SUSTAIN

Sharing & Utilizing Science & Technology to Aid in the Improvement of Nutrition

Report of

Micronutrient Compliance Review of Fortified PL 480 Commodities

October 2001

This report summarizes findings and recommendations of a review of PL 480 commodity quality assurance data by SUSTAIN conducted with support from USAID Bureau for Humanitarian Response, Office of Program, Policy and Evaluation. This review was undertaken as an activity under the Health Tech Project (Agreement Number: HRN-A-00-96-90007-00), a cooperative agreement between PATH and USAID Global Programs, Field Support and Research Bureau, Center for Population Health and Nutrition, Office of Child Survival. Revised February 23, 2004

SUSTAIN

SHARING SCIENCE & TECHNOLOGY TO AID IN THE IMPROVEMENT OF NUTRITION

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.

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Report prepared by
Peter Ranum, Senior Nutrition Advisor for SUSTAIN

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Dr. Thomas J. Marchione, Food and Nutrition Advisor, Office of Program, Planning and Evaluation, USAID/BHR/PPE
Dr. Samuel G. Kahn, Senior Health and Nutrition Advisor, Office of Health and Nutrition, USAID/G/PHN/NH
Elizabeth Turner, Executive Director, SUSTAIN
Paul Green, North American Millers Association
Dr. Debra Palmquist, USDA/ARS
Dean Jensen, USDA/GIPSA
Jim Riva, USDA/GIPSA

ABBREVIATIONS

ANOVA - Analysis of variance, or a statistical method to determine significance between means.

COV – Coefficient of variation, or the standard deviation as a percentage of the mean. A measure of variation in the data.

FGIS – Federal Grain Inspection Service of the USDA's Grain Inspection, Packers and Stockyard Administration (GIPSA) and Farm Service Agency. This acronym is used to refer to the USDA FGIS laboratory in Kansas City.

HPLC – High pressure liquid chromatography, the standard method used to measure vitamin A.

MAP - Micronutrient Assessment Program. A three year study run by SUSTAIN on the micronutrient content of PL480 commodities.

PL480 – Public Law 480 or the *Food for Peace* program administered by USAID

TQSA - Total Quality Systems Audit. A quality assurance program used by the USDA on government purchased commodities.

SUSTAIN - (Sharing U.S. Technology to Aid in the Improvement of Nutrition), the Washington, D.C.-based nonprofit organization dedicated to improving nutrition and food quality worldwide. www.sustaintech.org

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EXECUTIVE SUMMARY

This report by SUSTAIN for USAID/BHR reviews compliance by the cereal processing plants with the new micronutrient standards on fortified PL480 commodities that resulted from the Micronutrient Assessment Project (the MAP study), and assesses how well the new Total Quality System Audit (TQSA) system is working to assure proper micronutrient fortification of PL480 commodities. Vitamin A and iron analytical data from June 1 to August 31, 2000 that was collected from the commodity producers along with information on production volumes and quality assurance procedures.

The results of this review strongly suggest a <u>major improvement in the micronutrient content of fortified PL480 commodities</u>, particularly for wheat flour and bulgur, compared to observations made during the MAP study covering production in 1998. All producers are now routinely testing production lots for the two indicator micronutrients: vitamin A for all fortified food products and iron in the case of the blended foods. Mean vitamin A levels are well above what they were several years ago and lot assays, with very few exceptions, are above the new minimum standards. However, the uniformity, which is the variation from lot to lot in a particular commodity production run, which is not much improved over what it was previously.

A marked improvement was found in micronutrient levels in bulgur wheat, the product that posed the largest problem in meeting specification because of its large particle size relative to the added fortificant particles. In the previous study only 20% of the lots met the minimum specification for vitamin A containing on average 65% of the minimum standard. The present study found all of the lots meeting specifications with an average vitamin A content 126% of the minimum standard. Consequently, it is clear that the problems in fortifying bulgur wheat are being solved and bulgur can continue to be fortified.

In the case of wheat flour the mean vitamin A levels increased from 7,577 IU/lb or 86% of the minimum standard to 12,220 IU/lb or 139% of the minimum standard. 81% of the wheat flour lot samples fell below the 8800 IU/lb minimum standard in the MAP study, while only 0.35% of the wheat flour lot samples failed in the current study. Adequate levels of vitamin A in the blended foods (CSB and WSB) were found in the MAP study, averaging 128% of the minimum standard, but the mean vitamin A levels still increased in the current study to 155% of the minimum standard.

This improvement in fortification levels resulted from the following factors: (1) new USDA minimum micronutrient standards and enforcement under the TQSA program, (2) greater awareness by the industry to the importance and the need for maintaining proper micronutrient levels, (3) changes made by the premix manufacturers in the fortification premix composition, and (4) improvements made by the production plants in the premix addition and control.

This report makes the following recommendations:

1. USDA should audit premix producers and analytical laboratories.
2. Cereal processing plants in cooperation with their premix suppliers should continue to improve micronutrient premix quality and control.
3. USDA and USAID should establish guidelines on percentage of lots that should be tested related to lot size.
4. USDA in cooperation with manufacturers should standardize plant sampling procedures.
5. USDA in cooperation with manufacturers should improve and standardize the vitamin A analytical procedure.
6. USDA in cooperation with USAID should clarify whether and how the government should conduct independent monitoring and verification of micronutrient levels.
7. USAID and USDA should continue their cooperation to better monitor fortification.

BACKGROUND

The MAP Study

The Micronutrient Assessment Program (MAP)[1], launched in 1996 and completed in 1999, was a result of increased attention by USAID[2] to the effective delivery of micronutrients (i.e., vitamins and minerals) to their target populations and to the shared concern that the impact be optimized. The goal of the MAP was to determine the level of micronutrients in the fortified food commodities provided in the United States (U.S.) PL480 food assistance program which reaches the mothers, children, and refugees served by emergency and development feeding programs in developing countries.

In fiscal year (FY) 1999, under the Food for Peace Program (P.L. 480, Title II) alone, the U.S. donated more than 1.83 million metric tons of food commodities, reaching 43 million people in 53 countries worldwide. U.S. fortified food aid commodities have the potential to deliver micronutrients to the majority of these people. 40% of this food aid, or 740,000 metric tons worth $242 million was fortified with micronutrients.[3]

The MAP investigated the stability (from production to consumption) and uniformity in the manufacturing process of key micronutrients added to Title II food commodities. It focused on vitamin A, niacin, and the mineral iron, tracking the levels of these nutrients at both ends of the supply chain, from U.S. manufacturer to overseas consumer. Vitamin A was selected because of its significant health benefits, its relatively high cost when added as a fortificant and the challenge posed by the labile nature of this vitamin. Among other things, vitamin A plays an important role in maintaining eyesight and a strong immune system. Vitamin A deficiency (VAD) is a chronic, preventable problem, affecting 40 million and blinding over 1 million annually. The U.S. is part of a global effort to eliminate vitamin A deficiency and significantly reduce hunger by the early 21st Century. As a result, fortifying food aid commodities with vitamin A and eliminating the deficiency has become a high priority for the U.S. Congress, USAID, and other development/health organizations and nations worldwide.

The MAP studied the micronutrient levels in fortified PL480 commodities at the production plant by two separate means. The first was to sample the different commodities at production plants over a two to five day period and have them tested for select micronutrients. The second was to have official FGIS samples of wheat flour and bulgur tested for vitamin A. This was done because the results from the first part of the study indicated a problem with low vitamin A levels in these two commodities.

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[1] Ranum, P. (1999) Final Report on the Micronutrient Assessment Project. SUSTAIN, Washington DC.
[2] MAP was conducted by SUSTAIN with funding from the United States Agency for International Development's (USAID) Bureau for Humanitarian Response, Office of Program, Planning, and Evaluation (BHR/PPE) and support from the Global Programs, Field Support and Research Bureau, Center for Population, Health and Nutrition, Office of Health and Nutrition (G/PHN/HN).
[3] Taken from Data Summary Tables for Title II Purchase Detail FY 1999 compiled by USDA.

Both sets of results indicated serious shortcomings in the fortification of some PL 480 processed cereals, particularly with low levels of vitamin A just after production, in one case only a quarter of what it should have been. These findings of low vitamin A levels at production were corroborated for CSB by a separate study by the USDA[4] showing similar results. The reasons for these low vitamin A levels were thought to include: (1) poor quality vitamin A which is destroyed upon exposure to air during the production process; (2) low levels of the vitamin being added and; (3) separation of the vitamin from the commodity during production.

The MAP study demonstrated to the producers, USDA and PVOs the importance USAID attaches to micronutrient delivery in food aid commodities, particularly regarding vitamin A. The primary recommendation that came from this study was the need for the USDA to better monitor and enforce micronutrient fortification of Title II, PL 480 food commodities, recognizing the importance now attached to delivering needed vitamins and minerals to the recipients of this program.

The following specific recommendations to improve the levels of micronutrients in fortified PL480 commodities were made by the MAP report. All of these, with the exception for the last two, have been implemented.[5]

- Monitor and enforce current micronutrient minimum specifications currently applicable to processed fortified P.L. 480 cereals.
- Establish, monitor and enforce a minimum, end-product vitamin standard for fortified blended foods (CSB and WSB).
- Establish vitamin A as the micronutrient indicator for all PL480 fortified processed foods.
- Establish vitamin A and iron as the micronutrient indicators for PL480 blended foods.
- Remove all maximum standards on micronutrients and/or enforce minimum standards only.
- Vitamin premix manufacturers, bulgur and wheat flour producers need to correct the problem with low vitamin A levels found in those commodities.
- Incorporate micronutrient fortification in the Total Quality Systems Audit (TQSA).
- Consider allowing combined addition of vitamins and minerals to CSB and WSB.
- Continue fortifying processed and blended foods with vitamin A.
- Encourage mills and premix suppliers to improve vitamin A stability.
- Provide technical assistance to manufacturers of fortified P.L. 480 commodity producers on how to improve compliance and uniformity of micronutrient addition.
- Enforce the current stability specifications on the vitamin A required in fortified P.L. 480 commodities.

[4] Konstance, R. P; Onwalata, C.I. and Smith, P. W. et. al. (1998) Variations in Corn Soy Blends for Overseas Distribution. IFT Annual Meeting, Atlanta GA.
[5] There were additional recommendations made my MAP, such as finding ways to reduce vitamin C cooking losses that have yet to be addressed.

TQSA

USDA adopted a new quality control program, called the Total Quality Systems Audit (TQSA) program, which focuses on auditing the manufacturing process rather than product inspection. TQSA is an alternative to end-item inspections and verifies that a supplier has the capability to produce food products which consistently meet USDA standards, to deliver on time, and to respond to and resolve consumer complaints. TQSA evaluates capability and performance of these factors. Programs similar to TQSA have become one of the main tools used by the U.S. food industry to ensure continued quality.

USDA moved from its traditional on-site inspection and government (FGIS) testing program that was operating during the MAP study to TQSA shortly after the MAP study was completed. The MAP study endorsed TQSA as the way USDA would implement product specification monitoring and enforcement related to fortification. Appendix F lists the specific auditing questions related to fortification.

The objectives for TQSA appear to be helpful - getting industry to take increased responsibility for establishing systems to assure quality and safety. However, concerns remain regarding application of TQSA to micronutrient quality control. Discussions with the USDA on their TQSA program (Appendix E) revealed that maintaining proper micronutrient fortification is an important component of TQSA, but there are quality, monitoring and testing issues that need improvement or resolution.

Micronutrient Standards

As a result of the MAP findings and recommendations, USDA set up standards for vitamin A and iron analytical micronutrient “indicators”[6] to use to determine whether the different commodities have been properly fortified. The following table shows the new minimum or regulatory standards that were set for fortified PL480 commodities as of February 8, 2000. Also shown are the target levels[7] that existed before these new standards were set. All comparisons discussed in this report are to the minimum standards and not to the target levels.

Under current regulations, plants are not allowed to ship production lots that fail to meet the minimum micronutrient standards. If the assay falls below the minimum, the plant cannot ship it. It has the option to have the sample retested, or have another sample taken for assay, or have the lot reblended. In any case, some plants might be highly reluctant to report results that would show a lot to be low and in violation of the regulations.

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[6] Vitamin A was chosen as the primary indicator of proper fortification of all PL480 commodities because of its nutritional importance, high cost, absence from the unfortified food and labile nature. If the vitamin A in the fortified product meets specifications, it is a good assumption that the other micronutrients added by the same fortification premix will be correct, providing that premix has the proper level of micronutrients. Iron was chosen as an indicator of the mineral premix used to fortify blended foods (CSB and WSB).

[7] The target level is the amount added in the case of blended foods and the old minimum level in the case of processed foods, which was never actually enforced.

Table 1. Micronutrient Standards for Fortified PL480 commodities

Micronutrient Standards	Processed Foods[8]	Blended Foods[9]
Vitamin A		
Minimum (regulatory) Standard	8,800 IU/lb	8,400 IU/lb
Target	10,000 IU/lb	10,500 IU/lb
Iron		
Minimum (regulatory) Standard	NA[10]	14.7 mg/100g
Target	Varies	14.7 mg/100g

PURPOSE

The purpose of this review is to assist USAID/BHR in assessing the status of quality assurance technologies and systems used to improve the quality of PL 480 Title II commodities. A key objective of PL 480 is to combat malnutrition and its causes, and thus improve health among vulnerable groups, particularly women and children.

PROCEDURES

The total fortified PL480 procurement for the third and forth quarter of the 2000 calendar year broken down by plant and commodity was obtained from the USDA Kansas City Commodity Office (Appendix C). The commercial companies producing fortified PL480 commodities were identified with assistance from the USDA and the North American Millers Association (NAMA). Vitamin A analytical results for all fortified commodities and iron assays for corn soy blend (CSB) and wheat soy blend (WSB) were requested from these producers[11] for all commodities produced between June 1, 2000 and August 31, 2000.[12] Standard descriptive statistics were performed on the vitamin A and iron test results from the different laboratories for each product from the different plants, as shown in Appendix D. In addition, an ANOVA comparison was made between the different lab results to determine if they were statistically different.

The companies were also asked to fill out a questionnaire on the production and quality control of fortified PL480 commodities. A copy of the questionnaire and cover letter sent

[8] Fortified processed foods are wheat flour (bakers and all-purpose), corn meal, bulgur, sorghum and soy-fortified versions of these.

[9] Blended foods are Corn Soy Blend (CSB) and Wheat Soy Blend (WSB)

[10] Not Applicable. There is no iron standard for fortified processed cereals since they are fortified with a single premix containing iron along with the vitamins. Vitamin A can then act as an indicator for all the added micronutrients except for calcium, which is added separately.

[11] Under the original terms of this agreement, USDA was requested to gather the necessary data for these reviews from PL 480 Title II commodity producers. Due to the "Paperwork Reduction Act," USDA later reported that they would be unable to supply said information. Hence, it was determined that SUSTAIN would request the necessary information for the first review from the producing companies.

[12] A similar review of analytical data from the producers on production during the last quarter of 2000 was not performed because it was thought it would add no additional information to that already obtained.

to the plants is shown in Appendix A. A series of meeting were held with the USDA[13] and USAID to gain understanding on how the TQSA program worked.

RESULTS

Commodity Production Tested

Of the eleven companies making fortified PL480 commodities that were asked to supply analytic data (Appendix C), ten companies cooperated. General Mills said it was against their policy to provide data of this nature. All of the information provided by the plants (Appendix D) has been treated confidentially, identifying plants and their results by code, not by name.

The total fortified PL480 procurement for the third and forth quarter of 2000 from each plant is shown in Appendix C. This data was obtained from the USDA Kansas City Commodity Office in order to ascertain the total universe of procurement against which the plant data could be compared. 290,220 Metric Tons (MT) of fortified commodities were procured in the third quarter according to the USDA. Of this, 7% was bulgur, 36%, CSB and 48% wheat flour. In the forth quarter of 2000 only 85,090 MT of product was procured according to the USDA. Of that, 41% was bulgur, 8%, CSB and 33% wheat flour.

The USDA supplied contract numbers and tonnage figures on each contract but did not indicate the number of lots in each contract. The plants were asked in the questionnaires for the total volume of each commodity produced during the third quarter, which most provided. The plant production figures supplied by the companies did not match very well with the USDA procurement data, as shown in Appendix D. The reason for this appeared to be that the two sets of data were on different contracts with little overlap, as illustrated in the following example with WSB made by plant 1C.

The plant reported they made three contracts of WSB:
lot assays of VEPE00831
lot assays of VEPE00842
9 lot assays of VEPE00848

The USDA reported they purchased the following contracts of WSB:
550 MT of VEPE00848
330 MT of VEPE00856
420 MT of VEPE00870

As a rule, the contract numbers reported by the plants were lower, and therefore presumably earlier, than those reported by the USDA for this period. It may have been possible to obtain a better match with USDA procurement data from the first or second

[13] USDA's Grain Inspection, Packers and Stockyard Administration (GIPSA) and Farm Service Agency

quarter of 2000, but that was not requested since it was thought that production would have coincided with the assignment of procurement contract numbers since they have to be preprinted on each bag of product.

Because of these discrepancies and missing data, there is no way to determine the amount of production represented by the assay results with any degree of confidence. However, the large number of vitamin A lot assays that were provided suggests that a large portion if not all of the production during this period was tested.

Micronutrient Assays and Compliance with New Standards

The plants reported a total of 2251 vitamin A assays and 358 iron assays. At a typical cost of $60 per assay for vitamin A and $15 for iron that would have cost the plants a total of $140,430 in analytical costs for this three month period.

Many of the plants used more than one laboratory on the same samples, and some of these reported a few results falling below the minimum level. This would not be a problem for the plant as long as there was one result that showed the lot was within compliance, which was generally the case. Only one of the 356 iron results reported for the blended foods fell below the minimum (from plant 9A), while 179 vitamin A assays or 7.9% of the vitamin A results were below the minimum. There were 29 lots failing to show at least one vitamin A assay result above the minimum; 22 of these were bulgur. The remaining 7 either had vitamin A results from the FGIS lab only, whose results ran consistently lower than those from the other labs, or had a result very close to the minimum standard.

The fact that these low results were given at all suggests that the companies generally provided all or most of the test results they had on these samples, but there is no way of knowing that for sure. Most of the analytical results falling below the minimum came from the FGIS laboratory in Kansas City (coded lab U). The producers complained that the results from the FGIS during this period were often low and did not correlate with the results from other laboratories. On the other hand, it may have been that the results from the other labs ran higher. It is outside the scope of this study to determine the validity of the vitamin A testing by the different laboratories.

Comparison of micronutrient levels with those reported in the MAP study

A comparison between the vitamin A levels found in this study to those reported on samples in the MAP study provide a reasonable means to assess whether there has been any improvement in fortification since the new regulations went into effect. The limitation with this comparison is that this new data is on virtually all the fortified commodity production during a three-month period, while the composite lot sample assays used in the MAP study were only for wheat flour and bulgur. Also, the assays on blended foods used in the MAP study were based on results from a single laboratory, while this study has results from a number of different labs.

Wheat Flour

The MAP data for wheat flour was on 155 lot samples produced by at least five different mills the end of 1997. The current study had 1152+ lot samples produced by 17 different mills. The overall mean in the MAP study was 7,577 IU/lb or 86% of the minimum standard, while in this study the overall mean was 12,220 IU/lb or 139% of the minimum standard. Only 30 of the wheat flour lot samples (19%) met the 8800 IU/lb minimum standard in the MAP study, while only one of the wheat flour lot samples failed in the current study.

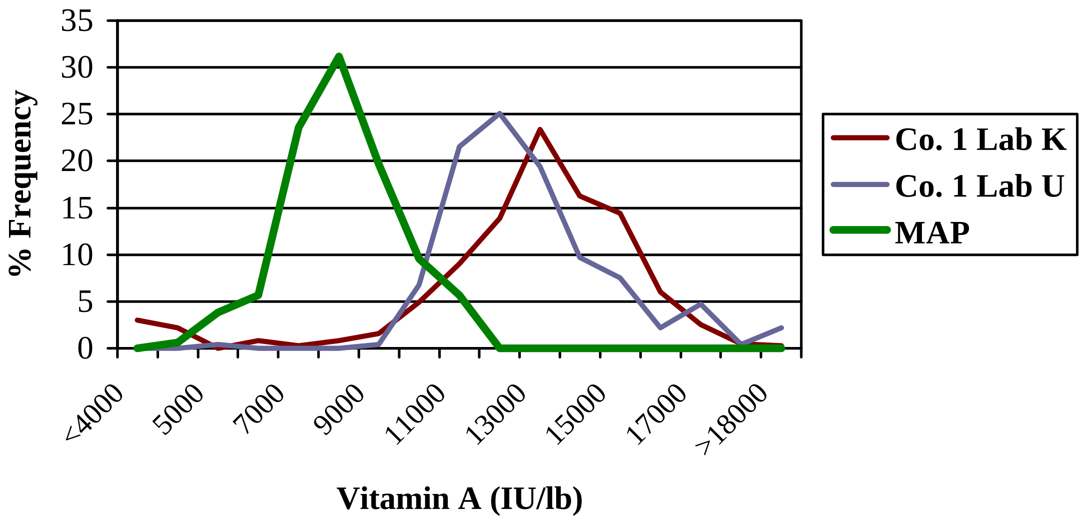

Figure 1. Frequency of vitamin A assays on ***wheat flour*** *comparing third quarter 2000 results from Company #1 from two different labs to the 1997 data from the MAP study.*

Figure 1 illustrates the improvement in the fortification of wheat flour by plotting the distribution of vitamin A levels found in the 279 lot samples from company #1 in the current study to levels found in the MAP study. Table 2 below shows the mean vitamin A levels on wheat flour found by the different laboratories doing the testing.

Table 2 Wheat Flour Vitamin A Results from Different Laboratories

Lab:	K	W	U	S	X	All
Number	279	138	522	17	362	1318
Average Vitamin A (IU/lb)	12,231	12,068	11,870	10,359	12,862	12,220
Number below minimum[14]	1	6	44	0	0	1

[14] The number of lots falling below the 8800 IU/lb minimum for each set of laboratory results. The last column labeled "all" gives the number of lots for which no assay result was above the minimum.

Bulgur

There were 56 FGIS bulgur lot samples from two different plants tested in the MAP study. Over half of these were very low in vitamin A, containing only a quarter of the minimum. The present study showed great improvement with vitamin A levels in bulgur, but continues to show some problems in fortifying the large particle size products of bulgur and sorghum grits. The distribution of bulgur results, plotted in Figure 2, shows higher means but wide variation as well as serious differences between labs. However, it should be noted, that the requirement to meet micronutrient standards was delayed until July 2000 for bulgur and sorghum and first became effective in the middle of the sampling period.

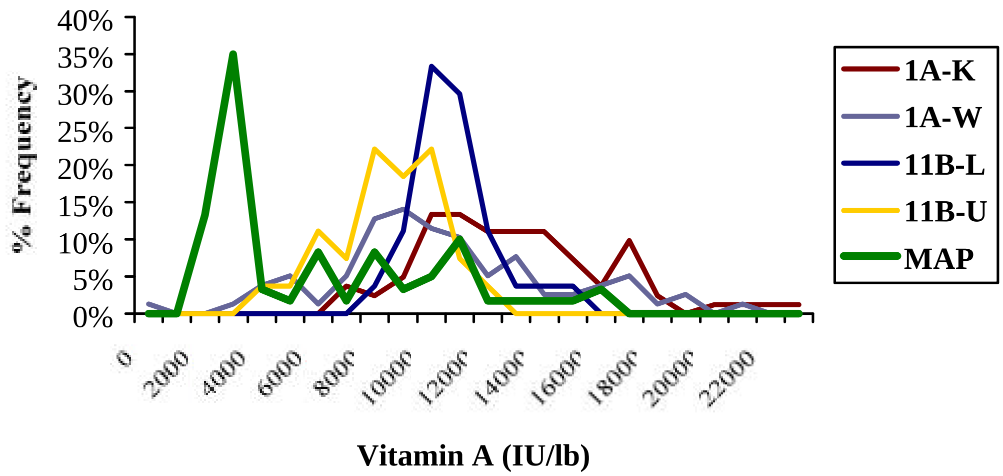

*Figure 2. Frequency of vitamin A assays on **bulgur** comparing third quarter 2000 results from plants 1A and 11B, each from two different labs, to the 1997 data from the MAP study. The MAP data is from a single lab while the other data is for different labs (K, W, L and U) on the same sample set from two plants.*

Bulgur plant 1A, which produced product with the lowest vitamin A levels in the past, showed great improvement in this study. The FGIS lab results on these samples ran low, with the average vitamin A level of 7941 IU/lb, or below the 8800 IU/lb minimum standard, while the other lab (code K) showed a higher average of 10,374 IU/lb. As a result of concerns from the MAP study, this plant found out that much of the vitamin A was being pneumatically removed from the bulgur. They changed the milling system and put new controls on the premix and its addition, which resulted in this large improvement.

The other bulgur plant (11B) has also struggled with achieving proper levels of vitamin A. Mean vitamin A levels was good but differed by lab; the mean FGIS lab result

(10,420 IU/lb) ran 19% lower than the mean (12,832 IU/lb) from the other lab (L) testing the product. This company believes that the sampling of bulgur is critical to get proper results and have instituted new sampling procedures to insure proper representation and uniformity. Also, they question whether the vitamin A procedure used by the FGIS extracts all the added vitamin A.

There was a serious question whether bulgur could be adequately fortified. If this study showed that there were major, continued, intractable problems with the fortification of the large particle size products of bulgur and sorghum grits, discontinuation of their fortification may have to be considered. This would involve determination of the nutritional consequences of providing unfortified product on the health of the recipients of these commodities. Fortunately, that does not appear to be the case. The two producers of these products have shown great improvement. They also believe even greater improvement has been achieved since this last study. Both of them supported continued fortification of these commodities, but would like to see improvements in the sampling and testing of vitamin A by the FGIS lab on these products.

Blended Foods (CSB and WSB)

The MAP study did not test vitamin A levels in retained FGIS lot samples of CSB or WSB as it did for wheat flour and bulgur because the testing of plant production samples did not indicate any problem with low levels in blended foods. Only one of the five plants sampled had a mean vitamin A level below the current 8400 IU/lb minimum, and that occurred only for a short period of time. There was no problem with low iron content in any of the plants.

The current study, likewise, indicated no problem with low vitamin A or iron levels in CSB, as shown in Table 3. Figure 3 illustrates that the vitamin A levels in CSB increased over what was found in MAP.

Table 3. CSB Vitamin A and Iron Results from Different Laboratories

Lab:	K	L	U	M	X	All
Vitamin A						
Number	20	94	15	13	87	229
Average Vitamin A (IU/lb)	11,590	14,110	13,380	18,440	15,128	14,475
Number below minimum	0	0	0	0	0	0
Iron						
Number	20	145	9	13	87	274
Average Iron (mg/100g)	15.2	20.4	17.7	17.9	18.0	19.0
Number below minimum	0	0	0	1	0	0

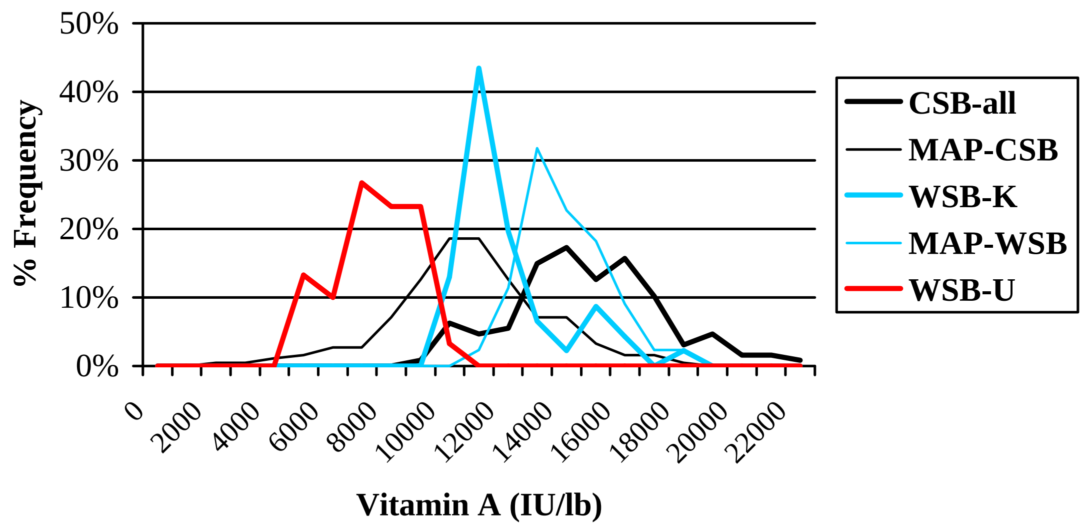

Figure 3. Frequency distribution of vitamin A assays on the blended foods [corn soy blend (CSB) and wheat soy blend (WSB)] comparing third quarter 2000 results to the 1996 data from the MAP study.

Labs U (the FGIS lab) and W found low vitamin A levels in WSB produced by plant 1C; but lab K found adequate levels in the same samples. It is unclear whether this is an analytical problem, but the fact that two labs found low levels lend credence to it having a production cause. The MAP study found no problem with vitamin A in WSB produced by this plant. Figure 3 shows that the vitamin A levels in WSB decreased from what was found in MAP and that there was virtually no agreement between the results from labs K and U.

Uniformity of Fortification

There is no way to assess the uniformity of added micronutrients *within* a lot from the data collected in this study, as was done in the MAP study, but we can determine the uniformity between lots. This is indicated by the Standard Deviation (STD), the Coefficient of Variation (COV) and the range of values (shown by the minimum and maximum values) on the results from each laboratory given in Appendix D.

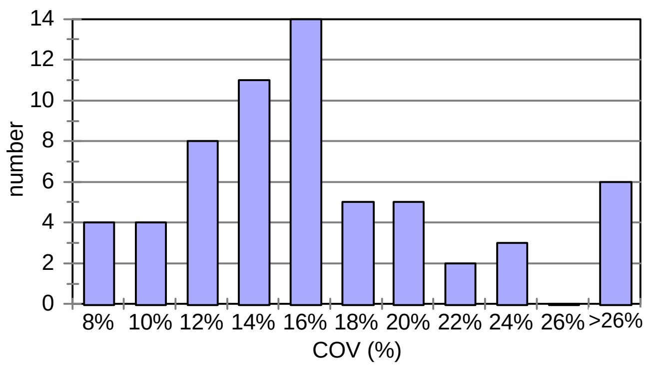

Figure 4. Distribution of coefficient of variation (COV) on vitamin A and iron assay sets.

Ideally, we would like to see a COV in the 10% to 18% range, where most of these were, as shown in the above frequency distribution (Figure 4). The COVs in the MAP study for wheat flour was 18.5%. COVs below 10% are suspect because they are lower than a normal analytical error. The plant results with high variability, indicated by COVs over 18% could be due to analytical problems or could be real production variability or both. Plants with high variability are much more likely to have individual lot assays fail.

Appendix D also shows the coefficient of variation for the production from a single plant between labs ("CV" in column 10) and indicates whether there was a statistically significant difference between the laboratory data sets ("Diff" in column 11).[15] Differences between lab COVs are much higher.[16]

Reported plant procedures used in fortification

The plants were asked to fill out a questionnaire regarding the production and quality control procedures used for fortified processed cereal commodities (see Appendix A). Answers are described in Appendix B.

[15] These calculations were provided by Debra Palmquist, statistician with USDA ARS in Peoria IL.
[16] A typical COV for vitamin A in enriched cereal products in the AACC check sample service is 17%.

Fortification premix

A standard vitamin premix is required for use on blended foods, while the vitamin/iron premix used to fortify processed foods differs in composition by product to be fortified and between the premix manufacturers (see the premix table in Appendix B. There were 6 different companies reported to be supplying premixes. All premix companies now provide certificate of analysis on each lot of premix. Some of the premix producers now provide an extra overage in vitamin A activity in the premixes for processed foods to make up for any loss during normal storage periods of the premix. The formulation of the bulgur premix was changed in order to provide a more controlled and uniform addition.

Producers differed greatly in how long they allow the premix to be stored prior to use. Vitamin A activity in the premix will decrease with time; so long storage periods can result in reduced vitamin A levels in the fortified food.

The plants were asked to provide the quantity of the fortification premix used during the period. Calculation of the premix addition rate provides a check on fortification. Of the four CSB plants that provided premix usage data, three were on target with the proper addition rate and one was twice the proper level. On the fortified processed commodities, 12 of the 14 plants reported premix usage in line with their commodity production. The other two reported lower than normal premix usage.

Premix addition

Some plants increased the addition rate of premix to flour and bulgur in order to better assure meeting the new vitamin A standards. All of the plants said they routinely checked the premix addition rates and 80% said they run iron spot tests as a check that the product is properly fortified.

Sampling and analytical testing

Two of the plants said they took individual grab samples for testing while most of the others use composite samples. The typical composite sample is made by blending from 6 to 36 samples taken over the production run of a lot, the larger the lot size the more samples that are taken. This is similar to the sampling used by the FGIS inspectors. Composite samples are much preferred since they average out composition within a run and give a more accurate estimate of the micronutrient content of a lot.

Twelve of 16 plants said they have been testing 100% of the production lots for vitamin A. One plant said they used to test 100% but now they tested 33% of the production. One plant said they test 50% and two plants said it varied from 17% to 70% depending on the product. There does not seem to be any clear-cut guidance on this from the USDA.

There were 9 laboratories identified as providing vitamin A or iron assays. Three were premix suppliers, four were independent labs, one was a government lab (FGIS) and one was part of the producing company. Many of the plants used more than one lab on the same set of samples, as shown in Appendix D, and some indicated they did comparison testing between labs.

General

The producing companies were generally satisfied with the new regulations on fortification. Some mentioned that they brought to light problems they did not know they were having, such as removing the vitamins through aspiration, but which they have since addressed. Reasons mentioned for the improvement in attaining proper fortification levels included: (1) USDA establishment of the new minimum micronutrient standards and enforcing it under the TQSA program, (2) a greater awareness by the industry to the importance and need of maintaining proper micronutrient levels, (3) changes made by the premix manufacturers in the fortification premix composition, and (4) improvements made by the production plants in the premix addition and control

ISSUES and RECOMMENDATIONS

Assuring compliance with the new standard

There are two ways plants can help assure compliance with the new vitamin A minimum standards. The first is to increase the amount of vitamin A added to the product and taking precautions that the vitamin A is not destroyed or physically removed. The second is to reduce variability. Process variability can be improved with better feeders and mixers, but a large contributor of the variability is the sampling and analysis. This survey has shown that the producing companies have considered all of these approaches; however, the results suggest that they have more heavily relied upon overages then on improved uniformity.

Processed foods

As mentioned above, the plants are now adding about 12,000 IU of vitamin A per pound of commodity, while in the past they added closer to 10,000 IU/lb. This level of vitamin A is necessary in order to achieve the new minimum standard of 8,800 IU/lb.[17] With a COV running around 15% on a mean of 12,220 IU/lb as found in this study with wheat flour, 3.1% of the assays would fall below the minimum. Since much of the variation is due to the analytical error, performing a second assay or retesting the samples would reduce the number of products not meeting specifications to nearly zero or very manageable numbers.

[17] Premix and commodity producers can add whatever level of vitamins or iron they feel is necessary to meet minimum specifications with processed foods, unlike blended foods where the premix composition is specified.

Blended foods

The blended foods had a higher vitamin A level averaging 14,475. This together with their lower minimum standard of 8400 IU/lb means that only 0.3% of the lots would fall below the minimum with a COV of 15%. Unlike the premixes for processed foods that differ by manufacturer, the USDA sets the premix for CSB and WSB. However, it appears that premix manufacturers, perhaps at the request of the producers, made sure the premix contained an excess of vitamin A in order insure adequate levels in the final product.

One of the producers suggested that it would benefit the program if they could blend to specifications (as done with the processed foods) rather than be forced to use a standard fortification premix as currently specified by the USDA for CSB and WSB. That same producer, however, stated that they are not having a problem with the current situation, nor does it appear that any of the other CSB producers are, so there does not appear much need to make any change in the premix now specified for blended foods.

Recommendations

*1. **USDA should audit premix producers and analytical laboratories.***
For TQSA to be successful, USDA needs to expand its monitoring and audit systems.[18] They should require proof that labs contracted to conduct micronutrient assays are reliable and accurate, and have a system established to effectively monitor and evaluate test data from producers. In addition to monitoring and auditing production plants, USDA should also monitor and audit vitamin and mineral suppliers and analytic laboratories conducting the micronutrient assays.

2. *Cereal processing plants in cooperation with their premix suppliers should continue to improve micronutrient premix quality and control*.
The plant survey showed variation in how the fortification premix was formulated and how well its use was controlled. The quality of the premix used to fortify the commodity can be a major factor determining whether micronutrient specifications will be met. The premix should be formulated to provide adequate amounts of vitamin A allowing for normal storage loss, and this level should be verified by assay and confirmed in a COA. Its dilution, which determines the addition rate and feeding characteristics, should be such that the plant can maintain good control of its addition. The coating and antioxidant levels in the vitamin A should provide adequate protection against vitamin A loss during storage. The plant should maintain good inventory control so as not to store the premix for excessively long periods or under improper conditions, such as high heat or in open boxes. The premix manufacturer should provide guidance by recommending maximum shelf life and proper storage conditions.

[18] Based on the situation in 2000. It may be that USDA has already included and performed some of these changes.

3. ***USDA and USAID should establish guidelines on percentage of lots that should be tested related to lot size.***
There was a difference of opinion within the USDA on what percentage of the production lots should be tested for micronutrients. Some believed it should be 100%, while others felt that it should start out at 100% but that could be reduced, to every third lot for example, if the results showed good compliance and uniformity. Some plants, as shown by this survey, follow the former and other the latter. This issue needs resolving; USDA should publish guidelines on testing requirements. Included in these guidelines should be some relationship between the quantity of product in each lot and the frequency of testing. For example, it would seem reasonable to require testing on all lots of two or more railcars but not on every lot of smaller size.

4. ***USDA in cooperation with manufacturers should standardize plant sampling procedures.***
There are questions on the sampling and sample handling that should be addressed. There needs to be some uniformity in sampling methods. The one recommended is a composite sample blended from multiple samples taken from a single lot, similar to the one previous taken by FGIS inspectors, rather than a single grab sample.

5. ***USDA in cooperation with manufacturers should improve and standardize the vitamin A analytical procedure.***
While it was not the purpose of this review to examine the types and validity of the micronutrient assay methods employed by the different labs, it is clear that analytical error could be a major contributor to the high variability, which makes compliance with the new minimum standards difficult. There are differences in the extraction procedure, analytical method and method of reporting results that affect how well some plants do in meeting the new standards. Some producers are very critical of the method employed by the USDA lab, claiming that it does not extract all the vitamin A, thereby giving erroneously low values. That the values from this lab are indeed low is confirmed by this survey. On the other hand, some labs may be biased toward providing high results.

TQSA does not require a standardized analytical procedure be used, but it would be possible for the USDA to recommend a procedure. The AACC has recently completed a collaborative study on a HPLC method for vitamin A[19], which could serve as the basis for such a method. The USDA could also encourage laboratories to participate in a monthly vitamin A check sample service, such as provided by the AACC, as a means of continually validating their procedures. Their results would be made available to TQSA auditors. Finally, the laboratories could make use of the AACC vitamin assay committee by having a collaborative study on the vitamin A methods employed. This could be as simple as having the committee experts examine the chromatographs, but it could also involve testing blind samples with known levels of vitamin A.

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[19] DeVries, J. W. and Silvera, K. R. (2001), AACC collaborative study of a method for determining vitamins A and E in foods by HPLC (AACC method 86-06). *Cereal Foods World*, 46(5):211-215)

*6. **USDA in cooperation with USAID should clarify whether and how the government should conduct independent monitoring and verification of micronutrient levels.***
Under the current TQSA system the producing companies or laboratories hired by the companies do most of the testing. The FGIS lab is available for hire, but companies may shy away from using them because of their reputation for giving low assay results. The main monitoring of micronutrient levels employed under TQSA is to review the assay results at a plant during an audit, but this relies on the analysis being accurate.

TQSA allows for independent government sampling and testing of production. This is more likely to be done if there is some indication of a problem at a plant. Government collected samples are supposed to be split so that the producer can have it independently tested. We were not aware of any such case of independent government testing during the period of our study. It is not clear what the position or actual practice is of the USDA on such sampling and testing. What are the criteria for sampling a particular plant or contract? How many lot samples would be taken? How would they handle conflicting laboratory results? What action would be taken if a government lot sample proved to be below the minimum when the plant has assay results showing the lot met specifications?

Another approach is to request assay results on specific lots from a particular plant in order to assess compliance outside an actual audit. How would this assay data be obtained? Would plants be chosen for this type of audit on some specified basis or randomly? How would the specific lot numbers be chosen and how many lots of each contract should be requested? These are all questions that the USDA and USAID should agree on if any of these verification and monitoring procedure is to be used.

*7.   **USAID and USDA should continue their cooperation to better monitor fortification.***
This study showed there is a difficulty in matching the production information kept by the mills, which would be available to TQSA audits, to that maintained by the USDA commodity office. It appears that the government has no convenient way to match vitamin A results to a particular lot or contract. The USDA and USAID should discuss how this could or should be done, assuming they ever need to do it. Much of the progress attained in improving the micronutrient fortification of PL480 commodities resulted from cooperation on this issue between the USDA and USAID, and it is strongly recommended that such cooperation should continue so as to provide the recipients of the PL480 *Food for Peace* Program high nutritional quality foods.

It is further recommend that there be as system for continued monitoring and improvement of the quality of fortified PL480 commodities. This should include acting on those MAP recommendations that have yet to be addressed, including:

- Enforcing the stability specifications of vitamin A used in fortification.
- Improving stability of vitamin A source.
- Investigating use of more heat stable forms of vitamin A and C.
- Investigation of precooked forms of cereals to reduce vitamin loss.

APPENDIX

APPENDIX A

MEMO TO PRODUCTION PLANTS

THE FOLLOWING LETTER AND QUESTIONNAIRE SENT TO PRODUCING PLANTS:

The US Agency for International Development (USAID) has asked SUSTAIN (Sharing United States Technology to Aid in the Improvement of Nutrition) to assist in a review and evaluation of the performance of P.L.480 commodity production plants in fortifying cereal products under the newly instituted TQSA program and minimum micronutrient standards. We are requesting your assistance in this review since you have been identified as a producer of fortified P.L.480 cereal commodities.

SUSTAIN is a non-profit organization that works closely with USAID and the US Department of Agriculture (USDA) on issues related to P.L.480 (the Food for Peace Program) commodities. SUSTAIN recently completed a three-year study on the fortification of these commodities for USAID. This Micronutrient Assessment Project (the MAP report) led to a number of recommendations on how fortification of these foods could be improved. USDA instituted many of these suggestions, including minimum vitamin A and iron analytic specifications. The MAP report endorsed TQSA (Total Quality System Audit) as a means to better ensure proper micronutrient fortification of these commodities and the success of the program.

In order to conduct the recently commissioned review and evaluation by USAID, SUSTAIN is requesting vitamin A analytical results in your possession for all commodities produced between June 1, 2000 and August 31, 2000. In addition, we request iron assays on corn soy blend (CSB) and wheat soy blend (WSB) produced in the same interval. Each lot assay result provided should be identified with the type of product, the lot number, the contract number, the date produced, and whether the lot was shipped, reprocessed, or rejected. In some cases the assays may have been performed in-house and/or by more than one laboratory or there may be multiple testing of the same lot. We would like to obtain **all** assay results since it will help us better evaluate any variation in analytic data between labs.

As in the MAP study, SUSTAIN will keep all records and information supplied by the producing companies strictly confidential. Individual plants will be identified in the final report by code and not by name. The intent of this study is to see how well the industry as a whole is doing in fortifying the commodities and not to single out individual plants.

In summary, we are requesting the following information for **each vitamin A assay and iron assay** (iron results for CSB & WSB only):

1. Assay result
2. Type of product
3. Contract number
4. Lot number
5. Date of production

6. Laboratory performing assay
7. Disposition of lot

We would prefer to have this data on a spreadsheet and sent as an e-mail attachment. If an e-mail file is not feasible we will accept whatever form your records are in. Please be advised that the agencies have expressed an interest in periodically monitoring micronutrient data and the progress of TQSA. We may be asking for the same data on production between September 1, 2000 and December 31, 2000 for a second review.

In addition to the above batch data we are asking you to complete the attached questionnaire regarding the production and testing of the fortified commodities. This can be submitted separately from the lot data. We will be contacting the laboratories to get information on their analytical and validation procedures used.

Your cooperation in this review is greatly appreciated. If you are not the proper contact at your company to provide this information, please pass this letter to the appropriate person. Any questions regarding this review can be directed to:

Peter Ranum, consultant at SUSTAIN, (716) 773-4742
Liz Turner, Executive Director at SUSTAIN, (202) 328-5180

Please send the requested information to SUSTAIN the attention of Peter Ranum by one of the following:

Email: pranum@aol.com
Fax: (716) 775-1037
Mail: Peter Ranum
c/o SUSTAIN
1400 16th ST NW Box 25
Washington DC 20036

Once again, thank you for your cooperation. We look forward to continued collaboration in assuring the highest quality of P.L. 480 cereal commodities.

Sincerely,

Liz Turner
Executive Director

cc: Tom Marchione, USAID
Samuel Kahn, USAID
Peter Ranum, SUSTAIN
Betsy Faga, NAMA
Paul Green, NAMA
Rebecca Ramsey, USDA

SUSTAIN questionnaire on fortification of P.L.480 commodities. Sept 2000

Please provide the following information for each producing plant in your company.

Company Name: ____

1. Plant Location: ____

   ____

2. P.L.480 products produced at location:

Product	Plant Production in MT (1000kg)		Fortification **premix** product used *	Lbs. of premix used June 1 to Aug. 31
	June 1 to August 31	Estimated annual for 2000		

* Please include type number and manufacturer.

3. **a.** Fortification Premixes – please provide a copy of the label for each fortification premix used at the plant.

   b. Does the premix manufacturer provide Certificates of Analysis (COA) on each lot of premix? ____Yes ____No If yes, please attach a copy of a COA

   c. How long do you normally keep a vitamin premix batch prior to being used up?
   ___ Less than 2 weeks
   ___ 2 to 4 weeks
   ___ 4 to 8 weeks
   ___ more than 8 weeks

4. **a.** Laboratories - List the name and contact information for all laboratories providing vitamin A and iron assays on these commodities (the address of the USDA FGIS in Kansas City need not be given.). If you perform analyses in-house, please provide contact information for your lab as well.

b. Has this plant submitted product samples for comparative laboratory testing to either the USDA FGIS or an independent lab.
____Yes ____No

If yes, please supply the results of that testing: ______________________

c. Do you perform in-house analyses on product samples for comparative testing?
____ Yes ____No

If yes, please supply the results of that testing: ______________________

5. If this plant has made any process or equipment changes in the last six months, outside of routine running of vitamin A or iron tests, in order to better comply with the new minimum analytical requirements for vitamin A, please describe. An estimate of how much money these changes cost the company would be useful information but it need not be supplied if considered proprietary.

6. Roughly, what percent of the production lots have you been testing for vitamin A?

7. Describe how you take the sample that is used for the vitamin A test and how the sample is packaged and handled prior to testing. What is the normal interval between sampling and testing?

8. Does the plant have a written protocol on how to ensure proper fortification?
____Yes ____No

If yes, please attach a copy of the written protocol.

9. What is the plant's normal procedure when a lot assay fails to meet the minimum analytical requirement for vitamin A?

10. Has any lot of product failed to meet the minimum analytical requirement for vitamin A since testing started?
____Yes ____No

If yes, how many?_______

11. How often is the feed rate on the fortification premix checked?

12. Are spot tests (e.g. iron spot tests) run on the fortified commodity?
____Yes ____No

If yes, how often?

13. Has this plant had an audit by a USDA inspector under the TQSA system?
____Yes ____No

Did the inspectors review data related to fortification?
____Yes ____No ____Uncertain

14. Please provide any comments you wish to make regarding problems in meeting the new minimum micronutrient requirements or how well the TQSA program is working as regards product fortification.

APPENDIX B

RESULTS OF PLANT QUESTIONNAIRE

All of the companies producing fortified PL480 commodities were sent a questionnaire (Appendix A) to gain information on their production practices and quality control procedures as they relate to fortification. In one case the questionnaire was filled out for the whole company rather than individual plants. General Mills was the only company that did not complete the questionnaire saying it was against company policy.

Fortification premixes (question #3)

Fortification premixes identified in the survey were

- Watson Foods
- ADM Paniplus
- Research Products (Repco)
- Wright Enrichment
- Roche Vitamins
- American Ingredients (AIC)

The following table shows the composition (in amount of each nutrient added at the designated feed rate) for the premixes designed for use in fortified processed foods.

Vitamin/iron Premixes used on Processed Foods

food to fortify	Company	Type number	Addition (oz/cwt)	Thiamin (mg/lb)	Riboflavin (mg/lb)	Niacin (mg/lb)	Folic Acid (mg/lb)	Vitamin A (IU/lb)	Iron (mg/lb)
Wheat Flour									
	ADM	113436	0.5	2.78	1.75	21.0	0.71	12,000	17.0
	Repco	17A	0.5	2.73	1.80	21.0	0.70	10,000	17.0
	AIC	60	0.5	2.65	1.80	21.0	0.70	10,700	17.0
Corn Meal or Sorghum Grits									
	Wright	WE-12915	0.5	1.90	1.30	14.0	0.75	10,500	12.5
	Repco	SA	0.5	1.90	1.15	13.7	0.70	10,000	12.0
Bulgur									
	Repco	BG	0.5	1.70	1.10	0.0	0.70	10,000	5.0

The length of time indicated for how long a vitamin premix batch is normally stored prior to use was: 3 for less than 2 weeks, 7 for 2 to 4 weeks, 6 for 4 to 8 weeks and 2 for more than 8 weeks. The maximum amount of time a premix lot was stored before being used was: 1 less that 2 weeks, 4 for 4 weeks, 4 for 8 weeks, 2 for 3 to 6 months and 4 for one year. The vitamin A in a premix can lose activity about the same rate as it can when added to a dry commodity.[20] Serious vitamin A loss can result after a couple months. These results indicate that most plants will use up the premix in that period, but some will not and these could have low vitamin A levels as a result unless they increase the premix addition rate accordingly.

[20] The rate of vitamin A loss depends on the type of vitamin A product employed and the storage conditions of the premix, so loss can vary greatly from plant to plant.

All of the plants said their premix supplier provided a certificate of analysis (COA) on every lot of material, but this is no guarantee that the premix has the proper amount of vitamin A by the time it is used after extended storage. There was one case reported where the premix was found to be low in vitamin A after low vitamin A levels were found in the fortified product. Normally, plants do not have the vitamin A levels in the premix checked by a second lab. One reason is that most labs outside of premix suppliers are not experienced at testing this type of sample.

Analytical Laboratories (question #4)
The following labs were used to test vitamin A in fortified products. The number after each lab indicates the number of times the lab was mentioned.

ADM Arkady (1)
American Ingredients (1)
Barrow-Agee (1)
Bunge (1)
Cereal Ingredients Laboratory Services (3)
Doty Laboratories (2)
ITS Intertek (1)
Research Products (6)
USDA FGIS (4)
Watson Foods (1)

Seven of the producing companies and 12 of the plants had done comparative laboratory testing or used more than one lab for testing. Four of the plants indicated they have not done this.

Proportion of lots tested (question #6)
12 of the responses said they tested 100% of the lots. One said they started off testing 100% but reduced that to 33% as they became more confident in the results. One said 50% and one said it ranged from 13% to 70% depending on the product.

Sampling (question # 7)
8 responses said they use a composite sample, similar to what USDA used to take. Two said they use a single grab sample.

Protocol and actions on assay failure (questions #8, #9 and #10)
All of the plants said they have a written protocol on fortification. Six companies said they had product failing assay during this period. One plant said they had 40 instances of lots that failed; another said 11 instances. Altogether, 60+ instances of lot failure were mentioned. The actions indicated in case a lot assay failed (with the number of times mention in parentheses) that were mentioned were: retesting (5), resampling (1), holding (1) and reworking (1).

Quality control procedures (questions #11 and #12)
All plants said they check the addition rate on the fortification premix feeder. Frequency of the check ranged mostly from every hour to once an 8 hr. shift, but one said weekly and one said monthly. 13 out of 16 responses said they run qualitative iron spot tests on the fortified commodity. The other 3 said they did not do this. Most said they run it on every lot.

TQSA audits (question #13)
11 of 16 plant said they had a TQSA audit in the last six months, with 9 of the 16 reporting that it included a review of micronutrient fortification.[21]

Process and equipment changes (question #5)
The main process change, mentioned by a number of the plants, was to increase the premix addition rate for wheat flour. A typical increase was to add 2 g/cwt or 14% more premix. This would result in 11,400 IU/lb of vitamin A being added assuming no loss, and cost the mill roughly $0.70 more per metric ton of flour fortified. This change was most common with the premix designed to add 10,000 IU/lb (see above table).

Another method used by one of the producers was to have the vitamin A content in the premix increased so that it added 12,000 IU/lb. Both methods helped insure that the new minimum vitamin A standard would be achieved by adding higher levels than used in the past. The average vitamin A content in wheat flour of 12,220 IU/lb corresponds nicely with these addition levels.

Two of the plants reported installing new equipment, one a feeder at $20,000 and the other a new mixer. The two bulgur plants made the most changes in order to get the vitamin A levels in compliance with the new specifications.

[21] The USDA said that all PL480 production plants would have by now had at least one TQSA audit, and all should have included a fortification review.

APPENDIX C

PR

FORTIFIED PL480 USDA PROCUREMENT FOR JULY 1 TO DECEMBER 31, 2000

			3rd Quarter 2000		***4th Quarter 2000***	
Product	***Producer***	***Mill***	***Contracts***	***Metric Tons***	***Contracts***	***Metric Tons***
Bulgur	ADM	Abilene	4	9,990	3	28,120
	Lauhoff	Crete	1	2,090	1	790
Bulgur-soy fortified	ADM	Abilene	2	5,210	2	5,750
	ADM	Crete	1	3,770		
TOTAL BULGUR				**21,060**		**34,660**
CSB	ADM	Milwaukee	3	3,810		
	Bethel	Benton	7	37,730	4	4,940
	Lauhoff	Crete	1	3,400	1	1,090
	Didion	Cambria	4	41,070	1	1,080
	Lauhoff	Danville	5	20,190		
TOTAL CSB				**106,200**		**7,110**
Cornmeal	ADM	Milwaukee	1	450		
	Agricor	Marion	2	560		
	ConAgra	Atchinson	1	1,380		
	Didion	Cambria	2	7,000	1	4,000
	Lauhoff	Danville	1	420	2	895
	Bethel	Benton			1	2,130
Cornmeal-Soy Fortified	ADM	Milwaukee	2	3,070		
	Didion	Cambria	2	3,770		
	Lauhoff	Danville	1	1,090	4	8,630
TOTAL CORNMEAL				**17,740**		**15,655**

Appendix C continued - *Fortified PL480 USDA Procurement*

Product	Producer	Mill	3rd Quarter 2000 Contracts	3rd Quarter 2000 Metric Tons	4th Quarter 2000 Contracts	4th Quarter 2000 Metric Tons
Wheat Flour - AP	ADM	Inman	4	13,410	2	3,310
	ADM	Salina	3	5,820		
	ADM	North Kansas City	4	8,300	2	6,080
	ADM	Mount Vernon	3	5,000	1	1,000
	ADM	Des Moines	2	1,750		
	ADM	Destrehan	1	750		
	ADM	Arkansas City	8	4,730		
	Bartlett	Coffeyville	4	15,070	2	3,530
	Cargill	Wichita	4	19,080	2	6,130
	Cenex	Galena Park	2	15,000		
	Cereal Foods	Wichita	2	810	1	2,170
	ConAgra	Commerce City	3	8,130	1	3,000
	ConAgra	Alton			1	1,360
	ConAgra	North Kansas City			1	1,090
	General Mills	Kansas City	5	6,380		
Wheat Flour - Bread	ADM	Des Moines	1	1,240		
	ADM	North Kansas City	1	6,970		
	ADM	Salina	2	2,780		
	ADM	Chattanooga	1	1,360		
	Bartlett	Coffeyville	1	5,000		
	Cargill	Wichita	2	10,530		
	Cargill	Lake City	1	450		
	ConAgra	Commerce City	2	6,000		
TOTAL FLOUR				**138,560**		**27,670**
Sorghum Grits-SF	ADM	Plainview	2	4,000		
	Cereal Foods	Wichita	1	1,360		
TOTAL SORGHUM				**5,360**		**0**
WSB	ADM	North Kansas City	3	1,300		
TOTAL WSB				**1,300**		**0**

Key to Appendix C Columns

Column Number	*Column Heading*	*Description*
1	Company Plant	The number refers to the company and the letter to a particular plant of that company.
2	Product	The fortified PL 480 product produced by the plant. Some plants produce more than one product.
3	MT-USDA	The metric tons of procurement reported by the USDA for the third quarter of 2000.
4	MT-mill	The metric tons of production reported by the plants for the third quarter of 2000
5	Premix	The pounds of the fortification premix the company reported using on that product for that period.
6	Lots	The number of different lots produced in that period.
7	Lab	A code for the lab running the vitamin A tests. "Fe" follows the code for iron assays (in mg/lb), otherwise it is vitamin A results (in IU/lb). Lab U is the USDA FGIS lab. The other labs are kept confidential because some of them represent the producing company.
8	Number	The number of lot samples for which there are analytical results.
9	Mean	The mean or average value, in IU/lb for vitamin A and mg/lb for iron.
10	CV	The coefficient of variation between the different lab results
11	Diff	* or different letters indicates that the results from the different labs are significantly (P=5%) different from each other. Similar letters means no difference. "nd" indicates no difference.
12	STD	The standard deviation, in IU/lb for vitamin A and mg/lb for iron.
13	COV	The coefficient of variation, or the STD as a percent of the mean.
14	Min	The minimum value, in IU/lb for vitamin A and mg/lb for iron.
15	Max	The maximum value, in IU/lb for vitamin A and mg/lb for iron.
16	Kurt	A measure of kurtosis. The kurtosis of a data set measures a distribution's closeness to normality, indicating relative peakedness or flatness. It is in the same units as the measurement. Kurtosis is a measure of the heaviness of the tails in a distribution relative to the normal distribution. A distribution with negative kurtosis is light-tailed relative to the normal distribution, while a distribution with positive kurtosis is heavy-tailed relative to the normal distribution.
17	Skew	A measure of skewness. Skewness characterizes the degree of asymmetry of a distribution around its mean value. It ranges from -1 to +1. A positive result means that the distribution is skewed to the right (the median is less than the mean). A negative result means that the distribution is skewed to the left (the median is greater than the mean).When skewness is 0 the distribution is symmetrical around its mean. Data from a positively skewed (skewed to the right) distribution have values that are bunched together below the mean, but have a long tail above the mean. Data from a negatively skewed (skewed to the left) distribution have values that are bunched together above the mean, but have a long tail below the mean.
18	%Under	The theoretical percentage of the lot samples that would fall under the minimum standard assuming a normal distribution.

APPENDIX D

SUMMARY OF RESULTS ON PL480 PRODUCTION FROM JUNE 1 TO AUGUST 31, 2000

Key: 1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**
Plant	***Product***	***MT-USDA***	***MT-mill***	***premix***	***Lots***	***Lab***	***Number***	***Mean***	***CV***	***Diff***	***STD***	***COV***	***Min***	***Max***	***Kurt***	***Skew***	***%Under***
1A	Bulgur	15,200	5,580		27	K	27	10,374	26	*	1,534	14.8%	7,459	14,224	1.38	0.91	15.2%
						W	27	7,941		*	1,855	23.4%	3,771	11,175	-0.41	-0.46	67.8%
1B	Corn Meal	3,520			130	K	112	11,058	16	nd	1,695	15.3%	8,984	21,064	12.12	2.77	9.1%
						W	25	10,527		nd	1,888	17.9%	8,610	14,361			18.0%
	CSB	3,810			20	K	20	11,590			1,830	15.8%	8,856	15,374	-0.71	0.39	4.1%
						W	2	10,449			330	3.2%	10,215	10,682			
						K-Fe	20	15.2			0.3	1.8%	14.7	15.6	-1.09	-0.00	4.1%
						Fe	2	24.9			4.7	19.1%	21.5	28.2			
1C	WSB	1,300			48	K	46	11,458	34	a	1,922	16.8%	9,028	17,701	1.63	1.44	5.6%
						K-Fe	33	15.6			0.5	3.1%	14.7	16.8	-0.02	0.18	3.1%
						U	30	7,050		b	1,368	19.4%	4,760	9,870			83.8%
						W	16	8,002		b	2,230	27.9%	4,380	12,040	-0.20	-0.05	57.1%
	Wheat Flour	15,270	2,505		64	K	51	12,095			2,531	20.9%	4,722	18,253	0.94	0.26	7.2%
						U	62	11,046			1,756	15.9%	7,300	14,900	-0.57	0.15	6.6%
						W	16	12,753			4,279	33.6%	8,606	25,891			15.5%
1D	Sorghum	4,000	5,000		65	K	48	10,720	27	a	1,793	16.7%	8,068	16,062	1.72	1.34	9.8%
						U	65	9,952		ab	2,074	20.8%	5,300	15,300	0.04	0.06	22.7%
						W	24	9,379		b	2,118	22.6%	6,247	13,668	-0.58	0.45	32.2%
1E	Wheat Flour	8,600	9,800		71	K	59	12,134			2,278	18.8%	9,015	18,990	0.49	1.06	5.1%
						U	62	9,602			4,832	50.3%	980	18,200	-1.23	-0.54	40.2%
						W	20	12,216			2,250	18.4%	8,555	16,092	-0.95	0.09	4.5%
1F	Wheat Flour	13,410			217	K	118	12,469			1,952	15.7%	8,960	19,922	2.23	1.28	1.9%
						U	148	13,440			1,724	12.8%	9,820	17,700	-0.82	0.11	0.2%
						W	16	13,472			1,970	14.6%	10,523	16,895			0.5%
1G	Wheat Flour	2,990			3	K	2	12,251			364	3.0%	11,993	12,508			
						U	2	16,699			2,601	15.6%	14,859	18,538			

Appendix D continued

Key: 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Plant	***Product***	***MT-USDQA***	***MT-mill***	***premix***	***Lots***	***Lab***	***Number***	***Mean***	***CV***	***Diff***	***STD***	***COV***	***Min***	***Max***	***Kurt***	***Skew***	***%Under***
1H	Wheat Flour	4,730			65	K	27	12,165			1,384	11.4%	9,288	14,953	-0.06	0.28	0.3%
						U	65	12,657			1,973	15.6%	3,230	15,200	12.40	-3.21	1.5%
						W	4	13,311			953	7.2%	12,567	14,676			
1I	Wheat Flour	0			30	K	22	11,612			1,229	10.6%	9,909	14,674	0.86	0.95	0.4%
						U	30	12,851			2,049	15.9%	6,110	16,100	2.69	-1.24	1.5%
						W	8	14,102			1,766	12.5%	11,642	17,058			0.1%
2A	Wheat Flour	560	1,000	700		S	17	10,359			1,467	14.2%	9,000	13,500	0.48	1.26	9.1%
						U	2	15,670									
3A	Wheat Flour	20,070	13,122	940		X	10	14,050			1,189	8.5%	11,500	15,000	0.87	-1.14	0.0%
4A	CSB	37,730	30,901	68,150		X	87	15,128			1,889	12.5%	9,530	21,690	1.66	-0.04	0.0%
						X-Fe	87	18.0			2.2	12.0%	14.9	27	2.59	1.14	6.2%
4	Corn Meal	0	400	300		X	3	20,732			608	2.9%	20,030	21,110		-1.72	
5A	Wheat Flour	0	5,155	4,262		X	29	12,362			1,631	13.2%	9,500	15,000	-0.83	-0.55	0.8%
						U	47	11,424			1,167	10.2%	8,770	13,100	-0.79	-0.57	0.5%
5B	Wheat Flour	0	1,156	800		X	20	12,450			1,224	9.8%	9,000	14,000	2.06	-1.36	0.0%
5C	Wheat Flour	0	6,214	4,818		X	89	12,517			1,455	11.6%	9,000	15,000	-0.32	-0.58	0.2%
5D	Wheat Flour	0	1,836	1,200		X	27	13,315			1,488	11.2%	9,000	16,000	1.68	-1.02	0.0%
5E	Wheat Flour	0	3,279	1,550		X	32	13,109			1,844	14.1%	9,000	15,500	-0.18	-0.93	0.5%
5F		29,610	0														
5G		450	0														
6A	Wheat Flour	15,000				U	14	12,127			1,511	12.5%	9,780	13,800	-1.73	-0.48	0.7%

Appendix D continued

Key: 1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**
Plant	***Product***	***MT-USDA***	***MT-mill***	***premix***	***Lots***	***Lab***	***Number***	***Mean***	***CV***	***Diff***	***STD***	***COV***	***Min***	***Max***	***Kurt***	***Skew***	***%Under***
7A	Wheat Flour	810	3,958	3,100		U	57	10,664	19	c	1,529	14.3%	7,430	13,500	-0.33	-0.27	6.9%
						X	58	12,759		a	1,339	10.5%	9,500	16,000	1.02	-0.72	0.1%
						W	43	11,942		b	2,790	23.4%	8,011	18,952	0.53	1.14	10.2%
7B	Wheat Flour	0	2,225	1,750		U	33	10,274	17	b	1,400	13.6%	7,170	12,600	-0.97	-0.22	9.0%
						X	32	12,594		a	1,139	9.0%	11,000	16,000	1.65	0.99	0.0%
						W	31	10,382		b	1,371	13.2%	8,660	14,266	0.70	1.06	7.4%
8A	Wheat Flour	0															
8B	Wheat Flour	14,130	6,078	4,427		X	65	13,415	19	*	1,780	13.3%	9,000	17,000	-0.06	0.14	
						U	65	10,896			798	7.3%	8,870	12,200	-0.55	-0.59	
9A	CSB	41,070	21,956	47,650		M	13	18,440			2,348	12.7%	12,910	21,840	1.34	-0.94	0.0%
						M-Fe	13	17.9			3.5	19.7%	9.8	24.1	1.49	-0.59	18.4%
9	Corn Meal	10,770	10,191	7,250		M	12	20,498			1,010	4.9%	18,260	21,640	1.20	-1.23	
10	Wheat Flour						no data supplied										
11A	CSB	20,190	9,103	23,130	201	L	33	13,422			2,308	17.2%	9,651	17,664			1.5%
						L-Fe	85	20.8			5.9	28.4%	14.8	53.5	11.42	2.73	15.1%
11A	Corn Meal	1,510	6,542	5,470		L	25	13,953			1,195	8.6%	11,440	16,571	0.53	0.42	0.0%
11B	CSM	3,400	13,256	56,000	73	L	61	14,482			2,668	18.4%	9,080	25,990	5.66	1.91	1.1%
						U	15	13,380			1,581	11.8%	10,800	16,600	0.07	0.37	0.1%
						L-Fe	60	19.8			3.1	15.9%	14.9	32.2	6.99	2.14	5.3%
						U-Fe	9	17.7			2.6	15.0%	13.7	20.7	-1.42	-0.12	13.1%
11B	Corn Meal	0	2,100	2,180		L	7	11,800			2,033	17.2%	9,810	15,700	1.72	1.30	4.7%
						L-Fe	7	16.3			1.9	11.5%	14.2	19.1	-1.34	0.64	20.3%
11B	Bulgur	0	9,350	17,091	112	L	82	12,832			4,745	37.0%	6,060	43,240	20.09	3.41	17.5%
						U	79	10,420			5,081	48.8%	0	31,640	3.78	1.36	34.5%
						W	9	12,002			1,632	13.6%	9,500	14,760			1.4%
						L-Fe	42	21.4			3.2	14.7%	14.9	28.7	-0.31	-0.04	1.7%

APPENDIX E

SUMMARY OF NOVEMBER 2000 MEETING WITH USDA ON TQSA

A meeting was held on November 8, 2000 in Kansas City with USDA personnel involved with commodity procurement and the TQSA program. The objective of the meeting was to brief personnel from USDA's KCCO on the Voluntary Review being conducted by SUSTAIN on producer's compliance with micronutrient specifications, and for SUSTAIN to better understand the TQSA program as it applies to micronutrient levels in fortified P.L.480 commodities.

Representatives:

USDA

Austen Merrick – Chief of Export Operations
Nelson Randall – Contracting Officer
Ned Bergman – Chief of Examination Branch
Ted Carlton – Supervisor of Audits
Jim Riva – TQSA expert
Lynelle Stealth – Auditing scheduling
Tim Mehl – Chief of warehouse inspections
Lynn Polston – FGIS Laboratory

SUSTAIN

Liz Turner
Peter Ranum

Voluntary Review of Producer's Compliance with Micronutrient Specifications

Liz and Peter described the objectives for the voluntary review of producer's micronutrient test data. The review has been commissioned by USAID to help evaluate P.L.480 Producer compliance with the new micronutrient specifications. USDA personnel appreciated the up-date and said they had some knowledge of the MAP study, but were not aware of the follow-up activity. They also mentioned that they have noticed more inquiries about the quality of food aid commodities and were interested in hearing any thoughts or recommendations SUSTAIN might have about the TQSA program.

TQSA Audits

There are different types of plant audits ranging from a general, initial one to surveillance ones in response to specific problems. Each audit has a multiple point checklist that takes a team of two auditors eight hours to complete. It covers all aspects of production and quality assurance. This results in a score on a 100-point scale. A plant fails with a score below 70 and is not approved to be a government vendor. The frequency of audits increases with lower scores. In the case of finding a specific non-compliance, the plant has ten days to respond on how they plan to correct it. Plants are asked to run mock recalls yearly. Auditors have the option of pulling a sample and having it tested. At the present time, the FGIS lab has the capability to test vitamin A; however, it may discontinue this service due to low sample volume and financial constraints.

The audit includes questions related to fortification, such as:

1. Who is your premix supplier?
2. How and why did you choose them?
3. Do you get COAs on fortification premixes?
4. Do you rotate your premix stock? How?
5. How much premix was used during a time period and how much product was produced during that period.
6. Show us invoices for the premix purchased since the last audit.
7. Is the premix lot traceable?
8. Do you take production samples for testing?
9. How do you take them?
10. How are they handled and stored?
11. What are they tested for? By whom?
12. How do you know the test method is properly calibrated?
13. Has the laboratory been audited?
14. What do you do with non-conforming analytical results?
15. What equipment do you use to add the premix?
16. How is it calibrated to a correct addition rate?
17. Who checks the calibration?
18. What training is provided for feeder calibrations?

At the time of this meeting the USDA had not performed any TQSA audits on premix suppliers or analytical laboratories. They said they would do an audit on these if requested by the processing plant, or volunteered by the premix supplier or lab itself.

There was a discussion on the percentage of the lots that should be tested for micronutrients. Some of the USDA people, like Nelson Randall, believed this should be 100%, while others, like Jim Riva, believed the percentage could be reduced if past results showed there was no problem and production consistently met specifications. Better guidelines on this are needed.

There was a mutual concern about the validity of the vitamin A testing and how that could be better assessed under TQSA. There was discussion of possibly using the AACC vitamin methods committee as a way of assessing methodology used by the different labs. Possible procedures include:

1. Routine testing of an AACC check sample with vitamin A.
2. Each lab sending HPLC chromatographs to the committee for evaluation.
3. Set up collaborative study on samples with different vitamin A levels and types.

USDA representatives said that, it is not the job of TQSA to specify how to sample products or by what method they should be tested. This makes the requirement of a standardized test method difficult. But the producers and labs need to show proof that the sampling and analytical methods employed are valid. The current method being used for this is to have two or more labs run the same samples. If both results show the sample is within specifications the method is believed to be valid.[22]

[22] The problem with this is that all of the samples submitted for laboratory testing are supposed to be properly fortified. The labs know the vitamin A levels should be above the minimum. Labs that report lower values or widely varying values might be "deselected" as the lab of choice to use in testing. Ideally, labs should be sent occasional samples with known and varying levels of vitamin A (some very low and some very high) as a check of their method, but this has not been done to our knowledge.

APPENDIX F

USDA DESCRIPTION OF TQSA

The Total Quality System Audit (TQSA) program is used to evaluate the supplier's ability to supply an acceptable quality product on a continual basis. One requirement of some of the product purchased by the USDA includes the addition of micronutrients at a specified level outlined in the product specification. This requirement is the responsibility of the supplier and is meet and verified using their quality system that has been audited by the TQSA program. Since the addition of micronutrients is just one requirement of the product announcement and specification the level of acceptance can be evaluated by using a combination of elements of the TQSA checklist. I have listed elements and question numbers of the checklist and outline where they would be relevant to the requirement of addition of micronutrients in USDA product. If you have any other questions please call. James Riva 202-720-3774

Element 4.3 Contract Review

<u>Question 1,3,4,5</u>
During an audit auditors review the processes in place conducted by the vendor to ensure that the right people in the plant understand the contract and specifications. This would pertain to the requirement for the addition of micro nutrients in the commodity and the required level.

<u>Question 2</u>
Domestic origin of all ingredients is reviewed during the audit. The supplement premix that is added to meet the requirement is traced back through records to verify it meets the requirements. During this process auditors will review that the supplement is purchased in quantities that would equate to the amount needed to meet specifications

Element 4.6 Purchasing

<u>Questions 1,2,3,4,5</u>
Vendors evaluate and select subcontractors, or in this case, suppliers of product, based on the product's ability to meet the requirements. Auditors review purchase order to verify that the proper nutrient premix was order and delivered. Documents reviewed indicated the amount needed to meet the required levels. Testing methods and their results of the premix ingredients are also reviewed during the audit.

Element 4.9 Process Control

<u>Questions 1, 2,3</u>
Process control is a very important part of the vendors operation. Auditors will evaluate the written process controls (procedures) and observe the vendor performing the procedures. In the case of addition of micronutrients the auditor will observe the

introduction of the premix into the product and determine if the process is in control and if the documented procedures are being carried out as written. If the premix feeder is set to run at a certain speed the auditor will check how the vendor verifies this, and will then compare the amount of premix used to the amount indicated by written procedures and formulas.

Question 4
A planned preventive maintenance system is reviewed during all audits. It is important to the USDA food program that processing activities such as automatic feeders of premix micro nutrients are included in preventive maintenance plans. This is to ensure the correct levels of premix are being added throughout the process on a consistence basis. Records and computer generated schedules for maintenance are reviewed and compared with actual operations performed in the plant

Question 7, 8
The work environment is reviewed during every audit, which is evaluated according to its cleanliness and organization. Good Manufacturing Practices (GMP) polices and their level of adherence are also reviewed. These two requirements are a very good indication of the overall operation of the facility and are considered a very important part of the TQSA audit.

Element 4.10 Inspection and Testing

This element of the TQSA checklist covers all the inspection and testing of product throughout the process from incoming product, to inline testing to the final inspection and testing of the finished product. It also addresses the issue of which type of laboratory facility the vendor can and does use.

Question 1
Incoming materials must be checked to verify that it meets the needs of the vendor and in USDA’s case the specification. Records reviewed during the audit will indicate that incoming material, premix micronutrients, have been check to verify that they will meet the end item requirements. A random selection of test results will initially be reviewed by the auditor. This will indicate to the auditor if the process is in control and whether the vendor is supplying an acceptable product to the USDA.

Element 4.11 Inspection, Measuring, and Test Equipment

Question 7
The addition of the Micronutrients could involve both weight scales and the speed of an automatic feeder auger. During the audit the auditor will review and verify that all scales have been checked, adjusted and that they are accurate. The operations of the automatic feeders will be reviewed, maintenance records and the method used to verify the speed of the automatic feeders will be reviewed.

Element 4.15 Handling, Storage, Packaging, Preservation and Delivery

Question 1 - 9
USDA products that have had micro nutrients added to them must be handled and packaged in a way to prevent deterioration of the micro nutrients. The audit process will review the blending, packaging, storage of both the finished product and the premix product, and the processing floor to verify that the product is being handled in a manner that would ensure the integrity of the added ingredients and protect the level of added micro nutrients from deterioration.

Element 4.16 Control of Quality Records

Questions 1,5
An extensive review of quality records is conducted during every audit. This includes certificates of conformance, certificates of analysis, control charts, inspection records, lab results and all contract specified records. Laboratory results indicating the level of micro nutrients in the finished product along with any other testing performed by the vendor on incoming, in process or finished product would be reviewed during each audit.

Element 4.17 Internal Quality Audits

Questions 1,2,3,4,5,6
Internal Quality Audits performed by the vendor are reviewed and compared with finding of the TQSA auditor during the current audit. This is a very important part of the quality system and indicates the level of commitment to the quality system by the vendor. It is a good overall review of the quality system in place and the ability of the system to supply an acceptable product to the USDA on a continual basis.

Element 4.18

Questions 1,2,3,4
The plant personnel training program at the vendors facility is reviewed with close attention being paid to personnel performing activities affecting quality. Training records are reviewed. Records of personnel performing laboratory or sampling procedures are reviewed and evaluated as to their compliance to the TQSA checklist. In-plant laboratory facilities are audited, interviews are conducted and certificates of compliance reviewed.