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FDA Hasn't Ruled Out Testing Burdens In Food Rule Just Yet

By Greg Ryan

Law360, New York (January 07, 2013, 9:21 PM ET) -- While a landmark food safety rule the U.S. Food and Drug Administration proposed Friday does not include the product testing and environmental monitoring requirements manufacturers had feared, experts warn that the proposal lays the groundwork for the agency to adopt the measures in a final rule.

The proposed rule, part of the Food Safety Modernization Act, would require food companies to create written plans for how to prevent their products from becoming contaminated. It is a key component of the 2011 law, which sought to improve the ability of the FDA and food industry to prevent foodborne illness rather than simply react to outbreaks.

Coming in at 680 pages, the proposal details the hazard analysis and recall plan that many food manufacturers will be expected to follow. Not included among all of those sections and subheads, however, is a requirement that companies test products or monitor the environment around their facility for contamination. Industry onlookers had watched closely to see whether the two programs would be included in the rule, worried they would be expected to implement costly new procedures or follow onerous new specifications.

The programs did not go entirely without mention, and attorneys say that by asking for comment on the programs in the proposed rule, the FDA is setting itself up to include some forms of product testing and environmental monitoring in the final version. Even if the requirements are drawn narrowly, as experts suspect, some companies could wind up with regulatory burdens they may have initially believed they had successfully avoided.

"Rather than whacking people over the head right out of the gate, they're saying, 'We may whack you over the head later,'" said David Acheson, the head of the food and import safety practice at Leavitt Partners.

Toward the beginning of the document, the FDA asks for comments "on when and how other elements of a preventative controls system are an appropriate means of implementing the statutory directives," including a product testing program, an environmental monitoring program and a supplier approval and verification program. Hundreds of pages later, it details the types of comments it seeks and even includes sections on the programs in the appendix.

Though the FDA stresses repeatedly that the programs are not required by the proposed rule, it goes on to ask a series of questions about each one. For product testing, for example, the agency requests comments on whether the practice should be limited to finished products or encompass raw materials, as well as the frequency of testing and whether frequency should be based on type of product.

The FDA even goes as far as estimating costs for implementing each program. Establishing a finished product testing program could cost a facility between $14,000 and $813,000 a year, depending on its size, according to the agency.

"The typical food company isn't necessarily going to have in-house expertise to set something like this up and make it effective," said Ricardo Carvajal of Hyman Phelps McNamara PC, a former FDA attorney.

Even companies that already conduct finished product testing or environmental monitoring have reservations about requiring the practices, according to experts. As it stands now, companies are not required to show the FDA records of their programs during the course of a normal inspection, according to Carvajal. If the programs are included in the preventative control rule, however, their files would be subject to recordkeeping and record access requirements, he said.

Manufacturers are used to running the programs their way, without oversight. Any blanket directives set out by FDA — such as the size and frequency of samples in an environmental monitoring program — would likely upset the programs they already have established, experts said.

"They're very tailored to the individual plants and facilities, and I think the general feeling [among companies] is it's a 'one size does not fit all' situation," Faegre Baker Daniels LLP partner Sarah Brew said.

In its requests for comments, the FDA appeared to acknowledge that any product testing or environmental monitoring would be tailored to certain products or certain types of companies, experts said, which should quell some of industry's fears. Brew pointed to qualifying language used by the FDA in reference to the programs, such as "when implemented appropriately in particular facilities."

"It seems like they're expressly recognizing it doesn't work across the board," Brew said. "They just want more comments on when the programs may be a good idea and what they should include."

The FDA's discussion of the costs involved in implementing the programs indicates they recognize that expenditures should generally be based on risk, according to Brew.

If the agency is considering requiring some product testing or environmental monitoring, it may have decided to leave it out of the proposed rule for a variety of reasons, experts said. It may have simply felt uncomfortable issuing anything definitive without further outside input, or it may not have wanted to take more time to develop its position on the programs, considering the rule was already six months overdue, attorneys said.

The FDA is soliciting comments on the proposed rule for 120 days. Experts told Law360 they expect a flood of comments on the preventative controls rule, especially in regard to product testing and environmental monitoring.

FDA officials seemed to indicate the same in a teleconference Friday, saying the agency might need as long as a year to review the comments it receives for the preventative controls rule and another rule proposed Friday regarding produce safety.

--Editing by Elizabeth Bowen and Richard McVay.