

ONE HUNDRED ELEVENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

May 4, 2010

To: Members of the Subcommittee on Oversight and Investigations

Fr: Committee on Energy and Commerce Staff

Re: Hearing on “The Role and Performance of FDA in Ensuring Food Safety”

On Thursday, May 6, 2010, at 2:00 p.m. in room 2123 of the Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled, “The Role and Performance of FDA in Ensuring Food Safety.” This hearing will examine two reports relating to the Food and Drug Administration’s management of international food imports and inspections of domestic food facilities.

The hearing continues the Subcommittee’s investigative activities on the adequacy of efforts to ensure the safety and security of the nation’s food supply. In the 110th Congress, the Subcommittee held nine hearings regarding food safety issues, including an *E. coli* outbreak traced to tainted spinach, melamine-contaminated pet food, and intentional exposure of meat and seafood to carbon monoxide. In this Congress, the Subcommittee has held hearings on a *Salmonella* outbreak associated with peanut products manufactured by the Peanut Corporation of America, the actions and obligations of food manufacturers and retailers that purchase tainted food products, and the safety of bottled water.

I. BACKGROUND

Fifteen federal agencies administer at least 30 federal laws concerning food safety. The Food and Drug Administration (FDA) and the U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) are primarily responsible for ensuring the safety of food products. FSIS oversees domestically-produced and imported meat, poultry, and processed egg products; FDA regulates all other foods, including fruits, vegetables, seafood, and milk.

A. U.S. Government Accountability Office

In September 2009, the Government Accountability Office (GAO) released a report on the safety of imported food, *Food Safety: Agencies Need to Address Gaps in Enforcement and*

*Collaboration to Enhance Safety of Imported Food.*¹ In the report, GAO examined FDA’s difficulties in coordinating information-sharing and enforcement efforts with Customs and Border Protection (CBP). CBP provides information on imported food shipments to FDA, but GAO found that the two agencies’ failure to assign unique identification numbers to import firms limits FDA’s ability to tackle problems with high-risk food shipments.²

GAO also found that FDA does not have sufficient authority to ensure importer compliance with existing requirements. After imported food enters the United States, it remains in the possession of the importing firm until the FDA approves its release. The importer posts a monetary bond with CBP that is intended to discourage the shipment’s unauthorized release prior to FDA approval. However, the report found that because the value of the bond penalty is low, GAO previously concluded, and many agency officials now agree, that the system does not provide an effective deterrent.³

B. U.S. Health and Human Services Office of the Inspector General

The Department of Health and Human Services Office of the Inspector General (OIG) also recently released a report, *FDA Inspections of Domestic Food Facilities*, which identified a number of challenges confronting FDA in safeguarding domestically-produced food.⁴ OIG found that, on average, FDA inspects only 24% of domestic food facilities annually; in addition, the number of inspections declined from 2004 to 2008.⁵ The report also found that over the past five years, FDA has not inspected 56% of the food facilities subject to its authority.⁶

OIG found that “when violations were identified, FDA did not routinely take swift and effective action to ensure that these violations were remedied.”⁷ Additionally, OIG reported that some facilities that had violations significant enough to warrant regulatory action refused to grant FDA inspectors access to their official records.⁸

¹ Government Accountability Office, *Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food* (Sept. 2009).

² *Id.*

³ *Id.*

⁴ Department of Health and Human Services Office of the Inspector General, *FDA Inspections of Domestic Food Facilities* (Apr. 2010).

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

II. WITNESSES

The following witnesses have been invited to testify:

- **Mr. Michael R. Taylor**
Deputy Commissioner for Foods
Food and Drug Administration

- **Ms. Lisa Shames**
Director
Agriculture and Food Safety
Government Accountability Office

- **Ms. Jodi Nudelman**
Regional Inspector General for Evaluation and Inspections, Region II
Health and Human Services Office of Inspector General