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Good morning, Madam Chairwoman and Members of the Subcommittee. I am Daniel Levinson, Inspector General for the U.S. Department of Health and Human Services.

Recent outbreaks of foodborne illness involving peanut butter, peppers, and spinach have raised serious questions about the Food and Drug Administration's (FDA) ability to protect the Nation's food supply. The Office of Inspector General (OIG) has identified FDA oversight of food, drugs, and medical devices as a top management challenge, and has conducted several reviews on FDA's oversight of food safety over the past decade. I recognize your leadership on this and other important issues related to FDA and appreciate the opportunity to appear before you today to discuss OIG's most recent work on the traceability of the food supply.

In short, our most recent work, being released today and now available on our Web site at http://oig.hhs.gov, found that only 5 of the 40 products we purchased could be traced through each stage of the food supply chain back to the farm or border. The ability to trace the remaining food products through each stage of the food supply chain was limited because: (1) food facilities often did not maintain lot-specific information, (2) some products were not labeled with lot-specific information, and (3) a number of food facilities mixed raw food products from a large number of farms. In addition, more than half of the facilities that handled these food products failed to meet FDA requirements to maintain records about their sources, recipients, and transporters of food. A quarter of food facilities reported that they were not even aware of these requirements. These factors affect FDA's ability to identify the source of a contamination and remove unsafe food products from the food supply chain.

ROLE AND RESPONSIBILITIES OF OIG

Our office was created in 1976 as the first statutory OIG in the Federal Government. Two years later, the Inspector General Act of 1978 established OIGs at other Cabinet-level departments of the Federal Government, as well as at some independent Government agencies. Congress created OIGs to be independent and objective units within Federal departments and agencies for the purposes of: (1) conducting audits and investigations of programs and operations; (2) coordinating and recommending policies to promote economy, efficiency, and effectiveness in the administration of programs; (3) preventing and detecting fraud and abuse; and (4) keeping the department Secretary or agency administrator and Congress informed about the necessity for corrective action.

To achieve these important objectives, our office reviews programs to identify systemic vulnerabilities; makes recommendations to improve programs' economy, efficiency and effectiveness; investigates instances of potential fraud or abuse and takes appropriate enforcement actions; audits specific payments, providers, and programs to identify and recommend recovery of overpayments; and promotes voluntary compliance by issuing guidance to industry.

BACKGROUND

Each year, more than 300,000 Americans are hospitalized and 5,000 die after consuming contaminated foods and beverages.[1] FDA is responsible for ensuring the safety of about 80 percent of the Nation's food supply, including $417 billion in domestic food and $49 billion in imported food.[2] In a food emergency, FDA's responsibilities include finding the source of the contamination and helping to remove unsafe food products from retail shelves. FDA's ability to fulfill its duties largely depends upon whether it can follow a food product's movement through each stage of the food supply chain, a process referred to as traceability. The food supply chain typically starts on farms and involves many different types of facilities—including processors, packers, distributors, transporters, and retail stores—before finally reaching the consumer.

Beginning in 2005, FDA required facilities that manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain records.[3] The purpose of these records is to help FDA trace a food product through each stage of the food supply chain if FDA has a reasonable belief that a food product presents a serious health threat. Pursuant to the regulations, these records must include contact information for all sources, recipients, and transporters.[4] Some of these facilities—specifically processors, packers, and manufacturers—must also record what is known as "lot-specific information" to the extent that this information exists.[5] Other facilities—including distributors, storage facilities, and retailers—are not required to record any lot-specific information. Lot-specific information distinguishes one production batch from another; it can be a number printed on the packaging or some other identifier, such as a "best if used by" date. Lot-specific information can help FDA trace a specific batch of food products through each stage of the food supply chain.

PURPOSE OF OUR REVIEW

Our review had two objectives: (1) to assess the traceability of selected domestic food products; and (2) to determine the extent to which selected food facilities maintain information about their sources, recipients, and transporters, as required by FDA. This review provides important information about FDA's ability to ensure the safety of our Nation's food supply. Our findings and recommendations are based on a traceability exercise of 40 selected food products, a review of the records maintained by the food facilities that handled these products, and structured interviews with managers at these facilities. For this exercise, we purchased 40 food products from retail stores around the country.[6] We then requested that each of the facilities that handled these food products provide information

[1] Centers for Disease Control and Prevention, "National Center for Infectious Diseases." Available online at http://www.cdc.gov/ncidod/diseases/food/. Accessed April 16, 2008.

[2] FDA is responsible for ensuring the safety of almost all food products sold in the United States, with the exception of meat, poultry, and some egg products, which are regulated by the U.S. Department of Agriculture.

[3] The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 made a number of significant amendments to the Federal Food, Drug, and Cosmetic Act. One of these amendments, the Maintenance and Inspection of Records provision, stipulates that FDA promulgate regulations to require persons who "manufacture, process, pack, transport, distribute, receive, hold, or import food" to establish and maintain records.

[4] The regulations refer to sources as "nontransporter immediate previous sources," to recipients as "nontransporter immediate subsequent recipients," and to transporters as "transporter immediate previous sources" and "transporter immediate subsequent recipients."

[5] 21 CFR § 1.337(a)(4) and § 1.345(a)(4).

[6] We purchased 10 food products in each of the following four Metropolitan Statistical Areas: New York City, Chicago, San Francisco, and Washington, DC. The products—selected in consultation with FDA officials—included bottled water, ice, milk, eggs, yogurt, flour, oatmeal, tomatoes, leafy vegetables, and juice.

about the products' sources, recipients, and transporters. We used this information to try to trace each product through the food chain back to the farm or border.[7]

Based upon the information we received from the facilities, we categorized the 40 food products into three groups: (1) products that could be traced through each stage of the food supply chain, meaning that every facility that handled the product could provide information that was specific to the product we purchased; (2) products that could not be traced but the facilities that likely handled the products could be identified; and (3) products that could not be traced and the facilities that handled the products could not be identified. Additionally, we determined the extent to which facilities maintained information required by FDA and were aware of these requirements.

TRACEABILITY OF FOOD PRODUCTS

Only 5 of the 40 products we purchased could be traced through each stage of the food supply chain. In these cases, every facility that handled these products was able to link the product we purchased to lot-specific information in their records. In a food emergency, if FDA is able to trace the product through each stage of the food supply chain, then it can more easily pinpoint the source of a contamination and target the products that need to be removed from retail shelves.

For 31 of the 40 products, we were unable to trace these products through each stage of the food supply chain; instead, we were only able to identify facilities that likely handled the products. Many of the facilities that handled these products did not maintain lot-specific information and, as a result, could only estimate a range of deliveries (from one or more facilities) that likely included the product we purchased. These estimates may have included more facilities than those that actually handled the product or may not have included all of the facilities that handled the product. For example, for one product—a bag of flour—the storage facility did not know the exact farms that contributed to the product and, therefore, had to give us information about every farm that provided wheat during the previous harvest season. If FDA is only able to identify those facilities that likely handled a food product, it may not be able to quickly or accurately pinpoint the source of a contamination or target which products need to be removed from the food supply.

For the remaining four products, we could not even identify the facilities that likely handled them. In these cases, at least one facility in the food supply chain failed to provide any information about the potential sources of the products. In a food emergency, there could be serious health consequences if FDA cannot—at a minimum—identify the facilities that potentially handled a contaminated food product.

FACTORS THAT AFFECT TRACEABILITY

We identified three factors that limited the traceability of food products. If FDA encounters any one of these three factors during a food emergency, it would also likely affect how quickly FDA could trace food products through the food supply chain.

First, food facilities did not always maintain lot-specific information. Although processors, packers, and manufacturers are required to maintain lot-specific information, 2 of the 38 in our review did not

[7] Our review only assessed traceability within the U.S. food supply. For eight of the products, the beginning of the food supply chain was a public or private water source. For the purposes of our review, these sources are referred to as farms.

do so. In addition, most distributors, wholesalers, and storage facilities in our review did not maintain lot-specific information. Note that these facilities are not required to do so by FDA; however, the lack of lot-specific information limits the ability to trace food products through each stage of the food supply chain back to the farm or border.

Second, some food products were not labeled with lot-specific information, which is not required by FDA. Six of the products we purchased had no lot-specific information on the product label or packaging. Three of the six products were unpackaged whole tomatoes. Another three of these products—a package of tomatoes, a bag of lettuce, and a bag of ice—were packaged products. None of the facilities that handled these products could link them to lot-specific information in their records.

Third, a number of facilities received and mixed raw food products from a large number of farms—a process known as commingling. For example, a single production batch of flour we purchased contained wheat from more than 100 farms. If this bag of flour were implicated in a foodborne illness, FDA would need to contact more than 100 farms to identify the source of the contamination.

RECORDS REQUIREMENTS

In addition to conducting the traceability exercise, we also assessed compliance with FDA's requirements to maintain contact information about sources, recipients, and transporters.[8] Of the facilities that were required to maintain these records, 59 percent did not maintain the contact information required by FDA about its sources, recipients, and transporters. Facilities reported that they could not provide all of the required contact information for several reasons. In some cases, managers had to look through large numbers of records—many of them paper, as opposed to electronic—for the required information. Additionally, some facilities did not have integrated recordkeeping systems that linked sources and recipients to specific shipments of products, and managers had to search multiple recordkeeping systems for the required information. In addition, a quarter of the food facilities reported that they were not aware of FDA's records requirements. A lack of compliance with these records requirements affects FDA's ability to trace food products through the food supply chain.

RECOMMENDATIONS

Based on these findings, we made six recommendations to FDA to improve traceability of the food supply. We recommended that FDA:

- Seek statutory authority, if necessary, to strengthen the existing records requirements regarding lot-specific information. Specifically, FDA should require processors, packers, and manufacturers to create lot-specific information—and maintain it—if it does not exist. FDA also should extend the requirements to include facilities that are currently not required to maintain this information.

- Consider seeking additional statutory authority to require food facilities to further strengthen the traceability of food products. This could include a variety of approaches such as requiring facilities that handle food products to maintain records about every facility or farm

[8] These requirements apply to facilities that manufacture, process, pack, transport, distribute, receive, hold, or import food.

that handled the product, or requiring facilities to use certain information technologies to help facilitate recordkeeping.

- Work with the food industry to develop guidance on traceability.

- Address issues related to mixing raw food products from a large number of farms.

- Seek statutory authority to request facilities' records at any time, as opposed to its current authority to request records only when FDA has a reasonable belief that an article of food presents a serious health threat. With this added authority, FDA could verify that facilities are complying with its records requirements during its food facility inspections.

- Conduct education and outreach activities to inform all segments of the food industry about its records requirements.

CONCLUSION

In conclusion, the traceability of food products and the ability of food facilities to provide information about their sources, recipients, and transporters are essential to ensuring the safety of our Nation's food supply. In the event of an outbreak of a foodborne illness, FDA needs to be able to quickly identify the source of a contamination and remove unsafe products from retail shelves. Our review found that several factors limit traceability and that a significant proportion of food facilities are not in compliance with FDA's records requirements. We also found that these requirements are not sufficient to ensure traceability. Taken together, these findings demonstrate that more needs to be done to protect public health and to ensure that FDA has the necessary resources and tools to respond to a food emergency.

OIG recognizes the importance of ensuring the safety of the food supply and will continue our work in this area. We are currently conducting a review that assesses the extent to which food facilities have registered with FDA, as required. We are also reviewing FDA's inspections of food facilities and the extent to which FDA follows up on violations. Finally, we are conducting several audits evaluating FDA's authority and procedures for recalls.

This concludes my testimony. I welcome your questions.