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What Do the Proposed FSMA Rules Mean to the Food Industry?

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On January 4, 2013, the U.S. Food and Drug Administration (FDA) released two draft regulations required by the Food Safety Modernization Act (FSMA):

- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food
- Standards for Growing, Harvesting, Packing and Holding of Produce for Human Consumption

The promulgation of these draft regulations, which originally were due January 4, 2012, is being heralded as a significant step toward improving food safety. These rules embody a significant portion of the roadmap by which FDA intends to transform its focus to preventing, rather than reacting, to foodborne illnesses. The rules are designed to close gaps in food production and manufacturing that are thought to be a cause of numerous food-related illnesses each year.

The Preventative Controls for Human Food regulation requires that a domestic or foreign manufacturer of food products mitigate risk of foodborne illness by, among other steps: (1) identifying and evaluating hazards; (2) developing controls that prevent the hazards from materializing; (3) creating a written food safety plan that addresses those hazards and implements the preventative controls; (4) monitoring to ensure that the preventative controls are appropriate and effective; (5) taking corrective actions where and when needed; (6) verifying compliance; and (7) maintaining the written food safety plan and other records necessary to demonstrate the preventative controls, monitoring, corrective actions and verification.

The Produce Safety regulation focuses on fruits and vegetables that are consumed in their raw or unprocessed state. That rule sets standards to address five areas in the growing and packaging of such foods that are identified most frequently with promoting biological hazards and contamination, including: (1) irrigation; (2) animal-based soil amendments; (3) worker training, health and hygiene; (4) animals contact with growing areas; and (5) equipment, tools and buildings used in washing and packaging produce and fruits. The rule also requires maintenance of records that show compliance with the rules. Certain farms with smaller-scale production and sales would be partially or, perhaps, fully exempt from the standards.

Questions remain regarding the regulations, including, notably, funding. The Congressional Budget Office estimates that \$1.4 billion is needed to implement FSMA, including these two proposed rules that form part of the core of FSMA. In the last budget, Congress only allocated an additional \$50 million to FDA. Some are wary that sufficient funding will materialize, whether from the U.S. government, states or fees imposed on food growers, processors or consumers, to fully implement these regulations and hire the inspectors needed to monitor compliance.

Regardless, the proposed regulations are intended to represent best practices—practices that some food growers, producers and monitors already employ. Not surprisingly, the proposed regulations are not a light read, comprising more than 1,200 pages. Nevertheless, it is important for food growers, processors and manufacturers to take advantage of an opportunity to shape the very rules that will control their operations and impact their success.

That is, an important comment opportunity presently exists. Before it promulgates a final regulation, FDA must consider comments from the public. The two regulations recently proposed are found on FDA's website at:

www.fda.gov/Food/FoodSafety/FSMA/ucm334115.htm (Preventative Controls for Human Food) and www.fda.gov/Food/FoodSafety/FSMA/ucm334114.htm (Produce Safety). Comments are due by May 16, 2013. Food growers, producers and manufacturers should review, analyze and, if appropriate, comment on the proposed regulations. For the unprepared or uninvolved, the new regulations, as with other FSMA-required regulations, could significantly impact your business.

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