

FSMA Readiness: The Challenge of Implementation

By [James Andrews](#) | May 18, 2015

Last month, the U.S. Food and Drug Administration (FDA) hosted a “Kickoff Meeting” in Washington, D.C., for a new law promised to revolutionize the nation’s food system into one focused on preventing foodborne illness.

That law, the Food Safety Modernization Act (FSMA), was enacted more than four years ago, but FDA is finally ready to implement its key rules over the coming year — whether food companies are ready or not.



The first of those wide-sweeping rules is coming up Aug. 30, with three more going into effect on Oct. 31. That’s fairly soon, and while many companies are prepared, or preparing, for them, the most common mistake the rest are making is waiting to implement compliance until the rules are finally here, said Melanie Neumann, executive vice president and chief financial officer of food safety consulting firm The Acheson Group.

FDA has already released draft proposals for its key rules, and the language of the final versions is likely to be 95-percent identical to the draft proposals, Neumann told **Food Safety News**. Because of that, there’s no reason to not start preparing right now, she said.

“The sooner you start, I believe the less expensive it will be,” Neumann said. “The longer you wait and shortchange yourself on time, the more costly it will be to implement.”

Implementing FSMA compliance doesn’t have to be complicated, she added, but it can be time-consuming and intimidating to begin. So, how does a company get up to speed?

Before a company can understand how to comply with FSMA, they need to know their current strengths and weaknesses. And they can do that through a readiness assessment, Neumann said.

First, companies should assess which of the seven upcoming FSMA rules apply to them, walk through the expectations of each one, and determine where the company currently stands. From there, they should map out a timeline trajectory for implementation steps wherever they have gaps.

One of the most common gaps for companies is in their lack of knowledge about their suppliers.

“Companies certainly need to start with who’s in their supply chain and who supply them,” Neumann said. “You’d be surprised to know how many managers don’t know their suppliers.”

In their defense, however, most companies source ingredients through brokers and distributors who want to keep their supplier list private. Regardless, Neumann said, companies need to learn as much as possible about their suppliers and the goods they source.

To simplify things, Neumann uses the example of black pepper on potato chips.

If a potato chip manufacturer sources pepper from a supplier and adds it to the chips after the frying kill step, they need to know whether or not the pepper already underwent a kill step at the supplier. Since pepper has been shown to potentially carry harmful bacteria, the potato chip company’s manufacturing process hinges on their knowledge of how the pepper was processed.

That knowledge of product risk is critical to creating an efficient, risk-based management program, Neumann said.

If a product has a historically low food-safety risk and comes from a supplier with a strong track record, that product likely needs less verification oversight compared to suppliers with riskier product or shakier performance. Companies should categorize their suppliers according to risk, Neumann said, and require more from higher-risk suppliers to prove they have their product and facilities under control.

Once a company understands the risks in its supply chain, leadership needs to act on that knowledge and potentially decide to cease doing business with risky suppliers, says Randy Fields, CEO of supply chain software firm Park City Group.

Utilizing traceability technology is the key for a company to understand its supply chain, said Tejas Bhatt, food safety programs manager at the Institute of Food Technologists.

“You can’t solve a problem you’re not aware of,” Bhatt said, “and without traceability technology, you don’t have a way to know what could go wrong with your supply.”

As a traceability consultant, Bhatt encourages food companies to assess their goals and resources before deciding on a specific technology to use. While he said there is no one-size-fits-all technological solution, all companies can use traceability technology as a foundation on which to develop all their FSMA compliance strategy.

And while conventional wisdom might suggest that large companies are in the best position to adopt new technologies because of larger budgets and greater access to resources, Bhatt said he feels the opposite is true. His observations leave him optimistic that mid-size and smaller companies are in a very advantageous position to take on new technologies and adapt to stringent supply chain management as FSMA rules come into effect.

For one thing, smaller companies are less complex, meaning they can adopt new technology more quickly. FDA has also given them a longer grace period to comply with rules — often one to two years longer than companies classified as large.

“If the right technology is selected, it doesn’t have to be cost-ineffective,” he said. “I have seen fishermen off the Solomon Islands using electronic traceability systems.”

Neumann shared a similar sentiment, reiterating that FSMA compliance doesn’t necessarily have to come at a huge cost. Waiting until the last minute to comply with the rules will likely result in plenty of headaches, though — if not haphazard spending.

“I think there are a lot of middle-ground solutions for many in the industry,” Neumann said. “Many think that this is going to be a very heavy lift and, with careful planning, it doesn’t have to be.”

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