REGS REPORT: Food Defense & the FSMA

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Chem.Info'*s recurring "Regs Report" feature presents new and emerging regulations and enables readers to better achieve compliance. In this installment, we explore food defense and the Food Safety Modernization Act (FSMA).*

As the Food Safety Modernization Act continues to be implemented, more regulations and guidelines will be focused on food defense and the prevention of intentional contamination events. Many resources are being released by both the FDA and industry to help food manufacturers improve their food defense strategies.

Last week, I attended the fourth annual Food Defense Strategy Exchange, sponsored by Tyco Integrated Security, in Chicago. This event provided a two-day crash course in the latest regulatory updates regarding food defense, as well as solutions to help food manufacturers improve their food defense strategies.

This year's event was especially informative, providing the most up-to-date information on the implementation of the FSMA. Jon Woody, Senior Policy Analyst for the Food Defense Oversight Team of the FDA's Center for Food Safety and Applied Nutrition, reviewed the latest FSMA developments, including progress the FDA [1] has made regarding Section 106, Protection Against Intentional Adulteration.

Sec. 106 requires that a vulnerability assessment of the nation’s food system must be conducted, which would include any “biological, chemical, radiological or other terrorism risk assessments.” Woody said the FDA is currently conducting assessments and gathering information before any rules on food defense will be proposed.

The eventual result of these assessments and data collection will be the release of an advanced notice of proposed ruling (ANPR), which then will be presented to the industry and other relevant players for comment. Woody said the FDA is hoping to release an ANPR on food defense by the end of 2013, but it could take longer than expected.

After an ANPR is released and comments are gathered and evaluated, the FDA will issue a proposed rule, which also has its own comment period. “We’re really looking at a multi-year process before we see anything related to food defense regulation,” Woody said.

In the meantime, Woody said the industry can expect to receive a steady stream of guidance [2] on food defense from the FDA. He said much of the guidance released by the agency over the past 10 years has relied on feedback from the industry. “I view food defense and the way we’ve been able to collaborate with industry in particular as a real success story. It really highlights the partnership that government and industry can have,” he said.

The high level of partnership between the FDA and industry is shown in the industry’s willingness to improve its food defense efforts on a voluntary basis. For example, food defense plans currently are not required by law, but many food manufacturers already have developed plans on their own.

To aid in this voluntary industry effort, FDA developed its own software for the food industry to make it easier for companies to create food defense plans. This free resource, known as the Food Defense Plan Builder (FDPB), is slated for release in Spring 2013. Designed to take the guesswork out of developing a food defense plan, the FDPB is a comprehensive, step-by-step method for companies to assess any gaps in their food defense efforts, and offers specific ideas for improvement.

Users of the FDPB will be able to enter basic company information and any mitigation strategies to prevent intentional contamination events currently in place at their facilities. The software then identifies any food defense “gaps” and suggests an “action plan” for companies to close these gaps, improving their facilities’ level of food defense. Any information entered and suggested actions can be exported into a final food defense plan. Users can also add any supporting documents — maps, evacuation plans, etc. — which may be helpful to attach to the food defense plan.

In addition to regulatory guidance, there is a wealth of industry resources designed to aid food manufacturers with their food defense efforts. For example, Tyco Integrated Security [3] offers a variety of solutions geared toward food defense, from identity management solutions to video analytics to supply chain protection.

Don Hsieh, director of commercial and industrial marketing for Tyco Integrated Security said that many food manufacturers have a head start on their food defense efforts because many food safety measures already in place can serve a dual purpose as a food defense control. “If you put in a camera, for example, at a mixing

point, it could be an opportunity to secure food safety as well as food defense," he said.

When it comes to food defense, Hsieh said that prevention is key. He said, "In most cases, food contaminations can be prevented by enforcing a comprehensive food defense strategy throughout the manufacturing process and across the supply chain."

Hsieh said that the core components of a proactive food defense program utilize "The Four A's":

- **Assess:** Vulnerability assessment of critical control points
- **Access:** Allow only authorized staff access to critical control points
- **Alert:** Continuously monitor the whole supply chain to alert appropriate individuals of intentional and unintentional instances of food adulteration
- **Audit**: Determine operational and regulatory compliance to best food defense practices and provide documentation of compliance to regulators

To help food manufacturers implement an effective food defense program, Tyco trains its sales representatives in the HACCP process. These representatives are able to visit food facilities to identify potential areas of vulnerability and suggest possible mitigation strategies to help facilities shore up their food defense controls.

Developing a food defense arsenal that combines both government and industry resources will help food manufacturers stay on top of new FSMA and food defense guidelines as they continue to develop. Creating a detailed food defense plan now will help food companies stay one step ahead of regulatory requirements — and ensure they are best positioned to prevent an intentional contamination event.

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