**2016-2017 USDA Fruit and Vegetable Industry Advisory Committee
Meeting Date: May 9-10, 2017**
Detailed Recommendations and Statements

**FOOD SAFETY**

1. Overview:
USDA, FDA, and the food industry are in the midst of the greatest food safety system overhaul in nearly a century: the development and execution of the Food Safety Modernization Act (FSMA). This important legislation and resultant regulation has significant benefits for public health. Regulators have choices in how to develop rules for industry that fully implement the legislation. When those rules are scientifically sound and effective and also reflect the practicalities and efficiencies of the regulated industry, those public health benefits will be achieved more quickly – a benefit to all. Throughout the FSMA process, USDA has had a staff position serving as a Liaison from AMS to FDA on FSMA, allowing USDA to bring extensive regulatory and scientific expertise and produce industry experience to bear in the development of FSMA regulations, guidance’s, and policy. The importance of continuing this position throughout the full FSMA implementation timeline cannot be overstated: It is critical to ensure that the staffer in this position continue to have the extremely high level of relevant knowledge and experience and that USDA maintain to the fullest extent consistency in the personnel assigned to this duty. We further believe that the existing arrangement, where FDA funds this position at USDA, should continue as both agencies benefit greatly: FDA benefits from USDA’s unique expertise, and USDA benefits by having funding for the position (in an agency that is primarily user-fee, not appropriation, funded), which is devoted to FSMA efforts, an FDA regulatory responsibility.

**Recommendation:**

The Fruit and Vegetable Industry Advisory Committee recommends, in the strongest terms, that the position of Liaison from AMS to FDA on FSMA Issues continue in its current format, scope, funding and staffing for the following reasons:

* This link in terms of scientific and practical expertise, particularly USDA staff’s deep understanding of the fruit and vegetable industry, has proved invaluable over the years of developing and executing FSMA, making regulations effective for public health and practical for the industry.
* The image and reality of collaboration between FDA and USDA on this common issue has reassured everyone that FSMA is about the right outcomes, and regulators are using resources in ways that focus on maximizing those outcomes.
* The long-term approach to dedicating consistent personnel resources over the full time of FSMA development and execution assures the continuity of expertise and experience that would not be possible with year-to-year changes.
* The existing funding mechanism recognizes within the regulatory community and the affected industry that USDA and FDA are committed to best outcomes and willing to work together, even through funding, to assure them.

USDA should approach FDA to prioritize and assure the continuation of this USDA staff position serving as liaison on FSMA to FDA per the existing arrangement through full completion of FSMA implementation, expected to be no earlier than 2022, pending compliance dates. The interaction should include both fully funding the USDA AMS position by FDA and undertaking the steps necessary to extend the arrangement through FSMA completion.

1. Overview:
The Food and Drug Administration’s regulations implementing the Food Safety Modernization Act (FSMA) require the supervisors of farms covered by the FSMA Produce Rule to “have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration.” FDA authorized the Produce Safety Alliance (PSA) to develop that standardized curriculum. The final PSA curriculum requires growers to attend an 8-hour course offered through the PSA or its approved agents. These course offerings cover the broad areas of the requirements of the FSMA Produce Rule. The growers who are subject to this requirement vary by geographical regions, scope of commodities, and various levels of food safety knowledge. The PSA curriculum aims to educate the industry in a “one glove fits all” approach. Due to significant differences across geographical regions, differences in the growing and handling practices of various crops, differences in food safety knowledge, and the unique challenges posed by these factors, the committee recommends the following:

**Recommendations:**

1. The Produce Safety Alliance should collaborate with commodity group organizations to provide commodity-specific trainings (i.e. tree fruits, brambles, vegetables, nuts, strawberries, etc.) that will be recognized as equivalent to the standard PSA curriculum and so satisfy the FSMA training requirement under 21 CFR 112.22(c).
2. The PSA should develop versions of its standard curriculum and any new commodity-specific trainings in a variety of languages to reflect the diversity of the labor force in the US specialty crop industry, and consult with Stakeholders to determine top priority languages for further development.
3. These additional curricula and translations should be developed as quickly as possible and prior to the implementation dates for the Produce Rule.
4. Overview:

As part of FSMA, Congress requires FDA to establish “science-based standards … based on known food safety risks” to govern the use of water in growing produce. FSMA further requires that those water standards “provide sufficient flexibility to be applicable to various types of entities engaged in production and harvesting of fruits and vegetables ... and be appropriate to the scale and diversity of the production and harvesting of such commodities.” Congress also gave the US Dept. of Agriculture a role in the development of those water standards, requiring FDA to establish them “in coordination with the Secretary of Agriculture,” as well as with the departments of agriculture across the individual states.

The final agricultural water requirements published November 27, 2015 as part of the regulations under the FSMA Produce Rule present a number of challenges with regard to risk assessment, the indicator organism, the tolerances for that organism, the testing frequencies and the sampling practices.

1. There is a strong scientific consensus that the proposed microbial quality standards do not correlate with pathogen contamination of agricultural water sources. The indicator organism FDA has selected for measuring agricultural water quality, generic E. coli, is not a reliable indicator of pathogen contamination at the microbial limits established in the rule. The indicator and tolerances were adopted from the Environmental Protection Agency’s (EPA) recreational water standard, and there is no scientific basis for applying the EPA standard to the production of fruits and vegetables as an appropriate test for foodborne pathogens. FDA acknowledges the EPA standard was “developed from epidemiological studies that correlated the risk of gastrointestinal illness to exposure to marine and freshwater by swimmers” and was not designed to assess the hazards posed by exposure to agricultural water since the “routes of infection and pathogen mortality rates are different” for exposure from swimming compared to the hazards posed by consumption of produce. The EPA/FDA standard is far more stringent than Word Health Organization benchmarks for irrigation water quality, which establish fecal coliform concentrations up to 1000 CFUs/100mL as acceptable.

2. Scientific research demonstrates that microbial water quality is dramatically impacted by variations in weather, climate patterns, regional soil and hydrological conditions and farming practices; scientific understanding of the relationship between these variations and the actual risk of contamination of fresh produce from agricultural water is limited. There is no justification in the current science on this subject for establishing a uniform national microbial water quality standard. FDA’s insistence on establishing such a uniform water standard violates the FSMA mandate that produce rules be risk-based, and places producers in some regions of the U.S. at an unfair competitive disadvantage.

3. There is insufficient scientific data to show that the water testing frequencies FDA requires reliably characterize the microbial quality of agricultural water. The record indicates that FDA’s 20-sample baseline for surface waters is a statistical construct; it was not selected as an indicator of food safety. The agency’s approach mandates that covered farms to adhere to a complicated and prescriptive testing regime that does not account for variations in critical risk factors such as climate, location, farming system, and water source. Scientific research in fact suggests that the variability in water quality tests due to climate conditions such as temperature, storm events, and diurnal cycles, along with anthropomorphic events, makes routine testing of agricultural water impractical; even multiple years’ worth of tests would be inadequate given these factors.

4. The basic procedures of evaluating water quality on farm—from the size of a sample, to the handling of vessels used in sampling, to the use of index organisms vs. indicator organisms as a benchmark—have not been scientifically validated. This presents challenges for implementing a water quality standard across farms.

The committee is also concerned that FDA has prescribed a particular laboratory protocol, EPA Method 1603, as the only analytical method that satisfies FSMA’s testing requirements for agricultural water. This protocol is not used widely among labs providing water testing services; for example, in Florida, out of over 200 water testing labs, only 5 perform the Method 1603 test, and there is only one lab in Virginia that provides it. Besides the logistical bottle neck of running hundreds of thousands of water tests annually through so few providers, the limited number of labs means that for many farms it will be impossible to physically deliver water samples to a lab within the six hours necessary to ensure valid test data. The typical cost charged by labs for this specific analysis is much higher than the testing methods normally used for agricultural water analysis. EPA and FDA recognize a number of other tests as equivalent for recreational and drinking water, and FDA offers no scientific justification for not allowing the use of those other testing methods under the Produce Rule.

The net result of the Produce Rule water standards is a testing regime that requires covered farms to excessively and unnecessarily test water at significant cost, and without correlation to food safety. This is not what Congress intended in passing FSMA.

**Recommendation**

On March 20, 2017 FDA announced that the agency is considering how it might simplify the water standards, and that it intends to work with stakeholders as these efforts related to the water standards proceed. The Fruit and Vegetable Industry Advisory Committee recommends that, as required by the FSMA statue, USDA actively engage and coordinate with the FDA in this plan to revisit the agricultural water requirements, and provide scientific and technical expertise regarding the establishment of sound, practicable science and risk-based agricultural water standards. In particular USDA should champion flexible, science- and risk-based regulation related to agricultural water under the rule, and should encourage FDA to consider the stated opportunity to revisit the water requirements as an indicator for review and possible withdrawal of subpart E of the Standards for Growing, Harvesting, Packing and Holding of Produce for Human Consumption found at 21 CFR 112, and Section 112.151 of those regulations relating to analytical methods for testing water, in their entirety until a through and comprehensive scientific analysis of the risks of foodborne illness arising from the use agricultural water, similar to long-term study FDA has already begun with regard to biological soil amendments of animal origin, is undertaken. Such analysis should include epidemiological evidence and unbiased evaluations of the effectiveness of water management practices in crop production in preventing pathogen contamination, taking into account: production conditions in different parts of the country and in different farming systems; climate conditions and weather patterns; and post-harvest interventions and time intervals. The goal of this analysis should be to determine the most cost-effective agricultural water management activities for reducing the risk of foodborne illness from fresh produce.

In support of these efforts, USDA should draw in its technical (i.e., water) research agencies, for example, the Agricultural Research Service, and others as expertise is available. The range of activities to be considered should include all aspects of the requirements, such as the microbial quality criteria, indicator organism, testing/sampling frequency, test methods (including recognition of the EPAs acceptance of other test methods), treatment options, and flexibility/alternatives allowed; each with a focus on practicality, availability and cost effectiveness. Further, USDA should consider providing consistent funding available for mid- and long-term research, and for grant and loan programs aimed at assisting the impacted stakeholders (e.g., growers and packers) with compliance with the FDA Produce Safety Rule.