



November 22nd, 2013

Division of Dockets Management (HFA---305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2011-N-0921; RIN 0910-AG35

Submitted electronically via www.regulations.gov

OWRC Comments on the Food Safety Modernization Act (FSMA) Proposed Rule for Produce Safety: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, Subpart E - Agricultural Water Standards

The Oregon Water Resources Congress (OWRC) appreciates the opportunity to comment on the Food Safety Modernization Act (FSMA) Proposed Rule for Produce Safety, Docket No. FDA-2011-N-0921. OWRC has some questions and concerns about the FSMA Proposed Rule for Produce Safety, specifically on the implementation of Subpart E- Agricultural Water Standards. OWRC is very supportive of efforts to increase food safety and prevent *E. Coli* outbreaks, which is detrimental to both the consumer and the grower. However, it is imperative that steps taken to improve water quality are proven methods that will be successful in protecting human health and preventing product recalls, while being feasible for farmers and the agricultural water suppliers that provide irrigation water deliveries to implement. Given the magnitude and complexity of this issue, we recommend that the Food and Drug Administration (FDA) to conduct a more thorough analysis of impacts and alternatives, revise the rule, and reissue for further public comment before implementation occurs to ensure the proposed rule will result in improved food safety.

OWRC is a nonprofit association that represents irrigation districts, water control districts, drainage districts, water improvement districts, and other agricultural water suppliers that deliver water to 1/3 of all irrigated land in Oregon. These local government entities operate complex water management systems, including water supply reservoirs, canals, pipelines, and hydropower production. OWRC has been promoting the protection and use of water rights and the wise stewardship of water resources on behalf of agricultural water suppliers for over 100 years.

Our major concern is that the Agricultural Water Standards in the FSMA Proposed Rule for Produce Safety has components which will be problematic to implement and may have serious unintended consequences for growers and the agricultural water suppliers they depend upon. We feel there are aspects of the rule that have not been fully evaluated in relation to water quality testing and treatment for growers within large water distribution systems, which may or may not be managed by an irrigation district. We urge the FDA to look into the issues presented in comments by growers and various agricultural groups that illustrate the need for further evaluation before implementation. There are many areas that need to be further analyzed and clarified to prevent unintended consequences and ensure that these efforts will lead to improved food safety. We also recommend providing the States with resources and assurances that they will have a lead role in implementing the rule in partnership with FDA to the extent practicable.

OWRC is very supportive of comments submitted by the Oregon Department of Agriculture (ODA) on November 13th, 2013. ODA has a well-established track record of working with the agricultural community on this issue through its Agricultural Water Quality Management program and has extensive experience working with a variety of state, federal, and local entities to improve water quality while ensuring the continued viability of Oregon's agriculture. We strongly encourage FDA to incorporate their suggestions and reissue the rules for additional comment.

To illustrate the need for further evaluation of the proposed rule, particularly related to agricultural water standards, we are providing some general information about irrigation districts and the diverse conditions under which they deliver water. Because of this diversity, it will be imperative to understand the impacts and available options for improving water quality to ensure that the implementation of the FSMA rules are successful in improving food safety. This also reiterates the need for Oregon and other states to have a lead role in executing the framework based on their unique knowledge of statewide issues.

In Oregon and in many other Western states, irrigation districts and other agricultural water suppliers are responsible for delivering a quantity of water to the water users they serve. District water users pay assessments based on the quantity of water they request. The districts receive the water they deliver from a variety of sources, including diversions on rivers and streams, stored water from reservoirs dams, and even water delivered from other districts. The districts have little or no control over the quality of the water they convey and can only deliver the water supplies that are available. Moreover, state water law and federal storage contracts have little to no legal basis for water quality assurances. Many irrigation districts are involved in collaborative projects with their water users, state and federal agencies, and other entities to improve water quality, but there is much that is outside of their control.

Furthermore, the size and complexity of agricultural water infrastructure varies widely from district to district and varies further between farms and other water users within the districts. Some districts have hundreds of miles of open canals, others have piped systems, and many have combinations of lined or unlined canals as well as enclosed pipelines. Other factors such as geography, urban density, local wildlife, and age of the infrastructure also vary widely and impact the water quality conditions. The types of crops, sizes and complexity of the agricultural operations also vary widely. Districts supply water to farms and other agricultural water users without prejudice as to the nature of the agricultural practice, whether it's a commercial large operation, a farm stand, or a hobby farm. Because of these factors it is crucial that growers within districts have a clear understanding of the rules and have an array of options to address water quality.

In summary, OWRC is supportive of improving food safety and prevention of *E. Coli* outbreaks but feels that the following revisions are needed:

- Conduct an additional evaluation of impacts and options to avoid unintended consequences as well as maximize available options for improving food safety
- Provide financial and technical resources for producers and states to implement rules
- Ensure that the States will have lead role in the implementation framework
- Revise rules and reissue for further public comment to ensure that the new FSMA produce safety rules are based on the best available information and fully vetted by stakeholders

These recommended actions will allow additional time to address the concerns that we and others in agricultural community have raised, allow for a more extensive evaluation of alternatives, and ensure that increased food safety will actually occur with the implementation of new rules. Thank you for your consideration of our comments on the FSMA Proposed Rule for Produce Safety, Docket No. FDA-2011-N-0921.

Sincerely,
April Snell
Executive Director