The Food Safety Modernization Act of 2010 is here to stay, and the best thing food manufacturers can do is to take a decidedly proactive stance.
EXECUTIVE SUMMARY

President Obama signed the Food Safety and Modernization Act (FSMA) into law in January 2011. Three years later, however, the FDA has published only two of the many provisions of the law, leaving the rest still open to public comment and political debate. As a result, food manufacturers are left wondering what they must do to comply with the existing rules and what actions they should take now to prepare for the regulations yet to come.

The spirit of the FSMA has shifted from a reactive to a proactive mode as it approaches food safety in the United States. Food companies are advised to do the same with regard to compliance. Portions of the new law are already in effect. More provisions are coming, and the FDA is now highly motivated to publish the main body of the Act quickly. Although many provisions of the law remain unclear, food manufacturers must act on those in effect today and prepare for those rules that are sure to be implemented in the coming months.

This paper discusses the ramifications of the FSMA – specifically…

• Provisions of the law that are in force today
• Provisions we know are coming
• Actions food manufacturers should take now in order to proactively protect their brand and prepare to comply with the new law in the most cost-effective manner possible.
**FSMA – WHAT WE HAVE NOW AND WHAT WE KNOW IS COMING**

There was much bipartisan fanfare when President Obama signed the Food Safety and Modernization Act (FSMA) into law in January 2011. The FDA hailed the Act as “the most sweeping reform of our food safety laws in more than 70 years.” Consumers applauded the law in hopes that it would significantly decrease the probability of food borne illness outbreaks. Even food industry executives saw the benefit in the form of lower costs in the event of a recall.

However, nearly three years after the bill became law, the effect of FSMA on the American food industry can only be described as nebulous. This certainly isn’t because the law has no substance. On the contrary. When fully implemented, FSMA will set the standard of food safety for all industrialized nations worldwide. Rather, the reason for FSMA’s modest effect is that so few of its provisions have been implemented yet.

When the law was passed in 2011, Congress mandated that the FDA write and publish all FSMA regulations no later than July 2012 – 18 months after the President signed the bill. For reasons known only to government regulators and beltway insiders, the FDA has been unable to meet this mandate, much to the dismay of the food industry they aim to regulate. In fact, they have missed the deadline so badly that in April 2013, U.S. District Judge Phyllis Hamilton publicly reprimanded the agency for taking so long to write and publish the food safety rules they are required by Congress to enforce.

Few things motivate a bureaucrat like negative publicity. This public chiding by a federal judge promised swift action from the FDA in the form of reams of hastily written regulations. However, increased time pressure would certainly have caused the agency to write over-reaching regulations laced with unintended consequences, putting many farms and food companies in dire financial straits.

Thankfully, Congress recognized this potential for over-regulation and took steps to rein it in. Together with the courts and the National Association of State Departments of Agriculture (NASDA), Congress granted the FDA more time to properly compose the FSMA rules, including the issuing of 2nd drafts of the rules for public comment. The new deadline for full FSMA implementation is June 30, 2015.

In short, the regulating agency now has a little more time to get the rules right. But make no mistake. The FDA is now in a place no bureaucrat wants to be: in the public spotlight and under a time constraint. Though the regulations have been slow in coming, they are sure to come far more quickly than they have in the past 3 years. And when they arrive, the FDA will have broad-based authority to enforce FSMA and a new set of technology-based tools to enforce it with. Therefore, food manufacturers should proactively equip their firms with the tools necessary to comply with the new law in the most efficient and cost-effective manner possible.

So how is a food manufacturer supposed to be proactive in the face of such uncertainty? The answer is clear, even if the impending rules are not. Act on what we have today and what we see coming tomorrow. There’s no better place to start than with the rules currently being enforced.

Ideally this work is carried out as part of software implementation. Training courses should be linked with in-depth consulting on in-house process optimization. Experienced experts train users in applying professional optimization methods, such as lean production and Kaizen. When working with personnel in all MES-relevant departments, daily workflows are analyzed, necessary changes are uncovered, and the organization is restructured. The goal should be to closely involve personnel in the process and thus eventually reduce production costs. However, each individual must develop a fundamental understanding of the value of the MES solution and of their role in the continuous improvement process. This awareness must be embedded at every hierarchy level in the manufacturing company. This is the only way to successfully reveal optimization potential in process and equipment, as well as to plan, realize, and measure the success of improvement efforts.

**FSMA REGULATIONS IN EFFECT TODAY, AND WHAT THEY MEAN FOR FOOD MANUFACTURERS**

When the President signed FSMA into law, the language in the act took somewhat of a reactive stance. Lawmakers who drew up the bill were primarily concerned with the food industry’s ability to counter a serious food borne illness outbreak, such as a large-scale...
bioterrorist attack. Since then, however, the FDA has steered the spirit of the law more in the direction of prevention than reaction.

As a result, the current FSMA provisions require all registered food facilities to document a written hazard analysis plan along with a detailed plan of risk-based preventive controls. These documents must also include any food known safety incidents (both past and present), along with verifiable steps taken to make sure they do not reoccur. While this may sound a lot like the USDA’s Hazard Analysis Critical Control Point (HACCP) which has been around for decades, FSMA goes much further in terms of documentation requirements.

No longer will it be sufficient to generally document the processing operations that take place in a food facility. New FSMA regulations require much more stringent data management procedures. The new law lays out exactly what data must be recorded, how to record it, when it must be recorded (with exact dates and times down to the minute), and which employees recorded it along with their titles and data access credentials.

In short, under the old system, it was okay for a food company to log their data using verbal generalities and ballpark figures. Under FSMA, this is most assuredly not okay. In fact, when auditors show up unannounced to make spot checks, they will be looking for these types of generalities. If they find any, they will regard them as evidence of a possible lack of control, prompting them to probe deeper into the food processing operation for more defects and violations.

Therefore, everyone in the food supply chain should begin documenting the details of their operations in a clear, understandable, and auditable way. Because of the sheer volume of data that must be recorded, IT leaders in the food services industry should seek to acquire an enterprise resource planning system that lends itself well to risk-based documentation and reporting. The system should be powerful enough to capture detailed data and flexible enough to produce reports suitable to hand to an auditor on demand.

But time is of the essence. The documentation provision of FSMA is already in place and currently being enforced. The FDA has already exercised its authority in this area, forcing one peanut products manufacturer to cease operations until corrective measures were taken. So the key to compliance with the current rule is robust data management. While the FDA may give smaller operations more time to meet this requirement, the majority of the food industry should address this issue immediately.

FSMA: COMING REGULATIONS AND HOW TO PREPARE FOR THEM

While the FSMA provisions we have now focus on data management, the regulations yet to come have much to do with visibility of food processing firms’ operations. This includes the ability to trace foods and ingredients entering and exiting a plant and the capacity to respond swiftly should the FDA invoke a recall.

Arguably, these sections are the most demanding provisions of the law. They will also be the most costly to for firms to implement, which could explain why they haven’t been published yet. New regulations will require food processing firms to verify the safety of all imported foods and to implement a food tracing system to streamline the process of pinpointing the contamination source if an outbreak occurs.

Realizing how important traceability is to food safety, Congress required the FDA to evaluate the food industry’s readiness to trace the origin of food borne illness. To this end, the agency commissioned the Institute of Food Technologists (IFT) to conduct two pilot projects for the purpose of testing various food tracing practices among producers of processed foods and fresh produce. In March 2013, they submitted the results of those pilots to the FDA along with ways to improve tracing in a way that benefits all interested parties throughout the food supply chain.

It didn’t take long for the IFT to conclude that paper-based systems are utterly insufficient for tracing a defective food product to its original source. Sifting through hundreds of pages to detect the source of contamination proved neither efficient nor effective. Even for small to medium sized operations, an automated traceability system with an intuitive user interface is necessary to trace problem foods quickly in the event of a recall.

Additionally, the IFT report recommends the FDA take the following actions:

- Clearly identify the types of data that industry needs to provide during an outbreak investigations
- Require each member of the food supply chain to develop, document and implement a product tracing plan
• Pursue the adoption of a technology platform to allow the FDA to efficiently aggregate and analyze data reported in response to regulatory requests

• Coordinate trace forward and trace back investigations and develop electronic response protocols between and among state and local health and regulatory agencies

• Offer extensive outreach and education around future regulations and expectations

Many American food firms are still operating on antiquated traceability systems as they await final traceability requirements from the FDA. Based on these pilot findings, however, there is little question how the final regulations will read. It is no longer a question of if, but when the FDA will require food processing companies to implement robust traceability systems. Firms who implement such systems sooner rather than later will enjoy decreased exposure to a financially disastrous recall.

### MARKET DRIVERS THAT DEMAND A SOLUTION

Globalization is having a tremendous effect on the food industry. Consumers today enjoy an incredible variety of foods from around the world on their supermarket shelves. Fruits and vegetables seem to know no season: there’s always an abundance of choices. Food imports into the U.S. continues to rise, with 15% of the current food supply, including 60 percent of fresh fruits and vegetables and 80 percent of seafood, being imported from other countries.

But while consumers enjoy wider availability and greater selection, a number of recalls have eroded public confidence in the safety of the foods they purchase. A study by IBM determined that less than 20% of consumers trust food companies to develop and sell foods that are safe and healthy. The study revealed that 60% of consumers are concerned about the safety of food they purchase, and 83% were able to name a food product (such as asparagus, peanut butter, or tomatoes) that was recalled in the past two years due to contamination or other concerns.

Meanwhile, economic and population growth in emerging nations has increased the demand for food, including meat and protein. The net effect of these international market factors puts a strain on the food supply, increasing the risk of quality control oversights that can create food safety problems.

With consumer confidence in food safety at a low point, something had to be done. Both the industry and the federal government had a responsibility to make changes to improve the situation. The market drivers and overwhelming consumer sentiment that made FSMA inevitable calls for a clear solution whose time has truly come.

### TRACEABILITY – THE TIME IS NOW

The increasing demand for supervision, regulation, and readily accessible information means that track and trace solutions are becoming a necessity for any company in the food industry. Mitigating risk and meeting compliance are two reasons for implementing a traceability solution, but there are many other benefits as well.

Traceability solutions help companies to become better connected to every part of the food supply chain. They are able to build the trust of their customers and consumers when they can demonstrate where ingredients came from, how food is handled, and where it is distributed.

By implementing a solution, companies are better able to monitor and track every step in the supply and production chain and gain insight into processes. And, if it becomes necessary, companies have the ability to conduct a targeted and efficient recall that minimizes potential harm and disruption to the manufacturers, distributors and retailers.

### MANAGING A COMPLEX AND INTERDEPENDENT FOOD SUPPLY CHAIN

As food availability and selection has grown, food supply chains have expanded in complexity and geography, involving an ever-expanding web that includes growers and harvesters, manufacturers of ingredients, intermediaries, and food packaging processors, plus storage and delivery. Every link in the food chain plays a vital role...
in the safe delivery and consumption of food products around the world.

This interdependency means that every participant has a responsibility to maintain product safety and to keep careful records documenting ingredient origination, food preparation, and distribution. Due to the complexity of the food supply chain today, being able to trace “farm to fork” is unlikely; however, it is essential that every point in the food chain should be able to trace “one up and one back.”

Companies also have to minimize the risk associated with product recalls that can cost millions of dollars. Today, the increase of factory farms and agribusiness has magnified the potential scope of an outbreak. When something goes wrong, recalls can span the globe and implicate dozens of products. While there’s no doubt that a recall damages short-term profitability, it can also cause long-term damage to a brand or a company’s reputation.

Companies like Campbell Soup are taking a proactive approach to food recalls: the company voluntarily recalled 35,000 cases of SpaghettiOs in June 2010 when they discovered the meat might not have been cooked properly. By initiating a recall, Campbell’s Soup was able to protect the integrity of the brand and the reputation of the company. Other companies are not so fortunate: a total recall in 2007 forced Topps Meats to close its doors forever after almost seventy years of doing business.

The retail food industry is taking action to protect its own brands by initiating food safety audits and mock recalls that require their suppliers to have quick access to accurate product lot information and detailed supporting results. Many national retail chains, such as Wal-Mart and Kroger, are now requiring their food suppliers to conduct mock recalls. Some are even validated by external audit firms as a part of comprehensive food safety audits. Even one failed mock recall can result in a food processor being dropped for another supplier. If an actual recall occurs, accurate lot-specific information can make the recall much more efficient, as well as less costly and damaging to a company’s reputation. If the information is unavailable, the recall may have to be expanded to include all lots on store shelves and home pantries. The financial costs and damage to the brand’s reputation can be disastrous.

**BENEFITS TO IMPLEMENTING A TRACEABILITY SOLUTION**

The challenge now facing food processors is to identify a traceability system that meets the requirements of its business operations in a cost-effective manner. Enterprise resource planning (ERP) systems providing product lot tracing functionality offer an effective way for food processors to automate and integrate traceability across their supply chains.

A solution with lot-tracing capabilities allows a company to trace back to the source of all ingredients and trace forward to the distribution of all food products made and sold. If a safety alert arises, the processor can access information about the grower, supplier, and date range associated with the affected lots. Armed with this information, a company can recall the affected product lots, preventing illness and avoid having to recall product that is perfectly safe and saleable. There are several key benefits to investing in a traceability solution integrated into the ERP system:

1. **Instant traceability.** By implementing an ERP-based solution, companies gain end-to-end traceability for every action that impacts food safety, from initial ingredient orders to shipping conditions to delivery details. At every point in the supply chain, a business can trace forward or back to pinpoint either the source of a compromise or to locate product that can potentially cause a problem.

2. **Increased market share.** Food processors earn greater trust from their customers and consumers when they have instant traceability capabilities. This ability also enhances confidence from auditors, regulators and inspectors. In today’s marketplace, establishing a reputation for food safety and easily accessible supply chain information is a competitive advantage that translates into higher market share among distribution channels and consumers.

3. **Better bottom line performance.** An integrated solution offers detailed visibility into costs, inventory management, product and customer activities, helping businesses to make better decisions and identify opportunities for improving efficiency and increasing profitability. A trace solution also helps companies avoid or minimize the expenses associated with recalls, while delivering the audit or mock recall performance that customers demand.
Getting Started – Use a Traceability Checklist

1. Can you trace each ingredient back to its original supplier and specific delivery?

2. Can you trace a supplier lot to customers in minutes instead of hours or days?

3. Can specific lot characteristics be viewed alongside the trace?

4. Can you validate that purchases are made from certified suppliers?

5. Can you identify and search specific ingredients contained in by-products, co-products and finished products?

6. Do you have the ability to search by supplier?

7. Does your traceability solution extract and present data in a graphical view, not just in reports with many line items that need to be analyzed?

8. Is your traceability solution part of ERP solution, not a stand-alone module?

9. Can traceability be built into everyday transactions, such as costing, quality control, inventory, production, and performance analysis?

10. Does the solution retain searchable data in a centralized database for a user determined retention period?

11. Will your solution support traceability across multiple locations, such as factories, plants and warehouses?

12. Can reports be e-mailed or downloaded for use in presentations or spreadsheets?

13. Is your information available in the trace solution in real time, no waiting period?

14. Does built-in data validation along with barcoding prevent transposing information and typos?

15. Will this solution meet GSFI Requirements such as SQF2000 or BRC, including customer initiated mock recalls?

16. Can you verify quality information for certifications such as kosher, organic, gluten-free, etc.?

17. Will your traceability solution include electronic signatures so that you’ll be ready when the FDA makes it mandatory?
DON’T WAIT FOR UNCLE SAM

In the food and beverage industry, regulatory compliance and supply accountability are critical. Ensuring product quality and proper management as well as control of the ingredient supply chain is of utmost importance to process manufacturers. New government rules like FSMA increase the need for better traceability, improved supply chain visibility, and more efficient process standardization.

FSMA is here to stay, and like all government regulation, these rules add complexity, which must be managed. Many provisions of the new law are already in effect and currently being enforced. And while the meat of the law has yet to be finalized, experts and food industry veterans all agree that coming regulations will require food processing firms to implement a computer-based data management and food traceability solution.

Time is of the essence. The best thing food firms can do now is to take a decidedly proactive stance. Prepare your firm now for the traceability regulations we know are coming. Effective data management and traceability takes a small level of effort on the front end, but it saves millions in the event of a recall. By taking action now, you get a jump on the systems the new law will require and identify obstacles before you find yourself under a time constraint for compliance. When it comes to satisfying FSMA, an ounce of prevention truly is worth a pound of cure.

The TraceExpress tracking and tracing solution is integrated into Ross ERP. The graphic display works like a map program, allowing you to zoom in for detail and zoom out for a big picture when tracking and tracing any ingredient or lot.

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