

FDA Updates Produce Safety Rule Small Entity Compliance Guide

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- On Sept. 23, 2024, FDA issued an updated guidance document titled “[Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: What You Need to Know About the FDA Regulation: Small Entity Compliance Guide](#).” The updates to the guidance reflect changes made to the Produce Safety Rule by the May 2024 final rule “[Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water](#)” (the agricultural water final rule).
- The Produce Safety Rule was initially issued in November 2015 and codified at 21 CFR Part 112 to establish science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables for human consumption. The agricultural water final rule revised requirements applicable to pre-harvest agricultural water for covered produce (other than sprouts) by:
 - Replacing the microbial quality criteria and uniform testing requirements with new provisions for conducting pre-harvest agricultural water assessments for hazard identification purposes and using the results in making risk management decisions;
 - Including a requirement to test pre-harvest agricultural water in certain circumstances;
 - Adding new options for mitigation measures, providing covered farms additional flexibility in responding to findings from pre-harvest agricultural water assessments;
 - Requiring expedited implementation of mitigation measures for known or reasonably foreseeable hazards related to certain adjacent and nearby land uses;
 - Requiring management review of pre-harvest agricultural water assessments; and
 - Adding new definitions of “agricultural water assessment” and “agricultural water system.”
- The agricultural water final rule is covered by pages 18-27 of the guidance document. The rule went into effect July 5, 2024. The first compliance date is April 7, 2025, for large farms, followed by small farms on April 6, 2026, and very small farms on April 5, 2027.

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