kept under 32° F at all times. The frozen CSB food samples from Tanzania were tested for vitamin C within two weeks of sampling. The frozen WSB food samples from Haiti were tested for vitamin C within three weeks of sampling. The temperature histories of these samples are shown in Appendix E.

The WSB and CSB samples taken before and after cooking were analyzed for vitamin C and moisture content. Samples taken before cooking were also analyzed for niacin and water activity.

Sample size

The number of samples needed to be collected of the food prepared in Haiti was calculated, taking into account the estimated variability of the WSB vitamin C content. The high variability of vitamin C in CSB from Plant A prevented SUSTAIN from making a similar calculation for the food preparation sampling in Tanzania. The summary of the sample sizes are listed in Table 4.

Table 4. Summary of Sample Sizes

WSB in Haiti	Sample Size	CSB in Tanzania	Sample Size
High vitamin C	5 gruel samples 5 dumplings samples	High vitamin C	10 samples
Conventional vitamin C	5 gruel samples 5 dumplings samples	Conventional vitamin C	10 samples

5. Analytical Methods

Stability of Vitamin C During Frozen Storage

Stability of vitamin C during frozen storage was determined because samples taken at production and sent to frozen storage at -20° C in Kansas City and in Lancaster Laboratories were to be analyzed only if the marked bag were found and sampled at the recipient site. The stability of vitamin C during such storage was checked by re-testing a number of samples after they had been kept frozen for 6 to 9 months.

The vitamin C content in CSB and WSB before and after frozen storage is shown in Appendix F, Table F-1. These data were log-transformed in order to obtain the following results on a percent retention basis. They showed no significant loss in vitamin C due to frozen storage.

Product	Retention Mean	95% Confidence Interval
CSB	95.6%	89.1% to 102.7%
WSB	103.4%	96.5% to 110.7%

Analytical Testing of Vitamins

The samples from the production runs of WSB and CSB were sent by overnight package delivery to Lancaster Laboratories in Lancaster, Pennsylvania, for immediate testing of vitamin C (ascorbic acid).

Vitamin C was tested by the fluorescent method, Association of Official Analytical Chemists (AOAC) 15th Ed. 967.22. This procedure is applicable to foods and feeds. It measures both reduced vitamin C (ascorbic acid) and the oxidized form (dehydroascorbic acid), both of which are antiscorbutic. The procedure does not measure the hydrolyzed form, 2,3-diketoguiortic acid, which does not have vitamin C activity. The procedure involves oxidizing ascorbic acid to dehydroascorbic acid in the presence of charcoal. The oxidized form reacts with 0-phenylenediamine to produce a fluorophor whose fluorescent intensity is proportional to the concentration. A blank is formed by adding dehydroascorbic acid to boric acid to form a quinoxaline prior to the addition of the diamine solution. Any remaining fluorescence is due to extraneous materials. A spike was run with every set of samples. The average spike recovery on a variety of matrices is 96.2%. The detection limit on this procedure is 1 mg/100g. A NIST (National Institute of Standards and Technology) dry infant cereal reference standard (AOAC, 1986, 1990) was run with each set. If the standard fell outside of a 108–121 mg/100g range, the results were not used and the set was repeated.

Niacin was analyzed by the American Association of Cereal Chemists approved method 86-52: Niacin Automated Determination. This method is an automated version of the colorimetric procedure in which an autoclaved calcium hydroxide extraction of a cereal product is acidified and reacted with cyanogen bromide to produce a blue color proportional to the amount of niacin present. The reading is adjusted for natural color by running a blank

with no cyanogen bromide. An AACC flour reference standard was run with each set. If the standard fell outside of a 22–27 mg/100g range, the results were not used and the set was repeated.

The same analytical methods were used on the prepared food samples as were used on the dry samples except for moisture content, which was measured by vacuum oven.

For the dry samples, moisture was tested by a standard loss of weight in oven drying. The laboratory ran the NIST dry infant cereal reference standard containing a certified level of vitamin C with each sample set. The whole run was repeated if the assay on the standard was outside of the acceptable range. For the cooked samples, moisture was tested by a standard loss of weight during vacuum oven drying. Samples high in sugars were dried at 70°C for 16 hours. Samples high in volatile oils were dried at 100°C for 5 hours. In all cases the samples were dried under pressure less than or equal to 100 mm Hg. The limit of detection is 0.01%.

Water activity (a_w) is a water energy measurement. Water activity is an indication of “free” water in a sample available for microbial growth, as well as enzyme and vitamin activity. “Free” refers to the water particles in a product that are not chemically or physically bound.

A representative sample was placed in the Atwater instrument and the a_w or equilibrium humidity (ERH) was measured as a ratio of water vapor pressure above the sample to the water vapor of pure water at the same temperature. Products with no “free” water have an a_w of 0.000; pure water has an a_w of 1.000 (Aqualab Model CX-2 Water Activity Measurement, Operator’s Manual).

Statistical Analysis

Data Obtained From Production of P.L. 480 Commodities

A commercial statistical software program was used to analyze data collected on production samples. This program calculates upper and lower control limits and a number of descriptive statistics useful in analyzing production data. It generates a control chart that can be examined to determine if the production is in control using a number of different rules or parameters. It also calculates the production capability index (C_p).

Data Collected From the Field

A statistical software program was used to determine how many samples needed to be taken from the field in order to detect a 20% decrease in vitamin C, as well as to determine what difference could be detected using the same number of samples as was collected from the production line. The program uses confidence limits, power estimations, standard deviations, and means in these calculations.

A number of different statistical methods were used to compare the data collected from the field to that from production in order to determine the percentage drop in vitamin C content. First, all data must fit a normal distribution. If so, a simple two-sample t-test can be used to

determine if there is a significant difference between the two sets of samples. If the data is not normal, steps can be taken to transform it to usable forms, or other statistical methods can be applied that do not require normal distribution. The data was then subjected to an analysis of variance test to determine the confidence intervals.

B. Results and Discussion

1. Uniformity of Vitamin C in the Commodities at Plant Sites

Description of Sampled CSB and WSB Processing Plants

As mentioned earlier, after the initial sampling of CSB showed poor uniformity of product, it was the consensus between USAID and the SUSTAIN Vitamin C Advisory Panel that each of the seven CSB/WSB plants that are being awarded production contracts should be sampled to assess the extent of the uniformity problem. Four of the six U.S. plants producing CSB and one of the two plants producing WSB were sampled using the procedures described above. Production at the five plants is summarized below and diagrams are provided to show how product is produced at each plant (Appendix G). There were no unusual temperature or weather conditions during any of the sampling periods. All of the plant personnel and FGIS inspectors were highly cooperative with SUSTAIN during sampling the products.

Plant A

This plant produces corn soy blend and corn meal. The vitamins and minerals were added by two small feeders within view of the person running the packer. One feeder fed the mineral premix and one fed the vitamin premix. A commercial vitamin premix from ADM Paniplus (item 113571) or Watson Enrichment Products (Type WT-2710B for the high vitamin C contract) was used.

The fortified product ran through a short mixer and then was blown out to the packing room. An auger carried the product from the bottom of a cyclone separator to the holding bin over the packer. A switch on this bin would automatically shut down the whole system, including the nutrient feeders, if this holding bin got too full. The system would also shut down automatically if the corn or soy ran out. The person running the bagger could shut down the system if packaging problems developed, if he went on a break, or when shifts changed. The plant ran two shifts; the first one started at 6:00 a.m. The second shift began work at 2:30 p.m.

Bags were filled, heat sealed, and conveyed to the railcars, where they were stacked by hand. It took three to four hours to fill a railcar with 2,500 bags. A lot was two railcars, or 135 MT. The lot number stamped on each bag was a simple sequential number: 1, 2, 3, etc. Sample numbers were written on approximately 140 bags, half from the production runs with the conventional level of vitamin C and half from the production run with the high level of vitamin C.

Plant B

This is a large flour mill that produces WSB on a dedicated batch system. The ground bulgur, soy flour, and wheat protein concentrate used to make up this product are kept in separate bins. The mixer operator used a load cell scale to weigh each ingredient sequentially into one of two ribbon blenders. Oil, a scoop of vitamin premix (the scoop was calibrated to provide one pound of ADM Paniplus vitamin premix), and a bag of mineral premix (from Roland Industries in 56 lb bags) were added, resulting in a total mixing weight of 2,005 lbs. This was then mixed three to four minutes and sent pneumatically to a 20,000 lb holding bin. From there it was packed out on a single line operating on only one shift. The lot number stamped on each bag was a simple sequential number: 1, 2, 3, etc. Sample numbers were written on approximately 65 bags for each vitamin C level (high and conventional).

Plant C

This grain processing plant produces CSB and exports corn meal products for the P.L. 480 program on the same continuous blending system specifically designed for the product CSB. Other degerminated corn meals manufactured at this location are sold commercially in the United States.

All dry ingredients are monitored and metered into a continuous blending system that utilizes a large diameter extended mixing conveyor. Three screw-type micro-ingredient feeders with large capacity hoppers meter the vitamin premix, salt/mineral premix, and the tricalcium phosphate into the mixing conveyor at the same time with the precooked corn meal and soy flour ingredients for blending. The refined soy oil with the antioxidants is atomized into the conveyor following the addition of these dry ingredients. The blending system is designed with an interlocking scheme of equipment, so if any of the ingredient feeders stop, the blending system will automatically shut down.

An industrial programmable logic controller (PLC) computer operates this continuous blending system. A primary scale controls the addition of the precooked corn meal or regular corn meal, which is set within a desired range. The secondary scales and feeders for the remaining ingredients are automatically adjusted by the load on the primary scale. Random rate checks are taken during the blending operation for all ingredients to confirm the addition rates versus the scale readings and product specifications.

The product is transferred pneumatically from the end of the mixing conveyor up several floors to a screw conveyor that transfers the blended product into six storage bins. A panel located on the packing floor controls the discharge feeders from these bins. Two bins are operated at the same time and the product is conveyed pneumatically to a holding bin located above the packing stations.

The holding bin above the packers remains filled by an electronic control mechanism that signals the feeders to stop and start to maintain a desired level. There are two packing lines that transfer bagged product to separate railcars. One side of the holding bin will feed line A;

the other side feeds line B. About 60% of the daily volume packed out is blended in advance of packing. The balance is blended the same day.

There are normally 2,722 bags per railcar and two cars per lot, or a total of 136.4 MT per lot. Plant C normally packs out two lots per day. Each bag is printed with a lot number followed by a consecutive bag number from 1 to 2,722. The packing line, lot number, and bag numbers were recorded by SUSTAIN for each sample taken. No special markings were placed on the bags sampled by SUSTAIN. Samples of CSB and corn meal were taken during two consecutive weeks of sampling.

Plant D

This is a large corn mill that produces corn soy blend, corn meal, and masa flour for PL 480. They also produce a number of commercial products. This plant works continuously 24 hours a day. Most of the CSB is packed out on line A from 8 a.m. to 5 p.m., but some CSB is packed out on line B during other times of the day. The lot number stamped on each bag is a simple three digit number: 907, 908, 909, etc.

The vitamin and mineral premixes are metered through W&T™ screw-type feeders onto the ground extruded corn in a screw conveyor. The corn is then dropped into a "drag belt" device in which the soy flour and tricalcium phosphate is added. From there, just after the oil is added the product drops down into an intensive mixer. The product is then blown up to a holding bin from which it is packed out. The plant has the ability to check weight and adjust the vitamin and mineral premixes, the TCP, the soy/TCP, and the oil.

Plant E

This is a small, privately owned plant producing mainly CSB with a small amount of corn meal. It recently changed management. The previous owners had been suspended from selling product to the government because of alleged discrepancies in fortification practices. The plant started operating in March 1994. It went out of business and was shut down for over a year and started up again during the start of 1997 under new ownership and new management, with new equipment installed to fortify the product with vitamin and minerals.

Each lot is three railcars (either 50-foot cars carrying 2,700 bags or 60-foot cars holding 3,000 bags). One lot can run from 202 MT to 225 MT. A consecutive lot number ("BG" followed by three digits) is printed on each bag: BG028, BG029, BG030, etc.

The pregelatinized corn meal (PCM) rate out of the bin is set using check weight (average of four 15-second weights) run each day. The soy flour rate is adjusted based on final product protein tested every 15 minutes. These two ingredients are blown from outside bins to be mixed with the other ingredients. This plant is unique in how they add the vitamins and minerals. The first batch mixes tricalcium phosphate (one 2,000 lb tote bag), minerals (one 700 lb tote bag of salt mix containing salt, ferrous fumarate, and zinc sulfate), and two 50 lb boxes of vitamin premix (Watson Vital Mix 138 CSB) in a ribbon blender. This mix is blown over to one of three holding bins, on the bottom of which are Merrick™ gravimetric belt

feeders over an auger. They run check weights on each belt feeder. The belt feeders have load cells that show on the monitor of a central controller what each one is delivering.

At the end of the auger, the vitamin/mineral mix is combined with the corn meal, soy flour, and oil and mixed in an intensive continuous mixer. From there the final product is elevated with buckets to the hopper over the packer and packed out.

Analytical Results for Production Samples

The analytical results on samples collected at the plants are summarized in Table 5. Full results for each plant can be found in Appendix H. Control charts for vitamin C (Appendix I), which plot the vitamin C result for each consecutive sample, help to visualize how the nutrient value varied over the production run and how close the results came to meeting the target. (To facilitate understanding of the data, all the graphs were drawn to the same scale. As a consequence, certain data points lie outside of the boundaries of these graphs. The x axis is the sample number with time running from left to right. Actual sampling times and sample numbers are not shown due to lack of space. The Upper Control Limit (UCL) is the mean plus three standard deviations and the Lower Control Limit (LCL) is the mean minus three standard deviations.)

Appendix J shows the histograms for vitamin C. These histograms were produced with commercial statistical quality control software. They show the distribution of the vitamin C contents in relation to the specifications and control limits. Additional descriptive statistics showing the skewness and kurtosis (flatness) of the distribution can be found on each histogram.

The ten blind duplicates taken at each production run allow calculation of the proportion of the variability due to analytical error, the remainder being due to production, as shown in Table 5. In CSB the analytical variability generally accounted for less than 30% of the total variability in Vitamin C. In WSB, variability was nearly equally split between production variability and analytical variability.

The summary Table 5 can be used to evaluate how well each plant did in fortifying the product with vitamin C. The minimum and maximum levels shown are based roughly on ones proposed to USAID for a future production of special CSB with conventional and high levels of vitamin C, as given in a letter to the USAID Food for Peace Program (Appendix K). These levels, based on suggestions from Plant C personnel, are rather tight in light of the results. They are used here only to be able to calculate the values in Table 5 and are not intended to represent real or suggested specifications.

Table 5. Summary of Vitamin C Results From Production Plants

Plant	A	A	B**	B**	C	D	E
Target (mg/100g)	40	90	40	90	40	40	40
Number of samples	43	56	42	48	47	48	47

Plant	A	A	B**	B**	C	D	E
Number of outliers removed	1	1	0	0	0	0	1
Minimum (mg/100g)	1	1	32	58	25	7	31
Maximum (mg/100g)	72	220	53	100	52	39	61
Average content (mg/100g)	27.0	81.1	42.7	76.2	37.0	27.4	43.2
Mean as percent of target	82	95	107	85	93	69	110
Uniformity							
Standard Deviation (mg/100g)	16.4	45.2	4.7	10.7	7.4	6.8	7.4
Coefficient of Variation (%)	61	56	11	14	17	25	17
Lower Control Limit (mg/100g)	0	0	29	44	18	7	18
Upper Control Limit (mg/100g)	160	248	57	108	56	48	70
Variability							
Due to production (%)	97.4	81.5	48.1	53.6	93.4	69.8	72.0
Due to analysis (%)	2.6	18.5	51.9	46.4	6.6	30.2	28.0
Process Capability							
Minimum level* (mg/100g)	24	54	24	54	24	24	24
Maximum level* (mg/100g)	56	126	56	126	56	56	56
Process capability (Cp)	0.32	0.27	1.12	1.11	0.83	0.78	0.72
Process capability index (Cpk)	-1.30	-0.82	0.47	0.51	0.73	0.50	0.61
Percent falling below minimum (%)	43	27	0	2	2	31	1
Percent falling above maximum (%)	4	16	0	0	0	0	4
Percent outside specifications (%)	47	43	0	2	2	31	5

* Proposed specification for a special pilot CSB production (not currently in effect).

** WSB samples.

The process capability (Cp) is the ratio of the UCL–LCL to the maximum–minimum specification. Ideally, the Cp should be above 1.0, meaning that specified range could be achieved 99% of the time. For low Cps, as in these cases, the Cpk is more meaningful. The Cpk is the minimum distance between a specification (upper or lower) and the production

mean, relative to the range in the data from the mean to either extreme. The Cpk is a truer index of how well the plant did in meeting specifications because it eliminates the bias of being high or low. Again, a value above 1.0 is good. Also calculated is the percentage of the production that would be expected to fall below the minimum specification and above the maximum specification, assuming a normal distribution. All of these calculations are based on hypothetical specifications. These product specifications need to be determined. Product specifications should be based on the needs of the consumer, not the capability of the production plants.

As might be expected, the batch process used by Plant B to produce WSB showed the least variation or best uniformity in vitamin C. They were on target with the conventional vitamin C level and a bit low with the high vitamin C. Plant C was the best of the continuous CSB producers followed closely by Plant E. Plant D had problems in meeting the vitamin C target, running 31% below the target level. Their problem may be primarily due to an incorrect feeder adjustment. The nutrient feeders at Plant D were old and worn and may not have been able to hold their calibration or deliver a consistent rate of product. The equipment for metering nutrients at Plants C and E were newer, well maintained, and correctly calibrated. Plant A, as previously discussed, had large variation in the vitamin C levels at both the conventional and high levels of added vitamin C.

Analytical Results for Vitamin Premix Samples

Samples of the vitamin premix used each day during production were taken directly from the vitamin feeder. This sample was tested for vitamin C and niacin by the quality control laboratories at two premix manufacturers (Watson Foods and American Ingredients) that routinely do this type of assay using high pressure liquid chromatography. The samples were identified only with a number, so the laboratory did not know whose products they were. In general, the assays on these premixes, given in Appendix C, Table C-3, showed that their nutrient content is close to the target. One sample of the vitamin/mineral blend used at Plant E was tested. The results of that were very close to target as well.

2. Stability of Vitamin C from Manufacture to Points of Distribution

The analytical results on the WSB samples collected in Haiti (Appendix H, Table H-2) and on the CSB samples collected in India are shown in Appendix L. This stability component of the study does not include data from Tanzania because the CSB pilot production run sent to Tanzania did not contain sufficiently uniform distribution of vitamin C to allow for an efficient test of stability.

Comparison of Mean Levels

The stability of vitamin C can be determined by comparing the mean vitamin C content in the set of samples collected at production to the mean vitamin C content of the same lot collected at the recipient location. This method turned out not to be possible with the CSB produced at

Plant A because the high variation made comparison of means statistically impractical. It can be used on the samples from Haiti and India, whose results are shown in Table 6. The 95% confidence interval on the difference between the two means is shown in the table. The change can be considered statistically significant if the interval does not encompass zero.

Table 6. Retention of Vitamin C in Dry Commodities

Commodity	WSB	WSB	CSB
Produced at plant	B	B	C
Recipient country	Haiti	Haiti	India
Level of Vitamin C added	Conventional	High	Conventional
Mean at production for lots AA and AB only (mg/100g)	42.7	76.2	38.4
Mean at recipient site (mg/100g)	37.1	79.7	39.4
Retention (%)	87.0	104.6	102.7
95% Confidence interval on difference (mg/100g)	4.1 to 7.0	-7.4 to 0.5	-13.6 to 1.6

The WSB with the conventional level of added vitamin C that was sent to Haiti showed a small but significant loss of vitamin C ($P < .01$). The retained vitamin C was over 80%, so the loss may not be considered a problem serious enough to look for solutions. The WSB with the high level of added vitamin C showed a small gain, but it was not significant at the 5% level when measured by the Student's t-test; also, the 95% confidence interval did not encompass zero.

The samples of CSB collected in India, which contained conventional levels of vitamin C, came mainly from two lots (AA and AB) produced on the same day. The mean vitamin C in those samples compared to the production mean of the same two lots showed a very slight gain that is not significant.

Comparison of Paired Samples in Specially Marked Bags

Of the labeled CSB product analyzed at production, only two bags were located in Tanzania and only one was located in India, making any comparison of paired samples for those two countries not meaningful. In Haiti, however, SUSTAIN collected 27 of the numbered bags with conventional vitamin C and 32 with high vitamin C. These results show a vitamin C retention of 87.6% in the conventional vitamin C samples and a retention of 105.4% in the high vitamin C samples (Appendix L, Table L-1). These values were very similar to those obtained by the first method, which is not surprising, as they were based on many of the same samples.

Vitamin C to Niacin Ratio

This method has a number of limitations. It is based on the following assumptions: (1) that there is a known and constant ratio between the two vitamins during production, (2) that there is no differential segregation of vitamins during handling and sampling, and (3) that no niacin is lost during storage. Some of these assumptions may not be true. Other limitations are that it requires knowledge of the natural niacin content of the product and the ratio being affected by error from two different analytical tests, vitamin C and niacin. As such, it was intended to be used only as a last resort if the other two methods failed because of inadequate data. SUSTAIN considers that the vitamin C contents of samples collected in the field are more reliable than the vitamin C niacin ratio. Therefore, this method was not used.

3. Within Bag Variability of Delivered Commodities

Within bag variation after shipping and handling was determined by sampling from bags of CSB in Tanzania and WSB in Haiti at three different positions on the bag: the top third of the bag (position “a”), the middle third (position “b”), and the bottom third (position “c”) (Appendix M).

There was variation between samples taken from the three bag locations but the variability was consistent throughout the bag, indicating that there was no systematic stratification or concentration of the vitamin within one part of the bag.

4. Vitamin C Retention During Food Preparation

Table 7 presents a summary of the food preparation samples that SUSTAIN collected in Haiti and in Tanzania.

Table 7. Summary of Food Preparation Samples Collected in Selected Countries

WSB in Haiti	Samples	CSB in Tanzania	Samples
High vitamin C	5 gruel 5 dumplings	High vitamin C	7 gruel 4 ugali
Conventional vitamin C	4 dumplings 3 gruel	Conventional vitamin C	9 gruel 1 ugali 1 fried cake

Note: for the special CSB with the higher vitamin C level, rather than one level of 90mg/100g, the CSB used for the food preparation had four levels of fortification (68, 93, 140, and 160 mg/100g) that were not known before the food preparation sampling in the field. The unexpected large variation in the levels of fortification indicated a possible problem with fortification at the plants (see the “Determination of Uniformity” section). It also gave

SUSTAIN the opportunity to determine the effects of different concentrations of vitamin C upon vitamin C retention in CSB after it was cooked in the field.

Cooking Methods

All preparations were cooked in an aluminum pot over charcoal or wood fire. All dishes had a pH of 6, with two exceptions where the pH was 7.

Haiti

a) Gruel (called “bouillie” in Creole)

The main ingredients were WSB, water, salt, and sugar. Other ingredients were sometimes used: condensed can milk, fresh cow milk, fresh coconut milk, mashed banana, vanilla, cinnamon, lemon peel, anise.

Part of the liquid (water and/or fresh cow milk and/or coconut milk) was placed into an aluminum pot and brought to boil, often with condiments (salt, cinnamon, anise, lemon peel, etc.). Meanwhile, the rest of the water was put in a bowl with the WSB (sometimes after passing the WSB through a sieve) to form a slurry. The slurry was then added to the boiling water and brought to a boil. Sugar, sometimes with other ingredients such as condensed milk and mashed banana, was added and the mixture was brought again back to a boil. The vanilla was added last. The gruel was ready after boiling another 1 to 3 minutes.

The average total cooking time for WSB gruel was 19 minutes (STD = 5, n = 8). On average, the WSB spent 9 minutes (STD = 3, n = 8) in the slurry comprised of WSB and water before cooking. This cooking time does not include any time that any other ingredients would have been cooked before WSB was added to the pot.

b) Dumplings (called “bouillon boy” in Creole)

These dough dumplings, made of WSB and shaped like fingers, were dumped into a vegetable broth, sometimes with meat or fish. The main ingredients for the dumplings were WSB, water, and salt. Sometimes wheat flour, oil, and margarine were added to the dough. The ingredients for the broth varied with the availability of the ingredients: water, fresh coconut milk, fresh vegetables, oil and/or margarine, plantain bananas, spinach, carrots, leeks, onion, tomato paste, potatoes, parsley, ground herring or pork, lemon, garlic, salt, pepper, thyme, bouillon cubes, MSG, watercress, and other green leaf vegetables not found in the United States.

The broth was prepared with the ingredients above. Usually the vegetables were added to the oil and/or margarine, then water and/or coconut milk were added. If meat was used, it was first rubbed with small lemons, and then cooked in the oil and margarine, then the vegetables and the liquid were added. While the broth was brought to a boil, the WSB was passed through a sieve. Sometimes, wheat flour was mixed with the WSB. Salt water was added to the WSB flour to form a dough which was often then worked by hand. Sometimes margarine

and oil were also added to the dough. The dough was shaped into finger-sized dumplings (the size varied according to the mother preference). These fingers were then dumped into the broth and cooked for several minutes.

The average total cooking time for WSB dumplings was 18 minutes (STD = 6, n = 9). On average, the WSB spent 10 minutes (STD = 3, n = 9) in the dumpling dough comprised of WSB and water before cooking. This cooking time does not include any time that any other ingredients would have been cooked before WSB was added to the pot.

Note that for the sampling of this dish, the dumplings and vegetable broth were added together in one pot. However, the dumplings were collected as samples without vegetable or broth.

Tanzania

a) Gruel

The ingredients were CSB and water only. (Of 16 gruel samples, only three included sugar. The refugees did not receive sugar, but could buy it if they had sufficient funds. No other ingredients were available to add to the gruel, except in special therapeutic feeding programs, in which vegetable oil and sugar were added.)

Gruel is the most common CSB food preparation. The CSB was mixed with a portion of cold water to form a slurry while the rest of the water was brought to a boil. The slurry was then added to the boiling water and stirred. The mixture was brought again to a boil and allowed to simmer for a few minutes. Several mothers prepared the porridge by mixing the CSB directly with the entire amount of cold water. The mixture was then brought to a boil and allowed to simmer for a few minutes.

The average total cooking time for CSB gruel was 12 minutes (STD = 6, n = 15). On average, the CSB spent 4 minutes (STD = 3, n = 10) in the slurry comprised of CSB and water before cooking. This cooking time does not include any time that any other ingredients would have been cooked before CSB was added to the pot.

b) Ugali

Ugali is a stiff paste comprised of CSB and water that accompanies another dish called “sauce.” The sauce is usually prepared with beans and vegetables such as tomatoes, onions, and cabbage. To make ugali, a small amount of water was brought to a boil. A portion of this water was removed just before it reached the boiling point and mixed with the CSB in another bowl into a thick dough. This dough was added to the boiling water and stirred for a few minutes to form a dry, thick paste. The average total cooking time for CSB ugali was 5 minutes (STD = 1, n = 5).

c) Soup

The soup was prepared in the same manner as the porridge except that the tomatoes and onions were first sautéed in oil. Water was added and the mixture was brought to boil. A slurry of CSB was added to the boiling liquid and let to simmer. In the statistical analysis, this soup sample was treated like the gruel samples because of the cooking similarities.

d) Fried Cake

Fried cakes were not prepared regularly by the refugees. The ingredients used to prepare fried cakes were CSB, vegetable oil, and water. The CSB was mixed with cold water to form a thick dough while the oil was heated. The CSB dough was shaped into small flat cakes and fried in hot oil for five minutes.

India

In addition, CSB food preparations were documented in Southern India from a CSB procurement with conventional level of vitamin C.

a) Gruel

The gruel recipe was the same in India as in the refugee camps in Tanzania.

b) Steamed CSB

Ingredients were CSB, water, carrots, and coconuts. CSB was combined with a small amount of water to form a dough. Carrots were chopped and added to the dough, which was then put into a small steamer layered with chopped coconut. It was steamed for 10 minutes.

Theoretical CSB/WSB Ration Size Observed in the Field

In Haiti, ADRA calculated the WSB ration size as follows: a family receives a total of four rations of 30 g/day: one food ration for the malnourished child, two rations for his/her siblings, and one ration for the mother. In many cases, the family size was larger, and more than four people were fed with the WSB. As a result, 30 g of WSB is probably not the actual ration size consumed by the beneficiary. SUSTAIN measured several servings of gruel and dumplings from six families, and from this data the serving size for a child is estimated to be, on average, 150 g of cooked gruel and 40 g of cooked dumplings (not including the broth).

In the refugee camps in Tanzania, WFP calculated the ration size as follows: number of persons per household x 7 days a week x 30 g of CSB per day. For example, for a 4-member household, the ration is 4 people x 7 days x 30 g = 840 g of CSB/week.

Vitamin C Content in Food Preparation

Food preparation study data is found in Appendix N. These data include the vitamin C and moisture contents of the WSB/CSB before and after cooking, the cooking times, the time that WSB/CSB spent in water before cooking, and the percentages of vitamin retention after cooking.

Gruel is the most commonly prepared food observed for both CSB and WSB, accounting for 24 out of the 39 samples collected. On average, 14 grams of CSB or WSB are used per 100g of liquid to prepare gruel (Appendix N, Table N-3). Table 8 summarizes the vitamin C content measured in the cooked food samples.

Table 8. Summary of Vitamin C Content of the WSB and CSB After Cooking

Commodity	Preparation Type	Vitamin C Level	Vitamin C in Cooked Food (average in mg/100g)	Serving Size Estimate	Vitamin C Content Estimate per Serving
WSB	gruel	conventional	2 mg/100g of gruel	150 g	3 mg/serving
	gruel	high	6 mg/100g of gruel	150 g	9 mg/serving
	dumplings	conventional	3 mg/100g of dumplings	40 g	1.2 mg/serving
	dumplings	high	12 mg/100g of dumplings	40 g	4.8 mg/serving
CSB	gruel	conventional	<1 mg/100g of gruel	N/A	N/A
	gruel	high (several levels)	4–16 mg/100g of gruel	N/A	N/A

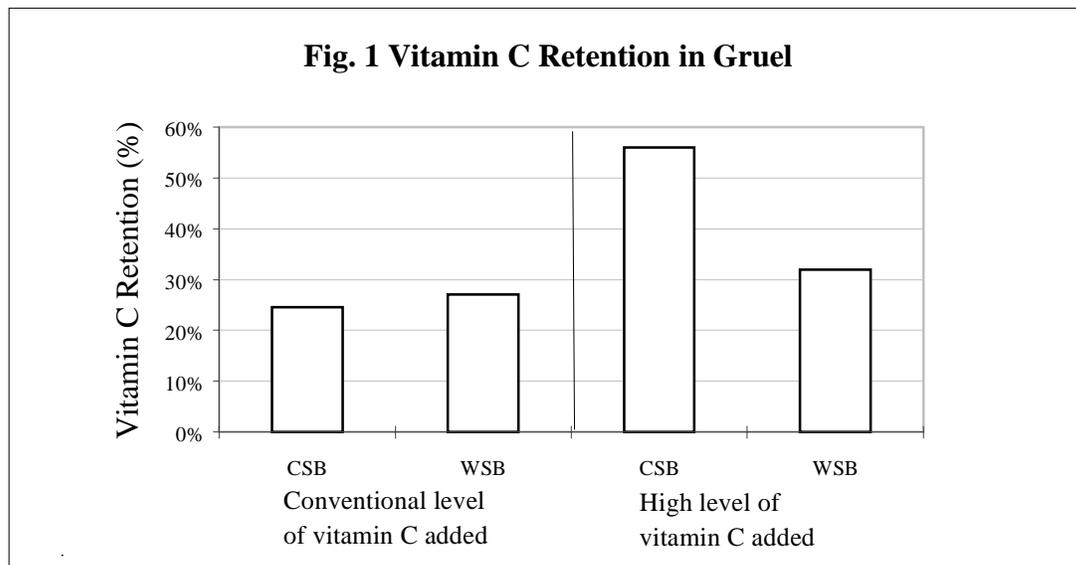
All of the vitamin C in the CSB samples came from the CSB itself: none of the samples contained any other source of vitamin C. (An exception to this is a soup sample included in the gruel analysis; however, after cooking, this sample showed less than 1 mg of vitamin C per 100g of cooked food.) In contrast, the samples of food made from WSB may contain vitamin C from other sources such as milk (in gruel) or vegetables (in dumpling broth). However, preliminary findings in samples of three vegetable broth in which dumplings had been cooked showed less than 1 mg vitamin C/100g.

The retention of vitamin C in the cooked food could then be determined from the ratio, corrected for concentration, of the amount of the vitamin in the cooked product to the amount of vitamin C in the CSB/WSB used to prepare the food. The concentration correction could be done by one of two methods. The first method is based on the weights of all the ingredients used to prepare the food. This method does not account for water lost during cooking. Also, some inaccuracies were caused by using a poor quality scale for half the

samples collected in Tanzania, and by the complexity of the recipes used in Haiti. The second method corrects for dilution on the basis of the analyzed moisture content in the CSB/WSB and the cooked food product. This second method was used to calculate the vitamin retention figures shown. These two different sets of data produced similar estimates of CSB/WSB concentration, as shown in Appendix N, Table N-3.

Figure 1 shows the vitamin C retention in gruel samples after cooking. Retention of vitamin C added at the conventional level was between 17 and 32% in CSB (n = 9) and 27% in WSB gruel samples (n = 3). At the high level of vitamin C, the retention of vitamin C was 44 to 74% for CSB gruel samples (n = 7) and on average 32% for WSB gruel samples (n = 5).

Five out of 9 gruel samples collected made from CSB with the conventional level of vitamin C showed vitamin C contents below the level of detection of 1 mg/100g. Therefore, the percentage of retention cannot be determined for these samples. However, minimum and maximum possible retention for these samples were calculated, using 0 and 1 mg as the lowest and highest possible amounts of vitamin C below the level of detection. Actual retention levels are somewhere in between these two figures. These values for CSB gruel prepared with conventional vitamin C level are included in Figure 1.



In the refugee camps of Tanzania, the next most common food made from CSB was ugali containing 40% CSB. Ugali prepared with CSB containing high levels of vitamin C (n = 4) showed an average vitamin C retention upon cooking of 36 to 74%. Only one sample of ugali prepared with CSB containing a conventional level of vitamin C was collected. This sample showed 51% retention. In Haiti, a dumpling dish prepared with vegetable broth was the second most cooked dish made from WSB. The dumplings contained 80% WSB. Using WSB with a conventional level, the dumplings showed a mean vitamin C retention of 18% (n

= 4), and using WSB with a high level of vitamin C, the dumplings showed a mean vitamin C retention of 33% (n = 5).

These results showed large losses of vitamin C in both CSB and WSB during the food preparation observed for these commodities. The magnitude of this loss is concentration dependent for CSB: the higher the level of the vitamin in the dry commodity before cooking, the greater the retention. This finding was not unexpected.

The food industry is well aware that vitamin C does not survive most cooking processes and therefore does not add it to foods that need to be cooked. This loss of vitamin C occurs during cooking because of oxidation: in the presence of water, vitamin C reacts with oxygen and other oxidizing substances in the food. Heat and enzymes probably accelerate these reactions. In the process, some of the vitamin C is destroyed. CSB and WSB containing low levels (below 24 mg/100g) of vitamin C lose nearly all of the vitamin C during cooking. Conversely, the higher vitamin C levels allow cooked food to retain some vitamin C at the time of consumption.

Statistical analysis of the data on the prepared food samples can be found in Appendix N.

5. Analysis of Vitamin C Cost

Conventional Fortification

CSB and WSB do not naturally contain vitamin C, so the vitamin level in the product reflects only what is added. The premix specifications for conventional CSB and WSB call for the addition of 364 grams of vitamin C per ton (2,000 lbs) of product (Table C-1, Appendix C). That translates to 40.1 mg/100g added vitamin C, which is normally reported rounded off to 40 mg/100g.

USDA specifications require a form of vitamin C with an ethyl cellulose (EC) coating, which, among other things, protects the ascorbic acid from oxidation. While the thickness of the EC coating is not specified, the product normally used contains 97.5 percent vitamin C and 2.5 percent EC. Therefore, to meet the vitamin C requirement of 40.1 mg/100g, the conventional CSB and WSB must have 41.1 mg/100g (0.411 kg per MT) of coated vitamin C added.

Like with other commodities, the cost of EC-coated vitamin C fluctuates. The 1996 list price from a large manufacturer was \$15.00/kg, but this recently dropped to a list price of \$9.00/kg. Using this recent figure, the base ingredient cost of conventional vitamin C is:

Amount added per MT (in kg)	0.411
Cost per kg	<u>x \$9.00</u>
Cost per MT (\$U.S.)	\$3.69

The “real” cost of the vitamin C fortification is somewhat higher, as the calculation above does not include the costs of producing and analyzing the vitamin premix, of which vitamin C is just one component. It also does not include the premix manufacturer’s profit.

In fiscal year 1996, USDA purchased 249,610 MT of CSB and WSB for USAID. Using the calculation above, the total cost of CSB and WSB with conventional vitamin C fortification was:

Vitamin C cost per MT	\$3.69
MT purchased in 1996	<u>x 249,610</u>
Total cost (\$U.S.)	\$921,061

High Fortification

Note: During the pilot commodity production, high-level vitamin C products were made from “scratch”—the vitamin premix was added to “raw” (i.e. non-fortified) CSB and WSB. This cost analysis, however, focuses on the *difference* between the conventional and high fortification levels, and assumes that more vitamin C would be added to the conventional product to make the high fortification product.

The proposed higher level of vitamin C (90 mg/100g) requires the addition of 50 mg/100g more vitamin C to the conventional product. Therefore, to account for the EC coating, the conventional CSB and WSB must have 51.3 mg/100g (0.513 kg per MT) vitamin C added to meet the proposed specification of 90 mg/100g. The added raw material cost for the higher level of vitamin C fortification is:

Amount added per MT (in kg)	0.513
Cost per kg	<u>x \$9.00</u>
Additional cost per MT (\$U.S.)	\$4.62

Again, this number does not reflect the real cost of higher vitamin C fortification. The higher level of vitamin C must be put into a more dilute premix with a higher addition rate (see the vitamin premix formulation in Appendix A). This increases packaging, shipping, and labor costs to vitamin premix manufacturers. John Watson of Watson Foods, Inc., the largest supplier of vitamin premixes for CSB and WSB, estimated that increasing the premix vitamin C level to 90 mg/100g would cost \$6.33/MT of CSB or WSB. Another premix manufacturer estimated this cost and calculated a similar figure.

The difference between the additional raw material cost (\$4.62/MT) and the manufacturer’s estimated real cost (\$6.33/MT) reflects the additional expenses of manufacturing, storing, and transporting this more dilute product, which requires 50 percent more premix for every MT of CSB or WSB fortified. It also includes profit for the premix manufacturer. There are no other costs to the manufacturer (e.g., for new or different equipment) to produce the high-level vitamin C premix.

In fiscal year 1996 USDA purchased 249,610 MT of CSB and WSB for USAID. Using the calculation above, the estimated additional cost of high-level vitamin C for that annual procurement is:

Additional vitamin C cost per MT	\$6.33
----------------------------------	--------

MT purchased in 1996	<u>x 249,610</u>
Additional cost (\$U.S.)	\$1,580,031

Like all commodity prices in an open market, the cost of EC-coated vitamin C fluctuates in response to supply and demand. The current base price for EC-coated vitamin C is at an all-time low, ranging from \$5.00/kg to \$7.00/kg. In 1995, the actual prices paid for ascorbic acid by a large vitamin premix manufacturer ranged from \$13.40/kg to \$15.75/kg. The current low price is attributed to a new supply of ascorbic acid from China, where it is produced in large quantities with new plants. By offering the commodity at low prices, manufacturers in China are hoping to capture a large portion of the world market. Once the situation stabilizes, the price of ascorbic acid and, as a result, the price of the EC coated vitamin C may increase. There is no way to accurately predict future ascorbic acid prices.

V. ADDITIONAL INFORMATION REQUESTED BY THE COMMITTEE ON INTERNATIONAL NUTRITION

This section of the report includes the information requested by the Committee on International Nutrition. Additional cost information can be found in the “Results of the Vitamin C Pilot Program” main report.

The text in italics below is cited from “Vitamin C in Food Aid Commodities: Initial Review of a Pilot Program” (Committee on International Nutrition, Institute of Medicine. 1996. Washington D.C.: National Academy Press, pp. 16–17).

Committee on International Nutrition (CIN): To address cost effectiveness and the advisability of increasing the level of vitamin C fortification in CSB and WSB, the committee will need to examine information on the vitamin C content (including variability) of the blends after production, storage, and food preparation. [...]. Therefore, the committee requests the following additional information in order to analyze cost-effectiveness and to have adequate data on which to base a judgment about the advisability of increasing the vitamin C content of CSB and WSB. [...].

1. Information on the worldwide prevalence of scurvy and of insufficient vitamin C and iron intakes in the two types of populations that are recipients of CSB and WSB: (1) refugees in camps, and (2) targeted beneficiary households in Title II development programs.

In addition to protein-energy malnutrition among displaced and refugee populations, micronutrient deficiencies play a key role in nutrition-related morbidity and mortality (CDC, 1992). Scurvy outbreaks have been documented in refugee populations during the past decade in addition to deficiencies of vitamin A and iron, conditions known to be important childhood problems in developing countries (CDC, 1992; WHO, 1993). “In Central America and South and South-east Asia, refugees generally either receive adequate diets or are able to find ones through trade, cultivation, or from other income” (Seaman et al., 1989). This is not the case in parts of Africa, where more than 100,000 cases of scurvy occurred among different East African refugee populations in the late 1970s and in the 1980s (Desenclos, 1989). Notably, no outbreaks have been reported from West or Southern African refugee situations that are widespread in areas including Liberia, Sierra Leone, the Great Lakes Region of Central Africa, and Angola.

Recommended dietary levels for refugees include 30 mg of vitamin C per day and 22 mg of iron per day (Toole, 1994). A typical daily refugee ration in Africa is made up of 400–500 g of cereal, 30–40 g of beans or lentils and 10–20 g of oil, and rarely dried skimmed milk (Henry and Seaman, 1992). This general food basket provides less than 6–10 mg/day of vitamin C (CDC, 1989; Desenclos, 1987, 1989; Refugee Health Unit, NW, 1985; WHO,

1989). In addition, the rations are estimated to supply on average 15.5 mg iron/day (Toole, 1994).

Until 1994, fortified cereal blends were occasionally provided in the general ration because these blends were normally reserved for targeted supplementary feeding programs (Van Nieuwenhuyse, 1997). They were about twice as expensive as the plain milled cereals normally distributed in general rations (UNHCR, 1989). Toole (1992) noted that despite guidelines, fortification levels of donor cereal rations lacked standardization and periodic shortages regularly took place. It was only in 1994 that a policy to distribute fortified cereals in the early stage of an emergency situation or to a population totally dependent on food aid was adopted by WFP and UNHCR. In their Memorandum of Understanding, signed in January 1994, UNHCR and WFP stated that “in an attempt to pre-empt any micronutrient deficiency, WFP will provide populations, wholly dependent on food aid, micronutrient fortified blended foods. UNHCR will be responsible for providing complementary food commodities (local fresh foods, condiments, dried skim milk/dried whole milk, high protein biscuits) whenever such are required.” Nevertheless, as Toole (1994) indicated, despite these guidelines, blended foods were not immediately available in several refugee relief operations, such as in the assistance program for Rwandan refugees in eastern Zaire, in July-August 1994. Note that the refugees fled their country in April 1994 but the intervention in Zaire could start only in July–August 1994.

Scurvy and insufficient vitamin C intake

Toole (1994) states that between 10 to 15 mg daily will probably prevent clinical manifestation of scurvy but many authors refer to 6 to 10 mg/day as a minimum requirement (CDC, 1989; Desenclos, 1987, 1989; Refugee Health Unit, NW, 1985; WHO, 1989). On a diet completely lacking in vitamin C, body stores last about 2 months and symptoms of scurvy (gum bleeding and joint bone pain with or without swelling) appear after four months (Desenclos et al., 1989; Magan et al., 1983). This length of time corresponds to the length of time that it took for scurvy to manifest in refugee camps. The scurvy outbreaks in refugee camps will be discussed in section 1.1.

Insufficient iron intake

Iron deficiency anemia occurs worldwide and is probably the most prevalent micronutrient deficiency disease (Toole, 1994). Worldwide, the majority of iron deficiency is the direct result of low dietary iron content (Yip, 1993). Vitamin C deficiency most likely contributes to iron deficiency anemia (Seaman and Rivers, 1989; Toole, 1992; Yip, 1994). In addition, certain food substances inhibit iron absorption: phosphates/phytates in cereal and proteins in legumes (WHO, 1993). Parasitic diseases such as hookworm and schistosomiasis also correspond to a high prevalence of anemia (Toole, 1992; Yip, 1994).

More prominent than scurvy, anemia has been found in some refugee populations (Toole, 1994; Yip, 1994). However, the numbers may be similar to those found in local development

populations (CDC, 1992). Iron deficiency has particularly been identified in many adult women upon arrival in a refugee camp (Toole, 1994).

Reports were cited in 1960 that 38% Somali nomads on a milk diet had deficiency of iron. Similarly, in the 1970's, severe iron deficiency was widespread in Kenyan Somalis (Greenham, 1989). Table 9 outlines this, along with other more recent examples.

Table 9. Reported Cases of Anemia In Refugee Populations

Refugee Population	Survey Date	Hemoglobin Concentration (g/dl)	Prevalence of Anemia	Reference
Kenyan Somalis	1970s	< 8	24%	Greenham, 1989
Northwest Somalia	1987	< 10	44–71% of pregnant women 59–90% of children 9–36 months	CDC, 1992
Ethiopians	1990	N/A	13% of children < 5 years old	CDC, 1992
Palestinians	1990	< 11–12	50–70% for infants and young children 25–50% for women	CDC, 1992; Yip, 1994

According to Yip (1994), the severe anemia observed in 1987 among the Ethiopian refugee population in Northern Somalia was a combination of iron, vitamin C, and possibly folate deficiencies.

In another example, low iron intake was considered the sole cause of anemia, as shown in a survey (in 1990) of Palestinian refugees from Syria, Jordan and the West Bank. This survey showed that the population had adequate general nutrition and no indication of scurvy (CDC, 1992; Yip, 1994).

To address the following two questions, we will focus on information that currently exists on refugees in camps. In 1992, the Centers for Disease Control indicated that scurvy has been rarely reported in stable populations in developing countries (CDC, 1992). Supporting this statement, a recent literature search did not identify cases of scurvy that were attributable to food aid development programs.

1.1 CIN: Comparing situations in which the conventionally fortified food is and is not provided, what is the difference in the prevalence of scurvy?

During the past fifteen years, a dozen surveys have been conducted in four countries in the Horn of Africa by relief organizations including the United Nations High Commissioner for Refugees, Medecins Sans Frontieres, Save the Children Fund and the International Federation

of Red Cross and Red Crescent Societies. All illustrated the plight of refugees developing clinical cases of scurvy (Table 10). As mentioned earlier, it is only in 1994 that a policy to distribute fortified cereals to populations totally dependent on food aid was adopted by WFP and UNHCR. Therefore, when distributed, fortified cereals were not part of the general ration but mainly used in special feeding programs.

Typical clinical indicators of scurvy that were cited include swollen gums with bleeding and swollen and/or painful joints, bones, or muscles of the lower extremities (hip, knee, ankle). (UNHCR, 1989). The prevalence of scurvy found in these surveys ranged from 1% to 44%. Four examples of surveys follow.

Ethiopian Refugees in Somalia, 1982

Magan et al. (1983) reported that more than 2,000 cases of scurvy were detected among Ethiopian refugees in Somalia in the summer of 1982, with 72 cases located in the Gedo sub-regions of Bur Dhubo and Hilomareer. “This major outbreak of scurvy occurred as a result of the problems of providing an adequate diet to a large population of displaced persons, gathered together in camps scattered throughout a large, semi-arid African country with limited local food supplies and poorly developed road and communication systems” (Magan et al., 1983). The population was 80% women, children, and elderly men. This population is pastoral nomads, and their traditional diet consisted of about 20% meat and cereal, and 80% camel's milk (up to 4 liters per day, which supplies sufficient vitamin C). When they became refugees, international donors provided them with a daily ration (listed below) that was adequate in many essential nutrients, but contained almost no vitamin C and very little bioavailable iron (Magan et al., 1983):

- ◆ 300 g cereals (mainly maize and sorghum)
- ◆ 75 g wheat flour
- ◆ 40 g dried skim milk
- ◆ 40 g beans
- ◆ 30 g edible oil

Although the refugees involved in the scurvy outbreak had been in the same camps for as long as 3 years, it was only in early 1982 that the first cases of scurvy were reported. Magan and coworkers (1983) believe that the refugees supplemented their rations with local vitamin C sources, including camel's milk, tomatoes, onions, and sweet potatoes purchased in the local markets until two to three months before the scurvy outbreak. For four camps, the refugees were unable to purchase sufficient amount of foods containing vitamin C because of a local market closure. For the other camps of the region, there is no clear explanation on why the outbreak occurred at that particular time, because the local markets remained open (Magan et al., 1983).

Ethiopian Refugees in Somalia and Sudan, 1984–1987

Desenclos et al. (1989) reviewed data collected from 1985 to 1987 in five refugee camps in Somalia (Table 10: Gannet, Biyoley, Bixin, Tugwajale, Dacawale) and one in Sudan (Wad-Kowli) where scurvy was identified. Scurvy occurred 3 to 10 months after refugees settled in camps; the highest incidences were during and immediately after the dry season. The risk of developing scurvy increased significantly with length of residence at the camp, with age, and among females, particularly pregnant and lactating women (Desenclos et al., 1989).

The food rations (<1400 kcal/day consisting of cereals, legumes, and oil) provided negligible amounts of vitamin C. In the case of the Gannet camp, dry skimmed milk (DSM), usually part of the general ration, was the only commodity containing some vitamin C (30g of DSM provides about 2 mg of vitamin C) but was not available for distribution during the three months prior to the outbreak (Refugee Health Unit, 1985). Refugees enrolled in supplementary feeding programs did not show decreased prevalence of scurvy although they received cooked rations prepared with corn soy milk (CSM) (Desenclos et al., 1989; Refugee Health Unit, 1985). Uncooked CSM contains 12 mg of vitamin C per 30 g.

Somali Refugees in Eastern Ethiopia, 1988–1989

In summer 1988, as many as 400,000 refugees from northern Somalia entered eastern Ethiopia (CDC, 1989). They were settled in several camps, including the Hartisheik camp. Routine nutritional surveys were conducted in the camps by Save the Children (SFK) between September 1988 and May 1989 and showed the severity of malnutrition among this population. In addition, in January 1989, the prevalence of scurvy by clinical examination was shown to be approximately 1%–2%. Delivery of rations (cereal, and occasional lentils and vegetable oil) was intermittent, leaving families with 10-day supplies for 3 or 4 week periods. Logistical difficulties precluded delivering perishable vitamin C containing foods (vegetables and fruit) to such remote regions. No fortified blended foods were distributed (CDC, 1989).

Somali Refugees in Kenya, 1994 and 1996

In 1994, at the time of a scurvy outbreak, Somali refugees in Kenya were receiving fortified blended food: 50 g of CSB/day providing 20 mg of vitamin C (Van Nieuwenhuysse, 1997). It was believed that no vitamin C remained after preparation because the beneficiaries cooked it for over 30 minutes. Purchased camel's milk, garden produce, and wild food were usually the main sources of vitamin C for this population (Van Nieuwenhuysse, 1997).

The scurvy outbreaks in the Dadaab camp appear to be more seasonal rather than related to the distribution of fortified blended food, with initial cases appearing in June and peaking around September (Van Nieuwenhuysse, 1997). This corresponded with lack of fresh food and high camel milk prices. In October 1995, the fortified blended food was withdrawn from the general ration. The absence of fortified cereal did not change the pattern of scurvy occurrence in 1996.

Table 10. Reported Scurvy Outbreaks in the Greater Horn of Africa: Somalia, Sudan, Ethiopia, and Kenya

Country and Location	Survey Date	Prevalence	Sample Size/ Population	Reference
Somalia				
Bur Dhubo, Hilomareer	June 1982	1.5%	72 cases / 20,000 in Gedo region	Magan, 1983
Gedo	1983	NA	NA	Magan, 1983; RHU, 1985
Derbie Xoore I	1984	NA	NA	RHU, 1985
Derbie Xoore II	1985	13%	NA	RHU, 1985
Gannet	Sept. 1985	25.3%	1038 / 30,000	Desenclos, 1989; RHU, 1985
Bixin	Sept. 1985	44%	535 / 35,000	Desenclos, 1989
	July 1987	5.2%	882 / 35,000	Desenclos, 1989
Tugwajale	April 1986	13.6%	1030 / 35,000	Desenclos, 1989
Biyoley	Aug. 1986	42.2%	1029 / 35,000	Desenclos, 1989
	July 1987	18.2%	921 / 35,000	Desenclos, 1989
Dacawale	July 1987	6.9%	966 / 25,000	Desenclos, 1989
Sudan				
Wad-Kowli	April 1985	22%	1016 / 50,000	Desenclos, 1989
Kassala *	1991	15%	N/A	Toole, 1992
Ethiopia				
Hartisheik	Jan. 1989	1–2%	< 1437 cases / 66,000	CDC, 1989
Kenya				
Dadaab	Nov. 1996	700/month	112,000	ACC/SCN, 1996

* Adult males (former Ethiopian soldiers).

Other cases of scurvy, with limited documentation, have been reported. As an example, scurvy occurred in 1994 among Bhutanese refugees in Nepal (Toole, 1994).

Vitamin C Tablets

As part of a solution to control scurvy outbreaks and to prevent further cases of scurvy, vitamin C tablets were sometimes distributed in emergency feeding programs. In most cases, it was reported that distributing vitamin C tablets was not viable, and it was not found to be an effective method for preventing vitamin C deficiency in refugee populations. The reasons for this include:

- ◆ Logistical difficulties to implement the program of tablet distribution (Seaman, 1989; Toole, 1994; UNHCR, 1989). UNHCR (1989) determined that an adequate supply of vitamin C tablets for 300,000 refugees in Eastern Sudan during the outbreak in 1985 would have been as many as three million vitamin C tablets a month. Also counting, packaging, and distributing tablets requires extensive effort (RHU, 1985).
- ◆ Poor compliance (Seaman, 1989; Toole, 1994). This can be due to the unfamiliarity with tablet consumption and suspicion of tablet consumption among traditional populations (non-compliance would render the activity cost-inefficient).
- ◆ Vitamin C tablets would need to be distributed on a weekly basis (UNHCR, 1989). The time required for supplementary distribution may interfere with the time health workers also need to spend on other essential tasks.

1.2 CIN: What are the salient characteristics for targeting those at risk of scurvy in populations in which scurvy has been identified?

General rations containing inadequate vitamin C, combined with a lack of diversity of food sources, have been blamed as the primary factors for outbreaks of scurvy in displaced and famine-affected populations, particularly during the first year of an emergency (CDC, 1992; Moren, 1994; Nieburg, 1992; Toole, 1994; UNHCR, 1989; WHO, 1989). Unfortunately, actual vitamin C intake in refugee camps is difficult to measure, since local food sources and cooking procedures may vary. A further complicating factor is that cigarette smoking is known to increase vitamin C requirements (WHO, 1993).

Scurvy outbreaks appear in the early stage of an emergency or in populations totally dependent on food aid, especially when access to local food is not possible. Refugees often exchange ration foods for fruit and vegetables among other items. “The most telling risk factor is duration of stay in a refugee camp, reflecting the time on rations lacking in vitamin C” (Toole, 1994).

Salient characteristics for targeting those at risk of scurvy include:

- ◆ Displaced and famine-affected populations (CDC, 1992).
- ◆ Dry season and incapability to cultivate (Desenclos, 1989; Henry and Seaman, 1992).
- ◆ Limited local supplies of fresh produce (Magan, 1983).
- ◆ Age (Toole, 1992).
- ◆ Female, particularly pregnant and lactating (Toole, 1992).
- ◆ Difficult access by relief organizations due to war or remoteness (International Federation of Red Cross and Red Crescent Societies, 1996).
- ◆ Lack of acceptance of food sources due to cultural preferences (Mason, 1992; Toole, 1992).
- ◆ Lack of resources (food or monetary) to trade for other food sources (Toole, 1992).

CIN: (Information on scurvy prevalence should be available from the Centers for Disease Control and Prevention, United Nations High Commissioner for Refugees, World Health Organization, CARE (at least for El Salvador and Guatemala), and

others. Secondary data on diet may be available from national or regional surveys, from Title II program evaluations, or other sources. The committee's objective is to obtain data useful for determining whether the populations already targeted to receive Title II commodities are in need and have benefited from the CSB and WSB provided.)

The following resources provided the information reported above:

Billinge Hospital, England
Centers for Disease Control, U.S.
Emory University, U.S.
London School of Hygiene and Tropical Medicine, England
Medecins Sans Frontières, France and Holland
Office of the United Nations High Commissioner for Refugees, Refugee Health Unit,
Somalia and Commission on Refugees, Sudan
OXFAM, UK
Oxford University, England
Program Against Micronutrient Malnutrition, U.S.
Save the Children Fund, UK
UNICEF
United Nations Administrative Committee on Coordination - Subcommittee on Nutrition,
U.S.
World Food Program, Italy
World Health Organization, Croatia and Switzerland

2. *CIN: Estimates of the cost of promising alternatives as the following:*

2.1 *CIN: Improved packaging, handling, and storage of the blended commodities.*

2.1.1 *CIN: Packaging methods to reduce moisture uptake include increasing the thickness of the polyethylene liners of the bags or inclusion of a desiccant in the plastic. Studies of vitamin C degradation in low-moisture foods suggest that water content greater than 10% results in a marked increase in the rate of loss of vitamin C (Bookwalter et al., 1980).*

Alternative Packaging

The Commodity Credit Corporation (CCC) is reported to have begun preliminary evaluations of alternative packaging systems for blended and fortified commodities used under foreign food assistance programs administered by CCC and USAID. This includes bags used for WSB and CSB. The primary objective of the evaluation is to find a bag with greater strength. It is not to find packaging that provides greater stability of micronutrients or to improve the

shelf life of the product, although those factors might be influenced by the new packaging and considered in the final decision.

During the first half of 1997, several proposed alternative constructions will be fabricated and subjected to laboratory evaluations by the Michigan State University School of Packaging. The laboratory evaluations will include shock, tensile and impact strength, puncture propagation and tear resistance testing. The new bag constructions being considered are:

1. A 2.5 mil linear low density polyethylene (LLDPE) film, 1/50-lb ply natural kraft paper, 1/50-lb ply natural kraft paper laminated to 2.5 mil oriented and cross-laminated polyethylene Valeron film.
2. A 2.5 mil Cross plastic XF film, 2/50-lb plies natural kraft.
3. A 2.5 mil LLDPE film, 2/50-lb plies natural kraft paper, 4.0 mil LLDPE film.
4. A 2.5 mil LLDPE film, 3/50-lb plies natural kraft paper.
5. A 2.5 mil LLDPE film, 3/50-lb plies natural kraft paper with a polyethylene coating applied to the inside of the outer paper ply.
6. A 2.5 mil LLDPE film, 4/50-lb plies natural kraft paper.

The above constructions are also being evaluated by commodity suppliers at their plants to determine such issues as filling line-speed, sealability, and equipment/controls modifications that may be needed.

It should be noted that the current bag is not totally airtight: it has a line of small perforations to let air escape. This prevents the bag from tolling or popping the seal when compressed.

The Protein Grain Products International (PGPI) association provided us with information (Appendix P) on possible alternative bags from some of their members who are bag manufacturers. Included is data on the moisture and oxygen permeability of the different constructions. No cost information is available but all of the constructions being evaluated cost more than the present bag.

2.1.2. CIN: Packaging methods to reduce vitamin C oxidation, which include the use of antioxidants or oxygen scavengers.

Use of Antioxidants and Oxygen Scavengers

The antioxidants butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT) are currently being added to CSB and WSB at a rate of 2.2 mg/100g each. The cost of these added antioxidants is approximately \$1.00/MT of CSB/WSB. These compounds or other antioxidants and oxygen scavengers could be included in the polyethylene packaging, but, according to General Mills, this technology is very expensive and not applicable to this type of low cost product.

2.2. *CIN: Cost estimates of increasing the level of vitamin C in only one of the blended commodities, especially the cost associated with the special handling that would be needed to target the highly fortified commodity to high-risk sites.*

Cost to Increase the Current Vitamin C Level in One Commodity Only

The additional costs of adding 50 mg/100g more vitamin C to CSB and WSB to bring the current level of 40 mg/100g up to the higher level of 90 mg/100g, based on FY 1996 (August 1995 to September 1996) call forward figures, are shown in Table 11.

As discussed in the analysis of vitamin C cost section, the \$6.33/MT increase in the cost of commodity figure used in these calculations is based on the current price of vitamin C, which will vary and is currently at an all time low compared to what it has run in the past.

The USDA stated in a letter (Appendix O) that special handling of P.L.480, such as air freighting them to recipient locations, is currently not permitted. This would not appear to be a viable solution to any vitamin activity lost on shipment because the cost, based on normal commercial charges for shipping bulk quantities, would easily exceed \$250/MT.

Table 11. Additional Costs of Adding 50 mg/100g more Vitamin C to CSB/WSB

	Units	CSB	WSB	Total
Quantity purchased	MT	238,300	11,310	249,610
Total cost	\$	\$79,768,542	\$5,184,617	\$84,953,159
Average cost	\$/MT	\$334.74	\$458.41	
Extra Vitamin C cost	\$/MT	\$6.33	\$6.33	
Total cost	\$	\$1,508,439	\$71,592	\$1,580,031

2.3 *CIN: Changing the vitamin premix or the mineral mix:*

2.3.1 *CIN: The use of other forms of stabilized coated vitamin C as an alternative to ethyl-cellulose coating. The 4% ethyl-cellulose water soluble coating, which is used to stabilize the vitamin C because ethyl cellulose coating is likely to be susceptible to moisture uptake.*

Alternative Forms of Vitamin C

There are some new technologies now available that offer possible solutions to the problem of loss of vitamin C during normal food preparation. These have been developed primarily for aquaculture applications, where a more stable form of vitamin C is needed, mainly to better survive extrusion into food pellets.

One technology is the chemically modified forms of ascorbic acid, such as sucrose esters and polyphosphates at the number two carbon position. An example is L-ascorbyl -2-polyphosphate or STAY-C™. BASF informed us they have a new form of vitamin C they will introduce this year that shows excellent heat stability. While these type of compounds are allowed in aquaculture, they are not approved for human consumption and so can not be considered for this application.

A technology that can be used is the various fat and hydroxypropyl cellulose coated forms of vitamin C now on the market. Table 12 lists a number of these showing what they would cost in terms of \$ per MT of CSB or WSB fortified to the current 40 mg/100g. The figures shown are retail prices from the companies involved.

Table 12. Costs of Stabilized Vitamin C Products for CSB/WSB Fortified at 40 mg/100g

Source	Coating	Retail Price (\$/kg)	Vitamin C Content (%)	Cost (\$/kg C)	Cost (\$/MT CSB/WSB)
Roche	EC **	9.00	98	9.23	3.69
Takeda	Fat	10.49	90	11.66	4.66
Balchem	Fat	26.40	70	37.71	15.09
Balchem	Fat	26.40	50	52.80	21.12
Various	None	7.00	100	7.00	2.80
Watson	EC **	8.50	98	8.72	3.49
Watson	HPC	8.50	95	8.95	3.58
Watson	HPC	8.50	90	9.44	3.78
Watson	EC	9.95	80	12.44	4.98
Watson	Fat	11.00	50	22.00	8.80
Watson	Fat	8.10	70	11.57	4.63
Watson	Fat	8.50	90	9.44	3.78

EC = ethyl cellulose

HPC = hydroxypropyl cellulose

** product currently used in CSB and WSB

Some of these products are very attractive from an economic viewpoint, costing little more than the current EC coated product now in use. It is not known how well these coated products protect the vitamin C from destruction during cooking or normal food preparation

methods used for CSB and WSB. Some of the coated forms have been shown by Park et al. to provide protection during baking. This will have to be investigated. Any form of vitamin C that would be more stable during cooking would be expected to be more stable during storage of the dry commodity.

2.3.2 CIN: The use of a thicker (>4%) coating on vitamin C crystals. Increasing the thickness of the coating may improve the stability of the vitamin C (Park et al., 1994).

Thickness of Vitamin C Coating

The 2.5% ethyl cellulose coating on the vitamin C in current use in CSB and WSB helps agglomerate the material but provides little protection, according to Mike Weibel of Watson Foods Co., Inc. The USDA specifications do not specify the thickness of the coating, only that it be stabilized with ethyl cellulose. Vitamin C with a thicker ethyl cellulose coating (20%) is currently available on the market (Table 12, Watson EC 80% vitamin C). But this coating, according to Dr. Weibel, while providing a very good moisture barrier, may give the vitamin C poor bioavailability.

2.3.3. CIN: The use of NaFe-EDTA to replace ferrous fumarate in the commodities, and the feasibility and acceptability of this strategy. This was recommended by the 1990 Technical Review of Vitamin C and Iron Levels in P.L. 480 II Commodities (USAID, 1990). Advantages should include higher iron absorption and reduced oxidation of vitamin C.

Alternative Forms of Iron

It is well known that the presence of iron and copper increases the destruction of vitamin C during cooking. The use of an insoluble form of iron, such as reduced iron or ferric orthophosphate, in place of the more soluble ferrous fumarate now being added might improve vitamin C stability, but these forms of iron are not recommended because of their poor bioavailability. A fat coated ferrous sulfate is commercially available from the Balchem Company. This would have to be tested to see if it does, indeed, improve cooking stability of vitamin C in CSB. The cost of adding the fat coated ferrous sulfate would be an increase of \$3.44 per MT of CSB/WSB. That is the difference between the cost of using the fat coated ferrous sulfate, which is \$5.05/MT of CSB/WSB, minus the current cost of using the ferrous fumarate, which is \$1.61/MT of CSB/WSB. A fat coated ferrous fumarate is also possible but it would cost a couple more dollars more per MT of CSB than the coated ferrous sulfate.

NaFe-EDTA and other chelated iron sources would be expected to be less chemically active and cause fewer problems with vitamin C stability, but this again would have to be tested. The main problem is its high cost, roughly eight times that of ferrous fumarate on an equal

iron basis. Because of its high bioavailability, one could reduce the amount of iron added by a half to a third, which would lower the cost.

Another possibility would be to just add disodium EDTA along with ferrous fumarate or ferrous sulfate. This is known to act much like iron EDTA when used along with a soluble iron salt in a one mole of iron to one mole of EDTA ratio. The EDTA might also help protect the ascorbic acid from loss during cooking, but that would need verification by testing. The amount of EDTA that would need to be added would be 1.84 pounds per ton of CSB/WSB. At a current cost of \$3.85/lb for EDTA (Dow Chemical Co.) that works out to an added cost of \$7.79 per MT of CSB/WSB.

Table 13. Cost of Different Forms of Iron

Iron Sources	Fe (%)	\$/kg*	\$/kg Fe*	\$/MT CSB/WSB **
Fat coated ferrous sulfate	16	5.50	34	5.05
Ferrous fumarate ***	32	3.50	11	1.61
Ferrous sulfate	32	1.50	5	0.69
Na Fe EDTA	13	9.90	76.15	11.20
Iron ascorbate chelate	10	9.10	91	13.25

* The retail prices listed were quoted from American Ingredients Co. with the exception of the fat coated ferrous sulfate which was the quoted retail price from Balchem Corporation.

** For adding 14.7 mg Fe/100g or 0.147 kg Fe/MT of CSB/WSB.

*** Currently used

3. CIN: Expected changes in numbers of people fed, composition of ration, size of ration, or any combination of these per \$100,000 of funds that would need to be expended for increasing the vitamin C fortification of CSB and WSB, assuming that a fixed amount of funds is allocated to the Food for Peace Program.

Possible Consequences of Added Cost From Higher Vitamin C Level

If the additional expense of increasing the vitamin C level in CSB and WSB from 40mg/100g to 90 mg/100g were to be subtracted from the total purchasing allocation, the effect on the number of people fed, the size of the ration, or the amount of equivalent product that would have to be removed from distribution to pay for the increase of vitamin C from 40 to 90 mg/100g, are shown in Table 14, is based on FY96 commodity purchases:

Table 14. Possible Consequences of Added Cost from Higher Vitamin C Level

	Units	CSB	WSB	Total
Quantity purchased	MT	238,300	11,310	249,610
Total cost	\$	\$79,768,542	\$5,184,617	\$84,953,159
Average cost	\$/MT	\$334.74	\$458.41	
Average cost	\$/bag	\$18.41	425.21	
Extra Vitamin C cost	\$/MT	\$6.33	\$6.33	
Total cost	\$	\$1,508,439	\$71,592	\$1,580,031
Equivalent product*	MT	4,506	156	4,662
Equivalent product*	bags	180,252	6,247	186,499
Fewer people that would be fed per year at 30g/person/day	people/day	411,534	14,263	425,797
Reduction in size of ration needed to pay for increase in vitamin C to 90 mg/100g	grams	-0.57	-0.41	-0.56

* This is the amount of product, in MT or in bags, that could not be distributed if the cost of the increase vitamin C (from 40 to 90 mg) was subtracted from the total amount of funds available during FY 96 to produce these commodities.

As discussed in the main report (Analysis of Vitamin C Cost), the vitamin C cost of \$6.33/MT of commodity is based on the current price of vitamin C (May 1997), which, like all commodities, fluctuates according to market supply and demand. This cost includes the cost required to raise the vitamin C level from 40 to 90 mg/100g, including the cost of raw vitamin C, which is currently low.

4. CIN: Clear identification of the stakeholders' rationale for promoting the increased content of vitamin C in CSB and WSB. This would inform the committee of specific aspects of effectiveness that Congress has been advised to expect from the increased level of fortification.

We are limited in our ability to comment on the request for information on the stakeholders' rationale because we have not been contacted by members of Congress, nor have we been encouraged to be in contact with members of Congress. We have also not been contacted by any interested parties who may have encouraged Congress to pursue action in this area. The

only information available at this time is the Congressional report language that you have already compiled. Any comments beyond this would be purely speculation.

We would encourage the Committee on International Nutrition at the Institute of Medicine to be in contact with USAID representatives who have had an opportunity to meet with and discuss these issues with staff members of the U.S. Congress.

5. CIN: Process control information from all plants that produce CSB and WSB. This includes calibration records for the metering equipment and usage records for the premixes. This information is needed to make an informed judgment about scaling-up the pilot program.

Process Control Information

Plants C and E were the only companies sampled that provided us process control and analytical data. This information is available but too copious to include in this report. It can be requested by writing to SUSTAIN.

6. CIN: Listings of all of the data that were collected by SUSTAIN, either in an Appendix to the final report or in electronic files on a computer diskette. This would allow further examination of the data or analyses, if needed.

Table 15. List of Data Files

Tables	Table	PC file
Vitamin Premix Analysis	C-3	Vitprmx.xls
Effect of Freezing on Vitamin C in WSB & CSB	F-1	Freezing.xls
Analytical Data on CSB from Plant A	H-1	PlantA.xls
Analytical Data on WSB from Plant B	H-2	PlantB.xls
Analytical Data on CSB from Plant C	H-3	PlantC.xls
Analytical Data on CSB from Plant D	H-4	PlantD.xls
Analytical Data on CSB from Plant E	H-5	PlantE.xls
CSB Samples Taken in India	L-3	India.xls
WSB Samples in Haiti Taken from Different Points in Bag	M-1	Csbbags.xls
CSB Samples in Tanzania Taken from Different Points in Bag	M-2	Wsbbags.xls
Haiti Samples - WSB Food Preparations	N-1	Haiti.xls
Tanzania Samples - CSB Food Preparations	N-2	Tanzania.xls
Table N-2 - continued (pgs. 2, 4)	N-2	Tanz2.xls
WSB and CSB Percent Concentration in Gruel Samples	N-3	CWSBdil.xls

REFERENCES

- ACC/SCN. 1996. Update on the nutrition situation of refugees and displaced people. United Nations Administrative Committee on Coordination, Sub-Committee on Nutrition (ACC/SCN), Refugee Nutrition Information System Update No. 2, November 11, pp. 3, 4.
- Briend A. 1994. Supplementary feeding programmes. ACC/SCN Workshop on the Improvement of the Nutrition of Refugees and Displaced People in Africa, Machakos, Kenya, Background document # 3B p.4.
- Centers for Disease Control (CDC). 1989. Nutritional status of Somali refugees - Eastern Ethiopia, September 1988–May 1989. *Morbidity and Mortality Weekly Report* 38(26): 455–456, 461–463.
- Centers for Disease Control (CDC). 1992. Famine-affected, refugee, and displaced populations: recommendations for public health issues. *Morbidity and Mortality Weekly Report* 41(RR–13): 14–16.
- Desenclos J.C. 1987. Relief food and vitamin C deficiency (Vitamin C letter). *The Lancet* Aug. 22: 462–463.
- Desenclos J.C., Berry A.M., Padt R., Farah B., Segala C., and Nabil A.M. 1989. Epidemiological patterns of scurvy among Ethiopian refugees. *Bulletin of the World Health Organization* 67(3): 309–316.
- Greenham R. 1989. Scurvy and anaemia in Refugees (letter). *The Lancet* July, 15 (8655): 170.
- Harrell-Bond B.E., Henry C.J.K., and Wilson K. 1989. Fortification of foods for refugees (letter). *The Lancet* 1(8651): 1392.
- Henry C.J.K. and Seaman J. 1992. The micronutrient fortification of refugee rations to prevent nutritional deficiencies in refugee diets. *Journal of Refugee Studies* 5(3/4): 359.
- Magan A.M., Warsame M., Ali-Salad A. and Toole M.J. 1983. An outbreak of scurvy in Somali refugee camps. *Disasters* 7(2): 94–97
- Mason J., Wallace J., Katona-Apte J., and Alnwick D. 1996. Nutrition and food aid, Methodologies. In: *World Disasters Report*. International Federation of Red Cross and Red Crescent Societies, Oxford University Press, Oxford, UK, pp. 35–41.
- Moren A. 1994. Health and nutrition information systems among refugees and displaced persons. ACC/SCN Workshop on the Improvement of the Nutrition of Refugees and Displaced People in Africa, Machakos, Kenya, Background document # 5.

- Nieburg P., Person-Karell B., and Toole, M.J. 1992. Malnutrition-mortality relationships among refugees. *Journal of Refugee Studies* 5(3/4): 253.
- RHU (Refugee Health Unit), NW of the Somali Ministry of Health, Medecins sans Frontieres, and League of Red Cross and Red Crescent Societies 1985. Scurvy Survey Report, Gannet B refugee camp/NW Somalia. Hargeysa, Somalia.
- Seaman J. and Rivers J.P.W. 1989. Scurvy and anaemia in refugees (letter). *The Lancet* May 27: 1204.
- Toole M.J., Nieburg P., Waldman R.J., and Person-Karell B. 1989. Adequacy of refugee relief rations (letter). *The Lancet* 2(8657): 268.
- Toole M.J. 1992. Micronutrient deficiencies in refugees. *The Lancet* 339: 1214–1216
- Toole M.J. 1994. Preventing micronutrient deficiency diseases. ACC/SCN Workshop on the Improvement of the Nutrition of Refugees and Displaced People in Africa, Machakos, Kenya, Background document #2 pp.1–4, 10–13, 20.
- UNHCR. 1989. Options to alleviate nutritional deficiency diseases in refugees. Discussion Paper. UNHCR Technical Support Service.
- Van Nieuwenhuysse C. 1997. Personal communication. World Food Program, Rome, Italy.
- Waler G. 1991. Provisional Guidelines for calculating food rations for refugees (letter). Office of the United Nations High Commissioner for refugees, Geneva, Switzerland. (UNHCR/IOM/66/91)
- WHO. 1989. Scurvy and food aid among refugees in the Horn of Africa. *Weekly Epidemiological Record* 64(12): 85–87.
- WHO. 1993. Guidelines on micronutrient supplementation. Guidelines. World Health Organization, Regional Office for Europe, Zagreb Area office, Zagreb, Croatia, pp.2–3, 8, 13.
- Yip R. 1994. Iron deficiency: contemporary scientific issues and international programmatic approaches. *Journal of Nutrition* 124: 1479S–1490S.