INTRODUCTION

The California Leafy Green Products Handler Marketing Agreement (LGMA) supports the Food Safety Modernization Act (FSMA) and the proposed produce rule issued by the US Food and Drug Administration (FDA). As an entity that verifies, through government audit, that its members are following an accepted set of food safety practices on the farm, the LGMA recognizes the critical importance of good agricultural practices, and believes that the proposed standards will help protect public health and create a safer food supply.

There are, however, elements of the proposed rules that we believe can be improved or that should be changed. Much of our input is based on our experience of the last six years, as the LGMA has overseen the implementation of a similar set of food safety standards in the leafy greens industry. We hope and trust that our experiences and learnings can shed additional light on the standards included in the produce rule, and we offer these comments with the objective of helping FDA strengthen the proposal.

This document includes comments on several issues that are of particular importance to the California leafy greens industry. These five priority issues are the following:

1. The proposal that FDA work closely with existing commodity specific programs like the LGMA to verify compliance with the new rules
2. The inclusion of kale on the list of products proposed for exemption from the FSMA requirements
3. The confusion and unintended consequences that may follow if the proposed definition of processing/manufacturing is adopted
4. Excessive testing requirements for surface water
5. Training and education as key elements of the proposed rule, and the need to recognize existing commodity-specific training programs
As stated above, these five comment areas have been identified as priority issues for the leafy greens industry; but we will be providing additional comments on several other elements of the proposed rules later in the comment period.

The LGMA is an instrumentality of the State of California, and operates under the authority of the California Department of Food and Agriculture (CDFA). While these comments have been reviewed by CDFA, they are the expression only of the leafy greens industry through the LGMA, and do not necessarily reflect the CDFA’s point of view.

**VERIFICATION OF COMPLIANCE: A PROPOSAL FOR A MEMORANDUM OF UNDERSTANDING (MOU) BETWEEN THE FDA AND EXISTING GOVERNMENT FOOD SAFETY PROGRAMS**

With the advent of new produce food safety rules under FSMA, FDA will be called upon to oversee a new regulatory structure. A central question for the FDA, beyond the creation of the actual rules and regulations that will make up FSMA, is how compliance with the new laws will be verified across the thousands of farms and ranches that produce food in the United States and around the world.

**LGMA Comment**

We propose that, where possible, the FDA partner with state, government and/or commodity organizations like the LGMA through Memoranda of Understanding (MOU) to verify compliance with the new rules, once they are finalized.

**Background/Rationale**

The FDA has stated publicly that its resources are not likely to allow for a rigorous program to verify compliance with the new FSMA produce food safety rules, and that it will be looking to industry, the states and third parties to play an important role. In a time of increasing budget pressures, the FDA is unlikely to have the resources available to being inspecting every farm and produce facility in the country and throughout the world.

In order to protect public health and to ensure that these important new food safety protections are being put in place, we propose that the FDA partner with industry organizations that provide government oversight of food safety practices in several US industries and states. Specifically, we recommend that FDA sign MOUs with organizations like the LGMA, the AZ LGMA, the California Cantaloupe Advisory Board and other organizations, provided said organizations can demonstrate the ability to verify compliance with all applicable FSMA requirements.

For this discussion, we will use the experiences of the LGMA but would note that there are other food safety organizations within the produce industry that could provide similar methods.
of compliance verification. These include the AZ LGMA, the California Cantaloupe Advisory Board and organizations representing the California and Florida fresh tomato industries.

Existing Food Safety Programs
Since 2007, growers and handlers of leafy greens in California have been subject to the food safety requirements of the LGMA. The marketing agreement is an instrumentality of the State of California, and its members are handlers of leafy green products grown in the state. Membership in the LGMA is voluntary, but once a company has joined the agreement, the law mandates compliance with all of the accepted food safety requirements. LGMA handlers market roughly 98% of California's leafy greens. Members pay assessments based on the volume of covered products marketed under the marketing agreement, and those assessments cover all costs of the LGMA audit program. The LGMA has committed to using government auditors to conduct mandatory food safety audits to verify compliance with the food safety requirements. The food safety audits conducted through these programs are performed by government auditors licensed and trained by the US Department of Agriculture (USDA).

Since its establishment in 2007, the LGMA has verified, through these government audits, that its handlers and their growers are implementing an accepted set of food safety practices that are designed to minimize the risk of microbial contamination of leafy greens. The same rules apply equally to all leafy greens farms, regardless of size, type of farming operation (conventional or organic) and products grown.

The LGMA is pleased to see that much of what is included in the proposed Produce Rule aligns closely with the LGMA's requirements. This is not surprising, as the key risk areas have long been recognized by food safety experts and government regulatory agencies. And while the LGMA’s “Metrics” are, in general, more detailed and far-reaching than those proposed in the preliminary Produce Rule, the proposed standards can be seen as a subset of the food safety practices already being adhered to by California and Arizona leafy greens handlers and growers. The LGMAs have been verifying compliance with these standards since 2007.

Since 2007, under the LGMA program in California:

- Over 3,000 farm audits have been conducted
- Over 350 individual growers are audited annually, generally multiple times
- Over 10,000 citations have been issued for non-compliance (most for minor issues)
- All citations issued required corrective actions to be developed, implemented and verified by auditor.
- Seven LGMA handlers have been decertified under the program, with severe economic impact resulting
Based on our analysis of the preliminary produce rule under FSMA, we can confidently state that the LGMA has been verifying the leafy greens industry’s compliance with food safety practices that essentially meet or exceed the specific rules being proposed under FSMA since 2007.

Industry Structure and Supplier Verification
Many of the concerns raised during the public comment period (both in written comments and public meetings held in Washington DC, Chicago and Portland) have focused on issues related to industry structure, FDA definitions of the farm, and supplier verification. We would like to point out that the LGMA food safety model, which makes the entry into commerce the primary point of control, ensures that all entities involved in the production and harvest of leafy green products in California are following prescribed food safety practices.

Under FSMA, the term "farm" is defined as follows: *Farm means a facility (as defined in § 1.227 of this chapter) in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood) or both.*

We recognize both the need for FDA to develop meaningful definitions for the purpose of developing regulations and the difficulty of doing so in the face of the broad diversity of farming practices and farm types throughout the world. But, as written, the definition raises many questions about who is in a position to ensure that food safety practices are followed on any given farm or ranch.

For example, in California, the following are some common scenarios:

- A farmer with twenty acres plants, fertilizes, tends and harvests his crop, using a labor force that he hires and supervises. This case, though probably representing a minority situation in the state, most closely aligns with the definitions in the Produce Rule.
- A farming operation farms 500 of its own acres, and contracts with other farmers to grow an additional 500 acres under his label. The crops are contracted to a dozen or more different handlers (or shippers). The farmers hire the crews to plant and cultivate the crops, but the individual handlers hire or provide harvest crews over which the farmer has no control.
- A processor of leafy greens has production contracts with dozens of growers in California, Arizona, other States and Mexico to provide raw product for bagged salad mixes. In some cases, the handler provides the harvest crews and in others the grower does. In most cases, the processor determines specific harvest practices to be implemented on each ranch, and the contracted growers produce a crop based on those specifications.
In order to meet market demand, a handler or processor purchases product already harvested from other handlers and/or growers. Large growers of vegetables in California maintain contracts and economic relationships with a dozen or more individual handlers, but has only partial controls on the implementation of food safety practices pertaining to the production and harvest of the crop.

Each of these scenarios presents different challenges to successful implementation of the produce rule. And few real world situations neatly fit the definitions as written in the proposed rule.

The LGMA model addresses this complexity by applying its regulatory oversight at the handler, rather than at the grower, level. Under the marketing agreement, LGMA handlers are legally responsible for ensuring that accepted food safety practices are implemented and carried out on all covered product handled. While the industry's trade and production processes remain as complex as ever, the LGMA model ensures that all entities who are required to implement specific food safety practices, i.e., growers, harvesting companies, soil amendments manufacturers, providers of field sanitary equipment, handlers, etc., are brought under the umbrella of the LGMA's regulation.

As noted, the LGMA’s regulatory structure is enforced through mandatory government audits. Conducted by CDFA auditors, licensed by the USDA, these audits are thorough and comprehensive, as summarized in the following list of activities performed by CDFA auditors during an audit:

- Review the grower and/or handler’s compliance plan to verify how all required food safety practices will be implemented and performed
- Verify that the grower and/or handler has a current grower list, a written compliance plan, a written recall plan, and a list of all current harvest activities
- Review documentation for all required food safety practices, including water tests, soil amendment testing documents, training documents, environmental assessments and other records for each harvest location.
- Review the grower and/or handlers SOP’s and SSOP’s, and SOPs and SSOP’s for any third parties who, under the handler’s compliance plan, are involved in the harvest or production of leafy greens at each harvest location.
- Conduct an on-site audit of each production block included in the audit that covers all required food safety practices
- Review the on-site documentation required, including daily harvest assessment, all required testing records, and any documentation of corrective actions taken on-site
- Review and verify any corrective actions undertaken from a previous audit
In summary, the auditor reviews all applicable paperwork, regardless of who is for collecting and maintaining it. In this way, the LGMA model ensures that all parties involved in the production and/or harvesting of any given farm’s leafy greens have followed all applicable metrics, rules and/or regulations.

**Utilizing Existing Programs to Verify Compliance with FSMA Rules**

As detailed above, the LGMA is already essentially enforcing the proposed produce rules. And the structure of the LGMA model also makes sure that the on-farm food safety practices are being implemented by all entities that have a part in the production and harvest of leafy green vegetables. We therefore believe the FDA can confidently partner with the LGMA (and with other similar programs that are in place in the produce industry) to verify compliance with the new laws included under the FSMA Produce Rule.

Such an agreement would not be unprecedented, as the FDA currently maintains similar arrangements with other entities. In fact, the FDA website spells out the criteria used to establish MOUs:

> A memorandum of Understanding (MOU) is a formal agreement between the Food and Drug Administration (FDA) and federal, state, or local government agencies; academic institutions; and other entities. The MOU constitutes an understanding between the parties but is a non-binding agreement. It is FDA’s policy to enter into MOUs with other entities whenever there is a need to define lines of authority or responsibility, or to clarify cooperative procedures. The intent of the MOU is to improve consumer protection through more effective use of collective resources and to eliminate duplication of activities.

One existing agreement is with the California Dried Fruit Association (DFA). In this case, an MOU between the DFA and FDA spells out the terms of an agreement by which the DFA conducts mandatory Good Manufacturing Practices (GMP) inspections of DFA’s member dried fruit and tree nut processors. Under the terms of that agreement, DFA inspectors conduct regular GMP inspections that are equivalent to an FDA inspection on a regular basis. FDA accepts the results of the DFA inspections, allowing it to redirect resources or manpower and not duplicate activities.

Under the terms of the MOU, DFA inspectors conduct three unannounced inspections a year on all 85 of DFA’s member facilities. The entire facility is inspected for compliance with GMPs, an inspection report is completed, personnel are interviewed and all relevant paperwork and the traceability program are reviewed. In other words, the DFA facility inspections function much like an LGMA audit, and with the MOU in place, the DFA is responsible for verifying compliance with federal regulations.

Once the rules and requirements under FSMA are finalized, it will fall to FDA to ensure compliance by the produce industry. As the agency is unlikely to have the resources required to
take on the compliance function in all industries and throughout the United States and the world, we believe it makes sense for the agency to partner with existing state and industry programs that are committed to protecting food safety through the adoption of food safety practices that are equivalent to or more rigorous that those included in the new FSMA rules.

The LGMA, AZ LGMA, California Cantaloupe Advisory Board and other commodity-specific programs have adopted a model which is very much in keeping with the goals of the federal government. In fact, as shown above, the proposed rules are already being implemented and verified through government audits by the CA and AZ LGMAs.

The LGMA therefore looks forward to working with FDA through an MOU or similar arrangement to verify that the leafy greens industry is compliant with FSMA’s produce rules, once those rules are finalized.

**KALE AS A COMMODITY “RARELY CONSUMED RAW”**

In section 112.2 of the proposed rule, the FDA provides the following “exhaustive” list of produce items that are “rarely consumed raw” and that are therefore exempt from the produce rule:

- arrowhead
- arrowroot
- artichokes
- asparagus
- beets
- black-eyed peas
- bok choy
- brussels sprouts
- chick-peas
- collard greens
- crabapples
- cranberries
- eggplant
- figs
- ginger root
- kale
- kidney beans
- lentils
- lima beans
- okra
- parsnips
- peanuts
- pinto beans
- plantains
- potatoes
- pumpkin
- rhubarb
- rutabaga
- sugarbeet
- sweet corn
- sweet potatoes
- taro
- turnips
- water chestnuts
- winter squash (acorn and butternut squash)
- and yams

**LGMA Comment**

The LGMA recommends that kale be removed from the list of raw agricultural products exempted from FSMA requirements. The LGMA also recommends that the list of products exempted from the proposed rules be maintained in guidance documents, rather than included as an exhaustive list in the regulation itself. This will allow FDA to update the list as times and tastes change, and as industry adapts its offerings to those changes.

**Background/Rationale**

The FDA, drawing on data included in the National Health and Nutrition Examination Survey (NHANES) has concluded that kale is a product that is rarely consumed raw. However, the data used by FDA covers the period of 1999-2006, and recent years have seen a rapid and dramatic increase in consumption of kale, both fresh and processed.

From 2007 through 2012, the volume of Kale handled by the largest LGMA members has increased 369%. LGMA members are only assessed for product that is shipped fresh and the majority of these assessments are for use in bagged salads that are clearly intended to be eaten
raw. Given this increase in sales and consumption, it is clear that kale is, in fact, a product that is consumed raw.

Kale is an example of how rapidly consumer preferences and demand can shift, and how quickly the country’s farmers can change their offerings to meet changing demand. Therefore, we believe it is not wise to include a definitive list of products to be exempted from the proposed rules because they may not currently be consumed raw. If such a list must be maintained at all, it should be incorporated by reference from a guidance document that can be more easily updated as times and tastes change.

The LGMA will continue to regulate kale as one of the products covered under its program, and we believe there should be alignment with federal regulations. Kale should be regulated under the produce rule.

**HARVEST DEFINITIONS**

Section VIII of the proposed Preventive Practices Rule provides background and rationale for decisions FDA has made related to what constitutes farming/harvesting and what activities will be defined as manufacturing or processing.

The original language of Section 201(gg) of the FD&C Act (21 U.S.C. 321 (gg) defines processed food to mean “any food other than raw agricultural commodities and includes raw agricultural commodities that have been subject to processing, such as canning, cooking, freezing, dehydration or milling.” However, in revising its definitions for the Produce and Preventive Practices rules, FDA has chosen to significantly broaden the list of practices that would be categorized as processing or manufacturing. The new definition reads as follows:

*Making food from 1 or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food. Includes packaging (putting food in a container that directly contacts food and that consumer receives). Examples: activities that fit this definition include washing, trimming of outer leaves, removing stems and husks, sifting, filtering, threshing, shelling, cooling, packaging, mixing, coating, stickering/labeling, drying, sorting/grading/culling not incidental to packing or holding, fumigating, slaughtering animals or post-slaughter operations, irradiation, cutting/coring/chopping/slicing, canning, artificial ripening, cooking, pasteurizing/homogenizing, infusing, distilling, salting, smoking, grinding/milling, and freezing (emphasis added)*

This definition includes practices that are often part of the harvest process. Including all of these practices could mean that nearly all farms in certain parts of the country would have to
be registered as facilities as those practices would be subject to the preventive practices rule, not the produce rule. We believe this would create unnecessary and burdensome requirements for farmers throughout the country.

LGMA Comment
FDA should clarify definitions to ensure that practices routinely undertaken in the field during harvest – including coring, trimming, bagging and packaging – be recognized as part of on-farm harvest activity and regulated under the produce rule.

Background/Rationale
Many raw agricultural products, including leafy green vegetables, have relatively short shelf lives and must be harvested, cooled and shipped to market as quickly as possible. As a result, on-farm harvest practices have been developed to streamline the process of moving product efficiently to market (or to a facility for further processing). Practices in the leafy greens industry like coring of product in the field, bagging of romaine hearts, and wrapping of individual heads of lettuce facilitate the effective movement of perishable products to the marketplace. These practices must be subject to food safety requirements, but should also be recognized as part of the harvest process and made subject to the produce rule.

Although these practices are a traditional part of the harvest process, they should not be seen as substantially changing the nature of the product, and should therefore be subject to the requirements of the produce rule, not the preventive practices rules.

Since all practices included in traditional harvest activities are subject to food safety practices under the LGMA, and will be under FSMA, we believe these changes in how such practices are defined or categorized will create costly and difficult documentation burdens and will add layers of verification complexities without providing any additional protections of public health.

It is impractical to impose the Preventive Controls requirements, particularly subpart B, on in-field operations that are often manual and may include equipment only for conveying and packing or packaging. Subpart B was clearly intended to apply to in-building operations; “plant” (i.e., “the building or establishment or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food”) is referred to in subpart B no less than 23 times, and field operations are not mentioned at all. The specific requirements in subpart B are either not applicable (e.g., § 117.20 Plant and grounds and § 117.80 Processes and controls) to in-field operations or better regulated under the language of the proposed Produce Safety rule (e.g., § 117.37 Sanitary facilities and controls and § 117.40 Equipment and utensils).

Therefore, we strongly recommend that FDA clarify its definitions in order to ensure that practices routinely and commonly undertaken as part of the harvest process – including coring, trimming of outer leaves, etc. – be regulated under the produce rule.
TESTING FREQUENCY FOR SURFACE WATER

Section 112.45 of the proposed Produce Rule calls for untreated surface water “from any source where a significant quantity of runoff is likely to drain into a source (for example, a river or natural lake)” to be tested “at least every seven days during the growing season.”

LGMA Comment
The LGMA recommends that the requirement that untreated surface water be tested every seven days be amended to require testing of these water sources on a schedule consistent with local conditions or identified risks.

In California and Arizona, leafy greens producers are required to test their surface waters on a monthly basis.

Background/Rationale
In a comprehensive research project funded by the Center for Produce Safety, Dr. Rob Atwill, Ph.D., University of California, Davis, showed that the levels of generic E. coli in two data sets, for the four growing regions of California, were well below the “action point” taken when the quality of agricultural water exceeded the established minimum quality standards in the LGMA. In data set #1, of the 44,000 samples reviewed, 79% had no detectable generic E. coli and only 0.86% had levels which exceeded the maximum allowable standard of ≥ of 235MPN/100 ml. In data set #2, of the 15,000 samples reviewed, 73% had no detectable levels of generic E. coli and .71% had levels ≥ 235MPN/100 ml. A final finding showed the mean E. coli concentration levels in reservoirs were 55.25 MPN/100 ml in the north central coast, 109.29 MPN/100 ml for the south central coast. Given the high compliance rate based upon a monthly sampling regime, it’s clear that a minimum sampling schedule of one per week is excessive and will not provide any significant increase in protecting public health.

Also, a review of hundreds of LGMA food safety audits conducted since 2007, which included a thorough review of all pertinent water testing results for the audited ranches, shows that less than one percent of said audits showed water tests that exceeded the acceptance criteria. This suggests that surface water flowing in canals is of sufficient quality that should only require monthly testing.

We would also point out that the irrigation systems used in the desert growing regions are not subject to excessive runoff, and are in fact generally elevated above the ground. This acts as a natural mitigation that greatly reduces the opportunity for potentially contaminated run-off into the canals. We urge FDA to reconsider its decision to require weekly testing of surface water and instead recommend that water testing be required in accordance with local conditions or identified risks.
STANDARDS DIRECTED TO PERSONNEL QUALIFICATIONS AND TRAINING

The LGMA strongly supports sections 112.21, 112.22 and 121.23 of the proposed Produce Rule and applauds FDA for placing a high priority on training under FSMA. Like the FDA, the LGMA recognizes that effective training for all workers involved in the production, harvesting, packing, storing and transporting of produce is a critical step in ensuring safety of the food supply. Food safety training for the leafy greens industry is a priority and its importance is reflected in the LGMA’s training and education program. Therefore, we would like to address our training and education program’s structure, format and objectives; and to provide our comments to FDA on this important component of the FSMA regulations.

LGMA Comment

The FDA should provide a means for industry-specific training programs to attain recognition for equivalency with the training curriculum being developed by the Produce Safety Alliance (PSA). As an active member of PSA (LGMA Technical Director Mike Villaneva currently co-chairs the train-the-trainer committee) we understand the need for a standardized training curriculum for growers. But we also see a need for a process to grant equivalency for existing training programs designed to address the specific needs of a given industry. We are confident that LGMA Tech will meet and/or exceed the training requirements for personnel under FSMA and recommend that a process to grant equivalency for industry food safety training programs be included in the rule.

Background/Rationale

The LGMA has an on-farm training and education program (LGMA Tech) designed to drive continuous improvement in food safety practices through proactive training and education. LGMA Tech is one of the planks in the LGMA’s strategic plan and reflects our Advisory Board’s strong support and commitment to training and education. Several considerations drive LGMA Tech’s philosophies, including:

1) Consideration of a diverse audience;
2) The need for convenience and accessibility for attendees;
3) Importance of a science-based training curriculum;
4) Emphasis on proven adult-learning training techniques;
5) Training delivered using train-the-trainer concepts and
6) Importance of developing training elements which reflect the practices and processes of the leafy greens industry.
LGMA Tech was established in 2010 and since that time has provided annual workshops for the industry. The target audience is designated food safety representatives for LGMA handlers, leafy green growers and produce harvesting companies who have management and/or supervisory responsibilities for their respective food safety programs. Through the 2012/13 growing season, LGMA Tech has conducted 37 workshops and trained more than 500 industry representatives. A significant increase in LGMA Tech funding will see a doubling of workshops provided for 2013/14 growing season, greatly expanding the potential training pool.

**Curriculum**

In recognition of the increasing demand for specialized training within the industry, work has begun on developing a core training program curriculum that reflects the specific needs and challenges facing the leafy greens industry. The full curriculum will include the following courses that will be developed and provided to the industry to meet the program’s goal of continuous improvement through improved compliance with the metrics:

- Employee Sanitation and Hygiene
- Conducting Risk Assessments
- Managing Personnel and Harvesting Operations
- Cleaning and Sanitizing Harvesting Equipment
- Testing and Sampling Procedures for Water and Sanitizers
- Train-the-Trainer

The design and content of the courses is based on findings from USDA food safety audits and the tracking of violations assigned by the LGMA’s Compliance Officer. Audit data is analyzed to identify persistent issues (like conducting risk assessments, crew member training and maintenance of field sanitation units), followed by course development which targets the issue areas.

A second component of the training program curriculum is our collaboration with our sister agency, the Arizona Leafy Greens Marketing Agreement (AZ LGMA). The AZ LGMA program also provides training for its members, but with a somewhat different emphasis. While the CA LGMA targets supervisors and/or management for its training using “train-the-trainer”, the AZ LGMA program focuses on providing training at the harvest crew level. To accomplish this, the AZ LGMA has developed a set of food safety training kits. The three modules focus on employee sanitation and hygiene, cross contamination and importance of food safety; they are designed primarily for tail-gate training conducted in the field.

The AZ LGMA’s training modules have proved to be a very successful teaching tool and they complement the LGMA Tech program as well. Both state organizations work closely together, with the CA LGMA conducting workshops in Arizona and also incorporating the AZ LGMA’s training kit as part of its training efforts.
This successful collaboration is providing a comprehensive level of training for all sectors of the industry that will continue in the future.

FSMA Personnel Qualifications and Training:

The LGMA’s objective is to ensure that the LGMA Tech program fully aligns with FSMA’s proposed training regulations. We are pleased that much of the current training we provide and future training planned meets and/or exceeds FSMA’s requirements. If there are areas or topics required by the final produce rule that are not currently part of the LGMA Tech curriculum, the LGMA will add those elements in order to be fully aligned and compliant with FSMA.

The LGMA Tech training curriculum is based upon train-the-trainer format and designed to train the respective handler, grower and Harvest Company’s management and/or supervisors, which is a specific training method under FSMA. LGMA Tech will also continue to provide the specialized training needed to complement the education and experience requirements for management and supervisors levels of responsibility, another key requirement under FSMA. Having attained this level of training competency, we are confident LGMA Tech can be structured to ensure that all remaining FSMA personnel qualifications and training will be met.

The LGMA therefore suggests that the final Produce Rule provide a means to recognize commodity specific training programs – like LGMA Tech – as being in compliance with FSMA.