

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**TRACEABILITY IN THE FOOD  
SUPPLY CHAIN**



Daniel R. Levinson  
Inspector General

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## OBJECTIVES

1. To assess the traceability of selected food products.
2. To determine the extent to which selected food facilities maintain information required by the Food and Drug Administration (FDA) in a food emergency.

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## BACKGROUND

Beginning in 2005, FDA required certain food facilities to maintain records identifying the sources, recipients, and transporters of food products. The purpose of these records is to allow FDA to trace an article of food through each stage of the food supply chain—from a retail shelf back to a farm—if FDA has a reasonable belief that a food product is adulterated and presents a serious health threat.

Traceability is the ability to follow the movement of a food product through the stages of production, processing, and distribution.

Traceability includes both traceback and trace forward. Traceback is the ability to trace a food product from the retail shelf back to the farm. Conversely, trace forward is the ability to trace a food product from the farm forward to the retail shelf. Traceability is often needed to identify the sources of food contamination and the recipients of contaminated food in product recalls and seizures. This study refers to such a situation as a “food emergency.”

This study is based on two primary data sources: (1) a traceability exercise of 40 selected food products and (2) structured interviews with the managers at the food facilities that handled the selected food products. For the traceability exercise, we purchased 40 food products from different retail stores and attempted to trace them through each stage of the food supply chain back to the farm(s) or the border. We asked the facilities that handled the food product for information about their sources, recipients, and transporters, which we used in an effort to trace the product.

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## FINDINGS

**We were able to trace 5 of the 40 products through each stage of the food supply chain; for most of the other products, we could identify the facilities that likely handled them.** Not all facilities are required

to maintain lot-specific information in their records, and those that are required to maintain lot-specific information are required to maintain it only if it exists. As a result, we were able to trace five of the specific products through each stage of the food supply chain. The facilities that handled each of these products were able to provide information about the specific product we purchased or were able to link that product to lot-specific information in their records.

For 31 of the 40 products, we were able to identify the facilities that likely handled the products. Most facilities that handled these products did not maintain lot-specific information in their records and could only estimate a range of deliveries (from one or more facilities) that may have included the product we purchased. As a result, we were not able to trace these specific products through each stage of the food supply chain. In addition, 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.

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.

**Several factors prevented us from tracing the specific products through the food supply chain.** Several factors limited our ability to trace the specific food products through each stage of the food supply chain. These factors included: (1) processors, packers, and manufacturers not always maintaining lot-specific information, as required; (2) other types of facilities not maintaining lot-specific information because it is not required; (3) retailers receiving products not labeled with lot-specific information; and (4) the mixing of products from a large number of farms. These factors also affect the speed with which FDA can trace specific food products through the food supply chain.

**Fifty-nine percent of the food facilities did not meet FDA's requirements to maintain records about their sources, recipients, and transporters.** Fifty-nine percent (70 of 118) of the food facilities in our traceability exercise did not provide all of the required contact information about their sources, recipients, and transporters. Twenty percent did not provide all of the required information about their sources, 52 percent did not provide all of the required information about their recipients, and 46 percent did not provide all of the required information about their transporters.

Facilities could not provide all required contact information for several reasons. In some cases, managers had to look through large numbers of records—some of them paper based—for contact information. Additionally, some facilities did not have integrated recordkeeping systems that linked sources and recipients to specific shipments or to transporters, and managers had to search separate systems to obtain the contact information.

**One-quarter of the food facilities were not aware of FDA's records requirements; others highlighted practices designed to improve traceability.** Twenty-five percent (26 of 104) of the managers who responded to our questions were not aware of FDA's records requirements. Specifically, 50 percent of the managers at retail facilities were not aware of FDA's records requirements, compared to 21 percent of the managers at distributor, wholesale, and storage facilities and 13 percent of the managers at processing, packing, and manufacturing facilities.

Over half of the managers (43 of 78) who were aware of the FDA records requirements reported making changes to their recordkeeping practices to meet these requirements. These changes included switching from paper-based to electronic recordkeeping systems, improving their existing electronic systems, and improving their facilities' ability to maintain lot-specific information.

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## RECOMMENDATIONS

To address the findings in this report, we recommend that FDA:

**Seek statutory authority, if necessary, to strengthen existing records requirements regarding lot-specific information.** FDA should seek statutory authority, if necessary, to require all processors, packers, and manufacturers to create and maintain lot-specific information for food products. FDA should also extend the requirements regarding

lot-specific information to other types of facilities, such as distributors, storage facilities, and retailers, in order to further strengthen the traceability of food products.

**Consider seeking additional statutory authority to improve traceability.** FDA should consider seeking additional statutory authority requiring food facilities to further strengthen the traceability of food products.

FDA should consider a variety of different approaches, such as expanding current requirements stipulating that facilities maintain information only for their immediate sources, recipients, and transporters. FDA may instead require each facility that handles a food product to maintain records about every facility or farm that handled the product, along with the relevant lot-specific information. This may allow FDA to more quickly and accurately trace food products during a food emergency. In addition, FDA should consider requiring facilities to use certain information technologies to help facilitate recordkeeping, such as interoperable recordkeeping systems. These interoperable systems, which would allow for information to be exchanged among all facilities in the food supply chain, may also allow FDA to more quickly and accurately trace food products during a food emergency.

**Work with the food industry to develop additional guidance to strengthen traceability.** FDA should work with the food industry to develop additional guidance on traceability. Among other things, this guidance could encourage facilities to assign a point person to be responsible for responding to food emergencies, conduct mock recalls, and contract with independent third-party auditors to monitor recordkeeping systems.

**Address issues related to mixing raw food products from a large number of farms.** FDA should work with the food industry to develop standards for mixing raw food products from a large number of farms. This would address a serious vulnerability in the traceability of the food supply chain.

**Seek statutory authority to conduct activities to ensure that facilities are complying with its records requirements.** FDA should 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. FDA should use this authority to conduct traceability exercises or other checks on facilities to ensure that they are complying with its records

requirements. With this added authority, FDA would be able to include a component in its food facility inspections to verify as a matter of course whether facilities are complying with its records requirements.

**Conduct education and outreach activities to inform the food industry about its records requirements.** FDA should develop education activities that focus on appropriate and reliable recordkeeping systems. These activities could include informational meetings, mailings, and other initiatives. FDA should use these efforts to clearly explain the specific types of information that must be maintained, such as transporter contact information. FDA should also target outreach efforts to facilities that have less familiarity with the records requirements, namely retailers, distributors, wholesalers, and storage facilities.

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## AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

FDA stated that it will consider our recommendations regarding seeking enhanced statutory authority, and it described its efforts in response to our recommendations to work with the food industry and to conduct education and outreach. FDA did not specifically state whether it concurred with these latter two recommendations.

FDA stated that it will consider our three recommendations to seek additional statutory authority to (1) strengthen existing records requirements, (2) improve traceability, and (3) ensure that facilities are complying with its records requirements, as well as our recommendation to address issues relating to mixing raw food products. FDA noted that it continues to work closely with its food safety partners to strengthen its ability to protect Americans from foodborne illness, which includes determining whether additional statutory authority is needed to better protect public health.

In response to our recommendation to work with the food industry, FDA stated it is continuing to work with the food industry and other stakeholders to develop additional guidance to strengthen traceability. Finally, in response to our recommendation to conduct education and outreach activities, FDA stated that it will continue to work with industry and trade association groups to communicate the requirements of the rule to stakeholders.

## E X E C U T I V E   S U M M A R Y

We support FDA's ongoing efforts to improve the traceability of the food supply and to ensure that it has the tools needed to better protect the public health in the event of a food emergency. We ask that, in its final management decision, FDA more clearly indicate whether it concurs with our recommendations to work with the food industry and to conduct education and outreach.





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## OBJECTIVES

1. To assess the traceability of selected food products.
2. To determine the extent to which selected food facilities maintain information required by the Food and Drug Administration (FDA) in a food emergency.

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## BACKGROUND

Each year, more than 300,000 Americans are hospitalized and 5,000 die after consuming contaminated foods and beverages.<sup>1</sup> In a food emergency, FDA is responsible for finding the source of the contamination and helping to remove the food products from the food supply chain. Recent food contaminations involving peppers, spinach, and peanut butter have demonstrated the importance of FDA's role and the challenge of quickly finding and removing unsafe food products from retail shelves.

Beginning in 2005, FDA required certain food facilities to maintain records on the sources, recipients, and transporters of food products.<sup>2</sup> The purpose of these records is to allow FDA to trace an article of food through each stage of the food supply chain—from a retail shelf back to a farm—if FDA has a reasonable belief that a food product is adulterated and presents a serious health threat.<sup>3</sup> This study refers to such a situation as a “food emergency.”

This study assesses the traceability of selected food products and determines the extent to which selected food facilities can provide information required by FDA about their sources and recipients. Food traceability is essential to ensuring the safety of our Nation's food supply and to enabling FDA to identify problems, respond quickly, and protect the public health.

### **Traceability in the Food Supply Chain**

The food supply chain typically starts on farms and involves many different types of facilities—including processors, packers, distributors,

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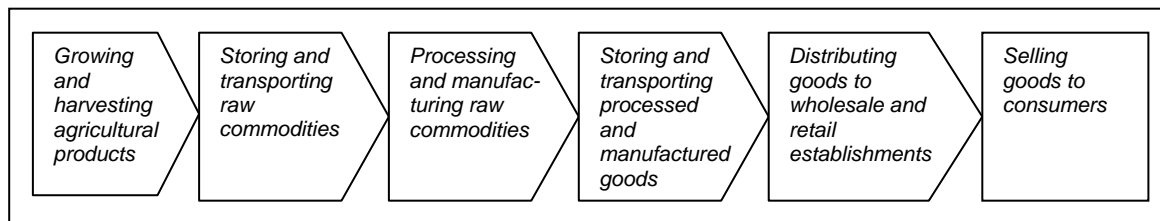
<sup>1</sup> Centers for Disease Control and Prevention, “National Center for Infectious Diseases.” Available online at <http://www.cdc.gov/ncidod/diseases/food/>. Accessed April 16, 2008.

<sup>2</sup> 21 CFR §§ 1.337 and 1.345.

<sup>3</sup> Federal Food, Drug, and Cosmetic Act, § 414(a), 21 U.S.C. § 350c(a), as amended by the Public Health Security and Bioterrorism Act of 2002, P.L. No. 107-188, §306.

transporters, and retail stores—before finally reaching the consumer. Figure 1 below shows an example of a food supply chain.

**Figure 1: Example of a food supply chain**



Source: Based on a graphic from “Terrorist Threats to Food: Guidance for Establishing and Strengthening Prevention and Response Systems,” Food Safety Department, World Health Organization, 2002.

Traceability is the ability to follow the movement of a food product through the stages of production, processing, and distribution.<sup>4</sup>

Traceability includes both traceback and trace forward. Traceback is

the ability to trace a food product from the retail shelf back to the farm.<sup>5</sup>

Conversely, trace forward is the ability to trace a food product from the

farm to the retail shelf. Traceability is often needed to identify the

sources of food contamination and the recipients of contaminated food in product recalls and seizures.

### **FDA and the Bioterrorism Act**

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. The Federal Food, Drug, and Cosmetic Act gives FDA the authority to regulate food safety.<sup>6</sup>

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act) is intended to “improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies” affecting a number of areas, including

<sup>4</sup> Codex Alimentarius Commission, “Procedural Manual, Seventeenth Edition,” 2007. The Codex Alimentarius Commission was created in 1963 by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) to develop food standards and guidelines. Available online at: <ftp://ftp.fao.org/docrep/fao/010/a1472e/a1472e.pdf>. Accessed October 6, 2008. In this study, traceability is defined as the ability to trace a food product through the domestic supply chain, which is different from the ability to trace a food product to its country of origin.

<sup>5</sup> FDA’s Center for Food Safety and Applied Nutrition, “Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables,” October 1998.

<sup>6</sup> Federal Food, Drug, and Cosmetic Act, Chapter IV, 21 U.S.C. §§ 341–350d.

the Nation's food supply.<sup>7</sup> The Act makes 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” (hereinafter referred to as food facilities) to establish and maintain records.<sup>8</sup> It also allows FDA to inspect those records if there is a reasonable belief that an article of food presents a serious health threat.<sup>9</sup>

In December 2004, FDA promulgated regulations authorized by the Maintenance and Inspection of Records provision.<sup>10</sup> The regulations require food facilities to maintain records on the sources and recipients of food products. The regulations also require food facilities to maintain records on the transporters of both incoming and outgoing shipments of food products.<sup>11</sup> These records must include contact information (i.e., complete names, addresses, and phone numbers whether domestic or foreign) for all sources, recipients, and transporters. In addition, the records must include the dates, quantities, and a description of the type of food and its packaging. The regulations do not apply to farms or to foreign entities operating outside the United States.<sup>12</sup>

Food manufacturers, processors, and packers must also record lot-specific information (i.e., a lot number, a code number, or another identifier) to the extent that this information exists.<sup>13</sup> Lot-specific information distinguishes one production batch from another and can be a number printed on the packaging or some other identifier, such as a

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<sup>7</sup> P.L. No. 107-188.

<sup>8</sup> P.L. No. 107-188, § 306(a) amending § 414(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 350c(b). The Federal Food, Drug, and Cosmetic Act at 21 U.S.C. § 321(e) defines a person to include an “individual, partnership, corporation, and association.” This study refers to persons as food facilities.

<sup>9</sup> Public Law 107-188, § 306(a), (b) amending § 414(a) and § 704(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 350c(a) and § 374(a). The technical standard is a reasonable belief “that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.”

<sup>10</sup> 69 Fed. Reg. 71562 (Dec. 9, 2004), corrected 70 Fed. Reg. 8726 (Feb. 23, 2005); codified at 21 CFR pt. 1, subpart J.

<sup>11</sup> 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.”

<sup>12</sup> 21 CFR § 1.327.

<sup>13</sup> 21 CFR § 1.337(a)(4) and § 1.345(a)(4).

“best if used by” date.<sup>14</sup> Finally, the records must be available for inspection and copying as soon as possible, but not to exceed 24 hours from the receipt of an official request.<sup>15</sup> See Appendix A for a more detailed description of the records requirements.

All food facilities were required to comply with the records maintenance provision by December 2006. Retailers with 10 or fewer full-time-equivalent employees are exempt from the records requirements; however, they are not exempt from the requirement to provide FDA with any records that they maintain, if requested.<sup>16</sup>

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## METHODOLOGY

### Scope

This study assesses the traceability of selected food products and determines the extent to which food facilities maintain the required information about their sources, recipients, and transporters. It is based on two primary data sources: (1) a traceability exercise of 40 selected food products and (2) structured interviews with the managers at the food facilities that handled the selected food products. This study includes only domestic food facilities.

### Traceability Exercise

We purchased 40 food products from different retail stores and attempted to trace them through each stage of the food supply chain back to the farm(s) or the border. We selected 10 different products for the study in consultation with FDA officials, and purchased these 10 food products in each of the following four Metropolitan Statistical Areas (MSA): New York City, Chicago, San Francisco, and Washington, DC.<sup>17</sup> Table 1 lists the food products that we selected. Appendix B provides more detailed information about how we selected the retail facilities and the products in each area.

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<sup>14</sup> The preamble to this rule states that “FDA acknowledges that most firms use lot or code numbers to identify specific batches of their products. However, some may use other technologies such as barcodes. The term ‘other identifier’ is intended to capture any other methods that the food industry may be using to identify specific lots of product.” 69 Fed. Reg. 71600.

<sup>15</sup> 21 CFR § 1.361.

<sup>16</sup> 21 CFR § 1.327(f).

<sup>17</sup> MSAs are areas designated by the Office of Management and Budget that include major cities and the suburban areas surrounding them.

**Table 1: Selected Food Products**

Market Sector	Food Product	Number of Products Purchased
Beverage	Bottled water	4
	Manufactured ice	4
Dairy	Whole milk	4
	Carton of eggs	4
	Plain yogurt	4
Grains	Milled unbleached flour	4
	Plain oatmeal	4
Produce	Tomatoes, fresh whole	4
	Bag of fresh-cut leaf vegetable	4
	Fruit juice	4
<b>Total Number of Market Sectors: 4</b>	<b>Total Types of Food Products: 10</b>	<b>Total Number of Food Products Purchased: 40</b>

For each of the 40 products, we provided the retailer with a description of the food product, including any information available on the packaging. We then requested that the retailer identify the source(s) of the food product and the transporter(s) from which the retailer received the food product. For each source, we specifically requested: (1) the name, address, and phone number of the source and the transporter; (2) the date when the retailer received the product; (3) the quantity of the product that the retailer received; and (4) a description of the product as it was received by the retailer. Note that three retailers did not respond to our request, and in these cases, we repurchased the food products from other retailers.<sup>18</sup>

To continue the traceability exercise, we then contacted the facility that the retailer identified as the source of the food product. As we did with the retailers, we provided these facilities with a description of the food product and requested that they provide us with product and contact information for the source(s) and transporter(s) of the food product.

We continued the process of moving backward through the food supply chain until: (1) we reached the farm(s) at the beginning of the chain,<sup>19</sup>

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<sup>18</sup> Because we could not determine whether these retailers had 10 or fewer full-time-equivalent employees and were, therefore, exempt from the records requirements, we did not include them in our study. Instead, we repurchased the food products from other retailers.

<sup>19</sup> For eight of the food products, the beginning of the food supply chain was a public or private water supply. For the purposes of this report, these sources are referred to as farms.

(2) we reached the border, or (3) we ended the exercise because a facility (other than the retailer) did not provide information about its source(s).<sup>20</sup> When we reached the farm(s), we asked them to verify the information given to us by the facility that listed them as a source. We did not ask them to provide us with any additional information, as farms are exempt from the records requirements.

In addition, for each facility that was not a retailer, we requested information about the recipient(s) of its food product. Specifically, we requested contact information for all recipient(s) of the food product and the transporter(s) that delivered it. We used this information to determine whether each facility could provide information about its recipients. We did not use this information to trace the product forward through the food supply chain.

### **Analysis of the Traceability Exercise**

We contacted a total of 220 facilities that handled the 40 selected food products. We analyzed the facilities' responses to assess the traceability of the 40 selected food products. To conduct this analysis, 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 and that 10 or fewer farms contributed to the lot of food product;<sup>21</sup> (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 likely handled the products could not be identified.

As noted earlier, not all facilities are required to maintain lot-specific information in their records, and those that are required to maintain lot-specific information are required to maintain the information only if it exists. This may have contributed to facilities not being able to provide information specific to either the product or the lot of product that we purchased.

### **Analysis of the Records Maintenance Requirement**

Of the 220 facilities we contacted, we included in our analysis 118 facilities that were required by FDA to maintain records. As shown

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<sup>20</sup> Note that if a facility identified more than five sources, we randomly selected and contacted only five of those sources.

<sup>21</sup> For retailers, we considered lot-specific information to mean that there was lot-specific information on the product we purchased or the retailers maintained lot-specific information in their records.

in Table 2, we excluded 84 farms because they were exempt from the records requirements. Similarly, we excluded 12 retailers that provided information about their sources but had 10 or fewer full-time-equivalent employees.<sup>22</sup> Finally, we excluded six brokers because brokers were not consistently identified as sources by facilities.<sup>23</sup>

<b>Table 2: Facilities From Traceability Exercise</b>			
<b>Facility Type</b>	<b>Total Number of Facilities</b>	<b>Number of Facilities Included in Analysis</b>	<b>Number of Facilities Interviewed</b>
Retailers	40	28	21
Distributors/ Wholesalers/ Storage Facilities	45	45	44
Processors/ Packers/ Manufacturers	45	45	38
Brokers	6	0	0
Farms	84	0	0
<b>Total</b>	<b>220</b>	<b>118</b>	<b>103</b>

Source: OIG analysis of food facility responses, 2008.

We then determined how many of the 118 facilities were unable to provide the information required by FDA. We considered a facility as having failed to provide the required source information if it did not provide a complete address and phone number for each source that it identified. We used the same criterion to determine whether a facility failed to provide the required recipient and transporter information.

### **Structured Telephone Interviews**

We conducted structured telephone interviews with managers or senior representatives (hereinafter referred to as managers) at each of the facilities. As shown in Table 2, we were able to contact managers at 103 of the 118 facilities, resulting in an 87-percent response rate. Our questions focused on facilities’ recordkeeping practices and the types of

<sup>22</sup> Retailers with 10 or fewer full-time-equivalent employees are exempt from the records requirements; however, they are not exempt from the requirement to provide FDA with any records that they maintain, if requested. See 21 CFR § 1.327(f). Twelve retailers with 10 or fewer full-time-equivalent employees provided information that we used in the traceability exercise, however, we did not include these 12 retailers in our analysis of the records maintenance requirements.

<sup>23</sup> A broker is a firm or an individual that is commissioned to negotiate sales of food products on behalf of food facilities. In many cases, brokers are required by FDA to maintain records.



## I N T R O D U C T I O N

information they maintained about the selected food products. These interviews provided additional information about the traceability of the food products, as well as about facilities' experiences in implementing the records requirements. We completed these interviews between April and September 2007.

### **Limitations**

Although the selected food products reflect a broad range of food types, our results are not generalizable to the entire food supply. In addition, we were not able to verify whether a facility provided a complete list of all of its sources, recipients, or transporters. The statements in this report are therefore based on the sources, recipients, and transporters that the facilities identified.

### **Standards**

This review was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

**We were able to trace 5 of the 40 products through each stage of the food supply chain; for most of the other products, we could identify the facilities that likely handled them**

Not all facilities are required to maintain lot-specific information in their records, and those that are required to maintain lot-specific information are required to maintain it only if

it exists.<sup>24</sup> As a result, we were able to trace 5 of the 40 specific products through each stage of the food supply chain. For another 31 of the 40 products, we could identify the facilities that likely handled them. For the remaining four products, we could not identify the facilities that likely handled them.

**We could trace 5 of the 40 products through each stage of the food supply chain**

We were able to trace five products through each stage of the food supply chain. The facilities that handled each of these products were able to provide information about the specific product we purchased or were able to link that product to lot-specific information in their records. These products were three cartons of eggs, a container of yogurt, and a bottle of water. For all three cartons of eggs, the food supply chain included only a retailer and a farm. In contrast, the supply chain for the container of yogurt included four facilities and four farms. The facilities that handled these five products were able to provide us with information that allowed us to trace the path these products took from the farm to the retail shelf.

**For 31 of the 40 products, we could identify the facilities that likely handled the products**

As noted earlier, not all facilities are required to maintain lot-specific information in their records, and those that are required to maintain lot-specific information are required to maintain it only if it exists. Therefore, many facilities were not able to provide information that was specific to the products we purchased.

For 31 of the 40 products, we were able to identify the facilities that likely handled the products. Most facilities that handled these products did not maintain lot-specific information in their records and could only estimate a range of deliveries (from one or more facilities) that may have included the product we purchased. As a result, we were not able to trace these specific products through each stage of the food supply

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<sup>24</sup> As noted earlier, FDA requires only processors, packers, and manufacturers to maintain lot-specific information in their records to the extent this information exists.

## FINDINGS

chain. In addition, for many of these products, 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 not able to trace a specific product through each stage of the food supply chain, it may have difficulty identifying the source of contamination or targeting which products need to be removed from retail shelves.

### **For 4 of the 40 products, we could not identify the facilities that likely handled them**

For four products—a tomato, a bag of ice, a bottle of fruit juice, and a bottle of water—at least one facility in the food supply chain failed to provide any information about the potential sources of the products. This prevented us from tracing these four products through each stage of the food supply chain back to the farm(s) or the border and from identifying all of the facilities that likely handled 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.

### **Several factors prevented us from tracing the specific products through the food supply chain**

Several factors limited our ability to trace the food products through each stage of the food

supply chain. These factors included: (1) processors, packers, and manufacturers not always maintaining lot-specific information, as required; (2) other types of facilities not maintaining lot-specific information because it is not required; (3) retailers receiving products not labeled with lot-specific information; and (4) the mixing of products from a large number of farms. These factors also affect the speed with which FDA can trace products through the food supply chain.

### **Processors, packers, and manufacturers did not always maintain lot-specific information**

FDA requires processors, packers, and manufacturers to maintain lot-specific information in their records to the extent this information exists. Of the 38 facilities we interviewed that were required to maintain this information, 2 failed to comply.

## F I N D I N G S

These facilities labeled the food product with lot-specific information; however, they did not maintain this information in their records. Further, two additional facilities did not maintain lot-specific information because it did not exist. One of these facilities, an ice manufacturer, did not establish lots that would allow it to distinguish one production batch from another. Although these facilities were in compliance with the records requirements because lot-specific information did not exist, the lack of lot-specific information can limit FDA's ability to trace a specific product through each stage of the food supply chain.

### **Other types of facilities did not maintain lot-specific information**

FDA does not require distributors, wholesalers, storage facilities, and retailers to maintain lot-specific information. However, this information could improve FDA's ability to identify the source of food contamination and help remove specific food products from retail shelves.

The distributors, wholesalers, storage facilities, and retailers that we interviewed did not commonly maintain lot-specific information. Of these facilities, 30 of the 44 distributors, wholesalers, and storage facilities and all of the 21 retailers did not maintain lot-specific information in their records.

### **Some retailers received products that were not labeled with lot-specific information**

Six of the forty food products that we purchased were not labeled with any lot-specific information. The lack of lot-specific information on the packaging can hinder FDA's ability to trace a specific product through the food supply chain.

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. For the packaged tomatoes, as well as two of the unpackaged tomatoes, the processors or packers labeled the cases of the product rather than the individual products available on the retail shelf. None of the six retailers, however, could link the purchased products to any lot-specific information.

### **Facilities sometimes mixed raw food products from a large number of farms**

The mixing of raw products from a large number of farms, a process that is often called commingling, can also limit FDA's ability to trace a specific product through the food supply chain.

## FINDINGS

Thirty-seven facilities in our traceability exercise received raw food products directly from farms. Of these, 15 facilities mixed raw products from more than 10 farms.<sup>25</sup> These facilities processed flour, juice, milk, and yogurt, and almost half of these facilities mixed raw products from 100 or more farms. Because of the large number of farms that contributed to these finished products, FDA may have difficulty identifying the source of food contamination and helping to remove the contaminated products from retail shelves. According to an estimate from a manager at a grain storage facility, if grain from one farm were contaminated, millions of bags of flour would be at risk and might have to be removed from retail shelves.

The remaining 22 facilities received raw food products from 10 or fewer farms. Several of these facilities that handled the eggs, leaf vegetables, and tomatoes received information from farms, such as expiration dates, the location of the field where the product was grown, and the date the product was harvested. In these cases, FDA would be able to more easily trace a contaminated food product through the food supply chain.

**Fifty-nine percent of the food facilities did not meet FDA's requirements to maintain records about their sources, recipients, and transporters**

FDA requires certain facilities to maintain contact information about their sources, recipients, and transporters.<sup>26</sup> This contact information helps to identify the

source of contamination and remove the products from retail shelves.

Fifty-nine percent (70 of 118) of the food facilities in our traceability exercise did not provide all of the required information. Six of the 118 facilities did not provide any of the required information. The remaining 64 facilities provided some but not all of the required information.

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<sup>25</sup> The four oatmeal chains are excluded because they ended at the U.S. border before reaching the beginning of the chain.

<sup>26</sup> FDA requires only certain facilities to meet these requirements. The facilities required to maintain contact information about their sources, recipients, and transporters include those that manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. See Appendix A for more detailed information about the types of facilities subject to these requirements and the information they are required to maintain.

## F I N D I N G S

### **Twenty percent of facilities did not provide all of the required contact information about their sources**

FDA requires certain food facilities to maintain the names, addresses, and telephone numbers of the sources of their food products.

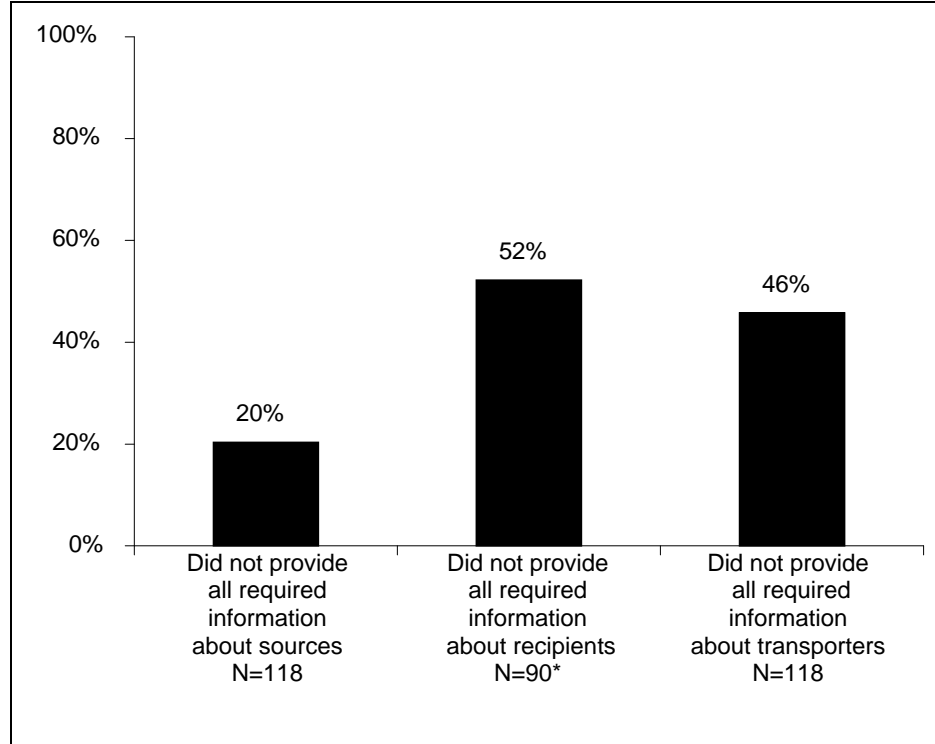
Twenty percent (24 of 118) of the facilities in our traceability exercise did not provide all of the required information about their sources. See Figure 2 on the following page for the percentage of facilities that did not provide the different types of required information. Six facilities did not provide any information about their source(s); the remaining 18 facilities did not provide some of the required information, such as a complete address or telephone number.

The six facilities did not provide any information about their sources for several reasons. One of the facilities, a produce distributor, bought its tomatoes from different vendors and did not maintain any records documenting these purchases. Another facility, an ice manufacturer, was not able to provide the information because it went out of business shortly after we purchased the product. In addition, one water bottler reported that it would be too difficult to provide the information because it did not include lot-specific information in its records. Three other facilities responsible for handling a bottle of juice did not provide any information about their sources or about why they did not provide this information.

The facilities that did provide information about their sources may have been able to do so because they typically had only one source. Seventy-two percent of all facilities had only one source for the selected food product. These facilities may not have had to look through large numbers of records or multiple recordkeeping systems to find the information. In several cases, managers noted that they did not have to look at records at all because they knew the one source of the product from memory.

## FINDINGS

Figure 2:  
Percentage of Food  
Facilities That Did  
Not Provide Required  
Information



\* Excludes retailers.

Source: OIG analysis of food facility responses, 2008.

### **Fifty-two percent of facilities did not provide all of the required contact information about their recipients**

FDA also requires certain food facilities to maintain the names, addresses, and telephone numbers of the recipients of their food products. Fifty-two percent (47 of 90) of the facilities did not provide all of the required information about their recipients.<sup>27</sup> Six facilities did not provide any information about their recipients. These facilities were the same ones that did not provide any information about their sources.

The remaining 41 facilities did not provide some of the required information, such as a complete address or telephone number.

Facilities may have had difficulty in providing all of the required information about their recipients because they typically had more than one recipient. Specifically, 62 percent of the 90 facilities in our traceability exercise had more than one recipient. In several of these

<sup>27</sup> FDA does not require retailers to provide information about their recipients if the recipients are consumers. Therefore, this requirement did not apply to the 28 retailers in our traceability exercise. See 21 CFR § 1.327(e).

## FINDINGS

cases, managers had to look through large numbers of records—some of them paper based—to identify recipients. A number of managers specifically reported that their facilities kept the contact information for recipients in a system separate from the one used to track incoming shipments, making it burdensome to provide the contact information for the selected food products.

### **Forty-six percent of facilities did not provide all of the required contact information about their transporters**

FDA requires certain food facilities to maintain the names, addresses, and telephone numbers for the transporters of both their incoming and outgoing shipments. Forty-six percent of food facilities (54 of 118) did not provide all of the required information about their transporters. Specifically, 27 facilities did not provide all of the information about their transporters of outgoing shipments, whereas 10 facilities did not provide all of the information about their transporters of incoming shipments. An additional 17 facilities did not provide all of the information about the transporters of either their incoming or outgoing shipments.

Facilities had difficulty in providing all of the required information about their transporters for several reasons. Several managers indicated that they did not keep records that identified their transporters when the transportation was arranged by either their source or their recipient. Several other managers reported that they kept the transporter information in a separate recordkeeping system that was not integrated with their system that tracked shipments. Some managers further noted that identifying the transporter associated with a particular incoming or outgoing shipment was very burdensome because they needed to manually search a large number of paper records.

**One-quarter of the food facilities were not aware of FDA’s records requirements; others highlighted practices designed to improve traceability**

Twenty-five percent (26 of 104) of the managers who responded to our questions were not aware of FDA’s records requirements.<sup>28</sup>

The percentage of managers who were not aware of the requirements varied by the type of facility. As shown in Figure 3, 50 percent of the managers at retail facilities were not aware of FDA’s records requirements, compared to 21 percent of the

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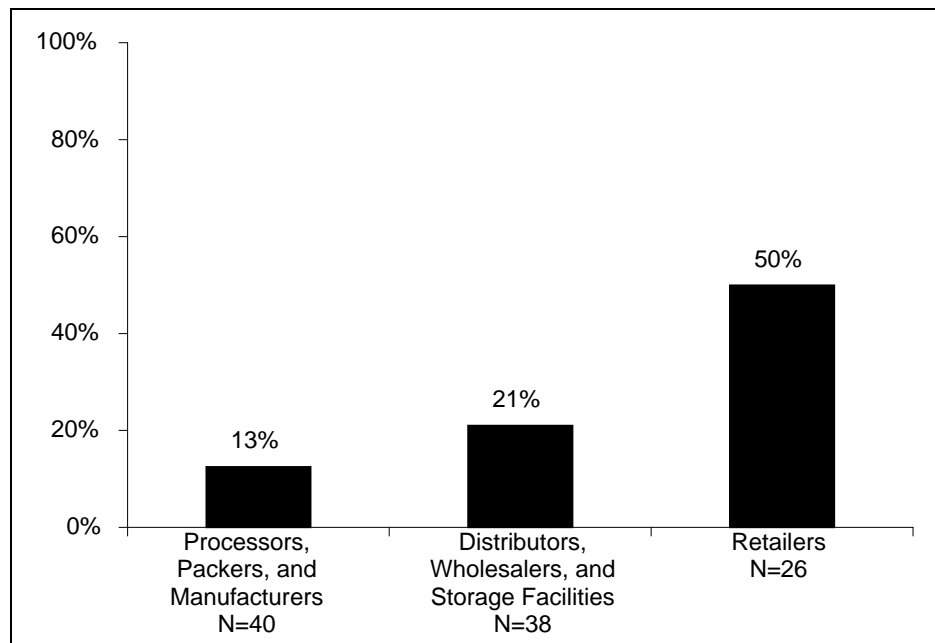
<sup>28</sup> Of the 118 facilities in our traceability exercise, 104 facilities responded to this question.



## FINDINGS

managers at distributor, wholesale, and storage facilities and 13 percent of the managers at processing, packing, and manufacturing facilities.

Figure 3:  
Percentage of  
Managers Who  
Reported Not  
Being Aware of  
FDA Records  
Requirements,  
by Facility Type



Source: OIG analysis of food facility responses, 2008.

Note: This information is based on 104 of the 118 facilities that responded to this question.

### Many facilities reported making changes to their recordkeeping practices to meet FDA's records requirements

Over half of the managers (43 of 78) who were aware of the FDA records requirements reported making changes to their recordkeeping practices to meet these requirements. For example, a number of these managers reported switching from paper-based to electronic recordkeeping systems or reported improving their existing electronic systems. Additionally, eight managers noted that they had developed or improved their facilities' ability to maintain lot-specific information. One of these managers purchased software to more easily keep track of products, whereas another began recording lot-specific information in a paper-based system.

Additionally, several managers reported making other types of changes. For example, eight managers reported making improvements to their transporter records. One manager began photocopying the driver's licenses of transporters, whereas another added the transporters' names and addresses to the receipts documenting the delivery of transported products. A few other managers noted that their facilities now

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designate a point person to respond to food emergencies or hire a third-party auditor to monitor their recordkeeping systems. A few others noted that they had started to keep their records for a longer period of time.



## R E C O M M E N D A T I O N S

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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 a food emergency, this information allows FDA to identify the source of contamination and help remove unsafe food products from retail shelves.

Based on our review, we were able to trace 5 of the 40 specific products we purchased. For 31 of the 40 products, we were able to identify the facilities that likely handled them. For the remaining four products, we could not identify the facilities that likely handled them. Several factors prevented us from tracing the specific products through each stage of the food supply chain. These factors included: (1) processors, packers, and manufacturers not always maintaining lot-specific information, as required; (2) other types of facilities not maintaining lot-specific information because it is not required; (3) retailers receiving products not labeled with lot-specific information; and (4) the mixing of products from a large number of farms.

In addition, we found that 59 percent of the food facilities in our traceability exercise did not meet FDA's requirements to maintain records about their sources, recipients, and transporters. We also found that one-quarter of the food facilities were not aware of FDA's records requirements, whereas others highlighted practices designed to improve traceability.

To address the findings in this report, we recommend that FDA:

**Seek statutory authority, if necessary, to strengthen existing records requirements regarding lot-specific information**

FDA should seek statutory authority, if necessary, to require all processors, packers, and manufacturers to create and maintain lot-specific information for food products. FDA should also extend the requirements regarding lot-specific information to other types of facilities, such as distributors, storage facilities, and retailers, in order to further strengthen the traceability of food products.

**Consider seeking additional statutory authority to improve traceability**

FDA should consider seeking additional statutory authority requiring food facilities to further strengthen the traceability of food products.

## R E C O M M E N D A T I O N S

FDA should consider a variety of different approaches, such as expanding current requirements stipulating that facilities maintain information only for their immediate sources, recipients, and transporters. FDA may instead require each facility that handles a food product to maintain records about every facility or farm that handled the product, along with the relevant lot-specific information. This may allow FDA to more quickly and accurately trace food products during a food emergency. In addition, FDA should consider requiring facilities to use certain information technologies to help facilitate recordkeeping, such as interoperable recordkeeping systems. These interoperable systems, which would allow for information to be exchanged among all facilities in the food supply chain, may also allow FDA to more quickly and accurately trace food products during a food emergency.

### **Work with the food industry to develop additional guidance to strengthen traceability**

FDA should work with the food industry to develop additional guidance on traceability. Among other things, this guidance could encourage facilities to assign a point person to be responsible for responding to food emergencies, conduct mock recalls, and contract with independent third-party auditors to monitor recordkeeping systems.

### **Address issues related to mixing raw food products from a large number of farms**

FDA should work with the food industry to develop standards for mixing raw food products from a large number of farms. This would address a serious vulnerability in the traceability of the food supply chain.

### **Seek statutory authority to conduct activities to ensure that facilities are complying with its records requirements**

FDA should 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. FDA should use this authority to conduct traceability exercises or other checks on facilities to ensure that they are complying with its records requirements. With this added authority, FDA would be able to include a component in its food facility inspections to verify as a matter of course whether facilities are complying with its records requirements.

**Conduct education and outreach activities to inform the food industry about its records requirements**

FDA should develop education activities that focus on appropriate and reliable recordkeeping systems. These activities could include informational meetings, mailings, and other initiatives. FDA should use these efforts to clearly explain the specific types of information that must be maintained, such as transporter contact information. FDA should also target outreach efforts to facilities that have less familiarity with the records requirements, namely retailers, distributors, wholesalers, and storage facilities.

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**AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

FDA stated that it will consider our recommendations regarding seeking enhanced statutory authority, and it described its efforts in response to our recommendations to work with the food industry and to conduct education and outreach. FDA did not specifically state whether it concurred with these latter two recommendations.

FDA stated that it will consider our three recommendations to seek additional statutory authority to (1) strengthen existing records requirements, (2) improve traceability, and (3) ensure that facilities are complying with records requirements, as well as our recommendation to address issues relating to mixing raw food products. FDA noted that it continues to work closely with its food safety partners to strengthen its ability to protect Americans from foodborne illness, which includes determining whether additional statutory authority is needed to ensure that it has the requisite tools to better protect public health.

In response to our recommendation to work with the food industry, FDA stated it is continuing to work with the food industry and other stakeholders to develop additional guidance to strengthen traceability. FDA noted that it is meeting with the food and feed industry and technology firms to better understand industry product tracing activities and technologies. FDA also stated that it has held two public meetings to stimulate discussions on enhancing product tracing systems, and has recently awarded a contract for a study on traceability in food systems. FDA also noted its plan to host a workshop to review the results of a traceability study being conducted by the European Union, which will allow FDA to learn from the findings and incorporate them into its decisionmaking.

## R E C O M M E N D A T I O N S

In response to our recommendation to conduct education and outreach activities, FDA stated that it is the responsibility of those providing food for American consumers to be aware of and comply with all laws and regulations that apply to their activities. FDA further noted that it had conducted extensive outreach activities in 2005 and had continued to provide assistance to the industry by developing a series of Question and Answer guidance documents, and that it will continue to work with industry and trade association groups to communicate the requirements of the rule to stakeholders.

We support FDA's ongoing efforts to improve the traceability of the food supply and to ensure that it has the tools needed to better protect the public health in the event of a food emergency. We ask that, in its final management decision, FDA more clearly indicate whether it concurs with our recommendations to work with the food industry and to conduct education and outreach.

For the full text of FDA's comments, see Appendix C.

### **The Establishment and Maintenance of Records Regulations**

Title 21 of the Code of Federal Regulations, Part 1, Subpart J, describes the specific information to be maintained under the Maintenance and Inspection of Records provision of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 for all persons, except transporters, who are subject to the Federal recordkeeping requirements. A person includes an individual, a partnership, a corporation, and an association (21 CFR § 1.328). Pursuant to 21 CFR § 1.337, facilities must establish and maintain the following records for food they receive:

- “The name of the firm, address, telephone number and, if available, the fax number and e-mail address of the nontransporter immediate previous source, whether domestic or foreign;
- “An adequate description of the type of food received, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);
- “The date you received the food;
- “For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent this information exists);
- “The quantity and how the food is packaged (e.g., 6-count bunches, 25-pound (lb) carton, 12-ounce (oz) bottle, 100-gallon (gal) tank); and
- “The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate previous source (the transporter who transported the food to you).”

Additionally, pursuant to 21 CFR § 1.345, facilities must establish and maintain the following records for food they release:

- “The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the nontransporter immediate subsequent recipient, whether domestic or foreign;
- “An adequate description of the type of food released, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

## A P P E N D I X ~ A

- “The date you released the food;
- “For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent this information exists);
- “The quantity and how the food is packaged (e.g., 6-count bunches, 25-lb carton, 12-oz bottle, 100-gal tank);
- “The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate subsequent recipient (the transporter who transported the food from you ); and
- “Your records must include information reasonably available to you to identify the specific source of each ingredient used to make every lot of finished product.”



**Selection of Retail Facilities**

We purchased 10 products in four areas based on the U.S. Census Bureau’s Metropolitan Statistical Areas (MSA). In each MSA, we purchased 10 food products, each from a different retail facility, for a total of 40 food products. We selected retail facilities in the two ZIP Codes with populations closest to the median population, or, if necessary, in a bordering ZIP Code. We purchased different brand names for each of the 40 products and, when possible, we selected lesser known brands. See Table 1 for a list of the MSAs and the targeted ZIP Codes.

<b>Table 1: MSAs in Our Traceability Exercise</b>				
<b>MSA</b>	<b>ZIP Code</b>	<b>County</b>	<b>State</b>	<b>Population</b>
New York-Northern New Jersey-Long Island, New York-New Jersey-Pennsylvania	07059	Somerset	New Jersey	14,219
	07001	Middlesex	New Jersey	14,188
Washington-Arlington-Alexandria, Washington, DC-Virginia-Maryland	20851	Montgomery	Maryland	13,038
	20187	Fauquier	Virginia	12,886
Chicago-Naperville-Joliet, Illinois-Indiana-Wisconsin	60093	Cook	Illinois	19,528
	60448	Will	Illinois	19,476
San Francisco-Oakland-Fremont, California	94947	Marin	California	24,724
	94608	Alameda	California	24,572

Source: U.S. Census Bureau, 2000.

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Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

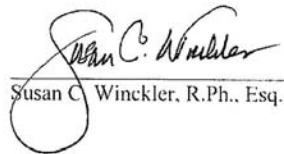
Food and Drug Administration  
Silver Spring, MD 20993

March 5, 2009

To: Inspector General  
From: Chief of Staff, FDA  
Subject: FDA Comments to OIG Draft Report Entitled. *Traceability in the Food Supply Chain* (OEI-02-06-00210)

FDA is providing the attached general comments to the Office of the Inspector General's Draft Report entitled, *Traceability in the Food Supply Chain* (OEI-02-06-00210).

FDA appreciates the opportunity to review and comment on this draft report before it is published.

  
Susan C. Winckler, R.Ph., Esq.

**FDA's General Comments to the Office of Inspector General's (OIG) Draft Report  
Entitled, *Traceability in the Food Supply Chain* (OEI-02-06-00210)**

FDA appreciates that OIG conducted this important and valuable study. Such studies are extremely helpful to FDA, especially under circumstances where it would not be possible for FDA to have access to such information otherwise, or to conduct such an analysis. FDA's responses to OIG's recommendations are as follows:

**OIG Recommendations**

- Seek statutory authority to strengthen existing records requirements regarding lot specific information.
- Consider seeking statutory authority to improve traceability.
- Address issues relating to mixing raw food products from a large number of farms.
- Seek statutory authority to conduct activities to ensure that facilities are complying with its records requirements.

**FDA Response**

The Agency continues to work closely with the Department of Health and Human Services (HHS), as well as other federal and state food safety partners, in identifying ways of strengthening the Agency's ability to protect Americans from foodborne illness. This includes determining whether additional statutory authority is needed to ensure that FDA has the requisite tools to better protect the public health in the event of an outbreak of foodborne illness. FDA will consider the OIG's recommendations regarding seeking enhanced statutory authority as part of this process.

**OIG Recommendation**

- Work with food industry to develop additional guidance to strengthen traceability.

**FDA Response**

The Agency is continuing its efforts to work with the food industry and other stakeholders to develop additional guidance to strengthen traceability. FDA has been meeting with the food and feed industry and technology firms to better understand industry product tracing activities and technologies that may be available to improve product tracing. FDA held two public meetings on product tracing systems for fresh produce: one in College Park, Maryland, in October 2008, and one in Oakland, California, in November 2008. The purpose of these meetings was to stimulate discussions on enhancing product tracing systems that ultimately could allow for more accurate and earlier tracing of products implicated in outbreaks of foodborne illness. The public meetings allowed FDA to hear public input on product tracing systems and practices from a wider audience. The comment period closed January 22, 2009. FDA is reviewing all comments received during the meetings and open comment period.

In addition, FDA recently awarded a contract for a study on traceability in food systems. The contract period is October 2008 through September 2009, and requires an in-depth review of industry product tracing practices and technologies. Contract deliverables include recommendations for process improvements and technologies to more rapidly and precisely track and trace products in the food continuum, information on whether the recommendations are suitable for use by businesses ranging in size from very small to large, and barriers to implementation. FDA also is continuing work on its goal of improving immediate response by enhancing product tracing capabilities.

Moreover, FDA is staying abreast of a four-year traceability study on tomatoes and dairy that the European Union (EU) began in 2007. The goal of the EU study is to ensure total traceability of food and feed along the whole chain from production to consumption. As part of this effort, the EU will develop, test, and evaluate two full pilot traceability systems, including one for the tomato food chain. The EU plans to disseminate the results of its study. FDA plans to host a workshop at the University of Maryland during 2009 to review the status of the EU study, which will help ensure that FDA can take advantage of relevant study conclusions when the EU completes its traceability project. This will allow FDA to learn from the EU experience and incorporate the study findings into its decision-making.

#### **OIG Recommendation**

- Conduct education and outreach activities to inform the food industry about its records requirements

#### **FDA Response**

It is the responsibility of those providing food for American consumers to be aware of and comply with all laws and regulations that apply to their activities, including the regulations implementing the authority granted to the Agency in 2002, i.e., the Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Final Rule, 21 CFR Part 1, Subpart J. To assist persons required to comply with the rule, FDA conducted extensive outreach activities in 2005, shortly after publishing it, which included holding numerous public meetings across the United States in locations such as Kansas City, Missouri; Los Angeles, California; College Park, Maryland; Bloomington, Minnesota; and Atlanta, Georgia. In addition, the Agency worked with other federal, state and local public health agencies, industry, academia, national trade associations and consumer protection advocacy groups to explain the requirements of the rule and to answer questions. These activities included giving presentations at numerous trade association meetings and webinars with different entities in order to reach out to entities subject to the rule and provide assistance on achieving compliance with the new rule. Further, subsequent to the initial outreach activities, the Agency continued to provide assistance to industry by developing a series of Question and Answer guidance documents that provided answers to frequently asked questions. These documents and other compliance information are

available on FDA's website at <http://www.fda.gov/oc/bioterrorism/bioact.html>. FDA will continue to work with industry and trade association groups to communicate the requirements of the rule to stakeholders.



## A C K N O W L E D G M E N T S

This report was prepared under the direction of Jodi Nudelman, Regional Inspector General for Evaluation and Inspections in the New York regional office, and Meridith Seife, Deputy Regional Inspector General.

Vincent Greiber served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the New York regional office who contributed to the report include Judy Bartlett and Lucia Fort; other central office staff who contributed include Ayana Everett, Robert Gibbons, Talisha Searcy, and Sandy Khoury.