



Prepare to Comply

By Kathleen A. Hardee

As the regulations required by the FSMA are implemented, the ultimate liability standards in negligence cases may turn at least in part upon a company's efforts to prevent harm to the food supply.

The Industry's Role in Our Nation's Food Safety

The Food Safety Modernization Act (FSMA), the most comprehensive reform in food-safety laws in more than 70 years, shifts the federal government's focus from responding to food contamination to preventing it. Although the

U.S. Food and Drug Administration (FDA) has yet to issue the sweeping regulations required by the FSMA, those regulations will affect every link in the food-supply chain from production to the consumer's table and including food transportation. Trucking companies must begin evaluating their current risk prevention policies even though the FDA has not completed the regulations and prepare to comply with the upcoming changes.

Background

The American trucking industry has a long and proud history of both self-regulation and governmental cooperation at both state and federal levels. Even before Congress passed the Motor Carrier Act in 1935, the American Highway Freight Association and the Federation Trucking Associations of America met in the spring of 1933 to form the American Trucking Association (ATA). Since that formation, the ATA has worked both independently and hand-in-

hand with governmental entities to promote public safety and fair competition within the industry.

Throughout the last 75 years, the governmental agencies that have had influence or control over various parts of the trucking industry have grown in a haphazard way, at times without cross-agency coordination or common purpose. Most agencies deem their purpose either to relate to rate competition, such as the Interstate Commerce Commission, the Federal Maritime Commission, or a state public utilities commission, or to safety, similar to U.S. Customs and Border Protection, the U.S. Department of Transportation, or a state department of motor vehicles. The industry has recognized through the years its duty to implement safeguards. Its safety initiatives have been designed not only to protect its drivers, but also to protect the public at large.

New Concerns Emerge

Media headlines are regularly fraught with



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news of outbreaks of foodborne illnesses. According to the Centers for Disease Control and Prevention, approximately 48 million people, or one in six Americans, become sick each year from foodborne diseases. Of that number, about 128,000 people are hospitalized, and 3,000 people die. See Centers for Disease Control and Prevention, CDC 2011 Estimates: Findings, <http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html> (last visited Oct. 23, 2012). These estimates are particularly troubling because a significant portion of this public health crisis is preventable. In response, various industries, consumer groups, and governmental agencies have initiated efforts to protect the public. As is often the case, the initial efforts lacked coordination among groups and often lacked the funds or authority needed for enforcement.

The Federal Government's Initial Response

As the trucking industry has grown in scope, the makeup of its cargo has changed. According to the U.S. secretaries of agriculture and transportation, by 2007 agriculture was the single largest cargo for freight transportation in the United States, constituting 31 percent of all ton-miles transported. See Transportation Research Board, *Trucking 101, An Industry Primer*, at 24, (Dec. 2010). Trucks move over 90 percent of the nation's fresh fruits and vegetables (by market share) and 95 percent of livestock. *Id.* From 1976 through 2011, at least 15 FDA regulations and guidelines were passed addressing the transportation of food products. In 1995, the Agricultural and Food Transporters Conference (AFTC) was founded to represent motor carriers and allied members of the ATA on critical issues affecting agricultural commodities and food transportation.

The role of inspecting food safety during transportation was first given to the U.S. Department of Transportation (DOT) under the Sanitary Food Transportation Act of 1990 (SFTA), 21 U.S.C. §305. However, because food inspection fell outside the DOT's area of expertise, Congress revised the SFTA in 2005 and amended it by transferring regulatory responsibility to the FDA. Under the SFTA, the FDA set standards to ensure that food was not transported under conditions that would

render it unsanitary or adulterated. The SFTA also heightened record-keeping requirements so that in the event of a food emergency, such as a necessary recall, food could be traced both back to its origin and forward to its destination. Each participant in the food chain had the obligation to document where it obtained the food cargo and where it delivered it. This requirement was known in the industry as the "one-up/one-down" rule. Unfortunately, a report issued in March of 2009 by the Office of the Inspector General, under the U.S. Department of Health and Human Services, entitled "Traceability in the Food Supply Chain" found that many participants in the food chain largely did not heed the SFTA's directives. Of the 118 food facilities studied, 59 percent failed to meet the FDA requirements to maintain records about their sources, recipients, and transporters. Twenty-five percent did not even know about the FDA records requirements.

Not to be dissuaded, in April 2010 the FDA issued yet another guidance through an advance notice of proposed rulemaking (ANPRM). There, the FDA stated that "[t]his guidance differs from the prior regulations and guidance in that it provides all sectors of the food industry with broadly applicable recommendations." The April 2010 guidance was quite specific, leaving little room for ambiguity. However, the guidance lacked in enforcement power what it gained in detail. Again, this was guidance, not an FDA rule, so the FDA had no way to enforce it. Although the April 2010 guidance was a significant step toward creating new regulations to govern sanitary transportation practices, the guidance was never finalized into regulations and weaknesses remained.

Safety Concerns

Food transportation raises multiple health and safety concerns. Abuse in the handling or storing of food can render a product unfit or unsafe for human consumption. See Larry Keener, *Transportation: The Squeaky Wheel of the Food Safety System*, Food Safety Magazine (Oct./Nov. 2003). Abuse can take the form of (1) sabotage or tampering, (2) temperature abuse, or (3) cross-contamination. Sabotage or tampering is largely addressed with tamper-resistant locks and seals. Temperature abuse and cross-contamination are more

prevalent dangers and are generally result from a lack of knowledge or lack of training of transporters.

During transportation and storage, one serious challenge is to maintain proper refrigeration temperatures. According to the International Food Distribution Association (IFDA), a trade organization of foodservice distributors, "maintenance of

Trucking company

staff, drivers, and others involved in the delivery chain are not always trained to understand the risk of cross-contamination.

the cold chain is an essential part of ensuring not only compliance with Good Manufacturing Practices under 21 C.F.R. §110.93, but product quality and cost containment as well." See *Temp-Controlled Food Transport: Safe Travels*, Inbound Logistics (Aug. 2011). Good manufacturing practices (GMP) regulations specify that storage and transportation of food is maintained at levels that protect against physical, chemical, and microbial contamination.

In addition to temperature control, cross-contamination is the second leading biological abuse of food during transportation. According to Nick Erdman, business development manager for Transport Security, "LTL [less than truckload] is really the most vulnerable link in a supply chain." See Larry Keener, *Transportation: The Squeaky Wheel of the Food Safety System*, Food Safety Magazine (Oct./Nov. 2003). Less than truckload or "LTL" loads can include literally dozens of shipments from various sources, including multiple food and nonfood shipments. Products from the following three classes are absolutely incompatible with each other in terms of food safety: fresh produce, fresh raw meat, and assorted chemicals. *Id.* However, trucking company staff, drivers, and others involved in the delivery chain are

not always trained to understand the risk of cross-contamination. Even in subsequent loads, measures must be undertaken to sanitize any bacterial or chemical residues that might remain in the vehicle from previous food loads. *Id.*

A Unified Response

On March 14, 2009, President Barack Obama

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created a Food Safety Working Group to study and provide recommendations for the creation of a coordinated system of federal laws that would protect the integrity of the nation's food supply. The working group was chaired by Secretary of Health and Human Services Kathleen Sebelius and Secretary of Agriculture Tom Vilsack. Participating agencies included the FDA, the Food Safety and Inspection Service (FSIS), the Centers for Disease Control and Prevention (CDC), the U.S. Department of Homeland Security, the U.S. Department of Commerce, the U.S. Environmental Protection Agency (EPA), and several offices of the White House. The working group held several "listening days" during which they received input from states, localities, food industry representatives, consumer advocates, and other experts.

The findings of the working group reflected exactly what those who had played various roles in the food industry had known for years: "At least a dozen Federal agencies, implementing at least 30 different laws, have roles in overseeing the safety of the nation's food supply." See President's Food Safety Working Group, *Food Safety Working Group: Key Findings 2*, http://www.foodsafetyworkinggroup.gov/FSWG_Key_Findings.pdf (last visited Oct. 23, 2012). The work-

ing group concluded, "Effective organization is essential to the performance of the food safety system. To build a more effective safety system, federal agencies need to improve management of their food safety responsibilities and coordinate more effectively with each other." *Id.* at 5. Then the working group went on to emphasize prevention, specifically finding that all participants in the food chain shared prevention responsibility. *Id.* at 3. The working group proposed an offensive rather than defensive approach to food safety, which spanned every link in the chain from farm to table. After a year and a half of wrangling, Congress passed the Food Safety Modernization Act in December 2010, and President Obama signed it into law on January 4, 2011. See Food Safety Modernization Act §101, *et seq.*, Pub. L. No. 111-353 (2011).

The Food Safety Modernization Act (FSMA) is described as the most comprehensive reform of U.S. food-safety laws in more than 70 years. The passage of this act established the critical foundation for a prevention-based food-safety system. This massive food-safety reform bill requires over a dozen separate rules and guidance documents. The FSMA is designed to ensure that the U.S. food supply is safe by shifting the focus of food-safety regulation to prevention. The FSMA is also comprehensive in conferring unprecedented cohesive enforcement authority to the FDA. Under the FSMA, the FDA will, for the first time, have a legislative mandate to require comprehensive, scientifically based preventative controls across the food supply.

For the first time in history, the FSMA brings every participant in the food chain together under one legal mandate with a specified purpose. The FSMA places responsibilities on every individual and entity that manufactures, processes, packs, transports, distributes, receives, or holds articles of food. The new law requires comprehensive, scientific-based, preventative controls across the food chain. The FSMA addresses not only the national food chain but global sources of imported food as well.

Despite its reach, the FSMA is surprisingly minimalistic. It outlined rough overarching themes but left it to the regulators to work out the most controversial details, which has resulted in implementation delays that continue. Beyond merely out-

lining concepts, the FSMA does little more than provide deadlines for rule making.

Some of the key concepts in the FSMA include establishing

- Broader, more in-depth, and more rapid records inspection,
- Hazard analysis and risk-based preventive controls
- Regulation to further the sanitary transportation of food
- A tracking and tracing methodology for food to "prevent or mitigate" an outbreak of foodborne illness or intentional contamination
- Mandatory recall authority
- Heightened controls over imported foods
- Whistle-blower protections.

Food Safety Modernization Act §101, *et seq.*, Pub. L. No. 111-353 (2011).

The FSMA includes a plan to hire 2,000 new FDA inspectors over the next five years at a cost of \$1.4 billion. See Rob Moseley, *The Food Safety Modernization Act*, SML Perspectives (Mar. 14, 2011), <http://smlperspectives.com/transportation/the-food-safety-modernization-act/> (last visited Oct. 23, 2012).

Where that money and the funds to pay for the other costs of the act will come from is unclear. Some speculate that the FDA will for the first time receive the authority to impose registration fees upon food facilities. See David Acheson, Leavitt Partners, Presentation, Food Safety Modernization Act, for Food Seminars International (Aug. 29, 2012).

The FSMA and the Trucking Industry

The transportation industry generally, and the trucking industry specifically, are integral parts of the food-supply chain. However, whether warranted or not, the transportation industry has been viewed as a "weak link" in the chain in terms of safety. See, e.g., Lisa Lupo, *Is Transportation the Weak Link?*, Quality Assurance & Food Safety, (Aug. 10, 2011), <http://www.qualityassurancemag.com/qa0811-supply-chain-safety-transportation.aspx> (last visited Oct. 23, 2012). David Acheson, managing director of food and import safety practice with Leavitt Partners and a former FDA associate commissioner for foods, has stated that in the transportation of food "[t]here is guidance but nobody is really regulating it." *Id.* Acheson went on to say, "I'm not sure if it is the weakest link, but it is a weakness that cer-

tainly needs looking at; it is a weakness that poses risk.” *Id.* Before the act passed, much of the regulation and tracking of food products focused on the processing stages. Fritz Buss, technical director for Nelson Jameson, has said, “What happens to it in between seems to be kind of an afterthought. There should be a strict chain of custody with seals and logs tracking it all the way through.” *Id.*

Several sections of the new FSMA are directed toward the transportation industry, either individually or in conjunction with other food handlers. Section 111 of the FSMA is specifically entitled “Sanitary Transportation of Food.” *See* Food Safety Modernization Act §111, Pub. L. No. 111-353 (2011). Additionally, provisions pertaining to records and food tracking and traceability will significantly affect how trucking companies do business. Food Safety Modernization Act §101, Pub. L. 111-353 (2011) (records) and §204 (food tracking and traceability). Understanding the purposes of these key sections is critical to preparing for a seamless transition to compliance with the new law.

Sanitary Transportation

The FSMA states, “Not later than 18 months after the date of enactment of this act, the Secretary shall promulgate regulations described in section 416(b) of the federal Food, Drug, and Cosmetic Act (21 U.S.C. 350e(b)).” Food Safety Modernization Act §111, Pub. L. 111-353 (2011). Section 416(b) of the federal Food, Drug, and Cosmetic Act requires the FDA to promulgate regulations that require “shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices prescribed by the Secretary to ensure that food is not transported under conditions that may render the food adulterated.” 21 U.S.C. §350e(b). The FSMA requires that the FDA sanitary transportation program to establish scientifically based minimum standards.

Section 111 is the only section of the FSMA directed specifically to the transportation industry. And despite the belief by some that transportation is the weakest link in the food-safety chain, the FDA has not yet commented or acted on this section. The July 4, 2012, deadline under section 111 of the FSMA for the implemen-

tation of a sanitary transportation program came and went without any new regulatory mandates. The delay of creation of regulations for the transportation industry seems to indicate that transportation is a lower priority and has done a good job of self-regulating to date.

Records Accessibility

Under the FSMA, the FDA has greater access to company records than previously existed. The scope of previous inquiries was limited to records related to articles of food that the FDA believed to be adulterated. The FDA may now demand records of the food believed to be affected and also records of any other article of food that it reasonably believes is “likely to be affected in a similar manner.” Food Safety Modernization Act §101, Pub. L. No. 111-353 (2011). Although not yet final, the FDA issued an interim final rule, draft guidance, and Q & A on February 23, 2012. There, the FDA found that §101 of the FSMA “provides FDA additional access to records relating to articles of food for which FDA believes that there is a reasonable probability that the use of or exposure to the article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals.” Establishment, Maintenance, and Availability of Records: Amendments to Records Availability Requirements, 77 Fed. Reg. 10,658-01 (Feb. 23, 2012). Records requested by the FDA must be provided as soon as is reasonably possible, but in no event later than 24 hours from the time of the request.

The expansion of this authority may have unintentional consequences. A plaintiff in private litigation would normally be entitled to obtain discovery relating to the food products that caused his or her injury only. But because of this broader FDA authority, plaintiffs will have access under the Freedom of Information Act to any documents obtained by the FDA, meaning other food that the FDA reasonably believed might be similarly affected at that time. *See* Gary Wolensky, *et al.*, *The Food Safety Modernization Act: Another Law of Unintended Consequences?*, Mass Torts Litigation Newsletter, Vol. 10, No. 1 (Fall 2011 ABA). Greater access to information about contaminated foods increases litigation and punitive dam-

age risks for food producers, and possibly for transportation companies.

Tracking and Traceability

Section 204 of the FSMA mandates the creation of a tracking and tracing methodology to “prevent or mitigate” an outbreak of foodborne illness or intentional contamination of food. *See* Food Safety Modernization Act §204, Pub. L. No. 111-353 (2011). This provision arose from recent high-profile food contaminations and necessary recalls: “Public and private sector officials often lack information about the sources of foods or ingredients, making the traceback process more cumbersome and leading to less-accurately targeted recalls. In addition, multiple Federal, State, and local agencies all play essential roles in managing outbreaks but lack a unified structure or adequate provisions for sharing data in an emergency.” *See* President’s Food Safety Working Group, *Key Findings, supra*. In recent disease outbreaks resulting from contaminated food discovering the source of the contamination has been difficult. *See* Perry A. Trunick, *Temp-Controlled Food Transport: Safe Travels*, Inbound Logistics (Aug. 2011), <http://www.inboundlogistics.com/cms/article/temp-controlled-food-transport-safe-travels/> (last visited Oct. 23, 2012). A more detailed tracking system will allow faster and more accurate tracing of adulterated food both back to sources and forward to markets.

Tracking and traceability efforts have two components. First, the FSMA requires the FDA to conduct pilot projects to evaluate methods and technologies. Food Safety Modernization Act §204(a), Pub. L. 111-353 (2011). The FDA also is to analyze the costs, benefits, and feasibilities of those potential methods and technologies and ultimately to implement the conclusions. *Id.* at §204 (b). Secondly, the FDA is to establish heightened record-keeping requirements for foods deemed to be “high-risk foods” for purposes of potential contamination outbreaks. *Id.* §204.

The FDA has made progress with the pilot projects. On September 7, 2011, the FDA announced that the Institute of Food Technologists (IFT) would conduct pilot projects to explore methods for rapid and effective tracking and tracing of food, “including types of data that are useful for

tracing, ways to connect the various points in the supply chain and how quickly data can be made available to the FDA.” See Food, Product Tracing: Pilot Projects for Improving Product Tracing along the Food Supply System, U.S. Food and Drug Admin., <http://www.fda.gov/Food/FoodSafety/FSMA/ucm270851.htm> (last visited Oct. 23, 2012). The food products for the pilots were

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tomatoes, for the produce selection, frozen Kung Pao-style dinners, for the frozen or ready to eat food selection, jarred peanut butter, and dry, packaged peanut/spice.

The pilots were completed on schedule in June 2012. The IFT final report on tracking and tracing was submitted to the FDA in July 2012. Once it receives approval from the FDA, the IFT intends to make the report public. Then the food industry will have a better indication of the parameters of the tracking and tracing requirements. It is fair to assume that responsibilities will far surpass the current one-up/one-down obligations.

After considering the IFT’s report, the FDA will publish the first proposed FSMA rules. A comment period will follow with the agency holding at least three public meetings in various geographic areas. After receiving input from the public, the FDA will issue final rules. Based on the current status of the process, the final rules probably will come to pass in late 2013. After the FDA issues final rules an affected industry commonly enjoys a period of “enforcement discretion” during which the FDA issues guidance on how the industry can comply with the new regulations. The author expects that the trucking industry will enjoy an FSMA enforcement discretion period.

Although the FDA has not yet released the full pilot results to the public, comments published in other sources by pilot participants provide some clues about what the final requirements might include. Tejas Bhatt, the IFT lead scientist for the pilot projects has indicated that traceability will require that all participants in the supply chain use a common language to communicate with one another and with governmental agencies. See Dorothy Noble, *Traceability and Produce Safety: Are you ready for the future?*, Growing Magazine (Mar. 2012), <http://www.growingmagazine.com/article-7909.aspx> (last visited Oct. 23, 2012). Early reports indicated that the IFT favored using a system-wide electronic tracking system. Ultimately, concern over the cost for smaller participants dissuaded the FDA against the idea. *Id.* The FDA will not recommend specific software, systems or technologies. Instead the entire tracking and tracing system will focus on the elements of the system. *Id.* Further, the FDA likely will phase in the system over some period of time. *Id.*

As of the writing of this article, the FDA has not finalized the second phase of its tracking and tracing efforts, the record-keeping requirements. The FSMA calls for heightened science-based record-keeping requirements for foods deemed to be “high-risk,” although it does not define high risk. The FDA has stated that it “must consider such factors as the known safety risks of a food based on foodborne illness data and the likelihood that a particular food has a high potential risk for contamination.” *Id.* Although it plans to release the record-keeping requirements by January 2012, the FDA has stated that it plans to wait until after completion of the product tracing pilots to turn its attention to the requirements. *Id.*

Perhaps the most surprising indication of what is to come for the tracking and tracing program can be found in the FDA comments in its January 20, 2012, abstract. The FDA stated that “the proposed rule will be based on prevention-oriented public health principles and incorporate what we have learned in the past decade since the agency issued general good agricultural practice guidelines entitled, “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables,” sometimes referred to as the “good agricultural practices guide” or the “GAPS guide.” U.S. Food

and Drug Admin., (1998). The proposed rule also will reflect comments received on the agency’s 1998 update of the guide and the July 2009 draft commodity specific guidance for tomatoes, leafy greens, and melons. Although the FDA will base the proposed rule on recommendations that are included in the guide, it *does not* intend to make the entire guidance mandatory. In the past the FDA’s food-safety actions have often been issued through guidance rather than regulation. As discussed below, that distinction has sometimes led to deadly results. Whether the portions of the tracking and tracing program that apply to the transportation industry will become mandatory or guidance remains to be seen.

Status of the FSMA Regulations

Deadlines set by Congress for the implementation of the various provisions of the FSMA and related regulations continue to come and go. Although Congress intended the FDA to issue the sanitary transportation regulations required under §111 of the FSMA within 18 months of enactment, they have not been published as of the date of the writing of this article.

Commentators have speculated about the reasons for the delay. The FDA completed several provisions in a timely manner and submitted them to the Office of Management and Budget (OMB), yet they still languish there. Some have suggested that election-year politics or uncertainty on the cost-and-benefit analysis of the rules account for the delays. See Tom Karst, *What’s Holding up Food Safety Regulations?*, The Packer (July 11, 2012), <http://www.thepacker.com/fruit-vegetable-news/-/Whats-holding-up-food-safety-regulations-162114145.html> (last visited Oct. 23, 2012).

Despite the passage of nearly two years since the enactment of the FSMA, the trucking industry still has few specifics about what its obligations will look like under the new law. Further, if the FDA’s comments bear true and some of the FSMA regulations are ultimately guidelines, not enforceable regulations, trucking companies will be left wondering about the nature and extent of their legal obligations in transporting the food supply.

Polls indicate that 93 percent of Americans believe that food suppliers should be held legally responsible in cases of food-

borne illness. See James Andrews, *Food Makers Eye Tech, Safety Innovations at Forum*, Food Safety News (May 23, 2011), <http://www.foodsafetynews.com/2011/05/a-look-at-2011-food-tech-innovation-and-safety/> (last visited Oct. 23, 2012). Transportation carriers in the past have not frequently been considered by plaintiffs as “food suppliers.” But with the passage of the FSMA, federal law has made it clear that every participant in the chain, including transportation carriers, has responsibility for preventing unsanitary conditions that may lead to disease. Without the completion of any relevant regulations, those responsibilities are ambiguous and as of yet have no real definition. Plaintiffs may argue that FDA “guidelines” and newly marketed technologies delineate best practices or the state of the art.

As has always been the case, plaintiffs may allege that defendant trucking companies acted negligently when they have not adhered to industry standards. All risk prevention policies should mandate constant monitoring and adherence to the most current industry best practices, whether or not binding law. Whether “guidelines” or directives, all regulations issued by the FDA under the FSMA for the trucking industry should be followed. Trucking companies for now should adhere to other previously approved rules and guidelines such as the “good manufacturing practices” (GMP) contained in Title 21 of the Code of Federal Regulations, the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, referred to as the GAPS guide, and advance notices of proposed rulemaking. Trucking companies also must adhere to industry standards. Further, participation in certification programs such as Safe Quality Foods Program (SQF) and the Global Food Safety Initiative (GFSI) may help to show initiative to comply with industry standards. See CERT ID, *GFSI Benchmarked and Farm to Fork Food Safety*, <http://www.cert-id.com/Certification-Programs/SQF-Certification.aspx> (last visited Oct. 23, 2012). The FDA already recommends that all links in the food chain, and those agencies charged with monitoring them, prepare vulnerability assessments, such as the FDA vulnerability assessment, which uses the “Carver + Shock methodology.” See U.S. Food and Drug Admin., *Vulnerability Assessment*, <http://www.fda.gov/>

[Food/FoodDefense/ToolsResources/ucm295900.htm](http://www.fda.gov/oc/food/Food/FoodDefense/ToolsResources/ucm295900.htm) (last visited Oct. 23, 2012).

Up to this point, some in the food industry have adopted the attitude that FDA “guidances” are not law, and therefore, the food industry does not need to follow them. See OIG Report, *Traceability in the Food Supply Chain* (Mar. 2009). In the recent cantaloupe listeria outbreak a third-party auditor had discovered unsanitary conditions at Jensen Farms but failed to report the problems because they only violated FDA guidance not regulations. See David Acheson, *Investigation of Cantaloupe Listeria Outbreak Has Congress Asking Serious Questions Around Third Party Audits*, Leavitt Partners blog (Jan. 10, 2012), <http://leavittpartnersblog.com/2012/01/investigation-of-cantaloupe-listeria-outbreak-has-congress-asking-serious-questions-around-third-party-audits/> (last visited Oct. 23, 2012). However, such attitudes are not consistent with industry best practices and are an open invitation to civil liability.

In alleging negligence against trucking companies, plaintiffs will also point to a company’s failure to use available “state of the art” technology and equipment. In response to the tracking and tracing concerns contained in the FSMA, new technologies are being released in rapid succession. Global Positioning System (GPS) devices placed on pallets can track the location of a shipment and transmit readings from sensors that monitor the temperature of produce in transit in real time. These systems track where a load is delivered and where it came from. Some trackers can provide data even months after delivery. See Trunick, *supra*. These devices can work in conjunction with the onboard recorders that register vehicle duty cycles and driver records to add data collection from temperature sensors monitoring a load. See Gretchen Goetz, *FSMA Means Updates for Trucking Industry*, Food Safety News (Jan. 30, 2012), <http://www.foodsafetynews.com/2012/01/fsma-means-updates-for-trucking-industry/> (last visited Oct. 23, 2012).

While trucking companies should adhere to all FDA regulations and industry best practices, they should approach large investments in new technologies with more caution. Understanding the technologies commonly used in the industry should be a consideration of any trucking

company. But when the IFT completes the tracking and tracing pilot programs and the FDA issues rules within the next year, waiting to make a major capital investment in technology seems appropriate to ensure that the technology will comply with the requirements of the new law. Although the FDA does not have the authority under the FSMA to dictate that trucking companies

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use particular software or technology, the regulations could require that a company’s tracking and tracing efforts are compatible with the efforts of the other participants in the food chain. See Noble, *supra*.

One thing must be kept in mind throughout the development of the FSMA and its attendant regulations. The FSMA expressly provides preemption of state law for “food production.” And respecting transportation, the FSMA states that there is no preemption for “fresh fruit and vegetables.” Other than that the FSMA does not address preemption. Without further clarification, preemption of state law is unclear. Currently, trucking carriers are subject to federal and state regulatory entities in every state in which they travel. In each state they are answerable to the state’s public utilities commission regulating intrastate trucking, permits, rates, and record keeping and its department of motor vehicles registration and licensing of drivers. Thus, carriers of food must continue to be mindful of liability under state laws while complying under the FSMA. This concern was highlighted in July 2012 when the Indiana legislature, at the urging of the Indiana State Department of Health, passed legislation making it a class A infraction to transport food that is more than two degrees above the acceptable tem-

perature that shows outward signs of contamination or spoilage or that is loaded in a way that risks cross-contamination. Megan Banta, *Overheated Food Trucks Raise Red Flags in Indiana*, Insurance Journal (Aug. 9, 2012), <http://www.insurancejournal.com/news/midwest/2012/08/09/258888.htm> (last visited Oct. 23, 2012).

Because the Indiana State Department of Health did not have the authority to stop trucks traveling through the state, Indiana state troopers instituted an initiative to conduct spot inspections. Troopers stopped random trucks, inspected loads with temperature sensors, and if they found that the carriers violated the Indiana law, they contacted the Indiana State Department of

Health, which helped destroy the dangerous loads.

Conclusion

Now isn't too soon to begin trying to anticipate and prepare for the new requirements that the FSMA will place on trucking companies. Begin by evaluating current record-keeping policies and procedures. Also, look at the ability and degree to which tracking and tracing is feasible. Once the federal government implements the FSMA, all trucking companies should create compliance committees and checklists outlining their compliance with the FSMA regulations. They should update vulnerability studies based on the new standards and

perform good agricultural practices (GAP) compliance assessments. And those entities without in-house legal counsel should identify potential outside counsel to evaluate their compliance with the new regulations, their potential exposure to liability under the regulations and any guidance provided by the FDA.

Remember, the overarching theme of the Food Safety Modernization Act is prevention. The FSMA regulations and the enforcement of those rules will likely occur with that goal in mind. Similarly, the ultimate liability standards in civil negligence cases may turn at least in part upon a company's efforts to prevent harm to the food supply. 