



STAKEHOLDERS'
DISCUSSION
SERIES

**Produce Safety Project
Stakeholders' Discussion Series
February 19th – April 27th 2010**

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**Produce Safety Project
Stakeholders' Discussion Series**
Executive Summary

Overview

The Produce Safety Project (PSP) – based at Georgetown University and funded by The Pew Charitable Trusts - is a research and advocacy organization that supports the development by the Food and Drug Administration (FDA) of a mandatory and enforceable produce safety standard for the growing, harvesting and packing of fresh fruits and vegetables. Among other activities, PSP sponsored six stakeholder discussions around the country with the goal of providing a platform for stakeholders, with particular emphasis on growers, to discuss their expertise in promoting produce safety through their current practices and offer input for consideration by FDA as it prepares to propose a produce safety rule. In addition, the Stakeholders' Discussion Series provided an opportunity for fruit and vegetable growers and other interested stakeholders (extension educators, food retailers, consultants, produce trade association personnel and others) to hear the science associated with four areas identified as important to produce safety: 1) Irrigation and Foliar Contact Water Quality¹, 2) Wildlife and Environmental Concerns²; 3) Composting Issues³; and 4) Worker Health and Hygiene⁴.

These four areas are noted as potential vectors for pathogens and causing food-borne illness outbreaks. Four papers were commissioned by PSP to present current information on these issues. These papers, and ideas contained in them, were briefly reviewed and presented during each of the sessions, and served as jumping off points for more detailed discussions organized in smaller group break out sessions.

The six locations for the Stakeholders' Discussion Series were:

1. Rochester, New York (February 19, 2010)
2. Columbus, Ohio (March 11, 2010)
3. Tifton, Georgia (March 25, 2010)
4. College Park, Maryland (April 7, 2010)
5. Monterey, California (April 26, 2010)
6. Salinas, California (Spanish-speaking session)(April 27, 2010)

Each of the Stakeholders' Discussion Series sessions has a summary, capturing overviews of the presentations, the main points emerging from the breakout sessions, and some of the observations, questions, and issues highlighted towards the end of the sessions.

¹ A summary of the white paper commissioned by PSP on issues related to irrigation and foliar water quality is available online at http://www.producesafetyproject.org/discussion_series.

² A summary of the paper Co-Managing for Food Safety and Ecological Health in California's Central Coast Region is available online at http://www.producesafetyproject.org/discussion_series

³ A summary of the white paper commissioned by PSP on compost issues is available online at http://www.producesafetyproject.org/discussion_series

⁴ A summary of the white paper on Worker Health and Hygiene commissioned by PSP is available online at http://www.producesafetyproject.org/discussion_series.

This document is intended to extract some of the key themes from the entire Stakeholders' Discussion Series, including common themes across all of the sessions, as well as unique insights, observations and suggestions – either particular to a region, practice, or other considerations. This document is not intended to interpret the information gathered or draw any conclusions.

The Stakeholders' Discussion Series promoted maximum dialogue and encouraged stakeholders to comment on these issues. The comments are sometimes in conflict or present a challenge in terms of balancing different interests. These conflicts were sometimes explored during the sessions, but there was not time or intent to fully reconcile these challenges.

General Themes

Several themes arose consistently during each of PSP Stakeholders' Discussion Series sessions. While there may be some regional variations among these themes as reflected in the suggestions, they are themes that clearly are on stakeholders' minds across the country as they think about a proposed produce safety rule.

Risk-Based Requirements

Many participants strongly recommended the new produce safety rule be risk-based and that the science drive the requirements and standards. This suggestion was voiced in the context of all topical areas - water, composting, wildlife, and worker health and hygiene, as well as a means of targeting regulations to address identified areas of greatest risk. For example, many stakeholders suggested that irrigation water used on ground level commodities, just prior to harvesting, merits testing and possibly a higher standard, than irrigation water used early in the growing season, and/or with tree crops. Other ideas included determining what wildlife pose the greatest risk, based on a scientific understanding of transmission from wildlife to produce, and developing steps to mitigate that risk. Scientists, growers, and government representatives alike recognized the need for additional science to support effectively targeted produce safety regulations. Stakeholders suggested including in the rule an amendment mechanism that can appropriately and expediently accommodate new scientific knowledge.

Commodity-Specific Regulations

Many stakeholders suggested commodity-specific regulations as a means of allowing for a more risk-based approach. However, small, multi-commodity farmers (including growers in many Amish and Mennonite communities) expressed concern about being over-burdened by commodity-specific regulations. Other growers, many of whom grow tree crops or crops often processed (such as pecans and peaches in Georgia, apples in New York, Brussel sprouts in Ohio, and almonds in California), thought some commodities should have less rigorous requirements, or be exempt.

Multiple/Competing Standards

Growers in all regions, particularly in regions such as Ohio and California – where they have had more experience with changing requirements from buyers – are particularly concerned about the proliferation, and sometimes contradiction, of different regulatory and proprietary standards. These growers and other stakeholders expressed growing frustration with increasing buyer pressure to implement policies, aimed at reducing legal liability or increasing market share, which are not scientifically supported. Several growers also speculated that private standards allow buyers to reject entire crops in an effort to manage fluctuating market saturation and demand. Some growers suggested that transparent, risk-based standards may help reduce these escalating demands. While

most growers indicated a need for minimum standards, many growers also conveyed a need for maximum standards. A “floor” and “ceiling” would protect against a food safety “arms race.”

Draw from Currently Existing Standards

Stakeholders, particularly those in regions with established produce safety requirements or programs (such as the Leafy Green Marketing Agreement in California) think the new rule should be developed from existing standards. Growers agreed this could provide a rule that embodies components of other standards without creating competing standards. Stakeholders also expressed hope that development of a national produce safety rule will also avoid, and even address, current multi-agency conflict emerging from water quality, conservation, and other requirements. One example of competing regulations or standards raised in many stakeholder discussions was the requirement to control wildlife to prevent pathogen transference, conflicting with prohibitions of the Migratory Bird Treaty Act. Another example discussed in California is the conflict between some proprietary private standards and state water regulations.

Many growers expressed the hope that a national rule could resolve some of these conflicts – and several participants noted the efforts of several national industry groups and retailers who are working on a Good Agricultural Practices (GAPs) harmonization plan.

Scalability

Scalability was discussed at each session and from several different aspects. Many participants voiced a concern that the proposed produce safety rule not be a “one size fits all” approach, and that the small acreage farmer not have the same burden as a large acreage farmer. While some participants – including small acreage, multi-commodity farmers, as well as those growers who directly market to consumers from their farms – proposed exemptions from some of the regulations, many others-of all sizes-strongly support a proposed regulation requiring compliance from all growers. As a participant from Columbus, Ohio during a water quality breakout session stated, “It takes just one pathogen to make someone sick and that can come from any farm.” Stakeholders offered other suggestions for scalability at the sessions. One idea suggested in several sessions was to establish regulatory mandates of specific outcomes, accompanied by the development of operation-based standard operating procedures (SOP) and Hazard Analysis Critical Control Points (HACCP) plans to meet the mandated outcomes. This approach would allow growers to come up with their own plan to meet the mandated outcomes that is tailored to their particular size, commodity grown, work force, practices and economics.

Consistent Interpretation and Enforcement of Standards

Some stakeholders voiced concern that an outcomes approach might increase auditor misinterpretation or inconsistent interpretation of regulations. Further, many growers expressed concern that without numbers-based regulations (or standards), there would be a lack of auditor consistency in enforcing regulations nationally.

Alternatively, some growers strongly supported the establishment of standards. Enthusiasm for this approach focused on clarity of the standards to be met, increasing consistency among auditors for inspection and review. However, some expressed concern that establishing standards could be too uniform and not allow the flexibility to adapt to different models for different growers’ operations. In addition, concerns were raised regarding whether and how the necessary infrastructure would be established (see below).

Auditor consistency was a theme that surfaced in many stakeholder discussions. Ideas to increase consistency as part of the proposed rule included an auditor training program to both stress consistency, and help ensure equal enforcement of new produce regulations. Growers cited experiences with trained auditors who have limited practical “in-field” experience. Growers also requested a feedback mechanism to review auditors. Growers also acknowledged that random, unannounced audits are likely to be the most effective.

Reasonable Record-Keeping Requirements

Another theme discussed extensively was documentation or record keeping. Sub-themes in this area included confidentiality, liability and proprietary standards. Documentation was often suggested as critical to the implementation, enforcement and credibility of an enhanced produce safety system – “If you do it, then you must document it. Otherwise, it doesn’t count.” (*Participant in the Rochester, NY session, break out group on worker health and hygiene*) Some participants further suggested that if documentation was not part of the requirements, then accountability would be too illusive. At the same time, participants also voiced concern about overly burdensome record-keeping that could take too much time and effort to complete – time that is taken away from growing food.

In addition to supporting record-keeping to ensure regulatory compliance, many growers expressed enthusiasm for including guidance in the new rules for how growers should keep records to increase audit efficiency. Stakeholders suggested that recording frequency could be tailored to different sized operations. For example, some suggested that smaller operations could record on a fortnightly or weekly basis, and large operations on a daily or bi-weekly basis. Scalable record-keeping is seen as a means of equalizing the costs of implementation to meet standards for different sized farms.

Economic Impacts

Stakeholders identified economic impacts of new regulations as a concern. Many growers view any additional demands on their time as less time dedicated to growing and harvesting food and therefore a cost. Economic impacts also are felt in some of the new, proprietary standards buyers have used as a basis to reject crops.

Ideas for how to minimize the economic impacts varied, and included ideas already mentioned in making the testing and documentation requirements “scalable,” as well as particular ideas for sharing and spreading the costs of implementing requirements. For example, farmers who use the same irrigation canal could share water quality testing costs and information. Shared testing records could increase testing efficiencies. Minimizing requirements that could cost the growers their whole crops were suggested as imperative. For example, wildlife control or audit failure for wildlife tracks with the associated rejection of a crop is a substantial concern and economic burden to growers. Growers expressed a strong interest in being given a list of options or corrective actions that they can take to address a science-based food safety risk, while preserving their ability to sell the rest of their crop that does not pose a risk.

“We’ve gone through GAPs audits, but never totally felt quite comfortable, because if you have protocol with a positive test result, you have to test again. In that process, you could be talking about huge time delays. If you’re talking about fresh produce, in that time it takes to re-test, the crop is all gone. Further, at the grower level, once you spot a problem and finalize to a point where you can pinpoint what it is, you are way past the point to stop the damage.” (*Participant in the Rochester, NY session, water quality break out group.*)

Other identified costs that, taken separately are not that substantial, but in combination, can add a difficult financial burden for growers, include multiple, expensive testing and costs for lab delivery and results, use of wildlife deterrents, substantial amounts of supplies, such as sinks, gloves, towels, clothing, or other equipment. While growers are not opposed to providing and complying with many of these types of efforts, combined or in proportions out of sync with their operations, they create a significant cost.

“I agree that we need common sense standards, but not at such a high implementation cost.”
(Participant at the College Park, MD session, water quality break out group.)

Supportive Infrastructure

Many growers identified an area of concern as the “mechanics” of, and support for, complying with any requirements – whether regulatory or from private contracting. Included in this theme are issues such as the following:

- The number, consistency among, and quality of auditors reviewing the growers’ plans and actions taken to comply, as well as interpreting testing results;
- The accessibility, quality, cost, consistency, and speed of the laboratories to which they send their samples and receive results;
- The availability of information and training for developing their own training programs, a tool kit of options for trouble shooting and addressing issues that arise without losing their whole crop or a significant amount of their crop, and
- Some mechanism for reconciling conflicting demands (such as conservation requirements and produce safety requirements).

Education and Training

Many stakeholders supported the idea of a strong education and training component for the proposed rule, preferably provided at no cost. The overall experiences with GAPs training programs expressed by the growers was very positive, both in terms of looking at their operations more analytically, as well as generating ideas and tools for addressing any risks they identified and encouraging good practices by the farmers and farm workers. Due to these positive experiences, many stakeholders strongly see education and training as very valuable – to them, their operations, and to producing safe food.

“After we had some training, we did general things to get cleaned up, such as training workers on hygiene and putting in some wildlife deterrents. Now I see [*these practices*] as common sense, but back then it wasn't. That’s why I think no one should be exempt.”
(Participant from the Monterey, CA session, wildlife break out group.)

Topical Themes

As mentioned above, each of the Stakeholder Discussion Series organized conversations and input around four main topics: 1) Worker health and hygiene; 2) Composting; 3) Irrigation and foliar contact water quality; and 4) Wildlife and environmental concerns. While some of the issues raised or input provided covered all of these topics, different ideas emerged in different locations – some shaped by the particular region or practices in that region, and some because participants provided a deeper level of insights or suggestions. Below are some of the ideas that emerged in each topical area.

Worker Health and Hygiene

Almost all of the participants in each session recognized the importance of worker health and hygiene. Many growers already have either taken or plan to take GAPs training courses and implement some of the recommendations for worker training and other tools to promote worker health and hygiene. Growers provided extensive information about their practices and how current methods might be integrated into the new produce safety rule. Growers also noted that workers want this information and once trained, often follow these good practices.

“Workers take pride in everything being clean – the floor, truck beds, themselves – all of it!” (*Participant in the Columbus, OH session, worker health and hygiene break out group.*)

The individual session summaries highlight the number and variety of the specific practices and suggestions for improving worker health and hygiene. A sampling of these ideas include:

- Providing adequate facilities and supplies for toilets and sinks to wash hands, water for hydration, and clothing and non-skid shoes for increasing safety and hygiene;
- Cross-training workers so that those who are ill have other options for working that are away from the produce and do not lose a day of pay;
- Using signage in the native language of the workers;
- Leading by example – having managers and the owner not only talk about proper, healthful behavior, but also demonstrate proper behavior; and,
- Monitoring and documenting to confirm training and implementation.

There was a particular concern for plant-and-animal farms and the risk of cross contamination by workers. While farmers are keen to adhere to best practices, they also conveyed the need to be cost effective; meeting the requirements can be time-consuming and challenging, particularly on farms with plants and animals. An additional sensitivity for some growers is a potential, albeit unintentional, interference with cultural or religious practices. For some Amish and Mennonite growers, a federal rule imposing requirements that supersede cultural norms and practices, such as eliminating the use of domesticated animals in their operations instead of machinery, is a major concern.

Growers from small, single-family farms expressed diverse views, from some who suggested that they do not need to document their family’s hand washing activities, and already have adequate access to toilets, to those who have already taken the GAPs training and use the training video every year to refresh their family’s practices for safety and hygiene.

Two sub-themes of great interest on the topic of worker health and hygiene were glove use and training. Growers recognized potential benefits to proper glove use, such as reducing pathogen transference. They also acknowledged the potential for unintended consequences as a result of improper glove use and management that can increase the risk of pathogen transference. If gloves are used, there are commodity-specific characteristics to consider. Using gloves to pick small berries and fragile fruits may reduce the employees’ ability to identify ripe fruit. Heavy fruits such as melons would require thick, re-usable gloves, which come with greater management responsibilities. These gloves require proper storage and cleaning (the most common practice identified by growers for the latter is a chlorine drip).

Training may be the greatest value-adding practice for worker health and hygiene. Training must address language and educational barriers. Since many farmers face illiteracy and multi-lingual work forces, they are often using videos and pictures combined with leading by example. There was a strong acknowledgement from growers that documentation of training is needed to ensure practices are being implemented effectively. Many participants have attended GAPs training programs, and have trained their supervisors and staff based on the information and materials from the training programs.

The worker health and hygiene presenters identified hand washing as a key route of fecal-oral contamination. To ensure proper hand washing protocol is followed, farmers are adopting unique practices such as keeping sinks outside (with hot water) and within eye-sight of supervisors, toilets close to work zones, and keeping first aid kits and hand sanitizers readily available at all times. Supervisors also remove or re-assign sick workers, a task many growers agreed was complicated by difficulties identifying sick workers.

Composting

Many growers practice composting or use compost or raw manure in a variety of ways. Many small farmers (such as the Amish and Mennonite populations of Ohio and Pennsylvania) use raw manure from their farm work animals. Other larger farms produce and manage compost on their own or purchase from a composter. Most of these participants suggested that one universal composting standard was needed to avoid duplication or inter-standard conflicts. Several small farmers, who in many cases apply raw manure to their fields during transitional seasons, feel that testing is not necessary.

Some common themes for composting were the need to retain flexibility in feedstock selection, application-harvest intervals, and commodity-specific rules. Growers indicated that a risk-ranking matrix for these categories could help provide the necessary guidance in managing their compost and applying it in safe practices. The Amish and Mennonite grower communities expressed great concern about managing their compost because of their limitations for using mechanized processes.

“How concerned is FDA with plain folks farming with animals in field and shedding manure? Is all that taken into consideration? We cherish the lifestyle we were raised in and plan to carry it on. It makes our practices a difficult situation with GAPs. What direction do we turn?” (*Participant in the College Park, MD session, composting break out group.*)

This grower group and other small farmers often integrate raw manure directly into their fields and adhere to 90, 120, or 160 day application-harvest intervals. Many stakeholders suggested that variable minimum application-harvest intervals should be regulated using science-based knowledge about pathogen levels and transference from compost. If compost tests pathogen-free, there should be no time limit between application, planting, and harvest. They further suggested that if raw manure is used, there should be a science and risk-based standard application-harvest interval.

Growers whose operations are certified for organic produce voiced concern that any regulation does not interfere with their certification or contradict these practices.

Stakeholders also stressed the importance of regulations including clear definitions for different types of compost. Participants suggested compost purchased from composters should be identified by a

batch number and date and be tested directly prior to sale. Additionally, they suggested that compost produced on the farm should be tested directly prior to application. Stakeholders suggested that the regulation should require vehicles used to transport compost be cleaned between uses to protect against cross-contamination.

Irrigation and Foliar Contact Water Quality

There are many regulatory themes that stakeholders suggested be included in produce safety regulations governing water quality. One particularly prominent theme was testing protocol. Many growers indicated confusion regarding where test samples should come from within their irrigation sources (from the edge or center of the pond?). There also was a tension over testing frequency. Some growers are concerned about the costs of testing. If they use one source, well water for example, and that source tests negative for harmful pathogens at both the application point and the well water source, then annual testing should be sufficient. Other growers indicated concern with lack of control over their water sources (such as shared irrigation canals) which may require excessive testing. Some growers suggested that shared irrigation sources effectively have shared liability and should therefore share testing burdens.

One common theme for water quality was a commodity-specific and irrigation source-specific risk assessment. Many stakeholders expressed frustration with the state of the science and the current inability to more specifically target or assess risks of pathogen transference from different water sources or application methods, and an associated testing protocol. Most growers and other stakeholders acknowledged the need to use potable water after harvest. However, suggestions for whether and when to test prior to harvest varied. Many stakeholders suggested that the regulations, coupled with supporting science, should focus on commodity-specific water use and intended use of that commodity. For example, water used just prior to harvest of leafy greens (eaten raw) should be tested, whereas irrigation water applied under plastic just before harvest of tree crops may not need testing. In another example, growers who re-capture excess irrigation water or harvest rainwater as an irrigation source are interested in tailored testing requirements to accommodate those unique sources.

All stakeholders acknowledged that variability in irrigation types and sources will be challenging to reconcile with standardized requirements, particularly with incomplete scientific understanding. Many growers also were concerned with a lack of consistency in testing protocols, time to receive results, and interpretation of the results. Some stakeholders suggested a federal certification mechanism for labs and technicians to help increase testing consistency. Stakeholders suggested that regulations mandate minimum baseline standards and require staggered testing “as-needed” prior to irrigation or post-harvest contact. Many growers expressed concern that testing for indicators is not truly indicative of the presence of pathogens at a level of risk. Finally, growers suggested that all members of the produce supply chain should be required to keep a microbiological history of their water, to manage legal liability in the event of a food-borne illness outbreak.

Wildlife and Environmental Concerns

One of the central themes growers discussed regarding wildlife and environmental concerns was the tension between wildlife preservation and food safety. The impetus for grower wildlife controls is predominantly driven by the economic cost of wildlife impact on crops – in terms of loss of the crop because of damage or being eaten, not food safety concerns. Stakeholders discussed a variety of wildlife control mechanisms from managing and tracking existing populations, to trapping and hunting, to preventing entry into fields. Many growers indicated they felt in conflict with federal or

state regulations that promote wildlife conservation and limit their ability to use wildlife deterrence mechanisms, including hunting. While other growers strongly encouraged wildlife as part of their food production ecosystem and did not want regulations imposed that would prevent them from this approach to farming.

The varying standards and lack of scientifically supported distances for buffer zones was another common theme throughout the stakeholder discussions. Some growers suggested that a wildlife prevention and reactive controls matrix would assist in developing standard operating procedures (SOP) for wildlife management. The matrix should suggest monitoring and controls measures, require minimum buffer distances for proximity to residential areas with domesticated animals, animal feces, tracks, and homes, and farm worker animals. Stakeholders suggested that there are many competing standards with different distances for buffer zones, and so a standardized protocol is desirable. This protocol could be specific to different kinds of animals with different levels of risk; for example, the buffer from feral pig tracks may be greater than the buffer for deer tracks. Several growers expressed frustration that the GAPs and other private regulations for wildlife control are unrealistic and lack a scientific basis.

Many growers conveyed a lack of clarity about which animals, including domestic animals used on the farm, they should expend the most resources trying to control from a food safety perspective. Dogs, for example, have been used as wildlife deterrents, but now are required to stay out of fields by some programs and auditors.

Some concerns were raised about various practices affecting land values. For example, extended buffer zone requirements in California, where property values are high, are of particular concern to farmers. Other requirements, such as wildlife management, could affect the long-term value of agricultural property.

Auditor consistency was an important theme for wildlife and environmental controls because of current variability. Regulations should clarify the definitions of key words such as “monitoring” and “measures” to reduce different interpretation. Stakeholders suggested that regulations encourage auditors to be flexible with wildlife control mechanisms, tailoring strategies that work for each operation. Growers also would like to have science-based options for addressing any risk from wildlife contact with the crop, while also salvaging and selling the safe portions of their crop. Some stakeholders suggested that there should be a wildlife exemption for growers who choose to integrate beneficial wildlife into their ecosystem.

“The rule should include acceptable deterrents to reduce wildlife, but not eliminate wildlife – we must have a balance in the ecosystem.” (*Participant in the Tifton, GA session, wildlife and environmental concerns break out group.*)

Other Areas of Interest

Throughout the Stakeholders’ Discussion Series, participants contributed ideas and suggestions related to produce safety but not *directly* related to the development of a produce safety rule or on farm requirements. Growers emphasized the need for a consumer education component to produce safety initiatives. Many stakeholders believe consumers are an integral component of the produce supply chain. Growers indicated a desire to be involved in consumer education and believe their involvement could increase the success rate of education initiatives. While many growers acknowledged that farmers are the first line of defense against food-borne illness outbreak, they also

are adamant about not being the only – or the last. Stakeholders noted and strongly suggested equivalent emphasis be placed in three other ways to secure the produce supply chain: (i) requirements for the safe transportation of food (Sanitary Food Transportation Act) can reduce the likelihood of cross-contamination during produce transportation; (ii) retailers and farmers’ markets should be regulated with rules to reduce pathogen transference; and (iii) school food programs should include a food safety component to educate future generations about proper food safety precautions. Also, stakeholders suggested that value added products should be of higher concern due to the nature of these products’ processing.

Stakeholders at each of the sessions raised the issue of establishing a level playing field for domestically grown and imported produce. Growers highlighted consistent, vigorous, third-party testing of imported produce as a necessary step towards national food security.

Continued Research

Growers, scientists and other stakeholders identified research and knowledge gaps in each of the focus areas. There are several steps that participants recommended to facilitate the gathering of new information and better science to support new regulations.

Many suggested that creating farmer incentives to participate in research would increase our national capacity to perform agricultural research. Growers often fear participating in research due to concerns over possible negative implications of the results. Strategic partnerships with universities and standard-setting (such as the National Organic Standards (NOS) and the Leafy Green Products Handler Marketing Agreement) could substantially expand the existing body of knowledge. Stakeholders suggested that research should focus on three areas; 1) developing universal testing protocols, 2) understanding pathogen transference and uptake, and 3) pathogen and outbreak traceability.

“We need a lot more research on what is actually happening with pathogens out in live field situations.” (*Participant in Rochester, NY water quality break out session discussion.*)

Below, in chronological order, are the six summaries which provide an overview of each session and compile the comments and ideas gathered at each Stakeholders’ Discussion Series meetings.

Final Summaries

Produce Safety Project Stakeholders' Discussion Series

Co-Sponsored by Cornell University

Meeting Summary

***February 19, 2010
Rochester, NY***

Goals and Outcomes

- *Increased understanding of the science underlying enhanced produce safety practices, including:*
 - *What we know, and*
 - *What we do not know*
- *Increased understanding of practices that are, or could be, contributing to enhanced produce safety.*
- *Identification and discussion of any regional practice considerations important for enhancing produce safety.*

I. Welcome and Introductions

Jim O'Hara, Director of the Produce Safety Project (PSP), welcomed the meeting participants and thanked them for attending. He told the group that the Food and Drug Administration (FDA) will develop a produce safety standard, which it is planning on releasing in the fall of 2010, for the growing, harvesting and packing of fresh fruits and vegetables. In order to help the FDA learn about practices currently implemented on farms and about the concerns and questions of growers, PSP is holding a series of stakeholder discussion meetings, of which Rochester is the first. At each of these meetings, PSP hopes to foster a conversation among the federal agencies, the growers, and the scientific/research community. The four scientific presentations are not meant to be the last word on these issues, but rather starting points for the conversations of the day. Mr. O'Hara explained that a record of each of meeting will be kept and the comments from the meetings will be compiled and submitted to the FDA for its consideration.

Dr. Bob Gravani, Professor of Food Science in the Department of Food Science at Cornell University and author of *Farm Worker Health and Hygiene*, echoed Mr. O'Hara's appreciation for the stakeholders' participation in the meeting and emphasized the importance of the FDA having the chance to learn from the stakeholders' input and expertise. He noted that the participants would be providing input about what they know best: growing fresh fruits and vegetables and supplying them to the market. Dr. Gravani urged the group to think positively about moving forward on food safety issues, which affect both lives and livelihoods.

Mike Taylor, the Deputy Commissioner for Foods at the FDA, emphasized that everyone in the room shared the common goal of achieving food safety. He said that food safety was (i) fundamental to people's daily lives, (ii) of national concern, and (iii) had a huge impact on the economy and public health. He noted that one of the themes of the current administration is healthy diets and ensuring that people have access to fresh produce. The FDA has been working with communities to elevate the importance of national food safety standards that will be implemented with community engagement. The FDA has been holding listening sessions and visiting farms around the country and has already learned a great deal about produce farming practices and the concerns of growers. Mr. Taylor mentioned that the agency acknowledged the great diversity in the produce sector, the need to use a risk-based and science-based approach to developing the standards and the necessity of standards that are scalable according to the size of the farming operation. The FDA is working closely with the U.S. Department of Agriculture (USDA) in the rulemaking process. The USDA is also assisting the FDA to understand the produce sector. The two agencies have issued a joint statement affirming their partnership and noting that the FDA rule will be consistent with any USDA marketing agreements. The FDA has also opened a docket to collect public comments in advance of the proposed rule.

Rayne Pegg, the Administrator of the Agricultural Marketing Service (AMS) at the USDA, stated that food safety is a top priority for both the FDA and USDA. She said that one outbreak could cripple an industry and have a huge impact on a family. Ms. Pegg noted that the meeting was an opportunity to discuss the issues, the reality of what was happening on farms, the real risks that exist, and the scientific uncertainties. Ms. Pegg explained that AMS has programs related to consistency in the marketplace and is considering the development of a national Leafy Green Marketing Agreement. The USDA encourages the use of the best available science to determine best practices and identify remaining questions. She reiterated what earlier speakers had said and encouraged the meeting participants to actively engage in the conversation and talk about the realities of what happens on the farm daily.

Larry Eckhart, of Kinderhook Creek Farm in Stephentown, NY, thanked all the producers and growers for attending the meeting. He said that he saw the meeting as an opportunity for the producers in the room to: (i) understand the perceived and real risks related to food safety, and (ii) help researchers and regulators understand the unique challenges faced by producers, particularly in the Northeast. He stated that food safety begins on the farm and that all producers, no matter the size or type, have the daily problem of producing safe and wholesome food for their customers. Producers in the Northeast have access to a large population of customers and therefore have the opportunity to be at the forefront of the food safety issue in the United States.

Abby Dilley, the meeting facilitator, then reviewed the meeting agenda, materials, and expectations. She expressed hope that the participants would gain an increased understanding of (i) the science, (ii) good practices to enhance produce safety, and (iii) about the variability of the produce sector.

The discussion topics for the meeting consisted of four issue areas that were identified as possible concerns for food safety: (1) composting of manure, (2) irrigation and foliar contact water quality, (3) worker health and hygiene, and (4) wildlife and environmental concerns. A researcher presented an overview of each issue area and the participants had the opportunity to attend breakout sessions to further discuss the issues. Summaries of the presentations and breakout sessions are below.

II. Composting Issues

Dr. Mike Doyle, Regents Professor of Food Microbiology and Director of the Center for Food Safety at the University of Georgia and author of *Composting Criteria for Animal Manure*, presented an overview of composting issues, and key scientific information.⁵ Dr. Doyle noted that there were three types of compost systems (aerated, windrow systems, and in-vessels) and that incomplete treatment of manure could contaminate food. Pathogens can be inactivated in compost during three stages: mixing the compost, raising the temperature, and curing. Dr. Doyle then reviewed some of the factors influencing pathogen inactivation.

Dr. Doyle explained that there were no universal standards for composting to eliminate harmful pathogens, such as *E. coli* and *Salmonella*. There is no federal agency with regulatory oversight, which is primarily regulated at the state and local level. However, state and local regulations vary greatly in scope and complexity. While many jurisdictions use EPA guidelines 40CFR Part 503 for end-product and process criteria, there are still variations in the current non-uniform standards with regard to time, temperature, finished product testing, and required frequency of facility monitoring.

In the report, the researchers made the following recommendations:

- Require insulating covers on all types of compost piles.
- Include a minimum curing period to ensure the completion of pathogen inactivation.
- Procedures to control risk, i.e., regular verification of equipment accuracy, detailed weather condition reporting.
- Require compost operations to have standard operating procedures, a quality assurance plan and a Hazard Analysis Critical Control Point (HACCP) program.

Following the presentation, Dr. Doyle made the following points in response to participants' questions:

- While the National Organics Standards (NOS) Board has compost standards, there are no national standards required by the industry as a whole. The NOS compost standards, as well as other existing standards, must be evaluated for their effectiveness and brought to the attention of regulators to be evaluated scientifically.
- Any HACCP plan developed would include regional variability as long as the plan also includes critical control points. For example, the time-temperature approach would be addressed regionally. However, there must be criteria which can be monitored and documented.
- There is a lot of variability based on region regarding data for raw manure.

Composting Issues Breakout Sessions

Following the morning presentations, meeting participants were given the opportunity to attend breakout sessions to further discuss composting issues. The following themes were raised in the sessions:

Regional Considerations

- Upstate New York has high humidity and low temperatures, which could affect the effectiveness of composting methods.
- Many of the growers in attendance use horse manure as composting material.

⁵ A summary of Dr. Doyle's paper is available online at http://www.producesafetyproject.org/discussion_series.

Local Practices

- Some growers who use manure tend to pile it in one location on the farm and let it sit until the next planting season in the spring or summer. Others disked it into the soil and planted a cover crop in the fall.
- The growers tend to rely on feel (“dirt-like”) and smell (odorless) to determine if the composting process was effective.
- Farmers with small operations believe that they place a lot of attention on the safety of their products and do not feel that their produce is as much of a food safety concern as produce from larger operations.

Standards and Audits

- Audits should be harmonized so farmers are not overburdened by repeated audits from different organizations.
- Because of the size of their operations, small growers believe they should be exempt or have more lenient reporting requirements (e.g., only require documentation when there is a problem).
- Growers were concerned about the cost of testing apparatuses and methods.
- The cost of undergoing multiple audits is burdensome for small growers. They believe that if a grower has been audited once (e.g., certified organic), they should not be audited again by other agencies.
- Compost standards should include risk-ranking by commodity (e.g., root vegetable, leafy green, tree fruit).
- Build compost standards on existing requirements (e.g., NOS Board).
- The compost standards should incorporate flexibility (based on commodity, region, method, size).
- The desired outcome should be clear (e.g., bacterial levels) and the standard should be goal-based rather than process-based so individual growers could be flexible and determine the best means to reach the goal.
- The FDA should look at the farm as a complete system, and acknowledge that requirements on one part of the farm’s operations (e.g., compost) may have implications for other aspects of the farm.

Research and Education Needs

- The producers need more guidance about the composition of compost, and the steps to take in order to compost.
- Growers wanted information about the risks associated with different types of manure (e.g., horse, chicken, cow). They also wanted to know if composting requirements would vary depending on type of manure.
- Growers wanted an instant and reliable indicator for pathogen testing.

III. Irrigation and Foliar Contact Water Quality

Dr. Trevor Suslow, the Extension Research Specialist at the University of California, Davis, Department of Plant Sciences, and author of *Standards for Irrigation and Foliar Contact Water*, presented an overview of issues related to irrigation and foliar contact water.⁶ Produce and niche-

⁶ A summary of Dr. Suslow’s paper is available online at http://www.producesafetyproject.org/discussion_series.

crops use controlled irrigation in a number of ways, and because of the intimate contact with the edible portion of the crop, the quality of the water is very important for food safety considerations. Water quality becomes more important the closer to harvest. There is still much unknown about how water quality affects food safety based on region, crop, or management practice. Dr. Suslow reviewed some of the ways irrigation and foliar contact water may become contaminated. For example, groundwater can be contaminated by surface water events, and fecal contaminants and pathogens have been found in irrigation water.

Dr. Suslow then reviewed the state of the science. There are two main concepts: the risk potential for water is very high and the risk exposure is highly variable. He noted that there is a knowledge gap for water quality because of a lack of uniformity in testing methods and standards, and a lack of a national database for irrigation water quality. Also, current water quality standards are inadequate, poorly defining the relationship between indicators, pathogens, and risk. Dr. Suslow noted that growers must be able to differentiate between high- and low-risk irrigation water, and that auditors need to recognize the variable risk based on a number of factors, including water, crop, location, and post-harvest handling.

Dr. Suslow noted that many regional Good Agricultural Practices (GAPs) and commodity-specific guidelines have adopted the EPA recreational water quality standards for irrigation water. He expressed concern about this trend because the EPA criteria were not intended to apply to risks associated with irrigation of edible crops and do not take into account the die-off of pathogens post-irrigation. He also noted that the FDA commodity-specific guidance recognizes that there are currently no clear standards, and growers are responsible for using water of “appropriate quality.”

Following Dr. Suslow’s presentation was a short question and answer session. Dr. Suslow made the following points in response to participants’ questions:

- There is a lot of research underway to understand the dynamics in water ecology.
- There is a fair amount that supports the idea of a clean pond devoid of plant life being a better buffer than a clean impoundment.
- Many of the mechanisms and standards that exist today could be outdated based on current scientific understanding and technology.
- Water is not as controllable an input as compost, so it is harder to apply the science and data to develop guidelines.

Irrigation and Foliar Contact Water Quality Breakout Sessions

Following the morning presentations, meeting participants were given the opportunity to attend breakout sessions to further discuss irrigation water issues. The following themes were raised in the sessions:

Regional Considerations

- Growers used a variety of water sources, including well and municipal, though the majority of the growers relied on on-farm surface water bodies. The Northeast depends on surface water, particularly during dry periods.
- Growers expressed concern about wildlife contaminating on-farm water bodies. The wildlife are attracted to the vegetative buffers put in for conservation reasons.

Local Practices

- A number of growers in the region relied on the National GAPs Program at Cornell University for help with designing their GAP plans.
- Producers are already doing much of what is included in GAP plans and audits, but the paperwork is time-consuming and expensive. There are also varied requirements depending on the program. In order to comply with the requirements, producers find themselves having to do away with other practices and activities.
- Some producers are testing their on-farm surface water regularly.
- If the water source is on the farm, the producer can control it. If the water source is a public waterway, the producer has very little control over what happens upstream to affect the water quality.
- If using irrigation water becomes too burdensome, farmers may choose to use municipal water (which is costly), or stop irrigating all together and potentially lose their harvest.
- Regulators should be aware that some farms have both produce and livestock, so excessive distance requirements between fields and domestic animals may be unmanageable for small, diversified operations.
- The water quality tests may be inadequate. The laboratories may not be testing for the specific circumstances on the farm, the timing for results is too long, and there is some question about whether the indicators being tested for are truly indicative of the presence of pathogens to a concerning level of risk.

Standards and Audits

- There will never be zero risk. There should be provisions in place to protect the farmers from liability if they can prove they followed all the guidelines.
- Audits and trainings are beneficial for the producers because the process educates them.
- The number of audits and certifications is a problem for growers. Just because a grower passes one audit does not mean they will pass a different audit or get a similar score. This is frustrating to growers. It also increases costs when growers must get different audits to satisfy different buyers (audit fatigue). A universal standard/audit is necessary.
- Crops are certified, not farms. Per-crop certification is costly, and many growers believed it made more sense for the farm itself to be certified.
- The participants want a uniform standard and protocol that all farmers must adhere to, yet it must still accommodate different sizes and types of operations. One grower suggested that the standard be outcome based, so that individual farms can determine the best way to reach it.
- Any standards should be flexible and consider factors, such as region, operation type, scale, commodity, and water source.
- There was concern that imported produce is not being scrutinized as well as domestic produce. Further, if imported produce is not held to the same standards as domestic produce, the imported produce may become less safe. Increasing the burden on domestic producers will drive domestic production down, leading to a related decrease in food safety.

Research and Education Needs

- Producers need more information about potential risk areas, about appropriate testing methods and schedules, and about possible sources of contamination.
- More research is needed about pathogens in live field situations, so efforts can be better targeted to prevent or address risk.

- Consumers and others in the production-supply chain must be better educated about their responsibilities for food safety (e.g., washing produce before consumption).

IV. Worker Health and Hygiene

Dr. Bob Gravani presented on issues related to worker health and hygiene.⁷ It would be impossible to run farms today without farm labor. Dr. Gravani reviewed the demographics of paid farm laborers, who are usually younger, less educated, white, Hispanic, male, married and more likely to be foreign born. As a group, they are also less likely to have access to proper health care. Because of their intimate contact with produce during harvest, sorting, and packing, infected workers have multiple opportunities to contaminate the food supply. Dr. Gravani listed the following as factors that contribute to outbreaks:

- Lack of adequate water supply;
- Limited hygiene education;
- Poor or no toilet facilities;
- Bare hand contact with produce items;
- Lack of food contact surface sanitation; and
- Lack of childcare for workers.

Dr. Gravani emphasized the importance of breaking the fecal-oral route of contamination. While most audit checklists address worker health and hygiene, a large portion of surveyed growers do not have worker training for proper hand washing procedures. Training programs must be practical, meaningful, aimed at the appropriate education level of the workers, and conducted by trainers who speak the native language of the employees. In addition, management should be committed to food safety, implementation of training programs, and promoting clear and enforceable rules for food safety and sanitation.

Worker Health and Hygiene Breakout Sessions

Following the afternoon presentations, meeting participants were given the opportunity to attend breakout sessions to further discuss worker health and hygiene issues. The following themes were raised in the sessions:

Regional Considerations

- Growers noted the challenge of enforcing clean clothes every day.
- Gloves are used in picking strawberries, corn, broccoli, and cauliflower.
- Most growers hire foreign-born workers on their farms. These workers are mainly Spanish-speaking, though a few growers had workers who spoke Laotian.

Local Practices

- To overcome personal clothing issues, some producers provide company shirts, non-skid shoes, and/or in-house laundry facilities.
- Much of the worker hygiene issues are already being covered under the GAPs program.
- Total management commitment to food safety is a critical factor, as management is the leadership and primary example to the workers.

⁷ A summary of Dr. Gravani's paper is available online at http://www.producesafetyproject.org/discussion_series.

- Gloves are both a benefit and a concern. Using gloves can protect against cross-contamination, but can also lull workers into thinking the gloves will always prevent contamination.
- Outdoor sinks (with hot water), toilet facilities, first aid kits, and hand sanitizers should be made available to the workers, and management should encourage and enforce their use, and ensure that they are replenished on a regular basis.
- To overcome language barriers, bilingual (usually Spanish and English) educational posters and signs can be helpful. However, sometimes the information must be translated into other languages.
- Management should encourage workers to seek medical attention when they are sick. In addition, removing sick workers from handling produce and assigning them to other tasks can be an effective approach to promoting worker health and food safety.
- Health and hygiene rules should be documented in a handbook, and enforced. Trainings should be documented and required annually.

Standards and Audits

- Include flexibility in the standards to take into account the scale and commodity produced at an operation.
- Current audits vary to some degree, and need to be consolidated.
- Whatever standards apply to domestic producers should also apply to foreign producers who import into the United States.

V. Wildlife and Environmental Concerns

Dr. Jeff Langholz, Associate Professor at the Monterey Institute of International Studies, and Dr. Karen Lowell, Lecturer at the University of California, Santa Cruz, presented on issues related to wildlife based on a case study of California's Central Coast region.⁸ The two helped author the report *Safe and Sustainable: Co-Managing for Food Safety and Ecological Health in California's Central Coast Region*, Dr. Langholz noted a tension existed between food safety and environmental concerns in that growers are being pressured by auditors and inspectors to change on-farm practices in response to food safety concerns, often to the detriment of conservation practices. Such changes include the restriction or elimination of wildlife and their habitat from farm land, removal of non-crop vegetation and removal of water bodies. Specific practices noted include the removal of wetlands and riparian buffers, which leads to a reduction in water quality, and loss of important wildlife movement corridors.

In the paper, the authors reviewed studies on how wildlife impacted food safety. The contamination processes are poorly understood and it is an area of active research. The Centers for Disease Control and Prevention (CDC) names five "animals of significant risk": cattle, sheep, goats, pigs, and deer. The Leafy Green Marketing Agreement, based on the CDC findings, identifies only deer and feral pigs as wildlife of concern. Private standards required by retailers, however, often list many more wildlife species with questionable scientific basis.

Dr. Langholz suggested the idea of "co-management," in which food safety and environmental concerns are both addressed. Co-management begins with the assumption that farmers want to

⁸ A summary of Dr. Lowell and Dr. Langholz's paper is available online at http://www.producesafetyproject.org/discussion_series.

produce safe food and be good land stewards, and that both can be achieved in an economically viable fashion. However, according to Dr. Langholz, a number of obstacles exist:

- Numerous and divergent private food safety standards are leading to inconsistent interpretation and application, contributing to a food safety “arms race,” and are developed with a lack of transparency and an unclear scientific basis;
- Mounting liability and litigation risk;
- The potential unintended consequences of national food safety standards, that may not necessarily support a co-management approach;
- An industry movement towards value-added products which are connected with food borne illness outbreaks, and cause a backlash against farmers; and
- A lack of scientific data about how to most effectively minimize risk.

A short question and answer session followed the presentation. Dr. Langholz and Dr. Lowell made the following points in response to participants’ questions:

- To some degree, the Migratory Bird Treaty Act addresses habitat conservation for migratory birds.
- Domestic animals are also of concern.
- The current Senate and House bills on food safety contain clauses about the importance of protecting wildlife and watersheds.

Wildlife and Environmental Concerns Breakout Sessions

Following the afternoon presentations, meeting participants were given the opportunity to attend breakout sessions to further discuss wildlife issues. The following themes were raised in the sessions:

Regional Considerations

- Growers reported problems with a wide variety of animals, including deer, groundhogs, rats, birds, and wild geese. The issues growers have with wildlife are mainly due to economic reasons/crop loss rather than for food safety concerns.
- Due to proximity of residential homes near farms, growers reported problems with domesticated dogs in their production fields. Neighbors also attract wildlife by feeding animals and cultivating vegetation that is wildlife habitat.
- Some participants suggested that food safety risks are higher in areas with confined animal feedlot operations as compared with having some wildlife near and in fields.
- The risk from wildlife will probably vary across the country, depending on a number of additional factors, such as heat, humidity, rain, etc.

Local Practices

- Growers are already working to control wildlife on their farms in order to protect the crops. The economic cost associated with animals destroying crops is a more immediate concern than any food safety risks from wildlife.
- Several growers report using dogs to deter wildlife movement into orchards and crop areas and were dismayed that this management tool might be unavailable if dogs are perceived to present food safety risk and are excluded from crop areas.
- Some growers do not view wildlife as a food safety concern and question the validity of spending resources to solve a problem that may not be scientifically supported or substantial.

- Methods that work on one farm to deter wildlife (e.g., fences, dogs and cats, baiting, noise cannons, repellent, holographic scare tape, lasers, rubberized coyotes, attractants, crop placement) may not work on another farm.
- It is impossible, and possibly detrimental, to completely eliminate wildlife. What is the acceptable level of risk?
- Some wildlife is beneficial. For example, birds of prey, coyotes, and foxes control populations of other animals such as small rodents and deer.
- Growers are very concerned that they are doing everything they can do to keep wildlife out of fields and it is impossible to exclude everything; so if there are regulations that stipulate complete exclusion, they fear they cannot meet that standard.

Standards and Audits

- Some of the requirements presented for wildlife management are neither realistic nor credible.
- The definitions for “monitoring” for wildlife and “measures” to control wildlife need to be clearly defined and realistic. Documentation requirements should be doable.
- There is a need for one standard for wildlife regulations, but the standard should be flexible enough to take into account issues specific to a region, crop, farming method, and scale.
- There should be one unified audit.

Research and Education Needs

- Currently, growers in the region are not being asked to manage wildlife for food safety. If the produce safety standard includes wildlife provisions, growers will need to be educated on the issue.
- There is a need for more science on the prevalence of pathogens, how long pathogens survive, and the risk that the pathogens will transfer from wildlife to produce. Researchers also need to identify which wildlife are concerns, if they are carrying pathogens, and the source of the pathogens.

VI. FDA and USDA Question and Answer Session

During the lunch break, Mike Taylor and Rayne Pegg answered questions from the meeting participants. Mr. Taylor acknowledged the huge diversity in the industry and the challenge of developing regulations that are risk-based, particularly in areas where there is scientific uncertainty. Ms. Pegg noted that many of the questions from the participants were the same as those the agencies are grappling with and considering. How should the regulations take into account regional variations? What are the real risks? These questions needed to be addressed.

In response to questions from participants, Mr. Taylor and Ms. Pegg made the following comments:

- The FDA is aware that the regulatory regime for produce will be different than what the agency has done in the past. It is impossible and not desirable for FDA inspectors to visit every farm in the country. The proposed regulation will probably involve a mix of activities, including USDA certification audits and state and local engagement. The agency will need community action to help make the regulations successful.
- The FDA is planning to release a series of white papers along with the proposed regulations to lay out the issues and explain the process used to develop the proposal.

- The cost and resources necessary to implement and enforce the standards must still be considered and addressed.
- Congress is considering legislation requiring foreign food imports to meet the same standards as domestic products. This is a critical tool for the FDA and will update the agency's ability to build a food safety system throughout the supply chain.

Individual meeting participants added the following points:

- Any legislation and regulation must be firmly based in sound science, and be applicable nationally and regionally.
- Producers are already taking on costs for audits and inspections. Any additional costs will be burdensome and could cause some farmers to go out of business.
- All producers should be required to adhere to a set of food safety requirements, a consistency which would level the playing field.

VII. Concluding Thoughts

Mr. O'Hara thanked the meeting participants for sharing their experience, expertise, and knowledge. He noted that the meeting was the first in a series to be held around the country. He reminded the group that the FDA has opened a docket to collect public comments, and that people should send in additional thoughts, comments and ideas. The website (<http://www.producesafetyproject.org/>) will also have information on how to stay involved throughout the process.

Betsy Bihn of the National GAPs Program at Cornell University informed the group that there were upcoming in-person training programs and a GAPs Online Produce Safety Course available if producers want to develop a GAPs plan for their farm. More information is available online at <http://www.gaps.cornell.edu/>.

Produce Safety Project Stakeholders' Discussion Series

Co-Sponsored by The Ohio State University

Meeting Summary

*March 11, 2010
Columbus, OH*

Goals and Outcomes

- *Increased understanding of the science underlying enhanced produce safety practices, including:*
 - *What we know, and*
 - *What we do not know*
- *Increased understanding of practices that are, or could be, contributing to enhanced produce safety.*
- *Identification and discussion of any regional practice considerations important for enhancing produce safety.*

I. Welcome and Introductions

Jim O'Hara, Director of the Produce Safety Project (PSP), welcomed the meeting participants and thanked them for attending. PSP is a research and advocacy organization that supports the development by the Food and Drug Administration (FDA) of a mandatory and enforceable produce safety standard for the growing, harvesting and packing of fresh fruits and vegetables. To that end, PSP commissioned reports on four issues it believes the FDA should consider as it moves through the rule development process. These four issues are (i) irrigation and foliar water quality, (ii) compost, (iii) worker health and hygiene, and (iv) wildlife and environmental concerns. Because it realized that the FDA and the U.S. Department of Agriculture (USDA) would benefit by hearing from stakeholders about the practices already being implemented on farms and the concerns and questions growers have about the standards to be established, PSP decided to hold a series of stakeholder discussion meetings, of which Columbus is the second. The four scientific presentations are not meant to be the last word on these issues, but rather starting points for the conversations of the day. Mr. O'Hara said that there will be a record of each of the meetings, and that comments will be compiled and submitted to the FDA for its consideration. He stressed how important it is that the FDA gets the produce safety rule right, and how input from the meeting participants will help ensure they do. Mr. O'Hara informed the group that the FDA has announced it will propose a produce safety rule by the end of the year. He noted that senior officials from both the FDA and the USDA are attending the meeting and listening to everyone's comments. Mr. O'Hara added that the FDA has opened a docket to receive comments prior to developing the rule,⁹ and encouraged participants to submit additional comments to FDA through this mechanism.

⁹ The PSP has prepared a handout outlining how to submit public comment to the docket, available online at http://www.producesafetyproject.org/admin/assets/files/HowtoGuide_theFDAOpenCommentPeriodv10.pdf

Jeff LeJeune, Associate Professor in the Food Animal Research Program at the Ohio State University, expressed his excitement at the high turnout for the meeting, and at the idea of moving forward on a scientific and risk-based approach to produce safety. He noted that there should be stakeholder involvement in all the stages of the risk-based approach: the assessment of the risk, the assessment of how to manage that risk, and the communication of the risk. He encouraged the meeting attendees to actively participate in the meeting and share their thoughts and experiences.

Dr. Nega Beru, the Director of the Office of Food Safety in the Center for Food Safety and Applied Nutrition at FDA, informed the group that the FDA intends for the planned produce safety regulation to be science-based with enforceable standards. Dr. Beru recounted the history of food safety within the FDA. The Good Agricultural Practices (GAPs) program was started by a presidential initiative in 1997 after the realization that the number of illnesses related to the consumption of fresh produce was rising. The FDA and the USDA worked with industry to develop the GAPs guidance documents; the agencies held meetings around the country to solicit comments. The FDA also developed commodity-specific guidance for produce most associated with outbreaks. Dr. Beru acknowledged the complexities involved in developing a produce safety rule, and the diversity of the industry. He noted that meetings such as this are very important for the agency to hear the opinions, thoughts, and experiences of those within the produce industry. The FDA and the USDA have held listening sessions around the country and several officials attended the first Stakeholders' Discussion Series meeting in Rochester, NY. From those meetings, the agencies have heard a number of themes: that the diversity of crops should be taken into account, the cost of the any measures should not outweigh the benefits, and the regulation should be scale-appropriate. Dr. Beru added that the FDA will work with the USDA throughout the rule-making process and implementation. Lastly, he encouraged the meeting participants to submit comments to the docket.

Ann Wright, the Deputy Under Secretary for Marketing and Regulatory Programs at USDA, noted that food safety is a critical issue for producers of all sizes as it influences both business and the direction of agriculture in general. While Congress gave the FDA regulatory authority over produce, the USDA also has been heavily involved in this area with the development of voluntary marketing agreements through the Agricultural Marketing Service. The USDA is currently considering developing a national Leafy Greens Marketing Agreement and the comments it receives during that process will be forwarded to the FDA. Ms. Wright noted that the produce industry is changing and the USDA wants to encourage and support the new opportunities and initiatives for growers. The USDA will work with the FDA throughout the rulemaking process.

Bob Jones, of The Chef's Garden in Huron, OH, observed that in the day's conversation, participants will find some common ground – the importance of good food safety. Food safety is important to consumers and to growers – not just for business reasons but because it is the right thing to do. Mr. Jones emphasized that the growers in the room have a tremendous opportunity to have their voices heard by federal regulators who will be developing and implementing the produce safety rule. He advised the group to discuss what practices are already occurring on the farm, what practices do not work or are not practical, and experiences that are unique to Ohio.

Abby Dilley, the meeting facilitator, reviewed the meeting agenda, materials, and expectations. She expressed the hope that participants will come away with an increased understanding of the science, good practices to enhance produce safety, and the variability in the produce sector, including whether

and what unique features in the Ohio region should be taken into consideration in developing the proposed produce safety rule.

The discussion topics for the meeting consisted of the four issue areas identified as possible concerns for food safety: compost, irrigation and foliar contact water quality, worker health and hygiene, and wildlife and environmental concerns. The authors or their designees of the reports on these topics presented an overview of each issue area, and the meeting participants were given the opportunity to attend breakout sessions to discuss the issues in more depth. The summaries of the presentations and the breakout sessions are below.

II. Worker Health and Hygiene

Betsy Bihn, program coordinator for the National Good Agricultural Practices (GAPs) Program at Cornell University, presented on issues related to worker health and hygiene.¹⁰ She noted that implementing worker health and hygiene measures is one of the easiest things to do on the farm and with the greatest food safety effect. Just over one million farm workers are hired in the United States. Ms. Bihn reviewed the demographics of farm laborers, who are usually younger, less educated, white, Hispanic, male, married and more likely to be foreign born. As a group, they also are less likely to have access to proper health care due to economic status, cultural or language barriers, access, or immigration status. Because of their intimate contact with produce during harvest, sorting, and packing, infected workers have multiple opportunities to contaminate the food supply. Ms. Bihn emphasized that any person who works on a farm is a farm worker, including the farmer and family members. She noted that the employees follow the example of the employer.

Ms. Bihn listed the following as factors that contribute to outbreaks:

- Lack of adequate water supply for consumption and handwashing;
- Limited hygiene education;
- Poor or no toilet facilities;
- Bare hand contact with produce items;
- Lack of food contact surface sanitation; and
- Lack of childcare for workers.

While most audit checklists address worker health and hygiene, a large portion of surveyed growers do not have worker training for proper handwashing procedures. Training programs must be practical, meaningful, aimed at the appropriate education level of the workers, and conducted by trainers who speak the native language of the employees. In addition, management should be committed to food safety, implement training programs with clear and enforceable rules for food safety and sanitation, and provide the means for workers to use the training (e.g., soap, first aid kits). Ms. Bihn added that farmers should verify the effectiveness of the training, for example, by tracking soap use.

In the short question and answer session that followed her presentation, Ms. Bihn made the following points:

- A number of programs exist to address health and hygiene further down the food supply chain, including for retailers and consumers.

¹⁰ A summary of the white paper on Worker Health and Hygiene commissioned by the PSP is available online at http://www.producesafetyproject.org/discussion_series.

- Legal cases involving liability for foodborne illness have included comments acknowledging that producing fresh fruits and vegetables is never without risk. However, this recognition does not mean that the grower is exempt from doing due diligence to reduce risk as much as possible at the farm level.
- Some pathogens can adversely affect an individual's health with a very small infectious dose. While ingesting some microorganisms may be a way to build resistance and immunity, growers should not assume it is their job to provide the inoculum through poor sanitation or hand washing procedures on the farm.
- Increasing the food safety protocols in places throughout the food supply chain will help consumers make a more knowledgeable choice about the foods they are buying.
- Growers should work to reduce risk on the farm, even if the risk is low, because of the importance of food safety on health, the industry, and individual farmers' livelihoods.

Worker Health and Hygiene Breakout Sessions

Following the morning presentations, meeting participants were given the opportunity to attend breakout sessions to further discuss worker health and hygiene issues. The following themes came out of the sessions:

Regional Considerations

- There are many small, multi-generational family farms in the region where most, if not all, of the farm workers are family members. Expectations for health and hygiene standards are conveyed through example and leadership.
- Many farms in the region operate using culturally-relevant practices. For example, farmers from the Amish community use horses during planting and harvesting. The region has a sizeable population of Amish or Mennonite growers who have limited or no mechanization on their farms.
- Due to the prevalence of integrated plant-and-animal farms in the region, cross-contamination is a real issue. The growers try to implement practices to prevent contamination, but workers do work with both plants and animals. Because of the frequent movement between areas, any standards put into place to prevent contamination could become very costly in terms of time (e.g., decontamination whenever a worker leaves the animal operation and moves to the produce field).

Local Practices

- Some measures may not be feasible in all conditions. Gloves, for example, are not practical when handling melons because they would wear through very quickly, or for picking fragile fruit, such as strawberries and blueberries.
- Growers are concerned with how to know when a worker is sick. Migrant workers will work if at all possible and may not inform their supervisor if they feel ill.
- Alternate jobs for sick workers may not be possible.
- Time is the major limiting factor for implementing and enforcing worker health and hygiene practices.
- The farmer needs to be aware of the issues related to worker health and hygiene so that he or she can act on them. There are good programs, such as the extension network, that help educate growers, particularly small and medium growers.
- It is the farmer's responsibility to provide the supplies necessary for worker hygiene, such as soap and water (for washing and drinking), toilet paper, and towels. Some farmers also provide a laundry facility, as well as apparel – shirts and non-skid shoes.

- Many of the practices for worker health and hygiene are common sense. The standards that come out of the regulation should be based in common sense.

Standards and Audits

- Audits are expensive and burdensome, particularly for small farms. However, the growers acknowledge the necessity of audits to ensure compliance with standards and regulations, and the importance of documentation.
- Many of the audits are similar. There should be a universal audit to reduce “audit fatigue” on the part of the growers. Audits are very time intensive, and time is a very important limitation for small growers.
- No grower should be exempt from the regulation and meeting the standards.
- The regulation should also be scalable to the size of the operation.
- Growers acknowledged the importance of food safety, and the standards and regulations should be grounded in common sense as well as science.
- Documentation would ensure that the regulations and standards are being implemented. However, the degree of documentation required should be scale appropriate so as not to be an overly burdensome amount of paperwork.

Research and Education Needs

- Attention should also be given to consumer education on how to safely handle and wash produce.
- It can be hard for smaller operations to implement trainings, so they rely on third party training materials supplied by the extension service, growers associations, and others.

III. Wildlife and Environmental Concerns

Dr. Jeff Langholz, Associate Professor at the Monterey Institute of International Studies, presented on issues related to wildlife based on a case study from the Central Coast region of California and presented in the paper *Co-Managing for Food Safety and Ecological Health in California’s Central Coast Region*.¹¹ Dr. Langholz noted a tension existed between food safety and environmental concerns in that growers are being pressured by auditors and inspectors to change on-farm practices in response to food safety concerns, often to the detriment of conservation practices. Such changes include the restriction or elimination of wildlife and their habitat from farm land, removal of non-crop vegetation and removal of water bodies. Specific practices noted include the removal of wetlands and riparian buffers, which leads to a reduction in water quality, and loss of important wildlife movement corridors.

In the paper, the authors reviewed studies on how wildlife impact food safety. The contamination processes are poorly understood and it is an area of active research. The Centers for Disease Control and Prevention (CDC) names five “animals of significant risk”: cattle, sheep, goats, pigs, and deer. The Leafy Green Marketing Agreement, based on the CDC findings, identifies only deer and feral pigs as wildlife of concern. Private standards required by buyers and retailers, however, often list many more wildlife species with questionable scientific basis for doing so.

¹¹ A summary of the paper *Co-Managing for Food Safety and Ecological Concerns in California’s Central Coast Region* is available online at http://www.producesafetyproject.org/discussion_series.

Dr. Langholz put forward the idea of “co-management” in which food safety and environmental concerns are both addressed. This concept emerged out of the discussions with and among growers, conservationists, and other interested parties involved in the study conducted in the central valley of California – a prime agricultural production area. Co-management begins with the assumption that farmers want to produce safe food and be good land stewards, and that both can be achieved in an economically viable fashion. However, according to Dr. Langholz, a number of obstacles exist, including:

- The numerous private food safety standards that (i) lead to inconsistent interpretation and application, (ii) contribute to a food safety “arms race,” (iii) are developed with a lack of transparency and (iv) are based on an unclear scientific basis;
- Mounting liability and litigation risk;
- The potential effects of national food safety standards, which may not necessarily support a co-management approach;
- An industry movement towards value-added products which are connected with foodborne illness outbreaks, and cause a backlash on the farmer; and
- A lack of scientific data on how to minimize risk.

In the short question and answer session that followed his presentation, Dr. Langholz made the following points:

- The process of contamination from wildlife is still poorly understood. In the case of the 2006 spinach outbreak, for example, the pathogen was found in water, cattle, and feral pigs close to the field where the particular crop was grown.
- Wildlife may be just one variable in the contamination pathway and act in conjunction with other variables such as contaminated water.
- It is very likely that cattle play a significant role in the contamination pathway. For example, the wildlife could drink water contaminated by the cattle and then carry the pathogen into the field.

Wildlife and Environmental Concerns Breakout Sessions

Following the morning presentations, meeting participants were given the opportunity to attend breakout sessions to further discuss wildlife issues. The following themes came out of the sessions:

Regional Considerations

- Growers in the region have a wide variety of interaction with wildlife, and a variety of responses. Deer and resident Canada geese are problems in Ohio, and are a particular concern for crop damage and loss. Many farmers already use barriers and other practices to decrease wildlife in their fields. Other growers encourage wildlife around their fields as they want to encourage an overall healthy ecosystem – and see wildlife as an essential part of that ecosystem.
- There is a feral pig problem in southeast Ohio that originated from escaped hunting pigs. The population is breeding and expanding its range.
- The growers in attendance are currently not under pressure from processors to control wildlife. This may be different for large, GAP-certified producers.
- There are a lot of small-scale farms in Ohio. Mandating buffers are not practical because of the small size of the field.

Local Practices

- Many farmers already try to control wildlife and exclude them from the fields for economic reasons, through such practices as fencing, netting, odor deterrents, and noise guns. These attempts are usually not one hundred percent effective. Other growers try to encourage wildlife to concentrate in slightly removed portions of their fields by planting with especially attractive plants, thereby minimizing broader foraging.
- Hunting is a means of controlling wildlife. With regard to deer, perhaps the hunting regulations should be expanded to encourage does to be taken, and for more animals to be killed overall.
- It is not feasible or practical to try to keep all wildlife out of the fields. Some farming practices even welcome wildlife, and several organic farmers were concerned about upsetting ecological systems by removing wildlife from their farms.
- Growers generally are not picking produce that has feces on it and are establishing a buffer zone around this produce.

Standards and Audits

- The standard should be risk-based and science-based.
- The regulations should be practical, feasible and affordable. They should not be a barrier to entry for new farmers, nor limit access to markets for the grower.
- To account for the differences in commodities, types of operations, and harvesting method, guidance may be more appropriate than a process-based standard for wildlife.
- The standards should take into account different commodities, and may be less stringent for commodities grown off the ground, those that are cooked before consumption, or not consumed at all (e.g., ornamental pumpkins).
- Some growers suggested that unconventional farms should be able to opt-out of the standard, while other growers believe all growers should be held to the same standard.

Research and Education Needs

- Methods to control wildlife are costly for farmers to implement. Before regulation, more research needs to be done on the real risks from wildlife, and the impact of wildlife in the fields. There needs to be scientific evidence that wildlife are a problem, and this needs to be accepted by the growers who have to implement the regulation.

IV. Composting Issues

Marilyn Erickson, of the University of Georgia, presented an overview of composting issues and key scientific information, as laid out in the paper *Composting Criteria for Animal Manure*.¹² Dr. Erickson noted that different manures have different compositions, which affect the composting process. She explained that incomplete treatment of manure can contaminate food. The prevalence of a type of manure varies by region, and the prevalence of pathogens in the manure also varies greatly.

Dr. Erickson listed three types of composting systems: aerated, windrow systems, and in-vessels systems. Pathogens can be inactivated in compost during three stages: mixing the compost, raising the temperature, and curing. Dr. Erickson then reviewed some of the factors influencing pathogen

¹² A summary of the white paper commissioned by the PSP on compost issues is available online at http://www.producesafetyproject.org/discussion_series.

inactivation, which can vary by type of manure. Dr. Erickson explained that even if compost tests free of pathogens, that does not mean that there are pathogens in the manure prior to the composting process.

Dr. Erickson noted that there are no universal standards for composting to eliminate harmful pathogens, such as *E. coli* and *Salmonella*. Manure is primarily regulated at the state and local level, and there is no federal oversight. These regulations vary greatly in scope and complexity. While many jurisdictions use EPA guidelines 40CFR Part 503 for end-product and process criteria, there are still variations in the current non-uniform standards with regard to time, temperature, finished product testing, and required frequency of facility monitoring.

In *Composting Criteria for Animal Manure*, the researchers made the following recommendations:

- Require insulating covers on all types of compost piles.
- Include a minimum curing period to ensure the completion of pathogen inactivation.
- Include procedures to control risk, i.e., regular verification of equipment accuracy, and requiring detailed weather condition reporting.
- Require compost operations to have standard operating procedures, a quality assurance plan and a Hazard Analysis Critical Control Point (HACCP) program.

In the short question and answer session that followed her presentation, Dr. Erickson made the following points:

- Recognizing the different types of operations in the Ohio area, and acknowledging the different levels of mechanization, compost piles do not need to be turned to be effective. Static piles with a cover layer to hold in heat should be sufficient. Another option is to mix in chicken manure to raise the ammonia levels.
- There may be less risk associated with composting kitchen scraps than with composting manure. Since this raw material would have been fed to humans, it should not contain any pathogens. Dr. Trevor Suslow added that raw kitchen scraps may attract animals, which may be pathogen vectors themselves.

Composting Issues Breakout Sessions

Following the afternoon presentations, meeting participants were given the opportunity to attend breakout sessions to further discuss composting issues. The following themes came out of the sessions:

Regional Considerations

- Ohio is a very manure-rich region of the country. Many farmers in the area rely on manure and compost and see it as integral to their farms.
- The region has a sizeable population of Amish and Mennonite growers who have limited or no mechanization on their farms.
- The region has a number of integrated plant-animal farms, and those growers wanted to continue to have both produce and animals on their land.

Local Practices

- Farmers from Amish and Mennonite communities also rely on animals in their operations and feel they cannot survive without them. They are very concerned that the proposed rule should not adversely affect their cultural and farming practices, such as using horses in the fields or laying down raw manure.

- For farmers from communities that limit the use of mechanization, aspects of composting that require heavy machinery (e.g., mixing) would be impossible.
- Many traditional practices employed by farmers, such as the time from application to planting or harvest or building structures over manure piles, may be effective in inactivating pathogens in raw manure and alleviating food safety risks. These practices should be identified and information about them given to the farming community.
- Currently, some small growers apply compost as if it were raw manure because the regulations and requirements are easier to follow for raw manure.
- Farmers would be willing to have longer periods between spreading and planting so long as the use of raw manure would still be permitted in the regulations.

Standards and Audits

- One uniform standard is unlikely to be implementable, given the variability in scale of operation, type of operation, mechanization on the farm, and commodities grown. Some meeting participants suggested different levels of compost certification given the size of the farm.

Research and Education Needs

- Growers would like information on best practices for compost and manure, particularly on the different risks given the different types of manure.
- More research needs to be done to identify and fill in knowledge gaps regarding pathogen occurrence and survival in compost, and uptake by the plant. New information gained from research should be disseminated to the farm community.

V. Irrigation and Foliar Contact Water Quality

Dr. Trevor Suslow, the Extension Research Specialist at the University of California, Davis, Department of Plant Sciences, presented an overview of issues related to irrigation and foliar contact water, as laid out in *Standards for Irrigation and Foliar Contact Water*.¹³ Produce and niche-crops use a variety of types of irrigation from diverse water sources. About seventy percent of U.S. commercial farmland is irrigated and because of issues related to nature, value, and perishability, much of the produce crop in this country are under some form of managed irrigation. Due to the intimate contact with the edible portion of the crop, the quality of the water is very important for food safety considerations. Water quality becomes more important the closer to harvest. There is still much unknown about how water quality affects food safety based on region, crop, or management practice. Dr. Suslow reviewed some of the ways irrigation and foliar contact water may become contaminated. For example, groundwater can be contaminated by surface water events, and fecal contaminants and pathogens have been found in irrigation water.

Dr. Suslow then reviewed the state of the science. He highlighted two main concepts: the risk potential for water is very high and the risk exposure is highly variable. Pathogens are known to survive in water and sediments for long periods of time. Dr. Suslow identified a knowledge gap for water quality because of a lack of uniformity in testing methods and standards, and a lack of a national database for irrigation water quality. Also, current water quality standards are inadequate, poorly defining the relationship between indicators, pathogens, and risk. Dr. Suslow noted that

¹³ A summary of the white paper commissioned by the PSP on issues related to irrigation and foliar water quality is available online at http://www.producesafetyproject.org/discussion_series.

growers need to be able to differentiate between high- and low-risk irrigation water, and that auditors need to recognize the variable risk based on a number of factors, including the water, the crop, the location, and the post-harvest handling.

Dr. Suslow noted that many regional GAPs and commodity-specific guidelines have adopted the EPA recreational water quality standards for irrigation water. He expressed concern about this trend because the EPA criteria were not intended to apply to risks associated with irrigation of edible crops and do not take into account the die-off of pathogens post-irrigation. He also noted that the FDA commodity-specific guidance recognizes that there are currently no clear standards, and growers are responsible for using water of “appropriate quality.”

Dr. Suslow ended his presentation with the following list of recommendations:

- Implement sanitary water surveys on the farm;
- Broaden the characterization of irrigation water sources before including the current GAPs standard;
- Commit to two seasons of frequent sampling;
- Find appropriations to assist small farms; and
- Adjust the water quality standards as justified by the data and models.

In the short question and answer session that followed his presentation, Dr. Suslow made the following points:

- Information is available in various GAPs on the appropriate distance between a potential contamination source, such as a compost pile, and a body of water.
- Produce safety is not just a grower issue; it’s an issue that has to be addressed on the landscape level and the regional level. Many of the solutions available are cost-prohibitive for the individual farmer or rancher to implement. The problem has to be addressed across the entire system.

Irrigation and Foliar Contact Water Quality Breakout Sessions

Following the afternoon presentations, meeting participants were given the opportunity to attend breakout sessions to further discuss irrigation water issues. The following themes came out of the sessions:

Regional Considerations

- Many of the farmers use a mix of water sources, including well, surface (river and pond), and city-sourced water to some degree in their operations. Use of surface water increases during periods of low precipitation.

Local Practices

- Generally, growers test water only when required by an audit. If testing is required, the growers usually move to potable water testing, which may not be the appropriate standard.
- Farmers have a lot of common sense, and can be trusted to use common-sense measures on their farm to determine safe water sources.
- Testing methods need to be affordable and accurate. The test needs to be conducted quickly and results available immediately so that the results can be linked back to on-farm practices. In order to reduce costs, perhaps watersheds can be tested, growers using

that watershed could pool resources to cover the costs of the tests, and the results would be relevant for those who use the watershed for their crops.

- It is extremely important that the final wash water be tested.

Standards and Audits

- Farmers that sell their produce to large chains have to undergo different audits with varying standards, all of which are time-consuming, burdensome, and expensive.
- The regulation needs to be science- and risk-based, practical, and affordable for farmers of all sizes to implement.
- Standard protocols need to be developed, such as where within the pond should samples be drawn, how frequently, and what do the results mean?

Research and Education Needs

- Research should be dedicated to finding options for appropriate and affordable actions to be taken when test results merit some action – such as treatment or use of different water sources.
- In developing the regulations for water, the FDA needs to consider different variables: for example, the water sources, how the water is used or applied, where the water is applied, the crop, and the many issues that can affect water quality. In order to provide the necessary flexibility, a tiering system may be appropriate.
- More research is needed, especially regarding pathogen survival in different sources of water. It is important to identify the particular problem with water so that it can be addressed directly.
- Farmers should be educated on the issues surrounding water quality and what potential sources of impacts to that water quality might be. Knowing more about water quality and what to look for is an overall benefit to farmers.

VI. FDA and USDA Question and Answer Session

Bob Jones opened the question and answer session by expressing the hope that the meeting participants found the day helpful and educational. He reminded the group of the open docket, which will help inform the FDA in writing the produce safety rule. He emphasized that the rule will be written; therefore the most constructive dialogue will be how the government can achieve its food safety objectives in a way that is manageable for farms of every size—from the small family farm to the large corporate farm—and sustainable for the industry as a whole.

Jim Gorny, Senior Advisor for Produce Safety, FDA Center for Food Safety and Applied Nutrition, reiterated some of the messages he had heard over the course of the meeting: (i) food safety is the responsibility of everyone in the food continuum, and every person needs to be aware of that; (ii) growers are willing to implement food safety practices if they are given guidance and instruction on what specific actions to take; (iii) take into account distribution channels and scale of operations; (iv) take into account region-specific issues and differences; and (v) more research is needed, particularly on the real risk from pathogens on the farm. Dr. Gorny added that the FDA appreciates not just the quantity of comment, but the quality of comment from the farming community. The FDA hopes this rule will facilitate commerce and boost consumer confidence.

Kathleen Staley, a Food Safety Officer for the USDA Agricultural Marketing Service (AMS) Fruit and Vegetable Programs, emphasized that the USDA and the FDA want feedback and comments

from the group. She listed some of the themes she heard during the meeting: (i) the importance of the small family farm in America; (ii) the rule has to be scalable; (iii) more research needs to be done; and (iv) grower education needs to be a large component of the rule and its implementation.

Sharon Natanblut, Senior Advisor for Strategic Communications, FDA food program, added that the FDA and the USDA understand the growers' concerns. They want to develop a rule that is doable for the farmers, with the understanding that if the rule is not implementable, then the United States would lose farmers. She emphasized that it was in everyone's best interest that food be safe, the public believes it safe, and has confidence in the food supply.

The meeting participants were then given the opportunity to ask questions of the USDA and the FDA representatives. In response to questions from participants, Dr. Gorny, Ms. Staley, and Ms. Natanblut made the following comments:

- A level playing field between imported and domestic produce is critical. The FDA has the responsibility to ensure the safety of America's food supply, wherever the origin. Imports will be taken into account in the proposed rule. There is current legislation pending in Congress that would give the FDA more authority over imports.
- Both the FDA and the USDA do consumer education. The FDA will be attending a food safety education conference in Atlanta towards the end of March where it will partner with different organizations to discuss this issue. Consumer education is vital to ensure the safety of the food supply chain, from "farm to fork." Farmers could play an important part of consumer education, as the consumers place great trust in them.
- The USDA is trying to increase the amount of fresh produce entering the schools; there is an educational component inherent in that. The USDA Food & Nutrition Service is also working to educate school buyers and cafeteria workers on how to properly handle food.

Individual meeting participants also made the following points:

- Imports should be subject to third-party inspections, just like domestic produce.
- Mandatory point-of-origin labeling would allow consumers to make an informed choice over where their food comes from.
- The USDA/USDA Animal Plant Health and Inspection Service (APHIS) works very closely with foreign agencies to address invasive species. The FDA could work with the APHIS to determine how to get foreign producers to meet the requirements.

In response to a participant's question, Dr. Gorny informed the group that the FDA would welcome comments on how the rule should take into account new information.

VII. Concluding Thoughts

Mr. O'Hara thanked the meeting participants for the commitment of their time, and expressed the hope that the meeting was valuable to them. The comments that come from the meeting will be collected into a summary and formally submitted to the FDA open docket. Recordings of each of the Stakeholders' Discussion Series meetings will be posted onto the PSP website (<http://www.producesafetyproject.org/>).

**Produce Safety Project
Stakeholders' Discussion Series**

Co-Sponsored by the Georgia Fruit and Vegetable Growers Association

Meeting Summary

***March 25, 2010
Tifton, GA***

Goals and Outcomes

- *Increased understanding of the science underlying enhanced produce safety practices, including:*
 - *What we know, and*
 - *What we do not know*
- *Increased understanding of practices that are, or could be, contributing to enhanced produce safety.*
- *Identification and discussion of any regional practice considerations important for enhancing produce safety.*

I. Welcome and Introductions

Jim O'Hara, Director of the Produce Safety Project (PSP), welcomed the meeting participants and thanked them for attending. He acknowledged that the growers attending the meeting are already doing a lot for food safety and he invited them to share their experiences.

PSP is a research and advocacy organization based at Georgetown University that supports the Food and Drug Administration (FDA) developing a mandatory and enforceable produce safety standard for the growing, harvesting and packing of fresh fruits and vegetables. To that end, PSP commissioned reports on four issues it believes the FDA should consider as it moves through the rule development process. These four issues are: (i) irrigation and foliar water quality, (ii) compost, (iii) worker health and hygiene, and (iv) wildlife and environmental concerns. In order for the standard to both protect public health and makes sense for the growers, PSP realized that the FDA and the United States Department of Agriculture (USDA) would benefit by hearing from stakeholders about the practices already being implemented on farms and the concerns and questions growers have about the standard. The four scientific presentations are not meant to be the last word on these issues, but rather starting points for the conversations of the day. The meeting in Tifton is the third in the Stakeholders' Discussion Series.

Mr. O'Hara said that there will be a record of each of the meetings, and that comments will be compiled and submitted to the FDA for its consideration. Senior officials from both the FDA and the

USDA are attending the meeting and listening to everyone's comments. Mr. O'Hara added that the FDA has opened a docket to receive comments prior to developing the rule.¹⁴

Dr. Mike Doyle, Regents Professor of Food Microbiology and Director of the Center for Food Safety at the University of Georgia and author of *Composting Criteria for Animal Manure*, expressed his pleasure in helping host the meeting and highlighted the importance of producing the safest food possible. Dr. Doyle acknowledged the challenges facing the food industry as a whole, including an increasingly effective surveillance system to detect outbreaks and the identification of new types of foods as vehicles of foodborne outbreaks, both of which lead to greater consumer awareness and concern. Dr. Doyle also suggested that despite these challenges, there are new opportunities for the industry as the government implements initiatives to increase the consumption of fresh fruits and vegetables in the United States. Dr. Doyle noted, however, that these initiatives are targeting children and the elderly, populations which are also the most sensitive to pathogens – it takes less pathogen exposure to make them sick and the illness will likely be more severe. He encouraged the meeting attendees to share with FDA their experiences and the practices currently being employed on the farm, so that the agency can use that information as it moves forward with rule development.

Mr. Jeff Farrar, Associate Commissioner for Food Protection in the FDA's Office of Foods, told participants that he was at the meeting to listen. He explained that food and food safety are a priority for the Obama Administration, and that both the FDA and the producers share the goals of keeping consumers healthy and food safe and nutritious. Mr. Farrar provided background about FDA, explaining that the agency works with local and state governments and associations when there is a foodborne illness outbreak. He explained that FDA wants to develop and implement realistic, common sense measures to ensure produce safety. He acknowledged the diversity of the produce industry – in geography, commodities, size of operations and practices such as irrigation and fertilization – and the complexity involved in attempting to regulate it in a risk- and science-based way. Mr. Farrar noted that the rule has to be risk-based and that the FDA has to take the risk profile of commodities that have previously been implicated in outbreaks and that have the potential to expose people on a large scale into account. The FDA also understands there are gaps in the scientific knowledge, which makes rulemaking more difficult. The agency has opened a docket to collect information to try and fill some of those knowledge gaps and to solicit comments from growers on the regulation. Mr. Farrar highlighted the fact that, unlike rulemaking in the past where FDA has written a proposed rule and put it out for comment, the agency is actively gathering input prior to writing the rule. In addition to listening sessions across the country, FDA is making a concerted effort to go out in the field and hear from the experts, the farmers. Mr. Farrar shared the hope that in the end, the regulation will be workable, based on common sense, and improve food safety.

Ms. Leanne Skelton, Chief of the Agricultural Marketing Services (AMS) Fresh Products Branch at the USDA, is currently on detail with the FDA to help develop the new safety regulations for produce. Ms. Skelton explained that both the FDA and USDA want to work together in a transparent manner to develop this rule. She explained that while FDA and USDA have different missions, USDA shares FDA's goal of improving food safety. USDA helps farmers market their produce and wants to do as much as possible to help farmers demonstrate they are minimizing food safety risks. Ms. Skelton shared that the USDA has proposed a national Leafy Greens Marketing Agreement

¹⁵ PSP has prepared a handout outlining how to submit public comment to the docket, available online at http://www.producesafetyproject.org/admin/assets/files/HowtoGuide_theFDAOpenCommentPeriodv10.pdf

similar to the California and Arizona agreements and is currently reviewing comments and testimony. She also informed the group that USDA has grant money available to land grant institutions and state departments of agriculture for research related to food safety issues. She encouraged meeting participants to submit comments to FDA's open docket.

Ms. Beth Bland, Director of Education for the Georgia Fruit and Vegetable Growers Association, noted that the FDA is for the first time writing mandatory, enforceable food safety regulation that will apply to producers of all sizes. She emphasized the fact that FDA has been talking to growers and having a conversation prior to writing the regulation. Ms. Bland informed the group that her association's board of directors has participated in the initial discussions about the regulation. She reminded participants that FDA has already decided to write this regulation, and the growers now have the opportunity to provide input to ensure the regulation makes sense.

Ms. Abby Dilley, the meeting facilitator, reviewed the meeting agenda, materials, and expectations. She expressed the hope that participants will come away with an increased understanding of the science, good practices to enhance produce safety, and the variability in the produce sector.

The discussion topics for the meeting consisted of the four issue areas identified as possible concerns for food safety: compost, irrigation and foliar contact water quality, worker health and hygiene, and wildlife and environmental concerns. The authors of each of the reports on these topics presented an overview of each issue area, and the meeting participants were given the opportunity to attend breakout sessions to discuss the issues in more depth. The summaries of the presentations and the breakout sessions are below.

II. Composting Issues

Dr. Doyle presented an overview of composting issues and key scientific information, as laid out in the paper *Composting Criteria for Animal Manure*.¹⁵ Dr. Doyle explained that incomplete treatment of manure can contaminate food. He listed three types of composting systems: aerated, windrow systems, and in-vessels systems. Pathogens can be inactivated in compost during three stages: mixing the compost, raising the temperature, and curing. Dr. Doyle then reviewed some of the factors influencing pathogen inactivation. He explained that the two main factors affecting the inactivation of pathogens are temperature (e.g., raising the heat) and pH. He also said that regional differences - such as weather, ambient temperature, and the type of manure being used - can affect the effectiveness of composting.

Dr. Doyle stated there are no universal standards for composting to eliminate harmful pathogens, such as *E. coli* and *Salmonella*. Manure is primarily regulated at the state and local level; however these regulations vary in scope and complexity. There is no federal oversight. While many jurisdictions use EPA guidelines 40CFR Part 503 for end-product and process criteria, there are still variations in the current non-uniform standards with regard to time, temperature, finished product testing, and required frequency of facility monitoring. The composting rules in existence may also be outdated. Dr. Doyle noted that these rules, for instance, were developed before *E. coli* 0157:H7 was identified as a pathogen of food safety concern.

¹⁶ A summary of the white paper commissioned by the PSP on compost issues is available online at http://www.producesafetyproject.org/discussion_series.

In *Composting Criteria for Animal Manure*, the researchers made the following recommendations:

- Require insulating covers on all types of compost piles.
- Include a minimum curing period to ensure the completion of pathogen inactivation.
- Procedures to control risk, i.e., regular verification of equipment accuracy, and requiring detailed weather condition reporting.
- Require compost operations to have standard operating procedures, quality assurance plan and a Hazard Analysis Critical Control Point (HACCP) program reviewed.

In the short question and answer session that followed his presentation, Dr. Doyle made the following points:

- In a field of leafy greens, uptake of pathogens into the plant through the root system is unlikely, although it has occurred in a laboratory setting. The risk of internalization of pathogens is greater during harvesting and processing.
- In Georgia, farmers are applying poultry litter to crops. Compost is commonly used for growing cotton. In northern Georgia some organic farmers use compost.

Composting Issues Breakout Sessions

Following the morning presentations, meeting participants were given the opportunity to attend breakout sessions to further discuss composting issues. The following themes came out of the sessions:

Regional Considerations

- Growers in the region have access to chicken litter.
- Melons (cantaloupe and watermelon), peaches and pecans, in addition to leafy greens, are a common commodity in the area.

Local Practices

- Litter is not considered compost by most growers, so they think it does not have to be tested for pathogens.
- Farmers expressed concern about using chicken litter on their melons because of uncertain risk.
- Some pecan growers use chicken litter.
- There is no certification process for compost. Growers who bought compost were concerned with the safety of the purchased compost.

Standards and Audits

- The standard should take into account the different risk associated with composting, given different commodities and practices. For example, netted melons (such as cantaloupe) would be more risky than un-netted melons (such as watermelons).
- There needs to be a universal standard for compost – what is the definition of compost?
- Compost is vital for increasing soil productivity. The regulation should not discourage compost use.
- Need to validate that compost meets all the necessary criteria.
- Standard needed for pathogen levels in compost.
- There should be testing/sampling protocol – to validate pathogen level.
- Manure and compost are two different things, and the two words should not be used interchangeably as it causes confusion.
- Current audits require that chicken litter be used on row crops 90 days before harvesting

Research and Education Needs

- More research needs to be done to identify the level of risk from compost given different crops and different types of compost.
- Research needs to identify other ways to inactivate pathogens other than temperature variations. Alternative approaches may be more practical for the farmer.
- The FDA should reach out to poultry farms, which supply the litter used by produce farmers, to try and minimize the pathogen load in the litter.
- All levels of agriculture need to understand the issues surrounding compost. The government needs to reach out to them.
- Growers want guidance for how and when to apply compost.

III. Irrigation and Foliar Contact Water Quality

Dr. Trevor Suslow, the Extension Research Specialist at the University of California, Davis, Department of Plant Sciences, presented an overview of issues related to irrigation and foliar contact water, as laid out in *Standards for Irrigation and Foliar Contact Water*.¹⁶ Produce and niche-crops use a variety of types of irrigation from diverse water sources. About seventy percent of U.S. commercial farmland is irrigated and because of issues related to nature, value, and perishability, much of the produce crop in this country are under some form of managed irrigation.

Dr. Suslow noted that in Georgia, the projections of agricultural water demand in 2009 estimated that 70 percent of the water used in agriculture would be from groundwater; 30 percent from surface water. He added that groundwater is often pumped to on-farm impoundments and becomes surface water.

Dr. Suslow explained that due to the intimate contact with the edible portion of the crop, the quality of the water is very important for food safety considerations. Water quality becomes more important the closer to harvest. There is still much unknown about how water quality affects food safety based on region, crop, or management practice. Dr. Suslow reviewed some of the ways irrigation and foliar contact water may become contaminated. For example, groundwater can be contaminated by surface water events, and fecal contaminants and pathogens have been found in irrigation water.

Dr. Suslow then reviewed the state of the science. He highlighted two main concepts: the risk potential for water is very high and the risk exposure is highly variable. Pathogens are known to survive in water and sediments for long periods of time. Dr. Suslow identified a knowledge gap for water quality because of a lack of uniformity in testing methods and standards, and a lack of a national database for irrigation water quality. Also, current water quality standards are inadequate, poorly defining the relationship between indicators, pathogens, and risk. Dr. Suslow noted that growers need to be able to differentiate between high- and low-risk irrigation water, and that auditors need to recognize the variable risk based on a number of factors, including the water, the crop, the location, and the post-harvest handling.

Dr. Suslow noted that many regional Good Agricultural Practices (GAPs) and commodity-specific guidelines have adopted the EPA recreational water quality standards for irrigation water. He

¹⁷ A summary of the white paper commissioned by the PSP on issues related to irrigation and foliar water quality is available online at http://www.producesafetyproject.org/discussion_series.

expressed concern about this trend because the EPA criteria were not intended to apply to risks associated with irrigation of edible crops and do not take into account the die-off of pathogens post-irrigation. He also noted that the FDA commodity-specific guidance recognizes that there are currently no clear standards, and growers are responsible for using water of “appropriate quality.”

Dr. Suslow ended his presentation with the following list of recommendations:

- Implement sanitary water surveys on the farm;
- Broaden the characterization of irrigation water sources before including the current GAPs standard;
- Commit to two seasons of frequent sampling;
- Find appropriations to assist small farms; and
- Adjust the water quality standards as justified by the data and models.

In the short question and answer session that followed his presentation, Dr. Suslow made the following points:

- Field research has not shown that water-uptake from the soil to the fruit of the plant to be a plausible contamination route. However, pathogens can be transported from the soil systematically in plants, though that tends to be very transitory. Dr. Doyle added that while the chance of uptake into the plant via the root structure was very slim, leafy greens can take in contaminated water once it has been cut.
- The level of risk of contamination from water varies by a number of factors, including the specific crop and nitrogen level in the soil. The standard time interval of waiting two weeks before harvest after using contaminated water is reasonable, but the risk is never zero.
- Taking a composite sample from one pond is a reasonable method for testing water. It is hard to judge the level of risk from irrigation water that originates from multiple locations since the small size of the grab sample (100 mL) is unlikely to contain detectable levels of pathogens. (Dr. Suslow stated that he takes 5L for pathogen sampling.)
- Contamination may occur within the water conveyance and distribution system. The water system is a component of the sanitary survey. When designing a plan for an operation, the distribution system should be considered.
- The other steps of the food supply chain need to have their own food safety plan in place to continue risk management throughout the system.

Irrigation and Foliar Contact Water Quality Breakout Sessions

Following the morning presentations, meeting participants were given the opportunity to attend breakout sessions to further discuss irrigation water issues. The following themes came out of the sessions:

Regional Considerations

- Most growers in southern Georgia get their water from deep wells, some of which are poorly constructed. In northern Georgia and Alabama, the water is mainly from surface water with some well water.
- Some water is municipal water
- In Florida, irrigation water tends to come from surface water. Water used during harvest is from wells.

Local Practices

- Growers test their water quality as often as required by audits. Some also test surface water after a rain.
- Some growers test once a year, before planting; others test twice a year once before and once during growing season.
- Growers feel pressure to test water quality from their buyers.
- Meeting participants were concerned with the time period between sampling and results. By the time a problem is detected, the produce could already be consumed. Or, harvest is delayed too long while waiting for results, and may cause the crop to be lost.
- The cost of the tests is an issue for farmers, particularly smaller ones. Growers reported that a test for generic coliform and *E. coli* is \$25.

Standards and Audits

- FDA should include laboratories in the regulation, standardizing the testing process, testing methods, the reporting process, and lab certification.
- No grower should be exempt from water quality standards, though different categories of growers should have the flexibility to meet the requirements.
- The standard should take into account the varying levels of risk, such as the type of commodity, source of the water, and type of irrigation.
- Testing frequency should vary depending on factors such as type of crop, length of growing season, and irrigation method. Growers need clear guidance on when to test, frequency of testing, where to test, what to test for, and what actions farmers should take if there is a positive result from a water sample.
- There should be guidance for sanitary survey standard operating procedures.
- Growers have audit fatigue and want a universal audit.
- There should be some oversight for the construction of wells.

Research and Education Needs

- More research needs to be done on the risk from contaminated water.
- Fecal coliform is a poor indicator. A better indicator needs to be identified.
- Laboratories should be educated on what standard to test for.

IV. Worker Health and Hygiene

Dr. Marvin Pritts, Chairman of the Department of Horticulture at Cornell University, presented on issues related to worker health and hygiene.¹⁷ He stated that because farm workers have direct contact with fresh produce during harvest, sorting, and packing, worker health and hygiene is vitally important. He noted that infected workers have been linked to foodborne illness outbreaks. Humans can spread these pathogens and contaminate produce. Dr. Pritts explained that to achieve the goal of risk reduction, it was vital for the workers to be healthy and clean, and for their work and living environments to be clean.

Dr. Pritts emphasized that everyone, including growers and their families, who works on a farm in the production of fresh produce, is a farm worker, and should follow health and hygiene standards to reduce risk of contamination.

¹⁷ A summary of the white paper on Worker Health and Hygiene commissioned by the PSP is available online at http://www.producesafetyproject.org/discussion_series.

Just over one million farm workers are hired in the United States. Dr. Pritts reviewed the demographics of farm laborers, who are usually younger, less educated, white, Hispanic, male, married and more likely to be foreign born. As a group, they also are less likely to have access to proper health care due to economic status, cultural or language barriers, access, or immigration status.

Dr. Pritts explained the importance of training, and listed what training programs should include. Training programs must be practical, meaningful, aimed at the appropriate education level of the workers, and conducted by trainers who speak the native language of the employees. In addition, management should be committed to food safety and implement such training programs with clear and enforceable rules for food safety and sanitation, and provide the means for workers to use the training (e.g., soap, first aid kits). Dr. Pritts added that farmers should verify the effectiveness of the training, for example, by tracking soap use.

Dr. Pritts noted that food safety practices are also good business practices. Most audits require worker health and hygiene training to be conducted and documented. Dr. Pritts added the implementing programs related to health and hygiene is a wise investment of resources as it reduces the risk of contamination, values the workers' health, and encourages workers to be actively thinking about their responsibility for food safety.

In response to a participant's question, Dr. Pritts noted that much of what was presented would apply to workers in packing houses too.

Worker Health and Hygiene Breakout Sessions

Following the morning presentations, meeting participants were given the opportunity to attend breakout sessions to further discuss worker health and hygiene issues. The following themes came out of the sessions

Local Practices

- Because there is a high level of illiteracy amongst Hispanic workers, signs are bilingual and pictorial.
- New employees are trained from day one, with follow-up training as needed. Some audits require the workers to sign forms or be tested after the training.
- Observation and leading by example are two critical components of ensuring workers comply with health and hygiene requirements.
- Documentation is important for compliance with audits.
- The responsibility for a given task (e.g., monitoring) should be assigned to a person, such as a supervisor.
- Health and hygiene requirements are a condition of employment. Employees are told they will be sent home if they do not comply.
- Growers check for sick workers by looking at the number of bathroom trips, fatigue, or a runny nose.
- Some growers enhance safety by removing knobs from the doors to the toilet facilities and keeping the sink outside so handwashing can be observed.
- Farmers are using a number of existing programs and materials to implement worker health and hygiene training and education, and believe the FDA could draw from these efforts.

Standards and Audits

- Required use of gloves is not practical for every commodity. Gloves cannot be used for melons because they would wear through too fast. Gloves are not feasible for berries because workers would lose the tactile sense necessary to determine ripeness.
- All producers should be required to meet some minimum level of worker health and hygiene standards.
- The standard has to be risk-based, feasible, practical and affordable for the farmer.
- The standards should be compatible with the National Organic Standards (NOS). Organic growers were concerned that the standard may require using non-organic or chemical products to sanitize or clean work areas, tools, gloves, and other equipment.
- Research should be done to ensure the effectiveness of third-party audits.
- Audits should be standardized and harmonized.
- Growers expect to, and usually do, sell audited produce at a premium.
- Many of the growers agreed that inspectors should do unannounced audits, though other growers were concerned about privacy.
- Certification is very important to farmers, as it increases market access.
- The government should not ignore the rest of the food supply chain, and should implement health and hygiene education from the farm to the consumer.
- Imported produce should be required to adhere to the same standards as domestic products.
- There should be traceability for produce, so that if there is a problem, it can be investigated down the supply chain.
- The FDA needs to figure out how to enforce all the regulations and auditing procedures to ensure that all growers are producing safe food. There are many farmers out there who may not be implementing food safety practices on their farms. The FDA may find it difficult to get these farmers involved and engaged.

V. Wildlife and Environmental Concerns

Dr. Karen Lowell, Lecturer at the University of California, Santa Cruz, presented on issues related to wildlife based on a case study of California's Central Coast and presented in the paper *Co-Managing for Food Safety and Ecological Health in California's Central Coast Region*.¹⁸ Dr. Lowell noted that the issues laid out in her presentation are not currently prominent in Georgia.

She noted a tension existed between food safety and environmental concerns in that growers are being pressured by auditors and inspectors to change on-farm practices in response to food safety concerns, often to the detriment of conservation practices. Such changes include the restriction or elimination of wildlife and their habitat from farm land, removal of non-crop vegetation and removal of water bodies. Specific practices noted include the removal of wetlands and riparian buffers, which leads to a reduction in water quality, and loss of important wildlife movement corridors.

In the paper, the authors reviewed studies on how wildlife impacted food safety. The contamination processes are poorly understood and it is an area of active research. The CDC names five "animals of significant risk": cattle, sheep, goats, pigs, and deer. The Leafy Green Marketing Agreement,

¹⁸ A summary of the paper *Co-Managing for Food Safety and Ecological Health in California's Central Coast Region* is available online at http://www.producesafetyproject.org/discussion_series.

based on the CDC findings, identifies only deer and feral pigs as wildlife of concern. Private standards required by retailers, however, often list many more wildlife species with questionable scientific basis.

Dr. Lowell put forward the idea of “co-management” in which food safety and environmental concerns are both addressed. Co-management begins with the assumption that farmers want to produce safe food and be good land stewards, and that both can be achieved in an economically viable fashion. However, according to Dr. Lowell, a number of obstacles exist, including:

- The numerous private food safety standards that (i) lead to inconsistent interpretation and application, (ii) contribute to a food safety “arms race,” (iii) are developed with a lack of transparency, and (iv) are based in an unclear scientific basis;
- Mounting liability and litigation risk;
- The potential effects of national food safety standards, which may not necessarily support a co-management approach;
- An industry movement towards value-added products which are connected with foodborne illness outbreaks, and cause a backlash on the farmer; and
- A lack of scientific data on just how to minimize risk.

In the short question and answer session that followed her presentation, Dr. Lowell made the following points:

- She has observed that growers are being asked to do things unrelated to food safety.
- There are many avenues for possible contamination in the field. Effective food safety standards must manage risk exposure. More research needs to be done to pinpoint just where the risks are, and the level of risk presented by various factors.
- In California, the growers are getting pressure to manage for food safety mainly from the buyers. At the same time, they have to follow federal environmental regulations. There are growers who are caught between the two and are asked to break the law in order to sell their product.

Wildlife and Environmental Concerns Breakout Sessions

Following the morning presentations, meeting participants were given the opportunity to attend breakout sessions to further discuss wildlife issues. The following themes came out of the sessions:

Regional Considerations

- There is a fairly consistent presence in the fields of wildlife – deer, rabbits, feral pigs, along with more exotic animals, like alligators (transitory).
- There are lots of wetlands in Georgia and birds come at different times of year. Domestic animals also come onto the fields.

Local Practices

- Growers are already actively trying to exclude wildlife from their crop fields for economic reasons/crop loss. Some of the things they are doing include growing alternative plots to entice animals away from the commodity fields, hunting, netting, and traps.
- Workers regularly walk the fields to identify plant damage. Georgia has not had to deal with wildlife as a food safety concern to a great extent, if at all.

Standards and Audits

- Quarantine and buffer zones may not be economically feasible for all farmers, as it reduces their productivity.
- Growers expressed concern with the environmental ramifications of eliminating wildlife. It is impossible to keep all types of wildlife out of the fields.
- If the new food safety regulation incorporates considerations for wildlife, it also has to include education for growers on what they could do to minimize impact from wildlife.
- The standard should take into account how the produce will be consumed (e.g., ready to eat, eaten raw, eaten cooked, or further processed).
- The standard should be cost-effective to implement, and reasonable for the farmer.
- Growers were concerned with the variability and diversity of audit requirements, and wanted standardization of audits.

Research and Education Needs

- Wildlife intrusion into fields is a problem, but the evidence conclusively linking wildlife to contamination is not there.
- Research needs to be done to determine which animals are more of a concern, and which crops are more vulnerable to contamination from wildlife.
- Researchers need to determine how far pathogens can spread from wildlife droppings, to set a reasonable and effective quarantine area.

VI. FDA and USDA Observations

Ms. Bland and representatives from the FDA and USDA shared some of their thoughts of the meeting and themes they observed.

Ms. Bland expressed her pleasure at the level and quality of participation over the course of the meeting. She noted that the comments she heard were very constructive and informative. She thanked the participants for their contributions.

Ms. Skelton echoed Ms. Bland's appreciation for the input from meeting participants. She emphasized the importance of FDA hearing from the farmers, and encouraged the meeting participants to continue submitting comment after the meeting.

Mr. Farrar also expressed his appreciation to the group for taking time out of their schedule to come and provide input. He noted that the FDA needs more data on which to base the standards, and requested the participants to continue providing information after the meeting through the public docket. He stated that FDA understands the frustration farmers feel from the different audit standards, and the varying interpretations of the same standards.

Mr. Farrar explained the rulemaking timeline. The proposed rule should be released for public comment by the end of 2010. After a public comment period, FDA will review all comments received. FDA will revise the rule based on the comments and release the final version.

The meeting participants were given the opportunity to ask questions of FDA and USDA. Representatives made the following points:

- FDA understands the importance of relieving the audit burden from farmers. The agency is considering ways to ensure that all growers comply to the same set of standards,

ensuring a level playing field. It will have to work with state officials, USDA, and third parties. Ms. Bland informed the group of an initiative to develop harmonized GAPs. Private industry, FDA and USDA, and Mexico and Canada's GAPs programs are at the table. The group has already achieved consensus on an audit for tomatoes.

- FDA realizes that it has to address imports as well as domestic produce. The agency is committed to working to ensure foreign products comply with the same regulations as domestic production.

VII. Closing Remarks

Mr. O'Hara thanked the group again for their participation throughout the meeting. He said that these conversations will help FDA get the regulation right the first time. Growers are already implementing food safety practices on the farm, and the regulations will codify those actions.

Mr. O'Hara reminded participants that their comments at the meeting will be captured in meeting summaries, which will be submitted to the FDA open docket. He encouraged participants to submit their own comments, noting that Ms. Bland's organization is available to help.

**Produce Safety Project
Stakeholders' Discussion Series**

Co-Sponsored by the University of Maryland Center for Food Safety and Security Systems
(CFS³)

Meeting Summary

*April 7, 2010
College Park, MD*

Goals and Outcomes

- *Increased understanding of the science underlying enhanced produce safety practices, including:*
 - *What we know, and*
 - *What we do not know*
- *Increased understanding of practices that are, or could be, contributing to enhanced produce safety.*
- *Identification and discussion of any regional practice considerations important for enhancing produce safety.*

I. Welcome and Introductions

Jim O'Hara, Director of the Produce Safety Project (PSP), welcomed meeting participants and thanked them for attending. PSP is a research and advocacy organization that supports the development by the Food and Drug Administration (FDA) of a mandatory and enforceable produce safety standard for the growing, harvesting and packing of fresh fruits and vegetables. To that end, PSP commissioned reports on four issues it believes the FDA should consider during the rule development process. These four issues are (i) irrigation and foliar water quality, (ii) compost, (iii) worker health and hygiene, and (iv) wildlife and environmental concerns. The four scientific presentations are not meant to be the last word on these issues, but rather starting points for the conversations of the day.

The series was designed by PSP to provide the FDA the details needed to develop a successful rule. The rule development process and FDA officials would benefit by hearing directly from growers about the practices already implemented on farms to ensure food safety, and to provide a dialogue about the questions and concerns growers have about the development of the standard. College Park is the forth meeting held to date.

Mr. O'Hara stated there will be a record of each meeting and comments will be compiled and submitted to the FDA docket and that the FDA announced the proposed produce safety rule will be released by the end of the year. He noted that senior officials from both the FDA and the U.S. Department of Agriculture (USDA) are participating in the meeting and listening to participants'

comments. Mr. O'Hara added that this is a unique situation where the FDA has opened a docket to receive comments *prior* to the drafting of a rule.¹⁹

Dr. Robert Buchanan, the Director of the University of Maryland's Center for Food Safety and Security Systems (CFS³), welcomed participants to College Park. He expressed his excitement in hosting this platform bringing both industry and government together to provide input to the FDA, assisting in the development of the new produce safety standard. Dr. Buchanan encouraged the meeting attendees to actively participate in the meeting and share their thoughts and experiences.

Michael Taylor, the Deputy Commissioner for Foods at the FDA, thanked PSP and the participants for their dedication to produce safety. He emphasized the importance of this issue and the American people's dependence on the produce supply chain for safe food. Mr. Taylor expects that food safety legislation will pass in the next few months. He discussed the importance of the FDA, USDA, state and local authorities, and producers working together to develop regulation that is protective and makes a practical difference for food safety. The FDA intends to develop regulation that is effective for differing regional growing conditions and practices, crop diversity, and scaled operations from local exchanges to global markets. The FDA's approach aims to meet two important public health goals: improving food safety by reducing the spreading of food contamination, and maintaining public confidence and access to fresh fruits and vegetables. Mr. Taylor informed the attendees that the new regulations will be risk-based and scale appropriate. He asked participants to contribute their knowledge about best practices and their related performance measures to help develop the most effective rule.

Ms. Leanne Skelton, the Chief of the Agricultural Marketing Services (AMS) Fresh Products Branch at the USDA, informed the group that she is on a temporary detail assignment to the FDA to assist in the writing of new produce safety regulations. Ms. Skelton echoed the other speakers' calls for partnership and collaboration. Although the FDA and USDA have different missions, the development of this produce rule is a joint effort that complements both organizations' missions. She informed participants that the federal program managers and state partners in this group are the ones that will help demonstrate that the producers are adhering to the agricultural rules for their products. She encouraged growers to talk to their county extension agents and to seek federal grant money to investigate food and produce safety practices. Ms. Skelton noted that the USDA AMS convenes the Fruit and Vegetable Industry Advisory Committee. At its March meeting, the Advisory Committee discussed issues facing the produce industry and how the USDA can help the industry address those issues. Lastly, Ms. Skelton encouraged participants to share their perspectives and practices to contribute to the development of a successful rule.

Mr. Raymond Yoder, a prominent Amish farmer from Ohio and representative of 71 produce auctions, emphasized the importance of produce grower participation in the development of the new rule and stressed that the new regulations should allow for the cultural practices of the Amish and Mennonite communities. He encouraged participants to speak up throughout the day and noted the availability of German-English interpreters to help in the breakout sessions. Mr. Yoder concluded by emphasizing that the group needs to work together with federal organizations to make this new rule effective in the fields.

¹⁹ The PSP has prepared a handout outlining how to submit public comment to the docket, available online at http://www.producesafetyproject.org/admin/assets/files/HowtoGuide_theFDAOpenCommentPeriodv10.pdf

Abby Dilley, the meeting facilitator, reviewed the day's agenda, participant materials, and meeting expectations. She expressed the hope that participants will come away with an increased understanding of the science, good practices to enhance produce safety, and the variability in the produce sector.

The discussion topics for the meeting consisted of the four issue areas identified as possible concerns for food safety: (i) compost, (ii) irrigation and foliar contact water quality, (iii) worker health and hygiene, and (iv) wildlife and environmental concerns. Report authors presented an overview of each issue area, followed by small group breakout sessions for a targeted in-depth discussion on the issues. The summaries of the presentations and the breakout sessions are below.

II. Worker Health and Hygiene

Dr. Bob Gravani, Professor of Food Science in the Department of Food Science at Cornell University and author of *Farm Worker Health and Hygiene*, presented on issues related to worker health and hygiene.²⁰ He noted that implementing worker health and hygiene measures is a wise investment of resources targeted with the goal of risk reduction. Dr. Gravani reviewed the demographics of farm laborers, who are usually younger, less educated, white, Hispanic, male, married and more likely to be foreign born. As a group, they also are less likely to have access to proper health care due to economic status, cultural or language barriers, access, or immigration status. Because of their intimate contact with produce during harvest, sorting, and packing, infected workers have multiple opportunities to contaminate the food supply. Dr. Gravani emphasized that any person who works on a farm is a farm worker, including the farmer. He noted that the employees follow the example of the employer.

Dr. Gravani listed the following as factors that contribute to outbreaks:

- Lack of adequate water supply for consumption and handwashing;
- Limited hygiene education;
- Poor or no toilet facilities;
- Bare hand contact with produce items;
- Lack of food contact surface sanitation; and
- Lack of childcare for workers.

Training programs must be practical, meaningful, aimed at the appropriate education level of the workers, and conducted by trainers who speak the native language of the employees. In addition, management should be committed to food safety, implement training programs with clear and enforceable rules for food safety and sanitation, and provide the means for workers to use the training (e.g., soap, first aid kits). Dr. Gravani added that farmers should verify the effectiveness of the training, for example, by tracking soap use.

Following his presentation, Dr. Gravani responded to a question about standards harmonization. He recognized the United Fresh Produce Association's meetings to harmonize standards between members of the produce supply chain, and encouraged participants in this conversation to provide practical, achievable, and manageable feedback.

²⁰ A summary of the white paper on Worker Health and Hygiene commissioned by the PSP is available online at http://www.producesafetyproject.org/discussion_series.

Worker Health and Hygiene Breakout Sessions

Following the morning presentations, meeting participants were given the opportunity to attend breakout sessions to further discuss worker health and hygiene issues. The following themes came out of the sessions:

Regional Considerations

- There are many multi-generational family farms in the region where most, if not all, of the farm workers are family members. Expectations for health and hygiene standards are conveyed through example and leadership, but still require adequate documentation and regular trainings.
- For the majority of the Amish or Mennonite growers, English is not their first language, and many are more comfortable with German. Training materials should reflect this.

Local Practices

- Good Agricultural Practices (GAPs) training programs already cover much of the worker hygiene issues.
- Training needs to cross language and culture barriers. Examples of effective training materials include multi-language videos, Penn State's GAPs training flipchart, and Cornell's multi-language signage. Participants recognized Ohio State's Agricultural Technical Institute as a successful food safety education program.
- Regular training is important, particularly for younger generations on family farms. One participant suggested monthly training requirements.
- State and regional GAPs training programs should be regularly accessible for small farmers. Their programs should provide farmers with binders to assist with record keeping.

Standards and Audits

- Participants voiced concern about regulation's impacts on generational family farms.
- Audits are both necessary to ensure compliance with standards but can be expensive and burdensome for small, multi-commodity, and generational family farmers. Specific audit preparation guidelines would assist farmers in preparation and ensure audit consistency.
- Documentation would ensure that the regulations and standards are being implemented. However, the degree of documentation required should be scale appropriate. Documentation should decrease the liability to the farmer.
- Include flexibility in the standards to take into account the scale and commodity produced at an operation. Small farms should have lower implementation costs than larger farms.
- Growers believed that the government should pay for produce inspections.
- Localized auditing among the plain people would be successful, and could be supported by USDA spot checks.

Research and Education Needs

- Training programs should include guidance and education on how to develop scale appropriate record keeping systems.
- Attention should also be given to consumer education on how to safely handle produce.

III. Wildlife and Environmental Concerns

Dr. Karen Lowell, Lecturer at the University of California, Santa Cruz, presented on issues related to wildlife based on a case study of California's Central Coast and presented in the paper *Co-Managing for Food Safety and Ecological Health in California's Central Coast Region*.²¹

Dr. Lowell noted a tension between food safety and environmental concerns in that growers are being pressured by auditors and inspectors to change on-farm practices in response to food safety concerns, often to the detriment of conservation practices. Such changes include the removal of non-crop vegetation and removal of water bodies. Specific practices noted include the removal of wetlands and riparian buffers, which leads to a reduction in water quality and loss of important wildlife movement corridors. The removal of vegetation can lead to decreased water quality, and the bare ground buffers that replace the vegetation can increase the ease of flow for pathogens. Dr. Lowell indicated that contamination processes are poorly understood, and it is an area of active research. In the paper, the authors reviewed studies on how wildlife affected food safety. The Centers for Disease Control and Prevention (CDC) names five "animals of significant risk": cattle, sheep, goats, pigs, and deer. The National Leafy Green Marketing Agreement, based on the CDC findings, identifies only deer and feral pigs as wildlife of concern. Private standards required by retailers, however, often list many more wildlife species with questionable scientific basis for doing so.

Dr. Lowell put forward the idea of "co-management" in which food safety and environmental concerns are both addressed. Co-management begins with the assumption that farmers want to produce safe food and be good land stewards, and that both can be achieved in an economically viable fashion. However, according to Dr. Lowell, a number of obstacles exist, including:

- The numerous private food safety standards that (i) lead to inconsistent interpretation and application, (ii) contribute to a food safety "arms race," (iii) are developed with a lack of transparency and (iv) are based on an unclear scientific basis;
- Mounting liability and litigation risk;
- The potential effects of national food safety standards, which may not necessarily support a co-management approach;
- An industry movement towards value-added products which are connected with food borne illness outbreaks, and cause a backlash on the farmer; and
- A lack of scientific data on how to minimize risk.

In the short question and answer session that followed her presentation, Dr. Lowell made the following points:

- The impacts of concentrated cattle farming are an important part of the discussion, particularly in understanding where the cattle pick up pathogens. The white paper does not discuss concentrated feeding operations.
- *E. coli* and *Salmonella* transmission through soil is an active area of research. The science is progressing and new information will help to address key pathogen transference issues moving forward.
- Dr. Jeff LeJeune at the Ohio State University has conducted research to understand the effects of horse use in fields on the transmission of *E. coli* 0157. One identified issue of concern is the shared housing of horses used for animal traction in crop fields with ruminants, such as goats, which are main carriers for the pathogen.

²¹ A summary of the paper *Co-Managing for Food Safety and Ecological Health in California's Central Coast Region* is available online at http://www.producesafetyproject.org/discussion_series.

- The risk posed by using domestic animals (i.e., dogs) as wildlife deterrents is unclear. Corporate buyers have enforced standards removing dogs from farmland in California.

Wildlife and Environmental Concerns Breakout Sessions

Following the morning presentations, meeting participants were given the opportunity to attend breakout sessions to continue discussing wildlife issues. The following themes came out of the sessions:

Regional Considerations

- Growers in the region have not been asked to control for wildlife on their farms as a food safety issue.
- Growers listed a number of animals as problems, including: seagulls, blackbirds, crows, deer, domesticated dogs, foxes, geese, groundhogs, horses, mice, rabbits, snakes, swans, and wild turkeys (North Carolina).

Local Practices

- Farmers already try to control wildlife and exclude them from the fields for economic reasons, i.e., crop loss, through such practices as fencing, netting, hunting, domesticated dogs, and trapping. These attempts are usually not one hundred percent effective.
- Hunting is a means of controlling wildlife. With regard to deer and Canadian geese, perhaps state hunting regulations should be revised to provide farmers the right to defend their crops. Regulations should encourage partnerships with organizations like Hunters for the Hungry.
- Neighbors often contribute to the problem by feeding the wildlife.
- It is not feasible or practical to try to keep all wildlife out of the fields. Some wildlife provides a balanced ecosystem such as foxes and snakes, which manage the mice population.

Standards and Audits

- Audits should focus on local concerns. Standardizing controls for wildlife do not account for local and regional ecosystem variance.
- The national GAPs self-assessment should count as a partial audit.
- Successful audits should effectively restrict legal pressure on growers to take excessive measures to make sure they are not involved in any outbreak.
- There should be a process for reviewing auditors to remove arrogant inspectors. Inspectors should be local and have hands-on agricultural experience.
- Inspectors/auditors should receive appropriate and adequate training.
- Regulations should create space for regional farmer advocates to handle claims about wrongful audit results.
- The standard needs to be risk-based and science-based.
- There should be one unified audit.
- Commodity, harvesting method, and wildlife specific guidance (or a hazards and control guide) may be more appropriate than a process-based standard for wildlife.
- Guidance should include recommendations for buffer zones around crops, tracks, and fecal matter, and controls guidelines for different commodities and wildlife. This could be a hazards and control guide to help farmers identify the best control mechanisms for their farms.
- Regulations should include a simple and integrated pest management system.

- Regulation needs to include the explicit statement that the presence of wildlife alone cannot be enough to disqualify produce.

Research and Education Needs

- Growers wanted to know what they would be audited on. The USDA audit book should be made readily available to farmers.

IV. Composting Issues

Dr. Mike Doyle, Regents Professor of Food Microbiology and Director of the Center for Food Safety at the University of Georgia and author of *Composting Criteria for Animal Manure*, presented an overview of composting issues and key scientific information, as laid out in the paper *Composting Criteria for Animal Manure*.²² Dr. Doyle noted that different manures have different compositions, which affect the composting process. He explained that incomplete treatment of manure can contaminate food. The prevalence of a type of manure varies by region, and the prevalence of pathogens in the manure varies greatly.

Dr. Doyle listed three types of composting systems: aerated, windrow systems, and in-vessels systems. Pathogens can be inactivated in compost with three stages: mixing the compost, raising the temperature, and curing. Dr. Doyle then reviewed some of the factors influencing pathogen inactivation, which can vary by type of manure. He explained that even if compost tests free of pathogens, that does not mean that there are pathogens in the manure prior to the composting process.

Dr. Doyle noted that there are no universal standards for composting to eliminate harmful pathogens, such as *E. coli* and *Salmonella*. Compost is primarily regulated at the state and local level, and there is no federal oversight. These regulations vary greatly in scope and complexity. While many jurisdictions use EPA guidelines 40CFR Part 503 for end product and process criteria, there are still variations in the current non-uniform standards with regard to time, temperature, finished product testing, and required frequency of facility monitoring.

In *Composting Criteria for Animal Manure*, the researchers made the following recommendations:

- Require insulating covers on all types of compost piles.
- Include a minimum curing period to ensure the completion of pathogen inactivation.
- Procedures to control risk, i.e., regular verification of equipment accuracy for pH and temperature testing.
- Require compost operations to have standard operating procedures, a quality assurance plan, and a Hazard Analysis Critical Control Point (HACCP) programs.

In the short question and answer session that followed his presentation, Dr. Doyle made the following points:

- Regulation and prevention are the focus of the GAPs program. The program requires record keeping verification, which should also be included in the new produce safety rule.

²² A summary of the white paper commissioned by the PSP on compost issues is available online at http://www.producesafetyproject.org/discussion_series.

- CDC and state health departments have developed a surveillance system that helps to identify outbreaks.
- Raw manure can be applied to soil if it is plowed and then given sufficient time before planting. Continued research will define minimum time requirements for the new produce safety rule.
- Future studies of the linkages between pathogens in manure and crops will need to validate the inactivation of harmful microbes in manure use. Research moving forward will consider many variables regarding the source of the manure, which may affect the risk analysis of using raw manure.
- Based on the state of science, we know there is increased risk using raw manure versus composted manure.
- Many farmers rotate livestock grazing as part of a fruit and vegetable rotation, and use composted manure in their crop rotations.

Composting Issues Breakout Sessions

Following the afternoon presentations, meeting participants were given the opportunity to attend breakout sessions to further discuss composting issues. The following themes came out of the sessions:

Regional Considerations

- Lancaster, PA, is a very manure-rich region of the country. Many farmers in the area rely on raw manure and see it as integral to their farms.
- There are sizeable Amish and Mennonite communities in Pennsylvania. Farmers in those communities rely on animals in their operations and feel they cannot survive without them.

Local Practices

- Types of inputs for compost; chicken, cows (solid and liquid), horses, mushrooms, sheep, steer, and vegetables.
- For farmers from communities that limit the use of mechanization, aspects of composting that require heavy machinery (e.g., mixing) would be impossible.

Standards and Audits

- Until science can support regulations, the new rule should include guidelines for compost and manure usage.
- One uniform standard is unlikely to be implementable, given the variability in scale of operation, type of operation, mechanization on the farm, and commodities grown. Some meeting participants suggested different levels of compost certification given the size of the farm, commodity, and individual farm risk analysis.
- Regulations need to include standards for pathogen mortality associated with composting practices.
- Regulatory compliance should limit liability to the farmer.

Research and Education Needs

- Many traditional practices employed by farmers, such as the time from application to planting or harvest or building structures over manure piles, may be effective in inactivating pathogens in raw manure and alleviating food safety risks. These practices should be identified and information about them provided to the farming community.

- More research needs to be done to identify and fill in knowledge gaps regarding pathogen occurrence and survival in compost, and uptake by the plant. New information gained from research should be disseminated to the farm community.
- Growers wanted guidance on best practices for compost, including implementing buffers between neighboring farms that use raw manure or raise cattle, and time limits between raw manure application and planting.

V. **Irrigation and Foliar Contact Water Quality**

Dr. Trevor, the Extension Research Specialist at the University of California, Davis, Department of Plant Sciences, presented an overview of issues related to irrigation and foliar contact water, as laid out in *Standards for Irrigation and Foliar Contact Water*.²³ Produce and niche-crops use a variety of types of irrigation from diverse water sources. About seventy percent of U.S. commercial farmland is irrigated and because of issues related to nature, value, and perishability, much of the produce crop in this country are under some form of managed irrigation. Due to the intimate contact with the edible portion of the crop, the quality of the water is very important for food safety considerations. Water quality becomes more important the closer to harvest. There is still much unknown about how water quality affects food safety based on region, crop, or management practice. Dr. Suslow reviewed some of the ways irrigation and foliar contact water may become contaminated. For example, groundwater can be contaminated by surface water events, and fecal contaminants and pathogens have been found in irrigation water.

Dr. Suslow then reviewed the state of the science. He highlighted two main concepts: the risk potential for water is very high and the risk exposure is highly variable. Pathogens are known to survive in water and sediments for long periods of time. Dr. Suslow identified a knowledge gap for water quality because of a lack of uniformity in testing methods and standards, and a lack of a national database for irrigation water quality. In addition, current water quality standards are inadequate, poorly defining the relationship between indicators, pathogens, and risk. Dr. Suslow noted that growers need to be able to differentiate between high- and low-risk irrigation water, and that auditors need to recognize the variable risk based on a number of factors, including the water, the crop, the location, and the post-harvest handling.

Dr. Suslow noted that many regional GAPs and commodity-specific guidelines have adopted the EPA recreational water quality standards for irrigation water. He expressed concern about this trend because the EPA criteria were not intended to apply to risks associated with irrigation of edible crops and do not take into account the die-off of pathogens post-irrigation. He also noted that the FDA commodity-specific guidance recognizes that there are currently no clear standards, and growers are responsible for using water of “appropriate quality.”

Dr. Suslow ended his presentation with the following list of recommendations:

- Implement sanitary water surveys on the farm;
- Broaden the characterization of irrigation water sources before including the current GAPs standard;
- Commit to two seasons of frequent sampling;
- Find appropriations to assist small farms; and

²³ A summary of the white paper commissioned by the PSP on issues related to irrigation and foliar water quality is available online at http://www.producesafetyproject.org/discussion_series.

- Adjust the water quality standards as justified by the data and models.

In the short question and answer session that followed his presentation, Dr. Suslow made the following points:

- Wildlife control of migratory and residential geese, which can increase pathogen exposure risks to irrigation sources, is difficult. Growers can prevent contamination through hunting; however state and federal agencies currently have conflicting interests and oversight. Dr. Suslow articulated that the new produce safety rule is unlikely to prescribe something that would create a conflict between federal requirements.
- EPA is considering developing use-specific water quality guidelines, and may revise recreational water quality standards. If that is the case, those new standards may not be appropriate for irrigation and/or foliar contact water quality.

Irrigation and Foliar Contact Water Quality Breakout Sessions

Following the afternoon presentations, meeting participants were given the opportunity to attend breakout sessions to further discuss irrigation water issues. The following themes came out of the sessions:

Regional Considerations

- Growers used water from a variety of sources, including on-farm ponds, municipal, well, rain capture, stream, and surface water.
- Growers irrigated in a variety of ways, including natural precipitation, drip irrigation, over-head irrigation, and in-ground irrigation.

Local Practices

- Water treatment controls used in the region include bromine, chlorine, chlorine gas, heat, hydrogen peroxide, and UV light.
- New Jersey law classifies water with nitrates as not-potable.

Standards and Audits

- Auditors should be local community representatives who are responsible for policing, enforcing, and educating agricultural producers in their locality.
- Some growers felt developing standards now to be premature, and wanted FDA to wait until problems are documented. Once science can support the standards, ensure that the standards are adaptive as new research becomes available.
- Until science can support standards, regulations should include guidelines on the time limit between water applications and harvesting based on irrigation source and commodity type.
- The regulation should focus on the problems where there is a clear, scientific basis for concern such as identified routes of bacterial transfer from water to produce.
- Regulations need to be commodity- and irrigation-type specific.
- Regulations should include separate standards for unique scenarios such as farmers markets and direct farmer to individual on-farm transactions.
- There was concern that imported produce is not held to the same standards as domestic produce.
- Stagger required water quality baseline testing (similar to recreational testing) coupled with frequent post major weather event testing.

Research and Education Needs

- More research needs to be done to determine the risk of bacterial transfer from water to produce.
- Identifying regional outbreaks may help to identify regional practices that may be problems. Focus research on regional practices and trends to help identify practices that may pose a problem.
- Recognize that there are risks all the way up the supply chain. Educate the entire supply chain through to the end consumer.
- Growers wanted guidelines to perform a water quality risk assessment. They wanted guidelines for when risks occur, source-specific risks and availability, and activities that affect bacterial counts would help farmers choose the appropriate water source at the appropriate time.

VI. FDA and USDA Question and Answer Session

Jim O'Hara opened the question and answer session by expressing the hope that the meeting participants found the day helpful and educational. He reminded the group of the open docket, which will help inform the FDA in writing the produce safety rule.

Michael Taylor, Deputy Commissioner for Foods at the FDA, reiterated some of the messages he had heard over the course of the meeting: (i) more research is needed, particularly with a risk-based approach; (ii) take into account distribution channels and scale of operations by writing a rule that is scalable; (iii) all growers will need to be held accountable to rules that make a practical difference. The FDA recognizes that it is in everyone's best interest that food be safe, that the people believe food is safe, and have confidence in their access to fresh fruits and vegetables.

Mr. Taylor responded to comments and concerns voiced during the day. He indicated that the FDA is investigating how imports can be held accountable. He highlighted that grower and consumer food safety education needs to be a large component of the rule and its implementation. He also noted that the rule will have minimum regulations and will be phased in to test its applications. He concluded that the new rule will take into account region-specific issues and differences.

The meeting participants were then given the opportunity to ask questions of FDA and USDA officials. In response to questions from participants, Mr. Taylor and Ms. Skelton provided the following comments:

- FDA has been developing good agricultural practice guidelines for over ten years. The impetus behind these discussions is the anticipation of congress passing legislation requiring a new produce safety rule. Mr. Taylor emphasized that the rule will not be one size fits all, and that continued research will help develop minimum requirements.
- FDA's food safety program focuses on each step along the produce supply chain, including the retail component.
- FDA cannot control what standards buyers demand of their suppliers. The new produce safety rule will serve as a common standard, which buyers will gravitate towards.
- FDA is currently developing regulations for sanitary food transportation practices as part of its implementation of the Sanitary Food Transportation Act of 2005, which empowers FDA to examine and enforce regulation about transporting food.

Individual meeting participants also made the following points:

- Congress is moving ahead with or without small farmer support. Farmers should assist in the development of a new rule, rather than fighting it.
- The rule needs to include mandatory, continual education for applicators of pesticides, as well as applicators of manure and composting materials.
- Manure is high value product to farmers who use it properly. Regulation should not limit resources or make the use of manure unfeasible.
- Among the many interests pushing this regulation, including Congress, FDA, consumer groups, and larger agricultural producers, the voices of small farmers need to be equally and fairly heard and represented.

In response to a participant's question, Mr. Taylor informed the group that the FDA would welcome comments on how the rule should take into account new information as it emerges.

VII. Concluding Thoughts

Mr. O'Hara thanked participants for their time, and expressed hope that they found the meeting valuable. He reiterated that comments collected would be summarized and formally submitted to the FDA's open docket. Mr. O'Hara encouraged participants to submit comments to the FDA open docket. PSP developed a guide on how to submit public comment, and that handout is available on the PSP website (<http://www.producesafetyproject.org/>).

**Produce Safety Project
Stakeholder Discussion Series**

Co-Sponsored by the University of California Division of Agriculture and Natural Resources

Meeting Summary

*April 26, 2010
Monterey Bay, CA*

Goals and Outcomes

- *Increased understanding of the science underlying enhanced produce safety practices, including:*
 - *What we know, and*
 - *What we do not know*
- *Increased understanding of practices that are, or could be, contributing to enhanced produce safety.*
- *Identification and discussion of any regional practice considerations important for enhancing produce safety.*

I. Welcome and Introductions

Jim O'Hara, Director of the Produce Safety Project (PSP), welcomed meeting participants and thanked them for attending. PSP is a research and advocacy organization that supports the development by the Food and Drug Administration (FDA) of a mandatory and enforceable produce safety standard for the growing, harvesting and packing of fresh fruits and vegetables. To that end, PSP commissioned reports on four issues it believes FDA should consider as it moves through the rule development process. These four issues are (i) irrigation and foliar water quality, (ii) compost, (iii) worker health and hygiene, and (iv) wildlife and environmental concerns. The four scientific presentations are not meant to be the last word on these issues, but rather starting points for the conversations of the day.

PSP designed the discussion series to engage stakeholders in a robust discussion regarding the development of the proposed FDA produce safety rule including a discussion on the current state of the science regarding four of the major issues concerning the safety of fresh produce and to discuss the practices already implemented on farms to ensure food safety. Monterey is the fifth meeting held to date.

Mr. O'Hara stated there will be a record of each meeting and comments will be compiled and submitted to the FDA docket²⁴ and that the FDA announced it will release the proposed produce safety rule by the end of the year. He noted that senior officials from both the FDA and the U.S.

²⁴ The PSP has prepared a handout outlining how to submit public comment to the docket, available online at http://www.producesafetyproject.org/admin/assets/files/HowtoGuide_theFDAOpenCommentPeriodv10.pdf

Department of Agriculture (USDA) are participating in the meeting to listen to participants' comments. Mr. O'Hara added that this is a unique situation where the FDA has opened a docket to receive comments prior to the drafting of a rule.

Ms. Sonya Hammond, the County Director of the University of California Cooperative Extension, Monterey County, welcomed participants to Monterey. She expressed her excitement for hosting the Stakeholders' Discussion Series in an agricultural region steeped in a history of technology and innovation. Ms. Hammond emphasized that FDA is listening to growers first and writing the regulation second. She encouraged participants to fully engage in the discussions and to share with FDA the practices they currently employ along with their ideas for what should be encompassed in the new regulation. Ms. Hammond noted that there is a tremendous marketing opportunity for growers with both the new anti-obesity campaign and its emphasis on eating vegetables, as well as the national security interest that America has in its own national food supply. She concluded by acknowledging that there are still more questions than answers related to food safety, and much more research that needs to be done.

Mr. Jeff Farrar, the Associate Commissioner for Food Protection in the FDA's Office of Foods, thanked participants for attending. He encouraged participants to share their detailed perspectives and practices to contribute to the development of a risk-based, science-based, practical, and scalable rule. He assured participants that the rule would level the playing field between importers and local producers. Mr. Farrar joined Jim O'Hara in encouraging participants to approach FDA and USDA representatives in attendance, with any questions they may have.

Mr. Tim York, President of Markon Cooperative, Inc., pointed to the value of good dialogue and constructive relationships between industry, growers, and federal agencies. He highlighted the need for balance between environmentalists and the agricultural community, both of whom want a healthy and vibrant wildlife community.

Abby Dilley, the meeting facilitator, reviewed the day's agenda, participant materials, and meeting expectations. She expressed the hope that participants will come away with an increased understanding of the science, good practices to enhance produce safety, and the variability in the produce sector.

The discussion topics for the meeting consisted of the four issue areas identified as possible concerns for food safety: compost, irrigation and foliar contact water quality, worker health and hygiene, and wildlife and environmental concerns. Report authors or their designee's presented an overview of each issue area, followed by small group breakout sessions for a targeted in-depth discussion on the issues. The summaries of the presentations and the breakout sessions are below.

II. Worker Health and Hygiene

Dr. Bob Gravani, Professor of Food Science in the Department of Food Science at Cornell University and author of *Farm Worker Health and Hygiene*, presented on issues related to worker health and hygiene.²⁵ He noted that implementing worker health and hygiene measures is a wise investment of resources targeted with the goal of risk reduction. Dr. Gravani reviewed the demographics of farm

²⁵ A summary of the white paper on Worker Health and Hygiene commissioned by the PSP is available online at http://www.producesafetyproject.org/discussion_series.

laborers, who are usually younger, less educated, white, Hispanic, male, married and more likely to be foreign born. As a group, they also are less likely to have access to proper health care due to economic status, cultural or language barriers, access, or immigration status. Because of their intimate contact with produce during harvest, sorting, and packing, infected workers have multiple opportunities to contaminate the food supply. Dr. Gravani emphasized that any person who works on a farm is a farm worker, including the farmer. He noted that the employees follow the example of the employer.

Dr. Gravani listed the following as factors that contribute to outbreaks:

- Lack of adequate water supply;
- Limited hygiene education;
- Poor or no toilet facilities;
- Bare hand contact with produce items;
- Lack of food contact surface sanitation; and
- Lack of childcare for workers.

Training programs must be practical, meaningful, aimed at the appropriate education level of the workers, and conducted by trainers who speak the native language of the employees. In addition, management should be committed to food safety, implement training programs with clear and enforceable rules for food safety and sanitation, and provide the means for workers to use the training (e.g., soap, first aid kits). Dr. Gravani added that training should create clear links between compliance, food safety, and the value for the individual employee.

In the short question and answer session that followed his presentation, Dr. Gravani made the following points:

- Training materials are easily scalable. The farm worker survey helped identify different ways to interact with different sized operations.
- There is good scientific information that gloves, when used appropriately, can reduce risk.
- Migratory status should not affect worker training, which needs to be accessible and appropriate for all workers.

Worker Health and Hygiene Breakout Sessions

Following the morning presentations, meeting participants were given the opportunity to attend breakout sessions to further discuss worker health and hygiene issues. The following themes came out of the sessions:

Regional Considerations

- Many growers in the region seasonally relocate their operations. For example, growers may spend 8 months in the Salinas Valley, and 2 months in the desert. Farm workers in desert operations tend to be more transient, working for short periods of time.

Local Practices

- The Leafy Green Marketing Agreement (LGMA) is the most prominent produce standard in the region; participants indicated a high level of comfort with this type of regulation.
- Gloves are common practice in this region. Inexpensive one-time use rubber gloves are effective. The most common treatment practice for reusable gloves is a chlorine dip.

- Growers described practices such as: cleaning the bathrooms every day, using paper towels, observing workers after their breaks, training supervisors to notice symptoms of illness, giving pop tests in the fields to check worker knowledge, and switching from carbon to stainless steel knives.

Standards and Audits

- The standard should have both a uniform minimum set of regulations, “floor,” and a “ceiling” to limit excessive and potentially harmful practices. This would help avoid the arms race problem for worker health and hygiene.
- Regulations should define the desired outcomes and allow the growers to determine how to reach those outcomes.
- Standard Operating Procedures (SOPs) articulating individualized methods for meeting new produce standards would allow for variability in different size and commodity operations with unique worker populations.
- Time limits are the biggest burden to successful worker health and hygiene training and practices. This includes record keeping – which should be limited to a weekly, not daily, requirement.
- Farmers who change staff on a regular or seasonal basis should not be hampered by excessive training regulations.
- Regulations should be commodity-specific.
- Regulations should be science-based.
- Regulations should include education on *why* worker health and hygiene is important.
- Regulations also need guidelines for treating and storing re-usable gloves.
- Regulations should provide guidelines for incentivizing supervisors to enforce regulations.
- Supervisors have difficulty identifying sick workers. Guidance for identifying sick workers (symptoms to look for, basic tests), and suggested leave-time based on specific illnesses would assist supervisors in managing sick workers.
- A universal grower audit would reduce “audit fatigue” for small farmers. Audits are very time intensive, and time is a limited resource for many small farmers.

III. Wildlife and Environmental Concerns

Dr. Karen Lowell, Lecturer at the University of California, Santa Cruz, presented on issues related to wildlife based on a case study of California’s Central Coast and presented in the paper *Co-Managing for Food Safety and Ecological Health in California’s Central Coast Region*.²⁶ Dr. Lowell acknowledged that some members of the audience may have contributed to the development of this report as approximately 100 growers in this region were interviewed.

Dr. Lowell noted the tension between food safety and environmental concerns. In the interviews and surveys 91% of growers from the region reported incorporating at least one conservation practice in their operation. They also reported being pressured by auditors and inspectors to change on-farm practices in response to food safety concerns, often to the detriment of conservation practices. Such changes include the restriction or elimination of wildlife and their habitat from farm land, removal of non-crop vegetation and removal of water bodies. Specific practices noted include the removal of

²⁶ A summary of the paper *Co-Managing for Food Safety and Ecological Health in California’s Central Coast Region* is available online at http://www.producesafetyproject.org/discussion_series.

wetlands and riparian buffers, which leads to a reduction in water quality, and the use of poisons to eradicate rodents and frogs. Dr. Lowell explained that the bare ground buffers that replace vegetation can increase the ease of flow for pathogens, and that the poison in bait can bioaccumulate up the food chain. Dr. Lowell indicated that contamination processes are poorly understood, and this is an area of active research. In the paper, the authors reviewed studies on how wildlife affected food safety. The CDC names five “animals of significant risk”: cattle, sheep, goats, pigs, and deer. The National Leafy Green Marketing Agreement, based on the CDC findings, identifies only deer and feral pigs as wildlife of concern. Private standards required by retailers, however, often list many more wildlife species with questionable scientific basis for doing so.

Dr. Lowell put forward the idea of “co-management” in which food safety and environmental concerns are both addressed. This concept emerged in the course of developing the report and through dialogue with many of the stakeholders involved with growing produce. Co-management begins with the assumption that farmers want to produce safe food and be good land stewards, and that both can be achieved in an economically viable fashion. However, according to Dr. Lowell, a number of obstacles exist, including:

- The numerous private food safety standards that (i) lead to inconsistent interpretation and application, (ii) contribute to a food safety “arms race,” (iii) are developed with a lack of transparency, and (iv) are based on an unclear scientific basis;
- Mounting liability and litigation risk;
- The potential effects of national food safety standards, which may not necessarily support a co-management approach;
- An industry movement towards value-added products which are connected with food borne illness outbreaks, and cause a backlash on the farmer; and
- A lack of scientific data on just how to minimize risk.

In the short question and answer session that followed her presentation, Dr. Lowell made the following points:

- Since corporate food safety standards are considered proprietary information, it is difficult to know how much the increase in value-added products is driving the use of these standards. The issue of rodents and frogs may be less about food safety risk and more about food quality.
- The agricultural industry needs to work collectively to ensure the new rule will be effective. Individual farm actions to deter wildlife, such as fencing along a stream, when combined with other neighbors who use the same practices, have a detrimental impact to the ecosystem (in this case, destabilization of wildlife migratory passages).

Wildlife and Environmental Concerns Breakout Sessions

Following the morning presentations, meeting participants were given the opportunity to attend breakout sessions to continue discussing wildlife issues. The following themes came out of the sessions:

Regional Considerations

- Some regional growers use rehabilitated wetlands as a control mechanism to promote wildlife in one area, effectively deterring that wildlife from damaging crops in other areas.
- Feral dogs are a great concern in desert farming areas.

- Property values in California are already extremely high, and growing valuable crops increases the property value – and the property costs – to growers even more. Some of this property has been in families for multiple generations. They have made investments for years to improve the fertility of their land, and now the various standards are ruining these investments.

Local Practices

- Most growers follow the LGMA.
- Tracking wildlife migratory patterns is an important part of understanding contamination risks. Wildlife tracking practices in the region range from visual confirmation and tracking, to laser fencing systems.
- There are many competing standards for buffer distances; for example, the LGMA requires a no-harvest buffer of 25 square feet around any feces, and a 3-foot radius around tracks for animals of significant risk such as cattle, sheep, and goats – other buyers require 50-foot buffers between field mice traps or feces and harvestable crops.

Standards and Audits

- The new regulation should closely mimic the LGMA. However, the paperwork is very time-consuming and costly.
- There needs to be coordination between FDA, USDA, and the Natural Resources Conservation Service at the federal level, and in California, between EPA and Water Quality Boards.
- Regulations should take into account what other agencies with purview over wildlife (e.g., Fish and Wildlife Service, EPA, and state agencies) require regarding wildlife. There should be explicit guidance for growers to follow.
- No grower should be exempt from any agency regulation.
- A risk assessment tool/matrix should include clear definitions of wildlife of concern, commodity-specific guidance, and wildlife specific guidelines for reaction controls specific to the proximity to feces, tracks, and traps.
- Regulation should aim to balance preventive controls with reactive practices. Prevention of pathogen transference is just as important as reactions to potential contamination.
- Regulations should include minimum requirements and maximum allowable wildlife control practices to ensure that all grower practices are in a safe range that avoids inter-agency conflicts. Constraints should ensure that “scorched earth” policies are not legal, while decreasing the risk of litigation against the growers, packers, shippers, and buyers. Make sure that control practices for one species do not have unintended consequences for another species.
- Commodities that are cooked or have a kill step have a significantly lower risk of outbreak and should be regulated differently.
- The regulations will need to be open to adaptation as new science supports different practices.
- Some of the control practices are not financially realistic for small farmers. For example, a 50-foot managed buffer around crops could force a small grower to lose a substantial percentage of their cropland. One acre is roughly valued at \$3800, and losing that property for buffer controls may outweigh the benefits to continuing business.
- Training for wildlife management and control is time-consuming and costly. Hiring staff that are technically capable to do this work increases financial, paperwork, and time

burdens on the grower. Small grower operations cannot hire a person to be dedicated to this task.

Research and Education

- There is a need for science on wildlife as a vector.

IV. Composting Issues

Ms. Betsy Bihn, Program Coordinator for the National Good Agricultural Practices (GAPs) Program at Cornell University, presented an overview of composting issues and key scientific information, as laid out in the paper *Composting Criteria for Animal Manure*.²⁷ Ms. Bihn noted that different manures have different compositions, which affect the composting process. She explained that incomplete treatment of manure can contaminate food. The prevalence of a type of manure varies by region, and the prevalence of pathogens in the manure varies greatly.

Ms. Bihn listed three types of composting systems: aerated, windrow systems, and in-vessels systems. Pathogens can be inactivated in compost during three stages: mixing the compost, raising the temperature, and curing. Ms. Bihn then reviewed some of the factors influencing pathogen inactivation, which can vary by type of manure. She explained that even if compost tests free of pathogens, that does not mean that there are pathogens in the manure prior to the composting process.

Ms. Bihn noted that there are no universal standards for composting to eliminate harmful pathogens, such as *E. coli* and *Salmonella*. Compost is primarily regulated at the state and local level, and there is no federal oversight. These regulations vary greatly in scope and complexity. While many jurisdictions use EPA guidelines 40CFR Part 503 for end product and process criteria, there are still variations in the current non-uniform standards with regard to time, temperature, finished product testing, and required frequency of facility monitoring.

In *Composting Criteria for Animal Manure*, the researchers made the following recommendations:

- Require insulating covers on all types of compost piles.
- Include a minimum curing period to ensure the completion of pathogen inactivation.
- Procedures to control risk, i.e., regular verification of equipment accuracy for pH and temperature testing.
- Require compost operations to have standard operating procedures, a quality assurance plan, and a Hazard Analysis Critical Control Point (HACCP) programs.

In the short question and answer session that followed his presentation, Ms. Bihn made the following points:

- Covered compost reduces the potential for contamination and increases the internal compost temperature to kill pathogens.
- Individualized Standard Operating Procedures (SOPs) may be the most appropriate way to certify regulatory compliance across regional variations. The important point is to have a compost management plan and then implement the steps necessary for safe use of compost.

²⁷ A summary of the white paper commissioned by the PSP on compost issues is available online at http://www.producesafetyproject.org/discussion_series.

- The EPA rule was developed for continued degradation and death of pathogens over time, not complete elimination of pathogens.
- The USDA National Organic Standards (NOS) rule is based on qualifying products as organic, not on safety and risk management.

Composting Issues Breakout Sessions

Following the afternoon presentations, meeting participants were given the opportunity to attend breakout sessions to further discuss composting issues. The following themes came out of the sessions:

Local Practices

- Many California based organic farmers follow the National Organic Standards (NOS) guidelines for composting.
- Growers indicated a regional preference and support for the adoption of the California code of regulations for composting yards as a baseline for new regulations.
- Several regional growers are requesting testing prior to purchase, and are refusing compost that has not been recently tested. Regulations should include mandated testing timeframes prior to the sale of compost.
- Small farmers are limited in their financial capacity to hire a third party to test for *E. coli* and *Salmonella*. Testing for additional pathogens is only a marginal increase to the cost of testing in general, the most expensive component of which is the man-hours.

Standards and Audits

- The California code of regulations for composting yards would be a good baseline for new regulations.
- Time and temperature requirements need to be science- and risk-based.
- There should be tracing of compost from feedstock, through the composting yard in individual batch piles, and up to application in the fields.
- Batch pile turning and sampling regulations should be adaptable for different sized operations.
- Compost transporters need standard operating procedures to prevent cross-contamination.
- If compost tests pathogen free there should not be time limits between application, planting, and harvesting.
- Tree crops have a different risk assessment for pathogen exposure through compost than in-ground crops and should be treated with different regulations.
- Record keeping is a necessary component to enforce regulatory compliance and provides legal defensibility for growers who use compost.

Research and Education

- There is a lack of available training resources for composting and the application of compost in this region.
- A variable minimum application-harvest interval that is risk-based and commodity-specific.

V. **Irrigation and Foliar Contact Water Quality**

Dr. Trevor Suslow, the Extension Research Specialist at the University of California, Davis, Department of Plant Sciences, presented an overview of issues related to irrigation and foliar contact water, as laid out in *Standards for Irrigation and Foliar Contact Water*.²⁸ Produce and niche-crops use a variety of types of irrigation from diverse water sources. About seventy percent of U.S. commercial farmland is irrigated and because of issues related to nature, value, and perishability, much of the produce crop in this country are under some form of managed irrigation. Due to the intimate contact with the edible portion of the crop, the quality of the water is very important for food safety considerations. Water quality becomes more important the closer to harvest. There is still much unknown about how water quality affects food safety based on region, crop, or management practice. Dr. Suslow reviewed some of the ways irrigation and foliar contact water may become contaminated. For example, groundwater can be contaminated by surface water events, and fecal contaminants and pathogens have been found in irrigation water.

Dr. Suslow then reviewed the state of the science. He highlighted two main concepts: the risk potential for water is very high and the risk exposure is highly variable. Pathogens are known to survive in water and sediments for long periods of time. Dr. Suslow identified a knowledge gap for water quality because of a lack of uniformity in testing methods and standards, and a lack of a national database for irrigation water quality. In addition, current water quality standards are inadequate, poorly defining the relationship between indicators, pathogens, and risk. Dr. Suslow noted that growers need to be able to differentiate between high- and low-risk irrigation water, and that auditors need to recognize the variable risk based on a number of factors, including the water, the crop, the location, and the post-harvest handling.

Dr. Suslow noted that many regional GAPs and commodity-specific guidelines have adopted the EPA recreational water quality standards for irrigation water. He expressed concern about this trend because the EPA criteria were not intended to apply to risks associated with irrigation of edible crops and do not take into account the die-off of pathogens post-irrigation. He also noted that the FDA commodity-specific guidance recognizes that there are currently no clear standards, and growers are responsible for using water of “appropriate quality.” Dr. Suslow recognized regional support for the LGMA metrics for water quality and shifting irrigation sources.

Dr. Suslow ended his presentation with the following list of recommendations:

- Implement sanitary water surveys on the farm;
- Broaden the characterization of irrigation water sources before including the current GAPs standard;
- Commit to two seasons of frequent sampling;
- Find appropriations to assist small farms; and
- Adjust the water quality standards as justified by the data and models.

In the short question and answer session that followed his presentation, Dr. Suslow made the following points:

- Testing regulations will need to be consistent across varying irrigation sources.
- Algae can harbor and protect harmful pathogens. More research is needed to understand the impact algae have on water sampling and pathogen transference.

²⁸ A summary of the white paper commissioned by the PSP on issues related to irrigation and foliar water quality is available online at http://www.producesafetyproject.org/discussion_series.

Irrigation and Foliar Contact Water Quality Breakout Sessions

Following the afternoon presentations, meeting participants were given the opportunity to attend breakout sessions to further discuss irrigation water issues. The following themes came out of the sessions:

Regional Considerations

- Growers noted a trend in outbreaks tied to seasonal change, specifically during late summer. Scientists should pursue research to understand what is different about water during that time and what can be done to prevent outbreaks.
- Regional lab and water quality testing infrastructures are not consistent, and in some regions are insufficient. Growers indicated costs for water quality testing range from \$12 per sample where labs are accessible to \$100 per sample where water samples need to be shipped long distances (Hawaii).

Local Practices

- Many regional growers are capturing runoff water for re-circulation into their irrigation systems.
- Many California growers are using rainwater harvesting as an irrigation source.

Standards and Audits

- The LGMA standards are widely accepted in the region, and many growers indicated a level of comfort in adopting similar standards nationally. The LGMA guidelines for sanitary surveys could be adopted into national regulations and offer adaptability to include regional variance.
- Regulations should recognize that the most effective risk management water quality testing is correlated with direct use periods. This ensures that testing is cost-effective and not an excessive burden on small farmers.
- Regulations need to ensure consistency in implementation costs across regions and commodities. (One grower indicated that current produce regulatory changes added \$400 in production costs per acre to growers in California, but only \$34 per acre to citrus farmers in Texas.)
- Regulations should be applicable to farmers of all sizes.
- Varying irrigation sources and water uses should be factored into water quality risk assessments.
- Regulations should be adaptable as new scientific research produces new information.
- Water quality testing regulations need to have a minimum standard for growers of all sizes, and a ceiling to protect growers from liability and the water quality testing “arms race.”
- All members of the produce supply chain should be required to keep a microbiological history of the water they use.
- There should be risk matrix for commodities that farmers could use in performing risk assessments for their variable water sources and irrigation methods.
- There should be a balance between the need for numbers-based regulations that ensure standardized auditor interpretations and the need for adaptable regulations for varying practices and Standard Operating Procedures.
- Regular auditor training is needed to ensure consistency in inspections and common sense enforcement of regulations.

- There is a tension between confidentiality and shared public knowledge of water quality test results. Confidentiality is needed to protect farmers against potential lawsuits, and shared knowledge is needed to create resource efficiencies.

Research and Education

- There is a lack of scientific knowledge supporting number-based standards for pathogen testing.
- Farmers who share water sources (such as irrigation canals) should share testing burdens and knowledge/results to maximize resource efficiency over potential shared risks.

VI. FDA and USDA Question and Answer Session

Jim O'Hara opened the question and answer session by expressing the hope that the meeting participants found the day helpful and educational.

Jim Gorny, Senior Advisor for Produce Safety, FDA Center for Food Safety and Applied Nutrition, summarized the messages he heard over the course of the meeting: (i) the complexity with regard to both the diversity in crops, practices and growing regions, as well as the multiple regulatory agencies involved in food safety points to the need for a holistic approach to regulation; 2) more research is needed on the science and economic costs of preventive controls; (ii) the rule will need to define risk and individual risk factors; (iii) the rule will need to provide uniform guidance for preventive controls for each risk factor; (iv) scale appropriate compliance and inspection regulations will define record keeping differences for different types and sizes of operations; and (v) there will be a level playing field for imports and domestically grown products.

Dr. Gorny reiterated that the FDA's docket is open until May 24th for public comments. He indicated that the role of state departments and federal agencies in enforcing regulatory compliance will be part of the discussion moving forward.

The meeting participants were then given the opportunity to ask questions of the USDA and the FDA representatives. In response to questions from participants, Dr. Gorny made the following comments:

- An effective FDA rule mandates outcomes and allows industry to figure out the best practices to meet those outcomes.
- Universal testing standards and timing will ensure a level playing field for different sized producers.
- The rule will be a combination of generic approaches and outcomes based language with FDA guidance. This will provide for a flexible rule that can respond to new learning and adapt over time.
- FDA inspections and compliance guides will ensure audit consistency.

Individual meeting participants also made the following points:

- The Produce Traceability Initiative (PTI) is an innovative effort to develop traceability systems, and should be considered as a component of regulation in the future.
- The rule should be simple, straight forward, and consistent for all producers.
- Imported produce should be vigorously tested.

VII. Concluding Thoughts

Mr. O'Hara thanked the meeting participants for the commitment of their time, and expressed the hope that the meeting was valuable to them. The comments that come from the meeting will be collected into a summary and formally submitted to the FDA open docket. Mr. O'Hara encouraged participants to submit comments to the FDA open docket using the road map on the PSP website (<http://www.producesafetyproject.org/>).

**Produce Safety Project
Stakeholders' Discussion Series**

Meeting Summary

*April 27, 2010
Salinas, CA*

Goals and Outcomes

- *Increased understanding of the science underlying enhanced produce safety practices, including:*
 - *What we know, and*
 - *What we do not know*
- *Increased understanding of practices that are, or could be, contributing to enhanced produce safety.*
- *Identification and discussion of any regional practice considerations important for enhancing produce safety.*

I. Welcome and Workshop Backgroundⁱ

Erin Bongard, Deputy Director of the Produce Safety Project (PSP), thanked the meeting participants for taking the time to attend the meeting. Ms. Bongard explained to the group that the Food and Drug Administration (FDA) is in the process of developing a produce safety rule which will govern the growing, harvesting, and packing of fresh fruits and vegetables. PSP designed the Stakeholders' Discussion Series, of which Salinas is the last of six meetings, to provide stakeholders an opportunity to share with FDA and the U.S. Department of Agriculture (USDA) their on-the-ground, firsthand knowledge and experiences of growing fresh fruits and vegetables, and to voice questions and concerns they have about the proposed rule. Ms. Bongard noted that this was a chance to talk to FDA officials about the proposed rule before it is issued.

Doriliz De Leon, Consumer Safety Officer in the Division of Enforcement, Office of Compliance, at FDA's Center for Food Safety and Applied Nutrition, stated that foodborne illness is an issue of increasing concern in the United States. She acknowledged that the produce industry is very complex and diverse with operations of varying sizes that utilize different practices. Ms. De Leon noted that the FDA has heard growers' concerns that any regulation must be based on risk and science and commented on the importance of the collaboration between the FDA, USDA and state and local governments. She noted that this rulemaking process was unique because the FDA has opened their public docket prior to the drafting of the proposed rule which will allow growers to share their comments early in the process. FDA officials have been meeting with growers across the country to

ⁱ The Salinas, CA meeting was held primarily in Spanish. Comments above have been translated from Spanish to English for this summary.

hear their comments and discuss their practices on the farm Ms. De Leon encouraged participants to submit comments to the open docket, which FDA will review and consider when drafting the rule.

Brett Melone, the Executive Director of the Agriculture and Land-Based Training Association (ALBA), explained that ALBA is an organization that connects growers to markets and thanked participants for coming to the meeting. He also thanked Ms. De Leon and the FDA for explaining the rulemaking process, which is not something that is well understood. Mr. Melone offered ALBA's assistance to any participant who would like to submit comments to the FDA as comments need to be submitted in English. ALBA will hold workshops or training sessions. ALBA will focus on food safety by offering technical assistance and training to growers.

Jessica Notini, the meeting facilitator, reviewed the meeting agenda, materials, and expectations. She stated that everyone has the same goal: to achieve food safety while allowing small farms to survive and prosper, and protecting the environment.

The discussion topics for the meeting consisted of the four issue areas identified as concerns for food safety: compost, irrigation and foliar contact water quality, worker health and hygiene, and wildlife and environmental concerns. The authors of the reports or their designees, presented an overview of each issue area, and the meeting participants were given the opportunity to attend breakout sessions to discuss the issues in more depth. The summaries of the presentations and the breakout sessions are below.

II. Worker Health and Hygiene

Dr. Bob Gravani, Professor of Food Science in the Department of Food Science at Cornell University and author of *Farm Worker Health and Hygiene*, presented on issues related to worker health and hygiene²⁹, gave an overview of the food safety issues surrounding worker health and hygiene. He explained that workers are vital in keeping produce safe because they are the ones who harvest, sort and pack the produce. He noted that farm workers tend to not have access to health care because of economic status, lack of insurance, a language barrier, or lack of physical access to medical services. Workers risk contaminating the produce they work with. Growers need to think about how to reduce the likelihood of contamination from farm workers.

Dr. Gravani listed the following factors that contribute to produce contamination:

- Lack of adequate hygiene education and training;
- Poor or inadequate toilet facilities;
- Bare-hand contact with the product;
- Lack of contact surface sanitation;
- Inadequate water supply for handwashing and personal consumption; and
- Lack of child care.

Dr. Gravani then noted that the following should be included in worker training:

- Basic health and hygiene education, and the importance to the home and family;
- Good hand washing techniques;
- Personal cleanliness standards;

²⁹ A summary of the white paper on Worker Health and Hygiene commissioned by the PSP is available online at http://www.producesafetyproject.org/discussion_series.

- Appropriate toilet use;
- Proper glove use;
- Jewelry and personal adornment; and
- First aid.

He emphasized that the final goal was risk reduction. He explained that produce safety should be a concern for everyone who comes into contact with the product.

In response to a question, Dr. Gravani noted that training programs can be tailored to meet the needs of workers in different situations, and can be scale-appropriate.

Following the presentation, meeting participants were given the opportunity to further discuss composting issues. The following themes were raised in the discussion session:

- The California Department of Environmental Health is changing the requirements for farmers' markets related to food safety. They will require more specific and higher standards.
- Many workers tend to be daily or short-term.
- Many workers live in high density housing where it may not be possible to get daily showers.
- Gloves are sometimes worn more to protect the worker than the product. If that is the case, the gloves may not be changed as frequently.
- If gloves are changed daily, the cost can be high depending on the size of the operation and the number of workers.
- If workers are sick, they do not have a real incentive to tell their boss because there is no paid sick leave, or they fear retribution or losing their job.
- One grower trained the supervisors at the beginning of the season on basic health and hygiene topics and taught them how to spot symptoms of illness in the workers. The supervisors then trained the workers. This was backed up with internal audits, weekly visits with each crew, and documentation. Before the day begins, the supervisor leads the crew through a series of stretching exercises, and a daily training session on a specific health and hygiene topic.
- One grower required his workers to shower before starting work every day, but that is not possible for every operation.
- Communication between the owner and the workers has to be daily and continuous.
- Smaller farmers need more help and attention from the government.
- No matter the size of the farm, it is important that workers wash their hands, have access to clean toilets, and have gloves.
- One grower recommended that growers should be required to go to a set number of hours of training a year as a prerequisite of selling their product.
- Using the internet for training materials is possible for some farmers, but not for others.
- The National Good Agricultural Practices (GAPs) Program at Cornell University has a course on GAPs in Spanish.

III. Wildlife and Environmental Concerns

Dr. Jeff Langholz, Associate Professor at the Monterey Institute of International Studies, presented on issues related to wildlife based on a case study of California. His presentation was based on a report, *Safe and Sustainable: Co-Managing for Food Safety and Ecological Health in California's Central Coast Region*. Dr. Langholz noted that the study was carried out because of food safety

concerns, and worries about the environmental consequences of food safety practices being implemented on the farm.

Dr. Langholz explained that the research team found that growers are under tremendous pressure to change on-farm practices to exclude wildlife, leading to substantial changes to the farm and creating serious environmental consequences. He stated that there is questionable evidence of significant benefits from removing wildlife, vegetation, or water bodies from farms, yet buyers are requiring growers to do so in order to sell their produce.

The study recommended the principles of “co-management” as a way forward. Co-management includes both food safety and environmental considerations, and would minimize the on-farm microbial risks associated with food, while preserving wildlife and natural resources.

Dr. Langholz noted that farmers are in a very precarious situation where they are making high-risk decisions with very little information. Yet if there is a problem, the farmers are the ones who will be held liable either in the court system or by public opinion. The new FDA produce safety rule could either help or hinder co-management. Dr. Langholz encouraged the meeting participants to provide input to the FDA.

In response to questions from meeting participants, Dr. Langholz made the following points:

- Animals are a problem in the field because they can potentially contaminate the plants.
- Studies have identified pathogens in the fecal matter of wildlife. The level of contamination varied by type of animal.
- Co-management is only an ideal that is hard to achieve if buyers continue to make removal of vegetation and wildlife a prerequisite for selling.

Following the presentation, meeting participants were given the opportunity to further discuss wildlife and environmental issues. The following themes were raised in the discussion session:

- None of the small farmers in attendance had animal production as well.
- Farmers have great pressure to control for animals, no matter the food safety risk, for economic reasons, such as crop loss. Growers noted problems with gophers, squirrels, deer, birds, and snails damaging and eating the crops. A number of growers grew strawberries.
- Birds are source of contamination. Growers see bird droppings on their produce.
- The growers attempted to control wildlife in a number of ways, including bombing gopher holes, flooding gopher holes, aluminum paper to scare birds, walking the fields daily and inspecting plants, scarecrows, barriers, planting less-attractive or tougher crops, and traps.
- One grower has personnel visit every field within seven days of harvest to evaluate if wild animals have intruded. If there is evidence of animal intrusion, then the produce is analyzed. If there is fecal matter, a no-harvest buffer zone of ten feet is put in place if it is a high-risk animal (e.g., cows, wild pigs, deer, goats, and sheep). Any other animal constitutes a buffer zone of five feet.
- Workers need to be educated on the potential of contamination from animal feces. If the worker is paid piece-rate, he may not care about contamination.
- FDA has to understand the risk from each species.
- Growers want information on what the risks are, so they control for those animals, and how to best manage for wildlife.

- There is information available through ALBA and on the Internet on pest management techniques.
- Any trials FDA carries out to control wildlife should be shared with farmers.

IV. Compost Issues

Ms. Besty Bihn, Program Coordinator for the National Good Agricultural Practices (GAPs) Program at Cornell University, provided an overview of issues related to the composting of manure. She explained that raw animal manure can carry pathogens that can spread onto the plant. If done correctly, composting can reduce the pathogen load and create a product that is beneficial for soil health.

Ms. Bihn listed the three main types of composting systems: static, windrow, and in-vessel. Composting can be either aerobic or anaerobic. And pathogens can be inactivated via thermal or non-thermal methods. She noted that the compost feedstocks may vary, which will affect the carbon-nitrogen ratio and influence heat production. The feedstocks also have varying bacterial compositions. The moisture level can also affect heat distribution and inactivation. In order to ensure effective temperature for pathogen inactivation, Ms. Bihn recommended pile insulation.

Ms. Bihn noted the lack of federal oversight for compost, which leads to standards being set at the state and local level, or by composting organizations. Many of these standards are based on EPA 40 CRF Part 503, which regulates municipal Class A biosolids. In California, compost is overseen by the California Compost Quality Council. The National Organic Standards and the United States Composting Council also have compost standards.

Ms. Bihn recommended (i) covering compost piles to retain heat; (ii) a minimum curing time; (iii) equipment verification; and (iv) if purchasing compost, to buy from a seller with standard operating procedures.

Following the presentation, meeting participants were given the opportunity to further discuss compost issues. The following themes were raised in the discussion session:

- None of the growers in attendance currently made their own compost, instead purchasing from a private company. Because of the time necessary to make compost, small growers tend to buy it ready-to-use. There was some concern over the quality of the compost received, despite assurances from the composting company.
- None of the growers used raw manure.
- A number of growers bought compost that had been certified by the CCOF, an organic certification organization.
- The growers depend on the compost seller to ensure the quality of the compost, and whether it is organic.
- Salinas Valley guidelines require compost to be incorporated immediately after application.
- Traceability is very important.
- The standard should require incorporating compost immediately after application, particularly if the compost includes a dusty material such as lime, so that neighboring fields are not contaminated.
- Because of the high variability in the raw material used in compost, perhaps compost should be regulated state-by-state.

- Growers agreed that compost should be covered during the composting process.
- The FDA should consider regulating the feedstock that goes into compost, and identify those that are higher risk for closer scrutiny.
- Growers felt the existing standards and regulations they operate under are sufficient.

V. Irrigation and Foliar Contact Water Quality

Dr. Trevor Suslow, the Extension Research Specialist at the University of California, Davis, Department of Plant Sciences, presented an overview of irrigation and foliar contact water quality. Dr. Suslow gave several examples of outbreaks associated with contaminated water. He noted that water source and use varies regionally and that in California, farmers use a large amount of reclaimed water – something unique to the region. Growers also use varying water sources. Some farms are close enough to municipal water to use that, while others have complex irrigation district systems where water is either from a large public managed reservoir (blue-valve pumps) or recycled water (purple-valve pumped).

Dr. Suslow explained that irrigation water was very susceptible to contamination because there are a variety of ways pathogens can be introduced to the system, particularly with surface water. Therefore, there are many types of prevention programs. For the purpose of his presentation, Dr. Suslow focused on pre-harvest use of irrigation water. He highlighted that the risk potential for water is very high, but the risk exposure tends to be very low and very variable. Pathogen presence in water changes regionally, seasonally, and is affected by human activities and weather events. Once in the water, pathogens can survive for longer than nine months and if in the soil or sediment, even longer.

For foliar contact water, Dr. Suslow explained that growers should ensure appropriate water quality when the water is being applied to a crop that is eaten fresh.

He recommended growers survey their water systems and develop a protection plan to understand what are high versus low risk sources of water. He also acknowledged there is very low correlation between the indicator and actual pathogen contamination, but the indicator testing is the tool currently available.

Dr. Suslow recommended that growers (i) really understand their water sources; (ii) get help if they need it; and (iii) perform at least two seasons of monthly sampling and testing, with additional sampling after any rain event. He also recommended the development of financial support for small farmers to achieve the above, and to adjust the standards for water quality with experience and new science.

Following the presentation, meeting participants were given the opportunity to further discuss compost issues. The following themes were raised in the discussion session:

- The water sources growers use depend on the zone and the weather. In Hollister, the water comes from a reservoir. In Yuma, the irrigation ditches are by canal.
- ALBA has two wells, one of which has high nitrate levels. That one is only used in the irrigation lines. The well with lower nitrates is used for drinking and washing.
- Water conservation is a critical issue in California. One grower determined how much water was necessary based on the soil, and also recycled and reused water. The recycled water is sampled. This grower was concerned that these conservation practices are being

- threatened because of food safety reasons. One private company set a maximum percentage of the total water source that can be recycled water.
- Despite testing the water to assure it is safe, there could still be problems in the field.
 - ALBA requires its growers to monitor their water and do monthly sampling. At the beginning of the season, growers have to look at their source water and their distribution system. Growers also have to test the soil.
 - Organic growers have to follow testing requirements for water and soil.
 - Small growers feel burdened by the amount of testing required, and can never achieve the level of testing that larger operations do.
 - Growers have multiple crops on their farms, and crops that have multiple harvests. A standard that requires water sampling prior to harvest may be very burdensome depending on how it is written and implemented.
 - Monthly testing is costly and may be unnecessary if the water repeatedly tests safe. The FDA should consider a less frequent monitoring schedule for lower-risk water sources.
 - Each crop has different norms for water use. For example, lettuce is irrigated by sprinklers and strawberries by drip. The regulation has to take into account the variety of crop and the variety of water uses.

VI. FDA and USDA Observations

Jim Gorny, Senior Advisor for Produce Safety, FDA Center for Food Safety and Applied Nutrition, thanked the meeting participants for taking the time to attend. He expressed his appreciation for the opportunity to hear from both small and large growers at the table and encouraged the growers to submit their thoughts, ideas, and comments to the public docket. He acknowledged the complexity and diversity of the produce industry. Dr. Gorny stated “nobody disagrees with the risk factors of water, workers, wildlife and compost. What we are struggling with in the FDA is how to achieve a regulation that assures public safety and confidence in the consumer and protects the vegetables and the livelihoods of our families safety, public confidence, and protects the livelihoods of growers of all sizes around the country.”

Dr. Gorny listed some of his observations from the meeting, including (i) the importance of training materials that are user friendly; (ii) economic impacts of wildlife are huge; (iii) the need to co-exist with wildlife while ensuring food safety on the farm; (iv) when purchasing compost, the growers are at the mercy of the seller; and (v) minimize the number of standards wherever possible, and build on what already exists.

The meeting participants then had a short discussion session with Dr. Gorny, and made the following comments:

- FDA should look into existing standards put out by other organizations, and learn from those. The agency should not start from the very beginning but should build on the work that has already been done.
- FDA needs to be aware of the risks that occur once produce has left the farm. For example, fresh produce is often transported in open air containers which present a risk that the grower has no control over.
- Many food safety problems occur when produce is processed and beyond the control of the grower.
- The FDA should consider identifying in the regulation practices farmers are asked to implement for food safety concerns, but have a questionable scientific basis. Mr. Gorny

- said he would have to consult with the FDA attorneys.
- Produce farms are moving into higher-risk areas, such as near roadways or downstream of potential contamination sources.
 - Different farms have different risk profiles and each should determine its own risk from water, wildlife, domesticated animals, etc.
 - The standard should be science-based.

In response to questions and comments, Dr. Gorny made the following additional points:

- The FDA is working closely with USDA and the National Organic Standards (NOS) to understand what each does and does not do. Most foodborne illness is caused at the point of handling, but those typically have no long-term health issues. When outbreaks are caused on the farm, those have been more severe. While FDA has been focusing on the farm and packing house, it understands that food safety is everyone's responsibility.
- The United Fresh Produce Association is spearheading an effort to pull together all the owners of the various standards to try and develop a harmonized good agricultural practice (GAP) audit, which FDA will receive a copy of. But the FDA rule cannot prevent company standards that ask more of the growers.

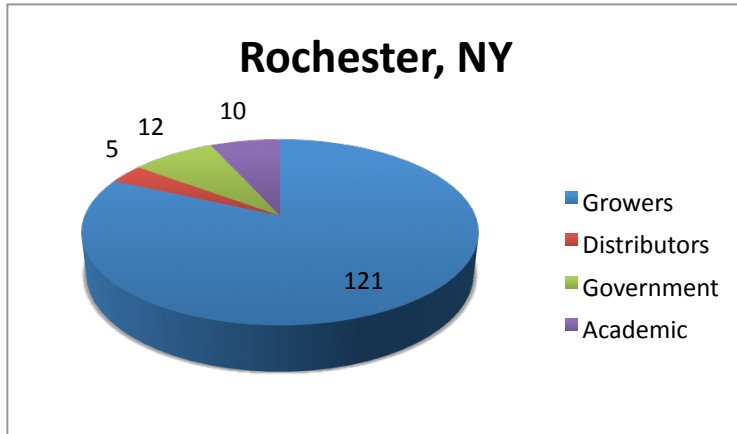
VII. Summary and Wrap-Up

Ms. Bongard thanked the participants again for their attendance and for sharing their experience, ideas, and concerns. She noted this was not the end of the conversation and encouraged the group to continue the dialogue through ALBA and the FDA open docket.

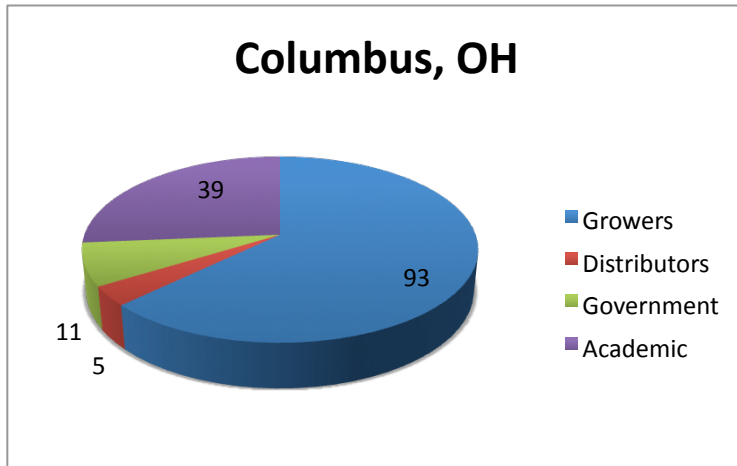
Appendix A Meeting Participants

Total Participants at all Meetings: 734
Total Growers at all Meetings: 530

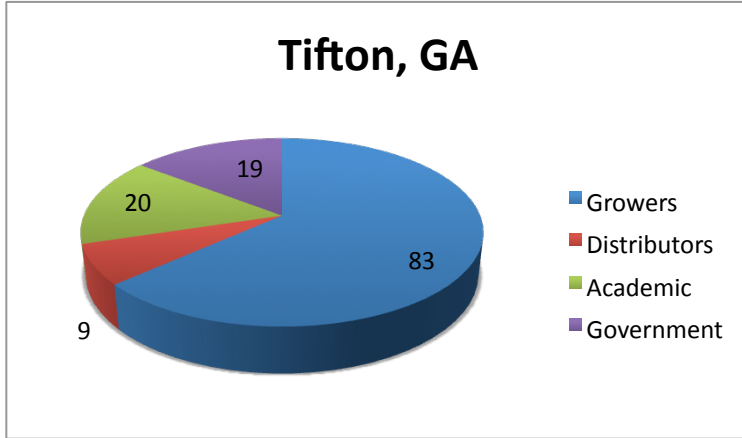
Rochester, NY - Total: 148



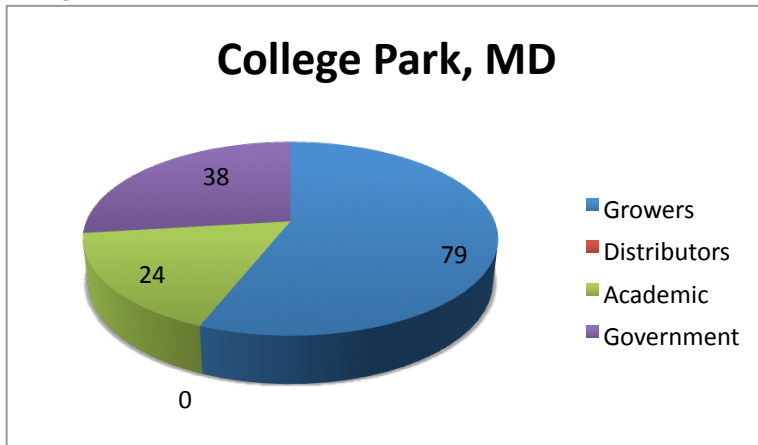
Columbus, Ohio - Total: 148



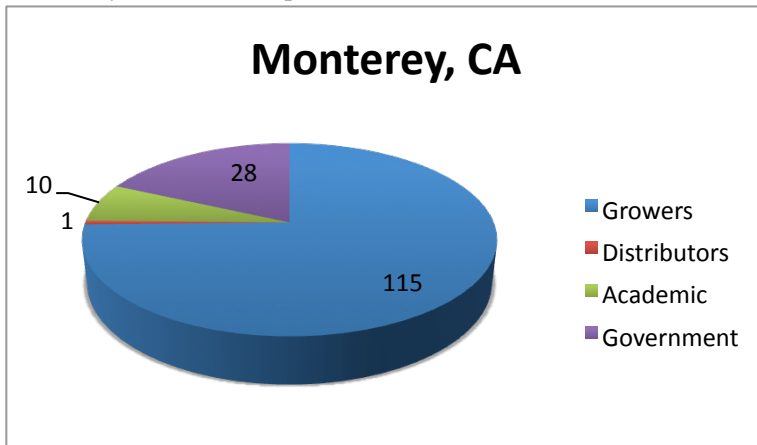
Tifton, GA - Total: 131



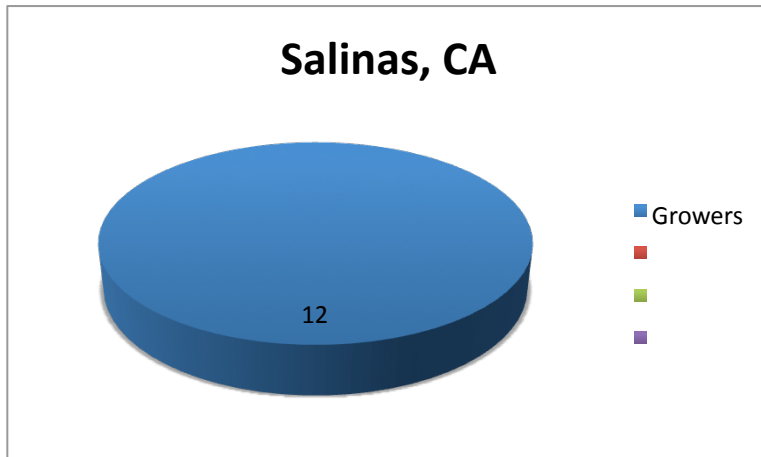
College Park, MD - Total: 141



Monterey, CA - Total spreadsheet: 154



Salinas, CA³⁰ - Total: 12 (combined)



³⁰ Participants were not asked to pre-register for this meeting

Appendix B Meeting Methodology

PSP contracted with RESOLVE, a non-profit mediation and facilitation organization, to partner on the design, facilitation, and summarization of the six sessions making up the Stakeholders' Discussion Series.

Sessions were designed to maximize opportunities for focused input from participants. Efforts to foster this aspect of the sessions included the following strategies:

- *Detailed preparatory work, including:*
 - Interviewing a cross-section of stakeholders for input on the focus and design of the sessions, as well as suggestions for key contacts
 - Identifying locations across the country to maximize opportunities for grower participation;
 - Holding a meeting for Spanish-speaking growers with simultaneous translation;
 - Upfront organizational work with local and regional contacts, as well as national stakeholders to gather their input for how best to make the sessions a success and fully take advantage of the opportunity to provide input on the developing produce safety rule;
 - Partnering with a local academic institutions, or organizations to sponsor the session;
 - Tapping networks of local and regional grower and other produce supply chain stakeholder organizations; and
 - Conversations with the speakers and other expert researchers to organize the presentations to best fit the audiences and convey the information most effectively to launch dialogue.

- *Agenda design, including:*
 - Setting an inviting tone up front through comments by Jim O'Hara, director of PSP, as well as officials from the Food and Drug Administration, the U.S. Department of Agriculture (USDA), the co-sponsor of the event, and a local leader of the grower community;
 - Establishing meeting protocols to encourage a positive, problem-solving and respectful tone;
 - Providing an appropriate mix of time allocated to presentations on the science for each topic, as well as time in small group break out sessions for more interactive discussions;
 - Professionally facilitating the full and small group break out sessions, including a full meeting conducted primarily in Spanish with simultaneous Spanish to English and English to Spanish interpretation.
 - Providing time toward the end of the session for federal officials from FDA, USDA, and the leaders from the local grower community to reflect on some of the ideas and suggestions they heard during the day to demonstrate their paying attention and respecting the input provided;

- Encouraging participants to communicate comments to the FDA through a “How-To Guide” with easy to follow instructions on how to submit further comments to the FDA docket via mail or email and including this information in their meeting packets.
- Providing additional information for how the information from the sessions will be used.
- *Meeting follow-up, including:*
 - Placing information on the PSP website, including full papers, video of the formal sessions, and other materials;
 - Developing summaries of each of the sessions and this Executive Summary; and,
 - Submitting comments directly to the FDA docket.