

Health and Human Services Inspector General Report Identifies Shortcomings in FDA Oversight of State Food Inspections

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On December 14, 2011, the Inspector General of the Department of Health and Human Services issued a report finding that the Food and Drug Administration (FDA) failed to properly oversee food facility inspections conducted by states because FDA had not ensured the requisite number of inspections and failed to follow-up appropriately when inspections occurred. The report was issued in response to a request from Rep. Rosa L. DeLauro (D-CT), Ranking Member on the Labor, Health and Human Services Appropriations Subcommittee of the House Committee on Appropriations, following a salmonella outbreak attributed to a Georgia peanut processing plant in 2009.

FDA enters into contracts with state agencies where FDA pays the state to conduct inspections of its food facilities. FDA relied on states for a total of 59 percent of the agency's food inspections in FY 2009, as opposed to only 42 percent in FY 2004, and spent over \$8 million on such inspections.

The report found that FDA failed to ensure that the requisite number of inspections were completed in 8 states, identifying a 10 percent shortage in inspections. FDA even paid for 130 of the 221 uncompleted inspections.

Additionally, FDA failed to appropriately classify state inspection results in at least 11 states. FDA policy dictates that inspections should result in one of three classifications. First, the inspection may reveal violations significant enough to potentially warrant regulatory action. Second, the inspection may reveal violations, but those violations do not cross "the threshold for regulatory action." Third, the inspection may reveal no violations. While FDA guidance indicates that uniform classification is critical to the success of FDA's food safety program, the report revealed that FDA officials overseeing inspections in 11 states used different criteria than used in classifying federal inspections.

The report also noted that FDA sometimes failed to appropriately follow-up after inspections to address identified violations. In order to promote the public health and ensure the effectiveness of state contract programs, the report recommended that FDA:

- ensure that all contract inspections are completed, properly documented, and appropriately paid for;
- ensure that contract inspections are properly classified in accordance with FDA guidance;
- ensure that all inspection violations are remedied by routinely tracking all actions taken to

correct violations;

- ensure that the minimum audit rate is met in all states;
- address any systemic problems identified by audits

In response to the report, FDA indicated its concurrence with each general recommendation, but noted in response to the recommendation that all inspection violations be remedied and tracked that some violations may not require follow-up.

The Food Safety and Modernization Act of 2011 (FSMA) provides FDA with new prevention-focused authority to conduct food inspections and protect food safety generally. Implementation of FSMA will require an increase in the number of food inspections, thus making oversight of state inspections all the more significant.

A copy of the Inspector General report is available [here](#).

This post was written by [Donnelly McDowell](#).