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TERRORISM REGULATIONS FINISH FDA'S FSMA IMPLEMENTATION

The U.S. Food and Drug Administration (FDA) recently released the last of its rules crafted to enforce the Food Safety Modernization Act (FSMA). These most recent rules aim to prevent the intentional adulteration of food in the supply chain. The FDA is specifically concerned about stopping insiders who could use their access to facilities to launch terrorist attacks resulting in wide-scale harm to the public health.

These rules shift the focus from responding to a contamination after it occurs to industry prevention. In addition, they are also a reminder that FDA's overall mandate under FSMA is to transfer compliance obligations onto industry and hold it accountable for its responsibility to produce safe human and animal food, rather than FDA taking on this duty exclusively. In order to accomplish this goal, each of the FSMA rules, including the intentional adulteration rule, will require industry to implement written policies and procedures that comply with extensive regulations.

Now that FDA has implemented the intentional adulteration regulations, the following is a complete listing of the compliance programs companies must implement involving the production, handling, packaging, importing, and distribution of human and animal food (unless an exemption applies):

- Preventative Controls for Human and Animal Food
 - Compliance program addressing monitoring, verification, corrective actions, and recalls.
- Produce Safety
 - Compliance program addressing water quality standards and overall produce safety.
- Foreign Supplier Verification Program
 - Compliance program that verifies foreign suppliers comply with FDA regulations and ensures they maintain the same level of public health protection and food safety as in the United States.

PEOPLE

F. Scott Galt, CIPP/E

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- Sanitary Transport
 - Compliance program that addresses vehicles, cleaning and inspecting, and employee training.
- Intentional Adulteration
 - Compliance program labeled as a food defense plan, designed to prevent terrorist or other attacks through the food supply, including vulnerability assessments.

The deadlines for when companies will be expected to have finalized their written compliance programs vary by rule, company size, and sales, but some take effect as early as 2017. It should be noted that some of these compliance programs potentially could take companies years to develop, draft, and implement depending on the complexity of their supply chain and product diversity.

Armstrong Teasdale can help your company create and implement the written compliance programs necessary to meet FSMA requirements. Interested in assessing your FSMA compliance obligations? <u>Click here</u> to take a brief, five-question survey so we may better assess your needs and be at your service.