



November 12, 2017

U.S. Food and Drug Administration
Division of Dockets Management, HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: **Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E [Docket No. 2016–D–2343]**

To Whom It May Concern:

On behalf of our members, the Produce Marketing Association (PMA) respectfully submits the following comments to the FDA Federal Register Notice entitled, “*Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E* [Docket No. 2016–D–2343].

PMA is the largest trade association representing companies in the fresh fruits and vegetables industry. Our association represents more than 2,700 member companies located in 45 countries. In the U.S., our members operate at every level in the supply chain; from growing to shipping, processing/manufacturing, distribution, wholesaling, retail and foodservice. Collectively, our members handle more than 90 percent of fresh produce sold to domestic consumers. Regardless of member size or scope of operations, our members are committed at every level in the supply chain to food safety.

PMA’s vision is to strengthen and lead the global produce community to increase produce consumption. Fruits and vegetables are an integral part of a nutritious and healthful diet, offering tremendous public health benefits. PMA believes that produce safety, taste, convenience and nutrition are the cornerstones of increasing fruit and vegetable consumption and fighting obesity.

The PMA concurs and supports the U.S. Food and Drug Administration’s (FDA) proposal to extend the compliance dates for Subpart E (Agricultural Water Standards) of the Food Safety Modernization Act (FSMA) Produce Safety regulation (21 CFR part 112). Defining and ensuring the microbial quality of agricultural water used to grow, harvest and pack fresh produce is undoubtedly the most complex and contentious issue associated with the FSMA Produce Safety regulation.

Defining and ensuring that agricultural water used on a farm is “safe and of adequate microbial quality for its intended use,” as required by subpart E of the Produce Safety Rule (21CFR112.41), is complex as on any given produce farm agricultural water can come from multiple sources (e.g., wells or surface water such as ponds, lakes, rivers or reservoirs), and it can be used for multiple purposes (irrigation, application of crop-protection chemicals, frost protection, etc.).

The reason there has been so much discussion and debate regarding what constitutes an appropriate standard for agricultural water used on produce farms is because there simply is not a one-size-fits all solution and more data, situation specific information and knowledge are needed.



However, this is not to say that produce farmers should do nothing as everyone agrees that agricultural water needs to be of appropriate quality for its intended purpose so as not to adulterate fresh produce.

The key to this debate is determining and defining what is “adequate” for the many situation specific agricultural water use scenario’s that occur on produce farms and development of means by which a produce farmer can make informed produce safety management decision by having the ability to determine the most effective preventive controls that can be practicably, and cost effectively implemented on their farm for their situation.

The PMA applauds the FDA’s efforts to *“address questions about the practical implementation of compliance with certain provisions and to consider how we might further reduce the regulatory burden or increase flexibility while continuing to achieve our regulatory objectives, in keeping with the Administration’s policies.”*

The PMA agrees that the current agricultural water provisions (Subpart E) of the Produce Safety Regulation need to be re-evaluated, because as currently formulated, they are overly prescriptive, cannot be practically implemented by most farms and provide limited value in protecting public health. A more flexible approach that incorporates new science and technology, such as the use of metagenomics, to better characterize agricultural water source and distribution system microbial quality is one solution going forward.

PMA has participated in the congressional debate about FSMA and has provided comment to FDA at every opportunity in the development of final rules and accompanying companion guidance documents. We greatly appreciate those opportunities and look forward to providing detailed public comments and input during FDA’s reevaluation of Subpart E (Agricultural Water Standards) of the FSMA Produce Safety regulation. We would also encourage the agency to review detailed and extensive comments already submitted to the agency in response to the FDA proposed and re-proposed FSMA Produce Safety regulation.

Respectfully,

A handwritten signature in cursive script that reads "James R. Gorny".

James R. Gorny, Ph.D.
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