December 15, 2014

U.S. Food and Drug Administration
Division of Dockets Management, HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: **"Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" Proposed rule; supplemental notice of proposed rulemaking (Docket No. FDA-2011-N-0921 / RIN 0910–AG35)**

Respectfully submitted by:
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## Introduction

The California Leafy Green Products Handler Marketing Agreement (LGMA) is an instrumentality of the State of California, and was created in 2007 to provide government food safety oversight to the leafy greens industry in California. The LGMA verifies, through government audit, that farmers providing product to LGMA members are implementing accepted food safety good agricultural practices on their farms. The LGMA welcomes the opportunity to comment on the supplemental produce rule published by the FDA on September 26, 2014.

We commend the FDA for its efforts throughout this rulemaking process to communicate with all stakeholders in an effort to create clear and understandable rules for farmers and shippers of fresh produce that protect public health to the extent possible.

We believe that the supplemental produce rule has been improved in several important ways. In particular we are pleased with the inclusion of new definitions for *farm* and *harvest* – definitions that are more in line with the realities of the way the farming community operates. While we have suggestions for further improvements in these definitions, we appreciate the positive changes that have already been made. We also recognize the effort to create a water testing process that offers farmers more flexibility than did the original proposal.

While the supplemental produce rule addresses several of the issues we raised in our original comments, we would like to reiterate one or two other areas of concern. Chief among these was the FDA's decision to exempt kale from the produce covered under FSMA – as we noted in our earlier comments, kale is one of the fastest-growing fresh produce items in the world, it is a product that is definitely consumed raw, and it is – and will continue to be – covered by the mandatory food safety practices that are in place in California and Arizona for LGMA members. Kale must be covered under FSMA as well.

As stressed in our earlier comments, we look forward to seeing how FSMA requirements for compliance verification will be implemented and, in particular, how existing government food safety programs like the LGMA can be part of that process. Likewise, we applaud the FDA for including requirements for training and education of workers who harvest and handle fresh produce, and we look forward to sharing the LGMA's educational programs with the FDA moving forward.

With that introduction, we now offer the following comments on and suggestions for the Produce Rule:

## Farm Definition

The supplemental Produce Rule improves the definition of *farm*. However, the revised definition still fails to apply to much of modern agriculture in the United States. It has the potential to generate a great deal of confusion about which entities are covered under which parts of the Food Safety Modernization Act (FSMA). Concepts like farms being "under one ownership" and existing "in one general physical location" severely limit modern farm operations in their ability to determine whether or not they comply with the rules.

We recommend that the FDA utilize the definition of *farm* proposed by the Produce Marketing Association (PMA) and other organizations in their comments to the public record:

> ***Farm*** *means an establishment where raw agricultural commodities are grown, harvested, packed and/or held, animals are raised (including seafood), or both and have a common, owner, operator(s) or agent in charge and are operated under a common food safety management scheme. The term "farm" includes establishments that, in addition to these activities:*
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> *(i) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (iii)(B)(1) of this definition; and*
> *(ii) Manufacture/process food, provided that:*
> *(A) All food used in such activities is consumed on that farm or another farm under the same ownership; or*
> *(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:*
> *(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and*
> *(2) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.*

Using this definition will improve the Produce Rule by aligning it more closely with the agricultural business in the United States today and will eliminate irrelevant concepts (like a farm being under one ownership or existing in one general location). This will make the rule more understandable and logical for farmers, shippers and processors of fresh produce and will clarify that farming and

harvest activities are subject to the Produce Rule rather than the Preventive Controls Rule (or to some combination of the two). This definition will also ensure that packing houses are more appropriately regulated based on risk, and not merely by definition of their ownership and location.

## Harvest Definition

The Produce and Preventive Practices Rules, as originally proposed, included definitions of *harvest* that would have proved problematic for growers of leafy greens and other produce. Many activities that are generally considered part of harvest, including field coring, removing outer leaves, etc. – were originally cited as examples of *processing* and would have compelled coverage under the Preventive Practices Rule. The revised definitions are greatly improved, in that those activities are now listed as examples of harvest. We commend the FDA for improving these definitions in the supplemental rules.

The definitions in the two rules are inconsistent in one key aspect, however. As shown below, the Preventive Practices and Produce Rules include identical definitions of *harvest*, with the exception that *Field Coring* is not included in the Produce Rule's list of activities that are considered part of harvest.

> *Produce Rule: Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food…Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm are examples of harvesting.*
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> *Preventive Practices Rule: Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food…Gathering, **field coring**, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm are examples of harvesting (*emphasis added*).*

We assume that the failure to include *Field Coring* is an oversight, and suggest that it be corrected in the final version by adding it to the list of harvest activities in the Produce Rule. Making this change will improve the Produce Rule by ensuring that the various rules under FSMA are consistent and by making it clear that field coring is considered a harvest activity under the Produce Rule.

## Water

We commend the FDA for seeking a better approach to managing water quality in the revision to the produce rule's requirements. However, the changes made in the revised produce rules

illustrate an ongoing problem with the FDA's approach – it is a daunting challenge to tailor specific standards in an area where comprehensive science is not available.

Like the FDA, the LGMA is looking forward to studies that will allow for the creation of even better water standards. For this reason, we continue to believe that whatever standards are considered appropriate at the present time should be maintained in guidance documents, rather than in regulation (see the next section of these comments). If the standards can be kept separate from the regulation, they can be improved and updated as science illustrates better ways to reduce risk through testing and/or monitoring water quality.

The revised water standards in the supplemental produce rule call for growers to create a *Water Quality Profile* (WQP) for each water source used on a farm. Testing for each *Water Quality Profile* would take place over a two-year period, with greater testing required for surface waters than for groundwater sources. Following the establishment of the initial WQP, the farmer would be required to test multiple times each growing season, and to evaluate those tests to make sure that they did not indicate any change to the existing WQP for the water source. A new WQP would be required every ten years, or if ongoing testing shows that "the GM and/or STV values of the annual survey samples do not support your water quality profile" 112.45 (3)(b)(l)(ii).

In the event that an individual test indicates a change in the WQP, and if the water had already been used on the crop, a grower would have four options for moving forward, including implementation of a harvest interval where any pathogens present are presumed to die off at a rate of .5 log per day.

This is consistent in many ways with approaches recommended by Western Growers Association (WGA) and in use in several industries, in which growers are encouraged to develop baseline information on their water sources and systems, to monitor those systems and sources and to take action when there are anomalies outside the baseline ranges. With this approach, a precise indicator of pathogens is less important than a general indicator of water quality and indicators of fecal contamination in water. The baseline and monitoring approach lends itself to the use of an indicator such as generic E. coli, and using recreational standards as potential action points is risk-based and protective. It is likely that programs such as the LGMAs in California and Arizona and the California Cantaloupe Marketing Order would be able to comply without having to adjust or change their current programs.

We therefore agree with many of the elements of this proposed water standard. It offers growers a level of flexibility that was not present in the original Produce Rule, but it also presents some significant barriers to adoption based on its complexity[1]. Among the elements we support are the following:

[1] We note that the FDA has indicated a desire to create a website or online tool that growers could use to help them in calculating a Water Quality Profile; if this requirement is included in the final rule, we believe such a tool will be useful and necessary.

- Use of generic E. coli and recreational water quality standards. Until such time that science identifies better indicator organisms and testing standards, we believe that the FDA's use of generic E. coli and EPA recreational water standards is appropriate. While we acknowledge that neither is perfect, many experts agree that they are the best indicators currently available to industry. As UC Davis scientist Trevor Susslow has noted, "indicators are meant to be associated with fecal contamination and possible broader pathogen possibilities."

  As noted earlier, generic E. coli is utilized as an indicator organism in the LGMA-accepted Good Agricultural Practices not because it is considered a stand-in for pathogens of concern, but because a high count can indicate fecal contamination of the water source, which should then result in further analysis and possibly mitigation. We look at the use of generic E. coli in the proposed produce rule, then, in the same way, and believe it provides – at the present time – the most appropriate means of monitoring water quality.

- Use of a Geometric Mean (GM). We also agree that a Geometric Mean (GM) is an appropriate way to monitor a water source's quality. The GM, coupled with a threshold value (235 MPN/100 Ml of water in the LGMA Metrics/410 MPN in the proposed Produce Rule) provides an ongoing look at a given water source's status.

Where we disagree on the proposal is with the introduction of new and complex concepts such as *Water Quality Profile*. The concept is not clearly explained, nor do we feel it is necessary given the other steps in the process are in place.

The approach we are suggesting is already in use in much of the produce industry, and is integral to several existing food safety guidance documents, including those used by the LGMA in California and Arizona[2]. By establishing a standard that is based on EPA recreational water standards, an adequate level of ongoing testing of water sources for generic e. Coli, and using a geometric mean along with sanitary water source surveys to track water quality over time, the FDA can have a robust water testing and monitoring system in place that much of the produce industry is already using, and one that does not necessitate the creation of new concepts like *Water Quality Profile*. Coupling the Geometric Mean with an appropriate maximum value that may indicate a need for corrective actions completes the model.
The approach presented above represents our suggested model for testing and evaluating water quality. However, should the FDA decide to proceed with the approach included in the supplemental regulation, we would make the following recommendations:

Better Definitions Are Needed. To our knowledge, the terms *Water Quality Profile* and *Statistical Threshold Value* are somewhat new to the discussion of on-farm food safety practices. They are not part of the California Leafy Greens Marketing Agreement's accepted Good Agricultural Practices, and are not included in other food safety guidance documents. Therefore they are not

[2] *Commodity Specific Food Safety Practices for the Production and Harvest of Lettuce and Leafy Greens*, available here: http://www.lgma.ca.gov/wp-content/uploads/2014/09/California-LGMA-metrics-08-26-13-Final.pdf

terms currently being used by growers who are implementing good agricultural practices on their farms. We believe that each needs to be better defined, and that guidance should be provided for growers so that they know how to calculate and track both terms.

The Use of Historic Testing Data. The revised Produce Rule calls for water testing for both surface and ground water. For surface water, twenty tests over two years would be the requirement, while for ground water the proposed regulation calls for four initial tests and a single annual test thereafter. The data obtained in these tests would be used by growers to create a *water quality profile* for each source of agricultural water.

For many farmers in the produce industry – and for virtually all of them in the commercial leafy greens industry in California and Arizona – monthly water testing has been the norm for at least eight years. We would therefore recommend that the FDA allow farmers to use historic data as the basis for their *Water Quality Profiles*. Growers who can demonstrate that they have tested their water sources to the standard required by the final Produce Rule should be permitted to utilize those tests as the basis of their *Water Quality Profile*.

Die-Off Rates. In the revised rule, the FDA has applied the concept of pathogen die-off as a means of controlling risk. Specifically, section 112.44 (c)(1) instructs growers to "apply a time interval (in days) between last irrigation and harvest using a microbial die-off rate of 0.5 log per day" when water exceeds the mandated levels of generic E. coli. While this change will indeed make it easier for many growers to comply with the requirements of the Produce Rule, questions arise about the scientific validity of the standard. We have some concerns about the science behind the contention that die-off rates operate as prescribed in real world conditions in farms across the country. And we encourage the FDA to provide a thorough review of the research findings that led them to accept this concept as the basis of regulation.

At the least, we concur with PMA and others that the recommended microbial die-off rate of 0.5 log per day only be assumed for a maximum of four days after application of water (with a maximum 2 log reduction).

## Guidance vs. Regulation

In our original comments on the Produce Rule we encouraged the FDA to utilize guidance documents and include them by reference, rather than to include all of the new standards in regulation. This would, we believe, make it possible to update those standards over time in accordance with new scientific findings. We continue to believe that the FDA should take this approach, particularly given some of the changes in the supplemental Produce Rule published in September. The FDA has acknowledged that new and better research will help identify long-term standards when it comes to both water testing and soil amendments, and putting current thinking into regulation that will be difficult to change should be avoided in these and other areas of the Produce Rule.

Along with the difficulties of changing regulation, we can also foresee a situation where, as new science reveals better ways to protect public health, the produce industry will have no choice but to apply for an array of variances and alternatives in order to stay current with science. Eventually, the law itself will be marked by outdated standards and the produce industry will have to maintain large numbers of alternate practices and standards for protecting the consumer.

We therefore encourage the FDA to include both the new water testing schemes and the soil amendment harvest interval standards in guidance documents, and to incorporate them by reference or to consider using qualitative regulatory provisions in the regulation as part of the FSMA rules.

This will improve the Produce Rule by ensuring that new science can be incorporated into long-term standards without requiring the difficult and time-consuming efforts to change regulation. This will minimize the use of variances and/or alternatives, allowing the FDA to keep the required practices up to date with new science.

## Soil Amendments

We have concerns about the changes to the soil amendment practices proposed in the supplemental Produce Rule. As written, it now appears that there will be no harvest intervals mandated for any of these potentially risky products, raw or otherwise.

Research has shown that soil amendments can present a risk in the production of fresh produce. We believe, therefore, that food safety standards should be in place to mitigate this risk to the extent possible. The LGMA standards do not allow the use of any raw manure, and we continue to believe this prohibition should apply to all fresh produce production. At the very least, the types of application-to-harvest intervals included in the original produce rule should be maintained to mitigate risk from both compost and raw manure.

We applaud the FDA's efforts to build greater scientific knowledge through a broader risk assessment and robust research strategy in the focus area of soil amendments; and the proposal to coordinate with USDA and stakeholders to transition the grower community to the use of compost rather than raw manure.

While the agency pursues avenues of scientific research and infrastructure development, we suggest the original minimum application intervals of 9 months for untreated biological soil amendments of animal origin and a 45 day harvest interval for composted biological soil amendments of animal origin be maintained in the Produce Rule.

## Exemptions

We believe, on principle, that all farmers of any size should adopt appropriate food safety practices to protect public health. As has been stated many times, pathogens do not heed farm size, and food on any farm can be contaminated.

Based on our experience utilizing a set of on-farm food safety practices that are far more prescriptive in many ways that what the Produce Rule will require, we believe that even small farms can adopt food safety practices scaled to meet their operations, without undue hardship. Therefore, we disagree with the proposal to exempt even more farms (by stipulating that the $25,000 limit for exemption applies to produce only and not to all food produced on a farm). We encourage the FDA to limit exemptions to the extent it possibly can, in the interest of protecting public health.