Food Safety Modernization … A Year Later

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Last January, President Obama signed the Food Safety Modernization Act (FSMA), the largest overhaul of the U.S. food safety system in decades. Since then, the Food and Drug Administration (FDA) has begun implementing various guidelines for the food industry.

As the FDA moves forward, it is important for the food industry to be aware of the agency's progress, assistance that will be provided to companies, and the challenges that face both the regulators and the companies affected by the new law.

According to the FDA [1], some of the major accomplishments of the agency since the passage of the FSMA include:

1. Issuing rules on criteria for administrative detention and rules on the prior notice of imported food.
2. Issuing guidance to the seafood industry on food safety hazards.
3. Inspecting the FSMA-required number of foreign food processors.

Aiding with Compliance

One of the most important FDA developments since the passage of the FSMA has been the creation of The Food Safety Preventive Controls Alliance [2] (FSPCA). The alliance was designed to help facilities maintain compliance under the new law, with a focus on developing effective food safety plans and identifying preventive controls

to protect against potential hazards.

The FSPCA performs in conjunction with the Illinois Institute of Technology's Institute for Food Safety and Health [3] (IFSH). The alliance is comprised of FDA members, local and state food protection agencies, the food industry and academia.

Some functions of the FSPCA include:

1. Designing a distance learning training portal at the IFSH campus in Bedford Park, IL.
2. Creating a technical assistance network for small- and medium-sized companies.
3. Assessing knowledge gaps and needs for further enhancement of preventive control measures.

The Rulemaking Process

As the FDA continues to make progress toward implementing the required rules of the FSMA, it is important for food manufacturers to be aware of the agency's rulemaking process. The FDA is currently utilizing a three-step process [4] for FSMA implementation:

Rules are proposed and comments requested. The agency will issue a proposed rule, known as a Notice of Proposed Rulemaking (NPRM). Comments are then requested from the public, with a time span anywhere from 30 to 90 days.

Comments are considered and the final rule is issued. Once the period for comments has ended, the FDA reviews them before issuing a final rule.

An effective date is determined. Once the final rule has been published, the agency establishes an effective date. The date on which companies must comply with the new regulation may be anywhere from six months to a year away from the final rule's publication. In addition, small businesses may be granted exemptions or other accommodations.

Addressing Challenges

The enactment of the FSMA offers its own set of challenges for both regulators and the food industry. At the same time the bill was signed, the federal government came face-to-face with a budget crisis, and agencies like the FDA and the USDA were confronted with the possibilities of budget cuts. In fact, the USDA recently closed 259 offices [5] as a cost-saving measure. Such cutbacks are cause for concern for food industry experts, who are wary of the impact this could have on food safety.

Though the FSMA calls for increased FDA inspections of food-processing facilities, shrinking budgets may make it difficult for the agency to do so. The agency is currently only able to inspect about 1 percent of food manufacturers each year, with third-party audits remaining as the top inspection method used by companies.

However, a recent congressional report [6] calls the effectiveness of such audits into question. Some manufacturers involved in large food recalls, including Jensen Farms — the cantaloupe farm involved in a deadly Listeria outbreak last year — have been given “superior” ratings by their third-party auditors prior to their recalls. As a result, Congress is calling on the FDA to closely monitor auditors, which are not currently monitored by the agency.

Food safety is of the utmost importance to food manufacturers, and third-party audits can be a good investment. However, the release of this report presents a challenge for companies. Perhaps in the future, the FDA will be tasked with regulating third-party audits; until then, processors should conduct thorough research regarding current and potential auditors to help guarantee their effectiveness.

It will be interesting to see what, if any, ancillary actions are taken by Congress and the FDA as FMSA regulations continue to be implemented. In the meantime, food processors should closely monitor regulatory news to ensure they are on top of the latest requirements.

What actions has your facility taken so far to comply with the FSMA? Let me know at lindsey.coblentz@advantagemedia.com *[7].*

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