

Regulatory Alert: FDA Proposes Delay of Produce Safety Rule Water Standards

Compliance Dates Extended an Additional Two to Four Years, Inspections Delayed for Farms

October 17, 2017

On September 13, 2017, FDA published a <u>proposed rule</u> in the Federal Register that extends the compliance dates for the <u>agricultural water requirements</u> in the Food Safety Modernization Act (FSMA) Produce Safety Rule for <u>produce other than sprouts</u>. For sprouts the agricultural water compliance dates remain unchanged. Note the proposed rule does not impact compliance dates for the other requirements of the Produce Safety Rule. FDA Commissioner Gottlieb announced the delay along with other FDA planned actions related to the Produce Safety Rule at the National Association of State Departments of Agriculture annual conference. His remarks may be found <u>here</u>.

Compliance Dates

If the proposed rule is finalized, the new compliance dates for the <u>agricultural water standards</u> will be as follows:

Business Category	Old Compliance Date	New Compliance Date
Very small businesses (\$25k-	January 26, 2022	January 26, 2024
\$250k annual produce sales)		
Small businesses (\$250,001-	January 26, 2021	January 26, 2023
\$500k annual produce sales)		
All other businesses (\$500,001+	January 26, 2020	January 26, 2022
annual produce sales)		

Enforcement Discretion

In addition to announcing the compliance date delay for the water standards, Commissioner Gottlieb also announced that the agency does not intend to take action to enforce the agricultural water requirements for produce other than sprouts while the rulemaking to extend the compliance dates is underway.

Stakeholder Engagement

Commissioner Gottlieb announced that the agency would be engaging stakeholders on agricultural water standards during the additional time afforded by the extended compliance dates.

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Water Testing Methods

Commissioner Gottlieb discussed FDA's efforts to provide for greater flexibility in water testing methods used for complying with the Produce Safety Rule. In a recent letter to Western Growers, FDA <u>listed eight</u> additional testing methods from EPA and other public health entities that it has determined are equivalent to the method incorporated by reference (Method 1603) in the Produce Safety Rule.

Produce Farm Inspections

Farms that are not small or very small businesses will be expected to meet all produce safety requirements set by the rule for produce other than sprouts, except those related to agricultural water, by the original January 26, 2018, compliance date. Commissioner Gottlieb announced however that inspections to assess compliance with the non-water requirements for produce other than sprouts will not begin until 2019.

Training Opportunities for Producers and Regulators

Commissioner Gottlieb stated that training of state regulators will be a top priority for FDA in 2018. Additional details on training opportunities and other FSMA related training courses will be provided at a webinar scheduled for October.

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