




# Partnering for Success


## How the USDA is helping growers comply with the Food Safety Modernization Act

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### Key Elements


As the final rules are put in place for implementation of the Food Safety Modernization Act:

-  farmers that grow, harvest, pack, and ship fruits and vegetables will be regulated by the FDA
-  multiple rules from the Act may apply, including Preventive Controls for Human Foods and the Foreign Supplier Verification Program
-  Cooperative Extension specialists will be trained to help growers comply with the new regulations.

To learn more about each key element, look for the  symbols throughout the article.

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The U.S. Department of Agriculture (USDA), Agricultural Marketing Service (AMS), and the U.S. Food and Drug Administration (FDA) are separate federal agencies with different missions. However, they share a robust working relationship when it comes to the 2011 Food Safety Modernization Act (FSMA), which shifts the focus from responding to food contamination after it occurs to preventing it in the first place.

 Once these FSMA directives are finalized and enforced, farmers that grow, harvest, pack, and ship fruits and vegetables will be regulated by the FDA. Since these are new federal regulations, many growers may find themselves in unfamiliar territory on their own farms; but the USDA is prepared to help the growing community comply with the new regulations with its many programs and services.

### BACKGROUND

The Food Safety Modernization Act was passed by Congress and signed by President Obama on January 4, 2011, and requires the FDA to draft the majority of the reports, studies, and regulations specified in the law. Two of the primary regulations or proposed rules drafted by the FDA will impact fruit and vegetable growers and packers, depending on their location, the size of their operation, farming activities, and agricultural practices used.

The Produce Safety rule lays out food safety requirements for many of the farmers who grow fruits and vegetables, while the Preventive Controls for Human Foods rule will affect businesses that process and manufacture food for human consumption. Some farms both grow and process food and will have to comply with the requirements of each category. Both rules have exemptions for the smallest farms and businesses (with sales of under \$500,000 annually).

Draft regulations were published in the *Federal Register* on January 16, 2013, inviting the public to submit comments. The FDA then held public meetings across the nation to get more comments and feedback. The agency also attended state and industry-sponsored listening sessions and farm tours.

The extended comment period closed in late November 2013 and the FDA then worked through the arduous task of reviewing each and every comment. This included reviewing more than 15,000 comments submitted for the proposed Produce Safety rule and several thousand comments for the Preventive Controls for Human Foods rule.

Based on these comments, the FDA published supplemental proposals revising specific technical requirements in these two regulations and asked for additional public comment. This comment period closed on December 15, 2014, and the FDA has been reviewing the latest comments.

### COMPLIANCE

The Produce Safety rule is expected to become “final” or take effect in late December 2015 with an extended, staggered compliance timeline. The timeline will be based on the dollar value of annual produce sales (over a rolling average of the three previous years) for farm businesses categorized as “very small,” “small,” and “all others,” and the compliance dates are proposed for December of 2019, 2018, and 2017, respectively. Each size category will have an additional

two years to comply with certain water requirements (2021, 2020, and 2019, respectively).

🔑 In addition to the Produce Safety rule, growers and packers may also be impacted by one or more of the other prevention-oriented FSMA regulations depending on the type of operation and its location. These are the aforementioned Preventive Controls for Human Foods rule, Preventive Controls for Animal Foods rule, and Foreign Supplier Verification Program.

Growers located outside the United States who export food into our country must also comply with the same regulations applicable to their operations. Other FSMA regulations that may impact various segments of the growing community include Intentional Adulteration, Sanitary Transportation, and Accredited Third-Party Certifiers—but these regulations will come into effect at a later date.

## EDUCATION

On many occasions, the FDA has stated the need to “educate before we regulate.” For this reason, the USDA is heavily involved in the educational components of the FDA’s implementation strategy via the Produce Safety Alliance and is involved to a lesser degree in the activities of the Food Safety Preventive Controls Alliance and the Sprouts Safety Alliance.

The Produce Safety Alliance was established in 2010 and will continue to at least 2017. The Alliance is supported financially and relies on staff from both the FDA and USDA represented on the Executive Committee. The standardized curriculum will be aimed at helping growers better understand food safety implications and integrate practices into their farming operations. This includes ensuring food safety and conservation practices can coexist (sometimes referred to as “co-management”), and helping farmers understand the specific requirements of the Produce Safety regulations.

🔑 Cooperative Extension specialists associated with the Land Grant University System are likely to take on a primary role as trainers working with farmers. There will also be instructional events held across the nation in farming communities, and growers can meet the training requirement in the Produce Safety rule by attending these workshops. Interest from agriculture consultant firms, trade associations, and others looking to become trainers for this curriculum is also expected. All are welcome to apply as trainers to the Produce Safety Alliance.

[www.producebluebook.com](http://www.producebluebook.com)

The USDA is committed to helping the FDA understand the diversity of the nation’s farming community and to assist growers and packers, processors, and sprouts producers of all sizes and production systems gain a better understanding of how to comply with the applicable regulations. Even growers excluded or exempt from the FDA’s regulations can benefit—as some buyers may expect all of their produce suppliers to meet the new FDA requirements. For this reason, exempt farms may want to come into compliance to maintain or gain access to these markets.

## ASSISTANCE

The USDA’s personnel serve as technical advisors on the produce safety and preventive controls “operational teams” established by the FDA to develop its implementation and compliance strategies. The USDA continues to provide input to the FDA related to the Good Agricultural Practices (GAP) program, the USDA’s voluntary food safety certification program. This program continues to be a useful tool for growers to demonstrate compliance with FDA’s *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*.

Once the FDA’s Produce Safety rules are final, there will be some modifications to the USDA GAP program to ensure that USDA GAP audits align with the new FDA regulations. Furthermore, the FDA has stated its intent to leverage existing marketplace accountability measures that stakeholders (i.e., farmers and packers) already have in place, such as one of the USDA GAP programs (e.g., harmonized GAP, generic GAP, mushroom GAP) or Marketing Orders/Agreements that incorporate food safety elements.

In effect, the USDA’s goal is to ensure that if a grower passes a GAP audit and is consistently implementing its own food safety plan, then the FDA would consider this farm in compliance with the Produce Safety regulation.

## FEEDBACK

As the implementation process continues, the USDA will continue to provide feedback on a variety of technical assistance approaches being developed by the FDA. These efforts include establishing a call or information center to address real-time issues; transitioning FDA field staff from generalists on all FDA-regulated products (food, drugs, medical devices, etc.) to specialists focusing on food; using research protocol framework documents aimed at supporting research on food safety practices

and standards for water quality and manure; and updating or developing new guidance documents for GAP, small entity compliance, and co-management, for example.

The role the USDA will play in helping farmers comply with FSMA regulations is varied and robust. We look forward to continuing our engagement with the FDA on behalf of our nation’s growers and packers of fruits and vegetables. **BP**

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## ONLINE

For more information on related topics, please see the following articles in the Blue Book Online Services Learning Center:

- “Quality and Certification Go Hand in Hand”  
– April 2014
- “Foreign Supplier Verification”  
– October 2014

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