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FOOD SAFETY**FDA**

The FDA has broad powers under the Food Safety Modernization Act to prevent food-borne illnesses, and continues to take an aggressive approach in addressing non-compliance, attorneys Sheila S. Boston and Candice A. Andalia say in this BNA Insight. Given the potential for criminal and monetary penalties, the authors urge food companies to be proactive by assessing their compliance with Current Good Manufacturing Practices, establishing and enforcing Hazard Analysis and Risk-Based Preventive Control plans, and adhering to industry standards relating to food safety.

BNA Insight

The FDA's Enforcement Powers Under the FSMA: Recipes for Compliance



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In response to several large-scale food contamination outbreaks and product recalls, on January 4, 2011, President Obama signed the Food Safety Modernization Act ("FSMA") into law.

The FSMA significantly broadened the authority of the Food and Drug Administration ("FDA") to regulate domestically produced and imported foods by providing the FDA with new regulatory tools to prevent foodborne illness prior to an outbreak—including broad surveillance and inspection powers, as well as the power to effect mandatory food recalls, suspension of FDA regis-

tration of food facilities, and administrative detention of food products.

This new law departs from the previous approach, under which the FDA acted only *after* an outbreak had occurred.

All of these changes have important consequences for companies in the food industry, because those companies that fail to evaluate and strengthen their compliance programs may find themselves subject to penalties as minor as monetary fines or as severe as the closure of food facilities, which can even lead to bankruptcy.

Thus, an understanding of the far-reaching powers established by the FSMA is vital for all food companies that are subject to FDA regulation.

Surveillance and Inspection

Prior to the enactment of the FSMA, states were traditionally responsible for monitoring foodborne illnesses, with assistance from the Centers for Disease Control and Prevention ("CDC"). Under the FSMA, however, a new surveillance system involving coordinated and integrated efforts from federal, state, and local agencies, and testing by accredited laboratories, requires an investigation when two or more occurrences

of a similar illness result from the ingestion of a certain food.

To that end, the FSMA seeks to improve the FDA's access to information by increasing the frequency with which companies must register with the FDA. Previously, foreign and domestic food facilities were only required to register with the FDA once. Under the FSMA, however, food facilities are now required to renew their registration every two years and must permit the FDA to inspect the facility. Companies must also update the FDA on any changes to their food categories if and when those changes arise.

Additionally, the FSMA expands the FDA's authority to access the records of all registered food facilities by eliminating the previous requirement that the FDA have a "reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death" before performing an inspection of records. H.R. 2751, 111th Cong. § 101 (2010).

Now, if there exists a *reasonable probability* that any article of food will cause "serious adverse health consequences or death," the FDA may demand to inspect records for the food in question and even different foods that are likely to be infected—including records of environmental and product testing, documentation of all supply chain monitoring, and any corrective actions that the company has taken. 21 U.S.C. § 350c(a)(1).

The FSMA also establishes a new inspection mandate, pursuant to which the FDA must increase the frequency of its inspections. All "high-risk" domestic facilities—those which process risky foods or have poor compliance history—must be inspected at least once in the five years following the enactment of the FSMA, and then at least once every three years. All other domestic facilities must be inspected at least once in the seven years following the enactment of the FSMA, and then at least once every five years.

Foreign facilities must be inspected as well, with a minimum of 600 facilities inspected within the first year after the enactment of the FSMA, and doubling every year thereafter, for the next five years. 21 U.S.C.A. § 350j(2)(D). To that end, the FDA has the power to work with foreign governments to inspect foreign facilities. 21 C.F.R. §§ 120.14, 123.12.

Despite more frequent physical inspections, the FDA's new access to food facility records signals that the FDA is transitioning from a regime based on the observation of facilities, to one based on the audit of food safety records. In light of this shift, it is likely that inadequate documentation can precipitate an FDA-ordered

inspection and even FDA action. As discussed in further detail below, now more than ever before, food companies should diligently maintain comprehensive and consistent recordkeeping of their food-safety protocols, including all decisionmaking relating to those controls.

Compliance

The previous approach to regulation relied on food companies to voluntarily adopt "Hazard Analysis Critical Control Point" plans—a food-safety management system designed to detect, reduce, and eliminate hazards from food production. FDA action was predominantly reactive—the agency would not act until the food-safety protocols had failed and there was a resulting outbreak of a foodborne illness.

By contrast, the FSMA gives the FDA the power to be proactive by imposing mandatory obligations on domestic food facilities to implement Hazard Analysis and Risk-Based Preventive Controls ("HARPC"). Food facilities are required to design HARPC plans for every "critical control point," which the FSMA defines as "a point . . . in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level." 21 U.S.C. § 350g.

As part of the HARPC, at least every three years, facilities must identify known or reasonably foreseeable food-safety hazards that could affect food manufactured, processed, packed, transported, or stored there, including chemical hazards, pesticides, parasites, and allergens.

The facilities must identify preventive steps and controls that will minimize and prevent the identified hazards, including employee training; control plans for the sanitation of food contact surfaces; employee hygiene; supplier verifications; pathogen and allergen controls; Current Good Manufacturing Practices ("cGMPs") for scientifically sound designs; processing methods; testing procedures; and recall plans. Facilities must also establish how they will monitor the effectiveness of those controls.

Finally, the facilities must conduct periodic reviews of the HARPC's efficacy and relevance, document any corrective actions deemed necessary, and maintain routine records of all monitoring for FDA review.

The FSMA also established new requirements for imported food that are virtually identical to the obligations imposed on domestic facilities. For example, the FSMA requires each importer to verify that imported foods are compliant with U.S. laws and regulations, by utilizing "reasonably appropriate risk-based preventative controls" such as monitoring records, lot-by-lot certification of compliance, annual on-site inspections, and/or the periodic testing and sampling of shipments of these foods. 21 U.S.C. § 384a.

It also establishes a program through which qualified third-parties, such as foreign governments, foreign co-operatives or other parties that the FDA deems appropriate, can certify that foreign food facilities comply with U.S. food safety standards. 21 U.S.C.A. § 384a. The FDA is required to audit these foreign third-parties every four years. Importers are required to maintain import-verification records for at least two years and make them available to the FDA upon request.

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Enforcement Tools

To enforce these new rules and regulations, the FDA continues to rely on its traditional practices, such as:

- partnerships with state and local agencies;
- untitled and warning letters;
- the provision of public and private third-party technical support and assistance in conducting audits or civil litigation; and
- criminal prosecution in appropriate cases.

The FSMA also provides the FDA with three new administrative enforcement tools: mandatory recall power, the authority to suspend FDA-registration from a regulated company that fails to comply with FSMA protocols, and administrative detention.

Mandatory Recall Power

Prior to the enactment of the FSMA, the FDA had two remedies at its disposal for preventing contaminated or misbranded food from entering the stream of commerce: the agency could either request that a company issue a voluntary recall for the adulterated or misbranded food or, if the company refused to issue a recall, the agency could obtain a court order to enjoin a company from introducing the food into the food supply. Both remedies were slow processes, prone to institutional delays that made it unlikely that FDA action would prevent adverse health consequences.

Under the FSMA, however, the FDA no longer needs a court order to stop a company from introducing food into the stream of commerce. Rather, if a company refuses the FDA's request that the company issue a voluntary recall,¹ the agency now has the authority to issue its own recall, if (1) there is a reasonable probability that the food is adulterated or misbranded, and (2) the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals. 21 U.S.C. § 3501(a).

After issuing the recall, the FDA must provide the company with an opportunity for an informal hearing, which must be held within two days of the order issuing the mandatory recall. In that short amount of time, the company must demonstrate, in writing, that a formal hearing is warranted by showing that a "genuine and substantial issue of fact" exists as to the grounds for the recall.

To this date, the FDA has not yet exercised its new recall power. This is likely because it is the least revolutionary of the new administrative devices available to the agency. Indeed, prior to the FSMA, food companies rarely viewed "voluntary recalls" as truly voluntary. Furthermore, the FDA's partnerships with state and local agencies meant that the FDA had the means to halt a food company's production without the broad power that is now delegated to it. For example, in 2010, the FDA relied on the State of Texas to shut down a San Antonio produce plant after lab tests found *Listeria monocytogenes* contamination that resulted in five

deaths and 10 cases of illness.² Similarly, in 2012, a California company voluntarily recalled one day's production of onions and celery after the FDA notified the company that a random sample of onions tested positive for *Listeria monocytogenes*.³

Nevertheless, the FDA's 2013 action with regard to the case of Kasel, a food-processing service company, signals the agency's willingness to use its new mandatory recall power. In September of 2012, inspectors from the FDA and the State of Colorado conducted testing of Kasel's manufacturing facility and pet treats that tested positive for *Salmonella bredeney*. The FDA investigators also identified inadequacies in Kasel's sanitation and cleanliness, including food-preparation and cleanup procedures, poor maintenance of manufacturing equipment, and rodent and insect infestation.

Shortly thereafter, over the course of the month of October 2012, Kasel issued several voluntary recalls of various products, but only after receiving more samples from Colorado investigators that had tested positive for *Salmonella*. In November, Colorado officials received another positive sample for *Salmonella bredeney* in yet another Kasel product; in response, the FDA recommended that Kasel recall the product. Kasel, however, refused. As a result, on December 6, 2012, the FDA issued a public health warning to consumers, announcing that Kasel products that were found to contain *Salmonella bredeney* had not been recalled.

The FDA then conducted a follow-up inspection, finding even more cases of *Salmonella* despite some alleged attempts by the company to take corrective measures. In response, the FDA issued a "last chance letter" requesting that the company issue a voluntary recall. The letter cited Kasel's history of food-safety deficiencies and multiple failures to address objectionable conditions, as evidence for the FDA's determination that Kasel's products were adulterated.

The FDA also relied on the frequency with which its investigation had turned up contaminated products as support for its assertion that there was a reasonable probability that the use of or exposure to the products would cause serious adverse health consequences or death to animals. The FDA then provided Kasel two days to issue a voluntary recall that would cease distribution of the affected products and give notice of their contamination, or face a mandatory recall by the FDA. Because Kasel chose to institute a voluntary recall of all potentially contaminated products, the FDA's mandatory recall became unnecessary.

Notably, even though this case included a significant record of non-compliance, the FDA still chose to rely on its more traditional tools—namely issuing a unilateral public health announcement—before resorting to the "last chance letter." To this date, the FDA has yet to exercise its new mandatory recall power.

Administrative Suspension of Registration

The most severe administrative sanction in the FSMA arsenal is the FDA's power to suspend the FDA registration of a food facility. The agency has the power to

¹ Such requests by the FDA are termed a Notification of Opportunity to Initiate a Voluntary Recall, known colloquially as a "last chance letter," which provides the company with an opportunity to issue a recall before FDA enforcement action.

² DSHS Orders Sangar Produce to Close, Recall Products, Texas Dep't of State Health Serv. (Oct. 20, 2010), available at <http://www.dshs.state.tx.us/news/releases/20101020.shtm>.

³ Recall—Firm Press Release, Food & Drug Admin. (July 19, 2012), available at <http://www.FDA.gov/Safety/Recalls/ucm312707.htm>.

do so if the agency determines that: (1) a “food manufactured, processed, packed, received, or held by a facility registered . . . has a reasonable probability of causing serious adverse health consequences or death to humans or animals”; or (2) the facility “knew of or had reason to know of such reasonable probability,” but still “packed, received or held such food.” 21 U.S.C. § 350d. A facility that is under suspension faces severe consequences, as it is prohibited from importing food, offering to import food, or introducing food into either intrastate or interstate commerce, which virtually puts the company out of business.

Like the mandatory recall, the FDA must offer the suspended facility a post-order opportunity for an informal hearing. The hearing must occur within two business days of the suspension order. After an informal hearing, if the agency decides to vacate the suspension order, it can require the company to submit a corrective action plan before vacature. Until such time as the order is vacated, the facility must comply with the order; failure to do so can result in an injunction, criminal prosecution, and/or heavy fines.

The FDA exercised this new power in 2012 when it suspended the FDA registration of Sunland, Inc., a producer of nuts, seeds, and nut and seed spreads. The FDA had previously investigated Sunland between 2009 and 2012, in response to over 40 reports of *Salmonella breedeney* outbreaks in 20 different states.

As a result, starting in September 2012, the FDA and CDC jointly investigated the outbreaks, linking them to peanut butter made by Sunland. In response, one distributor of Sunland’s peanut butter, Trader Joe’s, voluntarily recalled the product. Shortly thereafter, Sunland issued a voluntary, limited recall of its almond butter, peanut butter, and other nut and seed products. The FDA investigation continued, eventually revealing the presence of *Salmonella breedeney* in raw peanuts, as well as environmental samples from Sunland’s processing plant.

In November 2012, the FDA suspended Sunland’s registration and thereby barred it from introducing food into intra- and interstate commerce. In support of the suspension, the FDA cited Sunland’s violations of cGMPs—namely ineffective cleaning of brand packing equipment, the failure to sanitize storage and transportation containers, and a lack of hand-washing sinks in the production and packing areas.

The FDA reasoned that, taken together, these violations demonstrated a reasonable probability that “food manufactured, processed, packed, received, or held by Sunland [could cause] serious adverse health consequences or death to humans or animals.” Therefore, the FDA concluded that “based upon the current condition of the facility and past management policies and actions,” suspension was justified “until Sunland has completed and implemented certain corrective actions.” F.D.A. Letter to Sunland Inc. Concerning Suspension of Food Facility Registration (November 26, 2012) (“FDA Letter to Sunland”).

Sunland was provided with one business day from the receipt of the suspension order to request an informal hearing. Sunland’s attempt to rebut the FDA’s allegations of violations, was deemed inadequate by the agency for “omit[ting] significant details regarding planned physical repairs and corrective actions” taken in response. The agency also informed Sunland that it would “be necessary for the FDA to evaluate the com-

pleted corrective actions on site to assure their adequacy.” FDA Letter to Sunland. Although Sunland initially reopened after meeting the standards set by the FDA, within five months, the company declared bankruptcy.

Administrative Detention

Prior to the FSMA, in order for the FDA to exercise its power of administrative detention to prevent a company from introducing suspect food into commerce, the agency needed “credible evidence or information” that the food presented a threat of serious adverse health consequences or death to humans or animals. H.R. 2751, 111th Cong. § 307 (2010). Under the FSMA, however, the standard is more flexible—the agency may impose administrative detention if it has “reason to believe” that an article of food is “adulterated or misbranded.”⁴ *Id.* Notably, a deficient record of HARPC implementation and compliance could form the basis of such an FDA determination—even if none of the potential hazards the HARPC seeks to address, namely an outbreak, have been realized.

For example, in 2011, shortly after the FSMA was enacted, the FDA exercised its administrative detention authority twice. First, in September 2011, the FDA placed all articles of food seized from a storage and processing facility in Washington state that were not hermetically sealed under a 30-day administrative detention on the basis of “active and widespread rodent and insect infestation, and bird activity in the food warehouse and processing area.” Compl. ¶¶ 3-5 in *United States v. Dominguez Foods of Washington, Inc.*, E.D. Wash., No. 2:11-cv-03101-EFS, 10/5/11. In response to the detention, Dara A. Corrigan, the FDA’s associate commissioner for regulatory affairs, said, “We will aggressively use our enforcement tools to prevent adulterated food from reaching the public.” FDA News Release (October 11, 2011).

The agency exercised its administrative detention authority a second time after an inspection of a food processing and storage company in Maine found *Listeria* on processing equipment. The agency detained the cold-smoked salmon produced at the facility before the company agreed to destroy the detained salmon under FDA supervision.

The agency has indicated that it is “more likely to use administrative detention,” even in situations that are analogous to Class II recall situations⁵—namely where

⁴ As with the exercise of its other administrative tools, the FDA offers the facility whose foodstuffs are detained a post-order opportunity for an informal hearing, within three days of the order. The facility also has the opportunity to appeal the detention, even if it does not seek a hearing. For perishable food, the appeal must be filed within two days of receipt of the detention order; for nonperishable food, the facility must file a notice of intent to appeal within four days. 21 U.S.C. § 334.

⁵ FDA utilizes recall “classes” as an advisory scale for removing a product from the market, based on the severity of the risk posed by the product. Class I recalls are for dangerous or defective products that pose a reasonable probability of serious adverse health consequences or death. Class II recalls are for products that may cause temporary or medically reversible adverse health consequences or pose a remote threat of serious adverse health consequences. Class III recalls are for products that are unlikely to cause adverse health consequences but violate FDA labeling or manufacturing regulations. Investigations Operations Manual, Food & Drug Admin., § 7.1.1.1–

a product may cause “temporary or medically reversible” adverse health consequences, or where the possibility of serious adverse health consequences is “remote.” Criteria Used To Order Administrative Detention, 76 Fed. Reg. at 25,540 (interim final rule).

Recipes for Compliance With the FSMA

The FDA’s early and swift exercise of its newly expanded powers under the FSMA demonstrates the perils of underestimating the necessity of complying with the new food-safety obligations.

Pre-Audit Compliance

It is imperative for food companies to have a thorough and well-documented HARPC plan. An effective HARPC will require employee training, organized recordkeeping, as well as centralized and consistent enforcement of all HARPC-related protocols. An important rule of thumb is that when an activity has any impact on food safety, it should be documented and analyzed for inclusion into the HARPC plan, with all decisions regarding its treatment reduced to writing.

For example, when there are two or more cleaning products that a facility could use to ensure sanitary work surfaces, their use should be recorded, along with a statement of the basis for the decision that resulted in the use of one cleaning solution over another. Without such documentation, the FDA might have a “reason to believe” that sanitation is not occurring, and therefore, conclude that a product is adulterated. Thus, it is critical to establish and adhere to any rules set out for recordkeeping.

Companies should also

- (1) establish procedures for handling internal concerns about the compliance process;
- (2) establish procedures for addressing consumer complaints and inquiries; and
- (3) periodically re-evaluate the protocols and procedures necessary to minimize food-safety hazards.

In addition, companies should build relationships with their suppliers and set standards for incoming products, including written guarantees of the quality of these products. Companies should also periodically test those products for quality control.

7.1.1.2.3. (2014), available at <http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123513.pdf>.

Finally, companies should revisit HARPCs periodically and consider review by outside counsel and/or HARPC consultants. Non-compliance should be discussed immediately with outside counsel so that a compliance strategy can be designed in a manner that minimizes FDA involvement or action.

During and Post-Audit

A company facing FDA inspection or investigation into its food-safety protocols that has not taken the steps described above should immediately investigate its food-safety practices. The information will be necessary to reply to any FDA requests/demands the company will receive if an investigator finds food-safety violations. FDA, Field Management Directive 120: FDA-483, Inspectional Observations (Dec. 29, 2009). As illustrated by the Sunland case study, any corrective action plan offered in response to an inspection should address each and every concern raised by the investigator, and detail a realistic, yet comprehensive strategy for addressing the objectionable conditions. The more documentation, the better.

If a company is facing a potential mandatory recall or administrative detention, it should contact outside counsel to create a voluntary recall protocol that meets the scope expected by the FDA. As for suspension, although the agency can invoke its power only when a food item has a “reasonable probability of causing serious adverse health consequences or death,” if a company has conducted, or is asked to conduct, a Class I recall, a company should also be prepared to address a suspension of its registration. Accordingly, a company should take the necessary steps to prepare a request for an informal hearing, as the company will only have a maximum of two days to do so. Again, comprehensive documentation of compliance and/or corrective action will be vital to assure that the company is ready to face any type of FDA administrative action.

Conclusion

The FDA’s reliance on its new tools suggests that it will continue to take an aggressive approach in addressing any non-compliance by food companies that undermines the agency’s ability to be proactive in combating foodborne illness. Given the potential for criminal and monetary penalties, food companies should be proactive by assessing their compliance with cGMPs, establishing and enforcing HARPC plans, and adhering to industry standards relating to food safety.