

FDA ISSUES DRAFT GUIDANCE FOR FARMERS AND FOOD PROCESSORS UNDER THE FOOD SAFETY MODERNIZATION ACT

Agriculture Alert
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In late October, the FDA released two draft guidance documents intended to help farmers and food processors comply with the Food Safety Modernization Act. The Food Safety Modernization Act, enacted in 2011, provides the FDA with authority to regulate how foods are grown, harvested, and processed.

One of the FDA's draft guidance documents is meant to help farmers understand the actions they can take in order to comply with the Produce Safety Rule. The second FDA guidance document, directed at food processors, is meant to provide an understanding of the applicable provisions of the Preventive Controls Rule for fresh-cut produce.

Both sets of draft guidance are an important resource that provide insight into how the FDA views compliance activities. The draft guidance provides recommendations, rather than legally enforceable responsibilities, intended to help farmers and food processors assess whether their own activities comport with the law.

For farmers, the FDA's draft guidance entitled *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry* is a compliance and implementation guide that provides information and examples of how farmers can comply with the Produce Safety Rule's requirements. The Produce Safety Rule applies to domestic and foreign farms, and requires that covered farms adhere to science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables to protect against contamination and assure their suitability for human consumption. The draft guidance provides guidance for determining which provisions of the Produce Safety Rule, if any, apply to a farm and the food it produces. In addition, the draft guidance addresses, among other things, personnel qualifications and training, health and hygiene, biological soil amendments of animal origin, domesticated and wild animals, growing, harvesting, packing, and holding activities, and equipment, tools, buildings, and sanitation.

The FDA's *Guide to Minimize Food Safety Hazards of Fresh-cut Produce: Draft Guidance for Industry* is meant to help those who manufacture, process, pack or hold fresh-cut produce comply with the FDA's regulation set forth in 21 CFR part 117

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entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.” “Fresh-cut produce” is defined as “any fresh fruit or vegetable or combination thereof that has been physically altered from its whole state after being harvested from the field (e.g., by chopping, dicing, peeling, ricing, shredding, slicing, spiralizing, or tearing) without additional processing (such as blanching or cooking).” The draft guidance addresses several requirements that are relevant to fresh-cut processing establishments, for example, requirements regarding personnel, sanitary operations, equipment and utensils, supply-chain programs, preventative controls, records, and training, and provides specific recommendations related to those requirements.

The FDA will hold public meetings in November and December to address the draft guidance documents, and will accept comments to the draft guidance until April 22, 2019. Thereafter, the FDA will publish final versions of its guidance.

In the meantime, farmers and food processors would be well served by comparing their current activities with the recommendations and examples set forth in the draft guidance in order to assess the extent to which their operations either comply with or deviate from the applicable provisions of the Food Safety Modernization Act.

If you have questions about the draft guidance or the Food Safety Modernization Act and the FDA’s associated rules and regulations, please contact a member of our Agricultural or Food and Beverage practice areas.