July 23, 2010

To: U.S. Food and Drug Administration/Center for Food Safety and Applied Nutrition
http://www.regulations.gov

Subject: Preventive Controls for Fresh Produce: Request for Comments
Docket Number – FDA-2010-N-0085

Produce Marketing Association (PMA) is pleased to submit these comments to U.S. Food and Drug Administration (FDA) regarding the agency’s request for comments on preventive controls for fresh produce.

PMA is the largest global not-for-profit trade association representing companies across the supply chain that produce and market fresh fruits and vegetables. We represent over 3,000 companies from grower-shipper and supermarket retailers, to hotel and restaurant chains and overseas importers. Within the United States, PMA members handle more than 90 percent of fresh produce sold to consumers. PMA and our members are committed to improving food safety practices for produce, domestic and imported, to further enhance the safety of our food supply.

We have been actively engaged in produce industry development and implementation of food safety practices and have worked closely with FDA, U.S. Department of Agriculture (USDA), Centers for Disease Control and Prevention (CDC), as well as state and local agencies as a source of industry information and of technical inputs, and as a supporter of these agencies in assuring public health. In developing our response on this issue, we incorporated comments and thoughts from our Chief Science & Technology Officer, Robert Whitaker, Ph.D., and leveraged the expertise of our Produce Safety, Science and Technology committee. This group is a committee of PMA’s Board of Directors and is composed of industry leaders and food safety experts from the entire produce supply chain.

PMA has been a strong supporter of federal legislation on produce food safety that is risk- and science-based. PMA has played and will continue to play a catalytic role in working with our membership, related trade associations, FDA, USDA, state and local agencies to develop and implement improvements in food safety practices. PMA historically has provided technical expertise, input on industry practices and logistics, and constructive feedback to FDA on food safety issues ranging from traceback investigations to technical developments and agency guidance documents.

We will provide comments as requested by FDA organized according to the subject areas listed in the docket.
1. **Role of the Good Agricultural Practice (GAP) guidelines entitled “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables”**

FDA’s GAPs guidance has historically laid out a generalized framework of various agricultural production and product-handling practices, and offered potential risk management tools to mitigate contamination. Since their development and publication in 1998, FDA has asked for and the produce industry has responded with commodity-specific GAP guidance for tomatoes, leafy greens, melons and green onions. In 2009, FDA requested comments on draft commodity specific guidance for tomatoes, melons and leafy greens and PMA provided extensive comments at that time. PMA believes FDA’s GAP guidance and the subsequent commodity-specific guidance serve three very specific roles moving forward:

- **Education.** The FDA GAP guidance is an educational tool for growers, small and large, domestic or foreign, as to the agency’s view on the potential food safety risks that fruits and vegetables may be subject to during their production, harvest, cooling, sorting, packing, storage and shipping. The guidance can suggest general methods to control or manage these contamination risk factors and present examples of how growers, harvesters and shippers can develop food safety programs and verify their effectiveness.

- **Cornerstone for next-generation document development.** The FDA GAP guidance is a starting point from which the FDA can work with the produce industry based on demonstrated risk. Indeed, the original 1998 GAPs guide has been the basis for industry and FDA activities that led to the development of commodity-specific guidance for melons, tomatoes, leafy greens and green onions over the last several years. In some instances, the industry has developed food safety programs that are intended to be used in conjunction with the original 1998 FDA GAPs guidance. The Leafy Greens Marketing Agreement’s (LGMA) “metrics” program is an example where its metrics can be seen as an extension of the FDA GAP guidance, with measurements specific to leafy greens production.

Further, as various other commodity groups (e.g., green onions, watermelons, mushrooms and citrus) have sought to develop their own versions of commodity-specific food safety programs, the 1998 FDA GAPs guide has directly or indirectly served the framework for initial discussions and provided a roadmap to guide their risk assessment process. Going forward, as we gain knowledge from ongoing food safety research, improved epidemiological investigations of foodborne illnesses and enhanced risk profiling, the FDA GAP guide and subsequent commodity-specific guidances can serve as starting points for the agency and the industry to overlay this increased knowledge to develop improved general food safety regulation and/or additional commodity or production practice-specific guidance for industry implementation.
A component of a benchmarking tool. In late 2008, PMA provided comments to FDA suggesting that its guidance documents could form the basis of a benchmarking guidance. In recent years we have seen some industry acceptance of the concept of benchmarking as a mechanism to ensure that various standards and the audits derived from them address key food safety risk factors, and that the audit itself is conducted efficiently and consistently. The promise in this approach is that benchmarked standards can be recognized as equivalent, perhaps thereby alleviating some of the redundant auditing currently a concern for producers and buyers. Since originally commenting on this concept of the FDA GAP guide and its use as a component of a benchmarking guidance, PMA has refined our thoughts and will outline them further in the following section of these comments.

2. Standards for domestic and foreign growers and packers

A plethora of food safety “standards” have been developed for produce over the last decade. Indeed, the number and marketing of these “standards” and the audits that are derived from them have benefited the industry by encouraging food safety discussion and providing food safety tools for suppliers. However, they also have resulted in a great deal of frustration, duplication and confusion in the marketplace. The net result has been cries of “audit overload” from producers and ever-increasing costs balanced against the sincere desire to improve food safety performance. Even at a basic level, the use of the word “standard” has come to mean very different things within the produce industry and seemingly within FDA. Today, we have everything from Codex through globally benchmarked standards, to proprietary third party standards, to commodity-specific standards (e.g., LGMA GAP Metrics, Tomato GAPs, Melon GAPs). All are referred to commonly as “standards” when in fact they are very different documents designed for different purposes.

With those general comments in mind, PMA believes that FDA should consider the following in regards to food safety standards:

- Consumers expect our products to be safe. It is clear that the produce industry is at once both global and local. Our customers expect year-round availability of high quality fruits and vegetables, and they expect them to be safe every bite, every time. From a food safety perspective, it doesn’t matter where the produce comes from; consumers do not expect to be injured in the consumption of a food product. Therefore, any fruit or vegetable consumed in the United States should be produced under food safety standards that have the same degree of rigor, are risk-driven, and are based on the best science available and permit verification (e.g. documented and auditable). If a farmer in Florida produces vine-ripened tomatoes and ships them to a retailer who is also receiving vine-ripened tomatoes from a foreign supplier, the consumer should not be burdened with the possibility that the two products were produced under different food safety expectations. FDA and the produce industry need to operate under a common set of expectations. It would seem reasonable from an enforcement perspective that
FDA would desire as much uniformity as possible. The buying side of the produce industry (retail and foodservice) would also benefit from the adoption of this basic concept of uniform expectations for foreign and domestic producers as they seek to communicate with consumers on food safety and protect their brands. Producers would also be expected to benefit as everyone would be operating on a “level playing field”. In addition, a number of foreign producers are tied closely to U.S. producers, and this baseline expectation of food safety performance would help them focus resources internally and calibrate their programs regardless of geography.

- **We need to define what a food safety standard contains.** FDA can help the industry define the term “standard”. As indicated above, “standard” is commonly used and misused across the industry. Given the global nature of large sectors of the produce business, it seems that adopting a global view of a food safety standard may have some merit. FDA is certainly aware of the European origins and globally-focused activities of Global Food Safety Initiative (GFSI) and GlobalGAP and the elements of a food safety standard they have been prescribing. In order to have harmonized expectations and drive food safety performance, it seems that in the United States we need to place equal emphasis on both the food safety content (risk assessment, risk management practices, verification tools, employee training, traceability, etc.) and the process by which operators are audited to verify they are adhering to their food safety plans.

Historically, in the United States we have focused only on the former since the 1990s. FDA’s 1998 GAP guidance offers very little guidance on how verification should occur and the process for performing fair and equitable audits. Indeed, FDA just offered guidance on this piece of a comprehensive food safety standard in 2009. Absent direction from FDA, the operations of certifying bodies or third party auditors has been left to the marketplace.

Certainly, there are some excellent third parties that operate with utmost integrity and a passionate focus on serving their customers and contributing to the food safety performance of the industry. However, there has been enough inconsistency in their performance to erode producer, retail and foodservice confidence, resulting in the fragmented and redundant model we see today. Going forward, PMA encourages FDA to define the content of a food safety standard, setting expectations for both the food safety content and the process for certification. One could clearly see a “merger” of content between FDA’s 2009 Guidance for Third Parties and the 1998 GAP guidance (and the 2009 commodity-specific guidances) to form a complete FDA guidance for developing standards.

- **FDA and the produce industry need to work together to develop meaningful standards.** While PMA advocates the need for FDA to bring structure to defining the content of produce food safety standards, FDA should not solely take the burden of developing specific standards for each sector of the produce
industry. FDA does not have and never will attain the level of industry or operational knowledge to write produce food safety standards. That should not be construed as a criticism of the agency; it would be an unattainable expectation given the breadth of FDA responsibilities and resource allocations. Instead, we encourage the agency to engage industry’s expertise to develop specific standards, for several reasons.

PMA has previously argued that true improvement in food safety performance can only occur when, collectively as an industry and individually as companies in the supply chain, we accept responsibility for the safety of our products and act in our best interests to implement food safety programs. An extension of that argument is that the industry – i.e., commodity boards, trade associations, universities and industry members – must also accept responsibility for collectively developing risk- and science-based food safety standards, based on our intimate knowledge of our production practices and the environment we operate in every day. Using FDA guidance documents or benchmark guidances as a basic template, industry can develop standards that are specific to commodities, locations, seasons and production methods, and have real meaning to those who should and must adopt them. Moving away from the industry view to the individual companies’ view, an industry-developed food safety standard will ease development of an individual company’s written food safety program.

This industry-fed approach may serve to blunt criticisms of individuals in the produce industry that “one size fits all” standards (e.g., standards derived from FDA guidance by third parties, standard owners or buying groups) don’t work because they are not relevant to their commodity, daily production practices or operations. This industry-fed approach will also help foster industry buy-in. We have seen many times that the industry will rise to the occasion and work together to develop food safety standards or metrics, as evidenced by the several groups that have worked together at the commodity or regional level to develop many of the commodity-specific and regional programs we have today (e.g., CA/AZ LGMA, Tomato GAPs).

- **FDA needs to “benchmark” industry standards.** If the produce industry is to take on the role of using FDA benchmarking guidance to develop risk-based, commodity or practice specific food safety standards, then FDA must take on the role of ensuring those standards meet the agency’s definition of a comprehensive standard. PMA has previously suggested that FDA “recognize” standards that meet the criteria outlined in its guidance documents. In essence FDA would take on the role of a benchmarking entity; i.e., FDA would review industry-developed food safety standards to ensure they meet criteria outlined by FDA in its rules and accompanying guidance to protect public health. FDA’s GAP guidance, 2009 commodity specific guidances, 2009 third-party guidance and perhaps other guides would form the basis of a comprehensive benchmarking guidance document. This benchmark guidance would essentially serve as a roadmap for
industry groups to use in developing future standards or fine-tuning existing standards.

However, without an authoritative entity to measure whether the standard owners have developed standards that reflect FDA’s basic requirements and provide for sufficient verification, we would be no better off than we are today – that is, multiple and overlapping standards would engender confusion among producers and buyers. FDA can fill this role by providing a formal mechanism for benchmarking proposed food safety standards. This mechanism could take several forms but could be as simple as the following.

- A potential standard owner could prepare a food safety standard and submit it to FDA for benchmarking.
- FDA would organize a technical working group for produce, perhaps composed of agency scientific experts, USDA and CDC experts, academic scientists, extension personnel and industry experts. The technical working group could be organized further into commodity-specific review committees to bring subject specific focus.
- Proposed standards could be assigned to the appropriate review committee for consideration.
- Using FDA’s benchmark guidance, the review committees would conduct a benchmarking exercise to either approve the proposed standard, reject it or identify areas where modifications are necessary for re-submission. Clearly this process must be open and transparent. The rigor of the process – and the capabilities of the committee members – will be critical to the credibility of the program.
- The recommendation of the review committee might then be reviewed by the working group as a whole to be sure that all issues have been identified and addressed.
- Finally, the recommendations of the whole technical working group would be sent to FDA for consideration and to issue final judgment.

The over-simplified scenario illustrated above may or may not be workable, but it is based on a few critical concepts that would be necessary in any benchmark process: (1) it permits FDA to leverage industry expertise; (2) it creates several decision points that involve industry participation but reserves any final decisions for FDA alone; (3) a written protocol can be developed and used to conduct the benchmark exercise creating an open and transparent system where standard owners know what to expect and the consuming public can view the process; (4) it permits FDA to leverage its strengths to focus on the science of food safety and address policy issues; and (5) it permits multiple standards to be reviewed simultaneously by assigned review committees.

- **FDA can help reduce redundant auditing.** By providing a roadmap for developing standards and defining a process for recognizing them (and by extension the audits that are derived from them), FDA would relieve some of the
frustration – and perhaps reduce some of the costs associated with – auditing against multiple standards, as buyers gain confidence in the process and have a basis for recognizing equivalency among various standards.

3. **Identification and prioritization of risk factors/Environmental assessment of hazards and possible pathways of contamination**

As discussed in the previous section, PMA believes that the produce industry has an incredible store of knowledge and experience that is brought to bear every day in the production of fruits and vegetables. Though admitted often in a reactive mode following a foodborne illness event, segments of the industry have harnessed this knowledge to perform risk assessments and related food safety standards and best practices to address identified risks. In preparing a produce food-safety rule, FDA has the opportunity to codify the necessity for all commodities and all participants in the supply chain to use risk assessments as a foundation in developing food safety programs. While it should be the industry’s responsibility to perform these risk assessments, we cannot do so in a vacuum. It will require partnership between the FDA, USDA, CDC, universities, private service providers and the industry.

As FDA well knows, various groups have worked together to perform risk assessments in specific commodities, but in almost every instance we find ourselves stymied by gaps in our scientific knowledge base. We can map out our production and distribution practices, and identify junctures where contamination events might occur. We then proceed to outline management practices to reduce the risk that our products might become contaminated at those junctures. In essence, we erect multiple and redundant firewalls to manage contamination risks. These fire walls are necessary because we lack true “kill step” technologies for fresh fruits and vegetables. (This approach has almost certainly improved the industry’s awareness of food safety issues and likely prevented outbreaks, but our progress has been largely overshadowed by improvements in our public health surveillance capabilities to identify disease clusters and assign causative vehicles.)

To close the gap in our scientific knowledge base, the industry and the public health community clearly have to work together to prioritize risk factors and develop more effective management tools. In looking to move forward from our current state and begin to prioritize risk factors the industry often runs up against a knowledge “gap” where we find that we lack the scientific knowledge to understand how pathogens come into contact with a crop, how long they will survive on the crop or if they could cause disease if they do survive. Without answers to these questions, all of the potential risks we identify in risk assessment exercises have to be treated as having equal priority, and we are unable to quantify the potential impact of any specific risk effectively. In practice, the industry ends up treating every potential risk as a “number one” priority, which can cause our efforts to become diffuse and prevent proper prioritization of resources. The common response to this dilemma has been to ask for more research. Toward that end, FDA should consider the following:
Partner with the produce industry to evaluate government data. The agency, along with USDA and CDC, is in a unique position as a collector of real-time food safety information. The illness outbreaks and subsequent investigations, as well as the surveillance testing and facility inspections, of the last 10 years have resulted in a wealth of data that should be analyzed in partnership with the produce industry and academic experts to maximize the lessons that can be learned from that data. It is important to have industry and academic participation in that data review, as they can bring knowledge of production practices, product attributes, distribution logistics and food safety science to the table along with FDA’s expertise to see what we can all learn from history.

Historically, the roadblock to working together has always been cited by FDA as the confidential nature of the data, especially relating to outbreaks as it might pertain to the identity of victims or regulatory sanctions against producers. This is certainly understandable, but it does not seem insurmountable. In developing new rules for produce food safety, FDA should consider using confidentiality agreements, special government employee status or some novel mechanism(s) to permit the agency to convene working groups that include outside industry and academic experts.

Partner with industry to facilitate epidemiological traceback investigations. Along the same lines, PMA and United Fresh Produce Association have approached FDA in recent years to discuss mechanisms to work together with FDA and CDC during initial stages of produce-specific epidemiological and traceback investigations with a goal of assisting the agencies in providing industry knowledge of products, production practices, sourcing locales and supply chain logistics to help improve investigative efficiency. This improved efficiency might translate to identifying the causative vehicle and the source of the product more quickly, which may offer insights as to what might have caused the initial contamination to occur. The industry has been largely turned away in this effort due to the confidentiality issues and potential legal impediments under current statutes. As FDA looks to promulgate new rules for produce food safety, perhaps it should consider identifying mechanisms that permit the use of industry “experts” it could call upon as needed to advise the agencies during the early phases of outbreak investigation and traceback. The “learnings” from these types of industry/agency interactions might then be applied to our joint assessments of risks and how they might be managed in the future.

Develop a mechanism to permit confidential data sharing. The produce industry collects immense amounts of produce-specific food safety data every day. For example, we engage in audits, monitor storage and transportation temperatures, and we perform microbial testing on agricultural inputs, process environments, raw products and finished products. FDA and the industry essentially work in parallel, and as a result we both lose opportunities to better understand how contamination occurs and how we might better manage those
risks. In developing the new produce food safety rule, FDA should develop a mechanism that permits industry to share its data with the agency.

Historically, the hurdle here has been industry reluctance to share data that might be used against the industry to create over-restrictive regulations. However, our environment has changed substantially in the last decade. We have witnessed the tragedies of people sickened by consumption of contaminated produce items, and we have seen a related erosion of consumer confidence in our products. This industry has endured sporadic outbreaks that have shut down entire commodities or production regions, resulting in hundreds of millions of dollars in losses for producers who had no role in the outbreaks. These factors have caused our industry to realize that we need to have effective, risk- and science-based food safety regulations.

Given those paradigm-changing realities, the industry and FDA need to work together to identify what types of data would be useful in our mutual effort to understand and prioritize food safety risks and then elucidate a mechanism to mine that data from the industry. FDA developed a data portal to facilitate enactment of the Reportable Food Registry in 2009. Perhaps a similar approach could be used to permit individual companies to submit testing data or other types of information for research and analysis. Any numbers of possibilities exist for permitting data exchange. One could accomplish this indirectly via testing labs or existing research centers and universities where data could be collected and organized and then made available to the agency. This might also be accomplished directly with FDA creating a research data portal. In either scenario, protocols could be put in place to protect the data owner’s identity, which is in fact irrelevant to the intent of understanding contamination prevalence, seasonal trends, commodity risk factors, etc. For those who would criticize providing that confidentiality, it might be pointed out that it would remove a barrier in achieving meaningful data sharing between the industry and FDA. (Further, FDA already requires the industry to report contaminated products that threaten public health via the Reportable Food Registry.)

It is also important that both FDA and the industry understand that data alone is not sufficient. Data without context will not help us understand the issues we face with food safety. One of the key obstacles to sharing microbial data with outside interests is the assertion that a table of data, for example raw product testing data, is useless without also sharing the context around the data: how and why the material was tested (e.g., raw product testing, process validation, shelf life tests), how the material was sampled (random, patterned, risk based, etc.), the test method employed, the risk assessment that might correspond to that field, and other factors (e.g., dates, times, regions). Therefore, PMA recommends that FDA and the produce industry should work together to develop best practices that permit data sharing, while also promoting the types of discussions necessary to maximize the value of that data.
• **Work together to identify, prioritize and fund produce food safety research.** We have seen a gradual shift of research funding and resources towards produce food safety in the last five years. We have also seen greater receptivity by the produce industry to working with academic researchers to facilitate produce safety research. Indeed, the PMA-established Center for Produce Safety at the University of California at Davis – and other food safety research centers around the country – have been on the leading edge of reaching out to the produce community for their input and involvement in defining research priorities and enacting programs.

As a corollary activity of identifying risks, we also need to increase our collective efforts to fund research to better understand the significance of those risks or hazards, develop related priorities and enable management practices. PMA recommends that FDA engage the produce industry and its sister agencies to coordinate research activities and make best use of public and private resources to fund priority research. The points outlined above – i.e., using historical FDA surveillance information, outbreak data and mining industry data – can be used to identify future research priorities that fill the knowledge gaps the produce industry has in risk identification, prioritization and hazard management.

4. **The impact of scale of growing operations on the nature and degree of possible food safety hazards**

A consumer who becomes ill as a result of a produce contamination event does not care if the offending product comes from a small or large farm, from a local grower or one 3,000 miles away. Yet, some smaller-scale growers regularly express their concerns over potential food safety requirements, stating they view such requirements as too costly and not necessary for small-scale operations.

It has been argued that a small 10 acre farm distributing product only locally could only cause an illness outbreak that would be limited to a small number of people in a confined area, as contrasted to a larger grower on 1,000 acres who might distribute product over a broader region. However, the reality is that all contamination events that have been traced back to the farm level have traced back to a single 10- or 20-acre block. We simply have not seen massive contamination events where large acreages are contaminated with pathogens. The latest science indicates that field-level contaminations seem to be sporadic and random. With the increased frequency of pathogen testing by FDA, USDA and others in the past two years, we have actually seen a fairly equal distribution of positive samples by region, commodity and grower size. Hence, producers of all sizes must accept that they have a responsibility to food safety.

As FDA considers the question of scalability, it might be useful to consider the following:

• **Understanding the actual costs of a food safety investment.** While investing in food safety programs is not directly comparable to a capital investment, the
analogy still works that an investment made in food safety can deliver a beneficial return to a company. Investing in food safety can help protect a company from the devastating impact of a food safety crisis. Excuses for not building comprehensive food safety programs often include that food safety costs too much, but rarely has anyone defined just what a good program costs. PMA often presents the case to growers that they should first define what they would need to spend on food safety before declaring it too expensive. We encourage growers of all sizes to consider the following scenarios:

- **The labor cost associated with managing a food safety program.** By far the most expensive component of a food safety program is the cost of labor. Based on our experience, labor costs are directly scalable to the size of the operation. A small family farm of 100 acres or less would likely require about 4 hours per week to maintain related paperwork or documentation and record necessary data, based on our experience. We have often seen this performed by an existing employee who takes on the responsibility after receiving some training from a trade association or agricultural extension service. In other cases, growers hire an hourly person with experience in food safety to “consult” for four or five hours per week to manage the food safety efforts. Certainly this manpower assumption can vary based on individual grower preferences and the complexity of a specific operation. But, to calculate an estimated cost of this scenario, a part-time consultant working 4 hours per week at $30/hour over a 40-week season would result in an annual cost of $4,800.

A mid-sized operation of 100 to 1,000 acres may well justify a full-time food safety person, earning $40,000 to $65,000 per year depending on his or her educational level, experience and location. As the size of an operation increases to greater than 1,000 acres of production, you generally find a more experienced manager in charge of food safety and 1-2 field level workers to monitor food safety compliance. This labor expense can range up to $250,000 per year.

- **Microbial testing.** For discussion purposes, it is assumed that growers are testing the microbial quality of their irrigation water and doing some kind of swab testing to verify sanitation of harvest equipment. A smaller grower (<100 acres) might only have one water source for irrigation or general on-farm water use. For this exercise, assume that small grower’s risk assessment calls for monthly water testing, using generic *E. coli* as an indicator, as a preventive control. Over the same 40-week season, they would conduct approximately 9 tests at a cost of $12 per sample, for a total cost of $108 for water testing.

A mid-sized growing operation (100-1,000 acres) likely has 2-4 water sources operating at some point during the season, so their costs might approach $500 for water testing. It is also likely that mid-sized growers
might use harvest equipment or tools that require sanitation, and their risk assessment might identify use of simple adenosine triphosphate (ATP) bioluminescence swabs or similar tests to verify sanitation efficacy. These tests costs around $2 each, and a grower could easily use half dozen swabs a day. Harvesting 30 weeks of a 40-week season at 6 days per week translates to 180 days at $12 per day, or $2,160 per season.

The larger operations (>1,000 acres) may have 20 or more different water testing points to test every 30 days, resulting in costs of roughly $240/week over a 40-week season for a total seasonal cost of $2,160. These larger growers may be expected to have an additional $4,000 in costs for sanitation verification. (It is important to note that microbial testing costs can vary from location to location. The unit costs included here were developed based on conversations with a number of commercial laboratories and growers from around the country.)

- **Food safety audits.** The number of food safety audits a grower might have per season will likely be determined by the physical characteristics of the operation. For example, a single 100-acre farm might require a single audit per season – whereas a 100-acre operation that is divided into 3-4 distinct growing locations may require 3-4 separate audits per growing season. As always, there is some variability in the marketplace, but third-party GAP audits generally run $450-$600 for a single audit. If the operation also includes a packinghouse or cooling operation, additional costs of $800-$1,200 for those operations may also be encountered.

For a mid-size operation, the growing might be reasonably expected to be distributed on 2-4 farms. If these are located contiguously and operated on the same food safety plan, often these can be done as a single audit. However for this exercise, we assume four farms and four separate audits or $2,000 per season.

For larger operations, 10 or more farms might be in operation, requiring 10 audits or more. Here again, if the farms are located in proximity under the same management, fewer audits may be required or if multiple shippers are pulling product from the operation, often the shippers can split the cost of the audits so they pay only a portion of the total cost. $10,000 per season would be a reasonable estimate to use as an audit cost for a larger grower.

- **Sanitation chemicals and food safety supplies.** These include sanitizers used to clean equipment, rubber gloves for workers, hairnets and other items that might be identified as preventive control measures. The cost of these items is highly variable depending on the type of growing operation and the product being grown.
Walk-by acres. Growers are familiar with “walking by” portions of the crop due to quality issues. In recent times, growers have had to adapt to not harvesting portions of their crop due to potential food safety risks identified during pre-harvest risk assessment, such as animal intrusion, partial flooding, or other risk events. The cost of “walk-by” losses varies, depending upon that crop’s growing cost, its susceptibility to the risks presented by animals or flooding (e.g., a leafy green versus a crop like broccoli that is higher off the ground or an orchard crop that is further separated). For this exercise, we will estimate 1% of a grower’s acreage will be lost to harvesting. For estimation purposes, consider an average per-acre growing cost of $5,000/acre to calculate losses (here again, actual experience will be very highly dependent on crop, location and vulnerability).

The above cost discussion is intended to help provide perspective. Individual operators can use these categories and perhaps others to quantify their own food safety costs.

Using midpoints of these rough numbers, we can calculate an average cost for basic GAP programs in the range of $150-$200 per acre. These are significant costs, but they correlate well with costs reported by some third-party firms that work with growers to implement GAP programs. They also show that the cost of food safety is roughly scalable.

It is also important to put these costs in context. As a standalone number, they seem striking. However, if you look at them in terms of cost per carton or cost per pound, they can be compared to other inputs. For example, an acre of fresh spinach should yield 10,000-15,000 pounds per acre, depending on season and cultivation practices. Using the lower figure, the cost of food safety for that acre of spinach calculates to $0.02 per pound. Similarly, an acre of iceberg lettuce should yield 900-1,200 cartons per acre, resulting in a per-carton food safety cost of approximately $0.20/carton. Tomatoes yielding 1,600 cartons per acre translate to a food safety cost of $0.12/carton. Again, yields are variable and each grower needs to plug in their own historical data to be able to accurately quantify their costs, but this exercise should give FDA a sense of the actual costs of implementing food safety programs.

Training and communication. Often a lack of information makes it hard for growers and producers to understand why changes are necessary, let alone how to make those changes. Some efforts are underway to address this. Many industry members are already working to provide training opportunities for smaller or local growers, for example in order to “qualify” them as suppliers in specific markets. For example, retail leader Wegman’s Markets provides training programs and technical support to more than 800 local growers supplying that retail chain. Large grower/shippers such as the Giumarra Companies have an extensive grower training program that provides information and training for growers that have just a few acres of production to those with over a thousand acres of production domestically as well.
as off-shore, PMA is currently working with Sysco Corporation and Primuslabs to conduct regional food safety training programs to help local growers understand their role in securing the safety of their products, and identifying resources they can use as they develop their own, operation-specific programs. These efforts are merely examples of training programs ongoing in our industry, and they represent only a fraction of what is needed. In addition to these private efforts, there are numerous agricultural extension and university outreach programs seeking to communicate with and train local growers.

PMA recommends that FDA work with the produce industry to develop a comprehensive communication strategy that resonates with growers across the country, no matter the commodities they raise or the size of their operations. We still see periodic reports, 12 years after the original release of the agency’s 1998 GAP guidance, of growers who are not aware of GAPs or how they apply to their operations. Clearly, part of any FDA development process to promulgate a produce food safety rule needs to have a comprehensive strategy to ensure that participants all along the supply chain (including consumers) understand their roles, expectations of them, and where they can go to find the information they need to meet those demands.

It is important to acknowledge the intensive effort made by FDA over the last year to conduct listening sessions and to meet with various segments of the produce industry to gain a better understanding of industry needs as the agency prepares to write this food safety rule. That same type of effort will ultimately be required once the rule is written, in order to make sure the whole industry understands its implications. As always, the produce industry stands ready to cooperate with FDA to develop effective communications messaging.

A component of such a comprehensive communications strategy will ultimately include outreach and effective training programs and resource listings for growers. In preparing the final produce rule, FDA should consider training needs across the entire supply chain, the role industry and academia can play in accomplishing that training and accompanying guidance, and Q&As or other materials the agency could provide to augment that training.

- **Food safety programs are already being implemented regardless of size.** There are numerous examples in the produce industry where small to mid-sized growers have implemented food safety programs using third-party audits as verification tools. And as previous noted, select leading retailers and foodservice operators are working with their growers to provide food safety training and support in order to qualify growers as suppliers. This demonstrates that small to mid-sized growers can indeed develop and implement food safety programs; it’s more a matter of providing them with support and training they need, and setting goals with reasonable timelines to enable their compliance.
5. **Methods to tailor preventive controls to particular hazards and conditions affecting an operation**

Preventive controls can take on many forms, from a measurable parameter such as measuring the level of sanitizer used to clean a piece of equipment to a more task-driven control such as performing a risk assessment and developing a written food safety plan to manage identified risks. The industry has been aggressive in recent years in developing various commodity-specific guidelines, all of which focus on identifying potential hazards or risks, and suggesting management tools or controls that can be used to manage those risks. As pointed out in Section 2 above, PMA believes that risk assessment or hazard analysis is the foundation for building comprehensive food safety programs. Further, we believe the best risk assessments are performed by the grower, processor, harvester, distributor or others in the supply chain who are producing and distributing the products daily, because of the intimate knowledge they possess as previously discussed. It is unreasonable to expect that FDA could provide regulation that would speak to the variable hazards and multitude of preventive control practices that characterize the breadth of the produce industry. FDA also cannot be expected to anticipate the evolving science of produce food safety in its regulation. The only thing certain is that if FDA attempted to codify preventive controls based on today’s knowledge base, it would be outdated the day it was published.

However, while not new to our industry, risk assessment or hazard analysis is still a challenging concept for some. The produce industry is extremely diverse, and demonstrates virtually every degree of sophistication when it comes to performing risk or hazard analyses. Indeed, the terminology alone can be daunting to growers and others in the supply chain, especially if they deal in commodities not typically associated foodborne illness to date. Trade associations, agricultural extensions, the National GAPs Center at Cornell, commodity groups, USDA and others are working to develop training tools to help growers of all sizes and regions to perform effective risk assessments. FDA can play an important role in this process by working with the industry to provide guidance on hazards and controls that producers can use to model operation-, commodity- or region-specific hazard/risk analyses and best practices/preventive control programs. As discussed above in previous sections FDA’s 1998 GAP’s Guidance and subsequent commodity specific guidances have done an excellent job of laying a framework for the produce industry. PMA suggests FDA consider working with industry to organize portions of these materials so that they could be used as a comprehensive guide to accompany the Produce Food Safety Rule. It could underscore the importance of conducting a risk assessment and guide operators on how to properly conduct risk assessments.

6. **Possible approaches to tailoring preventive controls to the scale of an operation so that the controls achieve an appropriate level of food safety protection and are feasible for a wide range of large and small operations**

As discussed in Section 4, food safety programs can and must be scalable. It is important for operations of all sizes to have risk-based food safety programs. Animal intrusion,
water quality, worker hygiene, soil amendment uses and other commonly-identified potential risks exist on large farms and small ones alike, across the country and regardless of the commodity produced. It makes sense that a larger grower might have to expend proportionally larger resources to manage many irrigation water sources or train more workers or provide more hygiene facilities versus a smaller grower who may have a single irrigation water source or no other employees than himself. It follows that risk management practices or preventive controls can be designed to match the risk and the scale of the operation.

Based on recent public comments from senior agency officials, FDA is well aware of the anxiety that exists in some parts of the country that small growers cannot afford food safety programs and are not equipped to implement risk management practices or preventive controls. This is a very real issue that needs to be addressed by sharing information and by providing training, as previously discussed here. The industry stands ready to work with FDA to provide training to smaller growers to help reduce this anxiety. As already discussed, there are a number of examples where suppliers and buyers are already working together to provide smaller grower food safety training around the country.

Preventive control programs can seem overwhelming to someone how is just starting out, but the goal has to be improved food safety performance for the entire industry. However, it has been our experience that once growers understand the concepts of hazard analysis and management, they come to understand that very simple practices that are not expensive to implement can be effective preventive controls. Indeed, often these controls are simply good operational or business practices. For example, a preventive control that can help ensure appropriate water quality for irrigation might be as simple as a visual inspection of a well head, and a maintenance program to preserve the integrity of seals. Regardless of size, any grower would want to maintain the working order of their well, and a weekly visual inspection should not prove to be burdensome.

At the next level of preventative control, a microbial test or food safety audit might be a reasonable verification tool, yet many smaller growers fear the costs of services. Again, if one has not been using these types of preventive controls, they can appear daunting, but breaking down the costs involved in using these tools may provide a different perspective (see our examples in Section 4).

There may also be different options available by region or state to provide reduced costs for growers. For example, we are aware of cases where various departments of agriculture or agricultural extensions perform audits at reduced costs for growers. We have also seen examples in Central California, where third party audits have become commonplace, where growers work with third parties to negotiate reduced rates for audits when farms or ranches are located together.

As indicated in Section 5 above regarding preventive controls, it would not be prudent for FDA to prescribe preventive controls regardless of the size of the grower. Instead, the grower’s specific risk assessment plan should become the guide as to which preventive
controls should be employed. Again, FDA should strongly consider issuing guidance in this area to aid all growers in determining the range of preventive controls they might employ to manage identified potential risks

7. **Coordination of produce food safety practices and sustainable and/or organic production methods**

PMA represents both organic and conventional producers globally, and we have been actively involved in exploring development of metrics for sustainability. While industry’s long-term sustainability is critical to the future of our industry, regardless of the method of production, food must be safe. The best tool the industry and the FDA have to ensure that products are produced as safely as possible is to require that all food safety programs be based on risk assessment and management. This would mean that every grower would have to take the responsibility to perform a risk assessment of their specific operation, whether it be organic or conventional, to determine where the potential for contamination exists and then how best to manage that risk based on the best science available and the commodity-specific or individual practices employed by that grower. If properly performed, a risk assessment will not differentiate between organic and conventional production, it will simply identify potential risks. The critical element of developing best practices to manage those risks does have to take into account practices and procedures that have to be acceptable for organic certification. Many organic growers and processors already employ GAP practices and have comprehensive food safety programs, illustrating that organic production and risk-based food safety programs can be compatible.

8. **Coordination of produce food safety practices and environmental and/or conservation goals and practices**

A recurrent theme in these comments has been that food needs to be safe. As industry-driven food safety practices have become more structured in the last few years, we have seen instances where practices instituted in the name of food safety cause concern from an environmental sustainability perspective.

First and foremost, it is important to understand that fruit and vegetable growers have a significant personal and financial investment in their land and are by nature practicing “environmentalists”. The land and the resources required to raise a crop are a grower’s basis for making a living – and in some cases are the family heritage passed to future generations. In recent years, the drive to improve food safety performance has resulted in apparent contradictions between environmental sustainability and good food safety practices.

There are many factors that play into this seeming contradiction, but a portion of it is clearly the lack of clear direction from a food safety perspective as growers and buyers work to build management practices that eliminate food safety risks. While some practices are put in place with the best of intentions (e.g., certain fencing, buffering distances), the quantitative risk and science basis for some of these practices might not be
well understood. The net result has been that growers are put in the unfortunate position of trying to employ comprehensive food safety practices while at the same time trying to be environmentally responsible.

In some instances, there have been practices that have been undertaken in the name of food safety that really relate more to product quality or specification. For example, in some regions of the country where salad greens are grown and harvested for processing into ready-to-use salads, we typically see buffer zones that are cleared on the perimeters of the fields in an effort to eliminate harborage areas for rodents and amphibians that might enter the production field and be inadvertently “harvested” with the product. One can argue that these animals may be potential vectors of pathogens, but the real issue is the potential for these animals to pass through the process system and end up in a finished product – and the very real and emotional reaction of consumers when this happens, and its impact on the producers and sellers brand. The net result has been the use of rodent traps and buffer zones, and sometimes even fencing in virtually all commodities (not just those headed for processing) to manage this quality risk. These practices have stirred up a backlash from the environmentalist community, trapping growers in the middle between their environmental and food safety objectives.

At the end of the day, food safety has to be the dominant priority, but it does not have to be mutually exclusive of environmental sustainability. Indeed it is important to use science, risk assessment and commodity practices as an underpinning to assess the best practices to achieve both food safety goals and environmental balance. In moving forward with development of a Produce Food Safety Rule, FDA may want to consider the following:

- **Risk assessment has to play a central role.** PMA recommends that FDA work to ensure that every producer along the supply chain employs risk assessment as part of their food safety program. Part of this risk assessment is the identification of best practices to manage potential food safety risks. These risk management best practices should be based on the best science available and the specific practices, characteristics and intended use of the crop. In performing these individual, operations-based risk assessments, FDA might want to ask operators to simultaneously consider the impact of those management practices from an environmental sustainability perspective.

For example, a grower raising iceberg lettuce in the Salinas Valley of California for commodity or carton sales may want to include feral pig intrusion into the field as a possible contamination risk. It was suggested by FDA in 2006 that feral pigs may have played a role in the *E. coli* O157:H7 contamination of spinach that sickened more than 200 people and resulted in three deaths. Based on new information presented at the Center for Produce Safety Food Safety Symposium and the follow-up FDA meeting on research priorities held June 23-24, 2010, contamination from feral pigs only occurs in the immediate area where the pigs enter a field, so buffer zones of 10-20 feet from an intrusion site should be adequate to manage contamination. Additionally, pigs only cross iceberg
fields to get to food or water. Therefore, as a grower performs his/her individual risk assessment for that farm, he/she may want to consider the appropriateness of the field for iceberg production based on the surrounding crops that may attract pigs. Additionally, the grower may want to adopt a best practice of using a 10-20 foot buffer zone should feral pig intrusion occur. This practice of not harvesting iceberg in the buffer zone, and its costs should an intrusion occur, can be weighed against the costs of fencing in an entire production block. The economic impact of fencing vast production areas versus “walking by” buffered areas would likely fall toward using the buffer zone approach. By employing a risk assessment and utilizing the best science available, the food safety risk can be managed, avoiding the environmental impediment of fencing which impacts a diversity of wildlife.

- **Guidance and pilot-scale studies.** FDA has stated that the agency may chose to offer accompanying guidance to help producers understand how to meet the intent and/or requirements of the Produce Safety Rule. The subject of food safety and sustainability co-management may be an area where specific rules may be premature, and a combination of guidance and defined pilot studies may be more appropriate. At this juncture, it is PMA’s position that we do not have enough science for FDA to create specific rules or quantifiable metrics around the interface of food safety and environmental sustainability. PMA and others have been very involved in efforts inclusive of several nongovernmental organizations and industry representatives across the supply chain, to explore the development of sustainability metrics. These metrics would be based on the best science available and take into account many of the solid environmental practices already employed by the growing community. This may represent an opportunity for FDA to work with industry in relation with these ongoing efforts in a pilot program to evaluate food safety objectives relative to environmental sustainability.

- **Additional research is needed.** Absent scientifically valid data, the issue becomes a political and emotional issue with both producers and consumers trapped in the middle of confusing dialogue with no basis for making production or purchase decisions. FDA needs to work with the industry, USDA, EPA and academia to set research priorities to insure research is prioritized and funded at this very critical interface of food safety and environmental sustainability. Today we see a shift in momentum in research funding toward produce food safety and while still not adequate funding is starting to flow toward answering key questions regarding pathogen survival in the production environment, vectors for pathogen transfer and methods to kill pathogens. PMA would suggest that research also needs to be directed to the co-management of food safety and environmental sustainability and FDA can play a critical role in prioritizing that need and communicating it as a goal to the research community.
9. Coordination of produce food safety practices and Federal, State, local and tribal government statutes and regulations

PMA believes there needs to be a uniform regulatory approach between federal, state, local and tribal government statutes and regulations. The produce industry operates at every geographic level; globally, nationally, regionally and locally which makes uniform regulations a necessity. FDA has the opportunity to establish food safety requirements that take into consideration regional differences for commodities or production conditions (such as by broadly defining the structure and content of food safety standards and recognizing industry standards that meet those requirements; see sections 1 and 2 for more information). As discussed in previous sections this approach permits regional growers to address specific production or commodity food safety issues under the umbrella of a federal program. Absent strong leadership by FDA, we will continue to see individual states attempt to address food safety issues through legislation much as we have seen in Georgia this year. Pending legislation in other states dealing with food safety issues from testing to traceability underscore the urgent need for strong federal food safety rules.

Another aspect of this issue of coordination of food safety practices at various levels of government is the coordination between FDA, CDC and USDA in operating traceback and epidemiological investigations. We recognize recent efforts by the agencies to work together more effectively, e.g. co-participation in listening sessions around the country on food safety issues and exchange of personnel between the FDA and USDA to expedite the preparation of the proposed rule. We urge FDA to continue to work toward better coordination among the agencies. In a similar vein, it is equally important for FDA (and CDC) to coordinate with state and local agencies during regulatory inspections and/or traceback investigations. FDA should consider working with the industry to partner in providing produce-specific training for its inspectors and auditors. This same level of training also needs to be extended to state inspectors that often work in conjunction with FDA auditors.

In regard to traceback or epidemiological investigations, the initial work in identifying illness clusters and beginning the epidemiological traceback often starts at the local and state level. It is critical that procedures and processes are well defined and move seamlessly from the local levels to the states and then to CDC and FDA. In recent years, we have seen instances where initial state-level investigations have been misinformed, resulting in inefficient national investigations that were protracted and more disruptive and less effective than they might have otherwise been. We would encourage FDA and its sister agencies to develop common training and standard operating procedures to better coordinate traceback activities.

10. Microbial testing

The produce industry has historically employed microbial testing to measure irrigation water quality, verify wash water sanitation practices and measure the effectiveness of equipment and facility sanitation practices. While this type of testing is not yet universal
across the whole spectrum of the industry, more and more operators have been implementing these verification tests as the science has evolved, operators have sought to develop comprehensive food safety programs and the buying community has requested verification measures. Microbial testing in these areas falls out logically from risk assessment and management. The identification of a specific risk and the selection of a group a management practices should lead to the next question of how to measure that the management practice is effective. Therefore, if a grower or packer identifies irrigation or wash water as a potential risk factor, the logical step would be to employ management practices to insure the water used is free of pathogens and the way to verify those management are effective is to test for microbial quality. The same logic extends to verifying whether sanitation practices are effective or if a composting process has been sufficient to kill potentially available pathogens. It reasonable for FDA to expect industry to employ microbial testing as a tool to verify specific risk management practices. The old saying that “you cannot manage what you cannot measure” is likely applicable here.

The other old saying that also has applicability is “the devil is always in the details”. If microbial testing is used as a tool to verify a management practice, it is important that the test has the proper selectivity and sensitivity to detect the target organism in the biological, chemical or physical environment of the sample. It is equally important that the sampling method and frequency are appropriate to provide confidence that a “negative” result is really a negative result. In some instances, it is more economically feasible and faster to check for indicators instead of the actual pathogen, e.g. generic E. coli in water samples versus E. coli O157:H7.

While it is reasonable for FDA to expect the produce industry to use microbial testing to verify risk management practices, PMA believes that the selection of the type of test and the sampling method needs to be at the discretion of the individual operators. The selection of the type of test and the sampling protocol should be part of the original risk assessment and be focused on providing the verification answer desired. For example, if an operator wants to monitor the effectiveness of his/her sanitation program for a piece of harvest equipment, he/she simply need to know if there are any bacteria on the equipment or not. The sanitation program is certainly not selective, but should be stringent enough to kill all bacteria on the contact surfaces. Therefore, while the operator is worried about pathogenic bacteria, a simple test that identifies all bacteria is sufficient. So instead of a $70 test for E. coli O157:H7, the operator can select a $2 adenosine triphosphate (ATP)-based bioluminescence test, and get the verification and speed to results he/she needs.

Similarly, the operator should determine testing frequency and method based on the risk, the management practice being verified and historical data the operator or the industry has available. For example, testing irrigation water has been a priority for some sectors of the produce in the last 4-5 years. Of course, irrigation water can be sourced from a number of sources including wells, municipalities, public reservoirs, canals, rivers, ponds, on-farm reservoirs, etc. Based on the producer’s risk assessment for a commodity and the producer’s knowledge of the quality of the irrigation water source, testing frequency may vary. For instance, a leafy greens grower using sprinkle irrigation from a
deep well that has been tested monthly for 3-4 years without a significant generic E. coli test might choose to manage the risk of irrigation water contamination on their farm by using a generic E. coli test at the beginning of a season and sporadically throughout the season, along with a physical inspection of the well head weekly. Alternatively, that same leafy greens grower growing on a different ranch that uses an on-farm reservoir to irrigate the crop and has 3-4 years of data that show fluctuating populations of generic E. coli throughout the season might chose to manage the risk of irrigation water contamination by frequent testing of the reservoir during the periods where the data indicate conditions might exist that support generic E. coli growth—perhaps employing drip irrigation during periods of risk and performing frequent physical inspections of the reservoir to monitor potential sources of the contamination.

In the end, the type of test used and the sampling protocols employed need to be tailored to the situation and should not be generally defined by rule. From a practical perspective it would be unrealistic for FDA to try to define methodologies and sampling protocols for each scenario where testing might be used to validate an on-farm, packinghouse, cooling facility or processing risk management practice. A risk x commodity x production process assessment should drive the decision making on microbial testing, and can best be performed by the producer or regional commodity groups as they develop standards and metrics.

As described earlier under Section 2, FDA can assume leadership of this process by developing a mechanism to recognize food safety standards developed by various commodity groups, associations, etc. In addition, the technology for pathogen testing is evolving rapidly in both the private and public sectors. Codifying rules around testing as it exists today may prevent new innovations in testing from coming to market, or cause FDA to have to review these rules to accommodate new technologies. Lastly, FDA may want to consider offering guidance to accompany any requirement to use microbial testing to verify best practices to help producers develop or enhance testing programs. If this approach is chosen, the produce industry would be a willing partner in assisting FDA to prepare this guidance.

By far, the industry discussion around microbial testing to date is dominated by the value of raw or finished product testing. For some of the commodities that have been historically related to illness outbreaks, producers and buyers have developed raw and/or finished product testing programs for pathogens. Indeed, FDA, USDA and others have also implemented redundant testing programs focused on these commodities and targeted to various points in the supply chain. However, product testing represents a very different set of challenges compared to the process or practice verification testing discussed above. Some of these differences are:

- In contrast to the above examples where the presence of indicators or general presence or absence of any microorganism meets the need of the verification test, most product testing is directed at pathogen detection. These tests are often done in two parts: rapid screening via unique DNA sequences, followed by confirmation by Bacteriological Analytical Manual (BAM) microbial culture
methods. These tests are invariable more time consuming and considerably more expensive.

- Unlike testing water or equipment surfaces, testing plant tissues is much more complex owing to the presence of chemicals and other organic matter that frequently interfere with current molecular methods employed to isolate pathogen DNA or proteins. In a very real sense, test methods need to be optimized based on the crop to account for interference.

- There is generally less time pressure to perform microbial testing when it is being used to verify that a process or practice is performing properly. Sampling can be performed at specific time intervals as part of a routine protocol. Positive tests results for indicators do not trigger recalls and corrective actions can be implemented. On the other hand, product testing introduces a very real time element, as produce is perishable and any “positive” pathogen test would almost certainly trigger destruction of raw product or the recall of finished product already in commerce.

- While not trivial, sampling protocols for water and food contact surfaces have been established and their limitations and significance are understood. By comparison, achieving statistical significance for raw product testing at the field level or finished product testing is functionally impossible, since the testing is destructive and the sheer numbers of individual plants in a production lot and the apparent very low frequency of contamination renders product testing analogous to “finding a needle in a haystack”.

Given the developmental status of testing methodologies for produce and the current absence of validated sampling methods, FDA-mandated product testing would prove difficult to craft and enforce and would create confusion in the industry.

As a food category, produce is unique. Therefore, when considering how or even if pathogen testing in raw or finished products has value as a food safety tool and whether it should become a mandated component of food safety regulation, it is important to account for these unique characteristics. The following are some of the factors that merit consideration.

- **Fruits and vegetables are perishable.** The perishable nature of many fruits and vegetables dictates that these products must be harvested and shipped within 12-72 hours so that they can be received in distribution centers around the country with approximately 10 days of shelf life remaining. This permits adequate time to distribute produce to retail outlets and foodservice operations to be purchased by consumers. Failure to deliver products within these time constraints and with consistent quality can result in product being rejected at distribution centers, forcing its destruction and waste.
As FDA well knows, to reduce testing time the produce industry uses rapid, DNA-based polymerase chain reaction (PCR) tests based on sequences that are unique to specific pathogens to rapidly screen samples for contamination. Unfortunately, although these tests can be very useful, they have proven to be less than 100 percent conclusive. It turns out that “positives” are not always positive and, in some cases samples that are positive can be missed. As a result, positive samples must often be subjected to follow-on confirmation testing using proven FDA BAM methods. To offer perspective on timing of these activities:

- Products are sampled and these samples are shipped to a microbiology testing laboratory, which can take up to one day (depending on where the field or production facility is located relative to the testing lab and if express delivery systems can be used).

- Once received, the testing lab prepares the sample and generally uses an enrichment step to improve detection. This step generally takes 1-2 days, depending on the procedures used and the time needed to review results and transmit them to the produce company.

- If positive results are obtained by PCR test, further confirmatory testing by traditional BAM methodologies follows. This generally requires another 3-4 days as the potential pathogens must be cultured or grown out on plates containing growth media that use color changes and other factors to finally identify if the bacteria are indeed human pathogens.

With many produce commodities, 2-3 days – let alone another 3-4 days for confirmation testing – can mean the difference between product that can be sold into the market at market value and product that has to be disposed of owing to advanced age and/or post-harvest quality defects that develop over time. Operators have had to write off thousands of dollars of high-value product time and again, because product testing took valuable time that either diminished product quality or resulted in product that did not have sufficient time left on its shelf life to permit distribution. Any delay in a producer’s ability to ship finished products or commodities can be devastating whether the testing is generated by buyer requests or regulatory surveillance testing programs.

- **Not all pathogens and tests are equal.** Test sensitivity and selectivity are important factors when choosing an assay method. There are a variety of tests available commercially today for *E. coli* O157:H7, *Salmonella* and other potential pathogens. They can cost anywhere from $8-10 to nearly $100 per test, depending on the technology employed and the testing objective desired. When evaluating the appropriateness of a specific test type or protocol, it is important to consider whether a test meets one’s particular needs in its specificity (the ability to distinguish between closely related bacteria) and/or its
sensitivity (the ability to detect various bacterial species at a required level or concentration). If product testing were to become an FDA requirement, it would be incumbent on the agency to specify a standard test methodology for each commodity/pathogen combination. Failure to set very specific test criteria could result in producers using a test that might not have the specificity or sensitivity to achieve the intended objective. For example, if the objective of a mandated product testing program were to test all raw products for *Salmonella*, without further direction provided, a technically-inexperienced producer might opt for any one of the many immunological test kits developed for *Salmonella* detection as they are relatively inexpensive and generally simple to use. While these types of test kits are a reasonable choice for testing a sterilized food, they cannot be used reliably in raw produce because of the natural presence of closely related but non-pathogenic relatives of *Salmonella* that can cross-react with many of these tests.

- **Produce is a complex food matrix.** Further complicating the preceding discussion is the fact that produce represents a *very complex* chemical, physical and biological food matrix. Most obvious is the fact that commodities vary substantially in terms of chemical composition; for example a tomato is chemically very different from iceberg lettuce, which in turn is quite different from a green onion. The produce industry has witnessed several instances in recent years where pathogen testing procedures had to be modified to account for these compositional differences. It has been shown that specific plant metabolites (most often pigments associated with product color) can interfere with PCR reactions and can cause “false negatives”. For example, some plant chemicals may interfere with the test such that pathogens are not detected when they are indeed present. In effect, this means that testing procedures would need to be optimized for each pathogen/commodity combination. It is important to note that very few commercial pathogen tests have been validated on a commodity-specific basis.

- **Produce has a diverse microbial ecology.** Another important aspect of the complexity of testing for pathogens in raw produce is the fact that the exterior surfaces of fruits and vegetables have a vibrant microbial ecology; a number of microbial species are natural inhabitants of fruits and vegetables. Many of these are beneficial bacterial species that can actually protect its host from infection by plant pathogens, and perhaps even human pathogens. As already noted, the sensitivity and selectivity of a test is a very important consideration.

Since buyer-driven product testing has been introduced in the produce industry (especially in leafy greens), we have seen numerous instances where the rapid DNA-based screening methods like PCR have yielded “molecular positive” results. When these samples were further tested to confirm these putative test results using standard microbial plating techniques, those initial results were not verified. Indeed, often what triggered a positive result in a rapid test for a human pathogen like *Salmonella* actually turned out to be a common
nonpathogenic bacteria, like *Klebsiella* or *Citrobacter* that are phylogenetically related to *Salmonella* but not harmful to humans.

In other words, commonly-employed rapid test methods intended to minimize disruption to the supply chain and preserve product quality can actually result in false positive results if they are not selective enough to unequivocally target the desired pathogen’s unique DNA sequences. This lack of selectivity can have significant financial consequences and logistical impact if decisions regarding use of raw or finished product are based solely on these tests. For example, a 20-acre planting lot may be deemed unusable and is plowed under at a cost of several thousand dollars. Similarly, finished product may be destroyed based on an initial positive result, only to have confirmatory testing find that the original test was erroneous 3-4 days later. Clearly, these rapid DNA-based tests hold much promise for the future, but significant research is still required to ensure that they can be reliably employed with the proper specificity and selectivity.

- **Not all detected pathogens may be able to cause human illness.** Research is showing that not all pathogenic bacteria found via PCR on fruits or vegetables may actually be capable of growing or subsequently causing illness. Many of those pathogens most often associated with foodborne illnesses have in fact adapted to the warm, high moisture and nutrient-rich environment of the human digestive tract, where they can exist without causing illness to their human benefactor. In contrast, the surface of a fruit or vegetable is a comparatively harsh environment. The temperature and humidity of the growing or storage environment the fruit or vegetable resides in can fluctuate dramatically, creating an inhospitable environment for the pathogen. Meanwhile, nutrients that might support the bacteria are, in contrast, much less accessible on produce than what might be encountered in the human gut. Therefore, while a human pathogen might survive for some specified period of time on the surface of a fruit or vegetable, they are not in ideal conditions, compromising their ability to grow or cause illness.

In studies where pathogens have been purposely placed on the surface of a produce item and permitted to remain there for a period of time, researchers can often detect that pathogen’s presence using a DNA-based test but cannot actually recover or culture any living cells of the pathogen. Rather than thriving on the plant surface, the pathogen either goes into a dormant state or begins to die, yet its DNA retains enough structural integrity to permit detection by PCR testing although it cannot be physically isolated by traditional culture methods. So while one might get a “positive” test result using rapid DNA-based testing, in fact the test is detecting a dead or dying bacterium that may not represent a human health risk.

- **The role of enrichment.** Another consideration in product testing is the practice of enrichment. Most rapid DNA-based testing methods employ an “enrichment” step in the test process. Product samples are placed in a nutrient-
rich culture medium, allowing pathogen cells to grow in ideal conditions so that enough cells can be recovered and sufficient DNA extracted to perform PCR or PFGE tests. Pathogens sampled from the surface of a fruit or vegetable that are in a slowed metabolic condition or are dying may in fact recover in such enrichment conditions and be induced to grow if sufficient time is provided. Studies of various enrichment periods indicate that optimum enrichment times can vary based on the physiological condition of the pathogen, and can run anywhere from 8-20 hours. Many commercial test protocols specify the lower end of this time range, so that products that are being held pending test results can be released sooner rather than later to meet supply chain and quality demands. Clearly, if fruit or vegetable product testing was to be required by FDA, further research would be needed to permit definition of this practice so that consistent enrichment periods could be established.

When weighing the question of enrichment, FDA must also consider its implications. If a pathogen has been physiologically injured by the inhospitable environment on a plant or food surface, but can essentially be “rescued” by using laboratory culture methods, would that pathogen have actually been able to cause illness if the product had been consumed? This is another area of research that needs to be initiated to understand whether injured pathogen cells are capable, under any conditions, of causing disease in humans.

- **The zero tolerance standard may not reflect today’s best science.** The Federal Food, Drug and Cosmetic Act of 1931 states that the presence of human pathogens in food is considered an adulteration, and prohibits these foods from being placed in commerce. Given the scientific knowledge of that time, this seems reasonable and logical. However, today we know much more about how some human pathogens cause illness, and the dose rates required to illicit symptoms in humans. For instance, we know that new strains of *E. coli* have emerged in the last 30 years, most notably, *E. coli* O157:H7 and unlike its harmless brethren, this bacterium can cause significant human health issues or death at levels as few as 10 cells, especially in the young, old or in immunocompromised populations. Conversely, we recognize more than 2,000 strains of *Salmonella*, and current thinking points to the likelihood that the dose rates to cause illness are much higher than with *E. coli* O157:H7 maybe requiring as many as a thousand cells or more. Further, *Salmonella* infection is generally not lethal (although immune-compromised individuals face increased risk).

The implication is that while a zero-tolerance approach for a pathogen such as *E. coli* O157:H7 is appropriate, today’s science may or may not justify such a strict standard for other, perhaps less devastating pathogens. Clearly and unequivocally, the goal of food producers, government and the public health community should always be to reduce the risk of any pathogen contamination that could conceivable occur. Within the produce industry, there is no acceptable argument against that concept. However, absent an effective kill step that can guarantee elimination of all pathogens without compromising product
quality and nutrition, perhaps FDA should consider re-evaluating its zero-tolerance policy for one that is risk-based, and better reflects today’s science and epidemiological knowledge. This is an important concept when considering the issue of product testing and its production, cost and public health ramifications.

• **Which pathogens should the produce industry test for?** If product testing became an FDA requirement, FDA would need to determine which pathogens need to be tested on a commodity-specific, and perhaps even a location, basis. A number of bacterial, protozoan and viral pathogens have been associated with foodborne illness outbreaks linked to produce over the last 20 years. In some instances, patterns seem to emerge. For example, *Salmonella* is more consistently associated with tomatoes and melons, *E. coli* O157:H7 with leafy greens, Hepatitis A with green onions or berries, and *Shigella* in leafy herbs. However, there are also a number of examples where these relationships do not hold up. To manage the time element of produce logistics as described earlier in this document and to best utilize resources, it is important to avoid a “one size fits all approach.” Instead, we should employ a science- and risk-based approach to determine a commodity-specific and/or pathogen-specific strategy.

• **Sampling may be the most problematic aspect of product testing.** The specificity and selectivity of tests employed to identify a pathogen are only half of the equation in a product testing scheme. The other half is the sampling program. It is impractical to test every tomato in a field or every leaf in a head of lettuce as all the marketable product would be destroyed in the process. Instead, the number of samples collected, their distribution, the frequency of collection, the amount collected and other factors need to be carefully calculated if a “sample” is to be created that represents the entire production lot. This is important because the object of product testing is to create confidence that a specific production lot is not contaminated with a potentially harmful human pathogen. While there are many issues associated with actual pathogen tests, in many ways developing a sampling methodology that can achieve statistically significant confidence levels is more troublesome.

Based on the millions of pounds of produce that are harvested, packed or processed, shipped and consumed each day by millions of people throughout the country without illness, we can assume that the frequency of pathogen contamination is quite low. To add weight to this assumption, data from buyer-mandated product testing of some commodities and FDA/USDA surveillance product testing also reveal that contamination is indeed a low-frequency event. Therefore it is imperative that our sampling methods be constructed so that we can detect even these low-frequency events. Further, from some of these recent product testing programs we know that contamination, when it does occur, is not uniform. If contamination is found in a field, it tends to be random and isolated. For example, there have been occasions over the last few years where field-level raw product testing of leafy greens has resulted in a “molecular
positive” test result, indicating a pathogen may be present in a specific production block or lot. Typically, a 10-20 acre lot of a leafy green is sampled by taking 60, 25-150-gram samples from across the field in a “Z pattern”. The idea is that the samples thus taken represent some of the block’s edges, and traverse the interior of the acreage. These samples are generally combined into a composite sample and tested for pathogens.

When a “molecular positive” for a specific pathogen is found in a composite sample, often the grower or processor will go back to that lot, perform an observational risk assessment and establish a formal sampling grid in an attempt to determine how widespread the contamination is and perhaps point out where it might have originated. In the overwhelming majority of these instances, despite intensive individual plant sampling and testing, the initial positive test results are not repeated; thus the “needle in a haystack” analogy often associated with product testing.

For example, a spinach field has more than 4 million plants per acre, with anywhere from 4-6 harvestable leaves per plant. That’s 20 million individual leaves per acre; the lot might be 10-20 acres in size, meaning at least 200 million leaves are contained in that block. The current 60-sample practice might utilize 2-3,000 leaves, meaning that only a fraction of the material in any production block is actually tested. So, if you don’t happen to sample the specific contaminated plant or indeed the specific contaminated leaves, i.e. find that needle in the haystack, because of the limited sample taken, you could conclude that the field was not contaminated even though your sampling program was not really sufficient to draw that conclusion.

The question then becomes, why not just test more material? The problem there is determining how much more material to test, and in what location in the field. Remember, these contamination events are random, of low frequency and isolated. One could take a thousand samples from that same production block and only minimally increase the relative amount of product tested, and could just as easily fail to sample the exact location(s) in the field where the potential contamination resides. It must also be remembered that product testing is destructive, i.e. the product is “used up” by the test so if the test comes back negative, that product nonetheless is gone and not available for harvest.

Finished-product testing is analogous to the example given here on field-level testing. Today’s automated packing machines run at speeds anywhere from 50-100 bags per minute, and sampling 10, 20 or even 100 bags per line per hour only represents a fraction of the total material being processed. From these examples one can understand the inherent problem with developing statistically significant sampling programs that permit the producer to assign confidence levels that support a conclusion that the product in question is free of contamination.
It can be argued that today’s regulatory and buyer-driven product testing programs have really only enabled the industry to identify the limits of current sampling methods. Indeed, the only instance where pathogen contamination might be consistently and reliably detected in raw or finished products with today’s technologies is if the contamination were uniformly distributed across a substantial portion of a production field. The only example where that has been observed and validated is a single instance when water used to mix pesticides was contaminated with a pathogen and then sprayed over an entire field, i.e. there was a uniform and widespread contamination event.

- **When should products be sampled?** As FDA considers the proper role of product testing, it is important to understand the implications of testing based on where the product is sampled; i.e. raw or pre-harvest versus finished products. Simply put, in-field raw product testing versus finished product testing can be less disruptive. As the industry has sought to diminish the business impacts of finished product testing, some have implemented raw product or preharvest testing programs as a strategy to meet selected customer requirements without starting the “biological clock” ticking on product quality and shelf life. Basically, preharvest or raw product testing programs direct that products are sampled and tested prior to their scheduled harvest date, i.e. at the “raw” product stage. As an example, many growers and processors in the primary leafy greens production areas in California and Arizona have implemented such preharvest testing programs to satisfy customer requirements. Typically, these pathogen testing programs rely on field sampling 3-7 days prior to harvest. This permits enough time to sample and test the product and get the results back to the harvester so that a “negative” result can “clear” the field for the scheduled harvest date. In the event of an initial positive result requiring further confirmatory pathogen testing, harvest can be “held” until results from this second phase of testing is complete. While delaying harvest can have negative impacts on quality for some fruits and vegetables, for many commodities this is a better logistical and cost alternative than trying to hold harvested or even finished processed product. Additionally, if confirmation testing does reveal a “confirmed positive” for a pathogen, the affected product remains in the field, permitting follow-up studies on the cause for contamination, avoiding harvest and packaging costs, and minimizing disposal costs as well as the possibility that product is inadvertently shipped to the consuming public.

While generally less disruptive than finished product testing, field-level raw product testing can still be highly disruptive to the supply chain. Harvest windows for products can often be very narrow due to rapidly changing market opportunities. Delaying harvest to permit product testing can have significant impacts on profitability. This strategy also leaves a potential window of vulnerability, i.e. if the raw product is tested in the field 3-7 days prior to harvest, any contamination that might occur after sampling but before harvest could go undetected.
Clearly there remains a number of critical issues for FDA to consider regarding microbial testing, specifically pathogen testing on raw or finished products. Simply put, it is not possible to test one’s way to safety, and it is much more prudent to use resources that might otherwise be devoted to product testing to instead develop and manage practices that mitigate contamination in the first place. Given the developmental status of product testing methodologies for produce and the current absence of validated sampling methods, FDA rules requiring product testing would prove difficult to create, present enforcement challenges and create likely confusion in the industry.

That said, FDA should be encouraged to work with the industry, testing laboratories and method certification authorities to identify research needs to improve and validate risk-based pathogen testing methods. FDA is currently conducting exciting research on new methods to more precisely and efficiently detect pathogens in foods and private companies and academic institutions are pursuing similar objectives. The produce industry and FDA should work together to bring these innovations to bear as they are validated in production environments.

11. Post-harvest operations and the role of the current good manufacturing practices (cGMP) in 21 CFR Part 110

It is clear that many of the practices detailed in 21 CFR Part 110 have application to field packing, harvesting, packinghouse and cooling operations – i.e., fresh produce operations. However, the term “cGMP” should be reserved for operations where GMPs are already mandated by statute. For clarity, grower/shipper or packinghouse practices should simply be referred to as GAPs. As FDA prepares the Produce Food Safety Rule, it can adopt relevant portions of 21 CFR Part 110 that have applicability to grower/shipper and packing house operations – e.g., sanitation, worker hygiene, sick worker policies or other areas as appropriate based on general risk management needs – but they should be termed GAPs when used in this context.

12. Records and other documentation that would be useful to industry and regulators in ensuring the safety of fresh produce

Growers and others in the fresh produce supply chain often note excessive documentation as a frustration with current food safety programs. A significant part of this issue is the plethora of different standard/audit options being utilized in the industry today, and the inconsistent interpretation of these programs by individual auditors. It is not uncommon for an auditor to request that an operator amend a specific log or document with another measurement or change the format, sometimes for no apparent reason. A different auditor might ask for yet more changes, additional documents and so forth. After a time, the net result is a tangled collection of food safety documentation that often does nothing to improve food safety performance. (This is not to infer that the auditor is always wrong or that the audited is an innocent victim of the system. Indeed the root cause is a lack of understanding and insufficient training by both parties. If an audited party cannot produce documentation that verifies compliance to their risk-based food safety program, then the auditor has a duty to point out those deficiencies. At the same time, failure to
explain the basis for changes in the exit interview following the audit or demanding documentation not relevant to the operation being audited is unprofessional.)

As noted in earlier sections of these comments, FDA can help address documentation issues by defining produce safety standards so that they include the operational aspects of the audit and verification process. By stipulating that auditors have ongoing training programs, and that they themselves are “audited” by accreditation bodies to ensure their consistent performance, the confusion over required documentation could be alleviated. Of course, by providing the framework for comprehensive produce food safety standards, FDA also provides a basis for buying groups to recognize equivalency among standards, and perhaps reduce the number of audits producers must undergo.

It also seems reasonable that food safety documentation should ultimately be determined as a by-product of the risk assessment for any operation. For example, if the operation is performing a washing operation in a packinghouse, the risk assessment would like identify the use of a wash water sanitizer as an important preventive control to manage wash water quality. To verify the efficacy of the preventive control, the operator might choose to keep a wash water log that provides information on sanitizer concentration measurements over time. Similarly, a grower of vegetables that grows in close contact to the soil might identify incompletely composted soil amendments as a potential contamination risk and choose to manage that risk by sourcing compost only from suppliers that use validated composting processes and can provide COAs for each load. By comparison, a second grower raising orchard crops may not identify compost as a potential risk owing to the separation of the product from the soil and not require COAs from their suppliers.

FDA can review any number of industry sources to find examples of recommended food safety documentation records.

13. Strategies to enhance compliance

Compliance in the produce industry has been largely a function of suppliers meeting buyer’s demands. Clearly, FDA has provided the basis for producers, buyers and third parties to develop standards and audits through its GAP guidance documents but the FDA has not had a strong presence historically at the on-farm level in terms of audits and inspections. FDA can enhance compliance by considering the following actions:

- **Develop a mechanism to recognize third parties.** FDA should consider defining a mechanism to recognize or qualify third party auditors or other government auditors to perform audits both domestically and abroad. Clearly, FDA does not have the resources to perform audits itself throughout the domestic produce supply chain, and certainly not in foreign countries. Therefore, to maximize its resources and provide for a sufficient work force of qualified auditors, it is important for FDA to define basic requirements for third parties based on the guidance FDA issued in 2009 on third party auditors.
FDA could consider using internationally recognized accreditation bodies to accredit auditors to perform food safety audits according to the requirements promulgated in food safety standards benchmarked and recognized by the agency. This would ultimately promote compliance by making available qualified auditors to perform audits for the industry across the supply chain.

- **FDA should “benchmark” industry food safety standards.** Encouraging the fresh produce industry to develop commodity-specific or regional standards that FDA can benchmark to ensure these standards are appropriate. By permitting commodity group or regional development of standards (see Section 2), FDA encourages individuals to participate in the development of the food safety programs which they will implement. In other words, producers develop a sense of “ownership” over the program which in turn facilitates compliance. One needs to look no further than the California LGMA to see an example where an industry group participated and drove the development of a food safety system and have stridently implemented that system and police compliance.

- **Importer responsibility for food safety and expedited handling.** Importers must also be held responsible for ensuring that their suppliers are using risk-based food safety programs to produce their products. Toward this end, FDA should also recognize qualified third parties and/or developing working arrangements with foreign governments so that imported products are produced according to the same food safety criteria as required for domestic products. Operationally, FDA would recognize audits from accredited third parties and the companies that can provide audit documentation would receive expedited treatment at ports of entry. In this way, foreign growers and importers would have incentive to implement fully audited food safety programs.

- **Recognize testing laboratories.** Recognizing accredited testing laboratories (domestic and foreign) so that growers who identify microbial testing as a preventive control based on their risk assessments could participate in a data sharing program with FDA is described in Section 3. As discussed, FDA has increased the size and scope of its testing programs (contracted testing of market level samples, border testing, mobile lab deployments, etc.) in the name of surveillance to determine produce contamination levels. Those growers, packers, packinghouse operators or coolers using accredited laboratories and willing to share their data with FDA should be exempted from random market basket testing programs in exchange for supplying FDA with test data. In turn, FDA would benefit from potentially increased numbers of data points and the ability to deploy resources away from testing to preventative activities (e.g. training, research, inspections, etc.). For imported products, a mechanism to submit testing data from FDA recognized or accredited foreign laboratories could be a way to speed border entry and obviate the need to test those products at the border.
• **Use illness outbreak investigations as educational opportunities.** Increasing transparency in traceback investigations when contaminated product is found and/or recalls are mandated. The data and key learnings from these incidents should to be shared with the industry, so that growers and producers can better understand the real-world situations that can lead to a contamination event and a recall. It is instructive to note that in the last decade companies from all food categories that have been caught up in foodborne illness outbreaks associated with their products become the strongest advocates for strong food safety programs. Sometimes the reality of a situation can be a great incentive to comply.

• **Training and communications programs.** FDA should work with the industry, academia and other government agencies to develop training programs and listening sessions to enable producers, buyers and consumers to better understand critical food safety issues, as discussed elsewhere in these comments. Training increases awareness and awareness is a key factor in driving compliance.

• **Support food safety research.** FDA should work with industry scientists and academic researchers to help prioritize and focus food safety research to permit the reduction of the knowledge “gaps” that currently exist. By helping to provide scientifically verifiable data to support risk prioritization and identification of definitive preventive controls we may be able to alleviate the frustration the supply chain feels currently regarding confusing and contradictory requirements that are sometimes imposed. Science-based approaches may generate confidence that requirements are justified – and hence compliance can be more readily achieved.

These comments are respectfully submitted by the Produce Marketing Association. Any questions can be directed to:

Dr. Robert J. Whitaker  
Chief Science & Technology Officer  
1500 Casho Mill Road  
Newark, DE 19714  
302-738-7100