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# FDA proposes FSMA changes for produce

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The U.S. Food and Drug Administration issued a [proposed rule](#) that aims to enhance the safety of produce. It proposes to require farms to conduct comprehensive assessments that would help them identify and mitigate hazards in water used to grow produce. This is the latest step in the agency's implementation of the [FDA Food Safety Modernization Act](#), and it proposes to replace some of the existing requirements for agricultural water in the [Produce Safety Rule](#).

"There have been far too many foodborne illness outbreaks possibly linked to pre-harvest agricultural water in recent years, including water coming from lands nearby produce farms. As a federal government agency charged with protecting public health, the FDA is committed to implementing effective modern, science-based measures designed to prevent these outbreaks from occurring in the future," said Frank Yiannas, FDA deputy commissioner for food policy and response. "The proposed rule is the latest action taken by the FDA to continue working towards implementation of key provisions of FSMA. If finalized, we're confident this proposal would result in fewer outbreaks in the U.S. related to produce, protecting public health and saving lives. This proposed rule is a monumental step towards further improving the safety of the fruits and vegetables Americans serve their families every day, and the FDA looks forward to engaging with stakeholders on the proposed changes."

The proposed rule, if finalized, would change certain pre-harvest agricultural water requirements for produce and farms subject to the PSR, other than sprouts operations. Key provisions in the proposed rule include:

- A requirement for farms to manage their agricultural water quality based on the results of a comprehensive systems assessment that is adaptable to the wide variety of water sources

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and uses and future scientific advancements.

- An annual assessment by farms of their pre-harvest agricultural water to identify any conditions likely to introduce hazards into, or onto, covered produce or food contact surfaces. Based on these assessments, farms would then determine whether corrective or mitigation measures are reasonably necessary to reduce the potential for contamination. The assessment would include an evaluation of the farm's water system, agricultural water use practices, crop characteristics, environmental conditions and other relevant factors, such as the results of any testing conducted to inform the assessment.
- A requirement that farms implement expedited mitigation measures for hazards related to certain activities associated with adjacent and nearby lands, to protect the quality of the water used on produce. This is being included following several recent outbreak investigations on produce that revealed potential routes of contamination including activities and conditions, such as animal grazing and the presence of livestock and wildlife on land adjacent to, or near, produce farms or their water sources.
- The removal of certain testing requirements for pre-harvest agricultural water and replacing them with the agricultural water assessments identified above. The proposed revisions are intended to address stakeholder concerns about complexity and practical implementation challenges while protecting public health.

The FDA intends to continue working closely with stakeholders and state and tribal partners to provide necessary training, technical assistance, education and outreach. The agency will hold two virtual public meetings to discuss the proposal and hear feedback, and more details will be announced in a forthcoming Federal Register notice. In addition, the agency is also developing an online tool to assist growers in understanding agricultural water assessments.

Recognizing that the current [agricultural water compliance dates](#) for covered produce other than sprouts under the PSR are set to begin in January 2022, the agency intends to exercise enforcement discretion for those agricultural water requirements while pursuing another proposed rule to extend the compliance dates for all of the agricultural water requirements in the PSR for such covered produce. More information on the proposed compliance date extension will be announced in a forthcoming Federal Register notice.

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