Beginning Jan 26, 2023, farms began needing to comply with the agriculture water requirements for harvest and post-harvest water contained in Subpart E of the Produce Safety Rule.

While the exact date that FDA will finalize the preharvest agricultural water requirements in Subpart E of the Produce Safety Rule is unknown, the general support of the proposed rule leads IFPA to recommend that the industry begin thinking about how to comply with the rule.

IFPA is developing short resources on a variety of ag water related topics. This document will focus on the legalities of treating agricultural water, which applies to pre-harvest, harvest, and post-harvest water uses. From the standpoint of permitted uses of antimicrobials, options currently appear to be more limited for water used during pre-harvest, so the commentary will focus on pre-harvest considerations.

What is the requirement? As stated in the Produce Safety Rule,

§ 112.43 What requirements apply to treating agricultural water?

(a) When agricultural water is treated in accordance with § 112.45:

(1) Any method you use to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria in § 112.44, as applicable.

As noted above, EPA is the regulatory authority with jurisdiction over the use of chemical water treatments. Therefore, EPA (not FDA) is the agency that can approve various uses. The Produce Safety Alliance has compiled a list of antimicrobials approved by EPA for various purposes, including irrigation water. Note that "approved" for irrigation water does NOT necessarily mean it is intended to treat for human pathogens. The tool can be found here: https://resources.producesafetyalliance.cornell.edu/documents/PSA-Labeled-Sanitizers-for-Produce.xlsx. Expand the "Label Info", and sort the "Labeled for Use in Irrigation Water" column. Then you can click on the associated EPA label.

Each grower should determine if water treatment is appropriate based on their ag water assessment (also required by the rule). Treating water, especially water used in field, should not be the default because of the possible impacts to the broader ecosystem. These are some of the things EPA considers during the approval process. Off label use, especially for in-field water treatment, may result in unintended and detrimental environmental impacts.

Here is an example of label information, and IFPA's assessment of whether the use by the grower is appropriate, both from a scientific standpoint as well as how a regulator may view things. FDA does not have the authority to supersede EPA regulations or approvals. EPA approves antimicrobials for treating irrigation water; FDA enforces the Produce Safety Rule.

Example: a grower treats pre-harvest water that will be used for overhead irrigation with peroxyacetic acid.

The label states : "Bacteria, Slime, Odor and Algae Control in: Recirculating Cooling Water and Evaporative Coolers, Reverse Osmosis, Nano and Ultra Filtration, and Agricultural Waters."

The "**directions for use**" further states "AGRICULTURAL or HORTICULTURAL USES There is a Restricted-Entry-Interval of zero (0) hours after the use of this product. This product must never be mixed or combined with any other pesticide or fertilizer. Upon soil contact, this product decomposes rapidly to oxygen, carbon dioxide and water. This product may be harmful to fish if exposed on a continuous basis at concentrations of 0.5 ppm or more of active peroxyacetic acid. Meter this product into pressurized pipes using a plastic or stainless steel injection/backflow device installed far enough upstream from the target equipment to ensure thorough mixing. For open flowing bodies of water, apply this product as far upstream as possible to allow adequate mixing prior to the flow entering any larger body of water. If open pouring of this product is required, pour product as close to the surface of the water as possible to reduce odor exposure. **Treatment of Irrigation Water Systems** (sand filters, humidification systems, storage tanks, ponds, reservoirs, canals): *For the control of odor, sulfides, slime and algae* in water systems, apply this product at 2 oz. per 100 gal of water (10 ppm peroxyacetic acid). This feed rate equals 1.5 gal per 10,000 gallons of water. Repeat dose as necessary to maintain control, which will vary with seasonal conditions. For prevention of algae some systems may require continuous low level dosing during warm sunny periods. Drip Irrigation System Cleaning: To clean slime and algae from drip system tapes and emitters, meter this product upstream from pumps or filters at the rate of 1-2 oz per 50 gallons of water (10-20 ppm peroxyacetic acid). This feed rate equals 1.5-3 gal per 10,000 gallons of dilution water. When required, during normal irrigation cycles, use this product at the recommended dose for a minimum of 30 minutes. After an irrigation cycle do not flush the lines."

If the grower has conducted an ag water risk assessment and determined that the risk of pathogens such as E. coli O157:H7 and Salmonella need to be managed, is the use of PAA as detailed in this example acceptable?

Answer 1: Does the science support treatment efficacy to reduce or eliminate human pathogens?:

Possible. The grower would need to have conducted or evaluated scientific studies to determine if PAA was effective against the pathogens the grower identified as needing to be controlled. PAA is known to have an antimicrobial effect, but the grower would need to understand the concentrations and contact time needed within their water system in order to determine that the treatment would in fact be effective. It is possible that, from a scientific perspective, PAA could be used to treat irrigation water to reduce the risk of pathogens in the water.

Answer 2: Is the product used in a way that is compliant with current regulations?:

No. Directly under the "Directions for Use", it states "it is a violation of Federal law to use this product in a manner inconsistent with its labeling." The labeling indicates that the product, when used for the treatment of irrigation water systems, is used for the "control of odor, sulfides, slime and algae in water systems". It is not approved, in this application, for the treatment of bacteria of public health concern such as *E. coli* O157:H7 or *Salmonella*.

FDA and EPA have collaborated to develop a testing protocol so that chemical providers can gather the data needed to support registration or amend a current EPA label to include human pathogens. Growers can consider contacting their current antimicrobial suppliers to learn if the company intends to follow the protocol in order to add treatment for human pathogens to the labeled use.

In the meantime, growers should be weary of the off label use of a treatment regulated by EPA intended to control risks associated with human pathogen presence in agricultural water. Because FDA does not have regulatory authority over the use of these chemicals, FDA cannot exercise enforcement discretion. The label is the law.