



The Association for Packaging
and Processing Technologies



IMPLEMENTATION • DOCUMENTATION • VISION SYSTEMS • COMPLIANCE • CHALLENGES • SETBACKS • KEY PLAYERS

Food Safety & Traceability

2014

An overview of Food Safety and Traceability and an analysis of the effect of the Food Safety Modernization Act (FSMA) on packaging and processing.



The Association for Packaging
and Processing Technologies

FOOD SAFETY & TRACEABILITY

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EXECUTIVE SUMMARY AND PERSPECTIVE

FOOD SAFETY & TRACEABILITY REPORT



The Food Safety Modernization Act (FSMA), signed into law in 2011 but not yet fully implemented via regulations, represents the most comprehensive change to food safety regulation since the 1930s. The impetus for the law stemmed from a number of high-profile outbreaks of foodborne illness over the previous decade, with the Centers for Disease Control and Prevention (CDC) estimating that each year, foodborne diseases sicken one in six Americans (48 million people) and kill 3,000.

The FSMA will affect stakeholders throughout the food supply chain, including food packaging and processing equipment manufacturers. The law shifts the focus of food safety from *reacting* to contamination incidents to *preventing* such incidents. The Food and Drug Administration (FDA), the federal agency that implements the law, gains new powers under the FSMA. First, however, the agency must finish developing and finalizing the regulations that will provide the details on how it will implement the broad requirements of the Act.

It is these regulations – and the regulatory process itself – that food manufacturers are particularly concerned about. Food producers are anxious about the costs of meeting strict compliance requirements, including recordkeeping and traceability standards, and worried about training personnel in new procedures. Equipment makers would likely benefit if they better understand the struggles their customers will face in complying with FSMA regulations.

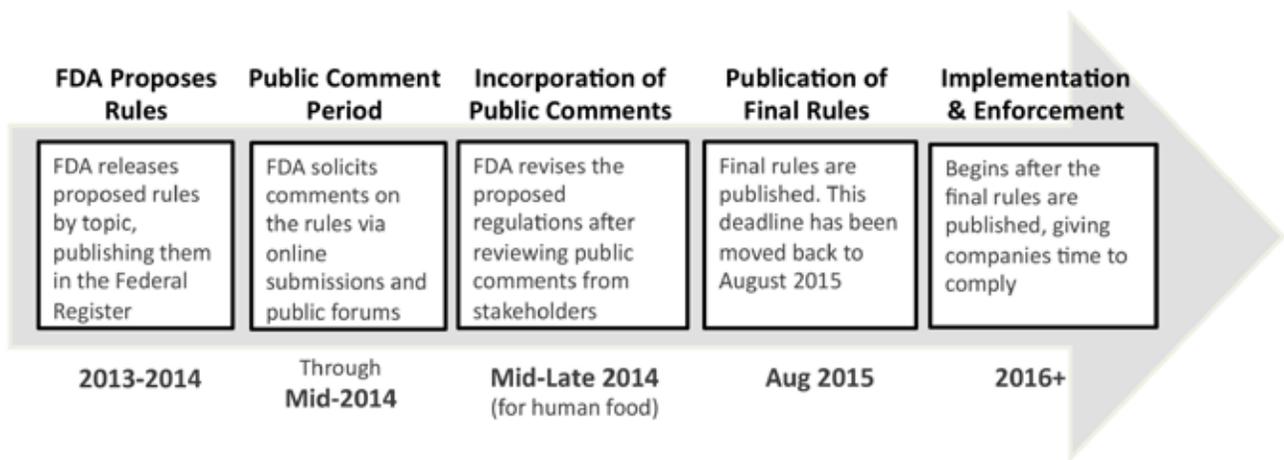
This report addresses the perceptions of food manufacturers, the impact of the FSMA and how equipment providers can best help them shape (through the public comment process) and respond to the upcoming regulations. The report is based on 64 in-depth interviews. Additional information on study demographics and methodology is included in the appendix.

Regulations: Implementation and Timelines

Although the FSMA was enacted over three years ago, the regulations that will implement the portions pertaining to human food are still being finalized. The rulemaking process – during which the legislative provisions of the FSMA are fleshed out with detailed administrative regulations, as enforced by the FDA, has been taking place in stages. Like all regulatory initiatives, the process includes a series of public comment periods before the FDA finalizes the rules. These comment periods, which are ongoing, provide opportunities for stakeholders (organizations and individuals) to provide their input on the proposed rules before they are finalized.

The FDA is proceeding along a typical rulemaking path to develop regulations to implement the FSMA, shown below:

FSMA: The Rulemaking and Regulatory Process



Many stakeholders across the food industry appear to be confused about implementation deadlines. This confusion has been heightened, in part, by shifting FDA timelines. After the rules become final, most companies will be given one to three years to comply. Produce farms will have from two to four years to comply.

FSMA Compliance Timeline for Food and Beverage Facilities Once Rules are Finalized

SIZE OF COMPANY	TIME TO COMPLY	DEFINITION
Medium to Large Businesses	1 year	More than 500 employees
Small Businesses	2 years	Fewer than 500 employees
Very Small Businesses	3 years	Three options have been proposed for the definition of a very small business, based on total annual sales of food, adjusted for inflation: 1. less than \$250,000 2. less than \$500,000 3. less than \$1 million

Standards and Level of Impact

FSMA requirements will be performance-based. That is, the FDA will not set specific standards for processing and packaging equipment; rather, regulations will focus on the performance that companies are required to achieve. This gives companies latitude in how they will meet the new requirements. For example, some companies will install new machinery, while others will attempt to squeeze acceptable performance out of legacy equipment with modifications and upgrades.

The three aspects of the FSMA that are most likely to impact both food producers and equipment manufacturers include rules governing:

- Preventive control
- Recordkeeping and traceability
- Sanitary equipment design

Several food safety experts indicated that, of the many new rules that will be implemented as part of the FSMA, the Preventive Control Rules are likely to have some of the earliest and most significant effects on food producers. These rules state that:

- Each facility in the food supply chain must implement a written food safety plan that focuses on preventing hazards in foods.
- Operators of each facility need to understand the hazards likely to occur in their operation and to have preventive controls to minimize or prevent the hazards.

Companies with inadequate preventive controls risk making people sick. This in turn may lead to poor publicity and brand destruction, which in turn risks a company’s viability. Thus, in reducing the risk of food safety incidents, preventive control rules will, ideally, help companies reduce business risks.

Traceability is expected to represent one of the greatest costs of FSMA compliance.. However, the food industry generally recognizes that successful systems will enhance public health and safety, and at the same time reduce manufacturer liability.

Sanitary equipment design is likely to be heavily influenced by new, updated Good Manufacturing Practices (GMP) regulations in the FSMA.

Industry Segments Affected by the FSMA

Small food processors and manufacturers will feel the impact of FSMA regulations most severely. Larger companies are at an advantage because they have the resources to better cope with FSMA-based changes, including upgrading machinery and training personnel. Additionally, larger companies more frequently operate voluntary programs, such as Hazard Analysis Critical Control Point (HACCP), and initiatives with standards that are likely to be incorporated into FSMA rules.

The FSMA regulations will affect different food segments to varying degrees. Such differences are largely based on which segments have been regulated in the past. Some segments that are ostensibly regulated under the FSMA will, in reality, face little impact from the law because they were already strictly regulated pre-FSMA. These segments include:

- Baby food
- Infant formula
- Nutraceuticals

Conversely, segments such as fresh produce that are not accustomed to substantial food safety oversight will face more impact.

FSMA Exemptions

The FSMA does not apply to food industry segments that are not regulated by the FDA. Some segments fall under the strict purview of the USDA rather than the FDA, placing them outside of the FSMA’s regulatory framework. Other segments have received special exemptions from FSMA’s Preventive Control Rules because they have already implemented similar controls.

Food Segments Not Fully Covered by FSMA

SEGMENT	REASON FOR LACK OF FSMA IMPACT
Meat	Regulated by USDA
Poultry	
Processed egg products (excludes shell eggs)	
Juice	Exempt from FSMA’s Preventive Control Rules
Low-acid canned foods	
Seafood	

Industry Reactions to the FSMA

Reactions to the FSMA across the food industry range from anxiety to anticipation. At one extreme end, companies that are facing high compliance costs and radical changes to operations see the FSMA and its associated regulations as government meddling. At the other end of the range, companies that are ahead of the game are pleased that others in the industry will be implementing similarly safe operations.

The broad, moderate middle of the spectrum is generally resigned to the compliance costs they will face while recognizing the benefits the FSMA will provide to America’s food system. These companies are pleased that the nation’s food system will become safer, with fewer incidents and faster recalls.

Food producers and equipment manufacturers do not expect FSMA to face much resistance from industry participants. However, parties are attempting to influence the regulations through the FDA's public comment mechanisms during the rulemaking process, both as individual companies and as trade organizations. The goal of many in the industry is to keep the regulations flexible, as they apply to many diverse segments of the food industry.

Third Party Guidelines

Third party food safety guidelines will be increasingly valuable to food processors and equipment manufacturers as FSMA regulations are implemented. Outside experts and food processors alike advise equipment makers to familiarize themselves with such guidelines so they can understand issues that their customers will be facing. Respondents most frequently identified the guidelines published by the Grocery Manufacturers Association (GMA), Safe Quality Food Institute (SQFI), the American Meat Institute (AMI), and the American Institute of Baking (AIB) as among the most valuable.

The GMA guidelines and principles for sanitary equipment design appear in the appendix.

PMMI's Alliance for Innovation & Operational Excellence (AIOE) provides additional third party resources that equipment manufacturers and their suppliers are likely to find valuable in understanding food safety issues. Recommended AIOE guidelines include *Validating the Reduction of Salmonella and Other Pathogens in Heat Processed Low-Moisture Foods* and *Hygienic Equipment Design for Low-Moisture Food Manufacturing – Process and Criteria*.

Traceability and Recordkeeping

Traceability systems currently in use vary widely in sophistication. Some companies have deployed high-end tracking and traceability systems, especially when demanded by major customers. Many companies, however, still use labor-intensive, paper-based systems.

Some experts suggest that food processors with archaic tracking systems will upgrade not because they will be commanded to do so by the FDA, but rather because it will be difficult and likely more costly to meet the FDA's performance standards (especially during a recall) using labor-intensive manual recordkeeping processes.

Although traceability is expected to represent one of the greatest costs of FSMA compliance, the food industry generally recognizes at least two benefits that will result from successful systems:

- Modern traceability systems can reduce liability. A company with proper systems can show precisely which supplier shipments it took in and where products went, potentially reducing its exposure to mandatory or widespread recalls.
- When recalls do occur, traceability systems can make these recalls "surgical," with only affected products having to be pulled from shelves.

Traceability Technologies

Four different technologies could greatly increase traceability capabilities among food processors and manufacturers, including:

1. **Bar coding:** Machinery that scans barcodes from bags of ingredients, tracks what ingredients are going into individual batches, and records and collates that data centrally.
2. **2D Matrix codes:** 2D matrix codes can carry much more data than standard barcodes and will likely speed up and simplify traceability and recall efforts due to the ease of scanning versus manually reading production codes on finished product.
3. **RFID tags:** Tags that would provide the same sort of information advantages as barcoding, but without the need to physically scan labels. Some respondents believe that RFID may not be a good solution because too often water and metal in products and packaging interfere with the signal.
4. **Integrated unit tracing options:** Equipment that could automate applying lot labels and recording corresponding database entries.

Need for Industry-wide Protocols

Respondents agree that the food industry would be wise to devise its own interoperable data standards and protocols, as the FDA is not likely to design or dictate such protocols. Participants describe the need for such interoperable systems but do not sense urgency within the industry to implement standards. Although industry-wide protocols might not yet exist, some large companies do currently operate their own traceability databases. Some of these databases could conceivably form the beginnings of an industry-wide protocol.

Traceability Pilot Studies and Recommendations to the FDA

Through the Institute of Food Technologists (IFT), the FDA conducted two food tracing pilot studies, one for processed food and one for produce. The final report came with 10 recommendations from the IFT that call for uniformity and standardization, improved recordkeeping, enhanced planning and preparedness, better coordination and communication, and better use of technology. The FDA is currently asking for public comment on this report before it develops its own recommendations.

Industry Needs and Expectations

Equipment Features

Food producers desire equipment design features that will help them address FSMA requirements. An overall hope is for features that integrate food quality and safety into efficient equipment design while not adding much cost. Such features include:

- Improved sanitary design
- Ease of disassembly
- Ease of cleaning
- Low-moisture equipment cleaning

Industry experts suggest that equipment makers can market efficiencies in cleaning and sanitizing equipment as a way for food producers simultaneously to meet food safety standards, reduce contamination risks, and reduce operating costs.

Training and Expertise

Companies anticipate using different strategies to understand and interpret FSMA regulations and then apply them to their operations. Smaller companies will be more likely to use third parties for assistance in interpreting the new rules. Large companies are more likely to use internal resources – most likely, existing employees who receive additional training/education and serve as part-time in-house FSMA experts. A smaller portion of companies will hire new employees explicitly to serve as food safety experts.

Equipment users desire more and better training, identified as follows:

- In-person training at the time of equipment setup
- Webinars for ongoing training
- Training materials/manuals integrated into the sides of equipment, perhaps as LCD screens

Food producers have recognized that additional and enhanced training could involve higher costs. They hope that some of these costs would be integrated into original quotes and would not be excessive. Some training costs are expected to be ongoing, extending past the traditional one year warranty period provided by most equipment makers.

Key Takeaways

The food industry is somewhat uncertain about the outcomes from the FSMA regulations. There is recognition not only that the rules are still being written, but that Congress could expand the law's scope. Future food safety laws are expected to address food defense and importing issues even more vigorously.

Meanwhile, the FSMA provides new business opportunities for manufacturers of food and beverage packaging and processing equipment. Equipment makers should study the proposed and final regulations and third party guidelines, participate in industry responses, incorporate the regulations into their strategy, and prepare to offer enhanced services for customers who will need training and consulting services.

Recommendations for the Food Industry in Dealing with FSMA Regulations

RECOMMENDATION	ELABORATION
1. Study Regulations to Fully Understand Customer Perspective	<ul style="list-style-type: none"> • Study the FDA's Hazard Analysis & Critical Control Points (HACCP) to fully understand the needs and perspectives of each segment of food and beverage producers. Leverage this understanding to provide equipment and services that address needs more directly. • Study the GMA sanitary equipment guidelines and the upcoming FSMA sanitary equipment, environment, and process guidelines to understand upcoming expectations.
2. Participate in Industry Responses during FSMA Comment Periods	<ul style="list-style-type: none"> • Submit comments to the FDA during public comment periods. Comments can be submitted by individual companies, groups of companies, or through industry associations. • Promote the development of industry-wide protocols for interoperable traceability data.
3. Incorporate Regulations into Company Strategy	<ul style="list-style-type: none"> • Begin to incorporate GMA, HACCP and FSMA design guidelines into current equipment while keeping in mind total cost of operation. • Food manufacturers specifically ask for equipment that is easy and quick to disassemble, sanitize, and keep clean throughout the manufacturing process. • Evaluate possibilities and opportunities to help past customers with recent and legacy equipment to modify equipment to better adhere to FSMA guidelines. • Market updated equipment to customers, clearly stating which sanitary guidelines are being adhered to. • Position equipment upgrades and additional services not only as a way for customers to minimize risk, but also as a way for customers to positively position and market their company. • When selling advanced traceability systems, focus on how pen-and-paper-based systems are labor intensive, prone to inaccuracies, cumbersome to work with especially when there is an issue, and might compromise relationships with customers.
4. Provide Enhanced Services	<ul style="list-style-type: none"> • Enhance training options for customers. Provide training in multiple modalities, for long term and short term training needs, and try to embed education and training into the price of the system. Or, rather than provide equipment discounts, include training costs within the regular pricing of machinery. • After substantial understanding of FSMA requirements is obtained, provide consulting services to help show customers how meeting FSMA requirements can be achieved cost effectively.

Additional Information and Resources

PMMI's Alliance for Innovation & Operational Excellence:

<http://pmmi.org/aioe>

Food Safety Modernization Act:

<http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf>

<http://goo.gl/vo8nJb>

Grocery Manufacturers Association's Technical Guidance & Tools Page:

<http://www.gmaonline.org/resources/research-tools/technical-guidance-and-tools/>

<http://goo.gl/DvJbXf>

FDA's Hazard Analysis & Critical Control Points (HACCP) Page:

<http://www.fda.gov/food/guidanceregulation/haccp/default.htm>

<http://goo.gl/22EmYj>



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