



**CPS 2009 RFP
FINAL PROJECT REPORT**

Project Title

Using leafy green marketing agreement audit data to determine non-compliance areas and preparation of training and recommendations for improvements in future growing seasons

Project Period

October 1, 2009 – June 30, 2012

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Objectives

1. Develop an acceptable plan for assuring audit data confidentiality with LGMA, CDFA, and CPS.
2. Determine if there are regional or other identifiable trends in compliance data.
3. Prepare training tools and use them to conduct region-specific producer workshops sponsored by LGMA and CPS.
4. Prepare recommendations for changes to the metrics and/or the audit methodology based on project results.

FINAL REPORT

Abstract

In 2009, Intertox was awarded a grant by the Center for Produce Safety to evaluate the Leafy Greens Marketing Agreement (LGMA) audit data. The grant entitled, “Using Leafy Green Marketing Agreement Audit Data to Determine Non-Compliance Areas and Preparation of Training and Recommendations for Improvements in Future Growing Season,” was funded under the U.S. Department of Agriculture’s Specialty Crop Block Grant Program. The Intertox grant calls for an evaluation of the data collected by the California Department of Food and Agriculture (CDFA) during audits of lettuce and other leafy green producers to determine if there are more efficient and effective methods that could prevent the microbial contamination of these crops. As part of the grant, Intertox worked jointly with the CDFA and the LGMA to obtain confidential audit data, analyze the data identifying trends and compliance issues, review previous training and develop new training material, and provide the LGMA with recommended changes to the best practices and/or the audit document. The overall project objective is to ensure leafy greens are safe for consumers while reducing audit compliance costs for producers and handlers.

Fundamental to the project was the utilization of benchmarking, a quality improvement process technique. Audits were scored to establish industry benchmark levels, and efficiency gaps were identified. Results provide handlers and growers with information that will allow them to learn from each other. The results and recommendations should also be viewed as providing opportunities for improvement that if implemented could lead to cost reductions. Based on the benchmarking and gap analysis, several training-related recommendations were made including:

- To reduce audit compliance costs for producers and handlers, the gap between benchmarked performance and optimal performance needs to be narrowed.
- In order to narrow the gap, training should be a combination of supply chain-specific training and functional training, i.e., handler-specific supply chain training to improve operational efficiencies and functional training to address specific areas such as worker practices that continue to affect audit results.
- The handler-specific supply chain training and the functional training could be outsourced to minimize handler costs. The LGMA, while not currently staffed to manage the expanded training, should be viewed as a strategic option for housing the additional training.
- Opportunities for functional training opportunities include worker-related training, testing (e.g., harvest equipment sanitation), documentation, and third party management. Training content was outlined for each of the areas.
- LGMA focused Internet-based tools could support the audit program, streamline paperwork requirements, reduce audit compliance costs.

Additional recommendations were suggested for changes to the LGMA program including:

- Certifying suppliers (e.g., harvesters, compost companies) to validate quality levels
- Establishing a process to use observations from audits to address industry issues
- Consider developing a mechanism for scoring the audit checklist to focus on the known contributors to food safety issues
- Providing grower and harvest company data to LGMA staff for training purposes

Background

Following the *E. coli* outbreak associated with California-grown spinach in September 2006, members of the leafy green industry in California and Arizona worked collaboratively with the U.S. Department of Agriculture (USDA) and the U.S. Food and Drug Administration (FDA) to develop best practices for the safe production of leafy greens. The best practices were developed using the FDA's *Guide to Minimize Microbial Food Safety Hazards in Fresh Fruits and Vegetables* as a framework. The guidelines were modified to specifically address leafy greens based on the available science and knowledge of actual growing operations and conditions. Once completed, the best practices were certified by the USDA. The California and Arizona Leafy Green Marketing Agreements (LGMA) were adopted and a management oversight organization was created in 2007. Today handlers representing 99% of California's leafy greens reaching consumers are members of the LGMA (LGMA Annual Report 2010). While membership in the LGMA is voluntary, members must conform to LGMA best practices in order to remain a member in good standing. After five years of operation, the LGMA is accepted as a leafy green standard in California and is a buyer requirement not only in the U.S., but also when exporting to Canada and Mexico.

The LGMA audit program is based on the *Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens* (the Metrics) (LGMA 2010). These guidelines contain best practices that would be part of a Good Agricultural Practice (GAP) program for a leafy greens growing operation. The LGMA guidelines were first introduced in March 2007 and revised several times prior to 2008. The best practices and the resulting audit checklist are organized to address general requirements, environmental assessments, water use, soil amendments and non-synthetic crop treatments, harvest equipment, field and harvest personnel, equipment and cross-contamination, flooding, and production locations.¹ To verify compliance with the LGMA best practices, a California Department of Food and Agriculture (CDFA) audit program was established. The first audits were conducted in 2007 as informational audits. Official audits began in July 2007. From September 2008 through March 2011, 1,382 audits were completed.

Audits vary in several ways. They can be conducted at the start of the season, during the harvest season, and post-harvest; they are announced or unannounced; and they can be part of a rotational schedule or follow-ups to verify a corrective action plan (CAP). Auditors use the audit checklists to conduct audits for both announced and unannounced audits (LGMA checklist 2008, LGMA checklist 2010). Data from the individual LGMA audits are entered into the database by CDFAs auditors. An LGMA Compliance Officer then analyzes the input and assigns a "level" or grower response if any is required. Handlers can view the records and interact with the LGMA Compliance Officer to respond to the audit findings. At this time, growers do not have access to the online audit results.

There were four primary goals for this audit data project: 1) To collaborate with the LGMA, the CDFAs, and the CPS to obtain confidential data for analysis, 2) To complete a statistical analysis of the data for trends and compliance issues, 3) To prepare training tools and training sessions for growers, and 4) To recommend changes to the Metrics and/or audit methodology based on results.

¹ The document entitled, "An Overview of the LGMA Audit Data Program," describes the LGMA audit program and the data collection methodology and processes, and is supplementary to this final report.

Research Methods and Results

The methodology consisted of statistical analysis, followed by benchmarking, gap, and root cause analysis. The dataset was first evaluated for trends. Then the data were scored and benchmarking levels were developed. Deviations from benchmarking levels were examined (gap analysis) as well as the underlying root causes. The results of the analyses were used to develop training recommendations for addressing deviations from benchmarks.

The LGMA Audit Data

The data received for the project contained audit results from September 2008 through March 2011 audits. Data fields included: an audit identification number, a date for the audit record, the grower name, the status of the audit, whether a CAP was required, the type of audit (scheduled or unannounced), comments on audit findings (email exchanges between handlers and compliance officer), question (audit checklist reference question), details (auditor explanations about the audit line item), level assignment (deviation or violation level assigned), level comment (comments from the compliance officer), and handler responses. Before Intertox had access to the data, Intertox Decision Sciences (IDS), a separate company, acquired the data from the LGMA and scrubbed proprietary details including grower and handler information. Each grower's name was replaced with a random number. No test result information or any location details were provided to Intertox.

After examining the data, it was determined that the relationship between the LGMA handler and the grower (ownership, number of years working with a particular grower) might have an impact on the audit results; however, data detailing the individual relationships were not available for this project. (The relationship between handlers and growers and the impact on supply chain effectiveness as it relates to LGMA results and quality in general would be an interesting subject for future work.)

Data Limitations

Potential for bias – Auditing is a human process and as such is subject to biases. Auditors, the auditing supervisor, the compliance officer, handler food safety personnel, grower food safety personnel, and third party suppliers all have the potential to affect the data and ultimate audit results.

Seasonality - Leafy green crops are grown in several counties in California. Growing mostly occurs in the north during the spring through early fall and in the south during the fall and winter. In the statistical analysis, efforts were made to separately examine the two growing areas; however, seasonality influences and hence regional influences were not accounted for throughout the benchmarking analysis.

Using audit results to measure food safety program performance - In quality programs, audits should not be used as the only measurement of performance. Growers, handlers, and others in the leafy green supply chain need to routinely measure and track performance against their own food safety metrics. Since audit results are measurements made at a particular moment in time and are not regular or continuous measurements, the results may miss critical performance issues or overstate the significance of issues that are captured. However, tracking audit results over time should tend to adjust for overstatements or understatements relating to the results.

No scoring methodology has been established to facilitate comparisons across audits and over time and to support prioritizing the checklist issues – More than 300 questions are included in the announced and unannounced audit checklists; however, without a scoring methodology, it is difficult to compare findings and prioritize issues. While efforts have been made to develop a means to

compare findings across audits and over time throughout this project, the LGMA and the CDFR auditors may not agree with the specific method applied.

Limited predictor variables – The limited data fields available for this study constrained the type of analyses that could be performed.

Statistical Analysis

Between the third quarter of 2008 and the first quarter of 2011, a total of 1,382 audits were conducted for a total of 303 growers. Of these, 1,220 were scheduled audits and 162 were unannounced audits. A total of 214 growers underwent scheduled audits only (ranging from one to 24 audits), 3 growers underwent unannounced audits only (each had only one audit), and 86 growers underwent both scheduled and unannounced audits (ranging from a total of two to 31 audits). Overall, each grower underwent between 1 and 31 audits, with a mean of 4.5 ± 4.4 audits, and a median of 3 audits, per grower. The mean number of scheduled audits was 4.0 ± 3.7 , and the mean number of unannounced audits was 0.5 ± 1.0 , per grower. Of the 303 growers, 170 (56.1%) were audited during the April-November (North) growing season only, and 62 (20.5%) were audited during the December-March (South) growing season only. Seventy-one growers (23.4%) were audited during both growing seasons. Most of the audits were also conducted during the North growing season (71% vs. 29% during the South growing season).

Excluding “blanks,” a total of 4,290 “levels” were assigned during the audits (comprised of the categories: potentially flagrant violation, major deviation, minor deviation, minor infraction, no violation, and observation). Of these, 2,956 were some type of violation (i.e., potentially flagrant violation, major deviation, minor deviation, or minor infraction). There were 1,071 observations and 263 “no violation” assignments. The overall mean number of violations per audit was 2.14 ± 2.79 . On average, the rate was higher for audits conducted during the South growing season (mean = 2.35 ± 2.35) than during the North growing season (mean 2.05 ± 2.55). The average number of violations per audit was also higher for scheduled audits (mean 2.26 ± 2.91) than for unannounced audits (mean 1.25 ± 1.39).

A total of 42 “main” questions were asked in the scheduled audits, in seven categories.² Of the audit categories, Field Observations comprised the greatest number of violations (n = 1,078, or 39.2% of the 2,753 violations recorded during the scheduled audits), followed by Water Use (n = 633, or 23.0%), Field Sanitation (n = 387, or 14.1%), Worker Practices (n = 308, or 11.2%), Soil Amendments (n = 146, or 5.3%), Environmental Assessments (n = 114, or 4.1%), and General Requirements (n = 87, or 3.2%). Five “main” questions were asked in the unannounced audits, and a total of 203 violations were recorded.

In the scheduled audits, the majority (48%) of assigned levels were characterized as “minor deviations” (n = 1,937). Only five potentially flagrant violations were reported (0.12%). A total of 108 major deviations (2.7%) and 703 minor infractions (17%) were reported. “No violations” were reported in 261 cases (6.5%) and observations were reported in 1,026 cases (25%). In sum, 2,753 violations of any level (potentially flagrant, major deviations, minor deviations, or minor infractions) were reported (68.1%).

In the unannounced audits, no potentially flagrant violations were reported. Again, the majority (47%) of assigned levels were characterized as “minor deviations” (n = 117). A total of 20 major deviations (8.0%) and 66 minor infractions (26%) were reported. “No violations” were reported in 2

² The term “main” question is used to indicate questions that are always asked as opposed to “follow-on” questions that are only asked based on the response to a prior question.

cases (0.80%) and observations only were reported in 45 cases (18%). In sum, 203 violations of any level (potentially flagrant, major deviations, minor deviations, or minor infractions) were reported (81.2%), a higher rate than reported in the scheduled audits.

The five potentially flagrant violations recorded during the scheduled audits fell within four audit categories: Field Observations (n =1), Field Sanitation (n =1), General Requirements (n= 2), and Worker Practices (n =1). Three of the potentially flagrant violations occurred during February 2011, and of these, two were recorded for the same grower. The other two occurred during May 2009 and December 2009. Four of the five potentially flagrant violations had to do with documentation—e.g., the availability of policies or plans or a growers list (See Table 1).

Table 1. Characteristics of Potentially Flagrant Violations

Month Reported	Audit Category	Audit Question
May 2009	General Requirements	GR 03 - Is an up to date growers list with contact and location information available for review?
December 2009	Field Observations	FO 04i - No other observations of improper work practices?
February 2011*	Field Sanitation	FS 01 - Is there a written policy for all employees and all visitors in the field location which describes the required field sanitation SOPs?
February 2011*	General Requirements	GR 01 - Is a written Leafy Greens Compliance Plan which specifically addresses the Best Practices of the LGMA available for review?
February 2011	Worker Practices	WP 01 - Is there a written policy for all employees and all visitors to the field location which describes the required hygiene rules?

*Same grower

Of the major deviations, most were categorized as Field Observations (n = 61, or 47.7%). The remaining were, in order, categorized as Water Use (n = 13, 10.2%), Soil Amendments (n = 10, 7.8%), Field Sanitation (n = 8, 6.3%), Environmental Assessment (n = 6, 4.7%), General Requirements (n = 6, 4.7%), and Worker Practices (n = 4, 3.1%). In addition, 20 major deviations were reported during the unannounced audits (15.6%).

As discussed below, for benchmarking purposes, each violation, deviation, infraction, and observation in every audit was assigned a score. The scoring was coded as: potentially flagrant violation = 5 points; major deviation = 4 points; minor deviations = 3 points; minor infraction = 2 points; observation = 1 point; and no violation = 0 points. The scores were then summed by audit. While an “observation” does not reflect noncompliance in most cases (e.g., it may reflect a listing of water test dates or similar information), in some cases it could reflect an issue that needs to be addressed. Since differences in these types of observations were not noted in the database, for the purposes of this evaluation, all observations were assigned a minimal score of “1.” the future, this scoring assignment could be revisited, or criteria for assigning an “observation” vs. “no violation” could be refined.

When evaluating audit scores compiled in scheduled audits for individual growers within a given growing season, the analysis reveals minimal correlation between the score for a specific audit category (e.g., Environmental Assessment, Field Observations, Field Sanitation, General

Requirements, Soil Amendments, Water Use, and Worker Practices) and any other category. The correlation scores that exceed 0.3, indicating at least a moderate linear relationship, are Worker Practices vs. Field Sanitation (correlation score = 0.57, where 1.0 represents a perfect positive linear relationship), and Water Use vs. Field Observations (0.59). For a particular audit, there is likewise minimal correlation between the total score for a specific audit category and any other category. The only correlation that exceeds 0.3 is Worker Practices vs. Field Sanitation (0.56). Thus this analysis suggests that a violation in one category does not appear to increase the likelihood of a violation in another category.

The LGMA Audit Data Analysis as an Analysis of Handler Supply Chains

Each audit is assigned a unique identification number that is organized by grower. This method of organization has an impact on this project given there are varying degrees of vertical integration in the California leafy green industry. Many of the growers are owned and operated by handlers. Other growers are independent and may grow for one or more handlers. However, the data provided for this project do not indicate the relationship between the grower and handler; therefore, it is difficult to know whether the data reflects a grower's food safety practices or a grower's food safety practices modified to meet a handler's LGMA food safety requirements. The distinction is relevant when performing a root cause analysis of why growers/handlers are less effective in a particular area and also when making recommendations for addressing inefficiencies. Ultimately, the handler as LGMA signatory is responsible for product safety and grower performance, but the question remains as to whether both grower and handler need training or just the grower.

Further complicating the audit data analysis is the relationship between growers and harvesters. Harvesting is a significant component of the LGMA best practices and hence also the audit checklist. Again, there are varying degrees of vertical integration among California leafy green handlers, growers, and harvesters. Some handlers own their growing and harvesting operations while others may outsource growing to one company and harvesting to another. This relationship is not captured in the audit results even though harvesting operations are part of individual grower records. As a result, a grower's audit data record may include harvesting operations data even though the harvester could be a separate company without any contractual relationship with the grower.

Finally, added complexity is contributed by other third party companies such as compost suppliers, chemical suppliers (pesticides, fungicides), water supply companies and municipalities, sanitation companies, etc., which can all have a direct impact on the individual audit and hence the audit results. For this reason, while these data are organized by grower, it should be considered reflective of handler food safety practices, particularly how effectively or efficiently handlers are managing their individual supply chains.

Outcomes and Accomplishments

LGMA Audit Data Performance Benchmarking, Gap, and Root Cause Analysis

Benchmarking is a quality process management tool that is used to evaluate where industry process levels are in comparison with ideal levels or customer requirements. Benchmarking identifies the best-in-class companies that are closest to or have achieved the ideal levels. Deviations from ideal levels are identified as "gaps." In order to narrow gaps, companies determine the probable cause (root cause analysis) for each gap and then identify process improvement plans and priorities (Pareto analysis) (Xerox, 1987). Benchmarking, gap, and root cause analysis were all applied to the LGMA audit data results. In this process, individual audits were first scored to develop benchmarks. Next,

deviations or gaps from the benchmarked levels were examined. Finally, each area was studied to discern the probable root cause and opportunities for improvement.

Benchmarking

For benchmarking purposes, each violation, deviation, infraction, and observation in every audit was assigned a score. Based on this scoring system, “0” is an ideal score. Of note, benchmarking as applied here may understate average scores since it does not account for audits where no levels were assigned. Many of the unscored audits occurred in 2011. Between September 2008 and March 2011, audit scores ranged from a low of 0 to a high of 138. Audits scored as a “0” were regarded as “best-in-class.” Seventeen growers were best-in-class growers (scoring a “0” on all audits) representing 5.6% of all growers. The average audit score was 8.6 in 2008, 7.7 in 2009, 5.4 in 2010, and 5.9 in 2011 (note that 2011 data were available for only three months). This information is beneficial to growers that would like to understand how they are performing in comparison to other leafy green growers. By comparing their individual results, growers can understand how large of a “gap” they have compared to the best and others in the industry.

After establishing benchmarks for complete audits, additional benchmarking analyses were conducted based on components of individual audits using the same scoring methodology. In the first analysis of this type, benchmarks were created by audit checklist category (Environmental Assessments, Field Observation, Field Sanitation, General Requirements, Soil Amendments, Water Use, and Worker Practices).

Between September 2008 and March 2011, audit-specific scores for each category were as follows:

- Environmental Assessments: Audit-specific scores ranged from 0 to 11. The average audit score for this category was 0.04 in 2008, 0.32 in 2009, 0.35 in 2010, and 0.21 in 2011.
- Field Observations: Audit-specific scores ranged from 0 to 19. The average audit score for this category was 2.8 in 2008, 2.9 in 2009, 1.9 in 2010, and 1.9 in 2011.
- Field Sanitation: Audit-specific scores ranged from 0 to 60. The average audit score for this category was 2.3 in 2008, 0.99 in 2009, 0.51 in 2010, and 0.42 in 2011.
- General Requirements: Audit-specific scores ranged from 0 to 15. The average audit score for this category was 0.21 in 2008, 0.15 in 2009, 0.23 in 2010, and 0.32 in 2011.
- Soil Amendments: Audit-specific scores ranged from 0 to 27. The average audit score for this category was 1.0 in 2008, 0.55 in 2009, 0.32 in 2010, and 0.29 in 2011.
- Water Use: Audit-specific scores ranged from 0 to 14. The average audit score for this category was 0.78 in 2008, 0.78 in 2009, 0.45 in 2010, and 0.50 in 2011.
- Worker Practices: Audit-specific scores ranged from 0 to 60. The average audit score for this category was 2.0 in 2008, 2.1 in 2009, 1.3 in 2010, and 1.6 in 2011.

Overall, average audit scores tended to decrease between September 2008 and March 2011 for five of the seven categories (Field Observations, Field Sanitation, Soil Amendments, Water Use, and Worker Practices).

In the second analysis, the audit checklist questions were re-classified into two categories: documentation and field observations. All of the questions in the audit checklist can be linked to these two categories. Field observations are made by auditors during the audits. Documentation includes all required documents and recordkeeping, whether it is reviewed during the office component of the audit (e.g., LGMA compliance plan, pre-season assessment, etc.) or during the

field component (e.g., equipment sanitation test results). The re-classification was based on review of the detailed auditor comments and audit findings in the data records. In the records, issues with documentation were frequently noted. Before benchmarking, the documentation category was further sub-divided to reflect supply chain data and individual grower data. To account for supply chain data, the documentation category was separated into documentation from growers (reflecting both availability of documentation and completeness of it) and documentation from third-party companies (e.g., laboratory, harvester, compost company, etc.). Benchmarking categories consisted of third-party documentation, documentation requirements and completeness (other than third-party), and field observations (Figures 1, 2, 3 and 4 in attachment).

Documentation scores ranged from 0 to 19, with 0 being the ideal or best-in-class level. Between September 2008 and March 2011, the average audit score for this category was 2.3 in 2008, 2.6 in 2009, 2.0 in 2010, and 1.2 in 2011. Factors contributing to documentation deviations included not having the required documents available for an audit, missing test records and issues with sanitary surveys.

Documentation completeness scores ranged from 0 to 90, with 0 being the ideal or best-in-class level. 4.8% of growers had a score of 0. The average audit score for this category was 6.7 in 2008, 3.7 in 2009, 2.7 in 2010, and 1.9 in 2011. Document completeness deviations arose from issues with sanitation facilities and field sanitation.

Third-party documentation scores ranged from 0 to 23, with 0 being the ideal or best-in-class level. 12% of growers had a score of 0. The average audit score for this category was 3.2 in 2008, 2.7 in 2009, 2.1 in 2010, and 1.9 in 2011. Examining the violations by source, the largest contributors to third-party documentation violations were laboratories and compost companies. The underlying issues were testing locations and frequency.

Average field observations scores remained relatively unchanged between September 2008 and March 2011. Scores ranged from 0 to 18 with 0 being the ideal or best-in-class level. 0.7% of growers had a score of 0. The average audit score for this category was 3.8 in 2008, 4.2 in 2009, 3.7 in 2010, and 3.2 in 2011. Contributors to field observation deviations were field sanitation and worker practice SOP violations, the improper use of water, and field sanitation facility SOP violations.

For all four categories (documentation, completeness, third-party documentation, and field observations), average audit scores tended to decrease between September 2008 and March 2011.

The final benchmarking analysis was developed by re-classifying the audit checklist questions into topics addressing the following categories: animal intrusion, chemicals, compost/manure and soil amendments, equipment, product containers, sanitary facilities, water, and worker field sanitation and hygiene, where appropriate. This classification included redefining field observations into the appropriate topical group.

Between September 2008 and March 2011, audit-specific scores for these categories were as follows:

- Animal intrusion: Audit-specific scores ranged from 0 to 7. The average audit score for this category was 0.10 in 2008, 0.20 in 2009, 0.19 in 2010, and 0.16 in 2011.
- Chemicals: Audit-specific scores ranged from 0 to 9. The average audit score for this category was 0.32 in 2008, 0.14 in 2009, 0.08 in 2010, and 0.05 in 2011.
- Compost/manure and soil amendments: Audit-specific scores ranged from 0 to 27. The average audit score for this category was 0.65 in 2008, 0.48 in 2009, 0.31 in 2010, and 0.28 in 2011.

- Equipment: Audit-specific scores ranged from 0 to 24. The average audit score for this category was 0.83 in 2008, 0.19 in 2009, 0.09 in 2010, and 0.0 in 2011.
- Product containers: Audit-specific scores ranged from 0 to 15. The average audit score for this category was 0.58 in 2008, 0.09 in 2009, 0.03 in 2010, and 0.02 in 2011.
- Sanitary facilities: Audit-specific scores ranged from 0 to 33. The average audit score for this category was 0.74 in 2008, 0.73 in 2009, 0.64 in 2010, and 0.70 in 2011.
- Water: Audit-specific scores ranged from 0 to 19. The average audit score for this category was 2.9 in 2008, 2.9 in 2009, 1.9 in 2010, and 2.0 in 2011.
- Worker field sanitation and hygiene: Audit-specific scores ranged from 0 to 45. The average audit score for this category was 1.6 in 2008, 2.0 in 2009, 1.4 in 2010, and 1.8 in 2011.

For these classifications, the highest average violation scores were recorded for worker field sanitation and hygiene and water related issues. Overall, average audit scores tended to decrease or remain approximately constant between September 2008 and March 2011 for all eight of the categories.

Gap and Root Cause Analysis

Non-compliance rates were used to identify subject areas that could explain gaps between scored and best-in-class audits. Using the audit checklist, those questions with a non-compliance rate of 5% or greater, regardless of the type of violation, were examined. Seven questions had a non-compliance rate > 5%; of these, five were related to water and two were related to worker practices and field sanitation. When non-compliance rates of 2% - <5% were examined, 17 questions were identified. Of these, seven were related to water, five to worker practices and field sanitation, four to food safety harvest and pre-harvest assessments, and one to other environmental factors.

Pareto analyses were conducted on non-compliance questions to discern and rank contributors in order of significance. The data used in the Pareto analysis was derived from individual audit data details and findings comments. Audits where no level was assigned were also included in the analysis. Key Pareto analysis findings included the following:

- Improper worker practice (non-compliance rate of 26%) contributors were knife sanitation and testing issues, harvest worker clothing SOP violations, gloves sanitation and testing issues, harvest equipment cleaning and sanitation issues, and produce containers and traceback issues.
- Deviations related to sanitation facilities that are not routinely clean and operational (non-compliance rate of 12%) stemmed from debris in and around the facilities, missing identification information on the units, uncapped water holding tanks, and gray water leaks from the facilities.
- Observations of improper water uses (non-compliance rate of 11%) resulted from hoses on the ground, damage or maintenance issues around the well and wellhead area, and a number of testing-related issues that if combined would be the largest contributor to improper water uses. Testing issues included the test results not meeting the handler's SOP, the individual tester not being able to perform the tests, missing required tests, missing test results, and failure to document where a sample was taken.
- Evidence that water sources and distribution systems may pose a contamination risk (non-compliance rate of 10%) came from well-related damage or repair issues, animal intrusion

events (feces or animal nests) near or in a water system, and unidentified wells (not on water system map).

- Missing water records (non-compliance rate of 8%) reflect the need for improved management oversight of testing programs. Often there appears to be a lack of testing plans detailing locations for the tests (particularly for distribution system testing) and testing frequency. As a result, source water testing deviations occur because the tests are not being conducted or, if they are conducted, documentation is missing or incomplete (e.g., including the planting dates on the test records). Distribution system water testing deviations occur because the tests are not being conducted or testing is not taking place in the required 35-day period. One audit report included a suggestion from the compliance officer to a grower/handler to implement a system to eliminate time gaps between water tests.
- Field maps showing permanent above ground fixtures (non-compliance rate of 7%) were missing valve locations, wells, and gates. In one audit report, a handler expressed concern with the amount of detail required on each map and the compliance officer suggested ways to satisfy the requirement without adding overwhelming details to the maps.
- Equipment cleaning process (non-compliance rate of 6%) issues included chlorine and pH levels not being tested as required, not having any equipment cleaning records available during the audit, and the SOP's missing test parameters.

Summary of Findings and Recommendations

Training Recommendations

Although average audit scores in the various categories tended to remain the same or decrease slightly between September 2008 and March 2011, actual score ranges indicate the need for further training to continue to improve performance. Based on the results of both the benchmarking and the Pareto analysis, two types of training are recommended. The first recommendation is for individual handler-specific supply chain training where all members of a handler's supply chain are trained as a group. This type of training would integrate the supply chain companies and facilitate working as a team with a common purpose. Supply chain training could take place prior to the start of each season. The benefits of this type of training are that the team members gain an understanding of the handler's requirements and SOPs (particularly useful if a grower works with multiple handlers and if SOPs are changed or updated), responsibilities are clearly communicated, and issues can be identified. Even if a handler is vertically integrated and already conducts training with its growers, consideration should be given to adding water testing laboratories, harvesting companies, sanitation suppliers, and soil amendment suppliers to the training groups.

The second type of training recommended is functional training (i.e., training on specific functions or processes). The analysis of deviation types reveals functional training needs exist at the industry level to address issues common across many of the growers and handlers (one example is knife sanitation and testing). The LGMA is currently positioned to offer this type of training. However, to ensure success, the LGMA would require direct access to grower and harvester lists and a documented training process including metrics for evaluating the training impacts.

Additional handler-specific training based on handler SOPs could be offered once industry training is complete. Handler requirements for harvesting companies could be extended to include industry level training and advanced handler-specific training.

In terms of individuals that would benefit from training, the analysis demonstrates a need for harvest worker training (including field workers, foremen, and supervisors) and a need for food safety personnel management training (including managing the supply chain and documentation process planning and management). Worker training could include how to perform knife dip tests, sanitization and proper storage of knives, sanitization and proper storage of gloves, and appropriate clothing and clothing storage for harvest workers. Because of the repeated cases of worker-related violations, daily tailgate training is recommended. If handlers are already training daily, it is recommended that they consider implementing quality circles. Workers could meet at the end of every shift and review harvest events and identify issues and how to fix them. This would allow team members to learn from each other, and quality or food safety would become a daily focus. Friendly competitions between harvest crews could provide incentives for participation. The benefit of quality circles is that all workers, and not just foremen and supervisors, would have ownership in product quality. It is recommended that quality circle efforts be documented and tracked as a measurement of harvest process quality.

Specific training topics recommended based on the research are:

- For the harvest worker, a one day training program could be structured to include the following classroom topics: how to perform knife dip tests, how to sanitize knives, how to properly store knives, how to sanitize gloves, determining when gloves should be replaced, and food safety issues associated with clothing, jewelry, and cell phones in the production areas. These topics could be followed by demonstrations and testing on processes (e.g., workers could demonstrate how to conduct a knife test, how to mix chemicals, and what to do if supplies are not available). The same day handler-specific training could address handler-specific SOPs for the same topics, and what to do if growers work with multiple handler SOPs.
- Food safety personnel training could cover three areas: testing, documentation, and third-party or supply line management. Specific components could include:
 - The testing session could help establish and/or provide training regarding sampling plans and protocols for required testing, and organize a daily tracking routine that ensures that required tests are scheduled (e.g., water testing) and completed (e.g., knife, glove, product spray, harvest equipment cleaning), and that results are logged correctly with complete documentation.
 - Documentation training could cover water testing, daily assessments, and ranch maps. Participants could include CDFA auditors, the compliance officer, handlers/growers, and food safety personnel. A breakout session could provide handlers/growers with an opportunity to share concerns with documentation and then, as a group, discuss solutions to simplify the process while ensuring LGMA best practice compliance. (One example is how to add required details to ranch maps without producing a map that is illegible.) Other training sessions could address documentation management issues such as revisions, storage, and retention planning processes. Tools to help organize and simplify documentation required for testing could be incorporated into the LGMA website linking directly to the audit database. The benefit of online tools would be reduction of paperwork and simplified documentation management.
 - Supply line management training topics might include training food safety personnel as project managers assigning responsibilities, establishing requirements, working to ensure the requirements are met, and tracking performance. This type of training would be helpful when working with sanitation companies, water testing laboratories, and compost companies.

Other Recommendations

In addition to training, recommendations for the LGMA and its operations include:

- Consider certification for LGMA supply chain participants that are not audited. Certification would benefit handlers given limited resources and staff time available to oversee supplier quality levels, and also offers handlers greater protection than letters of guarantee.
- Implement a feedback process for using observations from audits to address industry issues. Details and findings recorded in the audits sometimes identify issues that are common to all handlers and growers. If the issues re-occur, a process for discussing the issues and working on industry level solutions would be beneficial. (One example is covering the metal grates on harvest equipment to prevent potentially contaminated dirt from falling on harvested produce.)
- Consider developing a mechanism for scoring the audit checklist and by association the audit results; this would enable growers/handlers to focus on issues that are known to or believed to have the greatest impact on food safety. (For example, a soap dish that is not labeled is probably less of an issue than grey water leaking from a sanitation unit at the edge of a production field. Scoring would indicate the importance of the observation even if neither observation resulted in a CAP.)
- For the LGMA to offer successful training programs, handlers should provide the LGMA with direct access to growers and harvesting companies. Currently, only the CDFR receives the list of growers/harvesters each season from the handler. Without such a list, it would be difficult for the LGMA to identify training targets and verify training goals.
- Develop an Internet-based system to manage required documentation and testing results for all handlers/growers. An electronic system could help minimize audit time requirements and/or the work required to complete an audit after it occurs. Common templates for use by all LGMA members could reduce the time it takes to complete and maintain documentation.

Summary

While audit requirements and compliance with those requirements are not in and of themselves capable of measuring a grower's or a handler's entire food safety program, the LGMA audit results provide some insight into grower/handler food safety programs and performance. The value of this type of research is its ability to measure where the industry is in terms of ideal quality levels and then provide a means for individual growers and handlers to understand how they are positioned in the industry. By measuring and tracking performance against quality metrics, improvements can take place. Measuring performance levels in this research was not intended as a means to identify "bad actors." The LGMA audit process monitors performance and corrects issues through corrective action plans on a regular basis. This analysis examined every deviation and every comment, whether it resulted in a deviation or not, to determine what can be learned through the history of the program, and recommend what can be improved and how improvements can be made. According to quality principles, every issue, regardless of how insignificant, should be viewed as an opportunity for learning and improvement. The results of this study can be used to improve processes and reduce inefficiencies that will lead to reduced costs for the growers/handlers and along with additional training, lead to a greater ability to understand and address food safety issues.

References

Leafy Green Marketing Agreement. (LGMA). 2010. Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens. August 4.

Leafy Green Marketing Agreement. (LGMA). 2010. LGMA Agreement Annual Report 2009-2010. August.

Leafy Green Marketing Agreement. (LGMA). 2008. Unannounced Observational Audit Checklist. July 30, 2008.

Leafy Green Marketing Agreement. (LGMA). 2010. Audit Checklist. July 23.

Xerox Corporation. 1987. *Competitive Benchmarking: What It Is and What It Can Do For You*. Stamford, CT: Xerox Corporate Quality Office. Reference No. 700P90201. May.

APPENDICES

Budget Summary

The total Budget for this grant was \$133,540. The breakdown of the Budget was: \$114,992 for Salaries & Wages, \$1,976 for Computer Costs, \$5,572 for Travel, \$1,000 for Supplies and \$10,000 for Subcontractors. These costs have been billed at 100%. All grant funds were expended.

Figures

Figure 1. Average Monthly Audit Score for Third Party Documentation

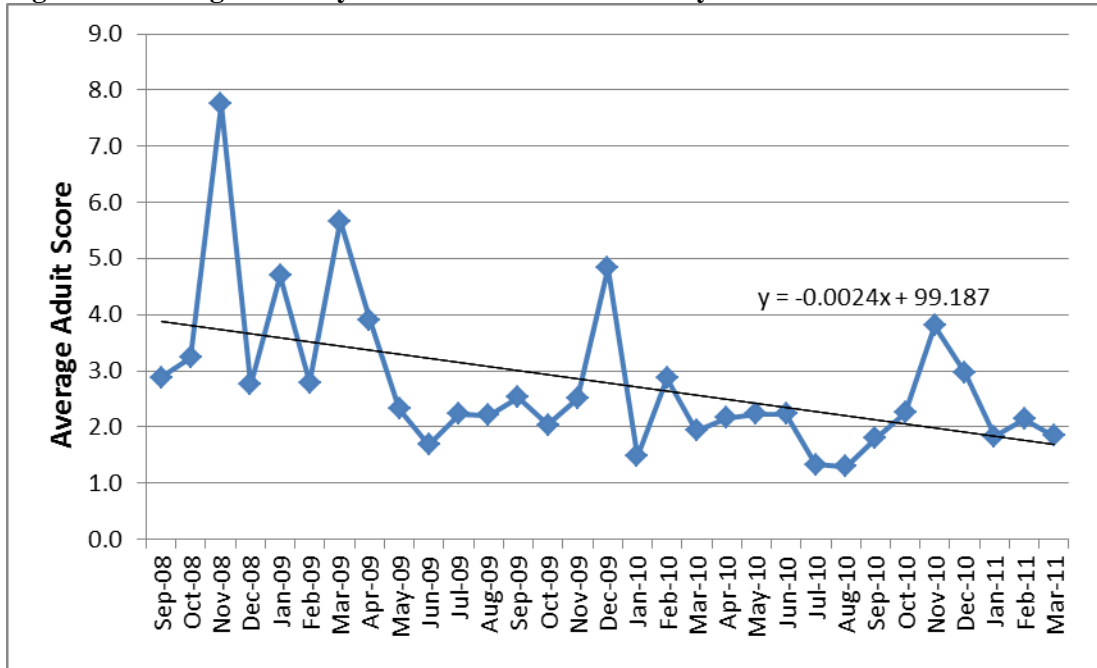


Figure 2. Average Monthly Audit Score for General Documentation

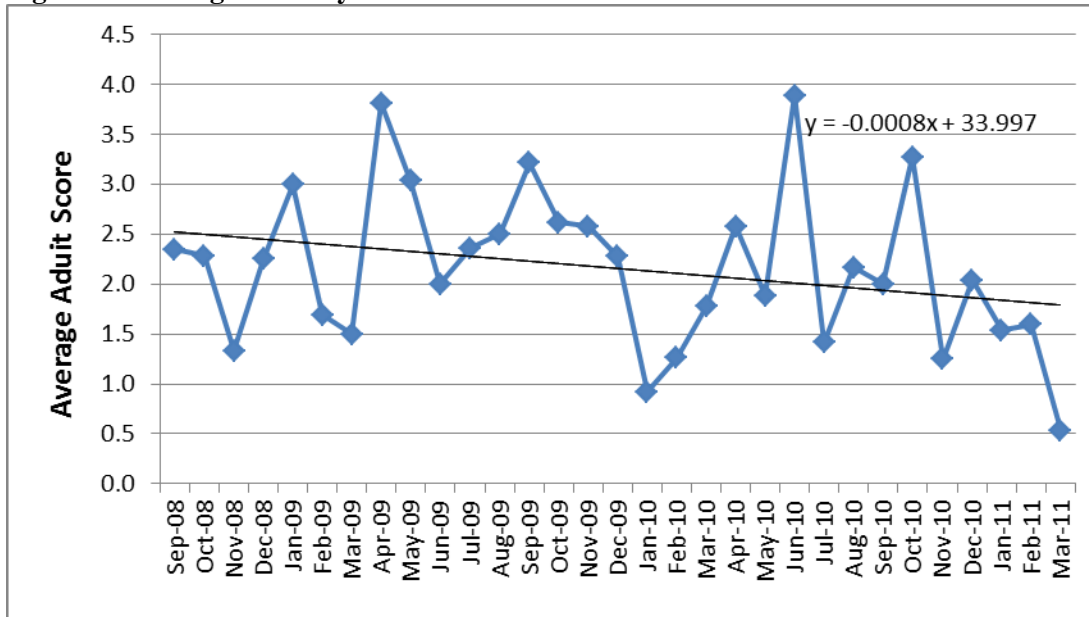


Figure 3. Average Monthly Audit Score for Documentation Completeness

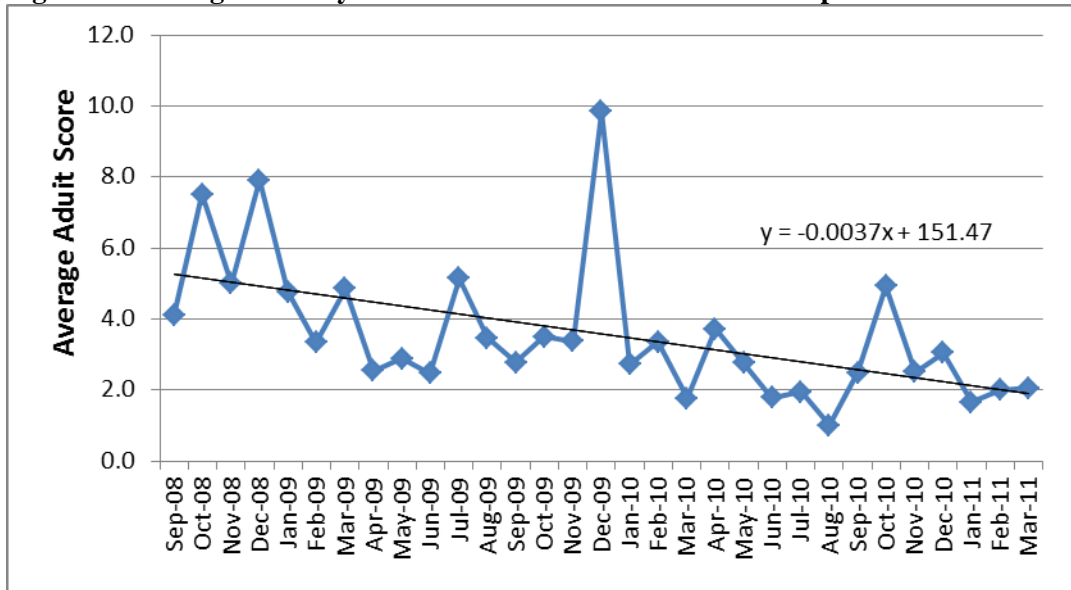
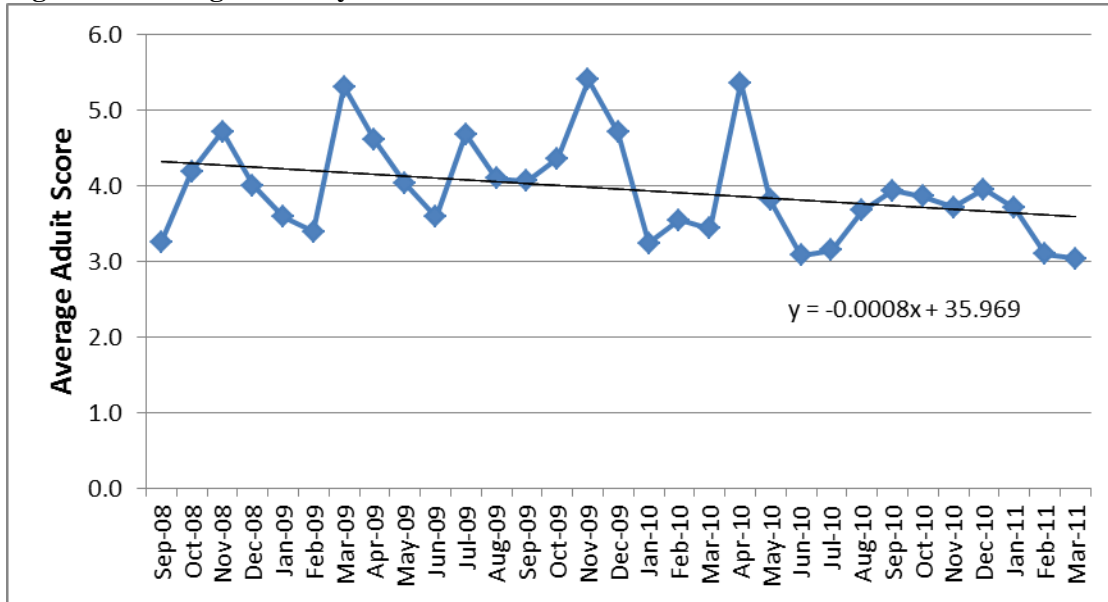


Figure 4. Average Monthly Audit Score for Field Observations



Publications and Presentations

“An Overview of the LGMA Audit Data Program and Data Collection Methodology,” report provided to the LGMA on December 7, 2011.

“Using Leafy Green Marketing Agreement Audit Data to Determine Non-compliance Areas and Preparation of Training and Recommendations for Improvements in Future Growing Seasons,” presentation to the LGMA on February 2, 2012.

“An Overview of the LGMA Audit Data Program and Data Collection Methodology,” report provided to the LGMA on July 13, 2012.

An Overview of the LGMA Audit Data Program and Data Collection Methodology

Prepared for:

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Using leafy green marketing agreement audit data to determine non-compliance areas and preparation of training and recommendations for improvements in future growing seasons

Overview

The purpose of “An Overview of the LGMA Audit Data Program,” is to document the workings of the LGMA audit program as a reference point for analyzing data collected during the audits. Drafts of this report were shared with the CDFA auditor head and the LGMA Compliance Officer for comments and corrections. The finalized version of this document will be included with the final report to the Center for Produce Safety for the grant scheduled for completion in January 2012.

The Audit Checklist

The LGMA audit program is based on the “Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens.”ⁱ These guidelines are considered to contain best practices that would be part of a GAP (Good Agricultural Practice) program. The best practices are organized to address several key areas:

- General requirements
- Environmental assessments
- Water use
- Soil amendments and non-synthetic crop treatments
- Harvest equipment
- Field and harvest personnel – pathogen transfer
- Equipment and cross-contamination
- Flooding
- Production locations

The audit checklist used to verify compliance with the LGMA metrics requirements are taken directly from these best practices and reorganized to focus on six areas:

- **General Requirements** – handlers must have: a LGMA best practices compliance plan, an updated grower list, confirmed registration according to the requirements of the Bioterrorism and Response Act of 2002, a designated individual responsible for food safety and a traceability process.
- **Environmental Assessments** – require pre-season assessments (animals of concern, adjacent land assessments, recent field history) and pre-harvest assessments (animal intrusion and unusual events).
- **Water Use** – covers water source and distribution systems, pre-harvest use (foliar and non-foliar), and post-harvest use (direct contact and food contact surfaces).
- **Soil Amendments** – consist of requirements for composted manure, biosolids and non-synthetic crop treatments.
- **Worker Practices** – apply to worker hygiene and health practices rules, sanitary facility and visitor practices programs.
- **Field Sanitation** – addresses sanitation and harvest SOPs.

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In addition field observations are made by the auditor based on the above list of six best practice areas. In total there are more than 300 questions in the announced and unannounced LGMA Audit Checklists.

LGMA auditsⁱⁱ

The purpose of the audit is to evaluate the handler and all operations from field to storage to ensure compliance with the LGMA best practices. There are differences in the nature of the audit depending on when it is conducted: at the start of the season, during a harvest season, and post-harvest, whether it is announced or unannounced or whether it is a rotationally scheduled audit or a follow-up audit to verify a corrective action plan.

The first audit of the season is the most extensive audit. As with all of the audits, this audit consists of both a desk component (e.g. reviewing general requirements, SOP's, tests and test results) and a field audit component (reviewing harvesting procedures and worker practices). During this audit, the auditor will go from the handler's office to the growing location and on to shipping and receiving where the traceability processes are reviewed, and finally end in the storage coolers. All SOP's and general requirements are reviewed. The entire LGMA Audit Checklist will be covered. Handler operations that shift with the growing season to another region will not undergo another first audit. Only companies seen for the first time in the new growing region would be considered as having a first audit of the season. The first audit is conducted at the start of harvest. Harvesting must be taking place at the time of the audit.

Most audits after the initial audit are conducted on a rotational basis scheduled as described in the next section. During these audits, the auditor will go through components of the LGMA Audit Checklist. The difference between these audits and the first audit of the season relates to SOP's. In the first audit of the season, all SOP's are thoroughly audited to ensure full compliance and in subsequent audits they are spot checked. As with the initial audit, these audits are scheduled to correspond with in-field harvesting and typically begin in the handler's office where SOP's and records are checked as needed, field practices are observed and workers are questioned on food safety activities, then move to the harvest area where workers are questioned, continue to the cooler's shipping and receiving to verify the traceability process, on to audit cooler water used on product and end at the handler's cooler door. The order in which the locations are audited may vary but not the locations covered.

Post-harvest audits are only conducted when a particular grower, for example small growers or growers with limited harvests, was not audited during the harvest cycle. Each post-harvest audit has a desk and a field component. The post-harvest audit differs from the harvest audit only with regard to what is actually observed in the field. The auditor verifies past harvest documentation including daily assessments, monitoring logs, and training records.

Lastly, there are audits conducted to verify compliance with corrective action plans or CAP's when one has been assigned. These audits focus only on the elements of the CAP.

LGMA audits can be either announced or unannounced. Unannounced audits are scheduled in addition to the regular two month audit cycle. When a handler is scheduled for a two month audit, the auditing supervisor will determine if the audit is going to be announced or unannounced. Handlers (not growers) will have one unannounced audit during harvest time. If the auditor shows up after a two hour advance notice and the grower is not harvesting, the auditor will go to another grower.

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Audit Scheduling

The Auditing Supervisor is responsible for scheduling handler audits. To develop the schedules, handlers provide the CDFA with lists of their growers and other suppliers each season. Based on the lists, the supervisor schedules four to six audits per year for each LGMA handler or roughly one every two months. All LGMA growers are audited a minimum of once per season to ensure compliance with LGMA guidelines. A grower who grows for multiple handlers will be audited more frequently. Large handlers that own or work with multiple growers will be audited as frequently as every six weeks to ensure all growers are audited. Once all growers have been audited, the large handler will move from being audited every six weeks to being audited every two months.

The audit supervisor prepares a rotation schedule for handlers based on harvest activity. One month prior to the audit, the supervisor will then contact each handler and ask for estimates of when their crops will be harvested. Using the harvest estimates, the supervisor will prepare an in-house schedule to assign weekly work duties to each of the auditors. The supervisor then contacts the handler to find out exactly what and where the handler will be harvesting the following week. With this information, the auditing supervisor determines which grower to audit. Handlers are contacted twenty-four to forty-eight hours in advance of the audit. Efforts are made to audit growers while they are harvesting and to try to get to ranches that have not been audited. If a grower is not harvesting and auditors are unable to schedule an audit due to size of the grower etc., auditors may schedule a post-harvest audit. If a handler/grower is harvesting, during the audit, the auditor must see the harvest.

LGMA Auditor qualifications and training

Auditors and the auditing supervisor are employees of the California Department of Food and Agriculture or CDFA. CDFA auditors conduct audits for several food safety programs in addition to the CLGMA including: the California Tomato Farmer's Cooperative (CTFC), the USDA tomato audits, the United Fresh harmonized audits as well as the United Fresh harmonized GAP and GAP/GHP. There are currently six auditors who have trained and been certified as LGMA auditors. All of the LGMA auditors went through the USDA AMS ISAAP or Agricultural Marketing Services Inspection Services Audit Accreditation Program. Four of the six auditors have more than ten years' experience working for the CDFA. These four auditors have been with the LGMA program since its beginning. The remaining two USDA accredited auditors have five years' experience each working for the CDFA. They have been LGMA auditors since November 2007. Prior to conducting an LGMA audit on their own, each auditor was trained for a year and then shadowed by USDA auditors.

Auditors receive additional training each year on GAP/GHP, auditing programs, updated policies and procedures, industry changes and news, and participate in periodic mock audits. The auditing supervisor will accompany each auditor on an audit once a month. Auditor evaluation forms are completed on each auditor and stored in the Branch Internal Quality Management System or BIQMS files. BIQMS is based on HACCP and ISO quality principles.ⁱⁱⁱ Once a year, the USDA audits the entire LGMA audit process. Also, once a year, the USDA selects a subset of auditors to evaluate their performance by matching hard copies to files in ExtraView. Documents are retained for three years.

LGMA Compliance Officer Qualifications and Training

The compliance officer is employed by the LGMA and is subject to USDA oversight and review. The Compliance Officer is an employee of the LGMA supporting both the Arizona and the California

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programs. The compliance officer has worked for the LGMA since 2006. During this time in addition to functioning as the compliance officer, he has had responsibility for the design and implementation of regulatory programs to enforce the provisions of the metrics for the leafy green industry and was instrumental in the design and implementation of the ExtraView data system. He has degrees from both California Polytechnic at San Luis Obispo and the University of California at Davis in agricultural business management and agricultural economics. Having worked in the specialty crop industry for over thirty five years beginning as an economist at the CDFA, he has had a great deal of experience working with federal and state inspection programs for fresh and processed products. As compliance officer he is responsible for reviewing, monitoring and assigning areas needing corrective actions in order for LGMA signatories to be in compliance with the LGMA metrics and USDA GAP/GHP.

Audit Details

Specific auditors are assigned the day before the audit. To prepare for an audit, the auditor will go through the ExtraView system to review the handler's last audit results and will focus on any previous Corrective Action Plans (CAP's). A typical audit, both in the office and field, will last approximately six hours. When conducting an audit, the LGMA auditor reviews the handler's and/or grower's operations and recordkeeping based on the LGMA Audit Checklist and notes observations for later entry into the ExtraView system. The auditor does not issue citations. If the auditor sees a minor non-conformance issue such as missing paperwork, he/she will give the handler the opportunity to correct the issue during the audit. The observation is still noted in the audit record. If at any time during the audit – at the field level, cooler facilities or in the office – an auditor observes any serious food safety health risk, that auditor is obligated to contact their supervisors who will then contact the public health department, CDFA and USDA. Aside from a health or non-conformance issue, the auditor is responsible for noting and making observations that can be useful to the compliance officer. The compliance officer does not participate in the audit or visit the field. He issues citations, assigns deviation levels and requirements for submission for CAP.

Post-Audit Process Overview and Data Entry

Once the auditor completes the office and field portions of the audit, he/she returns to the CDFA office and enters her observations into the ExtraView system. When complete, the auditing supervisor reviews the audit and signs-off on it. At this point in ExtraView, the audit status changes from auditor "reviewed" to auditor "complete." When the status becomes auditor "complete," an email notification is sent to both the handler and the LGMA compliance officer.

When the compliance officer receives the audit details, he reviews the auditor's observations and makes a determination based on the available information then assigns deviation levels to each audit. If the audit record contains observations, and no infractions or violations based on the LGMA Audit Checklist, he will assign a status of "LGMA complete." If a non-compliance issue is identified, meaning there is a lack of compliance with one or more of the LGMA practices as identified in the audit checklist, he will assign a status of "LGMA reviewed," meaning further action is required. There are three types of deviations^{iv}:

- **Minor Deviation** – A deviation of the LGMA practices which can be addressed within (5) days of the inspection, and the deviation does not necessarily increase the risk of a food-borne illness.
- **Major Deviation** – A violation of the LGMA practices that may inhibit the maintenance of food safety, but does not necessarily result in an unsafe product.
- **Potentially Flagrant Deviation** – A violation where the preponderance of evidence shows that the member company knew, or should have known exercising reasonable diligence, that the practice did

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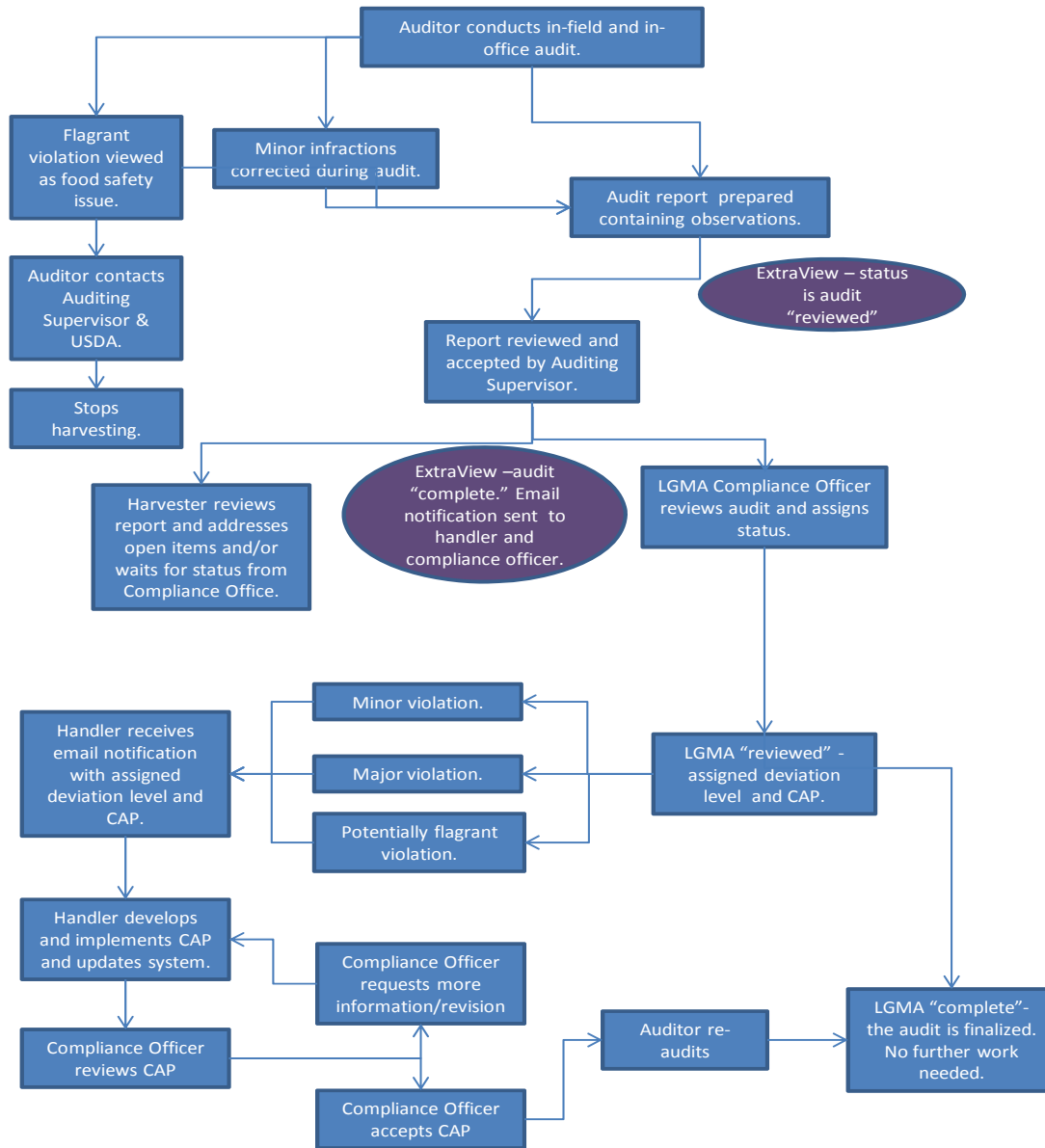
not conform to the measurable practices established in the LGMA, and the violation significantly increased the risk of delivering an unsafe product.

Minor and major deviations require a CAP. Potentially flagrant deviations can result in temporary or permanent member de-certification. Based on the information supplied by the auditor and other information that may have been supplied by the handler after the audit, the compliance officer will determine the appropriate action to address the non-compliance and will assign the handler a CAP. There are no ratings associated with the LGMA Audit Checklist. Additionally, there is no process to determine the root cause of the issue; therefore, the compliance officer must in effect determine the “probable cause” and determine the significance of each deviation before assigning a CAP. The LGMA audit and compliance procedure is summarized in Figure 1.

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FIGURE 1. LGMA Audit and Compliance Procedure



Audit Review and Completion Timeline

Within 48 hour after the audits, auditors enter their findings into ExtraView; the auditing supervisor reviews the findings and then codes the audit as audit "complete." While the policy states the auditors will send their findings to the compliance officer within 48 hours, the internal audit group policy is to forward the audit to the compliance officer in 24 hours if there is an issue. The compliance officer then

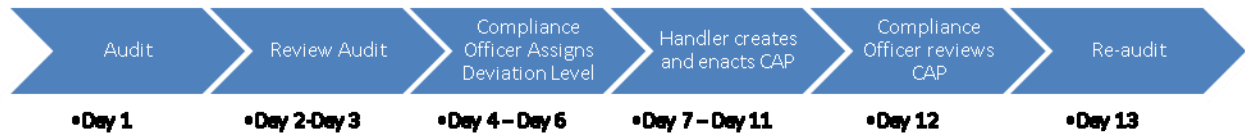
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has 72 hours to review the findings and assign a “status.” If the compliance officer reviews the information and determines a CAP or Corrective Action Plan is required, then a re-audit must be conducted within three days of handler notification (by compliance officer) or during the next scheduled audit.

Major deviations must be corrected and re-audited within three days. The re-audit will only be for the major deviation. While the auditor is conducting the re-audit, however; he/she will be looking for other issues. Minor deviations can be re-audited during the next scheduled audit. Re-audit findings are entered into ExtraView and once the auditing supervisor completes her review, the information is forwarded to the compliance officer. If the information is complete, then the audit is marked by the compliance officer as final. In some cases if the handler moves to prepare for the next growing season, an audit can remain open for 160 days. The timeline for conducting the audit review, developing and implementing CAP’s, re-auditing and finalizing the audit record is based on a workday schedule and does not include weekends. A timeline of the audit process is shown in Figure 2.

FIGURE 2. LGMA Audit Timeline



Note: timeline is based on work days and does not count weekends.

ⁱ “Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens,” July 22, 2011.

ⁱⁱ Content for this document was obtained through interviews with the LGMA staff, the LGMA Compliance Officer, the Auditing Supervisor, auditors, a handler interview and observations during an actual audit on August 22-23, 2011 in Salinas.

ⁱⁱⁱ U.S. Department of Agriculture Agricultural Marketing Service, Fresh Products Branch, 2010. Annual Report for Fiscal Year 2010.

^{iv} Definitions were obtained from the LGMA 2009-2010 Annual Report.

**USING LEAFY GREEN MARKETING AGREEMENT AUDIT DATA TO
DETERMINE NON-COMPLIANCE AREAS AND PREPARATION OF TRAINING
AND RECOMMENDATIONS FOR IMPROVEMENTS
IN FUTURE GROWING SEASONS**

LGMA TRAINING APPENDIX

Prepared for:

*THE CENTER FOR PRODUCE SAFETY
CALIFORNIA LEAFY GREEN MARKETING AGREEMENT*

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EXECUTIVE SUMMARY

In June 2012, the California Leafy Green Marketing Agreement (LGMA) conducted training sessions for pH, chlorine and water testing in Salinas, Santa Maria, and Oxnard, California. The course content incorporated findings from the February 29, 2012 California Department of Food and Agriculture (CDFA) grant report entitled, “Using Leafy Green Marketing Agreement Audit Data to Determine Non-Compliance Areas and Preparation of Training and Recommendations for Improvements in Future Growing Seasons.” Funding for the training was provided in part by a CDFA Specialty Crop Block Grant through the Center for Produce Safety (CPS). The 2009 grant proposal included a goal to “prepare training tools and use them to conduct region-specific producer workshops sponsored by the LGMA and CPS;” the June 2012 training sessions complete the training goal for the grant.

One of the recommendations in the grant report was for the LGMA to provide worker-related training that addressed sanitization issues and proper storage of knives and gloves. The LGMA, in conjunction with their annual training, was able to modify a course planned on pH and chlorine testing to include modules on knife and glove sanitization. Other recommendations such as the need for supply-chain training (e.g. handlers, growers, harvesters) and the use of quality circles were also incorporated into the training sessions.

Eight training sessions were conducted during the week of June 11, 2012 in various locations along the central coast of California. Attendee feedback was positive and there was wide support for additional training sessions similar in format to the June sessions.

The observations made during the interactive components of the sessions (hands on testing and breakout sessions) provide opportunities for the industry to focus on and resolve common issues facing many companies.

1.0 AUDIT DATA RESEARCH TRAINING RECOMMENDATIONS

As part of the grant “Using Leafy Green Marketing Agreement Audit Data to Determine Non-Compliance Areas and Preparation of Training and Recommendations for Improvements in Future Growing Seasons,” non-compliant audit results were scored and ranked by audit question. Then Pareto analyses were conducted to understand which factors contributed most significantly to the non-compliant areas using individual audit data details and auditor comments. Based on the ranking, the highest non-compliance rate was for audit questions related to worker practices (26%). Based on the Pareto analysis, the factors contributing most significantly to this non-compliance rate included knife sanitization and testing issues, harvest worker clothing standard operating procedure (SOP) violations, gloves sanitization and testing issues, harvest equipment cleaning and sanitization issues, and produce containers and traceback issues.

In the final grant report, a recommendation was made encouraging the industry to develop training programs centered on supply chain (e.g. handlers, growers, harvesters) and functional (where the emphasis is on specific functions or processes) issues. Recommended functional training topics included knife and glove sanitization SOPs and knife dip tests. Several of the recommendations in the final report were incorporated in the June 2012 training program. (A more thorough discussion of the training recommendations can be found in the final grant report and in the LGMA presentation on February 2, 2012.)

2.0 THE LGMA’S MOTIVATION AND GOALS FOR THE JUNE 2012 TRAINING PROGRAM

LGMA’s motivation for the June 2012 training program was to address deficiencies noted as auditor observations, documented as audit results, or identified in conversations with industry food safety managers. The LGMA’s goals for this training program were to train LGMA certified handlers and their growers and harvesters to improve field and supervisory personnel confidence in managing knife and glove sanitization and water sampling procedures and ultimately to improve LGMA members’ and associated companies’ testing and sampling audit results.

3.0 COURSE CONTENT

The LGMA Technical Director developed the classroom course “Testing and Sampling Procedures: chlorine, pH, and irrigation water.” The primary topic covered was sanitization, including objectives of sanitization, a review of the various types of sanitizers, how to prepare and test sanitizers and interpret test results, knife and glove dip sanitization, and how to collect direct contact water samples. An additional module on source dependent irrigation water focusing on water sampling SOPs and sampling techniques was presented if a class included attendees responsible for or involved with irrigation water testing. The course material included a PowerPoint presentation with photos of actual in-field demonstrations of the course content and copies of the PowerPoint slides bound and available in both English and Spanish.

4.0 WORKSHOP DETAILS

Training sessions were offered as a service to LGMA members and their growers and harvesting companies. Attendance was free of charge. Course announcements were emailed to LGMA members and details were made available on the LGMA website. Registration was provided online and by phone. Eight training workshops were conducted between June 11th and June 15th, 2012 in the central coast area of California (Salinas, Santa Maria and Oxnard). Each session lasted

approximately three hours and consisted of classroom, hands on, and breakout session components.

Intertox supplemented the LGMA-developed classroom training with hands on demonstrations (functional training) and a breakout session for cross company problem solving or quality circles. The goal of the hands on session was to simulate in field environments, and then to use breakout sessions as quality circles to identify solutions for common issues. In the breakout sessions, attendees were placed with employees of other companies to facilitate sharing about food safety procedures, issues, and issue resolution.

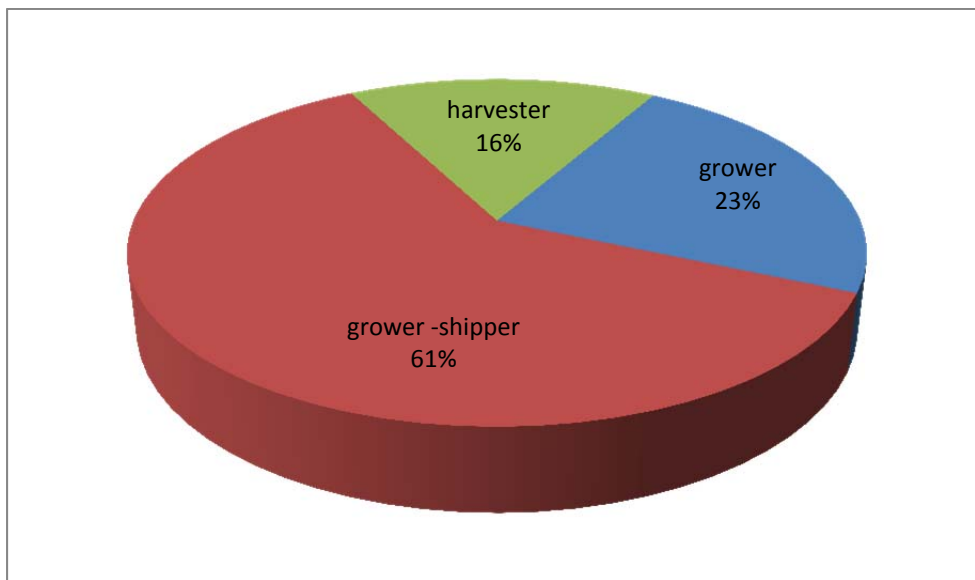
In summary, attendees were asked to do the following:

- Describe their company’s SOPs for knife and glove sanitization.
- Perform a pH and chlorine test (start of the course)
- Watch a PowerPoint presentation
- Participate in a breakout session
- Perform a pH and chlorine test (end of the course)
- Complete a brief quiz and course evaluation

5.0 COURSE ATTENDEES

A total of one hundred and thirty seven individuals from fifty six companies attended the eight sessions from June 11th through June 15th. Three classes were conducted in Spanish and five classes in English. Companies included grower-shippers, growers, and harvesters (Figure 1). For many of the companies, this was the first LGMA training session they had attended.

FIGURE 1. Companies Attending Training Sessions



Experience levels ranged from an employee on the first day of her job to an individual who had worked with his company for more than forty years. Attendee responsibilities in their companies ranged widely from human resources coordinators to crew foremen to handler food safety directors. The differing perspectives arising from the diversity in experience levels and job responsibilities was evident particularly in the hands on and breakout components of the course, as well as in the recommendations for future course offerings.

6.0 PH AND CHLORINE TEST RESULTS

At the beginning of the course, participants performed pH and chlorine tests to simulate knife and glove dip testing. Results were valuable not only as a measure of the change in participant knowledge before and after the training course, but also as feedback to the industry on potential causes of audit issues and/or SOP compliance difficulties.

The tests were conducted by placing small buckets of an identical water-based solution along with pH and chlorine testing equipment on every table. Each individual or group was asked to test the solution's pH and chlorine levels and record the results. Several test strip brands were provided including Micro Essential Laboratory's pHydrion papers (pH), pHydrion micro chlorine test papers (chlorine tests), Control Testing's Precision Chlorine Test Paper, and EMD Color test.

The pH and chlorine test results for each group are summarized in Tables 1 and 2. Of note, although each class was provided an identical water-based solution for testing (the solution was the same within the classes but not across classes), standard deviations of the pH readings varied greatly. For example, in Class B, the minimum pH reading was 5.5 and the maximum reading was 25.0 (using incorrect test strips) with a standard deviation of 5.3. In Class H the minimum reading was 4.5 and the maximum reading was 10.0 with a standard deviation of 1.6. Given that pH scale is logarithmic, the deviations are significant.

The differences in the chlorine test results are similar to the pH test results. In Class F, chlorine level readings ranged from 10.0 to 200.0 ppm with a standard deviation of 82.7. One class, Class D, appeared to be reading free chlorine and not total chlorine, reported a minimum of 2.5 and a maximum of 10.0.

Some of the deviations in the pH and chlorine readings can be explained by user error. In particular, for many participants, test equipment used in the hands on demonstration differed from the equipment they use on a daily basis. The brand name "pHydrion" was in particular confusing for some individuals: when seeing "pH" on the label, the assumption was that the test equipment was for measuring pH not chlorine. The significance of this observation is that if a crew runs out of test equipment, the company needs to ensure the same pH and chlorine reading test equipment is purchased and used. When deviating from frequently used equipment, the potential for human error will increase.

Other deviations in the readings occurred because of variability in test equipment itself. When conducting a test on the same liquid using equipment from different manufacturers, the results may vary across equipment.

Table 1. Summary of pH Results from LGMA Training Taken at Beginning of the Class

	Class A	Class B	Class C	Class D	Class E	Class F	Class G	Class H
Avg pH	7.1	8.3	6.9	6.5	7.0	7.4	9.0	5.7
Std dev	0.7	5.3	0.8	0.5	1.8	1.3	10.6	1.6
Min pH	6.0	5.5	5.5	5.5	5.5	6.0	5.5	4.5
Max pH	8.4	25.0	8.0	7.0	10.5	10.0	50.0	10.0

TABLE 2. Summary of Chlorine Results from LGMA Training Taken at Beginning of the Class

	Class A	Class B	Class C	Class D	Class E	Class F	Class G	Class H
Avg chlorine	64.4	40.1	30.5	5.5	95.5	118.3	24.4	24.2
Std dev	40.6	34.2	24.2	3.7	43.7	82.7	16.8	30.0
Min chlorine	10.0	3.0	10.0	2.5	50.0	10.0	7.0	0.0
Max chlorine	100.0	100.0	100.0	10.0	200.0	200.0	50.0	100.0

When conducting the second round of chlorine and pH readings at the end of the course, the standard deviations were lower yet still significant.

Overall, examination of the pH and chlorine test results suggests the following. First, after the second set of readings, most individuals were able to read the pH and test strips even if they had no prior experience with the equipment. Second, individuals reading test strips that require a distinction among colors and especially shades of one color will frequently disagree with one another on the color identity. Third, the color and hence pH and chlorine readings vary greatly across test equipment manufacturers.

Of particular significance for the industry is the finding that chlorine and pH test methods which rely on color ranges are subject to individual interpretation. In an audit situation, the tester and the auditor may not agree on the results. More significantly, individuals taking chlorine readings have a higher probability of reading the strips incorrectly or at least recording readings that may not be verifiable potentially resulting in accepting pH and chlorine levels that are outside of SOP levels. For these reasons, a focused analysis evaluating the effectiveness of sanitizer test equipment, costs, and ease of use would benefit the industry. (A few of the companies attending use ORP (oxidation reduction potential) readers. Given the cost of these handheld readers, they may not be practical for in field use; however, the digital display provides a reading that can be easily verified across individuals.)

7.0 KNIFE AND GLOVE SANITIZATION

After completing the classroom training component, attendees were divided into groups for the breakout session. If group members were from the same company, they were split up in order to diversify company participation in each group. Once in the breakout groups, individuals were asked to describe their company’s knife and glove sanitization SOPs in order to identify similarities and differences among companies and their approaches to sanitization. Then each group was given two

discussion items for the breakout session—the first was a question and the second was a series of situational issues for problem-solving (Table 3). The question covered experiences individuals/ companies have or have had with knife and glove sanitization. The situations considered were actual situations described in the audit data results. Group members discussed what they would do if faced with this situation and how they could prevent it from happening in the future.

TABLE 3. Breakout Discussion Topics

What problems do you experience with knife and glove sanitization? Think about test equipment availability, frequency of testing, recording test results, storage of equipment, glove replacement, etc.

Describe how you would handle the following situations and how you would prevent these situations from occurring.

1. The person trained to take pH readings is out for the day.
2. An employee was observed putting his knife in the dirt and then using the knife to cut lettuce.
3. Scheduled pH readings were missed.
4. At the end of the day, your test results were outside the stated range.
5. You are missing test equipment and need to take a test.

At the end of the breakout session, each group was asked to briefly summarize their group’s discussions and/or conclusions. Discussion areas included:

- Because of cultural differences, there are cases where workers are concerned if they train another individual to do their job, then the individual trained will take the trainer’s job. With this observation, individual companies may want to re-evaluate their train-the-trainer programs to ensure this cultural issue is addressed.
- Knives frequently contact the dirt when a worker is cutting leafy green heads. In fact, avoiding the dirt is probably impossible. For these cases, no additional sanitization is performed. However, when a worker is observed sticking his knife in the dirt or using it to scratch his head, etc. action is taken to sanitize the knives. Even with protective holders, knife sanitization issues still arise. The response the groups recommended is more training. Groups also recommended that LGMA revisit the requirement relating to knife soil contact.
- When scheduled pH readings are missing, the consensus was to make a note of the omission in the records and continue with the readings as scheduled. This should be an exception policy and not a change in SOPs (i.e., train to reduce omissions and not present omissions as part of standard practice). Not all companies have a policy for handling omissions; those that do not may want to revisit what they do in case a SOP is violated.
- Companies using chlorine in their operations find it difficult to effectively manage chlorine levels. For these companies, the suggestion was made to baseline their chlorine levels over several weeks by taking readings throughout the day and noting factors that could affect test results, e.g., the crew size, ranch location, time of day, temperature, etc. With the baseline

information, companies can then modify their testing SOPs to reflect the actual field situation(s). (One example is a company that does contract work for multiple handlers and receives different mixtures from each company.)

- To avoid the issue of running out of test equipment, some companies assign the equipment sourcing responsibility to one individual and that individual ensures every crew has the supplies they will need for the day. If the crew runs out of supplies during the day, the sourcing individual has inventory and can re-stock as required. Assigning one person responsibility for all supplies can alleviate pH and chlorine testing issues arising from the use of unfamiliar test equipment and also minimize any variability in test results associated with the use of different types of equipment.

Other recommendations and suggestions were:

- Chlorine testing should be standardized on free chlorine and not total chlorine.
- The industry should adopt a common SOP for knife and glove sanitization that companies could customize.
- Auditors need to standardize what they are looking for in terms of chlorine testing. Even if not required by a company’s SOP, some auditors are asking for an exact chlorine level reading as opposed to a range. Attendees believe they would have better audit results if they are asked to meet their SOP requirements.

Individuals also discussed and commented on the perspective that in-field food safety results are regarded as the foreman’s responsibility, underlying the need to understand the value of shared/individual responsibilities. An assessment of shared/individual responsibilities could be incorporated into the LGMA’s continuous improvement plan.

Finally, as a result of the breakout sessions, individuals began to share methods they had developed to help them comply with the LGMA food safety audit requirements. One food safety individual shared how he developed a method for collecting water samples using a golf ball retriever in order to capture water at a distance of six to seven feet out in the canal (free flow).

8.0 EVALUATING PROGRAM EFFECTIVENESS

The overall goal of this training program was to improve sampling and testing audit performance and compliance. In order to measure the effectiveness of the training, two methods were used. First, attendee reaction and feedback was captured in a course evaluation form. Second, to measure post-course knowledge, a test instrument was developed which attendees completed at the conclusion of the course. However, since no information was available on attendee prior knowledge, the test results are not reliable measures of course effectiveness. A third method— analyzing future audit results and auditor comments for attendees/companies to identify performance improvements and results —was not feasible during the grant period.

Based on attendee evaluation responses, the overall reaction to the course was very positive. Of the 102 attendees completing an evaluation form, 101 or 99% requested that LGMA host “more workshops like this” (one individual (1%) was unsure if they wanted additional workshops). Attendee rating of the course content and format is summarized in Tables 4 and 5. In terms of course content and format, top responses (ratings of 4 and 5) were 89.2% for both.

TABLE 4. The Content of the Course was:

	Score	Respondents	%
Very valuable	5	68	66.7%
	4	23	22.5%
	3	5	4.9%
	2	0	0.0%
of lesser value	1	1	1.0%
	Blank	5	4.9%
	Total	102	100.0%

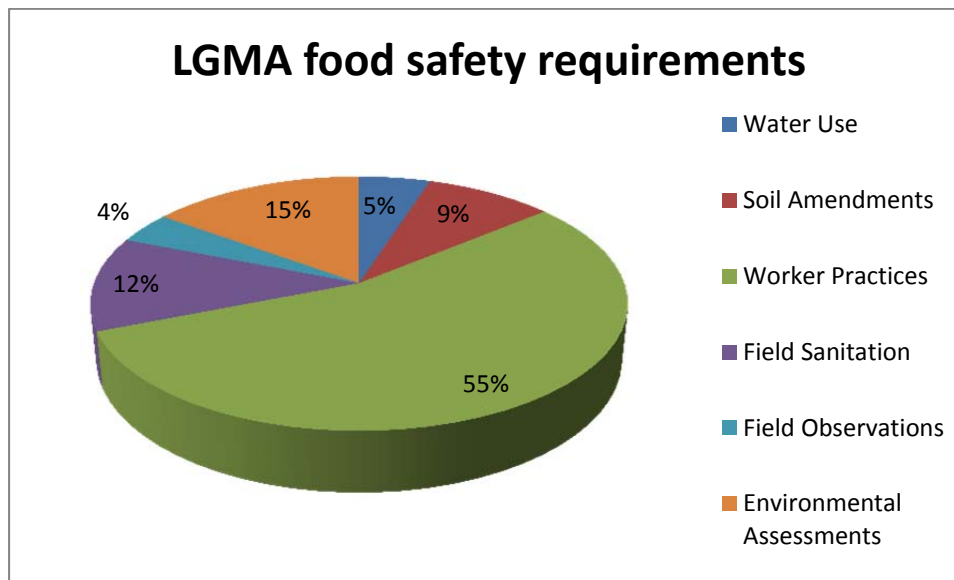
TABLE 5. The Format of the Course was:

	Score	Respondents	%
Very valuable	5	67	65.7%
	4	24	23.5%
	3	5	4.9%
	2	0	0.0%
of lesser value	1	1	1.0%
	Blank	5	4.9%
	Total	102	100.0%

9.0 FUTURE COURSE RECOMMENDATIONS

As part of the course evaluation process, attendees were asked to identify those LGMA food safety requirements with which they have the most difficulty complying. More than half of the attendees completing the evaluation identified worker practices (55%) as their most difficult compliance area (Figure 2). Other difficult compliance areas included environmental assessments (15%), field sanitation (12%), and soil amendments (9%).

FIGURE 2. What part of the LGMA food safety requirements do you find more difficult to comply with?



Attendee diversity was highlighted when individuals were asked to recommend future course topics. With regard to a follow-up course on pH, chlorine and water testing, it was recommended that the course go into greater detail on:

- Expanded pH and chlorine details
- Test strips
- Sanitizers
- Chlorine bottles
- Hands on training of how to read pH/chlorine strips
- Knives – how to sanitize and use properly
- Organic sanitization methods and auditor support for methods

Attendees also recommended topics for future courses in nine different areas ranging from how to train crews to dealing with leading scientific issues such as nitrogen leaching and pathogen testing (Table 6). Field level topics included crew training, hazard assessments (pre-harvest and environmental assessments), equipment selection and cleaning, and methods for improving audit performances. Interest was expressed in learning more about state and federal regulations and programs.

TABLE 6. Future Course Recommendations

<p>Training</p> <ul style="list-style-type: none"> • Crew training • Foremen training (basic class show/explain importance) • Training methods • Training content development • Train-the-trainer 	<p>Pathogen Testing</p> <ul style="list-style-type: none"> • Sampling • Ranch oriented • How to product test • Field crop testing 	<p>Audit Performance</p> <ul style="list-style-type: none"> • Audit tips • Audit scenarios • Field observation violations – how to prevent • What do auditors look for • Other audit observations • Audit paperwork 	<p>Hazard Assessment and Risk Management</p> <ul style="list-style-type: none"> • Environmental assessments • Pre-harvest assessments • Animal events • Adjacent land evaluation • Potential risks and how to manage (e.g. water risks such as a reservoir floods)
<p>Soil Amendments</p> <ul style="list-style-type: none"> • Compost • Nitrogen leaching issues <p>Other</p> <ul style="list-style-type: none"> • Bathroom sanitization – what is required/expected 	<p>Equipment</p> <ul style="list-style-type: none"> • Gloves- types to use for various commodities (twists) • Equipment cleaning • Gloves, sleeves and aprons appropriate material 	<p>Regulations and Standards</p> <ul style="list-style-type: none"> • Food Safety Modernization Act • CA laws • How LGMA can help with other food safety programs (GlobalGAP, GFSI) 	<p>Food Safety Program Support</p> <ul style="list-style-type: none"> • SOP, SSOP development • SOP procedures • Form development • Streamlining production crew documentation • Transportation food safety (field to processing plant)

10.0 SUMMARY AND CONCLUSIONS

Discussions, recommendations, and course evaluations from the “Testing and Sampling Procedures: chlorine, pH, and irrigation water” course offered in California in June 2012 validated the “Using Leafy Green Marketing Agreement Audit Data to Determine Non-Compliance Areas and Preparation of Training and Recommendations for Improvements in Future Growing Seasons” study findings. In particular in the grant study findings identified the need for further training specifically related to in-field practices such as knife and glove sanitization and pH and chlorine testing. Course attendees came from grower-shipper, grower, and harvesting companies and varied greatly in terms of individual experience and job responsibilities, demonstrating broad interest in the course content. Evaluation forms completed at the end of the course demonstrated support for the specific training topic and course format.

Discussions during the “quality circles” or breakout sessions identified other opportunities for industry improvement and/or additional research. The findings include:

- The industry could benefit from a cost-benefit evaluation of sanitizers that covers their effectiveness but also considers their ease of use and cost. Having a list of recommended commercially available products for companies to use would benefit companies that harvest products.
- The extent of cultural differences affecting the train-the-trainer programs warrants further investigation.

Session participants found the course “Testing and Sampling Procedures: chlorine, pH, and irrigation water” to be valuable and indicated interest in attending future training programs covering a variety of topics.