PRODUCTS LIABILITY
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NEWS & DEVELOPMENTS

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Federal Court Orders FDA to Issue New Food Safety Rules

Each year about 48 million people (1 in 6 Americans) report foodborne illnesses. On January 4, 2011, the Food Safety Modernization Act (FSMA) was signed into law. The purpose of the act was to shift the focus toward preventing foodborne diseases, rather than simply responding to outbreaks. To accomplish this goal, Congress provided the U.S. Food and Drug Administration (FDA) with new powers and directed it to enact new regulations covering several specific food safety areas: preventive controls, inspection and compliance, imported food safety, response, and enhanced partnerships between various federal and state food safety officials.

The FDA was expected to accomplish a relatively swift implementation of the FSMA; however, funding and resource limitations as well as the extensive nature of proposed changes have resulted in significant delays. As of June 2013, only a few provisions of the act are currently effective. Other regulations such as those pertaining to hazard analysis and prevention plans and procedures for tracking and tracing food products are in the study or comment phase. Regulations dealing with a foreign supplier verification program and the accreditation of third-party auditors are yet to be addressed.

On June 26, 2013, a federal judge in California ordered the FDA to finalize and publish food safety regulations mandated by the FSMA by June 30, 2015. The ruling resulted from a suit brought by the Center for Food Safety and the Center for Environmental Health challenging the FDA's failure to implement a regulatory scheme for the FSMA in accordance with certain timelines included in the act. The parties' proposed implementation schedules were vastly different. The consumer groups sought a relatively rapid implementation with finalization of regulations by May 1, 2014. The FDA's proposal included a longer timeline and only committed the agency to work toward meeting its targets, citing potential unforeseen circumstances. The court recognized the complexity of the new legislation and the need for comment periods and review by other federal agencies such as the Office of Management and Budget, but the judge wanted a definitive schedule that could result in an injunction if deadlines were not met.

Ultimately, the court ordered the FDA to propose various regulations by November 30, 2013. The agency can then accept comments until March 31, 2014, and has until June 30, 2015, to finalize the rules. Given the limited progress the FDA has made in the 30 months since the FSMA was signed into law, its ability to comply with the court's timetable will be a daunting task. The FDA has not yet indicated whether it intends to appeal the order.

Keywords: litigation, products liability, Food Safety Act, FDA

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