

The Food Safety Modernization Act: Increasing the FDA's Authority Over the Food Industry

On January 4, 2011, President Obama signed into law the Food Safety Modernization Act (FSMA). The [FSMA](#) represents the first major changes to the Federal Food, Drug, and Cosmetic Act since its passage in 1938. The FSMA applies to any food facility that manufactures, processes, packs, distributes, receives, holds or imports articles of food, but does not affect food regulated by the Department of Agriculture such as meat, poultry, and processed egg products.

Four important provisions of the FSMA go into effect immediately.

- **Mandatory Recall.** For the first time, the FDA has the authority to issue a mandatory recall if there is a reasonable probability that the food is adulterated or misbranded, and if the use or exposure to the food will cause serious adverse health consequences or death to humans or animals.
- **Stronger Access to Records.** The FDA also has the authority to access and copy all records relating to an article of food that the FDA reasonably believes will cause serious adverse health consequences or death.
- **Whistleblower Protection.** Food facility employers may not discharge or discriminate against any employee who provides information regarding potential violations to the FDA.
- **Foreign Facilities Must Allow FDA Inspection.** If a foreign facility refuses an FDA inspection, Customs and Border Protection will not admit any food from that facility into the United States.

Although the FDA must promulgate rules and design programs before other major provisions become effective, other important provisions of the FSMA include:

- **Hazard Analysis and Prevention.** Food facilities must develop a written hazard analysis, and must identify and implement preventative controls. Facilities must keep records, for not less than two years, documenting the use of preventative controls, instances of nonconformance material to food safety, and instances when the facility implemented corrective action.
- **Biennial Registration and More Frequent Inspections.** Food facilities will be required to renew their registration each even-numbered year. The FDA will increase the frequency of inspections. "High-risk facilities" will be inspected once every three years and lower-risk facilities will require inspection every five

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years.

- **Registration Suspension**. The FDA has the authority to suspend a food facility's registration if the food from the facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals.
- **Stricter Import Regulation**. The FDA also will promulgate regulations for a foreign supplier verification program. The FDA has the authority to require certification of high-risk imported foods. The FSMA also mandates increased inspection of foreign food facilities.
- **Fees**. The FSMA allows the FDA to assess and collect fees for food facility re-inspection, importer re-inspection, food recalls, and a voluntary qualified importer program.

The government's interest in food safety has never been greater. Although the ultimate business impact of this legislation might not be measured for a few years, all companies involved in the production and sale of food in the United States should immediately evaluate their processes and develop preventative controls, a hazard analysis and a document retention policy to comply with the Act.

Reinhart will continue to monitor implementation of the FSMA's provisions. For more information about the law, how it could affect your company, or how Reinhart attorneys can help you comply with the FSMA, please contact a member of Reinhart's Product Liability Team.

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