

Report to Congress
On Enhancing Tracking and Tracing of Food and Recordkeeping
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Executive Summary

The Food and Drug Administration (FDA or the Agency) has been exploring ways to improve tracing of foods in order to reduce the risk of consumers from becoming ill when a food is contaminated, and to learn from the contamination event to prevent an outbreak in the future. With the enactment of the FDA Food Safety Modernization Act (FSMA), (P.L. 111-353) Section 204, *Enhancing Tracking and Tracing of Food and Recordkeeping*, FDA has an opportunity, along with our food safety partners, to significantly advance these efforts. This opportunity comes with several obligations for FDA. First is for FDA to work with the United States Department of Agriculture (USDA) and State agencies to establish pilot projects in coordination with the food industry to explore and evaluate methods for rapid and effective tracking and tracing of foods. FSMA requires FDA to provide this report to Congress on the findings of the pilot projects together with FDA's recommendations for improving the tracking and tracing of food. The findings of the pilot projects, along with other information, will aid FDA in meeting another requirement of FSMA section 204, which is to publish a notice of proposed rulemaking to establish recordkeeping requirements for facilities that manufacture, process, pack, or hold foods which FDA designates as high-risk. This requirement is designed to facilitate rapid and effective tracing of food products to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death to humans or animals. For more on FDA FSMA requirements as they pertain to product tracing, please visit the FDA FSMA website at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm270851.htm>.

When a foodborne outbreak occurs, an accurate and efficient traceback of the implicated food permits the quickest identification of the source of the contamination, thus enabling regulatory and public health officials and food companies to ensure that all contaminated product is removed from the marketplace to prevent additional illnesses. The need to trace foods quickly in a focused manner encompasses not only foodborne outbreaks but also other food contamination incidents, such as the incident of pistachio-derived products contaminated with *Salmonella* spp. in 2009. Tracing foods back or forward in the supply chain is challenging due to the complexity of the food distribution system, differences in the terminology that companies use to describe ingredients and products, the quality of available tracing-related information and records, and the inability to quickly follow a product's movement both within a facility and as it moves through the supply chain. These challenges can lead to a delay in the identification of the source of contamination, or the contamination source may never be identified. As a result, additional illnesses might occur which could have been prevented. Current recordkeeping requirements stemming from the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) require firms to know and record the immediate source of their products and where they send products (commonly referred to as one-up one-back recordkeeping). Since implementation of these requirements over ten years ago, FDA has learned from experience that there are significant limitations in the available tracing-related information that government

agencies and firms need to conduct rapid and effective tracing of products. These limitations are due, in part, to gaps in the recordkeeping requirements including: exemptions for farms and restaurants; non-uniform data collection for the type and quantity of food and ingredient source, data collection of lot code, or other identifier, only if it exists; the lack of a means to link incoming with outgoing product within a firm and from one point in the supply chain to the next; and the firm address requirement do not distinguish between the corporate headquarters (e.g., for billing purposes) versus the physical location of the product.

Pilot Findings

FDA has been gathering information on product tracing through pilot projects, public meetings, and other mechanisms for obtaining stakeholder input, as well as learning from the challenges encountered in tracing food products, such as in the course of foodborne illness outbreak investigations. More recently, in response to the first mandate of FSMA section 204, FDA issued a task order to conduct two product tracing pilot projects through an existing contract with the Institute of Food Technologists (IFT), a nonprofit scientific society consisting of professionals engaged in food science, food technology, and related professions.

IFT's findings, as reported to FDA after the conclusion of the pilots, are consistent with previous studies and FDA's experiences, and provide a greater depth of knowledge on the basic, uniform elements needed for a tracing system, potentially useful technology enhancements, costs and benefits, and domestic and global product tracing practices and initiatives. Major findings of the pilot projects include significant gaps in communication and a lack of a common vocabulary indicating that key data elements (KDEs) are necessary to track and trace the movement of products. Many collaboration platforms, with minimal effort, were able to demonstrate the flow of specific lots of product through the supply chain, and some were able to identify convergence (e.g., common source). Notable were the difficulties in linking product data from different sources, highlighting the need for a more uniform system of recordkeeping requirements.

FDA Recommendations for Improving Product Tracing

FDA's recommendations are based on IFT's findings and recommendations stemming from the recent product tracing pilots, on FDA's experience obtained from tracing foods in the course of foodborne illness outbreak investigations, and on additional information obtained in the past from stakeholders through pilot projects and public meetings.

Establishing a uniform set of data elements, a method of linking product along the supply chain, and advancing FDA's ability to receive and analyze the data will provide the most basic and significant advancements and are a focus of FDA's recommendations. This will lead to improved risk-based decision making, allow for more efficient data sharing with States and other federal agencies, and ultimately result in more focused public messaging and more rapid product source identification and removal from the marketplace.

FDA's recommendations address the importance of stakeholder collaboration and enhanced training and outreach that will further improve product tracing during outbreaks and other food contamination events. Industry is key to these efforts. Potential improvements that may be achieved include increased accuracy and quality of electronic tracing-related data submitted to FDA, enhancement (via better documentation and mock exercises) of firms' processes for linking and tracing back ingredients and finished products within their establishment and further back in the supply chain, increased collaboration with FDA to develop resources and identify venues specifically for educating firms on the traceback process and information needed by FDA and other government food safety partners, and working with FDA to establish a more systematic process for engaging industry subject matter experts in the preliminary phase of product tracing investigations. In addition to industry leadership in advancing the ability to more effectively and efficiently trace food products, States and other federal partners also play a key role. In furthering existing collaborations and capacity building, FDA plans to continue to develop training materials and conduct trainings that will lead to more consistent approaches in working with industry and in the collection of information and records for product tracing, as well as continue efforts to share tracing related data with States and other federal officials under appropriate agreements.

FDA's recommendations encompass a broad spectrum of activities, including, but not limited to, encouraging voluntary and proactive efforts by industry, enhancing FDA internal processes and technology use, and identifying key data elements and ways to link foods as they move through the supply chain. It is important for the food industry to continue to show strong leadership to improve the product tracing system beyond any minimum national requirement for product tracing.

In addition to the collection of more accurate electronic source data, such as lot codes, described in this report, FDA is also aggressively pursuing the use of the latest laboratory based methods for tracking pathogens. Using sophisticated next generation whole genome sequencing technology and advanced data analysis, food pathogens can accurately be attributed to an environmental source based on their DNA fingerprints. Recognizing the power of this technology to assist in food contamination events, FDA has established the first-ever network of State and Federal laboratories dedicated to employing next generation whole genome sequencing technologies to track the source of foodborne pathogens. Known as GenomeTrakr, the network now consists of more 19 State and 14 Federal laboratories engaged in the real-time sequencing of food pathogens. Data collected through the network has already been used to focus, target and support Agency efforts in several foodborne outbreaks.

This holistic and multi-faceted approach will create a system that affords the public greater confidence that food producers and regulatory and public health officials can quickly trace a contaminated food to its source and remove it from the marketplace, thereby preventing additional illnesses. Rapid traceability can also help firms and the affected industry sector lessen the potential economic impact of recalls and public alert

messages by quickly establishing which foods/ingredients and firms can be eliminated from further consideration as a possible source of contamination.

Next Steps

While implementation of some of these recommendations is already underway, FDA is considering a comprehensive approach to implementing many of them through partnerships with academia, domestic and foreign industry, consumer groups, and government. The extent to which FDA can implement these recommendations will depend on resources, information technology support, and engagement by industry and government food safety partners. In keeping with section 204 of FSMA, at this time, FDA intends to establish additional recordkeeping requirements for foods FDA designates as high-risk. FDA will further evaluate whether any potential tracing issues not covered, or limited, by FSMA section 204 should be addressed, including whether new laws or changes to existing laws and regulations are needed.

FDA recognizes there may be a need for additional information gathering, such as gaining a better understanding of small and medium sized firms' product tracing practices, needs, and limitations. Specific to the proposed rulemaking process, FDA will seek public comments to inform FDA as the Agency develops a regulation that advances public health protection while being practical for industry implementation.

Introduction

On January 4, 2011, U.S. President Barack Obama signed into law the FDA Food Safety Modernization Act (Public Law 111-353). Section 204 of FSMA, *Enhancing Tracking and Tracing of Food and Recordkeeping*, requires the Secretary of Health and Human Services, taking into account recommendations from the Secretary of Agriculture and representatives of State departments of health and agriculture, to establish pilot projects in coordination with the food industry to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) or misbranded under section 403(w) of such Act (21 U.S.C. 343(w)). Section 204 requires the Secretary of Health and Human Services to provide a report to Congress on the findings of the pilot projects under this subsection together with recommendations for improving the tracking and tracing of food.

Background

Product tracing systems provide information that government agencies and firms can use to take timely action when an outbreak of foodborne illness occurs or a contaminated

product is identified. These actions, which help in preventing illnesses, may include removing a product from the marketplace and alerting the public if the product has already been distributed and may be present in consumers' homes. These actions enable consumers to take appropriate individual actions to assure their safety.

Many producers, manufacturers and retailers currently have the elements of product tracing systems in place but each system varies, depending on the amount of information the system records and collects, how far forward or backward in the supply chain the system tracks, the technologies used to maintain records, and the precision with which a system can pinpoint a product's movement across the supply and distribution chain. Some firms, especially smaller ones, primarily use paper records to track movement of a product in their firm and to the next point in the supply chain. Even these less sophisticated approaches have elements of a product tracing system, often as a way to track inventory and purchasing.

Product tracing can encompass tracing a food forward or back in the supply chain. Tracing foods back in the supply chain during a foodborne outbreak from the point of sale/service (POS) to a common source is a necessary step before a recall, or other means of removing the product from distribution, can occur. Identifying an adulterated food product through routine sampling may also result in a traceback. Following the movement of foods in the opposite direction, in a traceforward, is frequently discussed in the context of recalled product. Information on specific brands, lots, or other identifying information is used to follow the product's path from the manufacturer forward in order to remove it from the entire distribution chain. Tracking foods forward can be used in foodborne outbreaks to help explain how the distribution of product aligns with a majority of illnesses or illness clusters.

A traceback conducted by FDA in response to a foodborne illness outbreak can be considerably more complex than one conducted during a routine product sampling where chemical or microbial pathogen contamination is found. With routinely collected product samples, labeling and identifying information is usually available. In contrast, by the time an outbreak is identified by public health agencies, labeling and identifying information for the implicated food that ill individuals consumed is often not available. In general, a traceback of a sampled product that is found to be contaminated is easier and takes less time than a traceback conducted in response to a foodborne illness outbreak. However, there are some similar challenges in both situations.

Traceback Process in Foodborne Outbreaks

In order to understand the current challenges to conducting rapid and effective tracebacks and better understand the findings of the pilot studies, it is important to understand the process by which FDA traces a product in a foodborne illness outbreak investigation to find the common source in the supply chain where contamination occurred. Compared to the "single" traceback that FDA conducts when a routine product sample is found to have microbial pathogen or chemical contamination, the traceback conducted by FDA in response to a foodborne illness outbreak actually comprises multiple tracebacks

(traceback “legs”). The rationale for this approach is explained in detail below and illustrated in Figure 1. In some cases this process is made more straightforward when whole genome sequence data of the isolates from sick individuals matches a previously sampled food or food processing facility. In these cases, it is possible to start immediate inspections of the facilities or foods identified by whole genome sequence analysis.

Once epidemiologic investigations and studies conducted by State and local health departments and the Centers for Disease Control and Prevention (CDC) have shown an association between outbreak illnesses and consumption of a particular food, there are generally five major steps that FDA takes in tracing back a product:

1. Identify the specific product that is likely contaminated based on food exposure information from individuals who became ill as part of the outbreak (e.g., “tuna sushi” sold in supermarkets or served in restaurants where people who became ill shopped or dined, respectively).
2. Identify POS that will be the starting points for tracebacks. The POS typically chosen are stores or restaurants where multiple people who become sick in the outbreak purchased or consumed the likely contaminated product and where adequate documentation exists regarding the product and when the ill individual shopped or dined at the location (e.g., shopper card information or purchase receipts). Ideally, tracebacks will be performed for at least three POS located in distinct geographic areas of the United States.
3. For products not associated with a single manufacturer (e.g., raw produce), identify specific suppliers and corresponding shipments containing the product that would have been available at the time the ill individuals ate or purchased the product at each POS.
4. Using product information and records obtained from firms, trace the product’s path in the supply chain from each POS back to its original source.
5. Identify the common point in the supply chains for the different POS where the tracebacks converge. This particular location (e.g., farm, packing facility, manufacturing plant) is the common source of product that was consumed by the individuals who shopped or dined at the different POS and then became ill.

FDA’s traceback process for outbreak investigations is illustrated below in Figure 1. In this example there are three POS where multiple individuals shopped or dined and subsequently became ill as part of an outbreak: Restaurant “A”, Grocery Store “B”, and Restaurant “C”. They are located in three different states. The ill individuals either purchased the product at the grocery store or consumed the product as part of a meal they had at one of the restaurants. These are the three traceback legs in the traceback conducted for this outbreak. During the time period in which the ill individuals either purchased product or consumed meals at the POS, there were multiple distributors, repackers, packers, and growers in the supply chains to the two restaurants, while the

grocery store supply chain involved only one grower/packer (Grower and Packer C) and one distributor. Figure 1 shows that the three traceback legs converge on Grower and Packer C because this firm supplied product to all three POS via different distributors during the timeframe of interest.

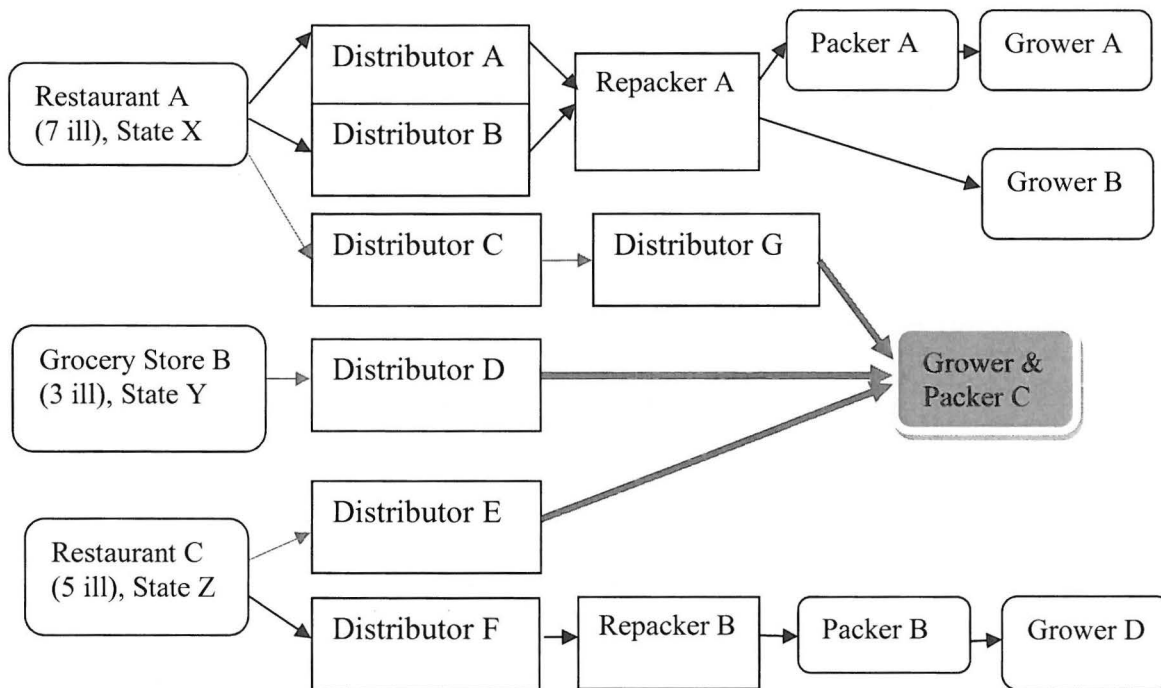


Figure 1: Illustration of a traceback in a foodborne illness outbreak investigation using three points of sale or service (POS), Restaurant A, Grocery Store B, and Restaurant C located in three different states as starting points; each is considered a traceback leg. The three POS obtained food associated with the outbreak from seven different distributors. Two repackers supplied three distributors in two of the three traceback legs (A and C). Three packers were involved with one in common to all three traceback legs. Three growers supplied traceback leg A; one supplied traceback leg B, and two supplied traceback leg C. The traceback illustrates using weighted arrows that one grower and packer was a common source for all three POS.

FDA requests and uses a variety of types and sources of information to identify all product shipments that ultimately led to product that was available at the POS when the ill individuals dined or shopped there. This effort is significantly easier if there are lot codes, or other specific identifiers, on any remaining product that was consumed by ill individuals. Even with lot codes, knowing exactly which shipment of product was sold to consumers or used in the meal served to the consumers who later became ill is essential for determining which suppliers and corresponding shipments are of most interest to trace back. Usually this is determined based on stock rotation and inventory practices, delivery schedules, delivery receipts, serving times, turn-around times of product, shipping dates and locations, product quantities, product descriptions, and other information that POS firms may have available to assist in this effort. This information is gathered from many different documents and systems, and from a given firm's practices. Once the shipments

of interest are identified at the POS, records and information from the firms that shipped the products to the POS are obtained. Typically, this is at the distributor level in the supply chain. The objective is to use product information maintained by the distributors to link incoming shipments to outgoing shipments and thereby identify the next firm(s) back in the supply chain. The process of linking outgoing to incoming product shipments continues at all subsequent firms identified; this process happens simultaneously for each of the traceback legs. The key to success in this traceback effort (i.e., identifying the firm at which the different traceback legs converge) is the availability of accurate and specific information at each firm that shows how incoming shipments are linked to outgoing shipments.

Recordkeeping Requirements Related to Tracing Prior to FSMA

Prior to enactment of FSMA, recordkeeping requirements related to product tracing were primarily covered under the Bioterrorism Act. The Bioterrorism Act requirements were a step forward given the lack of previous requirements specifically related to product tracing. It's been over ten years since implementation of these recordkeeping requirements and FDA has learned that there are critical gaps in the requirements that limit the ability of regulatory agencies to conduct prompt, effective product tracing, especially in response to foodborne illness outbreaks.

Comments received by FDA from industry during previous public meetings on product tracing and in response to a recent request for comments on the IFT recommendations contained in *Pilot Projects for Improving Product Tracing along the Food Supply System –Final Report*

(<http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM341810.pdf> , described below) indicate that most of industry believes that the current recordkeeping requirements are sufficient to track food in the supply chain. However, in FDA's extensive experience conducting tracebacks of food products, tracebacks often require extensive time and resources to complete and may be unsuccessful due to the current state of records maintained by firms in addition to other factors.

FDA believes that there are four major gaps in the existing recordkeeping requirements:

1. Lack of coverage of all establishments (e.g., farms and restaurants are excluded)
2. Lack of uniform data and record requirements
3. Inability to link incoming with outgoing product within a firm and from one point in the supply chain to the next
4. Inadequate mechanisms to rapidly capture, receive, and analyze tracing information (electronic and technology applications).

These limitations have been evident in multiple foodborne outbreaks since the recordkeeping requirements took effect over ten years ago. Congress aptly recognized the need for improvement and included product tracing in FSMA in section 204. With an improved ability to track and trace food in the supply chain, State and federal regulatory authorities, working with industry, can identify more rapidly the source of a contaminated product during an outbreak and reduce the risk of additional illnesses.

While the provisions under FSMA section 204 do not completely fill these voids, they create the opportunity for improvement in the identified gaps that will lead to enhanced public health protection and reduction in illnesses. For more on FDA FSMA requirements as they pertain to product tracing, please visit <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm#ProductTracing>.

Challenges in Product Tracing and Adverse Public Health Outcomes

The success, degree of focus, and speed of the process of tracing food products through the supply chain rests greatly on the quality of the data and information that industry holds. The Agency's ability to receive, aggregate, and analyze the data and information is also a rate-limiting step.

Analyzing information and data to determine a food product's movement through the supply chain and how it was used at different facilities requires examination of many types of records and information, including, but not limited to, receipt records, purchase orders, invoices, "pick sheets" or "put away sheets," bills of lading, batch and other records, standard operating procedures, interviews of firm employees, and observations of FDA or State investigators. Each firm has its own unique record and data systems (electronic and/or manual) and practices that need to be understood by investigators. Rarely are there identifiers that link the product as it moves from firm to firm through the supply chain, and often identifiers are lacking within a firm. One firm may assign a lot code to a product shipment to another firm, and the firm receiving the product may assign a new lot code or other identifying code that is not connected by records or a data system to the incoming product. Additionally, the incoming product may be processed and used as an ingredient in many different multiple products, thus compounding the challenge of linking incoming product within a firm to the outgoing product.

During a traceback investigation, a large volume of information is collected and must be analyzed in order to determine next steps and find convergence in the supply chain. FDA's current system for receiving, analyzing, and interpreting large volumes of emails, images, data files and other documents is a combination of computer processing and manual processing. Advances in applying technology to the tracing process would greatly enhance both industry's and FDA's efforts; common data elements and linkages would enable a clearer two-way data exchange and result in more rapid comprehension of the information supplied. These changes would greatly improve FDA's precision and efficiency in performing tracebacks.

Contamination can occur at almost any point, and the supply chain for a given type of product may be very complex. With fresh produce, for example, a packing firm may buy a particular type of vegetable from multiple farms, and then sort the vegetables by size, color, quality, or some other attribute before packing into containers and shipping them to distributors. Multiple distributors may receive the product before its sale to, or use by, the consumer at the POS. Parties in the supply chain may be within the United States or abroad; thus, product might be imported into or exported from any point in the supply

chain one or more times. The fresh produce supply chain may also include processors, who cut the produce into smaller pieces or combine different types of fresh produce to make another product (such as using lettuce to make a bagged salad mix). Even if a contaminated product could be traced back to the processor or through the distributors, the co-mingling, or mixing, of produce before it reaches these points make it difficult or near impossible to distinguish at which point in the supply chain the product became contaminated or from which farm it may have originated. While fresh produce is used in this example, the challenge is not unique to produce.

An additional challenge associated with traceback and traceforward investigations is that the product may not always retain the same description as it moves through the supply chain. Two examples illustrate this; one involved lettuce and the other raw tuna. In an FDA traceback of iceberg lettuce during a cyclosporiasis outbreak in 2013, the lettuce was referred to as “iceberg lettuce” by some firms and as “lettuce liner size 24” by others. In the 2012 *Salmonella* Barielly outbreak, tuna was identified as “tuna ground meat AAA” by one supplier and “frozen yellow fin tuna CO treated” by the next party in the supply chain. Different descriptions for the same product can make it very difficult or impossible to determine whether two records refer to the same or different products or shipments. Currently, there is no efficient way to link the product through the supply chain to determine its source.

Another challenge associated with traceback investigations, especially for fresh produce, is that there may be no identifier on the product, its package, its packing case, or in associated records. Moreover, currently there is no industry-wide or sector-wide standardization of the information captured in documentation. This lack of uniformity in how a product is named, described, transformed, and documented as it moves within a firm and along the supply chain makes it difficult and time-consuming to cross-reference information currently available in product tracing systems. This often results in delays in identifying the point in the supply chain where the contamination occurred and subsequent removal of the product from the marketplace. It may also result in multiple public health advisories alerting consumers to avoid a broader range of products than originally considered a concern.

FDA held two public meetings in 2008 that focused on the challenges associated with traceback investigations for produce. However, it is clear that these challenges are not limited to produce. Changes in consumer preferences and industry practices, and the rising volume of imports continue to pose significant challenges for government regulators. In the past few years, thousands of processed food products have been recalled due to contamination (or potential contamination) of ingredients (e.g., peanuts and peanut-derived products, pistachios, hydrolyzed vegetable protein, and dried milk) with a pathogenic microorganism (e.g., *Salmonella*) or chemical (e.g., melamine).

In 2008, an outbreak of *Salmonella* Typhimurium associated with peanuts and peanut products led to 714 reported illnesses and 9 deaths and resulted in the recall of 3,918 human and pet food products, making it one of the most extensive food recalls in United States history. This outbreak illustrates the complexity of a supply chain involving a

contaminated ingredient and far-reaching public health impact. This situation is not unique. In 2010 alone, there were 31 outbreaks involving ingredients regulated by FDA. These include a *Salmonella* Enteritidis outbreak linked to the use of raw shell eggs in products such as hollandaise sauce, profiteroles, other custard-containing desserts, rattlesnake cake, chili rellenos, tofu pancakes, and Vietnamese sandwiches made with homemade mayonnaise; and a *Salmonella* Montevideo outbreak linked to contaminated red and black pepper used as a post-process spice application on deli meats. These two outbreaks caused 2,211 reported illnesses; approximately 500 million eggs were recalled in response to the outbreak linked to shell eggs; 229 different spice products (over 108,000 pounds) and 1.3 million pounds of salami were recalled in response to the outbreak linked to contaminated pepper used on deli meats. Rapidly determining which ingredient is contaminated and tracing it to its source, and then tracing the contaminated ingredient forward to fully determine the scope of the products containing it so the products and the ingredient can be removed from the marketplace, affords critical public health protection. In the current system, locating and obtaining industry records relied upon to trace ingredients in the supply chain is a rate-limiting step which then results in a slower public health response. In addition, using the current records system is more resource intensive for both government and industry.

One of the deadliest foodborne illness outbreaks in the United States in nearly 90 years occurred in 2011 due to contamination of cantaloupes with *Listeria monocytogenes*, causing 146 illnesses and 30 deaths. Outbreaks such as this underscore the importance of continued improvement in product tracing, which allows FDA and State regulatory officials to identify the source of an outbreak more rapidly, thereby preventing further illnesses and deaths. While the traceback of the cantaloupe contaminated with *Listeria monocytogenes* was rapid, a more efficient tracing system might have required less time. This might have resulted in fewer illnesses and saved more lives from this deadly disease that affects primarily the elderly, immunocompromised individuals, and pregnant women.

Weaknesses in the current system have been identified by the Health and Human Services' Office of the Inspector General (OIG). In a 2009 report, OIG auditors attempted to trace 40 food products from retail sale back to the farm and only five food products were fully traceable. Problems identified in tracing the food by the OIG included failure by firms to maintain lot-specific information and the co-mingling of products from many farms. (OEI-02-06-00210 <http://oig.hhs.gov/oei/reports/oei-02-06-00210.pdf>) Soon after the OIG report was released, the White House Food Safety Working Group announced that "FDA will issue draft guidance on steps the food industry can take to establish product tracing systems to improve our national capacity for detecting the origins of foodborne illness" (July 9, *Obama Administration Delivers on Commitment to Upgrade U.S. Food Safety System* - http://www.whitehouse.gov/the_press_office/Obama-Administration-Delivers-on-Commitment-to-Upgrade-US-Food-Safety-System/).¹

¹ FDA began developing guidance in response to the White House Food Safety Group's recommendation. Shortly thereafter in 2009, Congress introduced food safety bills which included provisions for additional recordkeeping requirements relevant to product tracing. In light of the impending legislation, FDA halted

It is notable that some firms that volunteered to participate in the more recent pilot studies mandated by section 204 of FSMA reported that they never considered how their records would be analyzed together with those of their suppliers to aid in a traceback investigation. These studies found that some participants were surprised by how complex the process is, and expected the experience to be more like a mock recall where they would be provided with a lot number and asked where they shipped the product. The difficulties reported highlight the need for industry education on the traceback investigation process. More importantly, industry itself recognized that there are gaps in their tracking systems and these gaps hamper rapid tracing, and ultimately result in weaknesses in public health protection.

FDA Efforts to Gather Information for Improving Product Tracing

Over the past several years, FDA has initiated several activities to learn more about industry practices that have an impact on the ability to trace products and to identify ways to improve the process. Prior to FSMA and FDA's task order to IFT to conduct the two recent product tracing pilot projects, FDA had, in 2008, issued a task order for IFT to review industry practices for product tracing and identify best practices employed by these sectors involved in the growing, processing and distribution of food products regulated by FDA. Under the direction of FDA, IFT carried out this earlier work.

IFT Findings and Recommendations from 2008 Task Order

IFT collected product tracing-related information from 58 food companies categorized as produce, packaged consumer foods, processed ingredients, distributors, foodservice, retail, and animal feed. In addition, IFT examined non-food industries, including automobile, pharmaceutical, toys, parcel, clothing and appliance firms. In 2009, IFT issued a report to FDA stating that all of the food companies that participated in the study acknowledged the importance of an effective (rapid and precise) product tracing system to safeguard the supply chain. The majority of firms have recordkeeping systems in place that help in their own product tracing efforts. However, IFT found a general lack of consistency in the types of data collected by firms and a lack of consistency in definitions of key terms such as "lot" or "batch." Because there are no standard definitions that would help identify product as it moves along the supply chain, achieving effective product tracing is hindered. Records related to imported products may have an additional source of complexity in that they may be written in a language other than English.

Based on these findings, IFT recommended the establishment of an agreed-upon nomenclature and standard way of expressing the information collected and reported to help ensure consistency. While there are a number of globally recognized standards in many parts of the food industry, IFT reported in 2009 that these standards are not used. As a result, IFT recommended identifying a limited, select set of standards that can be

development of product tracing guidance; the FDA Food Safety Modernization Act was enacted in January 2011 including Section 204, *Enhancing Tracking and Tracing of Food and Recordkeeping*.

used as acceptable ways to communicate information for each data element. Also, IFT's report indicated that firms were concerned about the significant costs of implementing enhanced product tracing efforts, as well as tracking processed products that include a number of different ingredients. Although IFT found that the use of electronic systems was far more efficient than paper-based systems, firms that use only paper-based tracking systems were also concerned about the costs to change to electronic systems.

IFT recommended that certain data elements be made available electronically to FDA by the applicable supply chain partners (from farm to the retail/foodservice outlet) when a traceback investigation is underway. The content of the data elements proposed would ensure that linkages are maintained, thus allowing a product to be traced through the supply chain. These KDEs would include:

- The physical location where the product was last handled, whether or not it was the manufacturer, and, if applicable, contact information for the broker who handled the transaction;
- Incoming lot numbers of the product;
- Amount of product manufactured or shipped;
- The physical location where cases were shipped (including individual retail and foodservice locations);
- The lot number(s) shipped to each location; and
- When (date/time) the product was received and/or shipped.

For producers, processors, repackers, and others who transform products, IFT found that certain information needs to be provided to FDA, including:

- The date and time each lot was manufactured (or harvested);
- The list of all ingredients used in the manufacture of the product;
- Corresponding lot numbers (not item codes);
- The immediate source of the ingredients; and
- The date the items or ingredients were received.

IFT concluded that setting clear objectives for firms in the food supply chain, and allowing the industry to determine how to reach those objectives, was the most appropriate approach to effective product tracing. Firms reported that they saw benefits in making the investment to enhance their tracking systems, including improvements in the management of their supply chain, better control of inventory, and better access to contracts and markets. Firms also reported that a standard system allowed for better targeting of recalls and the ability to respond more quickly and more efficiently when a recall was implemented, ultimately lowering much of the costs incurred by recalls.

Under a separate task order issued by FDA in 2008, IFT conducted a pilot project creating a mock traceback scenario on tomatoes that included representatives of the industry, academia, States, and two technology companies. In this pilot project, tracebacks were expedited by visualizing supply chains to find points of convergence based on the availability of data, how those data are captured, and readiness of information. One of IFT's findings was that consistency in information, data collection, and recordkeeping continue to be key conditions for FDA and the firms to track products.

IFT recommended that the lot number and name of the manufacturing facility should appear on each case of product; and the lot number, quantity of items in the lot or shipment and the shipping location should appear on all invoices and bills of lading.

IFT recommended that each facility that handles a product maintain records of each critical tracking event (CTE) and be able to supply key data elements for all CTEs within 24 hours after a request from FDA. CTEs refer to instances where product is transported or transformed. CTEs may include instances when the product is moved between premises, transformed into another product -- such as slicing a tomato or adding chicken products to a frozen dish -- or some other point in processing when capturing data is necessary for internal tracing of a product. Neglecting to capture appropriate data elements at a CTE will result in a break in the product tracing chain. IFT recommended records should be maintained for two years or the shelf life of the product, whichever is longer.

IFT also recommended that food companies maintain accurate internal traceability processes; for products that are not manipulated (e.g., the packing case is not opened), a one-to-one relationship between incoming and outgoing lots must be maintained. In addition, the ability to trace product should be part of a standard third-party audit so the specific data elements can be correctly captured. The identification of appropriate CTEs and adherence to accurate internal traceability should also be assessed. Furthermore, IFT indicated that a set of required data elements should be established, along with guidance on how those elements would be captured, how the quality of the data collection would be assured and how all of the information collected would remain secure and not violate any confidentiality or proprietary information requirements.

Public Meetings

FDA sponsored two public meetings in 2008 that focused on the challenges associated with traceback investigations for produce. Building on the information obtained during these meetings, the findings and recommendations provided by IFT in their reports resulting from the 2008 task orders, and following the forward direction of the President's Food Safety Working Group, FDA and the USDA Food Safety and Inspection Service (FSIS) held a joint public meeting on December 9-10, 2009, to explore possible elements of an effective product tracing system. The meeting was intended to stimulate a discussion about mechanisms to enhance product tracing systems for all foods. (The *Federal Register* notice of this public meeting published on November 3, 2009 (74 FR 56843) <http://edocket.access.gpo.gov/2009/pdf/E9-26479.pdf>.) The docket for submission of public comments closed on March 3, 2010. Overall, public comments expressed a need for electronic recordkeeping and standardized language to facilitate rapid recalls and more effective traceback investigations. There was also strong support from the majority of presenters for standardized barcode-based, case-level identification to achieve whole chain traceability. Generally, stakeholders agreed that there was a need for efficient traceability enhancement, in addition to increased education regarding safe handling of food.

Results of IFT Product Tracing Pilots under FSMA

Section 204 of FSMA sets the framework for moving forward with establishing a uniform system for the tracking and tracing of foods that FDA designates as high risk. The first step in implementing this section of FSMA was to work with the USDA and State agencies to establish product tracing pilot projects in coordination with the food industry. The purpose of the pilots was to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death.

In September 2011, FDA announced two pilot projects, conducted through an existing contract with IFT, to explore and demonstrate practices, processes and technologies that could be used for the rapid and effective tracing of foods, including types of data that are useful for tracing product, how quickly the data are made available to the FDA, and ways to analyze the data to connect the various points in the supply chain. Additional information gathering, such as costs and benefits, was also a part of the pilot projects.

Scope of the Two Pilots

The two pilot projects were designed to explore and evaluate methods to rapidly and effectively identify a food supply chain associated with a foodborne illness outbreak. A key goal for the pilot projects was to develop the ability to identify a common source or supplier in the supply chain starting at multiple POS.

In the design and implementation of the pilot projects, IFT was to:

- Conduct two pilot projects in coordination with the (1) processed food and (2) produce sectors and in consultation with USDA, State public health agencies, and nongovernmental organizations that represent the interests of consumers;
- Address the diversity of the nation's food supply and the impact of confounding factors such as co-mingling and transshipment;
- Investigate different types of FDA-regulated foods that have been the subject of significant outbreaks between 2005 and 2010;
- Develop and demonstrate methods for rapid and effective tracking and tracing of the selected foods that are practical for facilities of varying sizes, including small businesses;
- Demonstrate the use of appropriate technologies that enhance the tracking and tracing of these selected foods along the supply chain from source to POS;
- Demonstrate the tracking and tracing of a (1) selected processed food and key ingredients (maximum of 2 ingredients) of the processed food and (2) selected fruit and/or vegetable along the supply chain;
- Assess the costs and benefits of the methods for rapid and effective tracking and tracing of the selected foods and key ingredients; and
- Determine the feasibility of such technologies to be adopted by different sectors of the food industry, including small businesses.

Representatives from more than 100 organizations, including State departments of agriculture and public health, the USDA Agricultural Marketing Service (AMS) and FSIS, industry trade associations, not-for-profit organizations, consumer groups, technology solution providers, and a diverse cross section of the food industry, including supply chain partners from farm to POS as well as large and small firms, collaborated with IFT to execute the product tracing pilots.

IFT conducted baseline evaluations to better understand the current state of product tracing and the factors that may delay or enable traceback investigations, and to inform the planning and execution of the pilots. For one study, IFT solicited input from State and federal traceback investigators. IFT's other baseline activity was a case study of a historical investigation for which records were available.

Consistent with the task order, IFT solicited input on the selection of food products for the pilot project scenarios. Shortly after the pilot projects were announced, IFT issued a request for formal input to nearly 700 individuals and organizations, posted the request on the IFT website and used social media outlets to further promote the opportunity for input. Nearly 70 organizations, including third-party technology providers, food industry representatives, trade associations, consumer groups, academics and others responded, either in writing or during one of three public stakeholder input sessions.

As the products were selected, IFT sought individuals with specific subject matter expertise who could provide additional advice as members of the produce or processed food panels. These individuals were selected to aid in the execution of the pilot projects, supplementing the efforts of an oversight panel comprising representatives from industry, government, academia, and a consumer advocacy group.

FSMA criteria served as the foundation for selection of the food products for the two pilot scenarios. Additionally, IFT obtained input from interviews with State and federal investigators and collected detailed information from trade associations and industry members to determine which foods and food products would address the challenges with product tracing as identified through the information gathering process. Based on all of the information and input collected, FDA made the final decision in selecting the three FDA-regulated food products to trace in the pilot projects:

- Tomatoes, both field- and greenhouse-grown, provided to retail and foodservice outlets both whole and sliced, were selected for the produce pilot because they have been involved in significant and repeat outbreaks, are representative of a complex food supply chain, and were identified by most industry associations as a top candidate for the produce-related pilot;
- Frozen Kung Pao-style dishes containing peanut products, red pepper spice, and chicken were selected as representative of processed food because they contain multiple ingredients that have been involved in significant outbreaks, offer a variety of supply chain distribution channels and, like tomatoes, can involve both domestic and import sources. The use of frozen Kung Pao-style dishes also offered an opportunity to collaborate with USDA.

- Jarred peanut butter and two dry, packaged Kung Pao products (peanuts and spice) were also selected because of the limited number of manufacturers of frozen Kung Pao-style dishes, making it necessary to expand the pilot project to include the additional products.

Under the pilot projects, IFT focused on the breadth, depth, and precision of product tracing systems that enable food products to be rapidly linked from multiple POS to a common source in the food continuum. Attention was given to ways in which technology would enhance how regulatory and public health officials receive, and might more rapidly analyze, the data during food related emergencies.

Key Findings

The pilots validated many of the concerns identified in the baseline evaluations that IFT conducted. Despite the differences between the tomato and processed food/ingredient pilots, these two pilot projects found many similarities in the various mock tracebacks. Major findings articulated by IFT in their report to FDA are identified below:

- Major gaps in communication and lack of common vocabulary made it more difficult to perform tracebacks and link information along the supply chain. There was a need for common terminology to be used among industry and regulatory partners to help ensure that the right product information could be identified and properly analyzed throughout the traceback process (e.g., comparisons of distribution information to that from the grower/producer).
- Through the analysis of the documents provided, IFT identified KDEs that were necessary to track and trace the movement of products. Although many of these KDEs were already being captured by some of the pilot participants, there was a lack of a standard structure or format. Use of proper KDEs could increase effectiveness of a tracing investigation.
- Many collaboration platforms, with minimal effort, were able to demonstrate the flow of specific lots of product through the supply chain, and some were able to identify convergence. However, due to inconsistencies in data supplied, some platforms had difficulty in making the proper connections, demonstrating again the need for a more standardized system of recordkeeping requirements.

IFT gathered additional information on the costs and benefits of improved product tracing and on domestic and international practices and initiatives for product tracing. IFT undertook a multi-pronged approach to review the costs and benefits of using various methods for rapid and effective tracking and tracing of foods including those selected in the pilot. This primarily involved conducting a literature review, gathering pilot participants and solution provider estimates, and obtaining non-published data. From the literature review, there were very few studies providing quantitative costs or benefits of product tracing. Instead, the studies described more qualitative characteristics in their observations and analysis.

The literature review and Produce Traceability Initiative case study showed that costs increase as technologies are employed to automate data capture and store information in a way that makes it more accessible. These costs are related to the size of the firm as well as their role in the supply chain. As more product is handled by a firm, there is more information to capture and communicate. Given these factors, there is a wide range of costs for making improvements to track products in the supply chain. Similarly, though more challenging to quantify, there is a range of benefits with varying applicability depending on a firm's role in the supply chain. From the literature review, the greatest benefit was increased public health protection and improved supply chain efficiencies and limited recall scope resulting in cost savings.

Within the context of the pilot studies, IFT identified nine improvement options and asked pilot participants to estimate costs associated with meeting those goals. The first four improvement options involved data capture as part of recordkeeping. The other five options related to the use of standards, communicating data forward to customers, and the use of a summary data sheet. The 22 firms that provided data reported that they had the ability for some form of data capture. The estimated costs for firms participating in the study to achieve the nine designated improvement options for tracing food products ranged from \$40,000 to \$4,500,000. The least costly improvement options involved capturing data by hand or manually converting the data to spreadsheets (\$40,000 – \$350,000), and more costly improvement options, such as capturing data by scanning, were at the higher end of the cost spectrum (\$125,000 – \$4,500,000). In addition to cost estimates, IFT gathered information from pilot participants on the benefits, mostly qualitative, from improved recordkeeping and product tracing capabilities. Benefits identified by participants included improved brand reputation, increased consumer confidence, expanded market availability, improved supply chain management, insurance cost reduction, increased supply chain confidence, decreased spoilage, and process improvements.

To gain more information on the benefits of improved product tracing, IFT examined eight previous foodborne illness outbreaks and analyzed the impact of reducing the time of the traceback to identify the common point in the supply chain where contamination likely occurred. A reduction in time to conduct the traceback is expected to reduce the number of ill individuals in the outbreak. In analyzing these eight previous outbreaks, a range of cost saving from fewer illnesses was estimated from \$18,000 and \$14,000,000.

With respect to current domestic and international practices and initiatives, the pilot projects included visits to industry sectors beyond those selected in the pilots. It was found that the product tracing practices, challenges and concerns for other types of food processors and those handling products other than those evaluated in the pilots were quite similar to those studied in the pilots. Another consistent theme was the need for a global standard for product tracing. There are several industry and government-led initiatives to improve product tracing, many examining similar elements needed in a system to track product along the supply chain.

IFT Recommendations

Based on the findings of these pilot projects, IFT provided ten recommendations to FDA:

1. From an overarching perspective, IFT recommends that FDA establish a uniform set of recordkeeping requirements for all FDA-regulated foods and not permit exemptions to recordkeeping requirements based on risk classification.
2. FDA should require firms that manufacture, process, pack, transport, distribute, receive, hold, or import food to identify and maintain records of CTEs and KDEs as determined by FDA.
3. Each member of the food supply chain should be required to develop, document, and exercise a product tracing plan.
4. FDA should encourage current industry-led initiatives and issue an advance notice of proposed rulemaking or use other similar mechanisms to seek stakeholder input.
5. FDA should clearly and more consistently articulate and communicate to industry the information it needs to conduct product tracing investigations.
6. FDA should develop standardized electronic mechanisms for the reporting and acquiring of CTEs and KDEs during product tracing investigations.
7. FDA should accept summarized CTE and KDE data that are submitted through standardized reporting mechanisms and initiate investigations based on such data.
8. If available, FDA should request more than one level of tracing data.
9. FDA should consider adopting a technology platform that would allow efficient aggregation and analysis of data submitted in response to a request from regulatory officials. The technology platform should be accessible to other regulatory entities.
10. FDA should coordinate traceback investigations and develop response protocols between State and local health and regulatory agencies, using existing commissioning and credentialing processes. In addition, FDA should formalize the use of industry subject matter experts in product tracing investigations.

The full IFT report to FDA, *Pilot Projects for Improving Product Tracing along the Food Supply System – Final Report*, can be found at <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM341810.pdf>.

Public Comment on IFT Recommendations

FDA opened a public docket and requested comments on ten specific questions pertaining to the IFT recommendations. There were 31 comments submitted. Submitters included representatives of industry, solution providers, academia, standard-setting organizations, and wildlife and consumer advocacy groups. The comments submitted were considered in preparing FDA's recommendations to Congress contained in this report.

There was wide support for FDA to adopt the majority of IFT's recommendations. In particular there was wide support for the recommendations requiring firms subject to the final rule, when it issues, to identify and maintain records of CTEs and KDEs, increasing communication and transparency on FDA's information needs in tracing products, improving coordination among federal and State food safety partners, and supporting industry-led efforts to improve tracing. Additionally, there was unanimous support for FDA to adopt a technology platform that enables aggregation and analysis of data resulting in more rapid progress during traceback investigations.

With regard to IFT's recommendation for FDA to require a Food Tracing Plan, the response was mixed, with some comments in favor and some against it; there was a suggestion that this could be incorporated into a Recall Plan. It is worth noting that many comments focused on tracing product forward in the supply chain, such as in a food recall. In contrast, the comments did not address the area where most of the challenges exist - tracing a food back in the supply chain in the setting of a foodborne outbreak. It is possible that commenters are simply more familiar with the traceforward process and understand it better. However, this signals a need for further education on the traceback aspect of product tracing and should be further evaluated by FDA, with appropriate measures taken by the Agency to address this issue (see FDA's recommendations in this report).

Some IFT recommendations were not supported by a majority of the submitters. One of those is that FDA should establish recordkeeping requirements for all FDA-regulated foods and not permit exemptions based on risk classifications. While lacking full support for additional recordkeeping requirements to be applied beyond high-risk foods, several industry groups highlighted the need for them, given how risk may change, the challenges in trying to manage two sets of requirements, and a desire to have a level playing field. At present, in keeping with section 204 of FSMA, FDA only intends to establish additional recordkeeping requirements for foods FDA designates as high-risk. The other recommendation not fully supported is FDA requiring records for more than one tracing level. Industry expressed a willingness to provide these records voluntarily if available and saw the advantage of potentially accelerating the traceback process by providing the additional data.

Other notable themes from the submitted comments included remaining within the confines of the provisions of FSMA, increasing FDA enforcement efforts to comply with existing recordkeeping requirements, and recognizing the limited cost analysis data collected in the pilot study for small- and medium-sized businesses.

FDA Recommendations

FDA's recommendations below are based on IFT's findings and recommendations stemming from the product tracing pilots, on FDA's experience obtained from tracing products in the course of foodborne illness outbreak investigations, and on additional information obtained in the past from stakeholders through pilot projects and public meetings. FDA will continue to evaluate information collected on improving product tracing and any new information as it becomes available. With respect to the recordkeeping requirements for high-risk foods that section 204(d) of FSMA directs the Agency to establish, FDA's approach will be informed by comments it receives during the rulemaking process, as well as by the above information sources.

Below are FDA's recommendations, many of which are already underway. These recommendations should not be interpreted as binding in any way.

Uniform Data Elements – Identify, Track, and Link:

1. FDA should identify a uniform set of data elements to be collected, recorded, and systematically maintained by firms for the purpose of product tracing.
2. The food industry should systematically maintain internal records that link product received, any transformation and/or repackaging of the product, and the outgoing product to the next point in the supply chain. The method of linking the product internally by the firm should be clearly defined and documented by the firm.
3. The food industry should identify ways to improve the accuracy and quality of electronic data submitted to FDA, thereby minimizing the need for FDA and State officials to verify information in-person and/or through additional documents, inventory control, or other in-house systems where product tracing records exist.
4. FDA should consider its regulatory options to establish the KDEs and documents necessary for product tracing, determine the acceptable methods for regulated industry (foreign and domestic) to provide this information when the Agency requests these records, and specify the amount of time firms have to compile and provide this information when requested for tracing high-risk foods.
5. Firms should have a written description of their process for tracking and tracing ingredients and finished products within their establishment that covers at least one step forward and back in the supply chain. This process should be documented in their Food Safety Plan or in another written plan. Both mock traceback and traceforward exercises of ingredients and finished products manufactured, held, or stored should be part of the firm's Food Safety Plan, including a documented recall procedure with internal and external audits.

Collaborations and Building Capacity:

6. FDA should collaborate with industry to develop resources and identify venues for educating firms on the traceback process and information needed by FDA, State, and local government officials to conduct a traceback of a food which has been linked to foodborne illness outbreak.
7. Industry, FDA, USDA, and CDC should explore ways to formalize the use of industry subject matter experts in the preliminary phase of product tracing investigations, within the confines of any relevant laws.
8. FDA should significantly advance the technology it uses to receive and analyze product tracing information and establish such updated technology as part of its standard procedures. This could lead to improved risk-based decision making and make data sharing with States and other Federal agencies more efficient. Additionally, these improvements could allow more focused public messaging and more rapid product source identification and removal from the marketplace.
9. FDA should continue to work with State partners and other competent authorities to ensure more consistent record collection for tracking and tracing of foods.
10. FDA should collaborate with State partners, and with CDC and USDA where applicable, to develop training materials to be used by FDA, State, and local officials to educate staff on standard practices for product tracing in foodborne illness investigations.
11. FDA should continue to work with State and local public health and agriculture agencies to ensure that an adequate number of appropriate officials in those agencies have confidentiality agreements in place with FDA to facilitate the sharing of product tracing information. Additionally, public health professional organizations should conduct outreach to state and local public health and agriculture officials among their membership and educate them on the importance of having confidentiality agreements in place with FDA and the process for establishing them.
12. Industry, both domestic and international, should receive training on tracking and tracing of ingredients and complex foods with emphasis on tracing back a food in the supply chain and submitting key data and documents to state and federal regulatory agencies. Industry should also take part in mock traceback exercises.
13. FDA should explore the use (and training) of third parties to develop standardized materials that third parties will later use to train industry and government officials, both foreign and domestic, on product tracing.
14. The food industry should continue showing strong leadership in improving the product tracing system beyond any minimum national requirement for product tracing. For foods not on the high-risk foods list to be designated by FDA as part of the FSMA section 204 requirements, FDA should encourage industry to enhance product tracing to better track and link the movement of products along the supply chain. Industry efforts should address different size firms, including small businesses, which handle product as well as brokers, encompass the entire spectrum from ingredients to finished complex foods, and embrace best practices.

Additional Items:

15. FDA should review the current process used by firms to submit records to the Reportable Food Registry to see if it can be used for complying with requests by the Agency for product tracing records. In the setting of a foodborne illness outbreak, FDA would prefer, when possible, to receive records electronically to be able to analyze the information more quickly.
16. FDA should gather additional information to gain a better understanding of small and medium firms' product tracing practices, needs, and limitations.
17. Beyond the limitations already identified in this document, FDA should further evaluate whether any potential tracing issues not covered, or limited, by FSMA section 204 should be addressed and whether new laws or changes to existing laws and regulations are needed.

Conclusion

In general, the findings of the pilot studies are consistent with the challenges FDA has experienced in tracing products during food contamination and foodborne outbreak investigations. A strategic combination of education, technology advancements, industry leadership, and establishment of uniform data and record requirements would provide the framework for a future product tracing system that will be more efficient and effective. Establishing a set of key data elements and mechanism to link the data elements among supply chain partners is critical to improving product tracing and affording better public health protection during a foodborne illness outbreak or other food contamination event. The Bioterrorism Act and associated regulations provided initial data requirements upon which to build under FSMA. Additionally, improvements are necessary in the way FDA is able to receive and analyze product tracing data from industry and share with other federal and state partners while assuring protection of non-public information. These changes will enable a more rapid identification of the source of a contaminated product and may allow FDA to better focus its alerts to the public on the specific product that needs to be removed from commerce and lessen the economic impact to industry. Depending on the resources available for implementation, these components would comprise the base system which would be enhanced through collaborative efforts to build capacity, improve upon the consistency with which state and FDA officials conduct trace investigations, and better communicate FDA's information needs for product tracing.

Implementation of all of FDA's recommendations to Congress will be resource-dependent. While many of the recommendations are already underway, FDA will prioritize its efforts. FDA's next steps are to continue information gathering, particularly with regard to small- and medium-sized businesses, and develop a proposed rule using all of the aforementioned information. Concurrently, a draft list of high-risk foods will be developed. As part of the rulemaking process, FDA will solicit public comments and hold three public meetings before issuing a final rule under this section of FSMA.

Once in place, ongoing evaluation of the effectiveness of the product tracing system will be necessary to ensure that FDA can rapidly identify the source of a contaminated food and take appropriate action to prevent further consumption of the product by the public. With greater importation of foods from many countries, consumption of more complex food products, and an abundance of produce year round in the marketplace, new hazards are being discovered and familiar ones continue to occur. FDA remains committed to working with all of our food safety partners to ensure the nation's food supply is safe for human and animal consumption.

Definitions and Abbreviations

AMS – United States Department of Agriculture Agricultural Marketing Service
Bioterrorism Act - Public Health Security and Bioterrorism Preparedness and Response Act of 2002
CDC – Centers for Disease Control and Prevention
CTE – Critical Tracking Event
FDA – United States Food and Drug Administration
FSIS – United States Department of Agriculture Food Safety and Inspection Service
FSMA – United States Food and Drug Administration Food Safety Modernization Act of 2011
IFT – Institute of Food Technologists
KDE – Key Data Element
OIG – Health and Human Services’ Office of the Inspector General
POS – Point of Sale/Service
USDA – United States Department of Agriculture

Information Sources

- White House Food Safety Working Group (July 7, 2009). Obama Administration Delivers on Commitment to Upgrade U.S. Food Safety System. Retrieved from http://www.whitehouse.gov/the_press_office/Obama-Administration-Delivers-on-Commitment-to-Upgrade-US-Food-Safety-System/.
- Food Safety Modernization Act (FSMA) Pub. L. No. 111-353 (2009). Retrieved from <http://www.fda.gov/Food/FoodSafety/FSMA/ucm247548.htm>.
- Food Safety Modernization Act (FSMA), Frequently Asked Questions (2014). Retrieved from <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm#>
- Institute of Food Technologists. (2012). *Pilot Projects for Improving Product Tracing along the Food Supply System*.
- Institute of Food Technologists. (2009). *Traceability in Food Systems: Technical Report* (Vol. 1).
- Institute of Food Technologists. (2009). *Traceability in Food Systems: Economic Report* (Vol. 2).
- Office of Inspector General. (2009). *Traceability in the Food Supply Chain* (DHHS OEI-02-06-00210).
- Product Tracing Systems for Food: Public Meeting, 74 Fed. Reg. 56843(2009).
- Multistate Outbreak of *Salmonella* Typhimurium Infections Linked to Peanut Butter, 2008-2009 (Final Update)
Retrieved from <http://www.cdc.gov/salmonella/typhimurium/update.html>
- Peanut Butter and other Peanut Containing Products Recall List
Retrieved from <http://www.accessdata.fda.gov/scripts/peanutbutterrecall/index.cfm>
- Frequently asked questions and answers: FDA's investigation into the *Salmonella* Enteritidis outbreak involving the recall of shell eggs
Retrieved archived content from <http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm223723.htm>
- Morbidity and Mortality Weekly Report. *Salmonella* Montevideo infections associated with salami products made with contaminated imported black and red pepper --- United States, July 2009--April 2010.
Retrieved from <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5950a3.htm>