Introduction

The purpose of this summary document is to record the key points and recommendations that were discussed over the course of the conference. We hope that the information contained herein will help stimulate further conversation and consensus on effective strategies to implement the agricultural water quality standards in the Produce Safety Rule. At the time of the conference, the re-proposed standards had not been released for public comment, so the issues discussed in this report do not require an understanding of the numeric value of the standards proposed in the supplemental. Instead, this conference which was held in April 24-25 focused on the issues of jurisdiction, economics, accessibility, and implications of water quality testing of irrigation water supplies.

Conference Overview

In April of 2014, the Western Center for Food Safety hosted a two-day conference on the campus of UC Davis aimed at identifying impediments to implementation of the agricultural water quality standards proposed under the Produce Safety Rule (PS Rule) portion of the 2011 Food Safety Modernization Act (FSMA). The conference was co-sponsored by the FDA’s Center for Food Safety and Applied Nutrition (CFSAN) and The University of California’s Division of Agriculture and Natural Resources (UC-ANR). The primary goals of the conference were to:

- Identify key impediments to widespread adoption of the agricultural water quality standards in the proposed Produce Safety Rule.
- Clarify the relationship between ownership of irrigation water and responsibility of meeting the microbiological standards of agricultural water.
- Clarify natural resource and drinking water policies that are congruent with adoption of FSMA’s agricultural water quality standards.
- Discuss potential consequences of microbial water quality regulation
- Identify actionable solutions to key impediments and to facilitate these solutions under FSMA.

More than 100 people were in attendance, representing 8 states, 7 academic institutions, 12 grower and commodity advocacy groups, 5 regulatory entities, 3 resource management agencies, and multiple advisory and consulting organizations. The following summary attempts to capture the key points that were discussed during the conference and does not represent opinions from any one organization or individual.

Update on the Proposed Rule and Timeline for Compliance

In 2011 Congress signed into law the Food Safety Modernization Act. Part of that law mandates that the FDA create and enforce a rule that addresses safe handling practices for fresh produce, including a microbial standard for water quality in the production system. The proposed PS Rule was announced in January, 2013.
and opened for public comment. After thousands of comments and public concern about specifics of the proposed PS Rule, FDA announced in December, 2013 that it would revise portions of the proposed PS Rule specifically relating to microbial water quality. The proposed “Supplemental Rule” was released in September of the 2014 and will be followed by an open comment period, similar to the first proposal.

Things we can anticipate in the Supplemental Rule:

- An objective, science-based, numerical standard
- A standard targeted toward particular commodities, growing methods, irrigation sources, and application methods
- A standard seen as part of the larger system, considering pre-/post-harvest practices and microbial die-off in the produce field
- A standard that is practical and achievable without imposing undue costs

Timeline: The Produce Safety Rule under FSMA will be finalized by October 2015. As proposed, there will be a tiered phase in period of compliance with larger operations needing to comply with majority of the PS Rule two years after the effective date. Operations defined as small business and very small business will have compliance dates three and four years (respectively) from the effective day. There is an additional two years from each compliance date to reach compliance with certain agricultural standards, including the microbial water quality standards.

The FDA has also stated that it will be developing an environmental impact statement to determine the scope of potential impacts.

**Identifying Impediments and Solutions**

The first day of the conference was organized to identify and address potential impediments to widespread adoption of the standards in the proposed rule. Panelists and speakers from a wide array of agencies and interests groups spoke on historical issues of water quality and water rights, while others discussed their perspectives on ownership of water and responsibility for water quality monitoring.

The purpose of the second day of this conference was to begin to work towards solutions to some of the issues discussed on day one. It should be emphasized that the FDA understands that outbreaks will still occur, however the purpose of these regulatory measures is to help reduce their frequency and mitigate a portion of the risk. As was elegantly expressed by one of our invited speakers, we are all on a food safety journey. Continued communication and coordination will be vital as we move forward, along with constructive input from the agricultural community as regulations are being implemented.

**Top Issues Discussed**

**Day One (Impediments):**

- Exemptions for small growers create uncertainty, yet adherence to proposed standards could be devastating to small growers.
- Irrigation districts unlikely to assume liability for delivery of water of a certain microbial standard, particularly when they do not control the source water or are responsible for delivery to covered and non-covered produce commodities.
- Good stewardship of water resources may require the use of recycled water, hence, a policy needs to be developed that will support and encourage responsible use of a potentially scarce commodity.
• Produce market drives majority of GAPs compliance, exemption from regulation does not make growers exempt from market demands.
• Currently too few labs can accommodate the influx of water monitoring samples, with lab access in many rural areas either non-existent or logistically infeasible given current sample hold times.
• Need to find ways of adding value back to growers, through increased efficiency, production or market value in order to gain greater acceptance of the new regulations.
• Issues of externalities, unintended consequences, or impacts must be considered carefully and addressed in collaboration with resource agencies and growers.
• Need for pooled resources and information sharing between growers and irrigation districts so that growers can make management decisions with the best available data.
• Extensive need for training and outreach programs that empower growers to know and understand the quality of their water and the implications of sources, timing and method of application.

Day Two (Solutions):
• Education and outreach are vital tools for reducing risks; training programs need to be developed that cater to growers, farm managers, field staff, and food safety personnel.
• It is important for growers to know and understand their water systems so changes in quality can be recognized and handled appropriately.
• There is a need for more research to support alternatives to the PS Rule.
• Practical consideration must be given to the enormous effort required to meet regulatory standards, including cost, time, lab access, infrastructure, etc.
• Collaboration is vital but needs leadership at the federal level to foster relationships.
• Proposed regulation is meant to provide significant risk reduction, not risk elimination. Outbreaks will still happen.
• Many treatment methods available for water, chlorine is still the most widely used and cost-effective.
• Treatment is never 100% effective, so reduction of contamination at the source combined with monitoring during distribution are the best strategies for achieving microbial standards.
• Growers are interested in solutions to issues of food safety, but need guidance and leadership.

The following summary comments and questions have been divided into major sub-categories for ease of understanding. While some phrasing may have been changed for readability, every effort was made to maintain the tone and speaker’s choice of words so as to not alter his/her meaning.

Day One Summary: Impediments
The first day of the conference was opened by our two key-note speakers, Mike Taylor, FDA Deputy Commissioner for Foods and Veterinary Medicine, and Karen Ross, Secretary of the California Department of Food and Agriculture. Both of the key-note speakers emphasized the importance of collaboration and partnerships between agencies and growers as we move forward with food safety regulations.

Appropriate standards and understanding of risk:
It is important to make distinctions between the perception of risk and the actual risk associated with water. While water may be able to spread contamination broadly through a system, water has been rarely identified as the source of contamination in the US. It is understood that consideration needs to be given to possible die-off in the field, especially on a per-commodity basis.
Single regions may have multiple water sources, irrigation systems, and commodities. The same may be true for a single grower. There needs to be a reasonable way for growers to understand the differences in risk and in the required standards for multiple practices. This will likely require further research and coordinated outreach and training efforts.

The current system of surface irrigation water conveyance is highly decentralized; multiple agencies and entities govern the distribution of irrigation water from surface sources. This means there are potentially multiple points of contamination and few ways to centrally manage water broadly.

The cost of a perfect system is infinite, therefore there will always be outbreaks, but multiple barriers can reduce potential points of contamination. However, the FDA has received a congressional mandate to address safe handling practices of fresh produce, including addressing the microbial risks pertaining to irrigation water quality. It is essential that the agricultural community recognize that regulation of irrigation water supplies is inevitable; yet this inevitability does not mean there is not room for continued dialogue on the topic.

**Jurisdiction of water:**
Agricultural water is an established beneficial use in some regions, therefore the state water authorities have jurisdiction to ensure that beneficial use is maintained. However, agricultural water not listed as a beneficial use in some states, like Georgia, so it is not protected.

In California, the State Water Resources Control Board (SWRCB) and the Regional Water Quality Control Boards (Boards) are responsible for the movement of water to honor water rights. State water authorities (e.g. SWRCB) have a mandate to protect beneficial and designated uses of water, so standards need to be set that ensure that the greatest use can come from each parcel of water. As our population grows, and water remains scarce or becomes scarcer, regulatory boards have an obligation to maintain flows for agriculture, wildlife, and humans. This will require compromises.

Resource protection agencies like the US EPA, National Marine Fisheries Service, and US Fish and Wildlife Services and similar statues preclude the destruction of habitat and the degradation of water quality without permits. The addition of some chemical treatment agents to an irrigation system could violate multiple statutes if that water is permitted to leave the property.

**Responsibility for water quality:**
It is the broad policy of the American Farm Bureau Federation that it is every grower’s responsibility to produce safe products. Many growers recognize it is their responsibility to make sure their commodities are safe if they expect to gain public trust; this requires an understanding of the quality of irrigation water at point of contact. While the idea of cost and data-sharing appears viable on the surface, most buyers and GAP programs require point of contact testing, therefore sharing testing results between growers or properties may not be feasible.

Growers that utilize ground water have ownership and clear responsibility for the quality of their water source; but many growers, particularly in the West, utilize surface water conveyed by an irrigation district and have limited control over quality. While the growers may order water delivery, irrigation districts do not guarantee either the quantity or the quality of delivered water. It is the responsibility of irrigation districts to deliver water by duty, rate and season of use. They do not have the authority to disinfect water and may open themselves up to legal action if they did.

Irrigation districts are run by boards that are elected or appointed from the local community. They are generally land owners and may be growers themselves. Boards that are made up of covered commodity
growers may decide to adopt water quality standards, or the growers may demand that the irrigation board take action on water quality. This will be different for every district.

However, in many instances covered commodities are grown alongside non-covered commodities yet all of the water is derived from the same source. It is unlikely the growers of non-covered commodities will want to share the cost of monitoring and potential disinfection/treatment if the irrigation districts were asked to do so. Many irrigation districts cover large areas of land and contain many miles of canals that run adjacent to a large variety of land uses not under their control. This much area can be impossible to police or effectively monitor.

If irrigation districts were somehow held responsible, it is unclear to whom they can turn if they receive low quality water from upstream sources (i.e. other districts, land owners, or state or federal sources). Given this fact, and the marketing demand for point-of-contact testing, it seems unlikely that irrigation districts will bear this responsibility in the future.

**Infrastructure, training, and other limitations:**
Currently there are not enough microbial testing labs to accommodate the number of growers and growing regions. Rural locations have difficulty with access to labs, especially within hold times; a backlog of samples may make decision making difficult; and small farms with limited staff cannot afford to leave and hand-deliver samples. Issues of infrastructure abound. There are currently not enough labs to process samples; not enough access to FedEx/UPS shipping; and there may not even be available cellphone or internet access to coordinate with testing labs. Further, some labs only run indicator samples on particular days of the week; there are concerns that if a grower misses that window then their samples are invalidated and they have to start over. Some municipalities perform their own water quality testing in-house, but most do not have the capacity to handle samples from outside sources. Even if growers were able to perform their tests in-house, most buyers demand testing by a certified third party.

Buyers demand point-of-contact testing. While current Leafy Green Marketing Agreement (LGMA) standards allow for 6-month testing if initial rolling geometric mean is below standard, buyers frequently require monthly testing. Some growers have no idea what the quality of their water is at this moment. Even if they did have it tested, they may never see the results. Even if they see the results, they are unlikely to be able to interpret or understand the results. While many microbiological tests are capable of being completed within 24 hours of collection, the reality is that many labs have backlogs and results may not be available for up to 2 weeks. This may pose an issue for growers trying to manage their risk and make appropriate decisions on the ground.

Effort should be made to notify the commercial labs of the planned increase in sampling in the future so that hiring and expansion can take place ahead of the regulation.

**Exemptions and the marketplace:**
While the FDA may not require compliance for a number of years, the retail partners of growers are unlikely to wait. The FDA, nor any regulatory authority, can dictate the standards demanded by the market.

It has been noted that many large growers do not feel comfortable with exemptions for small growers. The feeling is that a practice is either safe or it is not, so exemptions send a mixed message. Yet, many small growers cannot bear the cost and time associated with complying with the standard and could be driven out of business. However, exemption from the regulation does not mean exemption from the market, therefore if small growers hope to sell their commodity they will have to comply and risk going under.

In many instances, product is irrigated via drip or furrow methods that do not come in direct contact, but pesticide and fertilizer application requires direct contact. If pesticide companies mix themselves, they may
not be testing their water supplies. If water being used requires treatment, or the spray vessel needs treatment, there is some concern that chemical reactions between the pesticides and treatment chemicals may take place.

**Exceedances:**
It should be stated that the FDA does not consider product irrigated with water that exceeds the standard as adulterated. The microbial indicators are meant to convey the potential for contamination and provide data on the baseline status of an irrigation water supply. Monitoring allows the grower to see when changes in the irrigation water supply have occurred. The FDA does not require testing for pathogens because that would open the issue of adulteration.

There are currently no plans in place by growers as to how they would respond to an exceedance, mainly because there is insecurity about what an exceedance means. Indicators may be helpful for recognizing the occurrence of a mass fecal contamination, but interpreting the difference between 4 cfu below the standard and 4 above is difficult. If growers do encounter an exceedance, it is unclear what the required actions are beyond documentation of the event and repeated testing.

**Liability, externalities and the cost of complying:**
There are concerns about what happens to the results of irrigation water testing and whether those data impact a grower’s or irrigation district’s liability, or insurance premiums. Insurance companies are struggling to write policies when there is still poor understanding of the risk and the extent of the problem. Small growers may be driven out of business as they struggle to comply with standards driven by marketplace demand. The cost to the grower beyond the price of testing should not be overlooked.

There are multiple potential points of contamination in a produce growing and distribution system, including those that are post-farm. The grower can take all of the precautions required and necessary but once a commodity is in the buyer’s hands, it is out of the grower’s control.

There is a real need for recycled water policy in many arid regions, particularly in drought years. In many regions recycling and reuse of water is critical to agricultural systems and should be encouraged where it does not conflict with food safety goals.

Given the health goals set out by the medical industry, and the value of consuming more fruits and vegetables, the balance between food safety and overall health needs to be carefully considered.

**Silver linings:**
According to its members, the current LGMA testing strategy is relatively cost-efficient and not overly time consuming. It may be possible for other commodity groups to adopt similar strategies or create testing protocols of their own that suit the requirements without being overly taxing. Most growers are not opposed to standards that increase safety and public trust, but dislike the idea of exemptions and window-dressing of food safety regulation that is not grounded in science. Most growers are willing to adapt to increased food safety and water quality requirements, but they need to understand the context. They need help understanding the impact of timing and application methods, and what that means for testing requirements. Most big growers are already implementing GAPs, so it might be possible to pool GAP work to expand education capacity.

Food safety regulations have had some positive impacts, for instance they raise awareness of produce safety and the importance of water quality. There has also been increased willingness to attend trainings and learn about ways to manage for food safety. In the West, regulation has led to increased efficiency, cleaner farms and facilities, and growers have become overall better stewards of the environment.
There is a need for open lines of communication between the regulators and the growers about issues of concern; both sides have proven their willingness to work together.

**Day Two Summary: Solutions**

**Treatment/maintenance strategies:**
The FDA believes that treatment should be the last resort, however treatment may occasionally be necessary. It is important for growers and the rest of the industry to recognize that once you open your distribution to the environment, you can no longer ensure microbial quality, no matter how advanced your disinfection system.

There are multiple federal, state and municipal regulations that may dictate which disinfection and/or treatment practices should or should not be utilized. It is important for growers to recognize other existing statues and to avoid falling out of compliance with those requirements.

Sand filtration systems can be scaled to accommodate different operations and are efficient at removing organic material. They can also be engineered to include chlorine injection. Ozone and reverse osmosis systems are more expensive, but could be solutions for organic growers that must carefully consider their chlorine residuals.

Wells are frequently treated with the addition of chlorine, but it requires the ability to get chlorine to the source of the contamination. This may require taking the well offline temporarily as well as the removal of the pump. Pump removal alone can be hugely expensive, so the most cost effective strategy for well treatment is proper well installment and maintenance. Well location plays a significant role in microbial quality; some states like California have standards that dictate the placement of wells. Following state and county standards of well construction is effective at reducing microbial contamination. Wells installed with a casing and a seal to the proper depth are the best methods for preventing microbial contamination.

**Alternatives and variances:**
Variances apply to state or foreign governments and involve a formal petition process. Variances may be requested for all or a portion of the PS Rule, but include practices that still adhere to the PS Rule. Alternatives apply to growers and are meant to give growers options and flexibility in their monitoring and treatment practices to specific portions of the PS Rule.

Alternatives to provisions must not lead to adulteration of the product; must adhere to the same level of public safety as the practices in the PS Rule; and they need to be supported by scientifically valid research. For example, documentation of alternatives can be done either with peer-reviewed papers or with published guidance from agencies such as Cooperative Extension.

However, alternatives that work in one region or climate may not work in another, and there are currently few studies that examine regional variability in order to provide alternatives to everyone. Additionally, many scientific studies are conducted for different purposes than industry guidance and so publications may not provide interpretation of the data in a manner that is useful for documenting an alternative. Consequently, finding more than one study to back up an alternative could be difficult.

The burden of understanding data for possible alternatives is left on the grower. For many growers who are unfamiliar with scientific literature, it will be difficult to find information that can help support the use of an alternative. Therefore, it is vital that growers understand the behavior of their water systems in the light of the regulation in order to make good management decisions. Understanding water systems may require cooperation, but is a possibly effective strategy for risk reduction.
Training and outreach:
Many growers have a healthy distrust of regulation; it is through education and communication that trust and understanding is built. Yet not everyone learns the same way; training and education programs need to be tailored to different types of learners including visual, written, audio, and physical training.

For many growers, it may be hard to see the need for investment in water quality management practices when they’ve never experienced water quality problems. Educational information explaining the risks associated with water is necessary. While outreach is a valuable tool, many states lack the capacity to meet the need. Cooperation and partnerships are necessary to get growers the information they need to make good decisions.

Next Steps:
While the organizers feel that this conference was a success, it was clear that many issues require further discussion. Based on feedback following this conference it is recommended that an additional workshop be conducted to address and provide recommendations on the following issues:

- Need for outreach and training on proper water sampling, data interpretation, reacting to and resolving water quality concerns
- Addressing general lack of infrastructure in many regions to support regular testing of irrigation water supplies
- Addressing the impact of delayed water testing information on management decisions
- Further clarify who is responsible for improving microbial water quality for public water sources
- Consolidation of available research on microbial persistence, microbial die-off and the timing of water application for a variety of commodities
- Fostering collaboration and communication between regulators, irrigation managers, marketing associations, and growers on issues of irrigation water quality
We’d like to extend our gratitude to the many participants for their collaborative spirit and willingness to engage in active discussion on a topic of importance to us all. We are especially grateful to the University of California Division of Agriculture and Natural Resources for their financial support.

California Cattlemen's Association/SFPUC
California Citrus Quality Council
California Department of Fish and Wildlife
California Department of Food and Agriculture
California Department of Public Health
California Pistachio Research Board
California Poultry Federation
California Walnut Board
Center for Food Safety and Applied Nutrition-FDA
Center for Watershed Sciences-UC Davis
Chiquita Brands/Fresh Express
Dairy Cares
E3 Organics Inc.
Innovative Ag
JV Farms
Keenan Farms Inc.
LGM Consulting
Luhdorff & Scalmanini Consulting Engineers
Maccabee Seed Company
Metropolitan Water District of Southern California
Michigan State University-College of Agriculture and Natural Resources
Naches-Selah Irrigation District
Cornell University
NOAA-NMFS West Coast Region
National Sustainable Agriculture Coalition
Nature Fresh Farms
Northwest Horticultural Council
Oregon Department of Agriculture
Oregon Farm Bureau
Oregon State University
Produce Marketing Association
Ramco Enterprises LP
Rio Farms
San Mateo County Resource Conservation District
South Columbia Basin Irrigation District
California State Water Resources Control Board
Sunkist Growers
Surface Water Ambient Monitoring Program & Lahontan Regional Water Quality Control District
UC Cooperative Extension-Solano County
UC Cooperative Extension-Tulare County
UC Cooperative Extension-Alameda County
UC Cooperative Extension-Contra Costa County
UC Cooperative Extension-Imperial County
UC Cooperative Extension-San Luis Obispo County
United Fresh Produce Association
University of Arizona
University of California, Davis-College of Engineering
University of California, Davis-Department of Land, Air and Water Resources
University of California, Davis-Veterinary Medicine Extension
University of Georgia-College of Agricultural and Environmental Sciences
University of Hawaii
US Food and Drug Administration
USDA-National Resource Conservation Service
Washington State Horticulture Association
Washington State University
Washington Tree Fruit Research Council
Western Center for Food Safety
Western Institute for Food Safety and Security