

New Inspection and Compliance Mandates under FDA Food Safety Modernization Act

About **48 million people** (1 in 6 Americans) get sick, 128,000 are hospitalized, and **3,000 die each year** from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable.

The FDA Food Safety Modernization Act (FSMA), signed into law by President Obama enables FDA to better protect public health by strengthening the food safety system. It recognizes that preventive control standards improve food safety only to the extent that producers and processors comply with them. Therefore, it will be necessary for FDA to provide oversight, ensure compliance with requirements and respond effectively when problems emerge.

Building a new food safety system based on prevention will take time, and FDA is creating a process for getting this work done. Congress has established specific implementation dates in the legislation. The funding the Agency gets each year, which affects staffing and vital operations, will affect how quickly FDA can put this legislation into effect. FDA is committed to implementing the requirements through an open process with opportunity for input from all stakeholders.

FSMA provides FDA with important new tools for inspection and compliance. Specific implementation dates specified in the law are noted in parentheses:

- **Mandated inspection frequency:** The FSMA establishes a mandated inspection frequency, based on risk, for food facilities and requires the frequency of inspection to increase immediately. All high-risk domestic facilities must be inspected within five years of enactment and no less than every three years thereafter. Within one year of enactment, the law directs FDA to inspect at least 600 foreign facilities and double those inspections every year for the next five years.
- **Records access:** FDA will have access to records, including industry food safety plans and the records firms will be required to keep documenting implementation of their plans.
- **Testing by accredited laboratories:** The FSMA requires certain food testing to be carried out by accredited laboratories and directs FDA to establish a program for laboratory accreditation to ensure that U.S. food testing laboratories meet high- quality standards. (Establishment of accreditation program due 2 years after enactment)

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm257978.htm>