

FDA All Tribes Call on Final Rule

“Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water”

Background

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). 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.

On May 22, 2024, FDA invited Tribal leaders, their designees, and tribal organizations to participate in an All Tribes Call that took place on **June 24, 2024, at 3:00 pm EST**.

Summary

The final rule revises certain requirements in FDA’s 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.

Specifically, this final 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., 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 way 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

There were 23 registrants, including Tribal officials, Tribal community members, Tribal public health representatives, and federal FDA participants for the June 24, 2024 All-Tribes Call. Paul Allis, Senior Intergovernmental Affairs Specialist, opened the call with a welcome and announcements regarding the flow and expectations of the proceedings. He then discussed the unique government-to-government relationship that federally recognized tribes have with the federal government and reaffirmed FDA’s commitment to robust and meaningful consultation with Tribes.

Mr. Allis introduced Jim Jones, Deputy Commissioner for Human Foods at FDA’s Center for Food Safety and Applied Nutrition (CFSAN), who provided an introduction and overview of the Agency’s steps in implementing the FDA Food and Safety Modernization Act and stressed the importance of tribal engagement. Next, Kruti Ravaliya, Consumer Safety Officer, CFSAN provided an overview of the final rule; summary of comments received; an explanation of the final rule’s requirements; information on compliance dates; and supporting resource materials.

Following FDA’s presentation, there was a question-and-answer session moderated by Paul Allis, FDA Intergovernmental Affairs, to further the exchange and to provide clarity on requirements of the final rule. Additional anticipated questions generated by the FDA to facilitate additional clarity were also addressed. Questions were answered in detail by Ms. Ravaliya.

There were no additional questions, and the All-Tribes Call was concluded.

Next Steps

FDA subsequently posted a recording of the call on the Agency's website and shared it with registrants.