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## FDA & Healthcare LawFlash

November 5, 2012

### Food Retailers: FDA Is Coming to Town

*Agency's plan to conduct voluntary survey of retailers' foodborne illness risk signals FDA's increasing scrutiny in this area and the need for retailers to evaluate their food safety and risk management systems.*

The U.S. Food and Drug Administration (FDA or the Agency) recently announced its plan to conduct a voluntary survey of foodborne illness risk factors at selected retail and food service facilities. The initiative takes place in the midst of the Agency's ongoing efforts to implement the comprehensive, preventative safety approach contemplated by the Food Safety and Modernization Act, 21 U.S.C. §§ 2201 et seq. Among other things, FDA's actions suggest its receptiveness to arguments advanced by both consumer advocates and certain industry interests to the effect that this segment of the food chain should be receiving additional oversight, both federally and locally. Within this context, retailers should consider conducting a careful evaluation of their overall food safety and related risk management systems in anticipation of a climate of increasing scrutiny and risk—from a regulatory and litigation perspective.

#### Background

On October 29, FDA issued a *Federal Register* notice<sup>1</sup> regarding the Agency's proposed voluntary survey on the occurrence of foodborne illness risk factors in selected retail and food service facilities. The foundation for this survey, which is scheduled to begin in 2013, is the 10-year survey initiated by FDA's National Retail Food Team in 1998, which measured trends in the occurrence of foodborne illness risk factors.

#### Goals of the Survey

Like the survey initiated by the Agency in 1998, FDA has proposed a new voluntary survey encompassing annual data collections over a 10-year period. The survey will determine, among other things, foodborne illness risk factors that are in most need of priority attention, trends of improvement or regression in foodborne illness risk factor occurrence, and the impact of industry food safety management systems in controlling the occurrence of foodborne illness risk factors.

#### Purpose of the Survey

FDA will use the results of the proposed study to (1) formulate retail food safety policies and initiatives; (2) identify retail food work plan priorities and allocate resources to enhance retail food safety nationwide; (3) generate nationally representative estimates of the progress being made to reduce the occurrence of foodborne illness risk factors in retail and food service establishments; and (4) recommend best practices and targeted intervention strategies to assist the retail and food service industry and state, local, and tribal regulators with reducing foodborne illness risk factors.

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1. Survey on the Occurrence of Foodborne Illness Risk Factors, 77 Fed. Reg. 65,555 (Oct. 29, 2012), available at <http://www.gpo.gov/fdsys/pkg/FR-2012-10-29/pdf/2012-26472.pdf>.

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## Industry Segments/Facility Types to Be Surveyed

Included in the survey will be various types of restaurants, institutional food service entities, and retail food stores. According to FDA's notice, the vast majority of establishments selected to participate in the survey will be chosen from risk categories two through four of the *FDA Food Code*.<sup>2</sup>

## Impact on Facilities Selected to Participate

Based on its experience with the previous 10-year survey, FDA predicts that it will need to conduct approximately 400 data collection inspections of each facility type during the initial and subsequent data collection periods. To minimize the business interruption of the survey's related inspections, it is recommended that retailers have appropriate inspection protocols available, personnel are properly trained, and company policies concerning inspection issues (e.g., samples, photographs, and affidavits) be clear and well communicated. Companies may also benefit from using mock inspection exercises as a training tool.

## Contacts

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2. View the *FDA Food Code* at <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/default.htm>.