



May 22, 2024

Dear Tribal Leader,

On May 6, 2024, FDA published in the *Federal Register*, the final rule [“Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water”](#) (89 FR 37448). As discussed further below, the final rule replaces the microbial criteria and testing requirements for pre-harvest agricultural water for covered produce (other than sprouts).<sup>1</sup> It establishes requirements for systems-based assessments, with required testing in certain circumstances, that focus on key risk factors for contamination by pre-harvest agricultural water and will enable farms to implement effective preventive measures.

FDA published the [proposed rule](#) related to agricultural water on December 6, 2021 and received stakeholder comment, including through a Tribal consultation held on February 4, 2022. FDA published a [recording of the consultation](#) on the FDA Tribal Affairs website and shared a written summary with all registrants and attendees. A final consultation transcript was also included in the docket for the rule ([FDA-2021-N-0471](#)). All comments received in the docket were reviewed and given consideration in the development of the final rule.

FDA invites you and your elected Tribal official or designee to participate in an All Tribes’ Call on **June 24, 2024, at 3:00 pm EST**. During the call, the Agency will provide an overview of the final rule, discuss resources that are available to farms, and answer questions. A recording of the call and summary will be available at our [FDA Tribal Affairs](#) webpage. For information on accessing the recording, please contact FDA’s Office of Intergovernmental Affairs (IGA) at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov).

**All Tribes’ Call Information:**

June 24, 2024, at 3:00 pm EST.

**To participate in the call, you must register [here](#).**

The final rule revises certain requirements in the Produce Safety Rule applicable to pre-harvest agricultural water for covered produce other than sprouts. The revised regulatory approach incorporates recent science, findings from investigations of several produce-related outbreaks, and information and feedback from a variety of stakeholders. These revisions to the produce safety regulation will more comprehensively address a known route of microbial contamination that can lead to preventable foodborne illness that is a significant public health problem.

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<sup>1</sup> On November 27, 2015, FDA issued a final rule entitled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (“Produce Safety Rule”) (80 FR 74354) pursuant to section 419 of the Federal Food, Drug, and Cosmetic Act. Codified in 21 CFR part 112, the final rule established standards associated with identified routes of microbial contamination of produce, including agricultural water.

Specifically, this rule replaces the testing requirements that farms found to be complex and challenging to implement with requirements for annual systems-based pre-harvest agricultural water assessments that evaluate a broad range of factors to help farms identify and address potential sources of contamination. As compared to the pre-harvest agricultural water testing requirements in the 2015 final rule, the assessments are designed to achieve improved public health protections while also being more feasible to implement across the wide variety of agricultural water systems, uses, and practices, and adaptable to advancements in agricultural water quality science.

Additionally, this rule:

- Includes testing pre-harvest agricultural water as part of an assessment in certain circumstances;
- Requires farms to implement effective mitigation measures within specific timeframes based on findings from their assessments, including expedited mitigation for certain hazards associated with adjacent or nearby lands;
- Adds new options for mitigation measures, providing farms with additional flexibility; and
- Requires supervisory or management review of agricultural water assessments.

Farms may be eligible for an exemption from conducting a pre-harvest agricultural water assessment if they can demonstrate that their pre-harvest agricultural water for covered produce (other than sprouts) meets certain requirements that apply for higher-risk uses of water (such as harvest and post-harvest agricultural water); is received from a public water system or supply that meets certain requirements; or is treated in accordance with the rule. Additionally, it must be reasonably likely that the quality of the water will not change prior to use of the water (for example, due to the manner in which the water is held, stored, or conveyed).

The rule establishes compliance dates for the pre-harvest agricultural water provisions for covered produce (other than sprouts) as follows:

Very small businesses	2 years and 9 months after the effective date	April 5, 2027
Small businesses	1 year and 9 months after the effective date	April 6, 2026
All other businesses	9 months after the effective date	April 7, 2025

The effective date of the final rule is July 5, 2024.

The Agency is committed to taking an “educate before and while we regulate” approach to implementation of the rule. We intend to continue to work closely with educators and other partners, including State, Local, and Tribal partners, and industry organizations, to support education, training, and outreach on the agricultural water requirements.

FDA appreciates the feedback provided on the proposed rule by Tribal leaders and their representatives. We look forward to continuing to strengthen the relationship between FDA and Tribal governments as the Agency fulfills its mission to protect and promote public health.

For more information on the final rule, please contact Samir Assar, Director of the Division of Produce Safety in the Office of Food Safety, Center for Food Safety and Applied Nutrition at [Samir.Assar@fda.hhs.gov](mailto:Samir.Assar@fda.hhs.gov); Oscar Galagarza, Tribal Nations liaison for the FDA Produce Safety Network, at [Oscar.GalagarzaAngulo@fda.hhs.gov](mailto:Oscar.GalagarzaAngulo@fda.hhs.gov); or reach out to [AgWater@fda.hhs.gov](mailto:AgWater@fda.hhs.gov).

For Tribes in need of assistance with any FDA-related issue, please contact the FDA Intergovernmental Affairs (IGA) team at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) or contact Senior Intergovernmental / Tribal Affairs Specialist, Paul R. Allis at [Paul.Allis@fda.hhs.gov](mailto:Paul.Allis@fda.hhs.gov).

Sincerely,

A handwritten signature in cursive script that reads "Jim Jones". The signature is written in black ink and is positioned centrally below the word "Sincerely,".

Jim Jones  
Deputy Commissioner for Human Foods