Sage ERP X3

Net@Work

What food manufacturers need to know about the Food Safety Modernization Act

Major new food safety legislation is reshaping the food industry, and food companies need to be prepared.

Table of contents

Introduction
What is the Food Safety Modernization Act?

In the aftermath of the September 11, 2001, terrorist attack, American national security became a major priority—including food security. This led to the creation of the Bioterrorism Act of 2002, which created a registration system for food companies operating in the United States and implemented other controls intended to improve the safety of the American food system. That system of controls has now been further expanded by the Food Safety Modernization Act (FSMA), signed into law by President Obama in 2011. **The FSMA is the most expansive shift in regulation of the food and beverage industry in many years.** It greatly expands the powers of the Food and Drug Administration (FDA) and greatly increases the regulatory burden on food and beverage companies.

Purpose and impact

The FSMA's primary purpose is to shift the FDA's role in food safety from a reactive role to a preventive one—from responding to outbreaks of foodborne disease to preventing them. The act therefore greatly extends the powers and authority of the FDA over the entirety of the food system, from farm to table. The burden of compliance will be much higher, and the power of the FDA to enforce compliance will be much greater. The act grants the FDA many new powers and responsibilities, including mandatory recall authority, greater access to records, a much-expanded inspection program, and a variety of mandatory controls and documentation programs.

For food companies, this means **a much greater burden to prove that their entire operations are running with proper food safety prior to going to market, rather than merely becoming accountable after a safety violation**. Companies will need to invest in much-expanded testing, documentation, and auditing procedures. Failure to comply brings the threat of mandatory recalls, enhanced inspections, severe penalties from federal and other regulators, and even lawsuits. An automated enterprise resource management solution like Sage ERP X3 can greatly relieve the burden of these new requirements and allay the danger of negative consequences.

Failure to comply brings the threat of mandatory recalls, enhanced inspections, severe penalties from federal and other regulators, and even lawsuits.

Timeline

Although the FSMA was signed into law in January, 2011, implementation of the law is still under way. The FDA has gradually rolled out new regulations through a process that allowed for public and industry comment. In addition, the agency has only gradually increased its own internal resources to take on its expanded role. As of 2014, many statutes have been approved, but many have yet to be implemented or regulated by the FDA. The registration system had been implemented, with some exceptions, by 2012, but the product-tracing aspect of the law has yet to be finalized in 2014.

Most importantly, the FDA's increased inspection schedule has yet to be rolled out. The agency is still seeking an increased budget to support the greatly expanded inspection schedule called for by the FSMA, so food companies are not yet subject to this enhanced inspection schedule. The FDA is seeking greatly increased funding over the next few years to support these efforts.

All rules within FSMA are scheduled to be finalized by early 2016, with compliance deadlines following by one to four years. Accordingly, **all aspects of FSMA should be implemented by 2020 at the latest. However, most will be implemented much sooner, by 2016 or 2017.** This is especially true for larger companies, which have the shortest compliance windows.

FSMA implementation schedule

Rule	Final rule deadline	Compliance: non-small	Compliance: small
Preventive control human food	8/30/15	1 year	2 years
FSVP	10/31/15	6 months after preventive control rule becomes effective	2 years after preventive control rule becomes effective
Produce safety	10/31/15	2 years	3 years
Food defense	5/31/16	1 year	2 years
Sanitary transport	3/31/16	1 year	2 years
Third-party accreditation	10/31/15	N/A	N/A
Source: The Acheson Group			

Affected industries and producers

No food company in the United States—or outside the United States and doing business with domestic companies—is unaffected by the FSMA. Even producers of alcoholic beverages, whose industry is not regulated by the FDA but by the Bureau of Alcohol, Tobacco, Firearms and Explosives, have been affected by statutes regulating whether farmers can purchase spent grain from them for animal feed. However, **the nature and size of a given company affect how the act applies to it—whether directly or indirectly—and how stringent its compliance schedule will be.**

Very small businesses

The smallest local food producers are largely exempted from FSMA regulation if their revenue is under $500,000 a year and their sales are primarily local. This aspect of the FSMA aims to preserve local food systems by keeping these producers within state and local regulations. However, the act does mandate that these producers provide evidence of state or local certification and display the name of the farm or producer prominently on labels and other marketing materials.

Small businesses

Any food company with more than $500,000 in yearly revenue and/or a majority of sales outside their local area must comply with the full force of the FSMA. However, small businesses receive additional time to comply, generally a year or 18 months.

No food company in the United States is unaffected by the FSMA.

Key statutes

The FSMA can be divided into a few key sections affecting different areas of the food system. Each area has its own deadline and is being rolled out on its own schedule. The following highlights a few of the most important statutes for food manufacturers.

Preventive controls

Preventive controls are being implemented to mandate strong food safety plans throughout the food industry. The preventive control rule begins with facility registration, which has already been mandated throughout the industry. With registration accomplished, the next element of preventive controls lies in hazard analysis and the creation of a food safety plan. This statute will be finalized by the end of 2015, and compliance will be mandated for many companies by the end of 2016. Although some industries are exempt due to prior preventive controls (such as seafood and juice, which are already required to employ rigorous hazard analysis), **for many companies this will require a substantial investment in hazard analysis and a new or expanded food safety plan.**

Foreign Supplier Verification Program

The Foreign Supplier Verification Program Proposed Rule (FSVP) is an element of the act that requires more stringent checks on the quality and safety of imported products. Although food manufacturers have always been required to verify that their suppliers are not providing adulterated or misbranded food, **the FSVP requires both greatly expanded record keeping and more extensive verification that suppliers are conducting themselves appropriately**. Manufacturers will be required to keep a current suppliers list, which may be required to be furnished to the FDA at any time and must verify that suppliers are conducting hazard analysis, among numerous other checks.

Traceability

No element of the FSMA will have more impact on food manufacturers than the traceability requirements, which are included in the act under the category of “food defense.” Although this element of the act has yet to be fully defined, **the industry can expect that existing product tracking requirements will be expanded.** The current requirement of tracing one step forward and one step back has yet to be modified, but that situation is unlikely to hold true in years to come. Accordingly, food manufacturers will need to invest in more efficient and accurate tracking along their supply chains in order to comply with the transparency office.

No element of the FSMA will have more impact on food manufacturers than the traceability requirements.

Compliance for food manufacturers

Ultimately, for food manufacturers the FSMA will mean a new focus on risk assessment, food safety, record keeping, and transparency. **Companies will need to invest not just in training and education but also in an enhanced system for tracking ingredients and processes**, which often require additional human resources to implement new safety regulations and provide support for changes to operating procedures. The burden will be particularly heavy for companies not small enough to be exempt but which lack the resources of a major multinational operator.

For food manufacturers, FSMA will mean a new focus on risk assessment, food safety, and transparency.

How Sage ERP X3 can help

Sage ERP X3 provides a resource planning and automation solution for small and midsized food manufacturers, supporting record keeping, tracking, accounting, and a host of other essential business functions. **As the FSMA rolls out, Sage ERP X3 provides vital support to food manufacturers, often helping them avoid increased overhead despite expanding their compliance and transparency programs**. With Sage ERP X3 you can track your suppliers, lots, and processes and easily provide essential documentation to everyone who needs access.

For additional information about the FSMA, streamlining transparency in food manufacturing, or resolving resource management challenges, **visit our Sage ERP X3 Food Industry Resource Center at www.netatwork.com/sage-erp-x3, or call us at 1-800-719-3307.**