Produce Marketing Association (PMA) represents 3,000 member companies and organizations across the entire produce supply chain, from field production through the end users at retail and foodservice. For our members in the global produce industry, food safety is the most important and compelling issue facing the industry today. PMA is playing a catalytic role in working with our membership, related trade associations, Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), and state and local agencies to develop and implement improvements in our industry’s food safety practices. PMA is also providing technical expertise, input on industry practices and logistics, and constructive feedback to FDA on food safety issues ranging from product traceback to technical developments and agency guidance documents.

PMA has long advocated for produce-specific food safety legislation that is risk-based, commodity-specific, based on sound science, and applicable to domestic production as well as imports, with the goal of creating a level playing field for our industry. Our work includes industry food safety education, such as educational workshops at PMA events and symposia designed to promote an industry-wide food safety culture. Our commitment to food safety extends to donating more than $2.5 million to fund creation of the Center for Produce Safety at the University of California at Davis; CPS’ mission is to fund and disseminate research to answer the produce industry’s food safety questions.

We are pleased to comment on the FDA’s “Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens.” The industry has expended a great deal of effort in preparing food safety guidance for leafy greens over the last several years. More recently we have specifically focused on developing leafy greens metrics in California and Arizona as part of state marketing agreements.

PMA supports risk- and science-based federal regulation for produce safety that applies to fresh fruits and vegetables grown in or imported into the United States. Beyond general rules for all produce, we support the development of commodity-specific regulations for those commodities that FDA has identified as most likely to be associated with foodborne illness outbreaks. We applaud FDA for moving forward with this guidance. In addition to FDA’s efforts, PMA supports the state-level leafy greens marketing agreements in California and Arizona as well as the national effort for a leafy greens marketing agreement through the U.S. Department of Agriculture.
In preparing these comments, PMA enlisted input from growers, processors, retailers and foodservice operators to gather perspective on specific issues. We also participated with allied associations in an exchange of ideas and perspective from a broad cross section of the industry. Our comments here reflect those discussions and PMA’s commitment to improving food safety practices for leafy greens. We have used the headings of the FDA draft guidance to organize our comments as appropriate.

II. Background

The Background section of the draft guidance references two items about which PMA is hereby requesting more information.

First, this section states that from 1996 to 2008, “28 produce-related outbreaks were linked to the consumption of leafy greens.” It would be beneficial for the industry and the research community to know more detail concerning these outbreaks, i.e.:

- how strong was the link back to leafy greens from an epidemiological perspective;
- was the original cause of the contamination determined;
- were there any seasonal, geographic, product format or demographic trends identified within or between outbreaks that might be useful in formulating risk management strategies; and
- what did FDA learn from these outbreaks and the subsequent epidemiological and traceback activities that might help the industry better manage food safety risks and assist FDA (and CDC) in identifying causative products or conditions in future outbreaks?

Second, this section also references a joint activity of FDA and California Department of Health Services (Lettuce Safety Initiative) to study specific products and practices for lettuce and other leafy greens initiated in 2006. This draft guidance indicates that findings from this joint initiative will be incorporated into FDA’s final commodity specific guidance on leafy greens.

The industry would welcome an opportunity to review these findings with FDA so that they might be used to help growers, harvesters, processors and the research community to advance our food safety efforts on leafy greens production.

III. Scope and Use

- **Inclusion of Cilantro and Parsley:** In the first paragraph of this section, the draft guidance defines leafy greens by commodity and specifically omits leafy herbs like cilantro and parsley.

  The industry considered this issue when developing the Leafy Greens Marketing Agreement (LGMA) and decided to include these herbs in their marketing agreement. One of the underlying reasons these commodities were ultimately included was because growers produce parsley and cilantro on many of the same farms and ranches, using the same relative production and handling practices, as they do other leafy greens. The industry also recognizes that cilantro and parsley have had recurrent incidents of pathogen positive tests and sporadic recalls in recent years. Therefore, it makes practical and technical sense to implement the same risk-based food safety approaches to parsley and cilantro production in an effort to improve the food safety profile of these commodities.
It is also important to note that both parsley and cilantro are commonly included in specific spring mix formulations and can also be packed alone for use in foodservice.

Given these factors, we recommend that FDA expand or amend the definition of leafy greens to include parsley and cilantro.

- **Prevention and the Consumer’s Role:** Paragraph 2 of this section discusses the importance of employing prevention rather than elimination strategies to address microbial hazards. PMA strongly supports this philosophy as well as FDA’s further comments emphasizing a supply chain-wide focus on prevention. We also recommend that the consumer’s role in prevention also be recognized.

**IV. Definitions**

- **Leafy greens:** To avoid misunderstanding and for ease of use, we suggest repeating the definition of “Leafy Greens” here.

- **Fresh-cut fruits and vegetables or fresh cut produce:** With the exception of mushrooms, we are unaware of any fresh-cut products that are not washed as part of processing. Therefore we suggest revising the first sentence of the definition as follows: “Fresh-cut fruits and vegetables or fresh-cut produce refer to fresh fruits and vegetables for human consumption that have typically been washed, minimally processed and altered in form by peeling, slicing, chopping, shredding, coring, or trimming prior to being packaged for use by the consumer or a retail establishment (e.g., pre-cut, packaged, and ready-to-eat salad mixes).”

- **Water disinfectant:** The term “Water Disinfectant” is used throughout the document. We suggest adding the following definition for water disinfectant: “Antimicrobial agents approved for such use in 21 CFR Part 173.315, Chemicals used for washing or to assist in the peeling of fruits and vegetables. These include materials such as sodium hypochlorite (and the other related sources of the active agent hypochlorous acid), chlorine dioxide, various peroxides and ozone.”

**V. Production and Harvest**

- **Environmental Assessments and Risk Reduction Practices section:** Here FDA correctly focuses on the importance of risk assessment, listing potential sources of risk that producers should consider when conducting these assessments and building their food safety programs.

PMA strongly supports the emphasis on risk assessment. Indeed, risk assessment should be the cornerstone of any food safety program. Performing a true risk assessment prior to planting, again immediately before harvest (“pre-harvest”) and at harvest essentially forces involvement and focused attention to food safety by those who know their operations best: the growers, harvesters and processors. This unique, individual action is favorably contrasted to the all-too-common one-size-fits-all approach some operators have adopted to gain a favorable score on a mandated food safety audit. It is not uncommon for producers to use standards or audit checklists provided by customers, third parties or government sources as an outline to provide the required paperwork necessary to meet the audit criteria while not
performing a real risk evaluation for their specific operation. PMA believes improvements in food safety performance can only be achieved when individual operators all along the supply chain take responsibility for the safety of their products conduct an operation-specific risk assessment and develop the follow-on risk management practices.

While this section of the draft guidance clearly speaks to risk assessment, PMA urges FDA to consider adding a section (perhaps under “III. Scope and Use”) on the critical role of risk assessment throughout the supply chain (not just production and harvest), the basics of conducting a risk assessment, resources operators can use if they need assistance and the responsibilities each operator shares in evaluating risk and developing effective risk management practices.

- **Water section:** Here the draft guidance again has an underlying focus on assessing the food safety risks that might be posed by water source and/or application method. This is appropriate and provides broad opportunities for growers to use a wide variety of water sources for irrigation and pesticide mixing provided they perform a microbial risk assessment and implement strategies to mitigate potential contamination.

In lieu of adopting specific metrics, FDA recommends operators “ensure that water is of appropriate quality for its intended use, obtaining water from an appropriate source, or treating and testing water on a regular basis and as needed to ensure appropriate quality.” This is a strategic issue for FDA, i.e., whether the agency chooses to aim for setting a “floor” or a “ceiling” in these commodity specific guidance.

PMA recognizes the deficit of scientifically generated data that could be used by FDA to more specifically define “appropriate water quality” for irrigation water and pesticide mixing uses. Given this circumstance, FDA is encouraged to engage the produce industry through the Center for Produce Safety (CPS) and other agencies or academic institutions to provide research funding to support efforts to more scientifically define irrigation water risk factors.

Preliminary data collected by numerous California and Arizona leafy greens growers and shared on a limited basis with regulators suggests that even generic *E. coli* is rarely found in wells, public reservoirs, on-farm reservoirs and irrigation canals used to irrigate leafy greens. However, these limited data are not sufficient by themselves to provide for an adequate quantitative risk evaluation of water risk, nor can they be extrapolated to the rest of the United States.

CPS has recently funded a research project to more rigorously evaluate current data and add additional data points and other contextual observations to the database. We anticipate that this program will help the industry and FDA better assess the risk priority placed on irrigation water as a vehicle for pathogen contamination.

PMA and/or CPS would be happy to engage FDA to extend current research activities on irrigation water quality, and perhaps permit future quantitative measures that can be used by producers to guide decisions about water use. Note that this research could also have broader
application as many other commodities are produced (sometimes in the same geographic locations) with the same irrigation water sources as used for leafy greens.

- **Soil Amendments section:** This part of the draft guidance states that “FDA recommends verifying the time and temperature process used during the composting process to ensure that the potential of human pathogens being carried in the composted materials is reduced, controlled, or eliminated as applicable to regulatory requirements.”

Here again, PMA recognizes that both the industry and FDA lack sufficient data to more fully define the parameters for treating various types of composts to ensure they are pathogen-free. We are not aware of any documented, validated process for treating composts and handling processes for both raw and finished materials to diminish the chances for cross-contamination. Subsequently, the industry and FDA are left with recommending that producers ask their compost suppliers for time and temperature records in lieu of requiring documentation that a scientifically validated process has been followed.

The produce industry would benefit greatly from research that defines validated processes for reducing and/or eliminating pathogens from manure-containing composts. The use of compost is a necessary element in maintaining soil fertility, composition, texture and productivity. Yet, compost is also the only agricultural input where we know pathogens are reasonably likely to be present prior to the compost process. Therefore it is imperative that we develop validated processes to manage this potential risk.

It is also important to note that both conventional and organic growers employ a wide variety of composted or “treated” materials (e.g. bovine, chicken and pig composts, bird and bat guano, spent mushroom mulches, organic teas, heat-treated pellets, etc.) so that process validation is going to require a diversity of activities and programs. CPS has funded a research program to specifically look at this area but much more is needed to bring real understanding and measurable criteria to this critical need. Since sufficient experimentally developed data and validation processes do not currently exist, FDA could be in a pivotal position to partner with CPS, industry, universities and other government agencies to fund research to define validated composting processes for the array of materials currently in use by growers around the country.

- **Hand Harvest section:** In this section FDA describes a hand harvest practice where leafy greens may be harvested by cutting and then being stacked or placed back on the ground prior to packing in a carton. That soil contact represents a potential risk for pathogen attachment (if they are present) to the cut or exposed surfaces. As a result, the practice FDA describes has been replaced in major production areas by the use of harvest machines with conveyor belts whereby cut product is placed on a belt and conveyed to a packing station where the product is packed in a carton and then palletized. However, we are aware that the described practice is still employed by some growers, such as those harvesting only small quantities of varietal lettuces where a machine-assisted harvest would not be practical. Nonetheless, soil contact is a risk that requires management and as such harvested products should not be placed directly on the soil.
**Flooding section:** In this section dealing with formerly flooded production ground, FDA recommends “sampling previously flooded soil for the presence of microorganisms of significant public health concern or appropriate indicator microorganisms.” FDA also cautions that sampling and testing by themselves do not guarantee that all commodities subsequently grown on that formerly flooded ground will be free of human pathogens.

Given this caution and the reality it reflects – i.e., our basic lack of knowledge regarding survivability of pathogens in soils, mechanisms of transference of pathogens from soils to plants and statistical probabilities for construction of sufficient sampling paradigms – PMA requests that FDA delete this entire bullet point from the draft guidance. As it stands, the recommendation simply adds costs without really revealing information that might be actionable by the producer (i.e. a negative result is not proof of absence so why test in the first place?) If the grower follows the other FDA recommendations listed in this section and deems that all of these risk factors have been weighed and sufficiently managed, then testing will not likely change that outcome.

**Water Usage to Prevent Product Dehydration section:** FDA recommends “testing water periodically to ensure that it is of appropriate microbial quality for its intended use.” Since this water is applied directly to the product (and thereby any cut surfaces on the product) at or after harvest, and at least some of these products are moved directly into commerce without further processing, FDA may want to consider requiring water used for these purposes to be drinking water quality (as defined by the Code of Federal Regulations, i.e., 40 CFR Part 141.63). This removes the ambiguity of leaving it up to the grower or harvester to determine what “appropriate microbial quality” means, and clarifies the requirement that the water needs to be of high enough quality that it can be consumed directly by humans.

Verification testing periodically is still a reasonable recommendation to help ascertain that the water has not become contaminated prior to application, or that the delivery system has not been compromised. A recommendation to use drinking-quality water for product dehydration prevention purposes should not impose any significant hardship as growers and harvesters have or should have ready access to drinking water sources and generally provide drinking water to their work crews.

**Product Tracing section:** Here FDA details recommendations for producers to develop and maintain “standardized, clear records that can be used to enhance the ability to follow the movement of the product.”

During recent produce-related outbreaks of illness, FDA has expressed the difficulties it has faced in conducting efficient and effective tracebacks from the point of consumer purchase or consumption back through the supply chain to the original producer. As the industry and FDA well know, the issue of traceability really isn't about the producer maintaining clear records, it’s about linking the various components of the traceback – i.e. the various stops the product may make in the supply chain, and the venues where it may be handled along with the associated paperwork that verifies its identity that often proves difficult.
For example, buyers often require growers, shippers or processors to place stickers or print traceback codes on their products at either the case or unit level, if not both. These stickers can be as simple as a small half-inch square adhesive-backed paper sticker that has only a use by date and/or a supplier number to a larger sticker or jet print format that holds a proprietary code in both human readable and barcode forms. No matter the complexity or format of coding, they are generally tied to the grower’s lot number, harvest company, receipt information and the harvest date (and perhaps the best if used by date). These codes are also tied in with the original production documentation; i.e. production records, harvest records, bills of lading, quality assurance records, food safety documentation, shipping invoices, etc.

In essence, products can be traced at the grower/shipper level because that is how products are shipped (and buyers are invoiced) and received (and growers get paid). So inherently, the production segment of the industry can trace product one step back to the original source and one step forward to the initial customer as required by the Bioterrorism Act.

The real issue in traceability emerges as product moves up the supply chain and as the chain branches out to reflect the multiple sources of single products retailers and foodservice procure and sell, individual company practices for shipping and receiving, re-packing or raw product blending to meet quality performance standards, the lack of uniformity or format for product codes and the current inability to capture trace information along the supply chain. The key to linking each step of the supply chain to enable rapid trace in the event of an outbreak or product safety issue is to create a common format for the product coding information.

That is why the industry formed the Produce Traceability Initiative (PTI), consisting of growers, processors, retailers and foodservice companies, and coordinated via the industry trade associations, including PMA, United Fresh Produce Association and Canadian Produce Marketing Association. These trade associations have previously shared with FDA the features of the PTI. The initiative calls for chain-wide, electronic product traceability by prescribing a standard format based on globally-recognized GS1 coding standards for both human readable and machine readable (scan-able bar code) labeling at the case or carton level.

The PTI is not a trivial solution, and not without issue. PMA concurs with FDA that the industry needs to have an effective mechanism for product traceback; we have far too many recent instances where the market for entire categories or commodities was devastated when the issue really involved only a single producer. Therefore, PMA is committed to working with FDA to find a solution to produce traceback outside this current guidance. We urge you to consider the PTI model as the standard to follow to promote traceability.

VI. Postharvest

- **Cooling section:** In this section, FDA recommends “using single pass or one-use cooling water in hydrovacuum cooling of leafy greens”. The guidance then goes on to recommend, “using water disinfectants at sufficient levels if any leafy greens
hydrovacuum cooling water is re-circulated and monitoring the levels to reduce the potential risk of cross contamination”.

Many current hydrovac systems do indeed use water reservoirs and re-circulate this water throughout the day. Most cooling tube operators empty the reservoir and sanitize the equipment daily.

From a food safety perspective, it is important to chill leafy greens as soon as possible to decrease product damage that may facilitate migration of pathogens (if present) to damaged tissues, where they might grow if left at ambient temperatures. Additionally, from a product quality standpoint, any delay in cooling caused by a backlog of product can have dramatic negative impact on product quality (e.g. texture, flavor, color, etc.) that can result in reduced value of the product in the market.

Draining the cooling reservoir between loads to create a single pass system would hamper efficient use of the equipment and may actually result in increased food safety risk as well as product quality loss. And given the expense involved, this equipment is typically are operated at capacity – meaning it is not unusual in many operations to run hydrovac tubes from early morning when products begin to arrive from the fields to late at night when the final harvests of the day are transported to the cooling facility. Operators are not motivated to reduce their efficiency.

Recognizing this reality, FDA should consider the following.

- Recommend that hydrovac reservoir water be of drinking water quality. Cooling tubes are operated in proximity to cooling and distribution facilities. The water for these facilities is likely to be served by wells or municipal water sources. Therefore, recommending the use of drinking quality water should present no hardship to operators and it ensures that the water at the beginning of each day does not present a contamination risk. Water testing is the recommended verification that these municipal or well sources are indeed of drinking water quality.

- Recommend that hydrovac tube operators test the reservoir water for proper levels of active disinfectant(s) between loads, to ensure appropriate levels are maintained in the system and that the water does not represent a cross-contamination vehicle between loads. The operator would have to verify adherence to this recommendation by testing the retained reservoir water between loads and when make-up water is added. This is relatively easy and inexpensive to do, and would not significantly reduce machine efficiencies.

- **Postharvest Water section**: Here FDA recommends “testing the water source periodically at a sufficient frequency”. In consideration of the use of this water (e.g. water used to make ice slurries for cooling products, or water used to aid in packaging where it has direct contact with the harvested product), FDA should consider recommending that this water be of drinking water quality. This modification has the purpose of defining what water quality is expected and, in conjunction with the microbial
verification testing, sets a measureable objective for operators. Therefore, FDA should amend that specific recommendation to read: “testing the water source periodically at a sufficient frequency to ensure the water is of drinking water quality”.

- **Bulk Bin Modified Atmosphere Process (MAP) section:** Here the draft guidance points out that bulk bins are sometimes lined with plastic, and the atmosphere inside the lined bin is modified by introduction or back flushing of gas-phase nitrogen. This process is performed when either iceberg or romaine is to be held for a few days or shipped prior to processing to limit oxygen-dependant quality degradation.

FDA goes on to recommend that this process be “conducted in an environment that is protected from potential food safety hazards”. This phrasing seems awkward, because back flushing is generally conducted at cooling and distribution operations after the raw products have been cooled. These facilities should be operated under the risk-based food safety program for that specific facility and subject to Good Agricultural Practices programs as outlined elsewhere in this draft guidance (VIII. Distribution, Section B. Condition and Sanitation).

In light of this redundancy and with appropriate emphasis on risk assessment for individual operations, FDA should consider re-wording this recommendation to read: “performing a risk assessment for bulk bin modified atmosphere procedures and developing management practices to reduce or eliminate the potential for contamination of the raw products”.

**VII. Fresh-Cut/Value Added Processing**

- **New Technologies section:** In this section, FDA recommends that processors “determine the impact on food safety when evaluating new technologies, e.g. shelf life extenders”. This recommendation is certainly sensible and we strongly support its intent.

We would point out that FDA might want to consider anchoring this recommendation in the context of risk assessment, i.e. a change in process, product format or packaging execution might very well represent a change in an operation’s food safety risk profile. Therefore, the operator would need to re-examine the risk assessment and evaluate if current risk management tools are appropriate or need to be changed.

FDA should extend this argument to the entire supply chain and not just value-added processing. Along the supply chain, a new ranch, a new grower, an improved harvest machine, different bins, a new harvest crew, new cooling equipment, an alternative hauling company, new process equipment, new packaging, a new distribution center or updated display cases all may (or may not) change the operator’s risk assessment and the recommended approach is to update the assessment and assess management practices.
VIII. Distribution

- **Condition and Sanitation of Transportation Vehicles section:** Here FDA recommends: “Implementing inspection programs of shipping containers/trailers to verify that the food safety needs are being met. Evaluating items including the container/trailer condition, overall cleanliness of the walls and floor, good structural condition (e.g. free from damage to walls, floor or ceiling, such as exposed insulation and holes), absence of off-odors or unusual smells, and functional chilled air delivery chutes”.

FDA should add “evidence of pests” to this list of items. This is a common risk that is routinely checked by many in the industry already.

- **Techniques for Temperature Measurement of Product section:** This section recommends non-invasive methods for measuring temperature of leafy greens products, and goes further to recommend “pillowing” the temperature probe between packages. This indeed is the common practice to measure the temperature of packaged products, e.g. pre-cut salads, romaine hearts, etc.

This “pillowing” method is generally not used when measuring the temperature of commodity leafy greens products (i.e. raw, non-packaged products). Often, these products are penetrated with a temperature probe to measure temperature. As these carton products are often sold by count, e.g. 48-count whole romaine, 36-count iceberg, etc., discarding the heads is not a desirable option.

FDA should add a recommendation that would cover this scenario. The second bullet in this section could be amended to read: “When measuring the temperature of un-packaged products, if an invasive technique is used, the operator should discard any product penetrated, or alternatively the operator could use a disinfectant to sterilize the temperature probe prior to use and again after each measurement”.

IX. Retail and Foodservice

- **Retail and Foodservice Handling section:** Here FDA recommends “Ensuring water used to wash leafy greens is of appropriate microbial quality for its intended use”. Within this commentary, PMA has suggested FDA consider recommending any post-harvest wash water or water used for cooling or rehydration be of drinking water quality. This would bring consistency to the whole supply chain while removing the ambiguity of “appropriate microbial quality” without posing a hardship for retail or foodservice operators.

- **Leafy Greens Re-Crisping section:** FDA uses the introductory section to point out that any chlorine present in tap water would be quickly inactivated by the organic load presented by leafy greens, and that this may increase the potential for cross-contamination particularly if additional leafy greens are added to the re-crisping container.
In the first bullet, FDA recommends using water supplies of “drinking water quality” and changing the water for re-crisping leafy greens at a “frequency sufficient to ensure that it is of appropriate microbial quality for its intended use”. PMA supports the use of water that meets drinking water quality, but would urge FDA to recommend that when leafy greens are re-crisped by soaking, a disinfectant (as permitted by FDA in 21 CFR part 173.315) should be used to keep the water free of potential pathogens and prevent cross contamination in addition to changing the water frequently, as determined by turbidity or the amount of soil and debris in the water. This is consistent with what is recommended for produce washing operations. Additionally, operators should consider measuring the amount of active sanitizer periodically, and keeping verification records much as processors are required to do.

The second bulleted FDA recommendation, “Evaluating use of running water to re-crisp leafy greens as needed, in lieu of re-crisping by water soaking, to reduce the potential for cross contamination” is likely to be functionally impractical in a retail environment and may merit deletion from the document.

PMA appreciates the opportunity to comment on this draft guidance and looks forward to working with FDA to clarify any comments made here and to help finalize this guidance document.

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