

The food safety landscape

SECURING OUR FUTURE IN A CHANGING REGULATORY ENVIRONMENT

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The ongoing importance of food safety to our industry

In last year's edition of *Boardroom*, Oliver Wyman and FMI shared perspectives with the industry on how to create a culture of food safety within your organization. In some ways, not much has changed since then. Food safety remains the industry's number one priority. In other ways, however, everything has changed. The Food Safety Modernization Act (FSMA) has brought about some of the most significant regulatory changes to food safety that this country has seen in more than 70 years. FSMA is now going live and starting to impact all of our members in serious ways.

Revisiting some cautionary tales: Could this happen to you?

In our last edition, Oliver Wyman and FMI used two examples to illustrate the significance of food safety to two companies and the industry at large; our story was about peanuts and cantaloupes, drawing insights from the Peanut Corporation of America (PCA) and Jensen Farms food safety crises.

In 2016, unfortunately, there are new examples to illustrate the ongoing struggle with food safety - this time, tacos and ice cream.

Since July of 2015, Chipotle has been involved in six different food safety incidents in which more than more than 500 people fell ill. The culprits were threefold, varying by outbreak: E. coli, Salmonella, and noroviruses. Chipotle moved quickly to mitigate the crisis proactively: In December, Chipotle's CEO apologized on national TV, and Chipotle later hired a food safety expert to guide the company through the crisis. However, despite these actions, the crisis continues to plague the company even now.

Chipotle is now involved in multiple different lawsuits, which question Chipotle's response to the outbreak. The US Attorney's office of California served the company with a grand jury subpoena to investigate the August outbreak of norovirus in Simi Valley, Calif., that made 234 people ill. In late January, a class action lawsuit accusing Chipotle of a cover-up was filed in federal court.

Since the outbreaks were first uncovered, Chipotle's stock price has dropped by 36 percent, reaching a three-year low in January 2016. Additionally, all Chipotle stores faced mandated closures for three to four hours in February 2016 to address food safety concerns, resulting not only in a loss of revenue but in consumer confidence, too.

In another food retail segment, the response was quite different. Ice cream maker **Blue Bell's** food safety outbreak first became public in January 2015 when inspectors identified listeria germs in ice cream produced at the company's flagship Brenham, Texas, plant; subsequently, the company opted to "voluntarily" recall a few flavors. Eventually, listeria germs found in Blue Bell's ice cream were linked to 10 cases of listeriosis and three deaths that started as early as 2010, forcing the company to shut down production completely from April to August of 2015 and resulting in layoffs of 38 percent of Blue Bell's workforce.

Blue Bell has been widely criticized for failing to apologize fully and taking only limited actions to minimize commercial damage, only to find itself forced to expand the recall repeatedly. Already under criminal investigation by the Justice Department, Blue Bell announced in January 2016 that listeria might still be present in sections of the Brenham plant, and in September 2016 issued another recall of selected flavors due to listeria.

This last food safety outbreak has not been without consequences for the rest of the ice cream industry. Indeed, ice cream producers who were previously off the FDA's radar, as frozen food is assumed to be safer than fresh products, are now dealing with increasingly frequent listeria sampling and testing. The whole industry has been implicated by one organization that failed to meet the standards.

How prepared are retailers to address food safety?

The Blue Bell and Chipotle examples underscore how important food safety is to our industry and how high the stakes are to get it right. FMI members repeatedly say that food safety is our industry's number one priority, but until recently there weren't many metrics to evaluate industry performance. A poll of FMI's Food Protection Committee has provided greater insight into how these members believe their company and the industry performs on food safety issues today.

Some 81 percent of respondents from the Food Protection Committee believe that their organization is at least somewhat at risk. Further, when considering the industry at large, the perceived risk of food safety outbreaks soars to 97 percent. These numbers are staggering, and they illustrate just how much improvement is needed in raising food safety standards and preparedness within our own companies.

Within this context, we would like to address these key areas in this article:

- The importance of food safety to your organization
- What you need to know about FSMA
- Steps you should take to protect your organization
- What you should be doing for your organization on food safety
- FMI's commitment to your organization and the industry on food safety

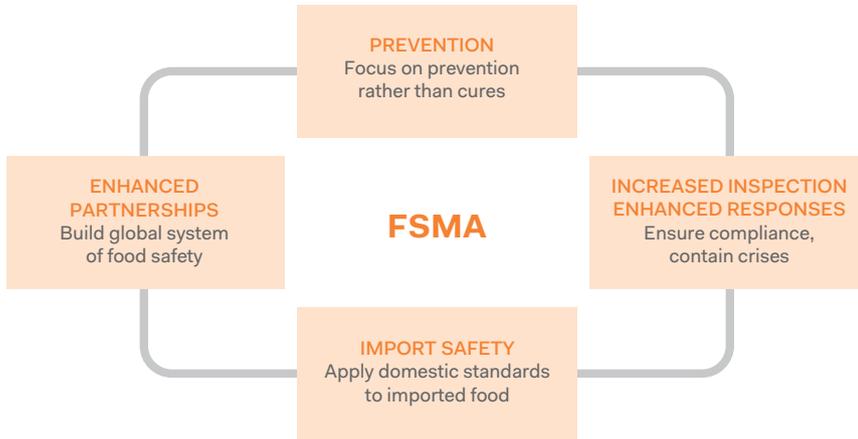


UNDERSTANDING THE FOOD SAFETY MODERNIZATION ACT (FSMA)

What you need to know

To address food safety appropriately, we need to start by understanding the Food Safety Modernization Act (FSMA), which aims to better protect public health by strengthening the food safety system on a global scale. Not only is the 2,000-plus page regulation daunting in length, it is the most sweeping reform of U.S. food safety laws in more than 70 years.

Exhibit 1: FSMA Objectives



Following a number of outbreaks and high-profile cases, FSMA has laid the groundwork for important consumer safeguards, doing so by placing greater responsibility on retailers, including increased corporate criminal liability. Addressing the new FSMA standards will require a culture change for retailers that process food or have food distribution centers.

FSMA enables the FDA to focus more on preventing food safety problems, instead of reacting to problems retrospectively. To achieve this end, the law provides the FDA with new enforcement authority and capabilities designed to achieve higher rates of compliance – and to better respond to and contain problems when they do occur. Finally, the law also gives the FDA important new tools to hold imported foods to the same standards as domestic ones.

In short, FSMA means four things for your firm:

1. **More responsibilities** for food retailers (especially for imported food)
2. **More stringent standards** to comply with
3. **More frequent and thorough inspections**
4. **More concrete legal consequences** in case of noncompliance (such as mandatory recalls, suspension of registration, and expanded administrative detention)

These key FSMA objectives translate into seven primary rules, four of which could directly impact retailers and wholesalers going forward:

- Preventive Controls
- Food Defense
- Sanitary Transportation
- Foreign Supplier Verification Program

How the rules impact you depends on how your business operates. Exhibit 2 illustrates how you may be affected by various FSMA regulations.

Importers take note: According to FSMA, an importer is either the US owner or consignee of an article of food that is being offered for import into the US, or, if there is no US owner or consignee of an article of food at the time of US entry, the importer is the US agent or representative of the foreign owner or consignee at the time of entry.

The regulation is fast approaching for retailers: Nearly all final FSMA

regulations have been published and in September 2016, select regulations will become enforceable. Compliance deadlines will continue through fourth quarter of 2017, at which point all FSMA regulations will be live and impacting your business.

WHAT IS AN IMPORTER, ACCORDING TO FSMA?

The **US owner or consignee of an article of food that is being offered for import into the US.** If there is no US owner or consignee of an article of food at the time of US entry, the importer is the **US agent or representative of the foreign owner or consignee at the time of entry**, as confirmed in a signed statement of consent to serve as the importer under this subpart.

Exhibit 2: What FSMA regulations impact you as a retailer/wholesaler?

POTENTIAL FSMA REGULATION IMPACTING FMI MEMBERS			
PREVENTIVE CONTROLS*	FOOD DEFENSE	SANITARY TRANSPORTATION	FOREIGN SUPPLIER VERIFICATION PROGRAM
IF YOU HAVE A CENTRAL KITCHEN OR AN OFFSITE PRODUCTION SITE			
			IF YOU IMPORT
IF YOU HAVE A DISTRIBUTION CENTER			
		IF YOU HAVE A TRUCK FLEET	
IF YOU ONLY HAVE RETAIL STORES: NO CURRENT FSMA REGULATION			

*Includes both Animal and Human Food rules

WHAT SHOULD YOU DO FOR YOUR ORGANIZATION

Is your company prepared to address food safety requirements? FMI can help

With so many regulations hitting quickly, FMI would like to ensure that you are prepared to address FSMA requirements – and to build a strong culture of food safety within your organization.

Let's start with a simple five step checklist:

- **Understand** the regulation
- **Design** food safety plans
- **Train** qualified individuals
- **Keep** records organized
- **Hold** your suppliers to the same standard as yourself

FMI has resources to help you accomplish each of these objectives.

As outlined above, the first step is to make sure you understand the regulation. FSMA is extremely complex and, considering its length, you may have questions about how to be in compliance. There is no better place to start than with FMI's in-house regulatory counsel and food safety team. FMI has extensive resources and research, including webinars on final FSMA rules, factsheets, regulation flowcharts, and summaries of each provision, which are targeted to our members who may not be food safety experts, as well as those who are.

Once your team understands the core requirements, FMI has templates and best practice guides to help you convert that knowledge into effective implementation plans.

In addition, your team will need to be trained and equipped to handle FSMA regulations, as well as the broader requirements of a food safety program, including safe in-store food handling. FMI offers lead instructors and training to develop both your team and your head of training to effectively embed food safety best practices into your organizational culture. On a store-specific level, SafeMark can help your teams learn food safety fundamentals on the ground.

For government compliance, you must assure that your records are organized and clear; FSMA stresses the importance of extensive recordkeeping and gives the FDA unprecedented records access. Required records have a retention period of two years and must be presented within 24 hours once requested. ReposiTrak is FMI's recommended solution, which centrally locates all of your documents, allowing you first to access and manage stores' documentation and then to track and trace suspect products within minutes – rather than months.

Additionally, should you have a recall, Rapid Recall Express is available to help you inform your stakeholders quickly. This fillable standardized form applies industry expertise and best practices to recall and withdrawal notifications.



Exhibit 3: What should I do for my organization?



FOOD SAFETY TO-DO LIST

FMI RESOURCES, FSMA SPECIFIC

ADDITIONAL FMI FOOD SAFETY RESOURCES

1 UNDERSTAND THE REGULATION	Extensive resources available from FMI's food safety and government relations teams, as well as from the FMI Foundation, including: regulatory counsel, webinars, best practice guides, and template plans	
2 DESIGN FOOD SAFETY PLANS		
3 TRAIN QUALIFIED INDIVIDUALS	FMI lead instructors and training available	SafeMark
4 KEEP RECORDS ORGANIZED	ReposiTrak	Rapid Recall Express
5 HOLD SUPPLIERS TO THE SAME STANDARDS THAT YOU ADHERE TO	SQF	

Finally, you'll need to make sure you are holding your suppliers – and not just your own organization – to the highest standards. Any issue in the value chain can be problematic for you as a retailer, considering today's food safety rules. SQF is a key tool to ensure that your suppliers have complied with the new food safety requirements under FSMA. There are a few food safety schemes recognized by the Global Food Safety Initiative. Among them, SQF is perceived as the highest quality scheme with the most stringent requirements. Owned by FMI, it is also the only scheme based in the US and therefore the one most familiar with the new FSMA requirements. As a result, using the SQF certification program will help you reduce assessment inconsistencies and costs of multiple assessment standards.

There is plenty to address, but luckily FMI has resources to support each step of your to-do list. (See Exhibit 3.) And when you or other FMI members are in a pinch, FMI is available 24/7 to assist in times of crisis. We will stand by our members and make sure that crises are handled appropriately and swiftly to minimize the damage.

HOW CAN WE RAISE FOOD SAFETY STANDARDS INDUSTRYWIDE?

Each food safety outbreak has consequences on the food industry at large, and FMI believes there is an opportunity to reduce our risk of a food safety issue not only within individual organizations, but also on an industrywide level. FMI is continuing to expand its portfolio of solutions to include industrywide offerings that help us understand our strengths and weaknesses in this area. We have a common goal to build a culture of food safety in our organizations and across our industry.

