Managing FSMA Regulations with ERP: Key features to look for when selecting your new system

By RKL Team

More and more, companies are under pressure to maintain their competitiveness while complying with an increasing array of regulatory requirements. How companies manage their response to these mounting regulations can have a significant impact on the bottom line. And having a process in place that is capable of collecting the information needed – while being easily tailored to specific company requirements – is paramount to the success of the business.

Compliance is Costly and Burdensome

While all public companies have to comply with the Sarbanes Oxley Act, manufacturers across a variety of industries have their own specific regulations with which they must comply. Chemical companies are subject to OSHA Hazard Communication Standard, SARA Title III, ANSI and the European Union REACH legislation. Medical device manufacturers and pharmaceutical companies are concerned with current Good Manufacturing Processes and 21 CFR Part 11. Food and beverage producers have to manage the Bioterrorism Act, HACCP, and more recently FSMA or the Food Safety Modernization Act. In addition, there is the U.S. Food and Drug Administration's new Reportable Food Registry electronic portal, which attempts to thwart potential cases of food borne illness by requiring food industry officials to alert the FDA within 24 hours if they find a reasonable probability that an article of food will cause severe health problems or death to a person or animal.

Managing government regulations is a necessity. It is also burdensome and costly. A recent survey by the National Association of Manufactures found that, in the U.S., the cost of complying with federal regulations is steep – over $19,000 per employee exceeding $2 trillion annually. This cost can be reduced by automating most of the compliance process. As a matter of fact, an Aberdeen Group report[1] found that F&B industry leaders that automate their business processes with an ERP solution have quicker response time in lot tracking and traceability, and better quality management. The report also mentioned that F&B compliance lagers who were still using manual processes spent an average of 23.2 hours responding to non-conforming shipments versus F&B leaders whose average response time to the same issues were under 4 hours.

The Food and Beverage (F&B) industry has its' own challenges too. The burden of foodborne illness is considerable. According to data provided by the US Centers for Disease Control and Prevention (CDC) an estimated 48 million, ie: 1 in 6 Americans are affected each year by foodborne illness – including 128,000 hospitalizations and 3000 deaths [Source CDC]. This is against varied consumer background, including changing demographics and the desire for year-round supply of fresh foods. These trends are driving the need to source fresh food and ingredients from around the world. Consequently, there are now more foods in the marketplace, presenting new and previously unknown hazards. Imported food currently accounts for 17% of the whole US food supply and has grown rapidly over the last 10 years, with certain products such as seafood and fresh produce accounting for the majority of imports [Source USDA].

What's new? The "Food Safety and Modernization Act" (FSMA)

The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama in January 2011, with the final rules for Preventive Control going into effect on 9/10/2015 (see Appendix for FSMA Proposed Rules Timeline). It effectively amends the Federal Food, Drug and Cosmetic Act (FFDCA) of 1938. The new statute, which received bipartisan support, encompasses 50 new regulations. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.

[1] "Food Safety and Quality: Ensuing Compliance and Traceability across the Enterprise", Aberdeen Group, January 2015.

In essence, the Food Safety Modernization Act (FSMA) "enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur."[2] The new law specifies FDA mandates and authorities in five specific areas:

1. **Prevention -** Controls for food facilities, safety standards for producing and harvesting produce and avoiding intentional food adulteration. Food facilities are required to implement a preventive controls plan including: evaluating the hazards that could affect food safety, specifying what preventive steps, or controls, will be put in place to significantly minimize or prevent the hazards, specifying how the facility will monitor these controls to ensure they are working, maintaining routine records of the monitoring, and specifying what actions the facility will take to correct problems that arise.

2. **Inspection and Compliance -** Inspection frequency, records and laboratory testing. The law directs the FDA to increase inspection to at least once every three years. Further, the FDA shall have access to food safety plans and implementation records. FSMA directs certain food testing be done by accredited laboratories and the FDA to establish a laboratory accreditation program.

3. **Response -** Tools that the FDA can use to effectively respond to problems when they occur. These tools include mandatory recalls, facility registration suspension, administrative product detention, product traceability, and records for high-risk foods. These tools give the FDA authority to take direct corrective action in the containment and removal of emerging food safety problems.

4. **Imports** are under tighter controls in an effort to increase importer accountability. Third party certification and testing requirements along with certification for high risk foods is mandated. Currently, the certifications are voluntary for qualified importer programs, providing them broader authority to deny entry of goods.

5. Business **Partnerships** - In addition to mandating increased controls associated with your own materials and processes, the FSMA makes you responsible for your suppliers' operations. This creates new challenges for internal systems that are required to manage contract manufacturing and packaging supply chain activities.

Additional information and updates can be found at http://www.fda.gov/fsma

ERP Software Can Help

Keep in mind that many food and beverage processors have taken steps over the past several years to improve their internal controls and compliancy systems. Often, this includes investment in a modern ERP software solution. ERP systems that provide specific functionality help them achieve compliance with the major provisions of the FSMA and other regulatory mandates.

More specifically, in order to meet the document management and traceability requirements of the Food Safety Modernization Act (including HACCP), food processors are in search of innovative Food and Beverage ERP solutions that provide more than just lot traceability. Today's leading Food ERP solutions go beyond finance, accounting, and supply chain management - they enable you to identify, document, monitor and follow up on critical control points, thereby supporting compliance with even the most stringent regulations and reporting requirements, including FSMA, GFSI, and SQF protocols.

[2] "Background on the FDA Food Safety Modernization Act (FSMA)", Food and Drug Administration, July 13, 2015.

An ERP solution plays a central role in regulatory compliance. Because it maintains one common database, the ERP system can help minimize reporting costs by providing a convenient and efficient way to gather and monitor relevant information and eliminating manual procedures throughout the manufacturing process.

Seek an ERP System that Promotes Compliance
Companies in government regulated industries need an ERP solution that includes integrated functionality designed to promote compliance. Some important features to look for include:

Lot Traceability
Traceability can be utilized as a competitive advantage by automating and giving visibility to continuous improvement initiatives. When lot traceability and automated batch processing information is easily accessible to those who need it, root cause analysis and real-time CAPA (corrective and preventive actions) become attainable best practices.

To be most effective, the ERP system should manage complete forward and backward traceability for each ingredient and finished product. It should also include user-defined technical sheets and operational detail instructions, along with lot and sub-lot control.

Audit Trail
Audit trails are essential to address compliance requirements for how data is obtained, used, managed and secured. The ERP system should, at a minimum, authenticate user name, date, time, previous data, new data and the reason for the change. Additionally, it should be able to maintain an archive of historical transactions for multi-year periods.

Quality Control
A fully integrated quality control process helps companies automate and streamline their paper processes for increased efficiency and regulatory compliance. Through a rules-based orientation, the ERP system should enforce inspections at key event points (HACCP) to assure item conformance to any required product characteristics, operational tolerances or expected results. The system should automatically quarantine items that fail any inspection rules, as well as suspicious items, and designate them for disposal or further inspection.

Sub-Contractor Management
Business partners, or, contract manufacturers, are often cumbersome to manage. Complete integration and monitoring of materials, laboratory testing and value added services must be controlled. End-to-end visibility of your contract manufactures are effectively monitored and relevant documentation is electronically associated with critical control points of the ERP system.

Document Management
Documents capture and transfer vital information. They are both generated from the data source and scanned as an electronic attachment. For documents requiring handwritten signatures – such as Certificates of Analysis, Certificates of Origin or Technical Sheets – scanned, digital or flattened digital signatures are often required. The ERP system should maintain controlled documents with an image linked to specified business partners, production and inventory activities.

Security Features
It's important to have security standards in place to safeguard against unauthorized use of the system and protect against both outsider crime, like industrial espionage, and insider crime, like embezzlement. The ERP system should, at a minimum, include features for automatic logoff after a period of inactivity, automatic logout after too many failed logon attempts and logging of all user activity.

Find a Flexible Solution That's Easily Tailored to Unique Business Processes
As mentioned earlier, manufacturers are under increasing pressure to remain competitive while complying with a variety of regulatory requirements. And it's likely that new regulations will continue to be enacted in the coming years. Companies can protect their investment in an enterprise system by selecting an ERP system that offers a two-fold approach to dealing with changing requirements.

First, the system should easily adapt to the company's unique needs. An ERP system that offers an integrated development environment (IDE) enables easier personalization of the system and enables the use of the company's formulas, rules and conditions without making programming changes.

Second, the system should offer flexibility in adapting to changing business conditions. Change is the norm in business today. Not only do companies need a software solution that's capable of supporting existing business processes, they need a system that can adapt to future business processes as well … one that offers simple parameterization features to make adjustments to information flows and procedures quickly, without additional development. The value of a flexible ERP system should not be underestimated.

Achieve Best-in-Class Status
The same Aberdeen Group report found that a majority of hardships in F&B manufacturing can be attributed to manual processes that manage compliance and traceability programs. Validating compliance can be time consuming sorting through filing cabinets, spreadsheets, and various notebooks. To become Best-in-Class, manufacturers should utilize automated solutions to "build in" compliance and traceability to production processes.

An advanced ERP solution will enable manufacturers to capture information electronically, helping them to achieve better compliance and to save the huge costs of managing paper-based systems. It can also increase the speed of product release, identify supplier issues and gain agility by being able to obtain the needed information quickly.

With real-time visibility into production processes and automated traceability, companies have a competitive advantage with the ability to address issues while still in process. During continuous improvement initiatives, manufacturers without these capabilities are often relegated to recreating situations and conducting root-cause analysis days after the events have occurred. Don't get left behind in piles of papers, be proactive.

Please contact us for a free assessment of how your company can benefit from Sage X3 at (717) 735-9109 or sales@rklesolutions.com.

Appendix

FSMA Proposed Rules Timeline

Rule	Final Status	Point of Contact	General Compliance Period	Small Business Compliance	Very Small Business Compliance
Preventive Controls for Human Food	9/10/2015	Jenny Scott, Center for Food Safety and Applied Nutrition, FDA	9/19/2016	9/18/2017	9/17/2018
Preventive Controls for Food for Animals	9/10/2015	Kim Young, Center for Veterinary Medicine, FDA	9/19/2016	9/18/2017	9/17/2018
Produce Safety	10/31/2015	Samir Assar, Center for Food Safety and Applied Nutrition, FDA	10/31/2017	10/31/2018	10/31/2019
Food Supplier Verification Programs (FSVP)	10/31/2015	Brian Pendleton, Office of Policy, FDA	5/1/2017	5/1/2017	5/1/2017
Accreditation of Third-Party Auditors	10/31/2015	Charlotte A. Christin, Office of the Commissioner, Office of Policy, FDA			
Food Defense	3/31/2016	Ryan Newkirk, Center for Food Safety and Applied Nutrition, FDA	3/31/2017	3/31/2018	3/31/2019
Sanitary Transportation	3/31/2016	Michael Kashtock, Center for Food Safety and Applied Nutrition, FDA	3/31/2017	3/31/2018	

Small businesses: a business that employs fewer than 500 persons; very small businesses: defined as having less than $1 million in total annual sales of human food, or 2.5 million in total annual sales of animal food, adjusted for inflation.

Small businesses, those with more than $250,000 but no more than $500,000 in produce sales; very small businesses, those with more than $25,000 but no more than $250,000 in annual produce sales.

The compliance dates for water quality standards, and related testing and record keeping provisions would be an additional two years beyond the compliance dates for the rest of the final rule.

In general, the compliance date would be 18 months after publication of the final FSVP regulations. There would be some exceptions.

For the importation of food that is also subject to the preventive controls and produce safety rules, the importer would be required to comply with FSVP regulations six months after the foreign supplier is required to comply with preventive controls or produce safety regulations. The compliance dates for those regulations vary, depending on the rule and size of the operation.

Small Businesses: a business employing fewer than 500 persons; very small businesses: a business that has less than $10,000,000 in total annual sales of food.

Source: IFT 2015