

Food and Drug Administration  
Food Safety Modernization Act

**Summary of Standards for Produce Safety  
May 2016**

The FDA proposed rules under the Food Safety Modernization Act in January 2013 to establish standards for the safe growing, harvesting, packing and holding of fruits and vegetables grown for human consumption.

In response to input received from public meetings, listening sessions and visits to farms, a supplemental notice of proposed revisions was issued in September 2014 in an attempt to make the originally proposed rules more practical and effective. In November 2015 a final rule was issued. This paper is intended to be an overview of some key requirements including exemptions for small producers.

The rules for produce safety cover six categories, as follows:

- Agricultural Water
- Biological Soil Amendments
- Sprouts
- Domesticated and Wild Animals
- Worker Training and Health and Hygiene
- Equipment, Tools and Buildings

**Agricultural Water**

The rule requires that agricultural water be safe for its intended use and requires farms to annually inspect the agricultural water supplies under their control. Furthermore, farms are prohibited from using untreated surface water and must insure that the water has no detectable E.coli if it is used for sprout irrigation, directly contacts covered produce during or after harvesting activities, directly contacts food contact surfaces, or is used for hand washing during or after harvest activities.

**Biological Soil Amendments**

The FDA does not object to farmers using the USDA standards that call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil. Untreated biological soil amendments of animal origin, such as raw manure, must be applied in a manner that does not contact covered produce during application and minimizes contact with covered produce after application.

**Sprouts**

Because sprouts have been frequently associated with food borne illness outbreaks, a separate set of stringent rules have been developed, such as testing of sprout irrigation water from each production batch for certain pathogens; testing the growing, harvesting, packing and holding environment for the

presence of *Listeria* and taking measures to prevent the introduction of dangerous microbes into or onto seeds or beans used for sprouting.

### **Domesticated and Wild Animals**

Farmers are required to take all measures reasonably necessary to identify and not harvest produce that is likely to be contaminated by animals. Farms are not required to exclude animals from outdoor growing areas.

### **Worker Training and Health and Hygiene**

Farm workers are required to have a combination of training, education and experience necessary to perform their assigned responsibilities including on the importance of health and hygiene. Measures must be put in place to prevent visitors from contaminating covered produce and food contact surfaces by making toilet and hand washing facilities accessible to visitors. Workers must be instructed to notify their supervisors if they may have a health concern that may result in contamination of covered produce or food contact services.

### **Equipment, Tools and Buildings**

The final rule requires measures to prevent contamination of covered produce and food contact surfaces such as appropriate storage, maintenance and cleaning of equipment and tools. It also requires recordkeeping related to the date and method of cleaning and sanitizing equipment used in growing sprouts.

The rule has identified various exemptions to which it does not apply:

- Produce that is not a raw agricultural commodity (a raw agricultural commodity is any food in its raw or natural state)
- Asparagus, black beans, great Northern beans, kidney beans, lima beans, navy beans and pinto beans, garden beets and sugar beets, cashews, sour cherries, chickpeas, cocoa beans, coffee beans, collards, sweet corn, cranberries, dates, dill, eggplants, figs horseradish, hazelnuts, lentils, okra, peanuts, pecans, peppermint, potatoes, pumpkins, winter squash, sweet potatoes and water chestnuts
- Food grains, including barley, dent or flint corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, oilseeds, rapeseed, soybean and sunflower seed.
- Farms that have an average annual value of produce sold during the previous three-year period of \$25,000 or less
- Farms can receive a qualified exemption and modified requirements if its food sales average less than \$500,000 per year during the previous three years and sales to qualified end users exceed sales to others (a qualified end-user can be either the consumer of the food or a restaurant or retail food establishment that is located in the same state or same Indian reservation as the farm, or not more than 275 miles away.
- Variances can be requested by states, tribes or foreign countries from which food is imported into the U.S. if it concludes that complying with one or more of the rule's requirements

would be problematic because of local growing conditions. The requesting entity must demonstrate that the requested variance is reasonably necessary to ensure that the produce is not adulterated and gives the same level of public health protection as the rule from which a variance is sought.

The Food and Drug Administration has issued various compliance dates, based on the size of the operation, for the implementation of these standards. For example: Very small businesses (between \$25,000 and \$250,000) have four years to comply. Small businesses (between \$250,000 and \$500,000) have three years to comply and all other farms have two years. There are different compliance time periods for sprout growing operations and for the implementation of certain aspects of the water quality standards.



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*SmartGrowth and the greater law firm of the North Caroling Association of Black Lawyers' Land Loss Prevention Project (LLPP) of which SmartGrowth is a part compiled the information in this document as a service to the public. The information in this document is up-to-date as of September 2016.*

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**About the Land Loss Prevention Project** The Land Loss Prevention Project is a non-profit law firm that offers legal representation of clients, community education, and professional outreach in the effort to promote wealth, land preservation, and rural livelihoods [www.landloss.org](http://www.landloss.org)

**About the W.K. Kellogg Foundation** - The W.K. Kellogg Foundation (WKKF), founded in 1930 as an independent, private foundation by breakfast cereal pioneer, Will Keith Kellogg, is among the largest philanthropic foundations in the United States. Guided by the belief that all children should have an equal opportunity to thrive, WKKF works with communities to create conditions for vulnerable children so they can realize their full potential in school, work, and life.

The Kellogg Foundation is based in Battle Creek, Michigan, and works throughout the United States and internationally, as well as with sovereign tribes. Special emphasis is paid to priority places where there are high concentrations of poverty and where children face significant barriers to success. WKKF priority places in the U.S. are in Michigan, Mississippi, New Mexico, and New Orleans; and internationally, are in Mexico and Haiti. For more information, visit [www.wkkf.org](http://www.wkkf.org).

**About the Local Food Promotion Program** The Local Food Promotion Program (LFPP) of the Agricultural Marketing Service, USDA, offers grant funds with a 25% match to support the development and expansion of local and regional food business enterprises to increase domestic consumption of, and access to, locally and regionally produced agricultural products, and to develop new market opportunities for farm and ranch operations serving local markets. For more information, visit <https://www.ams.usda.gov/services/grants/lfpp>