

# Food Safety Modernization Act (FSMA) Recent Updates

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## **FDA Releases Compliance Guide for Small Businesses under FSMA Intentional Adulteration Rule**

- This Small Entity Compliance Guide (SECG) is available to help small business comply with the Final Rule on Mitigation Strategies to Protect Food Against Intentional Adulteration (or Intentional Adulteration Rule), mandated by FSMA.

- This SECG was prepared in accordance with the Small Business Regulatory Enforcement and Fairness Act. It provides nonbinding recommendations on such topics as developing a food defense plan and records management.
- The compliance date for small businesses under the Intentional Adulteration Rule is July 27, 2020. Very small businesses are exempt from the rule, except for a documentation requirement described in the SECG, which has a compliance date of July 26, 2021.

<https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm572408.htm>



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## **FDA Releases Sixth Chapter of Draft Guidance for the PC-Human Food Rule**

This is the sixth chapter of the draft guidance, entitled “Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food,” designed to help food facilities comply with the preventive controls for human food rule, mandated by the FDA Food Safety Modernization Act.

<https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm573228.htm>



*September 2017*

## **FDA Releases Compliance Guide for Small Businesses under FSMA Produce Safety Rule**

This SECG can help small and very small businesses determine whether they are eligible for a qualified exemption, which would modify the requirements they are subject to under the Produce Safety Rule. This SECG can also help farmers better understand those modified requirements.

<https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm574599.htm>

*September 2017*



# **Proposed Rule - Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E**

FDA Commissioner Scott Gottlieb, M.D. outlined a number of immediate next steps in a comprehensive approach to ensuring successful implementation of the Produce Safety Rule established by the FDA FSMA.



In a speech given in New Orleans at the annual conference of the National Association of State Departments of Agriculture (NASDA), Dr. Gottlieb announced that the agency has recognized a need for additional efforts to educate the produce industry and state regulatory partners on the new produce safety requirements, and will continue its focus on training, guidance development, and outreach over the next year as well as addressing concerns related to the complexity and feasibility of implementing standards for agricultural water.

Next steps include the following:



**1. Agricultural Water Compliance Dates:** FDA issued a proposed rule September 13, 2017 (<https://www.federalregister.gov/documents/2017/09/13/2017-19434/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption-extension>) that, if finalized, would extend the compliance dates for the agricultural water requirements by an additional two to four years (for produce other than sprouts).

- The proposed extension will give the agency time to take another look at the water standards to ensure that they are feasible for farmers in all regions of the country, while protecting public health.

- The new agricultural water compliance date the FDA is proposing for the largest farms is January 26, 2022. Small farms and very small farms would have until January 26, 2023 and January 26, 2024, respectively.

## **The proposed rule is open for public comment for 60 days (closes Monday, November 13, 2017).**

(The proposed extension would simplify the compliance framework to give all of the water requirements a four-year delay compared to farms' primary compliance dates. The produce rule now includes a delay of two years in the compliance dates for certain agricultural water requirements, but for others there is no delay.)

- The FDA 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. Sprouts, because of their unique vulnerability to contamination, remain subject to applicable agricultural water requirements in the final rule and their original compliance dates.

## **2. Stakeholder Engagement on Agricultural Water Standards:**

During the additional time that would be afforded by the extended compliance dates, FDA plans to engage with and learn more from farmers, state regulatory partners and other stakeholders about the diverse ways water is used and ensure that the standards will be as practical and effective as possible for all farming operations. This will include a summit on agricultural water early next year -- we will provide more information on this planned summit later in the year.

### **3. Water Testing Methods:**

FDA listed eight additional testing methods from the U.S. Environmental Protection Agency and other public health entities that it has determined are equivalent to the method incorporated by reference (Method 1603) in the Produce Safety Rule. Numerous stakeholders have asked for the FDA to recognize other methods that are appropriate for use in agricultural water testing. The FDA has posted the list of methods (currently, there are eight methods) it has determined to be equivalent on its website,

<https://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm575251.htm>

and intends to add other methods to the list as they are identified.

## 4. Produce Farm Inspections:

- Large farming operations will still 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.
- Inspections to assess compliance with the non-water requirements of the Produce Safety Rule for produce other than sprouts will not begin until 2019. FDA and its state partners will use this time to provide more education, training and outreach on the new requirements. In particular, states -- in conjunction with NASDA and the FDA -- will expand On-Farm Readiness Reviews, already piloted in six states, in which a team of state officials, cooperative extension agents, and FDA produce experts provide farmers with an assessment of their “readiness” to meet the new requirements.

- State points of contact will receive further information on the change in upcoming weeks in the form of letters from the FDA's Office of Regulatory Affairs and calls are being scheduled to answer any questions.
- Earlier this year, the FDA awarded more than \$30 million to support 43 states in their development of produce safety programs. This builds on the nearly \$22 million that the FDA awarded last year to 42 states. States will receive information from the FDA in upcoming weeks on how existing cooperative agreement funding can be reallocated to provide for additional focus on educational and outreach activities in lieu of inspections.

## **5. Training Opportunities for Producers and Regulators:**

FDA remains committed to ensuring that produce farmers and state regulators have the training needed to implement the Produce Safety Rule. Training of state regulators will be a top priority for the FDA in 2018, and additional details on training opportunities and other FSMA related training courses will be provided at a webinar being scheduled for October.

# *Information Links*

- **Safety of Food Affected by Hurricanes, Flooding, and Power Outages**

<https://www.fda.gov/food/recallsoutbreaksemergencies/emergencies/ucm112723.htm>

- **Guidance for Industry: Evaluating the Safety of Flood-affected Food Crops for Human Consumption**

<https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm287808.htm>

- **Crops Harvested from Flooded Fields Intended for Animal Food**

<https://www.fda.gov/AnimalVeterinary/ResourcesforYou/ucm575263.htm>

# *Information Links*

- **Dr. Gottlieb's Speech to the 2017 NASDA Annual Meeting**

<https://www.fda.gov/NewsEvents/Speeches/ucm575499.htm>

- **Center for Food Safety and Applied Nutrition  
Constituent Update**

[https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/default.htm?source=govdelivery&utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/default.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery)



FDA has several subscription e-publications concerning food safety:

- Recalls, Market Withdrawals, & Safety Alerts
- Constituent Updates
- Quarterly News for Educators

Because distribution of these items is moving to a new vendor, sign-up is temporarily suspended, so please continue to check back using the Constituent Update link provided on the previous slide.



*Thank You!*