



December 21, 2021

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA or Agency) is initiating consultation with federally recognized Indian tribes on the proposed rule, “*Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water*.” The proposed rule [published](#) in the *Federal Register* on December 6, 2021.¹

FDA invites you and your designated consultation representative(s) to participate in this consultation through an all tribes’ conference call on **February 4, 2022 at 1:00 p.m. EST**. The Agency will provide an overview of the proposed rule, answer questions, and receive tribal feedback. A transcript of the consultation will be added to the docket for the proposed rule (Docket No. FDA-2021-N-0471). A recording of the consultation call will be available beginning approximately one hour after the call ends and will be available for 30 days.

Tribal Consultation Call Information:

February 4, 2022, at 1:00 p.m. EST

Toll-free number: 800-369-1932

Passcode: 3193530

Instant Replay Information:

Toll-free number: 866-373-1990

In addition to the consultation call, FDA welcomes your written comments on the proposed rule. All comments submitted to the docket by April 5, 2022, will be considered before the final rule is published. Comments must be submitted to FDA using any of the following methods:

- Electronic submissions: Follow the instructions for submitting comments on the Federal eRulemaking Portal at <http://www.regulations.gov>.
- Written submissions via Mail/Hand-Delivery/Courier: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

All comments must include the docket number for the proposed rule (Docket No. FDA-2021-N-0471). Received comments will be placed in the docket and publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9:00 a.m. and 4:00 p.m., Monday through Friday.

¹ <https://www.federalregister.gov/documents/2021/12/06/2021-26127/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption-relating>

Background Information

As part of FDA’s implementation of the FDA Food Safety Modernization Act (FSMA), FDA issued the “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” final rule (80 FR 74354, November 27, 2015) (2015 produce safety final rule). Since finalizing the 2015 produce safety final rule, we have heard consistent feedback from covered farms and other stakeholders that the microbial criteria and testing requirements for pre-harvest agricultural water are complex and challenging to implement. In this proposed rule, FDA is proposing to amend the agricultural water provisions (Subpart E) of the produce safety regulation (21 CFR Part 112) to address these concerns. A Coverage and Exemptions/Exclusions Flowchart is available on our website to assist you in determining whether you are subject to the regulation.²

In the proposed rule, FDA is proposing to replace the microbial criteria and testing requirements for pre-harvest agricultural water for covered produce (other than sprouts) with provisions for systems-based agricultural water assessments that are designed to be more feasible to implement across the wide variety of agricultural water systems, uses, and practices, while also being adaptable to future advancements in agricultural water quality science and achieving improved public health protections. Additionally, we are proposing to require expedited mitigation for hazards related to certain activities associated with adjacent and nearby lands, in light of findings from several recent produce outbreak investigations. These proposed revisions to the produce safety regulation, if finalized, would more comprehensively address a known route of microbial contamination that can lead to preventable foodborne illness that is a significant public health problem.

These proposed requirements are intended to address stakeholder concerns about the complexity and practical implementation of certain pre-harvest agricultural water requirements in the Produce Safety Rule while continuing to protect public health. The requirements also are designed to be adaptable to future advancements in agricultural water quality science.

If finalized as proposed, covered farms may need to implement corrective or mitigation measures based on the outcomes of their pre-harvest agricultural water assessments. This could include expedited mitigation measures to address known or reasonably foreseeable hazards in agricultural water systems associated with animal activity, biological soil amendments of animal origin (BSAAOs), or untreated or improperly treated human waste on adjacent and nearby land.

The proposed rule also includes a requirement for supervisory review of the written pre-harvest agricultural water assessment and the determinations that were made about corrective or mitigation measures based on the outcomes of the assessment.

The proposed rule exempts covered farms 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 harvest and post-harvest agricultural water

² See Standards for Product Safety: Coverage and Exemptions/Exclusions for 21 Part 112. Available at <https://www.fda.gov/media/94332/download>

(such as the microbial quality criterion and testing requirements for untreated ground water);

- is received from a public water system or supply that meets requirements established in the rule (provided that the farm has public water system results or certificates of compliance demonstrating that the water meets relevant requirements); or
- is treated in accordance with the standards outlined in the Produce Safety Rule.

FDA recognizes that the current agricultural water compliance dates are set to begin in January 2022. The agency intends to exercise enforcement discretion for the agricultural water requirements for covered produce (other than sprouts) while proposing to extend the compliance dates, with the goal of completing the compliance date rulemaking as quickly as possible. More information on the proposed compliance dates will be announced in a forthcoming notice in the *Federal Register*.

Importantly, the FDA also intends to work closely with our state partners to implement these changes, if finalized. Through the FDA-State Produce Safety Implementation Cooperative Agreement Program, most states have developed produce safety programs which have included training and educating farms and conducting inspections. The agency intends to continue to work closely with state regulators, educators and others, including the Produce Safety Alliance, to provide the necessary training for agricultural water requirements.

For more information on the proposed 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.

FDA encourages you to stay informed about further developments related to FSMA through the Center for Food Safety and Applied Nutrition website located at <https://www.fda.gov/about-fda/fda-organization/center-food-safety-and-applied-nutrition-cfsan> and Office of Food Policy and Response at <https://www.fda.gov/about-fda/office-commissioner/office-food-policy-and-response>. You may also contact the FDA via telephone at 1-888-INFO-FDA or via mail at 10903 New Hampshire Avenue, Silver Spring, MD 20993.

The FDA Intergovernmental Affairs Staff (IGA) is available to assist tribal officials for all FDA inquiries. IGA can be reached at IGA@fda.hhs.gov. For more information regarding FDA's activities with federally recognized tribal governments, including FDA's Dear Tribal Leader Letters, please visit www.fda.gov/tribal or contact the IGA staff at IGA@fda.hhs.gov.

I hope you can join us for the tribal consultation call on February 4, 2022. 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.

Sincerely,



Frank Yiannas
Deputy Commissioner
Food Policy and Response