The Food Safety Modernization Act
Responding to a new era of regulations

With world-leading technology and transportation supported by regulations and laws, the food supply in the United States is considered relatively safe and secure. Yet each year about 48 million Americans – about one of every six people – get sick from food-borne diseases, according to Home Food Safety. Of those, 128,000 are hospitalized and 3,000 die every year.

The 2011 Food Safety Modernization Act (FSMA), which puts greater emphasis on preventing food-borne illness, was enacted to enhance accountability in today's globally intertwined food supply chain. The law gives the Food & Drug Administration (FDA) broader authority to inspect records related to food. Under the provisions of the FSMA, which was signed into law in January and takes effect in stages, companies will be required to develop and implement written food safety plans.

In addition, the FDA also will have the authority to better respond to and require recalls when food safety problems occur as well as the ability to better ensure that imported foods are as safe for consumers as foods produced in the United States. Proponents say the law makes everyone responsible and accountable at each step in the food supply chain, whether producing, processing, transporting or preparing foods.

The law affects any factory, warehouse or importer that manufactures, processes, packs or stores food in the United States. The law's provisions include:

- Mandatory preventive controls for food facilities.
- Inspection and compliance, including records access and testing by accredited laboratories.
- Increased FDA response authority, including mandatory recall, expanded administrative detention, suspension of registration and enhanced product tracing abilities.
- Greater importer accountability and record keeping.
- Enhanced partnerships between state and local authorities.

This whitepaper analyzes three key issues related to the FSMA: Documentation, audits and traceability.

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Regardless of how the food industry reacts to the law, companies must adapt to these new regulatory realities and renewed scrutiny or face a stark reality: without making changes, they may very well be left behind.

**Documentation**  
**Keep critical records in compliance**

The Food Safety and Modernization Act expands FDA authority to inspect records related to food (with the exception of farms and restaurants.) Under the law, companies that manufacture, process, pack, distribute, receive, hold or import food must permit inspection of records where the FDA believes that there is a reasonable probability of serious adverse health consequences or death. The law also gives the FDA authority to suspend registration if the food has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

To ensure compliance, all registered facilities must conduct a hazard analysis and develop and implement a written preventive controls plan that evaluates hazards; identifies and implements preventive controls; monitors the performance of those controls; and maintains records of such monitoring and preventive controls for two years. In essence, it means companies need to have in place a current, validated and verified food safety program subject to annual review.

The key to responding to these new regulatory teeth is to organize and clean up existing documentation, establish a system to control documents going forward and implement adequate policies to ensure ongoing compliance.

Just as the new law is intended to modernize regulations, this is an opportunity for the industry to adapt to new technology that manages documents and information, including tools that can digitally and centrally store inspection records for easy access and action.

Just think – how much time do you spend each day managing documents and ensuring accurate records are available for auditors, customers and internal stakeholders? Things like transactions, shipping records, logs and employee training documents. It doesn’t matter if you’re reviewing, revising, circulating, printing, filing, faxing, scanning, mailing, or just storing a document. Paper-based processes take up time-consuming and valuable resources.

Companies seeking a solution should look for a system that provides electronic approval and access, efficient storage, document identification numbers that can easily be searched, automatic review, a full audit trail of previous revisions, and a fully reportable indexed document system. When new documents come in, they should be entered into the system and immediately tracked, stored, and instantly available for managers, employees – and auditors.

**Audits**  
**Access data timely and orderly**

Stepped-up and more complex audits will be more prevalent under the new law, and the industry needs to be prepared with quick access to systems that provide a robust and accurate history of records.
Preparing for audits, administering inspections, recording observations, and scoring and trending results is a necessary activity for any successful food company. Here are some questions managers should ask as they evaluate their company’s ability to conform to the new law:

- Are you pleased with your ability to manage audit specifications and preparation?
- Can you carry out efficient internal audits and provide actionable intelligence through insight into opportunities for improvement?
- Do you have the ability to predict trends and implement strategies to combat pending incidents before they happen?
- Can you provide an organizational ‘health-check’ report or status update on your audit criteria instantly on-demand?
- Can you segment the auditable documentation, process or records by customer, third-party or regulatory standards like SQF, BRC or ISO?

Today, a successful audit is a result of keeping all the information you need accessible, electronic and actionable.

Keeping employee training records up to date, ensuring the newest version of standard operating procedures, GMPs and other key documentation is given to employees, managing each new revision of every standard, and documenting company processes and procedures is a lot of work for one person or department – especially when audit readiness is a company-wide objective and critical to the safety of your products and health of consumers.

An electronic solution ensures only the most current documentation is available, that gaps in compliance can easily be found, and that all company processes are electronically routed. All the information you need for a successful audit is right at your (and your auditor’s) fingertips. With the right system, audit readiness is a matter of clicks, not hours.

**Traceability**

**Managing data for maximum recall**

Say there’s a food recall involving an ingredient that’s used in your facility. The producer would notify you with a lot number. Then you’d have to track where that ingredient was used in your product and where your product went. But with the complex chain of processing entities in today’s food industry there are a host of parties involved in processing, transportation and distribution.

When it comes to recalls, everyone involved has to own the process, isolate the potential for danger. You need to be able to have ability to provide records quickly. You need to track every retail establishment selling your product.

The Food Safety Modernization Act requires traceability one step up and one step back from your contribution to the production process. This includes packaging, processing, work in progress, rework, and potentially even your waste materials. Among other components, the law provides for whistleblower protection, increased inspection, increased record-keeping requirements and more authority to review records.
You’ll need to be ready – whether it’s HACCP records, inspection data, supplier history, customer complaints, corrective actions and more. These days the Five Ws (Who, What, When, Where, and Why) can create worthless records if not done correctly. This is what’s expected under the new legislation:

- **Who?** A complete name, initials, or electronic signature.
- **What?** The action taken or recorded must be clear including not just the activity, but the results of the activity.
- **When?** A complete date and time or shift.
- **Where?** The line or equipment location.
- **Why?** Justification for actions may need to be evident.

**Are you ready?**

**Industry at a crossroads**

**Long a solution, digitization is way forward**

Despite its restrictions and short-term pain, the new law is an opportunity to enhance quality in the food industry. Rather than spend countless hours compiling paper and verifying data to meet the new requirements, companies in the industry will need to fully embrace an electronic solution that ensures documents are up to date and performing under the rigors of the production environment.

Having the right compliance software helps you do what you say and say what you do with a controlled electronic environment that prevents issues and accidents associated with manual record-keeping.

One significant benefit of the new law is its emphasis on food safety plans and recall scenarios. Corporations of every size routinely test their emergency preparedness. An electronic system can reduce the time to plan and execute scenarios from weeks to days. With an electronic tool, data is linked and available, across facilities, with the ability to dig into the data and perform internal audits at any time.

Implementation of the Food Safety Modernization Act is also a good time to contemplate the future of your business – what automation will be needed to maximize your efficiency and profitability? What other regulations are around the corner that will impact your business? What can you afford to spend on the next audit or recall?

Managing regulations won’t be getting any easier. In fact, with more frequent audits and other mandates, it will indeed become more challenging. More tools and technology will be needed for better record keeping and growing demands.

The industry – finally – is embracing automation as a way to combat the growing complexity of regulations and bigger magnifying glass of compliance.