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The Food Safety Modernization Act:

What Supply Chain Managers Need To Know Now

by John T. Shapiro, Partner - March, 2013

A FREEBORN & PETERS FOOD INDUSTRY TEAM WHITE PAPER

ABOUT THIS WHITE PAPER:

The Food Safety Modernization Act (FSMA) has set in motion sweeping new requirements and improvements for the safety of our food supply. Preventative controls and proactive management against risk of food contamination are in; reaction as a chief measure of protection against the spread of foodborne illness is out. What does this mean for food manufacturers and distributors? FSMA places on them the primary responsibility for putting in place preventative controls!

This White Paper explains that in preparing for how FSMA will impact their operations, food companies should assess their supply relationships and agreements in light of FSMA obligations and ensure that their supply agreements account for supply disruptions that the failure of supply partners to satisfy FSMA may cause. This White Paper concludes with several broad points that companies should consider in assessing their supply partners for FSMA compatibility.

President Obama signed the Food Safety Modernization Act (FSMA) into law in January 2011 against the backdrop of a series of food contamination scares and foodborne illness outbreaks that had consumers calling for a renewed focus on food safety. Described by the Food and Drug Administration (FDA) as "the most sweeping reform of our food safety laws in more than 70 years," FSMA represents a shift in focus from reacting to adulterated food after it is already in the marketplace to prevention and proactive risk management. The statute encompasses 50 new regulations, guidance documents and reports to Congress, which will be implemented over the course of five years and will cost the government an estimated $1.4 billion.

FSMA places primary responsibility for food safety on food producers and processors. "Think of it as supply-chain management written into law," FDA Deputy Commissioner Michael Taylor told the New England Journal of Medicine in September 2011. With increasingly global and complex supply chains, food producers face unprecedented challenges in complying with the law. But failure to take heed of and account for the new regime FSMA imposes will affect your company's business.

FSMA Overview: Internal and External Controls

FSMA's focus on prevention starts with raising the bar for the internal controls food producers and processors must implement. Section 103 of the statute requires producers and processors to implement a detailed hazard analysis and preventative control plan. Under this section, all non-exempt facilities must:

1. identify and evaluate known and foreseeable hazards;
2. develop and implement a written plan for controlling the hazards;
3. monitor the plan to make sure it is carried out and verify that the plan is effective
4. establish procedures for corrective actions; and
5. maintain records of monitoring, instances of nonconformance and corrective actions taken.

(*See* Internal Operations Checklist on page 10.)

FSMA deputizes workers to help enforce the law by providing protection for whistleblowers. The statute makes it illegal for an employer to discharge or discriminate against employees who participate in an investigation of FSMA violations or provide information about what they reasonably believe to be a violation to the employer, the federal government, or the attorney general of a state. An employee who has been subject to retaliation for blowing the whistle on perceived FSMA violations is entitled to reinstatement, back pay, damages and attorney's fees.

FSMA calls for the FDA to take a more active role in enforcing food safety laws, including more frequent inspections of facilities that process and produce food. Under § 201 of FSMA, the FDA will inspect all domestic facilities identified as "high risk" once by January 2018, and at least once every three years thereafter. The FDA uses several factors to determine whether a facility is high-risk, including:

- known safety risks of the foods manufactured, processed, packed or held at the facility;
- food safety compliance history of the facility, including recalls, foodborne illness outbreaks and safety standards violations;
- thoroughness and effectiveness of the facility's hazard analysis and risk-based preventative controls;
- the facility's certifications concerning imported foods; and
- other factors the FDA deems necessary and appropriate for allocating inspection resources.

Non-high-risk facilities will be subject to inspections once by January 2018 and at least every five years thereafter.

FSMA also calls for stepped up monitoring of foreign facilities—600 inspections by January 4, 2012. In each of the five subsequent years that number will be doubled, resulting in 19,200 inspections by January 4, 2017. FSMA also calls for greater cooperation between FDA and other agencies to carry out these inspections, including state and local inspectors, the Department of Homeland Security, the National Oceanic and Atmospheric Administration, as well as foreign auditors.

FSMA § 101 also gives FDA unprecedented access to records of producers and processors. If the FDA reasonably believes that a certain food item poses a serious health hazard, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports the item must provide all records relating to the item on demand to any authorized FDA employee. The record-inspection provision extends to records in any format (paper or electronic) at any location, and also encompasses records related to other foods that may be similarly affected.

Regulatory Response

FSMA calls for more robust authority for the FDA to implement mandatory recalls. Under § 206, the FDA can require a recall where there is a reasonable probability that food is (i) adulterated or misbranded by failing to disclose major food allergens and (ii) serious adverse health consequences are reasonably likely to result. The statute provides an opportunity for a producer to undertake a voluntary recall. Failure to do so may result in the producer being on the hook for a civil penalty and payment of the FDA's costs in conducting a recall. FSMA § 207 also lowers the threshold for the FDA to administratively detain food. It may do so whenever it has reason to believe food is adulterated or misbranded.

Moreover, FSMA § 102 authorizes the FDA to take the drastic measure of suspending a facility's registration when it concludes there is a reasonable probability that the food produced there carries the potential of causing "serious adverse health consequences." Suspension of a facility's registration essentially shuts down its operations—foods produced at the facility cannot be introduced into commerce. A producer whose registration is suspended is entitled to an informal hearing within two days, after which the FDA has 14 days to consider a corrective plan.

Along with these regulatory schemes, the FDA will be implementing additional recordkeeping requirements. The FDA is currently grappling with the difficult issue of traceability—tracking the movement of food products throughout the supply chain. The ultimate goal is to implement recordkeeping requirements that will permit the agency to trace products from farm to fork. Likewise, the agency will be designating a list of "high-risk" foods and imposing additional recordkeeping requirements for the processing, transport and production of those items.

"The key, however, is that the new law explicitly places primary responsibility for food safety – prevention – on food producers and processors. Think of it as supply chain management written into law."

– *Source: Michael Taylor, FDA Deputy Commissioner Global Food Safety Conference (February 2011)*

Import Risks

Compliance with FSMA is complicated by the globalization of the food supply chain. Currently, 15 percent of American's food is imported, including 66 percent of produce and 80 percent of seafood. In 2010 alone, more than 10 million food shipments arrived at more than 320 ports, and food imports continue to grow at approximately 10 percent per year. Despite the complexities of dealing with a worldwide supply chain, one thing is clear: Under FSMA, your company is responsible for the food it imports.

To ensure importer accountability, FSMA § 301 calls for a Foreign Supplier Verification Program. This places the onus on importers to verify that their foreign suppliers have adequate preventative controls in place and that imported products, including sugar, cocoa beans and other raw materials typically used by confectionery companies, comply with U.S. standards. The FDA also may require importers to obtain third-party certification that a foreign food facility complies with U.S. standards. Foods deemed "high-risk" must be accompanied by a credible third-party certification as a condition of entry. Pursuant to § 306 of FSMA, the FDA can refuse entry of any food if it is denied access to inspect the foreign facility in which it is produced. FSMA also provides for a Volunteer Qualified Importer Program, which allows participants to obtain expedited review and entry of foods from certified foreign facilities.

Contracting Overview: Assessment of Supply Partners in Light of FSMA

Potential FSMA liabilities must be a standard consideration in contracts with suppliers. (*See* External Supply Partner Checklist Overview on page 10.) Careful drafting is essential to minimize liabilities. The key is anticipating and preparing for disputes regarding the parties' obligations, risks, and liabilities before they occur. That said, the essential questions do not always have easy answers as supply chains become more complex and global.

Broadly, there are numerous factors that a company should consider when assessing supply partners and the contracts that govern supply relationships. Of course, whether certain factors need be considered may depend on the company's particular business needs and operations and circumstances unique to the relationship. Similarly, the outcome of the assessment of factors that are considered may depend on the same considerations. But among other significant considerations, it is important that any supply agreement account for each party's responsibility to comply with the preventative controls FSMA imposes, provide access to facilities and records for auditing purposes and obtain insurance. Likewise, the agreement should address jurisdictional issues regarding what law applies to disputes and where and by whom disputes will be resolved.

One question that too often goes unresolved at the contract-formation stage is who the stakeholders and partners in the supply chain are. A 2011 court decision involving the Louisiana crawfish industry highlights the perils of failing to answer this question. The Louisiana crawfish industry suffered a major disruption in 1999 when farmers purchased rice seed allegedly coated with pesticide. Crawfish, which are raised in rice ponds, died off in great numbers due to pesticide exposure. Buyers and processors of crawfish, including restaurants and restaurant suppliers, sued the rice seed vendor in a class action suit under Louisiana products liability laws, arguing that the vendor was responsible for the damage to their businesses due to the faulty seeds. The court disagreed, ruling that the vendor was

not legally accountable. The court held instead that it was the buyers' responsibility to contract with the farmers to account for this risk or obtain insurance to guard against it. Since the buyers had not contracted with the farmers, they were unable to recover their losses. The takeaway lesson is that parties need to envision the broadest type of harm from their supply partners and contract against the risks that may arise.

Force Majeure

FSMA gives the FDA broad authority to effectively shut down a facility by suspending the registration of that facility or detaining food when the FDA has reason to believe that it is adulterated or misbranded. Either of these circumstances would result in major disruption of supply. Therefore, parties must consider whether their existing contracts account for the risk of FSMA disruptions. Two of the most important risk-shifting concepts in supplier contracts are indemnification and force majeure.

"Force majeure" clauses provide a legal excuse for non-performance under a contract due to events or circumstances outside of the party's control. Typically, these clauses encompass natural occurrences (such as hurricanes or tornados), manmade or social occurrences (such as a terrorist act or a

labor strike), market disruptions, or governmental actions. Companies must now evaluate whether under existing contracts FSMA enforcement allows them or their suppliers off the hook for a supply disruption. Companies should reevaluate the types of circumstance that their force majeure clauses cover and, if appropriate, specify that only governmental action not caused by the act or omission of a party will excuse performance. The failure to draft a proper force majeure clause can result in catastrophic consequences.

For example, in a 2008 court decision, the Iowa Supreme Court ruled that a contract manufacturer of ice cream was on the hook for a supply disruption caused by an explosion at its plant. The force majeure provision in the parties' contract stated:

> FORCE MAJEURE: Neither party will be liable for delays or suspension of performance (other than the obligation to pay for services and goods sold and delivered) caused by act of God or governmental authority, strikes, accidents, explosions, floods, fires or the total loss of manufacturing facilities or other cause that is beyond the reasonable control of that party ("Force Majeure") so long as that party has used its best efforts to perform despite such Force Majeure.

The court found that the manufacturer was liable because the explosion was not "beyond its reasonable control." The case highlights the need for precise drafting of force majeure clauses to clearly outline what circumstances will excuse performance.

"The law clarifies that people and businesses that provide food to the public whether they produce, process, transport or sell food are responsible for taking the steps necessary to ensure that they've identified and controlled hazards that could make food unsafe."

– *Source: Michael Taylor, FDA Deputy Commissioner New England Journal of Medicine (September 2011)*

Indemnification

Likewise, indemnification clauses are essential to manage risks associated with FSMA violations. Indemnification agreements define who will be legally responsible for claims. Without a precisely drafted indemnification clause, a person or company harmed by an adulterated food product or a disruption caused by an FDA action could attempt to obtain damages from any participant in the supply chain for that product—from producers to processors to sellers.

Such clauses should encompass who will bear the cost of conducting a recall, whether a party will cover costs associated with contamination due to negligent acts, and whether the parties' liabilities will be limited in any way by the amount of available insurance coverage. Before entering into any such agreement, it is important to conduct an audit to determine whether your supply chain partners have sufficient liability insurance to cover potential claims.

A comprehensive indemnification clause was key in a 2008 case involving lettuce. A distributor purchased lettuce from a processor/packager and resold it to a quick service chain restaurant. After an E. coli outbreak sickened consumers, the restaurant chain sued the distributor. The distributor was able to shift all liability to the processor/packager because the parties had an indemnification contract that stated:

> [Processor/packager shall] indemnify and hold harmless [distributor] and its customers from any claim, demand, loss, damage, liability, cost and expense, directly or indirectly, arising out of, or in connection with, or resulting from, the willful or negligent acts or omissions of [processor/packager] … relating to the manufacture, sale, use or consumption of any article of food … sold by [processor/packager] to [distributor]."

The court held that the particular language of the indemnity provision was "clear, inclusive and unequivocal." The processor/packager was on the hook for claims against both it and the distributor.

Immediate Steps

Regardless of the implementation timeframe for the various provisions (*see* Implementation Timeline on page 9), companies should be preparing now to comply with FSMA's demanding requirements. Aside from regulatory requirements, FSMA represents best practices. It thus is important for confectionery and other food companies to be proactive and to take steps now to assess internal operations, assess supply chain partners, prepare compliance plans and take steps to mitigate risks should disruption occur. Now is the time to assess and reevaluate supply partners and governing contractual relationships that may need to be retooled.

TIMELINE

FSMA Implementation Timeline

2011

- expanded record access (§ 101)
- fee collection authority (§ 107)
- increased facility inspection (§ 201)
- mandatory recall authority (§ 206)
- administrative detention (§ 207)
- inspection of foreign food facilities (§ 306)
- whistleblower protection (§ 402)

2012

- guidance on expanded records access (§ 101)
- re-registration of food facilities (§ 102)
- regulations to protect against intentional adulteration of foods (§ 106)
- regulations regarding sanitary transportation of food (§ 106)
- report on traceability projects (§ 204)

2013

- hazard analysis and risk-based preventative controls (§ 103)
- produce safety regulations (§ 105)

2013-2016

The remaining regulations will go into effect over the next three years, with full implementation expected by 2016. On the FDA's agenda for 2013 are:

- establishing a program for laboratory testing of food (§ 202)
- the list designating high-risk foods (§ 204; originally due Jan. 2012)
- recordkeeping requirements for high-risk foods (§ 204)
- foreign supplier verification program (§ 301)
- voluntary qualified importer program (§ 302)
- establishing a plan to evaluate the food safety capacity of foreign food industries (§ 305)
- establishing a system for accrediting third-party auditors in foreign countries (§ 307)

CHECKLISTS

Internal Operations Checklist

- Study FSMA requirements
- Undertake risk-based hazard analysis
- Implement hazard prevention and response plan
- Assess facilities
- Evaluate capabilities regarding traceability, forward and back
- Evaluate records generation and storage
- Determine if records are inspection-ready
- Conduct insurance audit
- Study science-based standards for your industry
- Prepare for inspection by governmental agency
- Prepare inspection and litigation readiness plan
- Prepare model inspection and litigation holds
- Prepare recall plan
- Train your employees on FSMA-based guidelines and practices
- Monitor FDA rulemaking activities and comment when appropriate

External Supply Partner Checklist Overview

- Assess supply partners
- Determine supplier qualifications, both domestic and foreign
- Assess supplier facilities and determine if they meet certification standards
- Determine if suppliers' products meet certification standards
- Assess if supplier has undertaken its own in-house assessment and developed plans against risk
- Determine and prepare plan for import compliance
- Assess supply chain contracts – are you protected?

John T. Shapiro

Partner

Chicago Office
(312) 360-6389

jshapiro@freeborn.com

John Shapiro is a Partner in the Litigation Practice Group and a member of the Food Industry Team. He focuses his practice on solving clients' complex business issues and disputes; counseling clients on litigation, employment and business issues; and providing general corporate advice. His litigation experience includes handling cases involving a wide-array of business issues in federal and state courts, in arbitration and before administrative agencies, including disputes concerning international and domestic supply chains, breaches of contract, corporate governance, non-compete and non-disclosure agreements, theft of trade secrets, ownership and protection of intellectual property, fraud, wages and hours, discrimination and other employment-related laws. In addition, John serves as General Counsel of Inspiration Corporation, a Chicago-based nonprofit that assists people affected by poverty and that operates Inspiration Kitchens, a 13-week restaurant skills training program, conducted in two for-public restaurants and a catering business, that is designed to provide participants with the tools they need to secure and retain jobs in the food service industry.

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The Freeborn & Peters Food Industry Team

America's food industry faces many challenges: a rapidly modernizing food safety regime; a complex network of suppliers and buyers with many risks and potential liabilities; stagnant domestic demand and intense price competition.

Our Food Industry Team helps food companies address these challenges. It also guides them as they build towards a better future: protecting investments in brands, innovation and facilities; structuring profitable ventures and M&A transactions; securing new financing; and taking advantage of foreign market opportunities.

The Team's partners bring many years of experience, gained at multiple points in the industry and across different legal disciplines, including regulation, litigation, corporate law and government affairs.

We combine legal know-how with business insight derived from careful attention to clients' needs and an ongoing focus on the food industry's specific opportunities and challenges.

CHICAGO
311 South Wacker Drive
Suite 3000
Chicago, IL 60606
(312) 360-6000
(312) 360-6520 fax

SPRINGFIELD
217 East Monroe Street
Suite 202
Springfield, IL 62701
(217) 535-1060
(217) 535-1069 fax

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