

Food Safety Modernization Act

December 7, 2011

Why would I ask my customer about the new FSMA?

Compliance requirements identified from the Food Safety Modernization Act 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 food safety plan to be in compliance.**

Food Safety Modernization Act

- Enacted January 4, 2011
- Most expansive changes since 1938 Act
- Sweeping new FDA powers
- Major new program activities for FDA
- Ambitious schedule for increased inspections

Registration of Food Facilities

- Who is impacted?
 - All facilities (any factory, warehouse, or establishment that manufactures, processes, packs or holds food)
 - Must re-register every even-numbered year (Oct. 1 – Dec. 31)
 - Introducing food into commerce without complying is a “prohibited act”

Hazard Analysis and Preventative 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 analyses and implement preventive controls plans similar to the HACCP (Hazard Analysis Critical Control Points) plans required of meat and poultry establishments.

Hazard Analysis and Preventative Controls

- 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. June 2012
- **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. June 2012

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.** June 2012

Fresh Produce Safety



- **The FSMA adds a new Section 419** to the FD&C Act (21 U.S.C. § 350h) that requires FDA to establish standards for the safe production and harvesting of fresh produce.
- Not later than 1 year after the date of enactment, FDA, in coordination with USDA and State departments of agriculture, is required to publish a proposed rule to establish minimum standards for the safe production and harvesting of those types of fruits and vegetables, “including specific mixes or categories of fruits and vegetables,” that are raw agricultural commodities for which FDA has determined that such standards minimize the risk of serious adverse health consequences or death.

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. June 2012

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.

Quotes



- **“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 finger tips and in real time.”

Fleet Interests

(Private and For Hire)



- The new Hazard Analysis, Preventative Controls, Food Security, and Sanitation compliance requirements for FSMA will be published NLT June 2012.
- How do my registered food facility customers intend to comply with these new FSMA requirements?
- What requirements will my customers determine appropriate for recording and transmitting data until traceability compliance requirements are determined?
- What mitigation strategies are required to protect against intentional adulteration of high risk food?
- Can I fulfill the compliance requirements identified by my customers?

So what do I do now?



- The Food Safety Modernization Act is evolving. It is important to understand how the compliance requirements will affect your customers and you.
- Private Fleets visit with their Quality Assurance Department and determine how to help outline a new FSMA Food Safety plan.
- For Hire Fleets visit with your Food Facility customers and understand how they intend to be in compliance with these requirements. What do those requirements mean to your fleet?
- Understand what Thermo King solutions you can provide your private fleet or your food facility customers.

Food Safety Modernization Act Website

<http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>

Thermo King Solutions for Compliance



- Risk Management Training – Web Portal or CD Set
- SVC Maintenance Programs
- Door Switch
- DAS – Data Acquisition System
- Data Print
- Trans Scan Recorders
- Wintrac Software or Pocket Wintrac Software
- i-Box
- Opti Set programming
- Thermo King Telematics Solution – Tracking
- Cargo Watch / HMI
- SR3