

# FOOD SAFETY MODERNIZATION ACT

The FDA Food Safety Modernization Act (FSMA) is the most sweeping reform of our food safety laws in more than 70 years. It was passed by Congress in 2010 and signed into law by President Obama on January 4, 2011. FSMA changes many aspects of how food is regulated, by aiming to ensure the safety of the U.S. food supply through a focus on prevention, rather than responding after a food safety event has occurred. Today, seven final FSMA rules are in varying stages of implementation and the fresh produce industry continues to move forward with education, training and compliance to the various regulations to which they are subject.

## The produce industry is most affected by:

The Produce Safety Rule  
The Preventive Controls for Human Food Rule

The Foreign Supplier Verification Programs Rule  
The Sanitary Transportation Rule

## United Fresh Position

United Fresh strongly believes that ensuring the safety of the fresh fruit and vegetable supply chain is of the utmost importance, as does industry. United Fresh has long advocated for sound science and risk-based approaches to food safety and will continue to work collaboratively with FDA and Congress. United Fresh appreciates the careful consideration FDA gave to stakeholder input and supports the underlying premise of the rules. However, there are a few key issues which challenge the industry.

## United Fresh Priority Issue: Farm vs. Facility – Which Rule Applies?

*Conflicting Standards for Similar Facilities and Operations Subject to Different Rules – FDA must move toward an activities-based approach to determine if an operation falls under The Produce Safety Rule or The Preventive Controls Rule, respectively. United Fresh appreciates FDA's enforcement discretion while a regulatory fix is developed.*

One of the unintended consequences of FSMA legislation was the inconsistent regulation of identical operations that pack, hold, or handle raw agricultural commodities (RACs) based on their physical location and ownership structure. Some of these facilities fall under the Produce Safety Rule, while others fall under the Preventive Controls for Human Food Rule, although these operations are identical in terms of food safety risk and nature. As the rules are written today, a "farm" can include some packinghouses, cooling operations, warehousing and storage facilities, while others, based on ownership and location, may be considered "registered facilities", subjecting them to different requirements. United Fresh estimates that 5,000 packinghouse facilities alone are impacted by this arbitrary definition.

United Fresh has encouraged FDA that products remaining in the same physical condition either during growing, postharvest handling, or storage activities, be subject to The Produce Safety rule, irrespective of where they are grown, harvested, packed or held. If the product is not substantially transformed (e.g., it's an apple going in and an apple going out), it should fall under the Produce Safety Rule; if the apple is transformed (e.g., a sliced apple going out) it should be under The Preventive Controls for Human Food Rule because that is a true processing activity.

Having a clear delineation between the coverage of The Produce Safety and The Preventive Controls Rule would not only strengthen enforcement, but reduce confusion for both industry and regulators. Furthermore, it provides uniform and effective regulation over all produce growing, handling, packing, storage and cooling activities, by classifying what activities are performed under each rule. Moreover, operations will have a strong and confident understanding of what rule they are supposed to follow, limiting the confusion that results in the wasteful expenditure of resources. United Fresh, together with allied associations, has worked with FDA to resolve this issue and we understand that it may need to be addressed through rule making, which is a slow process. In the meantime, FDA has announced enforcement discretion for preventive controls (e.g., not for cGMPs) for registered facilities that are solely engaged in packing or holding of fresh produce RACs.

## **United Fresh Priority Issue: Agricultural Water Testing**

*Prescriptive Requirements for Agricultural Water Testing: United Fresh appreciates that FDA has allowed for eight alternative testing methods in recognition of the overly burdensome and unworkable requirements of EPA test method 1603 – A Success for our Nations’ Growers.*

Prior to The Produce Safety Rule, growers have been performing various water testing for pathogens and have recorded years of historical records of those water sources. Also, most audits which are required by customers for products to be sold worldwide evaluate compliance with Good Agricultural Practices (GAPs), requiring some form of water testing to take place during the growing and harvesting seasons.

Water testing remains a foundational aspect of fresh produce production and the problem was not the water testing itself, rather the prescriptive test that must be performed for a farm’s water source (using EPA test method 1603). United Fresh, along with other industry trade associations, worked with FDA in quarterly meetings, written letters, etc. to address the limitations of having a single prescriptive test method for growers. In recognition of these prescriptive challenges the industry faced, United Fresh appreciated that FDA announced their intent to re-examine subpart E of The Produce Rule, to contemplate opportunities to simplify the rule for ag water standards.

As such, in September 2017, FDA proposed to extend the compliance date for the ag water testing requirement by at least 2 years. In the meantime, FDA also published eight additional test methods that can be used to quantify the amount of generic *E. coli* in agricultural water. The following methods are “scientifically valid” and “at least equivalent to the method of analysis in § 112.151(a) in accuracy, precision, and sensitivity”. United Fresh will continue to work with FDA to find workable solutions to ag water testing for our nation’s growers.

- [List equivalent test methods FDA has determined to be equivalent for Agricultural Water](#)
- [Ag Water Compliance Date Extension for Subpart E – Produce Safety Rule](#) Federal Register Notice
- Read an article on Agricultural Water by Jennifer McEntire, Ph.D United Fresh, and Jim Gorny, Ph.D, formerly with PMA in Food Safety Magazine’s August/September 2017 edition: [Fixing FSMA’s Ag Water Requirements.](#)