ALERT
JANUARY 11, 2011

GENERAL LITIGATION
News Concerning Recent Litigation Issues

COZEN O'CONNOR
www.cozen.com

NEW FOOD SAFETY MODERNIZATION ACT EXPANDS REGULATORY AUTHORITY OVER FOOD INDUSTRY

Abby J. Sher • 215.665.2761 • *asher@cozen.com*
Richard Fama • 212.908.1229 • *rfama@cozen.com*

On January 4, 2011, in response to concerns regarding food-borne illnesses and related product recalls, President Obama signed into law the Food and Drug Administration Food Safety Modernization Act, H.R. 2751 ("FSMA" or "the Act"),[1] which is being heralded as the most significant expansion of food safety requirements since the 1938 enactment of the Food, Drug, and Cosmetic Act. The Act focuses on preventive controls and expands the Food and Drug Administration's ("FDA") regulatory authority, giving the Secretary of the Department of Health and Human Services ("the secretary") various tools to increase prevention of food safety problems, detect and respond to such problems, and improve the overall safety of imported food. The Act applies to all food products with the exception of meat, poultry, and egg products, as those products are regulated by the U.S. Department of Agriculture.

This Alert provides an overview of the key provisions of this new law.

FDA's Mandatory Recall Authority

The Act grants the FDA the direct authority to order a mandatory recall when it determines that there is a reasonable probability that a food product is adulterated or misbranded and that its use will cause serious adverse health consequences or death to humans or animals. This is in contrast with the prior practice, by which the FDA was authorized only to negotiate voluntary recalls with businesses. The FDA will continue to initially provide the appropriate entity with the opportunity to recall the article, but if met with refusal, the Act allows the FDA to order a recall on its own accord.

Increased Inspections and Monitoring of Food Facilities

The Act also provides for an increased frequency of facility inspections in an effort to bolster the accountability and transparency of the food services industry. The secretary will allocate resources to identify high-risk facilities and assess their safety risks and compliance history. The secretary will identify high-risk facilities using criteria such as any previously known safety risks, compliance history, and the facility's hazard analysis and risk-based preventive controls. Inspections of high-risk facilities will occur at least every three years, while nonhigh-risk facilities will be inspected at least every five years.

Access to Records

The Act allows the secretary to access records of food production facilities when there is a reasonable belief that the use of, or exposure to, food will cause serious adverse health consequences. The FDA may then suspend food production at a facility if a possible health risk is suspected. Although "credible evidence" of a threat was previously required to detain food, the Act allows for such detention when there is a "reasonable belief" that the food at issue is likely to cause serious health consequences.

Safety of Imported Food

The Act also includes provisions that are intended to improve the domestic oversight of food imported from foreign countries. For example, importers must now verify that their foreign suppliers have adequate preventive controls. The FDA will establish offices in at least five foreign countries that export food to the United States, accredit third party auditors to certify that foreign facilities comply with U.S. standards, and will allocate resources to inspect foreign facilities. The Act allows the FDA to refuse to allow entry into the United States the food of a facility or importer who refuses inspection.

1 For full text of the Food and Drug Administration Food Safety Modernization Act, click here.

Enhanced Partnerships

The Act envisions comprehensive collaboration among the Secretary, food safety agencies, and state and local authorities. To develop preventive controls in the food industry, the Act authorizes the secretary and the secretary of Agriculture to study the incidence of food- borne illness. The Act also develops guidelines for continuing research and training programs with the National Agriculture and Food Defense Strategy, the secretary of Homeland Security and congressional committees. The goal of this research is to develop and implement science-based standards to evaluate and improve upon the preparedness of the agriculture and food system, the detection of potential food-related risks and emergency response and recovery.

Preventive Measures

The Act requires all food facilities to prepare and implement hazard analysis and risk-based preventive controls. The owner, operator, or agent in charge of a food facility must identify and develop a written analysis of known or reasonably foreseeable hazards associated with the facility that considers biological, chemical, physical, and radiological hazards and pesticides, parasites, additives, and hazards that may be intentionally introduced, including those introduced by acts of terrorism. The owner, operator or agent in charge of the facility must: provide assurances that hazards will be minimized or prevented; monitor the effectiveness of such procedures; establish corrective measures if such controls are ineffective; and keep records of, and periodically reevaluate, the controls. Food processors will be required to develop safety plans to assist the FDA in tracing recalled products, and specific guidelines will be developed with respect to fruits and vegetables. Federal grants will be available to schools and early childhood programs that implement food allergy and anaphylaxis guidelines.

Whistleblower Protection

The Act provides whistleblower protection to employees who: (1) provide an authority with information about any violation of the Act; (2) testify or assist in a proceeding concerning any such violation; or (3) who object to, or refuse to participate in, any practice that the employee reasonably believes to be in violation of the Act.

Tester-Hagan Amendment – Small Farm Exemption

In response to arguments that small farms and businesses would be unable to comply with the Act without being forced into bankruptcy, the law exempts "qualified facilities" from many of its provisions. Qualified facilities include those with under $500,000 in gross annual sales who generate more than half of their profit from direct-to-consumer sales and facilities that sell within 275 miles of their farm or within state lines. These facilities must provide documentation to confirm that they are implementing modified plans and complying with applicable nonfederal food safety laws.

Conclusion

The Act signals a sea change in the government's approach to food safety by focusing on prevention. In so doing, the Act seeks to transform regulation of the food industry into a proactive, rather than a reactive, system with an end goal of increasing safety controls and corrective actions in food production and distribution. While many of the Act's provisions require the FDA to develop rulemaking and guidance documents, certain provisions discussed above, such as the mandatory recall authority, standards for registration and increased inspection of food facilities and records, the requirement of certification for imported food, and whistleblower protection, will take effect immediately.