Why would my customer ask me about the new FSMA?

These are compliance requirements identified from the Food Safety Modernization Act. They require a food producer or processor to perform Hazard Analysis similar to HACCP and many other tasks to ensure that food is not adulterated. From the moment food products are placed into the staging area on the shipping dock until they are unloaded at the receiving dock and stored; that entire process and all aspects of it now require Hazard Analysis, Preventative Controls, Sanitation, Monitoring, Verification, Recordkeeping, and Corrective Actions written into a Preventive Controls Plan to be in compliance.

Requirements

Registered Food Facilities

- Registered food facilities required to have a preventive controls plan are required to make such plan and related records (including records of monitoring, verification, and corrective actions) available to FDA upon written or oral request.

Hazard Analysis and Preventive Controls

- The FSMA adds a new Section 418 to the FD&C Act (21 U.S.C. § 350g) requiring registered facilities to perform a hazard analysis and implement a preventive controls plan.
- Food facilities registered with FDA will have to perform hazard analysis and implement preventive controls plans similar to the HACCP (Hazard Analysis Critical Control Points) plans required of meat and poultry establishments.
- The written plan must include the following elements: hazard analysis, preventive controls (including preventive controls at critical control points, if any), monitoring, verification, corrective actions, and recordkeeping.
- Not later than 18 months after the date of enactment, FDA is required to promulgate regulations to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting implementation of preventive controls.
- **Section 418 will become effective 18 months after the date of enactment of the FSMA,** except that (a) for small businesses, it will become effective 6 months after the effective date of FDA implementing regulations; and (b) for very small businesses, it will become effective 18 months after the effective date of FDA implementing regulations.

Intentional Adulteration of Food

- **The FSMA adds a new Section 420** to the FD&C Act (21 U.S.C. § 350i). Section 420 requires FDA to conduct a vulnerability assessment of the food system and determine the types of mitigation strategies necessary to protect against intentional adulteration of food. Not later than 18 months after the date of enactment, FDA is required to issue regulations to protect against the intentional adulteration of food. Such regulations are to specify appropriate science-based "mitigation strategies or measures" to protect the food supply at specific vulnerable points. **They will apply only to food at high risk of intentional adulteration, as determined by FDA in consultation with DHS.**

Sanitary Transportation of Food

- Not later than 18 months after the date of enactment of the FSMA, FDA is required to issue regulations on the **sanitary transportation of food**, as required by Section 416(b) of the FD&C Act. FDA is also required to conduct a study of the transportation of food for consumption in the United States.

Traceability

- FDA, in consultation with USDA, is required to establish, as appropriate, "within the Food and Drug Administration a product tracing system to receive information that improves the capacity of the Secretary to effectively and rapidly track and trace food that is in the United States or offered for import into the United States." FSMA, § 204(c). Prior to establishing this tracing system, and not later than 270 days after the date of enactment, FDA is required to conduct at least 2 pilot projects (1 or more for processed foods, and 1 or more for fresh produce) to evaluate methods for improving traceability. Not later than 18 months after the date of enactment, FDA is required to report to Congress on the findings of these pilot projects. FDA is also required to engage in additional data gathering, including assessing the costs and benefits of several different product tracing technologies and evaluating domestic and international tracing practices in commercial use. FSMA, § 204(a), (b).
- No deadline is specified for the final rule.

"The key... is that the new law explicitly places primary responsibility for food safety -- for prevention -- on food producers and processors," Taylor said. (FDA Deputy Commissioner for Foods, Michael R. Taylor)

"Food and beverage manufacturers must automate product traceability across the supply chain. In the future, every manufacturer must have complete supplier, manufacturing and delivery data for every product at their fingertips and in real time."