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ALERTS

Two Food Safety Modernization Act Draft Guidance Documents Issued By FDA

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The FDA recently released two new draft guidance documents to help farmers and food processors comply with the Food Safety Modernization Act (FSMA) and some of the FDA's implementing rules. One of the guidance documents is designed to help farmers understand the range of steps they can take to comply with the Produce Safety Rule. The other is intended to help processors understand the relevant provisions of the Preventive Controls Rule for fresh-cut produce.

According to a statement by Dr. Scott Gottlieb, FDA commissioner, the 152-page draft guidance for farmers, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry," gives examples to illustrate how the Produce Safety Rule might be implemented on different kinds of produce farms to meet compliance standards. Not every scenario is covered in the draft guidance, and the FDA states that farmers can always use an alternate approach as long as they satisfy the requirements of the rule. The draft guidance can still be used, however, as a guide to help farmers evaluate their own on-farm practices.

The second draft guidance document, "Guide to Minimize Food Safety Hazards of Fresh-cut Produce," discusses how fresh-cut produce processors may comply with the new requirements for current good manufacturing practices (cGMP) and for hazard analysis and risk-based preventive controls. Fresh-cut fruits and vegetables are those that have been physically altered (e.g., chopped, diced, peeled, shredded, sliced, etc.) after being harvested without additional processing, such as cooking, that could kill potentially dangerous bacteria.

The FDA is accepting comments on the draft guidance documents until April 22, 2019, after which it will begin work on the final versions of the guidances.

As always, the FDA's guidance documents do not establish legally enforceable responsibilities, but rather describe the FDA's current thinking on a topic.

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