

FDA Rolls Out Long-Awaited Food Safety Rules

By **Greg Ryan**

Law360, New York (January 04, 2013, 7:08 PM ET) -- The U.S. Food and Drug Administration issued two highly anticipated rules Friday that will require food companies to abide by produce safety standards and devise plans to prevent foodborne illnesses, but projected companies may have two years or more to comply with the proposals.

The proposed rules will implement major portions of the Food Safety Modernization Act, the 2011 law that revamped food safety regulations to put a greater emphasis on the prevention of foodborne illness such as salmonella poisoning.

One proposed rule will require food companies to create written plans for how to prevent their products from becoming contaminated and how to respond in the event of contamination or an outbreak. The other rule will establish safety standards for the production of fruits and vegetables.

The FDA will accept comments on the proposals for 120 days.

Manufacturers may not be required to comply with the two proposed rules until 2015 or later. The FDA could need a year to review and respond to comments about the proposals, according to Michael Taylor, the FDA's deputy commissioner for foods. After the final rules are issued, many companies would then have a year to comply with the preventative control rule, with some small businesses receiving two or three years.

Large farms will have 26 months to comply with the final produce safety rule, with small farms receiving even more time.

The lengthy period between the rollout of the rules and the compliance date should be sufficient to allow companies to adhere to the rules, given how much many of them have already prepared for the proposals, Faegre Baker Daniels partner Sarah Brew said.

"The act itself is pretty specific about the controls and hazards you need to address, and a lot of these companies will have been doing these things already," Brew said. "One of the requirements for the preventative controls [rule] is you have a recall plan. Almost everyone with preventative controls has a recall plan."

The FDA would release additional rules implementing FSMA "soon," according to Taylor, including one rule to require companies to verify that foreign suppliers are meeting safety standards.

The plans outlined in the preventative control rule will be required to include an analysis of the potential sources of contamination; ways to prevent contamination, based on the risks posed by each hazard; procedures for monitoring for contamination; and the corrective actions to take in the event of contamination. The rule applies to U.S. and foreign facilities that make food that will be sold in the U.S.

"It will ensure there's a common set of standards," Taylor said.

The requirements resemble those laid out in the food safety system known as the Hazard Analysis and Critical Control Points, or HACCP, system. The FDA requires juice and seafood makers to follow the HACCP system.

The produce safety rule will set science-based safety standards for agricultural water, materials put into soil, farm employee hygiene, animals in the growing area, and equipment and facilities.

The rule does not apply to raw fruits and vegetables that are rarely eaten raw or that will be canned or otherwise put through processing that adequately reduces contaminants. It also does not apply to farms that have sold less than \$1.5 million in food in the previous three years and have sold more food to consumers and nearby restaurants or retailers than other entities over the same time frame.

"We've said all along we don't want a regulation that is one-size-fits-all," Taylor said.

The FDA has come under criticism for failing to roll out the outstanding rules by the deadlines set out in the FSMA. The agency was supposed to have issued the produce safety rule by January 2012 and the preventative control rule by July 2012.

Two consumer groups sued the FDA in August to force it to unveil the rules. The agency has moved to dismiss the suit, arguing the groups could not show the delay was egregious. The novelty and complexity of the regulations required additional time to implement them, the FDA said.

Consumer Reports publisher Consumers Union, which has made food safety one of its primary causes, expressed its support for the rules Friday, saying they would help prevent outbreaks.

"These rules really go to the heart of the problems we've had with food safety in recent years," Jean Halloran, director of food policy initiatives at the organization, said in a statement.

Marler Clark LLP managing partner William Marler told Law360 that though the rules are a positive step, the FDA may not have enough resources to adequately enforce the measures. Taylor and FDA Commissioner Margaret Hamburg stressed Friday that the agency would team with state health and agricultural departments on inspections, but funding is an issue with those agencies as well, he said.

"If you look at every major food outbreak that's happened, 90 percent of the time the FDA had either never been at that plant, or the last time they were in the plant was five or six years previously," Marler said.

--Additional reporting by Maria Chutchian. Editing by Elizabeth Bowen.