Stay Ahead of the Curve

The Importance of Hazard Analysis and Document Management Under the Food Safety Modernization Act

On January 13, 2009, the Peanut Corporation of America issued a recall that, in two weeks time, expanded to include over 400 consumer products ranging from Jenny Craig nutritional bars to Keebler snack crackers. The contamination originating from the company’s Georgia plant was allegedly responsible for over 500 illnesses and several deaths nationwide. The FDA inspection team uncovered multiple serious violations at the facility, prompting the company to quickly shut down the plant. Even Jif and other big players in the peanut butter industry whose products were not affected by the contamination suffered as a result of the bad publicity emanating from Georgia. Andrew Martin & Liz Robbins, “Fallout Widens as Buyers Shun Peanut Butter,” The New York Times, Feb. 6, 2009. One year later, Kellogg’s issued a recall of approximately 28 million boxes of several of its most popular cereal brands, including Corn Pops, Honey Smacks, Froot Loops, and Apple Jacks. Affected boxes were reported to have a “waxy flavor and smell” apparently caused by the plastic packaging, and some customers reported temporary stomach problems from consuming the cereal. Josh Hardwick, “Kellogg’s Cereal Recall 2010—Recalled Cereal Making Consumers Sick,” Apex News Network, June 29, 2010.

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In the wake of these and other high-profile food contamination outbreaks over the last few years, Food Safety Modernization Act (FSMA or “the Act”) passed the Senate and the House in December 2010, and was finally signed into law by President Obama on January 4, 2011. The Act amends the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.) with respect to the safety of the food supply. Commentators are calling the Act “the most significant overhaul to the U.S. food safety system in over 70 years.” David Acheson, “The Food Safety Modernization Act: The Immediate Impact,” Quality Assurance, Feb. 18, 2011. The legislation also serves as a response to criticism that the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services has taken a reactive, as opposed to proactive, approach to food safety. Foodborne diseases are responsible for an estimated 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths each year. Foodborne illness is a public health problem that is considered largely preventable. “Questions and Answers on the Food Safety Modernization Act,” http://www.fda.gov/Food/FoodSafety/FSMA/ucm238506.htm. Also among the key motivations to pass the bill is the fact that today’s food supply system has become more expensive and complex, and the current role that technology and communications play in making food recalls more visible to the public. Finally, commentators have noted that food safety, after taking a backseat to pressing health care and economic legislation, was a big issue on the Obama administration’s agenda. Jack Payne, “What the Food Safety Modernization Act Means to You,” Manufacturing Business Technology, http://www.mbtmag.com/Content.aspx?id=1707.

The changes included in the FSMA are vast, and a review of all of them would be well beyond the scope of this article. The Act grants the FDA several significant new authorities, which are sure to impact all segments of the industry both instantly and long-term. While some changes are in effect immediately, others require the FDA to issue regulations and guidance documents within certain time frames over the next few years. The precise impact of many provisions on various parties within the supply chain will depend on the regulations promulgated by the FDA and whether Congress provides the necessary funding. While many of the final regulations detailing how the FDA will enforce the FSMA are yet to be issued, it is advisable for companies to reevaluate their food safety policies and procedures now. This article evaluates several of the key provisions of the FSMA, then outlines some of the steps companies should take to stay ahead of the curve in preparing to meet new requirements and in avoiding the potentially serious consequences of noncompliance.

Key Provisions
The FSMA empowers the FDA to promulgate new regulations and to oversee and enforce a broader food safety regime. To achieve its main goals, the Act is divided into three substantive titles. The key provisions of Title I, “Improving Capacity to Prevent Food Safety Problems,” include those concerning inspection of records (§101), the registration of food facilities (§102), and hazard analysis/risk-based preventive controls (§103). Title II, “Improving Capacity to Detect and Respond to Food Safety Problems,” includes provisions for inspections of facilities (§201), mandatory recall authority (§206), and enhanced tracking and tracing of food and recordkeeping (§204). Title III, “Improving Safety of Imported Food,” contains several provisions relating to the regulation of imports. Imported food safety has become an increasingly hot topic in the United States, especially in light of the FDA’s current estimates that 15 percent of the U.S. food supply is imported, with particularly high percentages for fresh fruits and vegetables and seafood. “Food Safety Legislation Key Facts,” http://www.fda.gov/Food/FoodSafety/FSMA/ucm237934.htm.

Some of the key provisions contained in Title I and Title II of the Act are outlined below. Because of the distinct and complex nature of laws pertaining to imported foods, this article does not focus on the provisions of Title III.

Inspection of Records: Hazard Analysis and Risk-based Preventive Controls
The FSMA expands the authority of the FDA to access records related to articles of food believed to be adulterated. Specifically, the FDA can now access records related to the manufacturing, processing, packing, transportation, distribution, receipt, holding, or importation of adulterated food and “any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner.” FSMA §101. Prior to the new legislation, the FDA could only access records related to the particular articles of food believed to be adulterated. 21 U.S.C. §350c(a). Under the new law, the FDA can also obtain records related to other food handled by the facility. Notably, the authority to inspect records is still limited by the requirement that the FDA finds a reasonable probability that use or exposure to an article of food “will cause serious health consequences or death to humans or animals.” FSMA §101. Farms and restaurants are excluded from the requirements of this provision.

As part of its hazard analysis and risk-based preventive controls provisions, the FSMA also requires all registered facilities to have preventive plans in place. According to Donald Kraemer, Deputy Director for Operations of the FDA’s Center for Food Safety and Applied Nutrition, “preventive controls are just that—they’re a system that a manufacturer would put in place to first identify what are the hazards that product might be associated with and then to have a set of scientifically established controls that are designed to minimize the risk of occurrence of those hazards.” “Donald Kraemer on FSMA Preventive Controls,” Ask the FDA: The Food Safety Moderniza-
PRODUCT LIABILITY

14 In-House Defense Quarterly Summer 2011

finds that suspension remains necessary, be reinstated. If, after the hearing, the FDA
statement and why the registration should
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sion is entitled to an informal hearing no
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suspended may not import or export food
Id.
or introduce food into interstate or intra
states commerce in the United States. A
or establishment that manufactures, pro
§206. This provision affects all registered
ments for all registered faciliti
includes any factory, warehouse, or establi
processes, packs, or holds food (the FSMA
does not change the definition of “facili
ty”). FSMA §201. For domestic facilities,
resources are to be allocated in accordance
s, the new legislation is likely to expand this
bility). The new provisions require a facil
and corrective actions. Additionally, the faci
must prepare a written food safety plan that
documents the procedures used to comply
of these new requirements. All
of these written records must be made
promptly available to the FDA upon oral
written request. The new provisions also
include a requirement to reanalyze hazards
whenever there is a significant change in
the activities of the facility, or no less fre
quently than once every three years, which
ever is earlier.

Registration Requirements/ Authority to Suspend
The FSMA requires all food facilities to
register and to renew their registration
every two years on even numbered years.
FSMA §102. The FDA can abbreviate the
requirements of the renewal process for
facilities that have not had any changes
since submitting their previous registration
or registration renewal. The FDA also
has new authority under the Act to sus
pend a registration if the food manufactu
red, processed, packed, received, or held
by a facility has a reasonable probability
of causing serious adverse health con
sequences or death to humans or animals.
Id. A facility whose registration has been
suspended may not import or export food
or introduce food into interstate or intra
state commerce in the United States. A
registrant subject to an order of suspens
ion is entitled to an informal hearing no
more than two days following the issuance
of the order on actions required for rein
statement and why the registration should
be reinstated. If, after the hearing, the FDA
finds that suspension remains necessary,
the registrant is required to submit a cor
rective action plan to demonstrate how it
will correct the unsafe conditions. The
FDA is required to promulgate regulations
descrating standards for acting under the
new suspension authority. Facilities are
subject to the requirements of these pro
visions on the date the secretary issues the

Although food traceability technologies are already
employed by many in the food business, the new legislation
is likely to expand this market to foods other than meat,
poultry, and egg products.

Inspections of Facilities
The FSMA increases the frequencies of re
quired inspections for all registered faciliti
ties, which includes any factory, warehouse,
or establishment that manufactures, pro
cesses, packs, or holds food (the FSMA
does not change the definition of “facility”)
FSMA §201. For domestic facilities, in
spection resources are to be allocated in
accordance with a risk-assessment sched
ule. Domestic facilities identified as “high
risk” must be inspected at least once in the
five-year period following the date of en
actment and at least once every three years
thereafter. Domestic facilities identified as
“non-high-risk” must be inspected at least
once in the seven-year period following the
date of enactment and at least once every
five years thereafter. Id. Facilities are to be
classified as “high-risk” according to their
known safety risks based on several crite
ria, including the known safety risks of the
food, the compliance history of the facility,
the rigor and effectiveness of the facility’s
hazard analysis and risk-based preventive
controls, and whether the food or facility
has met certain certification requirements
for imported food. Id. To meet the domestic
inspection requirements, the FDA may rely
on inspections conducted by other federal,
state, or local agencies pursuant to agree
ment. The secretary is also authorized un
der the Act, from the 2010 fiscal year and
forward, to assess and collect fees from a faci
lity subject to reinspection in that fiscal
year to cover related costs. FSMA §107. To
tal reinspection-related fees are capped at
$25,000,000 per fiscal year. Id. The new law
further provides that the FDA shall inspect
no fewer than 600 foreign facilities in the
one-year period following the date of enact
ment, and that it shall double the number
of foreign facility inspections every year com
pared with the previous year for the next
five years. FSMA §201. Section 306 of the
Act, which authorizes the secretary to en
ter into arrangements and agreements with
foreign governments to facilitate the inspec
tion of registered foreign facilities, also re
quires the secretary to refuse admission of
food into the United States if permission to
inspect that food’s facility is denied by the
facility owner, operated, or agent, or by the
foreign country.

Mandatory Recall Authority: Administrative Detention
The FSMA authorizes the FDA to man
date a recall of unsafe food if the responsi
ble party does not do so voluntarily. FSMA
§206. This provision affects all registered
facilities that manufacture, process, pack,
distribute, receive, hold, or import food. If
the secretary determines that there is a rea
sonable probability that an article of food is
adulterated or misbranded and that it will
cause serious adverse health consequences
or death to humans or animals, the FDA
must first provide the responsible party
with the opportunity to voluntarily cease
distribution and recall the product. If the
responsible party does not comply, the FDA
can order them to immediately cease dis	tribution and to notify all persons manu
facturing, processing, packing, transporting,
distributing, receiving, holding, import
ing, and selling the product to immediately
distribute. When the FDA issues such an
order, it must within two days pro
vide the responsible party with an oppor

All images and text in this document are in the public domain. For more information, visit the FAQs at http://www.fda.gov/AboutFDA/Accessibility/FAQs/ucm249243.htm#preventive. Specifically, a facility must evaluate potential food hazards, implement preventive controls, monitor the performance of those controls, establish procedures for corrective actions, and maintain records of such monitoring. FSMA §103. With respect to recordkeeping, the new provisions require a facility to maintain for no less than two years records documenting the preventive controls implemented, instances of nonconformance, the results of testing, instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions. Additionally, the facility must prepare a written food safety plan that documents the procedures used to comply with these new requirements. All of these written records must be made promptly available to the FDA upon oral or written request. The new provisions also include a requirement to reanalyze hazards whenever there is a significant change in the activities of the facility, or no less frequently than once every three years, whichever is earlier.
portunity for an informal hearing to challenge the determination. If, during the hearing, the FDA confirms the necessity of a recall, it must issue an amended order specifying a timetable in which the recall will occur. If the hearing reveals a lack of adequate grounds for the recall, the FDA will vacate or modify the order. The new law makes refusal to obey a recall order subject to civil penalties under 21 U.S.C. §333(f)(2)(A) and a “prohibited act” subject to injunction and criminal prosecution under 21 U.S.C. §331. Additionally, the secretary is authorized to assess and collect fees from a facility that does not comply with a recall order to cover food recall activities associated with such order performed by the secretary. FSMA §107. Total recall-related fees are capped at $20,000,000 per fiscal year. Id.

Prior to the new legislation, food recalls were technically voluntary. The FDA could pressure manufacturers to recall their products through consumer notifications and press releases, and could also pursue court orders to seize the products. In response, the vast majority of manufacturers recalled their products voluntarily. The FDA has commented that it expects to exercise its new mandatory recall authority infrequently because of the industry’s practice of largely honoring requests for voluntary recalls. “Questions and Answers of the Food Safety Modernization Act,” http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm238506.htm. Nonetheless, the mandatory recall provision represents a significant new authority that has existed previously in other product markets, such as toys, home building products, and electronics, but not in the food arena. Remarks of FDA Commissioner Dr. Margaret Hamburg, FDA Media Call, Briefing on the Food Safety Modernization Act, Jan. 3, 2011.

The FMSA contains a provision related to mandatory recall authority that lowers the standard for administrative detention of food if the FDA has “reason to believe” that such article is “adulterated or misbranded.” FSMA §207. The previous law required the higher standard of “credible evidence or information indicating” that the article of food presented a “threat of serious adverse health consequences or death to humans or animals.” 21 U.S.C. 334(h)(1)(A).

Enhancing Tracking and Tracing of Food and Recordkeeping

The FSMA requires the FDA, within 270 days after enactment, to establish pilot projects in coordination with the food industry to explore and evaluate methods for rapidly and effectively tracking and tracing food. FSMA §204. The FDA must also assess the costs and benefits, feasibility, and compatibility of several product tracing technologies. Based on the information gathered, the secretary is directed to report to Congress and then establish within the FDA a product tracing system. Although the FDA has until 2013 to issue more specific rules on food traceability, commentators have observed that technology companies are wasting no time in trying to grab a piece of an emerging market in high-tech tracking solutions. Although food traceability technologies are already employed by many in the food business, the new legislation is likely to expand this market to foods other than meat, poultry, and egg products. As at least one industry expert has observed, the more comprehensive tracking requirements are comparable to those already established in the pharmaceutical industry: “Paul Chang, who leads the traceability initiative at IBM, said the company is basically taking the tracking system it uses for pharmaceutical industry and adopting it to the food business.” Lyndsey Layton, “Traceability rule represents big adjustment for food industry,” Washington Post, Jan. 24, 2011.

To aid the tracking and tracing capacity of the FDA, the FSMA also contains additional recordkeeping requirements for high-risk foods. FSMA §204. Within one year following the date of enactment, the secretary must develop and publish a list of foods designated as “high-risk,” based on the following criteria: the known safety risks of a particular food, likelihood of microbiological or chemical contamination, location in the manufacturing process, and likelihood that consuming the food will result in a foodborne illness. Id. The secretary has two years from the date of enactment to publish a notice of proposed rulemaking to establish the additional recordkeeping requirements for foods designated as high-risk. The additional recordkeeping requirements are subject to a number of limitations, including that they must relate only to information that is reasonably available, consider cost and public health benefit, be scale appropriate, not prescribe specific technologies, and not require a full pedigree. A violation of the new law’s recordkeeping requirements will be a “prohibited act” under 21 U.S.C. §331. High-risk foods produced and packaged on a farm are generally excluded from the requirements of this section.

Important Effective Dates

- Inspection of records (§101): upon enactment
- Increased frequency of facility inspections (§201): upon enactment
- Mandatory Recall Authority (§206): upon enactment
- Authority to require import certification for food (§303): upon enactment
- Facility registration requirements (§102): first of 180 days or FDA issuance of regulation
- FDA may require electronic submission: 5 years
- Hazard analysis and risk-based preventive controls (§103): 1.5 years from enactment
- Enhancing tracking and tracing of food and recordkeeping (§204):
  - FDA conduct pilot programs: 270 days
  - FDA report to Congress: 1.5 years
  - FDA publish list of high-risk foods for recordkeeping provisions: 1 year
  - Notice of proposed rulemaking on recordkeeping: 2 years
  - FDA establish product tracing system: not specified
- Foreign supplier verification program (§301):
  - FDA publish guidance and regulation: 1 year
  - Effective date: 2 years

For a more detailed summary of the timetables established by the FSMA, see “Important Dates for the FDA Food Safety Modernization Act,” Registrar Corp., http://fda-news.registrarcorp.com/2011/01/important-dates-for-the-fda-food-safety-modernization-act/.
The various imported food safety provisions will not be described in detail in this article, but the clear overarching goal of Title III is to ensure that foreign imports are subject to comparable safety standards to those regulating domestic food. Section 301, for instance, requires importers, within two years of the date of enactment, to have in place a “risk-based foreign supplier verification program” to ensure that food is produced in compliance with certain standards and that it is not adulterated or misbranded. Section 303 grants the FDA immediate authority to require that imported food be certified to ensure compliance with U.S. laws. The FDA must base its decision to require certification on factors such as the known safety risks associated with the food and with the country, territory, or region in which the article of food originated, and a finding by the secretary that the food safety systems and standards in place in that country, territory, or region are inadequate to ensure a level of safety comparable with that of food manufactured, processed, packed, or held in the United States. Consequences of these new regulations are significant for importers. Importing food without a foreign supplier verification program in place will be a “prohibited act” under 21 U.S.C. §331, and if it is determined that a food article or facility requires an import certification, the FDA can delay entry into the U.S. until the certification is obtained.

Taking a Proactive Approach to Compliance

The FSMA will likely bring about a level of inspection never before seen in the industry and an expectation of advanced food safety systems well beyond where most companies stand today. The sweeping changes contained in the Act mean that companies at every point of the supply chain must respond. The FDA has yet to promulgate the regulations that will determine many of the methods for enforcing the Act, and it remains to be seen whether adequate funding will be provided. Nonetheless, companies will be well served by taking a proactive approach to compliance in order to maintain consumer confidence and to stay ahead of the curve. The goal for each company, and likewise, the greatest challenge, is to develop a food safety program that is both cost-efficient and effective in enhancing overall compliance efforts.

Companies should begin by assembling a task force charged with developing steps for addressing the requirements of the FSMA. The task force should be comprised of representatives from various departments, including in-house counsel, outside counsel, information technology, insurance, regulatory compliance, quality control, and crisis team. Once assembled, the task force should start by evaluating the company’s current food safety programs and strategies to determine which areas need to be modified to support the new requirements and regulatory changes and to stay current with industry best practices. This individualized initial assessment will in part determine the course of action of the task force, but there are a few key factors all companies should consider in prioritizing preparation for the new responsibilities imposed by the Act. First, document management is of critical importance in preparing for nearly every new or expanded food safety responsibility. Second, the hazard analysis and preventive control plan required under Title I is a particularly significant undertaking that calls for immediate action by the task force. Finally, all companies should prioritize steps to avoid consequences arising out of the FDA’s new, immediately effective mandatory recall authority.

Document Management

Thorough and meticulous recordkeeping should be at the center of every company’s compliance efforts, as this is the most obvious way to avoid potentially serious consequences authorized under the FSMA. The Act increases the frequency of facility inspections and the authority of the FDA to access and inspect records. It also authorizes the FDA to impose additional record-keeping requirements on “high-risk” foods in order to further track and trace capabilities. To comply with the broader record-keeping requirements, companies should ensure that they have thorough and efficient document management systems in place. Operators should prepare for inspections by eliminating any gaps in documentation and by making sure that all forms are accurate, legible, and up to date. Companies should be mindful that frequency of inspections will increase under the Act for all facilities, both “high-risk” and “non-high-risk,” and that facilities requiring re-inspection can be issued fees for the costs.

The occurrence of an out-of-compliance event—specifically, the assessment and corrective actions taken—should be carefully and promptly documented. Under the hazard analysis provisions, companies are expected to maintain detailed records of each such event for at least two years and have it available upon request. A missing record may influence the FDA to invoke its new mandatory recall authority, because when a company is unable to show through documentation that a product is safe, the FDA is more likely to determine that the product is reasonably likely to cause serious adverse health consequences or death. Likewise, flaws in documentation might contribute to providing the FDA “reason to believe” that the food at issue is adulterated or misbranded, which could result in another serious consequence, administrative detention. FSMA §207. Essentially, the more uncertainty the FDA perceives through gaps or ambiguities in records, the more likely that company will be subject to increased inspections and oversight. The stakes are high, and to minimize business interruption, task forces should concentrate efforts on developing systems designed to avoid documentation problems.

As part of these efforts, companies should test their current record systems and look for any inconsistencies now to avoid problems with the FDA in the future.
They should ensure that their recording procedures are detailed; specifically, they should adhere to the policy of recording the “who, what, where, when, and why” of each action taken. A complete name, initials, or electronic signature should accompany every recorded entry. The action taken or recorded should be clear and should also include the results of the activity. A complete date and time or shift should also be present along with the location of the line or equipment involved. Finally, it may be necessary to provide justification for the actions taken. For this reason, companies should consider training employees to maximize understanding regarding legally sufficient recordkeeping. This includes managing documents so as to ensure proper but efficient compliance with regulatory mandates and the electronic discovery requirements imposed by the Federal Rules of Civil Procedure (see FRCP 16, 26, 33, 34, 37, and 45).

Hazard Analysis and Preventive Controls

The hazard analysis and preventive control provisions of the FSMA are perhaps the most robust new requirements that food companies must contend with. Most in the industry are well acquainted with hazard analysis and critical control points, or HACCP, plans, which are already established in many companies across the supply chain. The FDA describes HACCP as a “management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.” http://www.fda.gov/food/foodsafety/hazardanalysisiticalcontrolpointshaccp/default.htm. Significantly, the hazard analysis requirements of the FSMA do not explicitly use the term HACCP. Rather, the Act requires what could be described instead as a hazard analysis preventive control plan (HAPC). The HAPC requirements of the FSMA are clearly similar to HACCP, with the notable exception that there is no requirement to identify critical control points. The fact that the FSMA excludes from these requirements facilities subject to seafood or juice HACCP regulations indicates that HACCP plans are considered satisfactory under the Act. It is possible that Congress chose not to explicitly require HACCP because it can be both difficult to implement quickly with limited resources and difficult to enforce.

Whether companies choose to implement HACCP or HAPC plans, it is clear that they must take preliminary steps to develop programs that will comply with the hazard analysis provision of the FSMA. Participation of a task force will be critical for this undertaking. It is important to identify carefully all hazards associated with one’s products—including intentional and nonintentional adulteration risks—across the food safety system. Companies should err on the side of overinclusion when assessing these risks, as no risk that goes identified can be prevented. As plans take form, they should also be outlined and verified in flow charts. In light of the new regulations, companies should be particularly aware that their products are only as safe as the food coming from their suppliers and keep a close eye on each one. Procedures must also be in place to comply with the FSMA requirement that risk analysis and preventive control plans be updated frequently.

Preparing for Recalls

Several provisions of the FSMA may contribute to the likelihood of increased recall orders. These include the extensive whistleblower protections, increased inspections of facilities, increased recordkeeping requirements, and increased authority to review records. Overall, the FDA simply has more opportunity under the Act to detect potential food adulteration. Companies should keep in mind that a recall can be ordered based on a “reasonable probability” of adulteration; certainty is not required. Diligent recordkeeping is an important means of protecting your company against recalls, which are undoubtedly burdensome and costly. However, when public safety is at risk, food companies should be equipped to respond quickly and efficiently by identifying and removing a product.

In order to prepare for recalls, task forces should first ensure that their traceability capabilities cover at least one step back and one step forward on the supply chain. Traceability should be tested by conducting trace exercises to ensure a company can determine where its food comes from and where it lands. Companies should also prepare a recall plan and conduct recall exercises. This goes beyond testing the traceability, because merely locating the food along the chain does not mean that a company is prepared to actually bring a product home in a timely manner. A company must consider the practical implications of a recall, such as where it will store a recalled product, how it will physically handle the product, steps for reevaluating the product, and maintaining up-to-date consumer contact lists, and incorporate these concepts into the recall plan. Along with the ability to swiftly withdraw a product, companies should consider preparing to replace or substitute products in the event of a recall. In this regard, advanced preparation is sure to pay off in the form of brand protection in the event that something does go wrong with a product. A proactive approach is particularly important in this area so that a company is prepared to effectively manage a recall before an incident occurs.

Conclusion

Given the breadth of the FSMA, companies will be affected in different ways depending on a multitude of factors, such as the depth and quality of food safety systems already in place, location in the food supply chain, size, and status as an importer. As representatives from in-house counsel, outside counsel, information technology, insurance, regulatory compliance, quality control, and crisis team gather to form task forces, they should closely assess the impact of each of these factors, including examining whether any of the Act’s exemptions apply to them. For many of the Act’s provisions, changes will be realized as part of ongoing processes as the FDA develops regulations and issues guidances and companies take steps to modify their food safety practices. In many instances, industry groups, such as the United Fresh Produce Association, American Frozen Food Institute, and American Meat Institute, will (and have already begun to) collaborate and make their voices heard to help

FSMA ▶ page 54

In-House Defense Quarterly ▶ Summer 2011 ▶ 17
footing as they move forward into this new period in food safety regulation. The FSMA has raised the stakes, and companies must be proactive in order to remain competitive in the rapidly evolving climate of the food industry.