Pilot Projects for Improving Product Tracing along the Food Supply System – Final Report

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ABBREVIATIONS

AFFI	American Frozen Food Institute
ANPR	Advance Notice of Proposed Rulemaking
ANSI	American National Standards Institute
AOAC	Association of Analytical Chemists
APHIS	Animal and Plant Health Inspection Service
ARD	Agriculture and Rural Development Department
ASN	Advanced Ship Notice
ASTA	American Spice Trade Association
BMP	Best Management Practices
BOL	Bill(s) of Lading
BRC	British Retail Consortium
BT	Bio Terrorism
CDC	Centers for Disease Control and Prevention
CEO	Chief Executive Officer
CFSAN	Center for Food Safety and Applied Nutrition
COOL	Country of Origin Labeling
CORE	Coordinated Outbreak Response and Evaluation
CPMA	Canadian Produce Marketing Association
CSO	Consumer Safety Officer
CSV	Comma Separated Values
CTEs	Critical Tracking Events
DC	Distribution Center
DOC	Department of Commerce
DSD	Direct Store Delivery
ECO	Eastern Carolina Organics
EDI	Electronic Data Interchange
EPCIS	Electronic Product Code Information Service
ERP	Enterprise Resource Planning
ERS	Economic Research Service
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FAQ	Frequently Asked Questions
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFO	First In First Out
FMI	Food Marketing Institute
FNS	Food and Nutrition Service
FOIA	Freedom of Information Act
FS	Food Service
FSIS	Food Safety and Inspection Service
FSMA	Food Safety Modernization Act
FTE	Full Time Equivalent
GAO	U.S. Government Accountability Office
GAP	Good Agricultural Practices
GDSN	Global Data Synchronization Network
GFSI	Global Food Safety Initiative

GLN	Global Location Number
GMA	Grocery Manufacturers Association
GMI	General Mills Incorporated
GTIN	Global Trade Item Number
HACCP	Hazard Analysis and Critical Control Points
IAFP	International Association for Food Protection
IDDBA	International Dairy, Deli, Bakery Association
IDFA	International Dairy Foods Association
IFDA	International Foodservice Distributors Association
IFMA	International Foodservice Manufacturers Association
IFT	Institute of Food Technologists
ISEO	Institute of Shortening and Edible Oils
ISO	International Organization for Standardization
IT	Information Technology
KDEs	Key Data Elements
LP	Leavitt Partners
mpXML	Meat and Poultry XML
NAICS	North American Industry Classification System
NAPAR	North American Perishable Agricultural Receivers
NCFPD	National Center for Food Protection and Defense
NCSU	North Carolina State University
NFI	National Fisheries Institute
NGFA	National Grain and Feed Association
NOP	National Organic Program
OCR	Optical Character Recognition
OEO	Office of Emergency Operations
OGC	Organically Grown Company
OIG	Office of Inspector General
OMB	Office of Management & Budget
OP	Oversight Panel
OUOD	One Up One Down
PACA	Perishable Agricultural Commodities Act
PB	Peanut Butter
PCA	Peanut Corporation of America
PDF	Portable Document Format
PMA	Produce Marketing Association
PO	Purchase Order
PRP	Prerequisite Programs
PTI	Produce Traceability Initiative
QA	Quality Assurance
RASFF	Rapid Alert System for Food and Feed
RF	Radio Frequency
RFI	Request for Information
RFID	Radio Frequency Identification
RFR	Reportable Food Registry
ROI	Return on Investment
RTE	Ready to Eat
RTI	Research Triangle Institute

SBA	Small Business Administration
SKU	Stock-keeping Unit
SME	Subject Matter Expert
SQF	Safe Quality Food
SSCC	Serial Shipping Container Code
TBD	To Be Determined
TII	Traceability Improvement Initiative
TO	Task Order
UFPA	United Fresh Produce Association
UFPC	Unified Foodservice Purchasing Co-op
UL	Underwriters Laboratories
UN	United Nations
UPC	Universal Product Code
URL	Uniform Resource Locator
USCB	United States Census Bureau
USD	US Dollars
USDA	United States Department of Agriculture
USDA AMS	USDA Agricultural Marketing Service
VAF	Visual Aflavous
WMS	Warehouse Management System
XML	Extensible Markup Language

EXECUTIVE SUMMARY

Introduction

In September 2011, the U.S. Food and Drug Administration (FDA) asked the Institute of Food Technologists (IFT) to execute product tracing pilots as described in Section 204 of the FDA Food Safety Modernization Act (FSMA). IFT collaborated with representatives from more than 100 organizations—including the U.S. Department of Agriculture, state departments of agriculture and public health, industry, consumer groups, and not-for-profit organizations—to implement the pilots. To complete the task, IFT conducted two product tracing pilots of foods (including ingredients) that had been implicated in foodborne illness outbreaks between 2005 and 2010, assessed the costs and benefits of efficient and effective methods for tracking the designated foods, and determined the feasibility of such methodologies (including the use of technology) being adopted by different sectors of the food industry. One food pilot focused on the tracing of chicken, peanuts, and spices in processed foods; the other pilot focused on the tracing of tomatoes.

Objectives

The objectives of the pilot projects were 1) to identify and gather information on methods to improve product tracing of foods in the supply chain, and 2) to explore and evaluate methods to rapidly and effectively identify the recipient 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 or misbranded. It was important the projects reflect the diversity of the food supply and consider confounding factors, such as commingling and transshipment in order to 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. Another important objective was to involve numerous stakeholders throughout the process including the food industry, USDA, multiple state public health agencies, consumer groups, and other governmental agency partners.

Pilot Process

The pilot studies were opt-in and therefore firms who chose to participate were likely forward-leaning and not necessarily representative of the average with respect to their product tracing practices. To meet the timing requirements of FSMA, IFT did not implement any dramatic changes within firms participating in the pilots (e.g., installation of new technologies) but instead evaluated what the current capabilities are within the firms and which technologies are being used. IFT conducted evaluations to determine the impact of currently available technologies, types of data and formats, and the data acquisition process as well as the use of technology on the ability to follow product movement through the supply chain. Before conducting the mock tracebacks in each pilot, IFT spoke to participating firms, either on the phone or during a visit to their facility, to understand their current product tracing systems and practices. Industry experts and state-level traceback investigators worked together to conceptualize the types of situations (scenarios) that would prompt a traceback or traceforward within the pilots. These scenarios were used to request product tracing data from the participating supply chain members during the mock traceback and traceforward investigations.

Key Findings

IFT was successful in conducting 14 mock tracebacks / traceforwards, ranging from simple (e.g., tracing one shipment of tomatoes or one lot code of peanut butter) to complex (e.g., finding convergence when tomatoes were sourced from two different growers; finding a common lot of ingredient between different processed food products manufactured in different facilities). The process of conducting a step-wise product tracing investigation was complicated and often times confusing. Inconsistencies in the terminology, numbering systems, formatting, legibility, and occasionally the language sometimes required IFT to contact the submitting firm to gain clarity, increasing the time required to capture data before any meaningful analysis could begin. However, the pilot participants appeared to have many of the tools and processes in place which are required to allow the capture and communication of critical track and trace information (i.e., Key Data Elements; KDEs) at critical points of product transfer and transformation (i.e., Critical Tracking Events; CTEs). IFT observed that firms provided product tracing data in several ways. Ultimately, the way in which data were readily accessed and transmitted to IFT was dependent on the systems and processes in place within a firm to capture, store, and report this information.

Recommendations

Upon completion of the task, IFT determined that costs associated with implementing a product tracing system can vary widely as determined by numerous factors: the size of the firm/facility, the method of product tracing already in use (i.e., manual or electronic), and the range of each firm's capabilities to implement or improve its product tracing system, to name a few. Nevertheless, IFT is confident that a product tracing system incorporating its recommendations would greatly benefit the FDA as well as other state and federal partners, the food industry, and consumers. The recommendations are as follows:

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.

Conclusion

In summary, IFT found that there are several areas (such as uniformity and standardization, improved recordkeeping, enhanced planning and preparedness, better coordination and communication, and the use of technology) in which industry improvements and enhancements to FDA's processes would enable tracebacks and traceforwards to occur more rapidly. There was a range of costs associated with improving product tracing capabilities for certain sectors of the industry based on the specific technologies used to achieve the data capture and communication objectives. Case studies demonstrated the range of public health benefits from reduction in illnesses from improved product tracing. The recommendations outlined in this final report will enable FDA to conduct more rapid and effective investigations during foodborne illness outbreaks and other product tracing investigations, significantly enhancing protection of public health.

EXECUTIVE BRIEF

In September, 2011, the U.S. Food and Drug Administration (FDA) charged the Institute of Food Technologists (IFT) to coordinate and conduct the product tracing pilots required by Section 204 of the FDA Food Safety Modernization Act (FSMA), including an evaluation of costs and benefits to industry and consumers.

Representatives from more than 100 organizations, including state departments of agriculture and public health, the U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) and Food Safety Inspection Service (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 point of sale/service as well as large and small firms, collaborated with IFT to execute product tracing pilots for three ingredients (chicken, peanuts, and crushed red pepper) used in the production of four multi-ingredient processed food products (two dry and one frozen Kung Pao chicken products, and peanut butter) as well as tomatoes (both whole and sliced).

Background and Task Requirements

In the continuum of an outbreak—from the time a person becomes ill to the time that product has been removed from the distribution system—there are several points in the product tracing and recall processes where improvements can have positive and meaningful impacts on public health. This task primarily focused on traceback investigations. Tracebacks can occur when one or more foods (including ingredients) are suspected of being a potential health risk and there is a need to determine the path of a product through the supply chain. A traceback investigation generally involves documenting the distribution paths of products from several locations to determine if there is a common point of convergence in the supply chain - for example, a common date and location of harvest or place of manufacture. Determination of a convergence point is critical to the next step in conducting a source investigation to determine how the contamination occured in order to prevent future illnesses. A traceforward investigation, explored in this task but to a lesser extent than traceback investigations, follows the distribution path of a product from the point of convergence towards its point of consumption, including through manufacturing, distribution, retail and foodservice. During a traceback investigation, the key question is “What do these products have in common: a lot number, common date at the same location, etc.?” When that information is known, the key question in a traceforward is “Where did these specific products (defined by lot numbers, production dates, etc.) go?” These investigations often occur after some or all of the product has exited the supply chain, thus the investigations are heavily dependent on residual records.

Tracebacks and traceforwards rely primarily on recordkeeping. Current recordkeeping requirements stem, in part, from the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the BT Act; US Congress 2002). Requirements based on the BT Act include having firms know who they received products from and to whom they were sent, commonly referred to as one up - one down tracing; however some supply chain members, such as restaurants and farms, are exempt. The specific types of information required to be kept is dependent on the role of the firm in the supply chain. When a product is transformed, the regulations resulting from the BT Act state that lot numbers, if available, be used to link incoming ingredients to outgoing products (FDA 2004).

For the purpose of this task, IFT was required to:

- conduct two food product tracing pilot projects in coordination with the (1) processed food - ingredient and (2) produce sectors and in consultation with the U.S. Department of Agriculture, state public health agencies, and nongovernmental organizations that represent the interests of consumers;
- reflect the diversity of the food supply and consider / address confounding factors, such as commingling and trans-shipment;
- include at least two 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 these selected foods that are practical for facilities of varying sizes, including small businesses;
- demonstrate appropriate technologies that enhance the tracking and tracing of these selected foods along the supply chain from source to points of service;
- demonstrate the tracking and tracing of a (1) selected processed food and its key ingredients (minimum of two ingredients) 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.

Stakeholder Input

IFT solicited industry, government, consumer advocates and other stakeholders for input on the selection of food products and participation within the two pilots. Input was sought in a variety of ways:

- three stakeholder input sessions, held in the fall of 2011
- written comments, invited through December 1, 2011
- information from technology providers, who were asked to share how their technologies could improve product tracing
- presentations and webinars (at 24 venues), which included substantial time for questions and comments

IFT disseminated a request for formal input and publicized the three stakeholder input sessions through a variety of outreach mechanisms, including posting the request on the IFT website, emailing all individuals who had previously expressed interest in IFT's product tracing work (approximately 700 contacts), and using social media outlets. Nearly 70 organizations, including third party technology providers, food industry representatives, trade associations, consumer groups, academicians, and others responded, either in writing or at one of three public stakeholder input sessions.

Later, IFT advertised the opportunity for technology providers to serve as "collaboration platforms." Recognizing the multitude of technologies available to assist firms or regulators in tracing products, IFT also solicited input regarding additional technologies in existence or in development that enhance the ability to track and trace foods.

Determining the Current Baseline

In order to identify and quantify product tracing improvement opportunities, it was necessary to develop a clear sense of the current processes used during traceback investigations and document any obstacles (and enablers) to effective product tracing. IFT spoke to numerous state-level traceback investigators, epidemiologists, and representatives from USDA FSIS and FDA. Each individual shared their thoughts and experiences and several themes emerged. It was clear that the amount of epidemiological information, and the confidence in that information, played a notable role in the distinction between "easy" and "difficult" tracebacks.

Product Tracing Pilots

Process

To meet the requirements of FSMA, IFT did not implement any dramatic changes within firms participating in the pilots (e.g., installation of new technologies) but instead evaluated what the current capabilities are within the firms and which technologies are being used. Specifically, IFT sought to engage a diverse group of pilot participants in order to conduct the following evaluations:

- determine how currently available technologies impact their ability to respond in a timely manner to track and trace data requests in a way that facilitates the ability to analyze the reported data
- evaluate the types of data needed to follow a product forwards or backwards through the supply chain, including movement within a single facility, as well as the data needed to link product shipped and received between trading partners
- compare how the reporting format or presentation of data impact the ease with which track and trace information can be analyzed by evaluating the usefulness of data provided in native form (e.g., Bills of Lading [BOL], Purchase Orders [POs], etc.) versus standardized, summary-level data templates
- assess how the data acquisition processes impact the time needed to conduct a traceback by comparing the manual approach currently in use against the use of a collaborative platform.
- examine how technology can be used by investigators to more readily identify convergence and other insightful or actionable patterns within the track and trace data

IFT considered stakeholder input and the requirements of FSMA when presenting FDA with recommendations for the types of foods that would be good candidates for the pilot projects. Ultimately, FDA determined that IFT should evaluate the tomato supply chain in the produce pilot. Ingredients were a key focus for the processed food pilot, and given the range of recent outbreaks and recalls associated with nuts (including peanuts) and spices, FDA tasked IFT with conducting the pilot with products that contained these ingredients. Further, FSMA requires FDA to collaborate with USDA FSIS. FDA asked IFT to determine the feasibility of working with several food ingredients, including chicken, in the pilots. Frozen or dried Kung Pao chicken (containing one or more of the following ingredients: peanuts, spices, and chicken) was identified by FDA as the best candidate for the processed food - ingredients pilot. While efforts were underway to identify participants for the pilot studies, IFT was approached by a peanut butter manufacturer who sells both private-label and branded peanut butter. FDA agreed that this product was also a suitable candidate for the processed food - ingredient pilot.

In total, the two separate pilots included the following:

- 5 tomato growers (United States and Mexico)
- 7 tomato re-packers
- 3 tomato processors (sliced tomatoes)
- 15 distributors (12 in the tomato and 3 in the processed food - ingredients pilots)
- 5 retailers (4 in the tomato and 3 in the processed food - ingredients pilots)
- 2 foodservice chains (both with multiple locations; both in tomato pilots)
- 3 processed food manufacturers
- 4 ingredient suppliers
- 1 importer

Before conducting the mock tracebacks, IFT spoke to each participating firm, either on the phone or during a visit to their facility, to understand their current product tracing systems and practices. This information was later linked to the performance in the mock tracebacks, and was also used to inform the cost evaluation component of the task. Since the pilot studies were opt-in, firms who chose to participate were likely forward-leaning and not necessarily representative of the average with respect to their product tracing practices. Other limitations and assumptions are discussed in Chapter 8.

Two teams of individuals, including industry experts and state-level traceback investigators, and in the case of the processed food - ingredient pilot USDA FSIS, worked together to conceptualize the types of situations that would prompt a traceback or traceforward. Given the potential for a brand and label to be associated with processed food products at retail, the team working on that pilot determined that the four pilot scenarios should be constructed to vary the nature of the information provided at the beginning of the mock traceback. Accordingly, the timeframes for which records were requested also varied (ranging from asking for information on a specific lot to product produced during the course of a 10-month timeframe).

Given the multitude of participants in the tomato pilot, and the known diversity in product tracing practices and processes within similar portions of the supply chain, it was determined that each of the twelve scenarios executed through the mock tracebacks should be based upon a similar “story”. Depending on the exact scenario, participants at the retail and foodservice points in the supply chain (where most of the requests began) were generally asked for records covering a one- to five-week timeframe. Eight of the scenarios were conducted as multi-step tracebacks, beginning with restaurants or retail outlets, and following the paths backwards through the supply chain, based on the pre-existing relationships between trading partners. However, there were four participants in the tomato pilots who were not linked to other pilot participants. These firms—two re-packers and two wholesalers—were each asked to trace one shipment of tomatoes forwards and backwards within their own operations. While these four scenarios were not like typical tracebacks, they did allow IFT to assess the technologies and processes used by these firms, of which some were small businesses.

IFT developed summary response templates based on previous work, which expanded on the concepts for Critical Tracking Events (CTEs) and Key Data Elements (KDEs) that IFT developed in 2009 (McEntire and others 2010). The use of the summary templates was optional. Firms were asked to provide the information they deemed necessary to respond to the IFT request. Each participant and their supply chain was evaluated on the basis of a number of factors:

- **breadth and precision**: the amount, nature, quality, and accuracy of information provided
- **access**: a combination of the following factors:
    - **total time**: cumulative supply chain and individual firm response times
    - **minimum time**: time before convergence was found (or the trace was otherwise ended)
    - **analysis time**: time needed by IFT to understand and analyze participant-provided data
- **depth**: a firm's ability to readily provide information for more than one supplier back in their supply chain (whether they themselves had the information or could readily acquire it)
- **system ranking**: the sum of a firm's self-reported abilities, including the technologies currently in use by the firm that enable them to link incoming and outgoing product and their reported ability to meet nine options for improved product tracing (described below in the next section)
- **quantity**: total number of pages of documents provided
- **format**: use of IFT-supplied or company-generated summary document

Collaboration Platforms and Other Uses of Technology

Key to this task was the exploration of how technology can be used by investigators to enhance the speed, effectiveness, and accuracy of the product tracing process. Additionally, IFT also conducted a qualitative study of industry's use of technology to improve product tracing capabilities.

IFT was tasked with using a "collaboration platform" for the mock tracebacks involving ingredients and processed foods, and opted to use similar platforms for select mock tomato tracebacks. Because the term "collaboration platform" was not defined in the task, this was one area around which IFT solicited stakeholder input. Ultimately, the "collaboration platform" functioned as more of a data analysis system, which could be used by FDA (or other regulators) to share and analyze data collected from industry. Collaboration platforms were not used in this task by food industry members to submit data. Instead, industry data was collected by IFT through these pilots. IFT in turn blinded and supplied these data to the collaboration platform providers. These collaboration platforms were then used to query the data to look for convergence and conduct tracebacks.

A transparent process was used to broadly solicit input on how the collaboration platforms should be selected. Ultimately, nine firms that currently offer commercially available track and trace solutions participated in the evaluation process. During the evaluation, roughly half the firms received identical data sets for the tomato pilot and the other half received data for the ingredients and processed foods pilot. The names of the supply chain participants were blinded before being shared with the collaboration platform providers (identified only generically as "Distributor 7," for example). The data were provided to the collaboration platform providers in the same format that IFT received them from the pilot supply chain participants (e.g., in PDFs, spreadsheets).

After uploading the data, all nine collaboration platform providers explained their approach and demonstrated their systems, using the provided pilot data, for a broad panel that included FDA, pilot participants, and other Subject Matter Experts. The goal of the demonstrations was not to select one provider; rather it was to observe capabilities that seemed to improve the speed and accuracy of traceback investigations.

MOCK TRACEBACK RESULTS

IFT was successful in conducting 14 mock tracebacks, ranging from simple (e.g., tracing one shipment of tomatoes or one lot code of peanut butter) to complex (e.g., finding convergence when tomatoes were thought to be sourced from two different growers; finding a common lot of ingredient between different processed food products manufactured in different locations). Traceforwards were also explored as elements of some of the scenarios, however when firms provided information on the recipients of one or more lots of product, the lists were often lengthy and the majority of recipients were not pilot participants which caused the traceforward to end.

The process of conducting a step-wise traceback (one supply chain node at a time) was complicated and often times confusing. Most firms provided information in the form of PDF documents. While information in this format can be transmitted electronically via email, the information is image-based and cannot be manipulated electronically, which makes analysis of data slow and potentially error prone as data must be re-entered or extracted via optical character recognition for software analysis. Additionally, inconsistencies in the terminology, numbering systems, formatting, legibility, and occasionally the language sometimes required IFT to contact the submitting firm to gain clarity, increasing the time required to capture data before any meaningful analysis could begin. In many instances, firms provided a document to explain how the numerous documents and reports (in some cases, scores of pages) were linked together to demonstrate how the product moved through the facility. This was extremely helpful, as was the use of summary documents. While there were occasional errors in the summary documents, they provided an "at a glance" means to better understand the information provided in the detailed source documentation.

Most notably, IFT found that some participating firms were surprised by the process used, and expected an experience more like a mock recall in which they would be provided with a lot number and asked to identify where the product was sent. Many had never considered how their records would need to be pieced together with those of their supply chain partners to facilitate an effective traceback.

Challenges aside, the pilot participants appeared to have many of the tools and processes in place which are required to allow the capture and communication of critical track and trace data (i.e., KDEs) at critical points of product transfer and transformation (i.e., CTEs). Many of the collaboration platforms were able to demonstrate the flow of specific lots of product through the supply chain with minimal effort, and some were able to identify convergence. However, while querying occurred within seconds, the collaboration platform providers reported spending between 3 - 7 days uploading the data into their systems due to the lack of a standard structure or format and the need to re-enter data.

Based on the discussions with the pilot participants and other industry stakeholders, IFT observed that firms provided track and trace data in several ways. Ultimately, the way in which data were readily accessed and transmitted to IFT was dependent on the systems and processes in place within a firm to capture, store, and report this information.

IFT identified nine specific processes firms could use to improve product tracing. The first four options revolve around data capture. IFT believes that capture of the right data, regardless of format, is a prerequisite to any substantial improvements in product tracing. Thus, the first four options explore different ways that the same data could be captured to account for what is practicable for facilities of varying sizes, including small businesses. For reasons described below, the KDEs included in the options presented to pilot participants did not include lot/batch number.

The first four options (for which questions were asked around current capabilities and costs) were:

- capture KDEs (Supplier ID, Product ID, Purchase Order Number, Quantity-pack size, Receipt Date) by **writing on paper**
- capture KDEs (Supplier ID, Product ID, Purchase Order Number, Quantity-pack size, Receipt Date) by **writing on paper and later entering into a database/spreadsheet**
- capture KDEs (Supplier ID, Product ID, Purchase Order Number, Quantity-pack size, Receipt Date) by **scanning labels**
- capture KDEs (Supplier ID, Product ID, Purchase Order Number, Quantity-pack size, Receipt Date) by **electronic message**

IFT observed that some segments of the distribution chain did not generally record the grower/producer-assigned lot number. Distributors, for example, are not required to record this information and those who manufacture, process or pack food are required to record lot numbers only if the information exists (FDA 2004). Therefore, as noted above, lot/batch number was not included as a data element in the four options above, but was treated as its own question. The remaining five options related to the use of standards, communicating data forward to customers, and the use of a summary data sheet. They included a firm's ability to:

- capture incoming quantity by received lot number, assuming a lot number is provided
- link incoming and outgoing product, whether there is transformation (e.g., ingredients into a finished product) or not (e.g., relating lot numbers received to lot numbers shipped)
- use non-proprietary standards (e.g., Global Trade Item Number [GTIN], Global Location Number [GLN], state-issued plant/registration number)
- send KDEs electronically to customers
- provide a data summary sheet (or template such as that provided by IFT) that highlights the links between KDEs for the products of interest

Costs

To conduct the in-depth assessment of the costs associated with product tracing, IFT conducted a literature review and sought information from pilot participants and others (e.g., technology providers, companies, and organizations) that generally was not published.

A literature review was conducted to analyze previously published studies on the costs and benefits of improving recordkeeping and product tracing capabilities. However, there were very few studies that published quantitative costs or benefits. Instead, they described more qualitative characteristics in their observations and analysis. For example, the costs associated with improvements include fixed and variable costs, like capital equipment, software, consulting, design and implementation, training, labor, materials and impact on speed of business operations. The qualitative benefits associated with improvements include protection of public health, improved trade, sustainability tracking, limited recall scope, increased market access, quality assurance and supply chain efficiencies. Due to the limited availability of published studies, IFT collected additional data through the use of non-peer reviewed case studies and white papers including data from technology solution providers and standards organizations. Several non-peer reviewed studies, some of which are tied to implementing bar code systems in produce, show that there are a range of capabilities and associated costs and benefits to the firm by implementing or improving a firm's product tracing system.

In addition, Deloitte Consulting worked with the pilot participants to determine costs associated with the nine identified options, as well as the types of benefits that firms had realized from their investments. Pilot participants were asked to indicate whether they had systems and processes in place

to perform any of the nine activities listed above (as options), and for any activity not already in place to provide an estimate of the resources needed and cost required to attain the goal.

In terms of the costs needed to implement the nine options identified above, the 22 firms who provided data reported the ability for some form of data capture. For those capturing data by hand or who had invested to convert manually captured data to spreadsheets, the cost of this capability ranged between $40 - $350K. In contrast, capturing the same types of data, but doing it by scanning (e.g., a bar code) was reported to be roughly an order of magnitude more expensive, ranging between $125K- $4.5M. This is consistent with the experience reported by firms implementing PTI (which requires the use of GS1 128 bar codes); the reported range of costs was generally from several hundred thousand to a few million dollars. Further, these ranges reflect all business sizes and supply chain segments; full details are provided in Chapter 7 of this report.

Many firms reported the ability to capture incoming lot numbers (assuming they were provided), however, the pilot demonstrated that even if this capability exists, it is more likely to be used by processors, especially of multi-ingredient products, compared to others in the supply chain. Therefore, while the estimate to reach this capability ranged from $0-$150K, IFT expects that implementation of this practice would be more costly, although a focused effort would be required to quantify these costs.

Of all the options presented, the development of a data summary, whereby industry would present the KDEs in a logical fashion that illustrates the internal and external links, was deemed the easiest to achieve in terms of expenditures. Firms generally reported this capability, and where resources were required, they were never reported to be in excess of $10K annually.

Benefits

To assess the benefits associated with improved product tracing, IFT conducted a literature review, evaluated eight case studies of previous outbreaks and sought information from pilot and non-pilot participants. The benefits associated with improved recordkeeping and therefore improved product tracing, fall into three general categories:

- **Benefits to the FDA**. FDA expends resources during an investigation that can presumably be decreased if investigations could be conducted more rapidly and with less manual manipulation and analysis of trace data. IFT did not quantify the resources used by FDA in investigations to ascertain the extent of the benefit.
- **Benefits to public health**. Protecting public health is the key goal of an improved product tracing system. To quantify the benefits to public health, IFT examined eight previous outbreak investigations. The duration of the traceback investigation and the illnesses that occurred during this timeframe were determined. Working with Deloitte Consulting, IFT translated the number of illnesses into costs using existing government figures. The cost savings (driven by reductions in illness) resulting from reducing traceback duration by 25, 50, and 75% were calculated. The range of the public health benefit per outbreak spanned $18K to $14M depending on the characteristics of the outbreak.
- **Benefits to the industry**. Quantifying the benefits to a particular firm is completely dependent on the way a firm chooses to meet the required track and trace objectives and was therefore difficult to calculate. The literature and non-peer reviewed information was either qualitative or demonstrated the benefits of a very specific system. The types of benefits described by pilot participants were consistent with those suggested in the published literature. Table 1 identifies areas of benefit which were reported by the pilot participants and illustrates how these benefits varied depending on a firm's location in the supply chain.

Table 1. Benefits of Recordkeeping Identified by % Pilot Participants

Recordkeeping Benefits	Growers (n=2)	Processor (n=6)	Distributors (n=8)	Retailers (n=4)
Improved Brand Reputation	100%	33%	62%	50%
Increased Consumer Confidence	0%	67%	75%	25%
Expanded Markets	50%	33%	50%	25%
Improved Supply Chain Management	50%	67%	62%	100%
Insurance Cost Reduction	50%	33%	12%	0%
Supply Chain Confidence	0%	83%	75%	25%
Decreased Spoilage	50%	67%	75%	25%
Process Improvement	100%	33%	100%	100%

*If the response to an individual benefit was left blank, it was treated as a "does not identify this benefit" answer in the calculations above. (Percent of Pilot Participants Identifying the Recordkeeping Benefit

It was noted that many of the tangible benefits to industry of recordkeeping could potentially be enabled through process and technology improvements that may or may not also enable product tracing. It is unclear if the identified tangible benefits can be fully captured by all industry participants and whether these benefits will be sufficient to cover the investment required for improving product tracing. Therefore, recognition of public health benefits is critical.

Current Product Tracing Landscape: Domestic and Global

There are a number of industry initiatives and availability of implementation guidelines that aid in the adoption of uniform product tracing practices in select segments of the food industry. Additionally, there are a number of global factors in play (like trade agreements, global sourcing of foods, and cross-boundary harmonization of standards) that should be considered when the approaches to product tracing are considered.

In the United States, the produce, meat and poultry, foodservice, and seafood industries have developed and published guides for their industries, and the dairy, deli, and bakery industries are currently working to develop similar guidelines.

"Traceability" is a requirement of the Global Food Safety Initiative, a concept with growing recognition from which audit schemes are developed. Underwriters Laboratories is also developing an audit standard for product tracing. Additionally, both ISO and Codex Alimentarius have produced standards for product tracing.

Recommendations

The pilots demonstrated some of the challenges that FDA has in achieving its goal of being both fast and accurate when conducting traceback investigations. However, the pilots also demonstrated areas in which improvements can be implemented to reduce traceback time and ensure the accuracy of information.

IFT has one overarching recommendation to improve product tracing, two recommendations for FDA to consider during the rule making process, and seven additional recommendations. While these recommendations are actions FDA can take, those in the food supply chain should view these recommendations in the context of the nature of improvements that may be expected of them.

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. Further, FDA should issue guidance documents defining these requirements.**

IFT anticipates that confusion and difficulty would arise if there were two different recordkeeping requirements for firms based on the risk classification of the food that they produce, distribute or sell. It is widely recognized that several foods and ingredients previously identified as "low-risk" have been associated with recent outbreaks. If additional recordkeeping were required for only "high-risk" foods, FDA may ultimately be involved in investigating outbreaks associated with "non-high-risk" foods. Additionally, it is noteworthy that high-risk ingredients may be used in lower risk products, and vice versa.

Moreover, the definition of "high-risk" may change with time as a result of future outbreaks or other circumstances, and it would be difficult for "low-risk" firms to quickly comply with new regulations if one or more of the products that they produce or handle were suddenly reclassified as "high-risk." Thus, IFT recommends that FDA establish a single set of recordkeeping requirements.

Further, IFT recommends that FDA create guidance or educational programs specifically for small businesses including produce terminal market vendors, growers, egg producers, manufacturers, distributors, wholesalers, independent retail stores, and farmers markets to facilitate the understanding and adoption of effective product tracing practices.

2. **With regard to future rulemaking, IFT recommends that FDA require firms who manufacture, process, pack, transport, distribute, receive, hold, or import food to identify and maintain CTE and corresponding KDE-related records as defined by FDA based on input from the food industry.**

FDA should require companies involved in the food supply chain to capture and maintain internal trace records based on the IFT recommended CTE and KDE framework described below. This framework provides information on the what, where, and when with respect to food products that traverse the supply chain.

The clear definition of CTEs and KDEs, along with guidance to facilitate understanding and implementation, will allow individual supply chain companies to correctly identify the CTEs that they are responsible for and ensure that KDEs for each CTE are captured and available for reporting as needed based on a specific request from regulatory officials.

The recommended KDEs are defined in the accompanying glossary; many are already part of the requirements based on the BT Act and the implementing regulations codified at 21 CFR Part 1, Subpart J (FDA 2004). The bottom half of the table (linking KDE's) represents the CTEs that IFT feels should be captured in order to establish the links needed to trace product movement through the supply chain.

One data element that is of particular relevance and is not required by current regulation is an "Activity ID" which is an identifier associated with an "Activity Type" such as a Purchase Order or invoice number that can be used to link products between supply chain partners. Another type of Activity ID is a specific Work Order, which links ingredients with finished products. The pilot showed that Activity IDs were a key piece of information used to follow the path a product takes through the supply chain.

Table 2 illustrates the data elements that IFT believes are key to tracking and tracing the movement of food. There are various points in a supply chain, termed Critical Tracking Events, where data capture is necessary to follow product movement. These include shipping from one facility to another (Transport), receipt at another facility (Transport), and changes that occur as products are manufactured or transformed during processing (Transformation). Traceforward requires an accounting of all suspect products, therefore it is important for firms to also record the ways in which products exit the supply chain through depletion events (Depletion). The table below is a mixture of elements that stemmed from the BT Act implementing regulations and some that are not currently required (FDA 2004). Thus the table does not reflect the overall current state of requirements but reflects IFT's recommendation to FDA regarding the Key Data Elements that FDA should require or encourage at each Critical Tracking Event, as well as those that may be required depending on the circumstances and their applicability (termed Conditional).

Table 2. Requirements and Best Practice CTEs and KDEs for Improved Recordkeeping

CTEs	Transportation (exchange of goods) - Shipping	Transportation (exchange of goods) - Receiving	Transformation (creation / manipulation of products) – Input	Transformation (creation/manipulation of products) – Output	Depletion (exit from system) – Consumption	Depletion (exit from system) – Disposal
Currently Required KDEs						
Event Owner (firm submitting information)	R	R	R	R	R	R
Date/ Time	R	R	R	R	R	R
Event Location	R	R	R	R	R	R
Trading Partner [1]	R	R	R			
Item (the good)	R	R	R	R	R	R
Lot/Batch/Serial#	BP*	BP*	R	R	BP	BP
Quantity	R	R	R	R	R	R
Unit of Measure	R	R	R	R	R	R
Linking KDEs						
Activity Type (e.g., PO, BOL, Work Order)	C*	C*	R	R		
Activity ID (number associated with PO, BOL, Work Order)	C*	C*	R	R		
Transfer Type[2]	C	C				
Transfer Number[2]	C	C				
Lot/Batch Relevant Date[3]	C	C	C	C	BP	BP
Carrier ID	C	C				
Trailer Number	C	C				

R = Required Field

C = Conditional Field; the need for this field would be determined by business circumstances, and in the instance of transport events that do not capture batch/lot numbers, this field may be required (*)

BP = Best practice is to capture the batch/lot number or relevant date whenever possible; however, in recognizing the current difficulty in capturing this information for transport and depletion events, Activity ID or other KDEs that provide links, as identified in the table, must be provided (*) as the industry prepares to meet a future requirement to capture lot/batch numbers

[1] In the event of a shipping CTE, the trading partner is the immediate subsequent recipient of the shipment; in the event of a receiving CTE, the trading partner is the immediate previous supplier of the product; in the event of a transformation CTE, the trading partner is the supplier of the input into the transformation

[2] If the Activity Type and ID are not linked to a particular shipment of a product (e.g., a purchase order that is fulfilled by multiple shipments over time), then the Transfer Type and ID are used to indicate the particular shipments that are linked to the Activity Type and ID

[3] If there is a different lot/batch designation on a consumer-level product, such as a “best by” date, it must link to the manufacturer-assigned lot number

Because there are a number of barriers to implementing in the near term the capture of batch/lot/serial numbers for all depletion and transport events, initially the capture and reporting of these data for these events should be encouraged as a best practice and the Activity ID and Type should be required to be recorded. The pilot showed that Activity IDs could be used to trace products if a firm maintained good internal tracing (i.e., the ability to link incoming shipments with outgoing shipments), although not quite as accurately as if batch/lot numbers were captured throughout the supply chain. However, using Activity IDs to trace products results in much more data (compared to using batch/lot/serial numbers) and, thus, is only efficient when used in conjunction with a collaboration platform by the regulators (see recommendation 9 below). Further, following products through a string of Activity IDs obfuscates the manufacturer- (or other transformer-) assigned lot numbers until they are revealed by the manufacturer (or transformer). Clearly, capturing lot numbers along the supply chain would provide investigators with instant access to the lot numbers assigned at the most recent transformation event. For these reasons, IFT recommends that FDA consult with the industry and then establish a reasonable effective date when the capture and reporting of the batch/lot/serial number (or equivalent) will be required for all CTEs.

3. **Also in regards to rulemaking, IFT recommends that FDA require each member of the food supply chain to develop, document, and exercise a product tracing plan.**

Having a "Product Tracing Plan" at each facility in the food system, from farm to food manufacturing facility to retail/foodservice establishments, will improve communication between the industry and regulatory agencies, raise awareness of the responsibilities of the industry during an investigation, and catalyze more effective traceback and traceforward (recall) investigations. The development and documentation of a company Product Tracing Plan and regular exercising of the plan will increase the speed with which a firm can respond to an investigation and reduce the likelihood of errors. Firms should expect their plan to be reviewed by regulatory agencies upon request, including during an inspection.

4. **FDA should encourage and support existing industry-led initiatives for the development of implementation guidelines and should seek stakeholder input by issuing an Advance Notice of Proposed Rulemaking (ANPR) or using other input mechanisms**

As in IFT's previous report to FDA on product tracing (McEntire and others 2010), IFT maintains that FDA should not prescribe the specific means that industry uses to meet the FDA objectives recommended by IFT. Several industry groups have begun identifying ways in which the industry can improve product tracing capabilities, and FDA should support these efforts. IFT believes that FDA's support for these industry-led implementation initiatives will enable real-world adoption of improved product tracing capability at a more rapid pace than would otherwise be possible and avoid costly and time-consuming company and industry level "resets" that would result from disruption of these initiatives.

Through an ANPR or other input mechanisms, FDA can seek targeted input, and provide an opportunity for the food industry to show how the steps that certain industry segments have proposed can meet FDA's objectives of more rapid and effective tracebacks.

5. **FDA should clearly and more consistently articulate and communicate to industry the information needed during a product tracing investigation.**

IFT encourages FDA to provide context to a request for product tracing records to help the food industry in determining the appropriate records that contain information that may aid in an investigation. For example, the investigator might consider explaining whether a sample of a product tested positive for an adulterant or an epidemiological investigation identified the product as a potential suspect vehicle. This may enable the firm to identify records or other types of information of which FDA might not have been aware.

Individual firms should be responsible for identifying the appropriate records that provide internal and external linking information, and investigators should clearly request the specific pieces of information (e.g., supplier names, lot numbers) that are necessary for the investigation to proceed (as opposed to the specific types of documents, such as invoices, and Bills of Lading that may or may not contain all the needed information).

Additionally, IFT believes that industry would respond positively to an investigation if they were able to participate as a partner with a role in protecting public health as opposed to a suspect in an investigation.

6. FDA should develop standardized, structured, and electronic mechanisms for industry to provide the Agency CTE and KDE product tracing data when requested during a specific food safety investigation.

The pilot findings confirm that standardized, structured, and electronic reporting of CTEs and KDEs increases the speed by which product trace data can be collected, compiled and analyzed, and indicate that any structured reporting templates will need to vary based on the needs of specific industry segments (e.g., grower, supplier/packer, distributor, foodservice operator and retailer), and possibly commodity categories (e.g., seafood, produce).

In accordance with provisions in FSMA, IFT also recommends that firms be allowed to maintain their internal records using the systems and processes currently in place, including paper-based recordkeeping systems. IFT recommends that these records only be required to be transposed to the standardized and structured reporting format when data are being requested in relation to a specific request from regulatory officials. IFT also recommends that any standardized and structured reporting format be adapted to appropriate data communication vehicles, including spreadsheet, web-based portal, or EDI electronic message, to accommodate the varied needs and capabilities of large and small firms alike. FDA may find value in working with global standards organizations to develop standardized message formats (e.g., xml, EDI) as one of the reporting options.

7. FDA should accept CTE and KDE data sent in summary form through standardized and structured reporting mechanisms and initiate investigations based on this data.

In order to expedite traceback investigations to protect public health and limit impact on industry and individual brands and products, FDA should request summaries of CTEs and KDEs from firms and use this information to quickly “rule in or out” products or supply chains that may or may not be associated with a specific food safety concern. IFT recognizes the risks associated with relying on un-authenticated data, and particularly the risk of following the “wrong path.” IFT expects that a firm will be able to generate a summary document quickly, within 24 hours, since a firm would be able to interpret and summarize their own data/records much faster than FDA. The time needed for FDA to learn and understand each firm's system (as they did in past outbreak tracebacks) can be reduced. The general data needs should be similar in most traces, enabling firms to develop processes and systems in advance of a traceback that could automatically generate summary information when needed.

IFT is not suggesting that FDA rely exclusively on summary data. Rather IFT encourages FDA to continue the practice of collecting “hard copy” supporting information (e.g., Invoice, Purchase Order, Bills of Lading) from firms associated with products that are not readily excluded from an investigation. While this process may add an extra step by asking industry to provide a summary, and then later to provide more detailed documentation, this process will have the benefits of enabling FDA to quickly obtain information and focus investigation on protecting public health and providing industry more time to collect hard copy records in advance of a possible subsequent FDA verification request.

8. **If available, FDA should request CTE and KDE data for more than one up - one back in the supply chain.**

IFT found that in both the produce and processed food - ingredient pilots there were some companies who are quasi-vertically integrated or who otherwise have strong control (and therefore visibility) through their supply chains and can provide information more than one step back. Thus, in such instances, FDA should request and act on this information for the sake of public health; and as a second priority, should verify information with the individual firms in a supply chain who may have handled the product. During the pilots, there were instances where several supply chain partners shared and analyzed product tracing data through teleconference calls. Firms should consider inviting regulators to participate in these discussions and FDA should be open to collaborating with industry on such discussions in order to rapidly gain meaningful information. During the pilots IFT noted that availability of more than one level of traceback data from firms was more the exception than the norm, but that in some instances firms reporting more than one level of information do not keep the information themselves as a part of regular operations but can readily access the information via supply chain partners. In such instances, it would be important to minimize duplicative requests coming from both supply chain partners and regulatory agencies. This recommendation is based on the availability of information from capable supply chain partners and is not recommended as a requirement for all supply chain partners.

9. **FDA should pursue the adoption of a technology platform to allow the Agency to efficiently aggregate and analyze data reported in response to a specific request from regulatory officials. The technology platform should also be available to regulatory counterparts.**

An FDA-managed information system for collecting requested information would decrease the resources required by industry to respond (e.g., submitting information once rather than in response to multiple requests from state and federal regulators) and would decrease redundant efforts of local, state and federal governments by granting public health and regulatory partners secure access to the information system during an investigation. State and local regulatory agencies should be involved in the development and implementation of such a system, and should have equal access to any "technology collaboration platform" to the extent permitted by law.

IFT does not advocate the establishment of a common "cloud"-based repository as a continuously standing collection of all CTE and KDE data captured across the supply chain. The information system envisioned here would be managed and hosted by FDA and collect only CTE and KDE data related to past or current outbreak investigations.

IFT notes that the utility of an FDA-managed platform for collaboration with public health partners is completely dependent on the submission of accurate, complete event data. Technology should not be expected to compensate for poor recordkeeping.

10. **FDA should coordinate traceback investigations and develop response protocols between and among state and local health and regulatory agencies using existing commissioning and credentialing processes. Further, FDA should formalize the use of industry Subject Matter Experts (SMEs) to address FDA's general questions about the characteristics of a particular supply chain at the outset of an investigation.**

FDA should continue to collaborate with state and local counterparts to ensure that investigations proceed rapidly and with minimal duplication of efforts.

The establishment of the Coordinated Outbreak Response and Evaluation (CORE) network within FDA was an important step in coordinating efforts internal to FDA, and IFT encourages the Agency to identify,

train, and deploy a select group FDA staff in response to traceback investigations, similar to the way in which food protection rapid response teams function at the state level (FDA 2012a). These investigators could be housed at CFSAN or embedded within the districts, but would be the lead points of contact in the field during traceback investigations.

IFT also encourages FDA to pre-identify SMEs (regulatory, academic, industry) in a variety of food product - commodity areas as well as those representing diverse portions of the supply chain, who can advise the Agency in the early stages of investigations regarding general industry practices, product flow (including as relates to seasonality, regionality), terminology, etc. in a given industry segment.

Barriers to Implementation

IFT recognizes that there are several barriers to implementing the recommendations presented above. Barriers include issues related to: current availability of KDEs and other prerequisites to efficient data capture and sharing; availability and accessibility of technology, particularly to small businesses and firms in developing countries; and need for continued education and recognition of cultural differences.

Final Comments

With FDA positioned to commence the rulemaking process requiring additional records for high-risk foods, the food industry is anxiously awaiting direction from the Agency regarding the expectations of a product tracing system. Many of the industry-led initiatives have met a level of resistance owing to the concern that FDA might require something at odds with the initiatives and implementation guidance. Numerous individuals contributing to the pilot studies expressed their hope that the results of this work would be used to inform industry best practices and drive change. There are many documents discussing the challenges associated with tracing food products, and some that offer a path forward. Recognizing that change takes time, our hope is that with this report, and FDA's subsequent report to Congress, change starts now.

PREFACE. ACTIVITIES AND DELIVERABLES (FROM FDA)

As provided by FDA to IFT, the objective of the task was to: "review the scientific literature published since the previous IFT task order on product tracing, coordinate with the food industry and consult with USDA and multiple state public health agencies, consumer groups, and other experts and consider the requirements of stakeholders and governmental agency partners to address the activities described within this task order.

This task order will be used to address, in part, the requirements in the FDA Food Safety Modernization Act, Title II, Section 204 Enhancing Tracking and Tracing of Food and Recordkeeping by conducting two product tracing pilots at the direction of FDA's Center for Food Safety and Applied Nutrition (CFSAN), College Park, MD."

Activity 1: Development of Two Pilots and Overall Project Plan

"Specific Activities: Arrange a meeting with FDA officials to review the task order requirements and also have preliminary discussion on the content and information to be included in the two pilot projects, overall plan and estimated timeframe for each deliverable. Thereafter, obtain input from the processed food and produce industry sectors and consult with USDA, multiple state agencies (health and agriculture), and consumer groups to develop the parameters and propose specific foods and/or ingredients to demonstrate methods for rapid and effective tracking and tracing through the supply chain from source to point of service. This shall include identification of technologies to enhance the tracking and tracing of proposed foods.

The pilot projects shall explore and evaluate methods to rapidly and effectively identify the recipient 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 or misbranded. A key goal in the traceback of selected foods and/or ingredients in the pilot projects shall be to identify a common source or supplier in the supply chain starting at multiple points of sale.

In the design and implementation of the pilot projects, IFT shall:

- conduct two pilot projects in coordination with the (1) processed food and (2) produce sectors and in consultation with the U.S. Department of Agriculture, state public health agencies, and nongovernmental organizations that represent the interests of consumers;
- reflect the diversity of the food supply and consider/address confounding factors, such as commingling and transshipment;
- include at least 2 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 these selected foods that are practical for facilities of varying sizes, including small businesses;
- demonstrate appropriate technologies that enhance the tracking and tracing of these selected foods along the supply chain from source to points of service;
- demonstrate the tracking and tracing of a (1) selected processed food and key ingredients (minimum 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.

IFT shall pay particular attention to the breadth, depth, and precision of product tracing systems that enable food product to be rapidly linked from multiple points of sale to a common source in the food continuum. Products and systems to be examined include the selected processed product and selected fruit and/or vegetable that may or may not have a label and lot number associated with them, as well as key ingredients that may go into multiple finished products (i.e. processed foods). Attention shall also be given to the accessibility of information by regulatory and public health officials in food related emergencies. IFT will build upon previous IFT Task Order 6 (contract 2) report pertaining to critical data elements and employ/test these during the pilots.

Breadth: the amount of information the product tracing system records

Depth: how far upstream or downstream in the supply chain the system tracks

Precision: the degree of assurance with which the system can pinpoint a particular product's movement or characteristics

Access: the speed with which track and trace information can be communicated to supply chain members and the speed with which requested information could be disseminated to public health officials during food related emergencies

IFT shall conduct a kick-off meeting with the FDA Officials within ten (10) days of task order award to achieve a clear and mutual understanding of all task order requirements.

Deliverable 1.1: IFT shall submit a detailed Project Plan within thirty (30) days of task order award that identifies the scope of the project, the project description, and any assumptions or constraints that have been identified as well as the project milestones and an estimated timeline for completion of the milestones. The Project Plan shall reflect the input obtained from industry, state and federal agencies, and consumer groups consistent with Activity 1. The project plan shall be updated, as needed based on FDA feedback, and the final version shall be included in the final report. FDA shall have the final decision in selecting the food(s) and key ingredients involved in the pilots.

Deliverable 1.2. The contractor shall meet with the Project Officer and subject matter experts within the FDA within forty-five (45) days of the award of this task order for the purpose of reviewing the project plan and timelines associated with the completion of this task order."

Activity 2: Implement Pilot Projects including Mock Traceback/Traceforward Exercise

"Specific Activities: Implement the Project Plan for the pilot projects including a mock traceback/traceforward exercise. Collect and document costs and benefits throughout the pilots related to the adoption and use of several product tracing technologies. Particular attention shall be given to those links where dissimilar practices and technology are used in the food continuum (e.g. incompatible data standards and paper-based systems versus electronic systems).

Deliverable 2.1. The contractor shall explore and demonstrate methods that enable products in the food continuum to be rapidly and effectively linked from the point of sale back to the point of production/source. The contractor, as part of exploring and demonstrating these methods, shall organize and implement a mock traceback/traceforward exercise, in which FDA and other food protection experts will participate, utilizing a collaboration platform to share data from processed food sector to establish whether common data elements or data sets and the technology platform(s) allow for expedited electronic traceback and traceforward. The methods should allow for multiple traceback and traceforward scenarios, ranging from simple to complex. Any traceback shall have a key goal of identifying a common source in the supply chain. The exercise should include data from the ingredient

suppliers, processors, distributors, and retailers as appropriate to the foods selected. This deliverable shall be completed within seven months (210 days) of task order award.

Deliverable 2.2. IFT shall evaluate domestic and international product tracing practices in or available for commercial use not previously evaluated by IFT in Task Order 6, unless updated practices are applicable, and consult with a diverse and broad range of experts and stakeholders, including representatives of the food industry, agricultural producers, and nongovernmental organizations that represent the interests of consumers. This aspect shall be completed within eight months (240 days) of task order award."

Activity 3: Costs and Benefits

"Specific Activities: Conduct an in-depth review of the costs and benefits associated with the adoption and use of several product tracing technologies including those used in the mock traceback/traceforward exercise. These costs would include, but are not limited to: costs for capital equipment improvements, costs for additional recordkeeping that may be necessary, and costs for the harvesting, processing, and point of sale improvements to assist in the product tracing systems. This examination will focus on how traceback can be accomplished rapidly from the point of service back to the point of production and to a lesser degree traceforward as well.

Deliverable 3.1. The contractor shall provide a report of its in-depth review of the costs and benefits associated with the adoption and use of several product tracing technologies including those used in the mock traceback/traceforward exercise. The contractor shall submit this report within nine months (270 days) from award of task order. This report may be included as part of the final report."

Activity 4: Summarize Findings, Provide Recommendations and Final Report

"Specific Activities: IFT shall summarize findings, develop recommendations, and provide a final report of the pilot projects, with an executive summary, to the FDA, describing the outcomes of all Activity-based deliverables. The final report shall include a summation of the work performed and shall be in sufficient detail to describe comprehensively the extent of revisions that were required within this task.

In developing recommendations, IFT shall consider international efforts, including an assessment of whether product tracing requirements developed are compatible with global tracing systems, as appropriate.

Deliverable 4.1. The contractor shall provide a final report that summarizes the findings and includes a description of all deliverables submitted that will fully document the project outcomes. The extent and detail of the scoping analysis for the mock exercise, evaluation of technologies, and costs and benefits, are to be mutually agreed upon by the FDA and the contractor and the outcomes shall be incorporated in to the final report. The final report shall be submitted within 9 months (270 days) of task award.

Deliverable 4.2. IFT shall provide recommendations as part of the final report for process improvements and technologies to more rapidly and precisely track and trace product in the food continuum. IFT shall provide additional information on the suitability and feasibility of the recommendations for use by large versus very small business and barriers to implementation. The recommendations shall be submitted within 9 months (270 days) of task award."

All pilot deliverables and descriptions can be found in Appendix A.

CHAPTER 1. BACKGROUND

FDA has responded to food safety problems with contaminated leafy greens, peanut butter, and more recently with cantaloupe, sushi, and spices on deli meats. Whether contamination is unintentional or deliberate, there is a need to respond quickly and communicate effectively with consumers and other stakeholders with respect to the specific product that is contaminated and the mitigating actions that can be taken to prevent illness from such products.

The requirements based on the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BT Act) include provisions for recordkeeping to enable regulators to respond quickly to such events. The Final Rule provides an excellent explanation of the steps in an outbreak investigation (US Congress 2002):

"There are four stages in an outbreak investigation. The first stage is the preliminary investigation of laboratory results and epidemiological evidence used to determine the parameters of the outbreak, including the following: number ill, food vehicle contaminated, microbial or other agent responsible, potential commercial sources of contamination, as well as the degree of confidence in the information on each of these parameters. The second stage of the outbreak investigation is the decision making part, when FDA determines what resources will be committed to proceed further in the investigation. The third stage is the traceback investigation, which is conducted to do the following: (1) Identify the source and distribution of the implicated food and remove the contaminated food from the marketplace; (2) distinguish between two or more implicated food products; and (3) determine potential routes and sources of contamination in order to prevent future illnesses, or to treat persons sooner for the identified contaminants. The traceback investigation involves investigative visits by FDA inspectors to points of service, which are the facilities where consumers had purchased the contaminated food, and also distribution facilities... A fourth stage is the source investigation of the specific practices at the farm, transportation, or other facility that may have led to the outbreak. For many outbreaks, the source investigation occurs well after any preventive action can be taken to limit the number of illnesses (US Congress 2002)."

The FDA Food Safety Modernization Act (FSMA), which was signed into law by President Obama on January 4, 2011, aims to increase the safety of the U.S. food supply by shifting the focus of federal regulators from responding to contamination to preventing it. In foodborne outbreaks the focus is response, and further illnesses may be prevented by rapid tracebacks of the food involved in order to remove that food from the market place more quickly minimizing the risk to consumers of eating the contaminated product. Additionally, if we are able to successfully identify the source of the outbreak through more rapid traceback investigations, FDA and other public health agencies working with industry will be better positioned to prevent future outbreaks by implementing future food safety policies and practices. The food safety system in the U.S. has many stakeholders; the success of this system will be enhanced by building an integrated national food safety system in partnership with state and local authorities who are vital in outbreak and traceback investigations; FDA relies greatly on state and local authorities to conduct the epidemiological investigations that identify suspect or implicated foods causing illness.

To that end, FSMA Title II, Sec. 204 Enhancing Tracking and Tracing of Food and Recordkeeping, mandates, in part, FDA to establish tracking and tracing pilots by September 2011 to explore and evaluate methods to rapidly and effectively track and trace food to prevent or mitigate a foodborne illness outbreak. Additionally, Sec. 204 of FSMA Title II requires that the content of such pilots include at least one pilot project be conducted in coordination with the processed foods sector and one conducted with processors or distributors of fruits and vegetables that are raw agricultural commodities. There are

further provisions in Sec. 204 describing the content and objectives of the pilot projects as well as additional data gathering efforts.

Improving response and recovery is one of the three core principles under the President's Food Safety Working Group. Building a system that permits rapid traceback to the source of foods linked to foodborne illness is identified as a component of improving response in foodborne outbreaks thereby resulting in a more rapid and targeted response to identify the source of contamination and ultimately taking preventive and mitigating actions**.**

In 2009, FDA held a public meeting jointly with the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) to explore ways to enhance product tracing in the food supply. FDA also commissioned two studies with IFT pertaining to product tracing. This current task order built upon those efforts to identify and gather information on methods to improve product tracing of foods in the supply chain in order to provide greater public health protection in a foodborne outbreak and in developing preventive food safety policies.

Defining Traceability and Product Tracing

In general, product tracing is understood as the ability to follow the movement of a food product and its constituents through the stages of production, processing, and distribution, both backward and forward. Traceback is the ability to trace a food product from the retail shelf back to the source. Conversely, traceforward is the ability to trace a food product from the farm forward to the retail shelf (Levinson 2009). More recently, traceability has been distinguished from product tracing, with traceability often being recognized as the practices within a single firm, whereas product tracing is the supply chain wide system that provides for trace back and forward (McEntire and others 2010). In the international context, traceability also refers to the ability to distinguish products at a molecular level (Picarro 2012). Trautman and others (2008) provided a literature review of food product tracing and found over 30 definitions of the term "traceability". Without a common understanding of traceability and product tracing, it will be difficult for stakeholders to understand their roles and responsibilities during a traceback investigation.

In order to trace the movement of certain food item(s) through its supply chain, there has to be a trail (or series) of transactions that can be followed logically. In order to recreate that trail, each participant in the supply chain must maintain records on when the product was received and where the product came from and where the product was shipped to, when. This is commonly known as the one-up-one-back approach.

Although often discussed in the context of food safety, there is a difference between food safety and product tracing (McEntire and others 2010). Food safety is obtained through the proper growing, harvesting, processing, packaging, shipping, handling, and preparation of food products and ingredients. Tracing is obtained by being able to track the movement of the food through the food supply chain. Although both initiatives are related to public health, food safety is largely recognized as a collection of best management and production practices to prevent foodborne illnesses, whereas product tracing generally comes into play as a reactive set of tools meant to find the source and subsequently remove food in commerce that may be contaminated.

Product tracing encompasses traceback and traceforward. However, when speaking with the food industry, most consider product tracing as the traceforward/recall process only. This can cause major misunderstandings when tracebacks are being conducted. Unlike a recall, the implicated "source" is not known during a traceback investigation, and in fact, the source is precisely what a traceback seeks to determine. In the investigation of a foodborne outbreak, a traceback *begins* at the points of sale (e.g.,

retailers) and/or points of service (e.g., food service establishment or restaurant) where affected individuals are reported to have consumed contaminated food (in certain situations, a traceback can also begin at the manufacturing stage and seek to identify the common ingredients used in processed food products). Multiple paths are followed for one or more product types to determine if there is a point of convergence which can be investigated as a possible source of the contamination. Lot numbers or other identifying information are generally not known. Traceback investigations often begin at the state or local level. Because the terms "traceback" and "recall" are often used interchangeably, it is critical to convey that, during the investigation of a foodborne outbreak, tracebacks generally precede recalls and seek to determine, with specificity, the physical location and point in time during which contamination occurred, as opposed to recall, which focuses on products that could have been contaminated within that location/point in time that should be removed from the supply chain in order to protect public health.

Product Tracing Complexities and Complicating Factors

The ability to trace the movement of products through the supply chain depends in large part on industry recordkeeping. The recordkeeping requirements stemming from the BT Act provide the basis for recordkeeping associated with FDA regulated products. It and other pertinent rules and regulations are summarized in Appendix B. In 2009, the Office of the Inspector General of the Department of Health and Human Services found deficiencies in the awareness and compliance with FDA's recordkeeping requirements (FDA 2004), and the results of that work are provided in Appendix C.

This task focused primarily on tracebacks, which have historically been conducted after epidemiologists have interviewed cases to obtain a sense of the product(s) potentially linked to illness. Because of the time it takes between the consumption of a contaminated product, presentation of illness, and subsequent pursuit of medical attention and testing to diagnose the causative agent, it is typically several weeks before health agencies recognize that an outbreak might be occurring. For perishable products, this may limit the ability of a laboratory to find a food product that tests positive for the contaminant, as the product may be past its shelf life before the first indication of an outbreak. Thus, records obtained through tracebacks provide the information needed to determine the products linked with illnesses.

Once a traceback investigation is initiated, there are still many factors that affect the ability to rapidly and effectively trace food products, and the challenges associated with product tracing are not wholly the fault of government or industry. While these pilots focused on improvements that industry can make to more rapidly provide regulators with the information necessary to link products through a supply chain, it is important to also note the regulatory structure that can complicate the ability to conduct rapid, thorough investigations.

Increasingly there are examples of "stealth foods" (CDC 2011c) – components of a product that may not be readily apparent through a food history questionnaire- where the cause of an outbreak is not initially obvious. These examples include the 1996 outbreak linked to Cyclospora associated with a cake garnish (raspberries), and the 2008 outbreak eventually linked to jalapeno peppers, a minor ingredient in salsa compared to tomatoes, which was initially implicated. More recent examples involving ground pepper used as a spice in restaurants (*Salmonella* Rissen) and on processed meats (*Salmonella* Montevideo (CDC 2010b)) point to how difficult it can be to identify vehicles from epidemiological studies. Investigators are looking for additional tools such as product testing and ingredient tracebacks to identify vehicles of contamination that epidemiological studies alone cannot tease out.

Similar problems have been vexing investigators in outbreaks where multiple-ingredient foods like tomatoes and lettuce are served in the same dish (e.g., salad, sandwich). Mexican style foods have been

involved in several outbreaks where tomatoes, lettuce, cheese and ground-meat were served together in tacos and other similar dishes (CDC 2000). All of these ingredients have been identified as food vehicles in the past so how do investigators discover which one was contaminated in an outbreak when they are served and eaten together? This necessitates the evaluation of each ingredient, looking for a common source or point in the supply chain where contamination could have occurred.

In other cases, the traceforward investigation has highlighted the difficulty in assessing if a company received and used a particular ingredient after the ingredient passed through several supply chain nodes and may have been transformed or renamed. In this instance, the ingredient may have been recalled, but is difficult to trace forward all the products that used the ingredient through the supply chain. The *Salmonella* outbreak associated with the Peanut Corporation of America (PCA) peanut products (CDC 2009b) is the prime example for this issue.

Recognizing the difficulties associated with product tracing, and specifically the way that records that enable product tracing are maintained by the food industry, a few pilot studies have been conducted (Appendix D). In most cases the pilots involved only a single or very few firms and employed a very specific solution. For the most part, the complexities of tracing products *through a supply chain* have seldom been tackled. Exceptions include a mock tomato traceback and three pilots involving pork, beef, and produce (Can-Trace 2004a, IFT 2009).

CHAPTER 2. APPROACH TO OVERALL TASK AND BASELINE EVALUATIONS

Over 100 individuals and organizations actively participated in the execution of the product tracing pilots, and scores more offered valuable input and insight. While gathering input to help shape the task, IFT contacted individuals from state and federal agencies who have been involved in traceback and traceforward activities to better understand the current landscape and identify areas that could be evaluated through the pilots.

Oversight Panel

IFT assembled several groups, including an oversight panel (OP), two groups focusing on each of the two pilots, a team focusing on the economic aspects of the task, and an ad hoc group of state traceback investigators. The OP was involved in all aspects of this task, and its activities included participating in a kickoff meeting, pilot meetings, a final synthesis meeting, and several conference calls during the timeframe of the task.

The following individuals served as members of the OP:

- Douglas Bailey, USDA Agricultural Marketing Service
    - After IFT put forth the concept of CTEs, Doug Bailey expanded on them and has been a thought leader with respect to KDEs, CTEs, and technology. Doug also has deep contacts in the meat and poultry supply chain that aided in the execution of the processed food pilot.
- Benjamin Miller, Minnesota Department of Agriculture
    - Ben Miller has current, hands-on experience in conducting tracebacks. Trained as an epidemiologist, Miller now works for the state of Minnesota in regulatory traceback.
- Bruce Welt, University of Florida
    - During the final meeting of IFT's 2008-09 FDA product tracing task, Welt conceptualized and articulated the concept of CTEs. Welt's training in packaging and engineering led him to research Radio Frequency Identification (RFID), and more recently, other technology options for product tracing.
- Brenda Lloyd, UFPC/Yum! Brands
    - Lloyd leads the UFPC initiative to trace food products through the Yum! distribution chain to the retail stores. Brenda has conducted a pilot involving manufacturers, distribution centers, and restaurants.
- Jack Guzewich, Consultant
    - During his careers with FDA and the state of New York, Guzewich was instrumental in epidemiological and traceback investigations of foodborne outbreaks.
- Thomas Breuer, Deloitte Consulting, LLP
    - Breuer, who has a background in engineering, is a senior marketing and management executive who has assisted firms in identifying costs and benefits of technological changes.
- Caroline Smith DeWaal, Center for Science in the Public Interest
    - Smith DeWaal has used her background in law to advocate for food safety on behalf of consumers. She is a well-recognized spokesperson with a keen awareness of food safety regulatory systems, challenges, and practices worldwide.

This group was responsible for ensuring that the pilots were constructed to determine:

a) If the right KDEs and CTEs were defined and identified
b) If the data could be linked throughout the supply chain to trace the product
c) Which factors facilitated or hindered the ability to trace products (e.g., the use of standards, the use of technology)

Key discussion items at the first meeting included: approach for the baseline studies; utility of testing the findings of a small industry work group that has further developed and identified CTEs, KDEs, and definitions; applicability of trying to use components of the Reportable Food Registry in the pilots; and the process for conducting the cost analysis. After considering input from stakeholders, the OP identified food products that could potentially be evaluated in the pilots. A matrix for evaluating and prioritizing food products for evaluation in the pilots was developed (Appendix E). The panel also discussed approaches to solicit participation and types of tests that could be conducted through the pilots.

The OP met via conference call or face to face approximately monthly and provided critical input to all aspects of the task.

Stakeholder Input

Based on the kickoff meeting with FDA, and questions received after the IFT and FDA press releases, IFT determined that there was a need to hold sessions to obtain input from all interested stakeholders. Throughout the task FDA continued to stress the importance of soliciting stakeholder input, and IFT used a variety of means to publicly announce numerous opportunities to provide input.

IFT maintains a product tracing contact list that is currently comprised of the following:

- 308 food industry members
- 189 technology providers
- 49 trade association contacts
- 39 government representatives
  - Representatives of 10 countries; U.S. agencies included: USDA APHIS, AMS, FNS; DOC
- 31 allied organizations
- 88 academicians (worldwide)
- 81 consultants
- 22 news media (they did not receive stakeholder meeting announcements)
- 13 consumer groups
- FAO
- 21 others

The contact list was generated and is updated on the basis of visitors to IFT's product tracing web page (IFT 2012a), individuals participating in IFT's product tracing work begun in 2008, and others who have asked to be informed of product tracing information. In addition to posting information on the IFT website and in various public web forums (e.g., numerous "Linked In" groups related to food safety and product tracing), IFT used this contact list to announce on September 14, 2011 that there would be stakeholder input sessions. Meeting details along with a "frequently asked questions" (FAQ) document (Appendix F) and the specific questions (Appendix G) for which IFT sought input on were provided on September 19, 2011. The dates and locations of the sessions and the number of participants in each are shown in Table 3.

Table 3. IFT Product Tracing Stakeholder Input Sessions

Date	Location	Number of Stakeholder Attendees	Number of Individuals Providing Oral Comments (Speakers)
Oct 3, 2011	**Seattle, WA**	12	5
Oct 5, 2011	**Washington, DC**	40	11
Nov 2, 2011	**Chicago, IL**	~55	23

Each individual requesting to provide oral comments was allowed 8 - 10 minutes to speak. Each session was recorded and the audio files were posted at ift.org/traceability. IFT also requested that individuals provide written versions of their comments.

Figure 1. Stakeholder Input Session Attendees, by Category

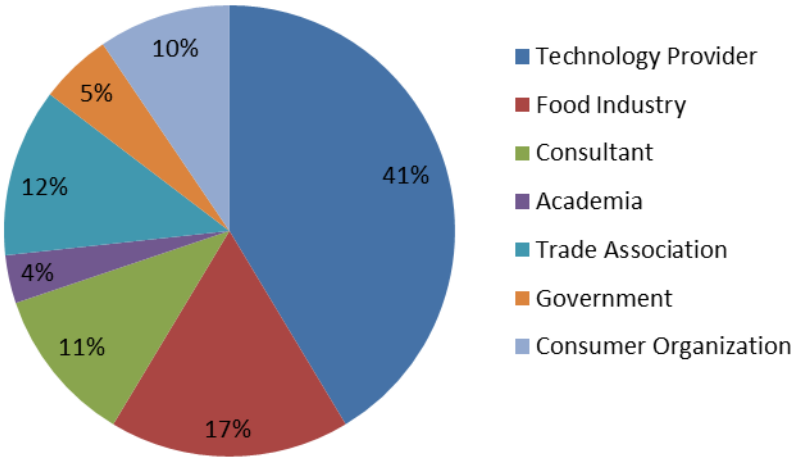
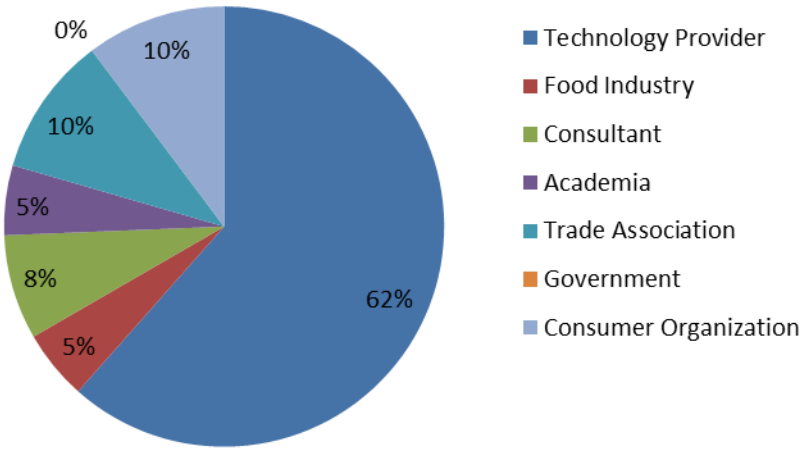


Figure 2. Stakeholder Input Session Speakers, by Category



As shown in Figure 1 and Figure 2, a cross section of stakeholders participated in the input sessions, with technology providers having the greatest representation. While food industry members were the second largest group in attendance, they provided only 5% of the oral comments.

IFT also had the opportunity to give presentations on the pilots to several industry groups. As a condition of speaking, IFT asked that at least 15 minutes of the meeting agenda be allotted to IFT capturing stakeholder input. In some cases, the meeting stakeholder input led to discussion that was more than two hours. Detailed notes on the stakeholder input were captured during each speaking engagement, and shared with the OP. The venues in which input was sought and the forthcoming speaking engagements are shown in Appendix H, and include presentations to the international food safety community.

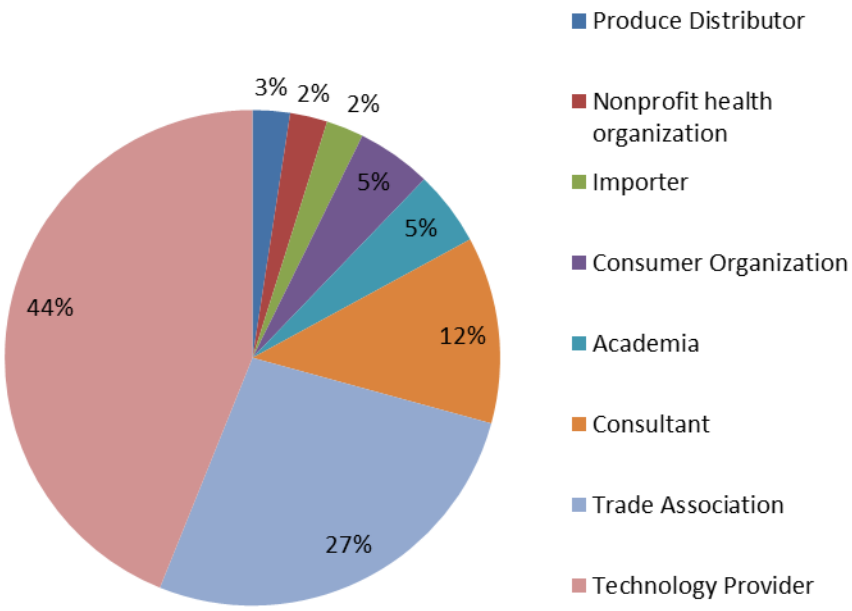
Stakeholder Input Results

A total of 69 people or organizations submitted comments to IFT, either orally, in writing, or both. The number and categories of individuals who submitted written comment in response to IFT's specific questions (Appendix G) are shown in Table 4, Figure 2 and Figure 3.

Table 4. Stakeholders Submitting Comments to IFT

Stakeholder Category	Number of Individuals Providing Input	
	Written	Oral
Produce Distributor	1	0
Nonprofit health organization	1	0
Importer	1	1
Consumer Organization	2	4
Academia	2	1
Consultant	5	4
Trade Association	11	4
Technology Provider	18	25
Total	**41**	**39**

Figure 3. Stakeholders Submitting Written Comment, by Category



RESPONSE TO QUESTIONS

The specific questions presented by IFT are provided below, immediately followed by a summary of the comments that IFT received from stakeholders.

1. **FSMA requires that the pilots examine foods associated with outbreaks between 2005-2010.**
    a. **How should the products evaluated in the pilots be selected? Which products are best for evaluation?**

There were common threads within stakeholders' thoughts on how the products evaluated in the pilots should be selected. Most felt the focus should be on products that are the hardest to follow throughout the supply chain, including those with complex distribution from farm to restaurant. A few comments were more general, requesting that fresh products and ready made products be covered by the pilot. Another point raised by several stakeholders was the suggestions to include foods that have had the greatest contribution to foodborne illnesses and outbreaks in the past five years, or foods most susceptible to contamination. Many of the technology providers suggested selecting products with a challenging and complex supply chain, as one company stated, to "increase the potential for lessons learned." Specific products suggested were:

- produce
- meats
- commingled products
- leafy greens
- berries
- tomatoes
- lettuce
- spinach
- radishes
- bean sprouts
- cantaloupes
- romaine lettuce
- papaya
- strawberries

Products with a longer shelf life and higher volume than others were also suggested, to represent specific challenges in product tracing. Additionally, imported products were also suggested for inclusion in the processed food – ingredient pilot.

2. **How heavily should each of the following factors be weighted in selecting the products?**
    a. **willingness of supply chain partners to participate;**
    b. **distribution complexity, including number of "points" in the supply chain, inclusion of very small and small businesses, and crossing of international boundaries;**
    c. **food product complexity, including number of ingredients, commingling, etc.;**
    d. **processing/harvesting conditions that may increase the likelihood of contamination**

Willingness of participants to participate was generally regarded as highly important. This was deemed critical to getting the needed results and a good sampling. One stakeholder suggested engaging participants through a major retailer willing to show their supply chain.

Distribution complexity was viewed as highly important, as the "number of points adds to the bigger picture" and "the best way to study product tracing is at many stages in the supply chain." Stakeholders from different sectors advocated for the inclusion of complex and simple supply chains, stating that "both direct to market and highly complex chains need review." A common response to this question was to be sure to "address concerns of as many types of trading partners as possible by inclusion of very small and small businesses and crossing of international boundaries." A common response among stakeholders was that the highly complex distribution system would yield more data and create more opportunity to gain valuable results.

Another thought was that company size should not be the sole deciding factor; the focus should be on "the level and type of communication that is needed to acquire the necessary information to illuminate the distribution system."

The majority of stakeholders responded that product complexity is much more relevant to the processed food – ingredient pilot than the fresh food pilot, because complexity is "representative of products most susceptible to contamination." Products with a greater number of ingredients were favored, with an emphasis on commingling, than other products for the pilots.

Some responded that processing conditions should weigh heavily in product selection, but most leaned towards this being unimportant and less relevant. One technology provider who felt strongly about this being less relevant expressed the view that the issue should be addressed within food safety focused projects and not in a tracing pilot, and stating: "Having these specialized cases will not add much value to the pilots and may in fact, prevent focus on the more representative situations."

3. Several segments of the food industry, such as produce and seafood, have encouraged the adoption of a method to trace products (e.g., PTI). To what extent should these initiatives and other industry-led pilots and projects be considered by IFT?

Many of the comments for this question focused on the effects that adoption of certain methods by small processors and distributors will have. Suggestions were made such as "IFT should only consider methods that will be able to be easily adopted by both small and large processors/distributors." Several of the comments indicated that such initiatives should be reviewed to see what lessons can be used to develop the pilots so as to be aware of any significant findings. It was suggested that IFT study the product tracing requirements established through the federal National Organic Program (NOP) which requires product tracing from field to consumer (USDA-AMS 2012). Additionally, it was recommended that IFT study the product tracing parameters of the Organically Grown Company (OGC), which is the largest cooperative wholesaler of organic fruits, vegetables and herbs in the Pacific Northwest and which handles the produce of over 40 farms, and Eastern Carolina Organics (ECO), the largest farmer-owned wholesaler of organic fruits and vegetables in the Carolinas and which handles the produce of over 20 farms (OGC 2012).

In addition, some encouraged IFT to involve those in other countries who are driving product tracing, noting, for example, "In countries such as Costa Rica we found that the brokers and shipping agents are the ones that educate the shippers on product tracing issues, FDA requirements and what data/information to keep. They help their clients be FDA compliant. They should be included."

Existing industry-led initiatives are further described in Chapter 9.

4. **A two phased approach to the pilots was proposed, focusing first on enhancing practices already in place in the food industry, and then on determining the impact of using collaboration platforms to analyze data. In the first phase, IFT proposed to explore how defining Critical Tracking Events and focusing on Key Data Elements might improve the ability to trace products. To what extent should the pilots seek to:**
    a. **test which points in the supply chain (internal and external) need to capture data, the level of granularity needed, and the logistical unit to be tracked?**
    b. **test the data that are needed to link ingredients and finished products as well as shipments between trading partners?**
    c. **explore how standardizing data formats (e.g., a common system to identify locations) could facilitate product tracing?**

Responses to question 3 were in favor of IFT testing which points in the supply chain need to capture data and the level of granularity. One of the technology providers suggested that "for practical reasons, the 'minimum detail' necessary to manage a traceback situation be used and not to include 'nice-to-have' product detail that could later be justified to the industry participants." Additionally, it was suggested that IFT include products reflective of instances in which produce and mixed ingredients from multiple manufacturing plant failures had occurred in the past, but in which "recall or investigation efforts were delayed or hampered due to the lack of the aforementioned tracing product mix and handing details." Exploring standardized data formats was widely deemed not as important as testing which points in the supply chain need to capture data linking ingredients with finished products. In response to question 3 c, a technology provider responded that although standardized formats would help, "the enormity will limit the effort." Stakeholders were generally more concerned with a pilot showing how different data formats can be used to obtain the right information for product tracing and less concerned that a standard data format be tested throughout one supply chain.

5. **The intent of the FSMA is to improve product tracing beyond the BT Act requirements. Several points in the supply chain are exempt from the BT Act recordkeeping requirements. To what extent should the pilots include those who are exempt from the BT Act requirements (e.g., those at the beginning and ends of the supply chain, brokers, overseas sources, etc.)?**

Responses to what extent the pilot should include those exempt from the requirements based on the BT Act requirements were fairly wide in scope. One of the trade associations stated that "information at the bottom end of the chain is available beyond the initial BT Act regulated point. The BT Act information seems to be adequate if the understanding and communication of the information is accomplished by the system." A common thought was that the pilots should focus on the questions that need to be answered. There were some common thoughts expressed about making sure the pilots include those who are exempt. People generally wanted to include organizations that have any "physical association" with a product so they are accountable. One stakeholder stated that, "exemptions destroy product tracing. There should be no exemptions."

One technology provider expressed this point: "The rules of the market place tend to dictate what will and will not be tolerated even if there is an exemption. While the pilot may include exempt entities, it is likely that when the practice settles in they will be in compliance."

Some also expressed the view that consumers should be provided with traceback information, delivered at one or more key communication points in a user-friendly manner at the point of sale, on food producers' websites, via codes on product labels, and other means.

6. **Should the pilots consider paper-based information (batch logs, bills of lading, etc.) or should the focus be on information that is available in electronic form only? To what extent should we consider data carriers such as bar codes and RFID tags?**

Responses to whether the pilots should consider paper-based information or focus only on electronic form were split. Those supporting electronic forms only expressed the view that it is "not practical to have a timely product tracing system that includes data that is not electronically captured." Reasons given for this view included human error and inefficiency associated with non-electronic forms, and speed of access of electronic forms. One person responded that electronic is the "only way the end-to-end procedure will really be managed and controlled or monitored by any federal entity." The basic message was to avoid being constrained by limitations in the requirements based on the BT Act or FSMA and to look at the food chain as broadly as possible. RFID technology was suggested by several (trade associations, technology providers, and consultants) who favored electronic records. However, a technology provider favoring electronic records responded that "RFID tags should be left to the next phase of analysis."

Some technology providers indicated that the focus should not be on electronic form only. One person responded that if a processor or distributor can "manage product tracing correctly, they should have the opportunity to manage product tracing their way." A trade association open to all types of records suggested that "IFT could provide insight about how best to move towards using electronic information and a likely timeframe for doing so." A few technology providers submitted comments that were again centered on the cost to small businesses if bar codes or RFID tags are forced upon them and how difficult that would be for them. The idea that things should be tested to reflect the reality of the industry was common among those open to any kind of record being used.

7. **Should the pilots leverage defined industry logistical standards and practices for defining and marking information on product packaging or should new standards and tracking systems be given equal consideration?**

The overall response was that the pilots should consider all standards and practices. There were technology providers that thought new standards should be given fair and equal consideration. One technology provider recommended "contacting Codex Alimentarius, the United Nations and even government officials in other countries for work that has been done on data standards for product tracing" to save time and avoid duplicative work. GS1 industry standards (further described in Chapter 9) were also suggested because of their wide use "by all major manufacturers and retailers in the world." Several stakeholders commented that current practices are incomplete and should be reviewed to create new standards for product tracing. It was suggested that utilizing existing standards would be the most cost-effective and mitigate risks between the supply chains. Also, the comment was made that: "in the event that the pilots may reveal gaps in the existing standards, these should be captured as opportunities for improving upon the standards."

8. **IFT was charged with using a "collaboration platform". IFT will not be developing a "collaboration platform" as part of this task.**
    a. **Given that scores of technology and service providers exist, how should the "collaboration platform" be selected?**

A common theme in response to this question was the suggestion that numerous software providers be used with a goal of "developing a solution set that will allow multiple pilot participants across an entire chain to exchange data easily and securely" and that "successful models do exist." Additionally, it was suggested that serious consideration be given to the "ease of tracking products, (and) ability in providing applicable reports and accuracy." Also, it was suggested that the solution should be made as generic as

possible so as not to advertise what solution is selected. A common view conveyed was that there are many options on the market that will perform as needed. Another point made by different stakeholders was that there should be a structured selection process and various platform providers should be given the opportunity to present their technology to IFT to show how they can respond to the requirements. One technology provider suggested the use of multiple platforms to help facilitate the process, and demonstrate the speed and usefulness of each.

Another major point was that the platforms considered should be very low cost to the producer. To help drive cost down, 'multi-purpose' solutions that satisfy other business needs were preferred.

b. To what extent should proprietary systems be considered? Should systems that are not yet commercially available be used? If only one or a limited number of systems is used, how can the results of the study be applied broadly, rather than just to the firm providing the platform?

Non-proprietary systems were favored heavily in the responses to this question. It was also recommended that results should be able to be exported into a format that can be shared and that such systems should be able to demonstrate how they can aid in the product tracing effort required.

One trade association strongly supported the use of proprietary systems, indicating that "each company must be allowed to work within its own domain, and not have a collaboration platform forced upon them."

9. IFT must conduct a cost/benefit analysis. Many benefits reported by industry are the result of using data that may be "above and beyond" what is needed to simply trace products. To what extent should tangential benefits be quantified?

Most responses indicated that tangential benefits are required, and that these are important to consider. Several stakeholders felt that the "tangential benefits may be what justify the cost of the tracking system" and that "these extra benefits will ultimately be what lead to widespread adoption by the industry." The comment was made, however, that "tangential benefits should be quantified only to the extent that they pertain to realistic costs, not above and beyond." One stakeholder commented that part of the equation should consider "when governments decide how much support they are willing to provide to develop a system that reduces impacts on public health and welfare and avoid the costs of imprecise and lengthy recalls and allows industry to use that system for other purposes." A challenge is avoiding any additional costs to businesses that already have the data needed for effective product tracing. One technology provider suggested asking this question: "If there is a regulation that requires the collection, storage and sharing of information through some system, what tangible benefits can be demonstrated through other uses of that data?"

10. All processors and industry stakeholders have expenses related to capture of information that is relevant to product tracing. In some cases, this information is included as ancillary in procurement and invoicing systems. To what extent can IFT gather data and segregate the current cost of collecting product tracing information in existing industry systems?

It was generally stated that a significant amount of effort should be made to identify the cost of collecting tracing information and making it accessible for each point in the supply chain. One stakeholder stated that the "key is to tie the tracing standards into business processes such that the cost of meeting the FDA regulations are far outweighed by the business benefits accrued through new tracking system technology." One technology provider recommended that "all participants involved in the pilot jointly and separately submit their estimated operational costs as well as the proposed costs should a more thorough and integrated data capture and interface structure be put in place." Two

pricing models were suggested: “one with the data captured and controlled internally for the specific business unit, and a second (assuming the data would be transmitted via EDI or another internet process to a common central database operated by a third party) at a future time.” Another technology provider summarized their advice by saying: “much of the information needed for product tracing is already being used by businesses along the food chain. They use this data for their own commercial purposes and extract value from it based on their unique needs.” Further, the comment was made that a higher level of adoption might be possible if companies can be shown that product tracing data are already in their systems with a: “this isn’t so hard, you are already doing it” mentality. Another suggestion was to “determine the costs of collecting product tracing information manually, searching for and finding that information when needed instead of using technology to perform the task.”

ADDITIONAL INPUT

Several stakeholders provided input above and beyond the questions presented, and offered some thought provoking perspectives. The input is summarized briefly in the following paragraphs.

Maintain Flexibility in Lot Identification Systems

Some perspectives were offered regarding lot coding and designation. Systems that are appropriate at the consumer level may not work throughout the supply chain. For example, a regulated lot code standard could require re-engineering of current legacy systems, which would have a significant impact on a small business. Some indicated that lot codes should be random unique identifiers assigned by the manufacturer and should not contain additional product tracing data so that the information is meaningful only to the manufacturer to protect intellectual property and ensure the security of the food supply. Comments reflected a preference for prioritizing the demonstration of good product tracing performance rather than standardized lot codes across all systems. That said, there was not consensus on this view; one person commented that FDA should “require unique product identification and lot specific coding as product tracing tools.”

FDA-Industry Collaboration

Comments were beyond the scope of the pilot studies, requesting that FDA:

- Provide training/educational outreach about product tracing to farmers, food processors, warehouse managers, transporters, retail providers, and food inspectors.
- Offer incentives to food safety stakeholders to stimulate the development of product tracing technologies.
- Increase product testing to determine the risk associated with specific foods so that traceback on the highest risk foods can become more accurate and timely.
- Improve data sharing between and within federal agencies and between food oversight agencies and food industries.

Impact of Cost on Smaller Farms and Food Businesses

Although IFT did not ask specific questions pertaining to small and very small businesses in the formal request for input, many stakeholders commented on small business concerns. IFT was urged to evaluate appropriate low-cost product tracing solutions for those participating in local and regional sectors of the food production supply chain, and to assess the compliance costs of all product tracing platforms based on the size of the producer. The FSMA includes a number of provisions that require FDA to take into consideration the limited resources of smaller-scale farms and food producers, including reduced paperwork/compliance mandates. There is concern that unlike large businesses that can afford staff dedicated to handling regulatory compliance along with investments in electronic monitoring

equipment, small scale farmers and food businesses are not financially able to bear the costs of similar oversight functions, and any unreasonable mandates can quickly put them out of business. Input was offered that the product tracing solutions that would be effective for large-scale, highly-capitalized supply chains would not only be beyond the resources of small producers participating in local and regional distribution networks, but would also be inefficient to apply among those producers due to limited cost/benefit effectiveness in terms of protecting public health. One individual also noted that some populations, such as the Amish, do not subscribe to electronic systems and considerations for their participation in a product tracing system should be evaluated.

Baseline Evaluations

This task required IFT to identify rapid and effective methods for product tracing. Since "rapid" is a relative term, IFT decided to conduct an activity to better understand the current state of product tracing, including the time required to conduct tracebacks and the factors that make an investigation "easy" or "difficult." Prior to implementing the pilots, IFT sought to establish and analyze a baseline of product tracing to identify factors that may delay or enable traceback investigations, and also inform the pilots. Specifically, information collected in this baseline activity influenced the variables that IFT evaluated in the pilots.

IFT collected data for the baseline through a two-pronged approach. In one component of the baseline activity, qualitative in nature, IFT had discussions with 12 state traceback investigators as well as a several investigators with FDA and one representative of USDA FSIS. In the other component of the activity, a case study, IFT considered the details of a historical investigation, for which records were available, to gain a sense of the traceback process and identify the types of issues that can be faced during an investigation.

Discussions with Traceback Investigators

IFT spoke to state traceback investigators as well as a representative from USDA FSIS and investigators with FDA, asking them to identify outbreaks that were memorable to them as being particularly easy or difficult and discussing the attributes that aided or hindered their ability to trace in those situations. The objective of this analysis was to identify factors that may delay or enable traceback investigations. The background shared with the investigators and details of the findings are provided in Appendix I. To the extent possible, IFT attempted to identify factors such as time and resources to test in the pilots and potential improvements that may increase the speed and accuracy of traceback investigations. Through the discussions, IFT learned that there are many factors that impact the ease or difficulty with which food products are traced. Some of these aspects can be evaluated by the pilot studies and contribute to IFT recommendations for improvements. However, other aspects (i.e., those relating to epidemiological investigation and issues of coordination) fall outside the scope of the pilot studies. Table 5 summarizes the factors that differentiate investigations on the basis of difficulty. Those with a * were assessed in the pilots.

Table 5. Factors Impacting Investigation Difficulty

Less Complicated Investigations	More Complicated Investigations
Initiated within one day	Initiated in 1 - 5 days
Duration of up to 2.5 weeks	2 months or more in duration
4 - 20 hours required	8 - 240 hours required
Clear epidemiological link	Poor consumer recall; multiple potential items
Longer shelf life product	Shorter shelf life product
Label/bar code information captured*	No label or bar code; reuse of boxes*
Records kept on site	Records stored off-site
Legible, English records*	Records illegible, not English*
Good internal tracing*	No record of ingredients used in finished products or record of cases shipped within the distribution center*
Shipping/receiving information captured*	Invoices do not reflect change orders; use of undocumented "fill-in" product*
*Electronic records	Paper records; errors in data entry*

Historical Investigation Evaluation (Baseline Case Study)

In addition to perspectives offered by state and federal traceback investigators, IFT considered the details of one investigation to gain a sense of the traceback process and identify the types of issues that can be faced during an investigation. IFT requested access to or copies of records and data (including copies of emails, invoices, bills of lading, other "commercial paper," any electronic records or reports and other related communications and documents) that FDA collected during the investigation of an outbreak. IFT provided access to this historical traceback information only to state officials who are subject to confidentiality agreements with FDA. Information pertaining to the spring, 2008 investigation of *Salmonella* Litchfield in cantaloupe was deemed to be the best set of records for this evaluation as the records were readily accessible for three separate legs of the traceback, including a grocery store, foodservice establishment and an institution (CDC 2008b). In a traceback, a "leg" typically refers to the documented path of a product starting at the point of exposure where consumers purchased or ate the product suspected of causing illness. The objective of tracing a particular "leg" is to follow the product through that distribution chain to determine if it connects with other "legs" at a common convergence point in the supply chain.

The specific areas evaluated through the review of these records included:

- Time between when the traceback assignment was made to FDA investigators and when the final set of records was obtained for that leg
- Time between request for records and receipt of records (both between regulators and food companies as well as within the regulatory community)
- Nature of the records collected, including:
    - legibility
    - completeness of information
    - granularity and specificity
    - accuracy

- ease of linking data between trading partners

The *Salmonella* Litchfield-contaminated cantaloupe traceback exemplified some of the challenges and obstacles associated with traceback investigations. IFT was provided with a complete set of records for three of the legs, including email communication between the FDA headquarters and the FDA investigators visiting establishments. The email communication, but not company records, was supplied for one additional leg of the investigation. Table 6 presents a summary of the legs of the investigation, based on the information provided to FDA.

Table 6. Summary of *Salmonella* Litchfield Traceback Investigation (Baseline Case Study) Evaluated by IFT

"Leg"	Number of Days of Investigation	Number of Supply Chain Nodes	Number of Documentation Pages
Foodservice A	14	5	340
Retail grocery store	13; with follow up/verification through day 21	3	n/a
Foodservice B	16	3	47
Institution	5	4	74

In the "Foodservice A" leg of the investigation, the invoice dates at the restaurant were not a perfect match to the information provided by the distributor. Records kept by the first-level distributor did not identify the brand name of the product or the country of origin. This distributor needed to contact their supplier (the second-level distributor) for this information. The first-level distributor provided a summary spreadsheet identifying shipments to the restaurant, but verification against the provided documentation showed that two purchase orders were missing. At the second-level supplier, the key individual responsible for tracebacks was not available, and the communication showed that the records were not sent from the local FDA office until five days after they were requested. Additionally, this distributor sourced product from two different locations, which were distinguished by the fact that one location consistently wrote the time of receipt on paperwork while the other did not. The third-level supplier received the product from the grower and was able to provide information on the grower. When FDA telephoned the grower and provided the reference numbers for the product of interest, the grower requested faxed copies of the grower manifest from FDA and only confirmed the information provided by the third-level supplier, but did not respond to FDA's additional inquiries regarding the farm of origin.

In the "Retail Grocery Store" investigation leg, when FDA visited the retail location, the company representative contacted the chain's headquarters, but the key individual in the company responsible for handling tracebacks was in a meeting until the following day. Still, a senior executive at the company returned FDA's call and provided records for the retailer-owned distribution center. It was not possible to definitively tie the store receipts to the shipments from the distribution center. In this part of the investigation, it appeared that FDA was able to visit the facility and obtain information relatively quickly, however there may have been some delay in forwarding the records to FDA headquarters. In this leg, the nature of the records was such that it necessitated clarification and follow up.

In the "Foodservice B" investigation leg, there was a weekend and a day between the time that FDA headquarters issued the assignment and when the FDA investigator visited the establishment. The restaurant noted that they would "fill in" product from two local grocers, and one receipt simply said "produce," with no description nor shopper card information to better identify the product. When the first-level distributor was contacted, the facility needed to contact their supplier to provide FDA with the requested information. There seemed to be discrepancies in how the number of cantaloupes per case was communicated—the number seemed to change based on various pieces of paper. The first-level distributor noted that they used one stock-keeping unit (SKU) to represent three different case configurations with different numbers of melons. There was a delay of a few days before FDA headquarters could issue an assignment to collect records from the second-level distributor, since the address for that distributor on the Bill of Lading (BOL) was for an office, not the facility of interest. The second-tier distributor did provide FDA with a summary spreadsheet, which had some errors that were later corrected. This distributor noted that similar records had been provided to another FDA investigator the week prior.

The "Institution" investigation leg occurred several weeks after the other three legs. This was the third time the same distributor had been contacted regarding the outbreak, and FDA headquarters was in touch with the distributor directly rather than by means of sending an investigator to the facility.

In this investigation case study, IFT observed that regardless of the leg of the investigation there were several issues associated with some of the documents provided to FDA, as well as practices that consistently impacted the speed or accuracy of the investigation. The issues and practices observed are:

- Errors in spreadsheets containing key shipment information
    - IFT did not see the spreadsheets and therefore could not determine the extent or nature of errors in the spreadsheet, but observed in the email communication that in one instance a revised spreadsheet was provided; in another instance, a review of the "hard copy" paperwork showed that some receipts were not recorded on the spreadsheet.
- First in first out (FIFO) inventory rotation
    - Nearly all of the distributors involved in the legs of the investigation used FIFO inventory rotation in which there may be overlap between products when the areas where products are held for immediate order fulfillment (picking slots) have just been replenished. Those establishments that seemed better able to definitively link shipments and receipts with their trading partners were generally those receiving product directly from the grower.
- Use of "fill in" product
    - One foodservice establishment acknowledged purchasing product from two local retailers in addition to the regular supplier. The lack of specificity on the receipts from one retailer resulted in additional effort expended to determine whether the product of interest had been purchased at that retail store.
- Use of one SKU to represent multiple products
    - There were many instances in which the quantity of product in the case caused confusion. In some cases it was explained that net weight was the same and that the count differed depending on the size of the product so that the case counts were used somewhat interchangeably. One firm carried three different case counts, but sold them under one SKU. This too caused confusion in trying to link which product was sent by one firm to the product that arrived at the receiving firm.
- Not having lots, brand, or Country of Origin Labeling (COOL) on paperwork

    - Lot identification did not generally appear on paperwork. In this investigation, FDA had a sense that the implicated product was imported from a particular country, and having information pertaining to the country of origin could have ruled in or out products or shipments more readily.
- Not having the "right" people available to respond
    - In more than one instance, FDA investigators were told that the "right" company contact was not available. In one instance, another individual at the company responded to FDA, although he was not always sure how certain paperwork was used to trace products. In another case, the requested records were provided several days after the initial request.
- Duplicative contacts at one facility
    - When making assignments to FDA field investigators, FDA headquarters generally seemed to inform investigators if the firm had already been contacted by another investigator, either by FDA or the state. In one instance, a firm advised FDA that the request was nearly duplicative of a request a week earlier.
- Delays in sending information internally
    - It appeared that the local FDA investigator typically visited the firm a day after receiving the assignment, and provided information (e.g., records) back to FDA headquarters the day of or the day after the visit. However, in some instances there was a delay of a day or two, and in several cases, although the records may have been provided promptly, the investigator's full report, which often included insightful analysis, was not sent to FDA headquarters until several days later.
- Illegible scanned/faxed copies
    - In many instances, "hard copies" of documents were either copied or faxed, and the local FDA office would fax the information to FDA headquarters. This resulted in some documents which were extremely difficult or impossible to read. Documents which had tables or other information that was shaded often became black and the information contained within them could not be discerned. Additionally, it appeared that in some cases the faxes were imperfect copies that failed to show the entirety of the document. In one case the top of the document containing the date was not visible.

Summary of Baseline Evaluations

Through this two-pronged baseline activity IFT identified factors that may delay or enable traceback investigations and evaluate how to improve product tracing during a regulatory traceback investigation. IFT learned that the qualities that make a traceback easier are: better consumer recollection, targeted epidemiological clusters, branded or labeled product identification, and standardized data sharing between supply chain nodes. The qualities that make traceback more difficult are: poor consumer recollection, processing (e.g., commingling or dicing) of products, poor recordkeeping by supply chain nodes, lack of coordination among all stakeholders (regulatory and industry), and lack of resources and external factors (e.g., political or media). The historical case study showed that once FDA initiated a traceback and the field assignments were made, it generally took about two weeks to obtain all records, regardless of the number of supply chain nodes (which ranged from three to five). IFT also observed several issues relating to the industry (i.e., availability and recordkeeping) and the investigative process (which potentially contributed to the duration). Many of the specific observations IFT documented in the case study were consistent with the descriptions IFT heard during the qualitative component of the baseline activity. The baseline evaluations provided IFT with a clear sense of the issues to be tested in the pilots.

Selection of Food Products for the Pilots

The OP developed a matrix (Appendix E) to assist in the identification of factors that should be considered, based on the feedback from stakeholders, in selecting products for the pilots. The OP overwhelmingly thought that many products could be good candidates for the pilots, and that industry participation and cooperation should be key in the selection of the specific products and supply chains.

PRODUCE

FSMA requires that the pilots include foods that have been the subject of significant outbreaks between 2005 - 2010. Shin (2006) speculated that the number of produce-related outbreaks of foodborne illness has increased from about 40 in 1999 to 86 in 2004, according to the Center for Science in the Public Interest. Americans are now more likely to get sick from eating contaminated produce than from any other food item, the center said (Shin 2006). Shin (2006) reported that several factors have contributed to the rise in outbreaks: greater consumption of fresh produce, especially cut fruits and vegetables; wider distribution; improved electronic reporting of outbreaks; and an aging population more susceptible to foodborne illness. Fresh produce presents a special food safety challenge because there is no bacterial "kill step" where bacteria can be eliminated through proper cooking. FSMA specified that one of the pilots should focus on fresh produce.

Stakeholder Input

IFT received multiple requests to explore more than one produce item, with many indicating that conducting just one pilot for produce could not adequately reflect the extremely different practices associated with the different products categorized as "produce." IFT received input indicating that products that have been associated with outbreaks in the past are already making improvements in product tracing (along with other food safety concerns). Stakeholder input suggested the following categorization of produce items:

- Short shelf life, wide distribution, limited commingling of growers (e.g., tomatoes or leafy greens)
- Short shelf life, wide distribution, many growers commingled into commercial lots (e.g., avocados or lemons)
- Long shelf life, wide distribution, many growers commingled into commercial lots (e.g., potatoes or apples)

Along similar lines, other stakeholders requested that IFT compare products that are field vs. shed packed, those which have comparatively long and short shelf lives, and those that are commingled vs. not.

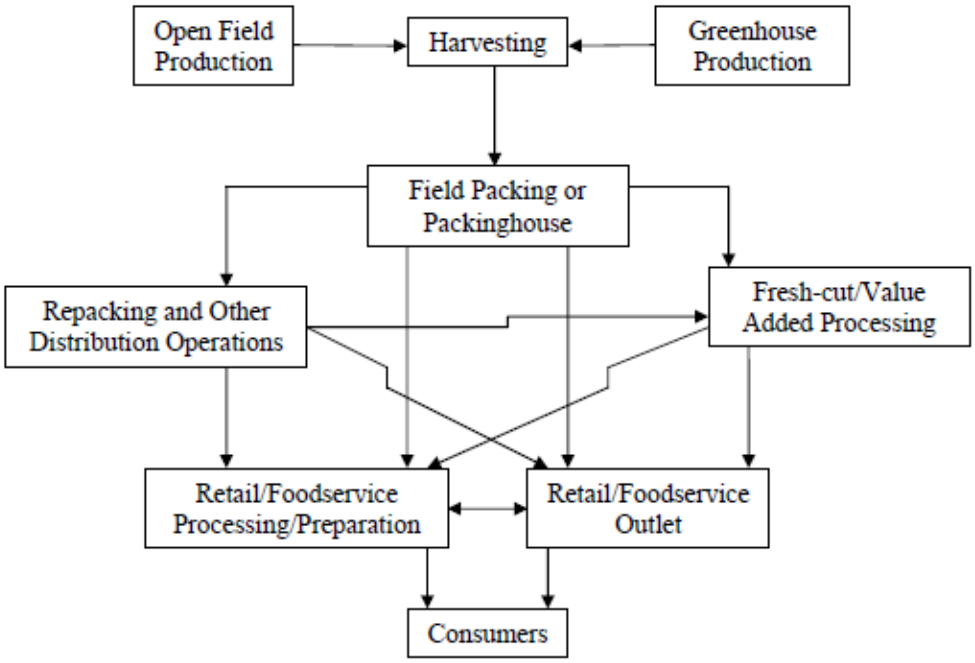
Since the FSMA states that products should be those that have been associated with outbreaks during the past few years, IFT worked with FDA to identify potential products to be evaluated. These included:

- cantaloupe
- tomatoes
- leafy greens, specifically romaine lettuce
- sprouts

The FDA ultimately determined that tomatoes were an appropriate produce item to evaluate in the pilots. Discussion about the other pilot candidates is provided in Appendix J. While FDA initially indicated reluctance at exploring tomatoes, since a previous pilot focused on tomatoes, the OP felt that tomatoes

as a product category have many attributes (e.g., diverse growing region, potential to be imported, complex supply chain, potential for use as an ingredient [such as in salsa], issues with nomenclature) that warranted serious consideration for a pilot. Additionally, this industry expressed a willingness to participate (through the California and Florida tomato farmers). The PTI leadership council indicated that tomatoes were their top choice, and the Food Marketing Institute's Food Protection Committee unanimously agreed that tomatoes would be the best product to evaluate. IFT's outreach to the tomato industry clearly stated that the approach of these pilots would differ from the previous task (IFT 2009), in that the assumption will not be "industry has the data." As shown in Appendix J, throughout the year a high percent of tomatoes are imported, making this product a more complex one to trace. Some states' Departments of Agriculture (Florida and Virginia) were particularly interested in tomatoes, while others (Michigan) expressed general concurrence with several produce candidates. An illustration of the tomato supply chain is provided in Figure 4.

Figure 4. General Supply Chain Flow for Fresh Tomatoes



From UFPA (2008), used with permission.

Associated Outbreaks

During the past five years, there have been several outbreaks associated with the consumption of tomato products. One of the more notable outbreaks occurred in 2008 when 1,440 people were infected with the same genetic fingerprint of *Salmonella* Saintpaul in 43 states, the District of Columbia, and Canada (CDC 2010a). The initial epidemiological information pointed to tomatoes, although

convergence within the tomato supply chain was not found. Jalapeno and Serrano peppers were identified as the vehicles of the pathogen, but the outbreak pointed out the difficulties in the ability to trace tomatoes. In June 2008 FDA advised consumers not to eat raw red plum, red Roma, and red round tomatoes, and products containing raw red tomatoes *unless* the tomatoes were from FDA's list of states, territories, and countries where tomatoes were grown and harvested and which were not associated with the outbreak (CDC 2008a). The tomato industry estimated it lost at least $100 million in sales due to the outbreak, and as a result, FDA worked with Harvard University, tomato industry stakeholders, states, and IFT to explore tracing issues within the tomato industry (IFT 2009).

There have been 15 outbreaks related to tomatoes between 1996 and 2009, which among all produce-related outbreaks is second to only lettuce (Table 7) (Levine 2011).

Table 7. History of Tomato- *Salmonella* Outbreaks in the United States

Year	Serotype	Number of Cases
1998	S. Baildon	86
2000	S. Thompson	29
2002	S. Newport	512
2002	S. Newport	12
2002	S. Javiana	90
2004	S. Javiana	471
2004	S. Braenderup	123
2005	S. Newport	71
2005	S. Braenderup	76
2005	S. Enteritidis	77
2006	S. Newport	107
2006	S. Typhimurium	186
2007	S. Newport	57
2008	S. Saintpaul (tomatoes?/peppers)	1442
2010	S. Newport (suspected)	46

Source: Levine (2011).

Because tomatoes are consumed raw and often as part of another dish (e.g., salad, salsa, sandwich), epidemiological investigations involving the product are difficult, and must rely on the regulatory trace to discern whether or not tomatoes, or another item, are the causative outbreak vehicle. Other issues that have complicated investigations, highlighted by Walker (2008), are:

- "Tomatoes aren't sold with a bar code, like a bag of spinach, which would allow for easier traceback.
- Tomatoes from various farms are mixed together at re-packing houses, in order to meet size and color requirements for particular buyers, making it difficult to determine their origin.
- Tomatoes don't last long in consumers' homes, so there is no product left to go back and test after someone gets sick."

Another challenge can be going through paper sales-and-distribution records at many points along the supply chain.

PROCESSED FOOD AND INGREDIENTS

Stakeholder Input

An effective product tracing system would not only apply to FDA-regulated food products in commerce in the United States. For this reason, IFT supported FDA's notion that a suitable product to test in this pilot should be one that contains both USDA FSIS and FDA regulated constituents/ingredients and to the extent possible contain imported ingredients. Products containing ingredients like these that have been associated with outbreaks within the past several years include:

- tree nuts or treenut-containing ingredients such as almonds
- seasoned deli meats or other spice-containing products
- peanut or peanut paste-containing products

The sense of the OP was that tracing manufactured, processed food products would be generally facilitated by the fact that a single manufacturer was implicated and the number of SKUs/UPCs were limited (e.g., refrigerated cookie dough). The OP felt that with respect to processed foods, those associated with ingredient-driven outbreaks resulting from contaminated spices, peanuts or tree nuts are the most difficult for epidemiologists, which would boost the potential impact of product tracing in contributing to the identification of the root vehicle of contamination. Additionally, both spices and nuts are commingled, which is an element that FDA specifically charged IFT with exploring. In the stakeholder input received, very few mentioned a particular processed product or ingredient for consideration, indicating only that the supply chain should be complicated.

The task required IFT to select a processed food containing at least two ingredients to be traced. In considering ingredients associated with outbreaks that could be combined in a single processed food, peanuts or a peanut derivative (i.e., peanut paste) was highlighted, as were several spices. Additionally, FDA charged IFT with working closely with USDA FSIS, and the inclusion of chicken as an ingredient to trace was viewed favorably. A dish containing these three ingredients that have previously been associated with outbreaks (chicken, crushed and whole red chili pepper, and peanuts) was selected by FDA: an Asian-style meal with a spicy peanut sauce or peanut topping, like a Kung Pao or Pad Thai dish.

Because there are a limited number of manufacturers of these types of products (frozen meals containing chicken, a peanut component, and crushed red pepper), when one manufacturer expressed willingness to work with a dry version of the product (without chicken) FDA agreed. Later, IFT was introduced to a peanut butter manufacturer who was also willing to participate in the study, and given the association of peanut butter with outbreaks, FDA again agreed with their inclusion in the pilot.

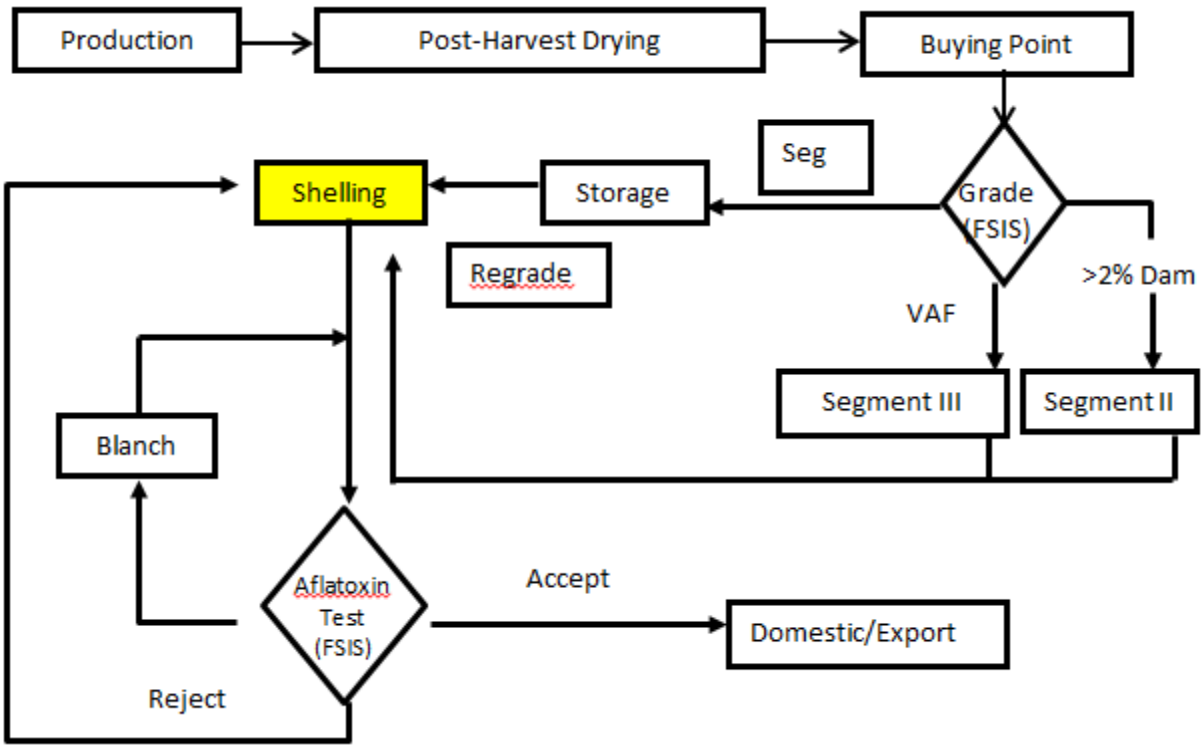
Ultimately, the pilot involving processed foods and ingredients examined three different types of consumer-level products and included three traced ingredients.

- Peanut butter
    - peanuts were traced as the ingredient of interest
- Frozen Kung Pao Chicken
    - peanuts, crushed red pepper via a sauce, and chicken were traced
- Dry Kung Pao Chicken
    - peanuts and spices (crushed red pepper via a sauce, and whole red chili pepper) were traced

Industry Profile: Peanuts

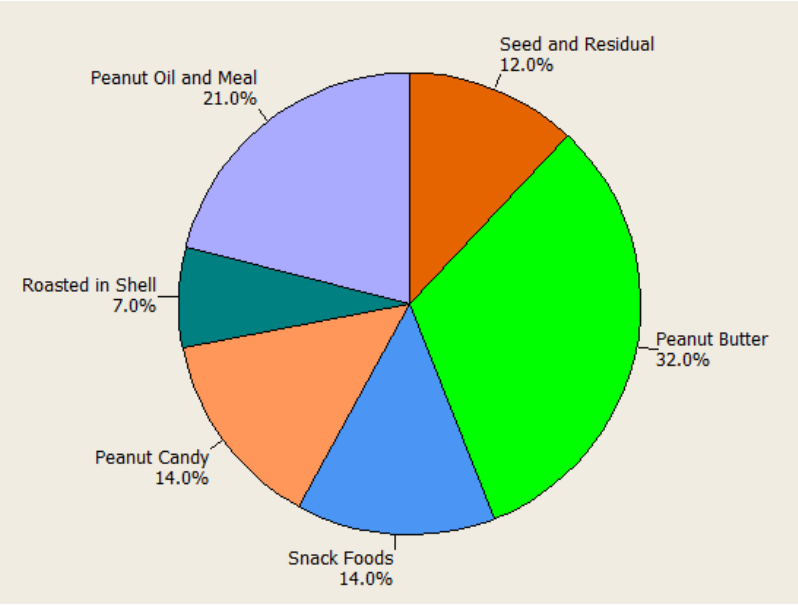
Given the bulk commodity nature of the product and the extent of commingling that occurs at several points in the supply chain, it is difficult to trace peanuts to a particular farm. In most cases, peanuts lose their farm-related identity once they are delivered to the buying point, similar to the grain industry. Peanuts produced in the United States are delivered to one of the 399 buying points in wagons or in larger semi-capacity trailers. Before they are unloaded, the peanuts are graded for quality and are allowed to cure via an air-drying process. Some growers will choose to cure their peanuts prior to delivery, while others will allow the buyer to dry them. The grading process is administered by Federal-State Inspection Services. The wagons can usually haul anywhere from 8,000 to 12,000 lbs., and the semi loads can contain up to 40,000 lbs. Once cured, the peanuts are unloaded and stored by variety and quality. An illustration of the peanut supply chain is provided in Figure 5 (Source: Dr. Tom Whitaker, NCSU). Additional details about peanut farming and production are included in Appendix K.

Figure 5. General Supply Chain Flow for Peanuts



Source: Dr. Tom Whitaker, NCSU.

Figure 6. Use of Domestic Peanuts



Source: Pooley (2005).

Peanut-containing products such as peanut butter can serve as a vehicle for pathogens. Roasting is the only kill step in peanut processing, and contamination introduced post-roasting can survive in peanut products for an extended time (GMA 2009).

Peanut-containing ingredients have been associated with *Salmonella* on a few occasions. Some complexities in peanut product-associated outbreak investigations are due to the vast number of products that contain peanut ingredients (Figure 6), the widespread consumption of these products, as well as a long shelf life. In late 2006-2007, peanut butter was statistically associated with a *Salmonella* Tennessee outbreak that affected 425 people in 44 states. A more notable outbreak associated with peanuts occurred from late 2008 to early 2009 when 529 people in 43 states were affected by *Salmonella* Typhimurium. Epidemiologists initially determined that King Nut creamy peanut butter, produced by the Peanut Corporation of America (PCA), was consumed by the majority of those who were ill. Later in the investigation, it was determined that other peanut-containing products were also causing illnesses. Recalling all implicated products was a long and arduous process, and the peanut industry lost as much as $500 million dollars after the recalls (Greis and others 2011).

Peanuts are also an ingredient of interest since they are used not only in human food, but also in a wide variety of pet foods. Dogs and cats rarely present with salmonellosis, but may serve as important vehicles of transmission to their owners, particularly children. The handling of pet foods and treats by humans is of greater concern than the possibility of pets becoming ill (FDA 2009).

The 2009 PCA recall affected pet treats and bird suet to an appreciable extent. This included dog biscuits, some packaged as multi flavor with one of the varieties being peanut flavored (FDA 2009). Peanut butter-filled hooves are a common dog treat along with the filled beef shank and rawhide.

Industry Profile: Dried Red Pepper

Within the Capsicum family, there are more than 200 types of chili peppers (ASTA 2008). Chili peppers, red peppers, green peppers, sweet peppers, and bell peppers are all part of the Capsicum family. The hot species of the Capsicum family are generally referred to as chili peppers, banana peppers, or simply hot peppers. To qualify as a spice, red peppers are dried and then either crushed or ground.

Table 8. Top Worldwide Producers of Chili Peppers

Country	% worldwide market provided
India	25
China	24
Spain	17
Mexico	8
Pakistan	7
Morocco	7
Turkey	4

Derived from ASTA (2008).

As shown in Table 8, the top worldwide producers of chili peppers are, in decreasing percentage of markets served, India, China, Spain, Mexico, Pakistan, Morocco, and Turkey (ASTA 2008). The crushed pepper used in the product explored in the pilots was from India. The United States also produces chili peppers. In New Mexico and California, each state contributes roughly equal amounts of the 85 million pounds of dried chilis grown annually (USDA-ERS 2010).

Chili peppers are generally hand-harvested (depending on the cost of labor). They may be cured and are then dried and ground. Ground product can be untreated, treated with ethylene gas, steam sterilized, or irradiated. Under ideal storage conditions, chili peppers have a shelf life of roughly 12 months (ASTA 2008).

Spices and seasonings can serve as a vehicle for bacterial pathogens, particularly when they are not treated or improperly treated and are added to “finished” products after thermal processing.

A large multi-state *Salmonella* Montevideo foodborne illness outbreak that occurred in late 2009 - early 2010 related to red and black pepper spice. A total of 272 known individuals were infected with a matching strain of *Salmonella* Montevideo in 44 states and the District of Columbia. Testing found the outbreak strain of *Salmonella* Montevideo in samples of red and black pepper for use in Italian-style meats. The meat processor as well as multiple spice processors voluntarily recalled products that may have been associated with the outbreak (CDC 2010b).

Another multi-state outbreak occurred in July 2007, infecting a reported 65 persons from 20 states, and was linked to Veggie Booty. This puffed rice and corn snack had a vegetable seasoning used as a coating, which was deemed responsible for the illnesses (CDC 2007). White pepper was also implicated in a 2009 outbreak of *Salmonella* Rissen, affecting 32 people in multiple states.

General Approach

Scale and Scope of Pilots

The pilots involved actual companies and evaluated their actual operating systems and real transactions. However, given the complexity of supply chains, had every trading partner of every pilot participant been a part of the study, as well as their trading partners, the task to IFT would have been unmanageable.

Two main ways to conduct the pilots were identified:

- Collect all data from all participants for a set period of time, and then query those data
- Collect specific data from pilot participants in response to a hypothetical scenario

In the 2009 tomato traceback pilot (IFT 2009), the former approach—collect all data from all participants for a set period of time and then query the data—was taken. Knowing the shelf life of tomatoes, participants in that project were asked to submit data in a standardized spreadsheet for a two-week period. The data were entered into a single database, which was used by a technology company to illuminate supply chain pathways. That project sought to answer the question "do the data exist to follow a product through the supply chain?" Upon querying the data in an attempt to respond to a hypothetical traceback scenario, it was found that the data as collected were insufficient to conduct robust tests.

Thus, for the current study, the latter approach was taken. Since a key objective of this task was to identify ways to more rapidly and effectively conduct a traceback investigation, it did not seem that having participants load data into a spreadsheet for a single evaluation at one point in time would help reach the task objectives. Recognizing the amount of time within which IFT had to complete the task, asking participating firms to make major changes to their systems in order to identify mechanisms to more rapidly obtain information, or to more efficiently analyze the information, seemed unrealistic. Therefore, instead, IFT took the approach of engaging many participants (more than what was recommended through stakeholder input) and having in-depth conversations or visits with nearly each one in advance of launching the pilot scenarios in order to better understand their current approaches to recordkeeping and gain an understanding of how their supply chain functions. In this way, the results of the pilots, including the amount of time it took for information to be shared with IFT, and the format/nature of the information, could be more readily assessed by IFT. These results, combined with follow up conversations conducted by Deloitte Consulting as part of the cost-benefit evaluation, allowed firms to be grouped by the "maturity" of their tracing systems and correlated with how they responded and performed in the pilots.

The pilots were designed as conference-room based. IFT did not visit each facility to verify CTEs, and in general, did not ask participants to modify their systems or employ new technologies as part of the pilot. IFT accepted the data provided by participants and description of their practices on good faith. Although FDA expressed a preference in the kick-off meeting for real-time data, after discussion with the OP and select industry representatives, it seemed that this would be extremely difficult and that historical data should be used.

IFT has had great success in soliciting food industry participation in previous tasks, including sharing of data. IFT informed all pilot participants that IFT would not remove any company-identifying information from materials supplied by companies in connection with the study, and that FDA would redact any documents or data that are to be made public in keeping with the applicable laws and regulations governing disclosure. Additionally, all contributors were required to sign the confidentiality statement required by the contract.

Data, Standards, and Technology

IFT expected that different supply chain partners currently collect and capture a variety of data, in different formats, on different types of documents, and in different ways. For the purposes of the pilots, IFT considered specifying the types of data to be collected. IFT did not seek, through this task, to build a central database or other data management system for FDA. Instead, IFT tested how the KDEs can be linked (ideally through technology or technologies) without undertaking considerable technology development or requiring industry to substantially change their practices. IFT was encouraged, through stakeholder input, to consider the technologies currently in use in food companies, including accounting software, enterprise resource planning (ERP), and warehouse management systems (WMS), which are further described in Chapter 7.

IFT was tasked with using a "collaboration platform." Attributes associated with a collaboration platform and the process used to select a platform vendor were considered in light of the stakeholder input received. Details about the collaboration platform are provided in Chapter 5.

Development of "Key Questions"

A "Key Questions" document was drafted to indicate what the pilots would be specifically addressing (Appendix L). A master list of key questions was originally developed and vetted through the OP. These questions were then refined and separated into four categories: depth, breadth, precision, and access, to ensure that the specific areas of interest to FDA as described in the task (Activity 1) would each be addressed by the pilots. The produce and processed food/ingredient groups reviewed and finalized the key questions and proceeded to develop the pilot scenarios for each supply chain. Once the scenarios were finalized, the key questions were overlaid with the scenarios, to identify which scenarios answered which key questions and to identify any gaps.

Development of Scenarios and Initiation of Mock Tracebacks

IFT worked with state investigators and others, as described in Chapters 3 and 4, to determine what to request and how to present the request for records to pilot participants. Miller and others (2012) also provided a "checklist" of the information that should be requested of firms during an investigation. The "FDA Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations" (FDA 2001) also provides excellent direction on how an investigation should be approached. IFT did not visit the facilities in order to collect records, unlike the process used by federal investigators. IFT also did not ask about how the product was used, since these questions are typically asked to determine if contamination was possible at a given point. IFT opted to not ask for specific records but asked for any records that had the information necessary to trace the product. Each request was scripted so that the requests were consistent between different pilot participants, enabling a comparison between their responses. The number of scenarios launched was based on the existing supply chain relationships. More firms/supply chains volunteered for the tomato pilot, so 12 mock tracebacks were conducted. Participation in the processed food-ingredient pilot was more limited, permitting 4 mock tracebacks to be executed. One of these four was highly complex. Details of each scenario are presented in Chapters 3 (produce) and 4 (processed food - ingredient).

Use of a Data Summary Template

In an early conversation with a pilot participant, the firm asked if IFT would provide a template so that the firm could easily provide the information needed. Initially, IFT had not planned to provide a template, fearing that it would be viewed as pre-selecting the data that were deemed necessary for tracing products rather than more objectively testing the value of various pieces of information.

However, in considering this request (which was followed by subsequent independent requests for a template), IFT, in consultation with the groups advising the pilots, determined that there would be benefit in determining: (a) if a template would result in a more rapid analysis of data and (b) if the KDEs identified by a previous group (Bhatt and others 2012) were sufficient to link products internally within a company and externally between trading partners.

IFT was aware that the PMA had previously developed a "recall template" that seemed to have data elements consistent with the IFT Traceability Improvement Initiative (TII) recommendations (Bhatt and others, 2012). PMA agreed to provide that template as the foundation for the pilot response template. Recognizing the differences between recalls and tracebacks, each pilot group offered suggestions for adaptation of the template, and an ad hoc subgroup was formed to refine the document. Two versions of the template were produced: one specific to tracebacks and one for traceforwards. Both templates were provided as multi-tab spreadsheets that requested contact information for the party providing the information, the immediate previous supplier(s) or subsequent recipient(s) as appropriate, and the data for shipping, receiving, and transformations.

Within the discussion of required versus optional data, the discussion of standardized numbers began. There were questions as to whether FDA would find utility in requesting that firms provide them with their FDA facility registration number. Some expressed concern that, for a system to operate on a truly global scale, a U.S.-centric (and FDA-centric) approach should not be taken and offered that a more universal numbering system, such as the Dun and Bradstreet DUNS number or GS1 GLN, be used as a facility reference number.

The use of the template was entirely optional but was offered to all pilot participants. A copy of the template is provided as Appendix M.

Evaluation of Results

IFT developed a spreadsheet to internally track each scenario, which included the following elements:

- company, name and email of contact
- date and time of outreach
- date and time of response
- indication of whether follow up questions were asked ("re-contact"), and the reason for the follow up
- types of information provided (e.g., bills of lading, Purchase Orders)
- format of provided information (e.g., PDF, spreadsheet)
- identification of whether the IFT-supplied template was used
- time required for IFT to analyze the information provided

IFT used the information provided by pilot participants to identify how products moved through the supply chain, from the point of sale/service to consumers back as far in the supply chain as possible. IFT found it helpful to create a visual diagram of the flow of product, identifying the data used to link the incoming and outgoing product within a facility, as well as link the shipments of a particular product between establishments.

Based on the previous discussions with pilot participants, IFT had a sense of the types of systems and processes that were used, which in some cases aided in the analysis of results. In addition to tabulating the time required for each firm to respond and IFT to analyze, IFT also evaluated each firm on:

- Time to identify source/convergence

    - This value represents the amount of time between the initial outreach to the first firm contacted (generally retail or foodservice provider) and the time when IFT either could not trace the product back further due to non-participation or the time when IFT had received enough information to identify the point of convergence in the supply chain. The time value was a sum of industry response time and IFT analysis time. This value is equal to or shorter than the sum of "cumulative industry response time" and "IFT analysis time." When it is shorter, it is because supply chains had greater visibility which enabled the acquisition of information more than "one step back." For example, a foodservice chain was able to provide information through the distributor back to the grower. In another instance, a manufacturer assembled the supply chain participants associated with the product on conference calls resulting in a more rapid determination of the point of convergence than the "one back" process used by IFT.
- Cumulative industry response time
    - This value represents the sum of the response times for each participant in the supply chain for that scenario. IFT tracked the time between when the firm was contacted with a request and the time when adequate records were provided that allowed IFT to progress to the next supply chain participant in the scenario.
- Total document pages
    - IFT counted each page sent by each firm. When information was contained in a spreadsheet, IFT considered each spreadsheet tab a separate page.
- IFT analysis time
    - IFT tracked the amount of time needed to find the relevant information contained within records, match it with information provided by other supply chain partners (as applicable) and interact with participants to gain clarity as needed.
- Number of participants using IFT template or summary document
    - Participants were allowed the option of providing information to IFT using a template document (Appendix M; discussed earlier in this chapter). IFT noted if participants used this template or if they provided another summary-level document.
- Number of re-contacts of IFT with participants
    - IFT found that it was often necessary to follow up with a participant to request additional information or seek explanation of the records provided.
- Breadth and precision
    - Breadth was defined in the Statement of Work as the amount of information the tracing system records. Precision was defined as the ability to pinpoint the movement of a product. IFT combined these two elements to reflect that certain information, or combinations of information, is needed to track a product with specificity. In addition to evaluating the information captured and provided by a firm against the KDEs identified in the Recommendations (Chapter 10), IFT also considered how a firm's practices impacted the ability to trace a product. When the FIFO inventory rotation system was used, which relied only on a timeframe to estimate when a product was "likely" sold (i.e., not being able to relate the outbound product with the inbound product), a firm could receive no more than a "medium" in this category. When errors were found in information, this also had a negative impact on the ranking.
- Access
    - Access was defined in the Statement of Work as the speed with which information is communicated and disseminated. In considering how to evaluate firms against this parameter, IFT considered not only the amount of time needed for a firm to respond to IFT,

but also the ease with which IFT could understand and act on the provided information, and considered this in light of the request made (e.g., information for one Purchase Order versus for a two-month time frame). As a rule of thumb, when IFT received responses within 10 hours and the records were readily analyzed by IFT, firms often received an access score of "high." When a firm took more than 24 hours to respond and/or understanding the information provided was difficult, firms received an access score of low. When errors were found that delayed the progression of the scenario, this had a negative impact on the access score. The use of the IFT template or a participant-developed summary sheet generally had a favorable impact on the ranking as did the ability to provide information for more than one-back in the supply chain (e.g., if the time to respond was long, but more useful information was provided, a firm was not penalized with a low access score).

- Depth
    - Depth is the ability of the system to capture information more than one up - back. "Average" firms were able to identify their immediate previous supplier, and some were asked to identify immediate subsequent recipients. There were a few firms who, because of the nature of their business relationships, had greater visibility through their supply chain and were either able to access data more readily than expected in a one up - back system or who held these data themselves. These were rated "above average."
- System ranking
    - This metric uses a three-point scale (with three being the highest) to quantitatively assess the technological capabilities and sophistication of a firm with respect to product tracing. The score equally weighted three categories: Self-Reported Product Tracing System Ranking, Responses to Nine Improvement Options, and System Type Rating. System Type Rating considered a firm's ability to capture information in an automated way, demonstrate the movement of the product within the facility and establish links to supply chain partners. Because this measure relied on the firms capabilities with respect to the nine improvement options described in Chapter 7, only firms who responded to those questions received a system ranking.

IFT considered the results in light of the "timeframe for which records were requested." Each scenario was slightly different. In some instances, the lot code was pre-identified (e.g., peanut butter) and IFT requested information from the manufacturer for just this lot code. In other instances, less information was presumed to be known so a retailer or foodservice chain was asked for records for a several-week to several-month timeframe. IFT then used the information provided by the retail/foodservice participant to guide the records request further through the supply chain. IFT expected that, as a general rule, the longer the timeframe, the more information would be provided, and the more time firms would need to respond.

Identifying Participants

When FDA selected the products to be explored by the pilots, IFT quickly sought participants by posting notices on the ift.org/traceability website, LinkedIn groups, the IFT community pages, IFT's twitter page, as well an email sent to IFT's contact list (including trade associations). IFT expended substantial effort to obtain an adequate number of participants (who can be linked to each other as trading partners). IFT provided information (shown in Appendix N) detailing the conditions of participation and describing participants' roles and obligations.

In general, there were several concerns that IFT needed to address to ensure that firms understood the benefits to participating, were clear on the limited scope of the study (e.g., that we were not going to review their HACCP plans), and understood the expected time commitment associated with varying

levels of participation. IFT had dozens of conversations with potential participants prior to their agreeing to volunteer for the pilots. Often times, these conversations were with the uppermost levels of management (e.g., company CEOs, Presidents).

Each food company participating in the pilots was invited to serve on a group that would help document the limitations of the pilots resulting from the composition of the participants, ask the right questions in the test, analyze results, and assist in drawing conclusions and recommendations from the tests.

IFT recognized that the task and the pilots could benefit from the inclusion of a number of individuals with expertise in product tracing. Therefore, IFT issued a call for nominations to the groups using the same outreach mechanisms employed to solicit stakeholder input. A letter (Appendix O) was sent to roughly 20 individuals selected to serve on the groups.

Small and Very Small Businesses

An attempt was made to include representatives from small and/or very small businesses throughout the pilots as per the task requirements. During the stakeholder input sessions, there were several comments regarding the need to address small business concerns. When IFT encountered difficulty soliciting participation of certain types of small and very small business, IFT extended invitations to representatives to serve on the respective pilot panels. For example, the National Grocers Association, which represents small and independent grocers, participated in the processed foods group, and a consultant who works with entrepreneurs, including small produce growers, contributed to the tomato group. The produce trade associations recommended that IFT contact the Delaware Growers Association (and provided a contact) as well as local extension services in order to identify small tomato farmers who could contribute to the panel deliberations, although none were identified by the organizations contacted. The North American Perishable Agricultural Receivers, which consists primarily of produce wholesaler receivers, including those operating on terminal markets, was instrumental in soliciting the participation of two produce wholesalers, representing two terminal markets, both of whom were small, and also facilitated some of the discussions with small businesses pertaining to cost described in Chapter 7.

Chapter Summary

IFT sought stakeholder input regarding several aspects of the task through written and oral comment. Given the FSMA requirement that the foods evaluated in the pilots must have been associated with significant outbreaks between 2005-2010, stakeholder input suggesting that more complex supply chains should be studied, and that products that were more complex (e.g., multi-ingredient, commingled, etc.) should be part of the pilots, FDA selected tomatoes as the produce item, and spices, peanuts and chicken as the ingredients in the second pilot, for which dry and frozen Kung Pao Chicken and peanut butter were independently evaluated. IFT actively sought participants by reaching out through a network of contacts as well as other public postings.

IFT spoke with nearly each firm in advance of launching the pilot scenarios to understand the recordkeeping and handling processes in place in order to evaluate their impact on the firm's ability to trace products. The key areas IFT sought to address in the pilots were identified and reviewed by two groups—one for each pilot—consisting of pilot participants and other subject matter experts.

The pilots relied on historical data, collected in whatever fashion the firm employed. IFT developed a reporting template that could be used by participants if desired. Results were evaluated based on a number of factors, including the time for a firm to respond to a request for track and trace records, as well as IFT's ability to analyze the information provided.

CHAPTER 3. PRODUCE PILOT

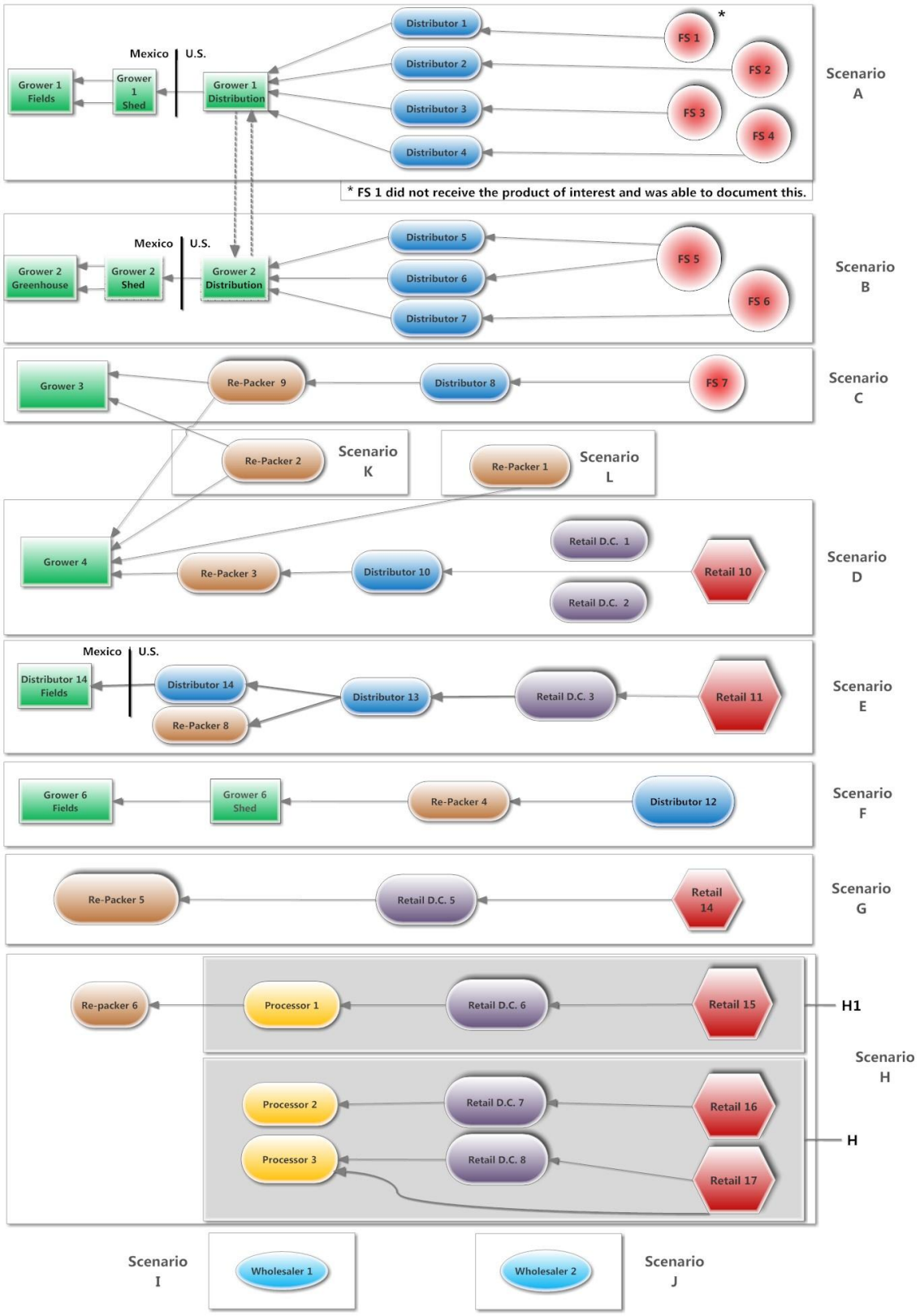
Finding Participants

The produce industry, including the tomato industry, overall expressed great support for the pilots. In particular, The PMA, United Fresh Produce Association (UFPA), California Tomato Farmers and the Florida Tomato Growers each actively solicited their members and encouraged participation in the produce pilot. One foodservice chain in particular rallied a number of their tomato growers, suppliers and distributors. Several other retail and foodservice participants also reached out to their supply chain partners (and further back within the supply chain) to secure participants.

IFT was able to assemble a complex but related network of foreign and domestic tomato growers, packers, re-packers, distributors and several end users despite the varied seasonality of tomato production and the timeframe within which the pilot was conducted.

A diagram illustrating how the participants were divided between scenarios and the relationships between the participating firms is presented in Figure 7. Each box represents an actual firm or entity and existing relationship to trading partners. The diagram does not include all supply chain partners (i.e., each customer or each supplier) but only includes those firms agreeing to participate in the study. In several scenarios IFT requested traceforward information but the inclusion of this information in the figures (sometimes hundreds of customers linked to one participant) was deemed unnecessary.

Figure 7. Flow Diagrams of Supply Chains (Scenarios) of Produce Pilot Participants



(FS = Foodservice)

Scenarios

Seventeen individuals, including two state traceback investigators and industry experts, spent two hours discussing the details of the scenarios to be used for the tomato pilots. Prior to the call, each participant received the supply chain flow diagram as well as an outline of potential scenarios and/or situations that could be tested. After much discussion, because of the number of parallel supply chain paths, the group felt that a comparison of product tracing methods and systems could best be achieved by applying similar "simple" scenarios to each of the supply chain paths.

A rough draft of the scenarios was provided to the OP members and FDA, and based on their input, the scenarios were further refined and finalized. After the scenarios were finalized, they were mapped to the required "key questions" (Appendix L) to ensure that as developed, the scenarios, in combination with those tested in the prior tomato pilot, would sufficiently cover all the aspects identified for the current tomato pilot.

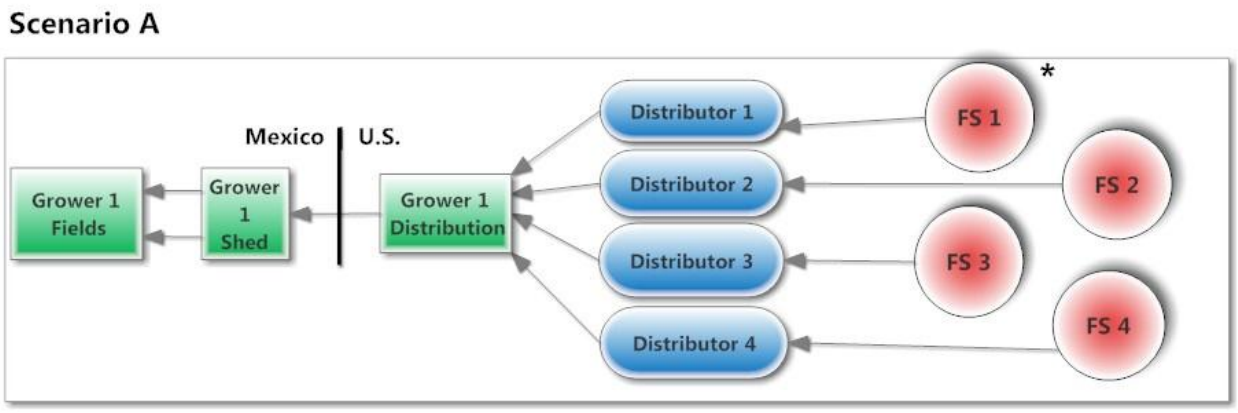
RESULTS

The results of each scenario, including the firm's response and IFT's analysis, were evaluated based on the factors described in Chapter 2, and should be viewed in light of the assumptions and limitations discussed in Chapter 8, particularly that as an opt-in study, participants may be skewed toward those that have better-than-average tracing practices.

Scenario A

In Scenario A (Figure 8, Table 9), restaurants in non-contiguous states were associated with a foodborne illness. This foodservice chain, known to have great visibility throughout their supply chain, provided traceback information about their grower and fields in just over 24 hours. Although the chain provided pertinent documentation, such as invoices, purchase orders etc., IFT still contacted each point in the supply chain directly to ensure that similar information was provided. A twist in this scenario occurred with one restaurant location that was initially reported to have received only one case of tomatoes in the three-week timeframe, but was ultimately discovered (by the foodservice chain working with the distributor) to have had three cases delivered on three different dates. The initial confusion was due to the fact that the distributor was operating under two different names unbeknownst to the foodservice chain. IFT noticed that the way tomatoes were described changed many times within a relatively simple supply chain path, and the foodservice chain provided clarification. The distributor's information pointed back to a single provider of tomatoes (Grower A), but the documentation showed that in some instances tomatoes from the grower in Scenario B were provided to Grower A. These tomatoes were traced to nine different lots, of which one was common to all three distributors. The same tomatoes were referred to as "5x5," "5x6" and "Tomatoes 25#." Those in the tomato industry submitted that the name should not matter if the lot number is carried through, but IFT found that many invoices and purchase orders had several different tomato items on them, and lot numbers were not associated with each tomato line.

Figure 8. Pilot Scenario A



Timeframe for which records were requested	Time to Identify Convergence	Total Document Pages	Cumulative Industry Response Time	IFT Analysis Time	# Using IFT Template or Summary Doc	# Re-contacts
2 weeks	22 hr 45 min	278	36 hr 18 min	~5 hr 30 min	3	6

Table 9. Pilot Scenario A, Node Breakdown

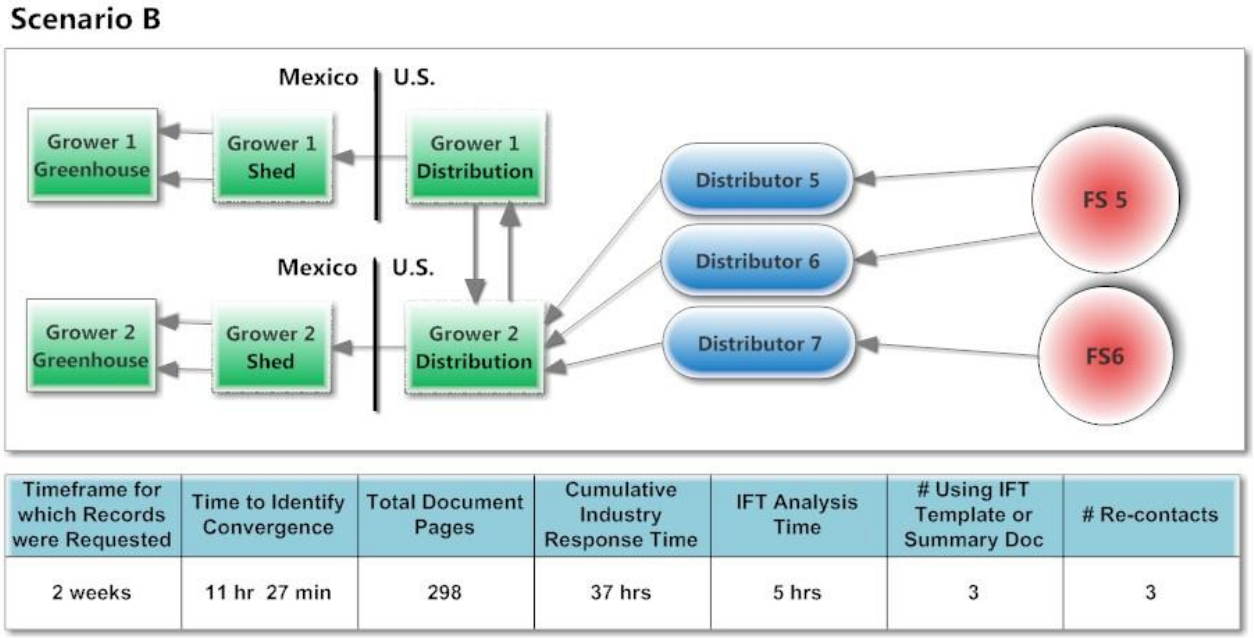
Node	Response Time	IFT Analysis Time	Breadth, Precision*	Access*	Depth*	System Ranking*
Grower 1 Grower 1 Shed Grower 1 Distribution	3:47	0:50	Medium	Medium	Average	N/A
Distributor 1	Did not get product	N/A	N/A	N/A	N/A	N/A
Distributor 2	2:08	0:35	Medium	High	Average	N/A
Distributor 3	1:56	0:25	Medium	Medium	Average	3.00
Distributor 4	7:12	1:10	Medium	Low	Average	N/A
FS 1, 2, 3 and 4 (same chain)	21:15	2:30	Medium	High	Above	N/A

*The ways in which these factors were evaluated are described in Chapter 2. System Ranking could only be performed for participants providing information about cost (see Chapter 7)

Scenario B

Scenario B (Figure 9, Table 10) was very similar to Scenario A in that the same foodservice chain was contacted. However, the restaurants and distributors involved received tomatoes from a different grower than in Scenario A. One distributor was involved in both Scenario B and C, and therefore received requests from two major customers that were serviced by different distribution center locations and both requests were managed through the same headquarters. As in Scenario A, the grower in Scenario B ("substitute" grower from Scenario A), provided tomatoes sourced from Grower A as well as their own tomatoes. The point of convergence identified in Scenario A (the lot common to all distributors and restaurants in that scenario) also appeared in Scenario B, which enabled a more complex scenario to be tested using the collaboration platforms (Chapter 5).

Figure 9. Pilot Scenario B



Timeframe for which Records were Requested	Time to Identify Convergence	Total Document Pages	Cumulative Industry Response Time	IFT Analysis Time	# Using IFT Template or Summary Doc	# Re-contacts
2 weeks	11 hr 27 min	298	37 hrs	5 hrs	3	3

Table 10. Pilot Scenario B, Node Breakdown

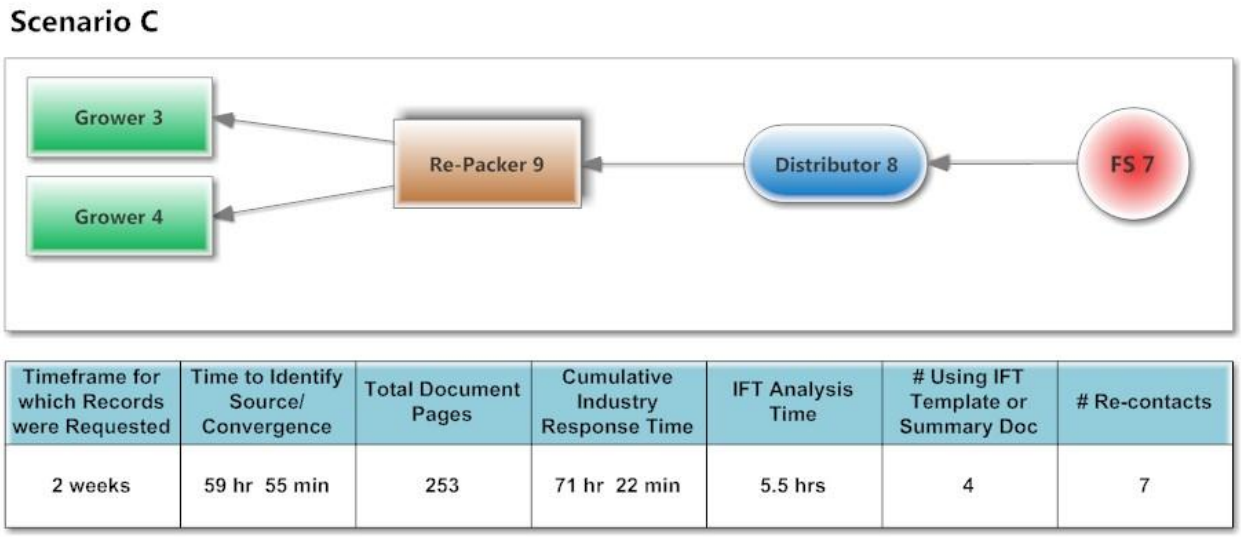
Node	Response Time	IFT Analysis Time	Breadth, Precision*	Access*	Depth*	System Ranking*
Grower 2	1:31	1:30	High	High	Above	3.00
Distributor 5	0:49	0:10	Medium	High	Average	2.00
Distributor 6	0:55	0:45	Medium	High	Average	N/A
Distributor 7	21:27	0:45	Medium	Medium	Average	N/A
FS 5 & FS 6 (same chain)	9:27	2:00	Medium	High	Above	N/A

*The ways in which these factors were evaluated are described in Chapter 2. System Ranking could only be performed for participants providing information about cost (see Chapter 7)

Scenario C

Scenario C (Figure 10, Table 11) involved a different foodservice chain and information was needed for three different restaurant locations receiving tomatoes from a common distributor. These restaurants were asked to provide information about tomatoes received during a two-week window. In contrast to Scenarios A and B, this scenario included a re-packer who needed to provide information related to 26 POs. Additionally, this re-packer received tomatoes from two different growers that also participated in the study. One grower was asked about tomatoes from 12 POs and the other for 16 POs. This scenario was unique because the re-packer was asked for information about more POs than in any other scenario. In addition, it was fortunate to have more than one grower in the supply chain participate.

Figure 10. Pilot Scenario C



Timeframe for which Records were Requested	Time to Identify Source/ Convergence	Total Document Pages	Cumulative Industry Response Time	IFT Analysis Time	# Using IFT Template or Summary Doc	# Re-contacts
2 weeks	59 hr 55 min	253	71 hr 22 min	5.5 hrs	4	7

Table 11. Pilot Scenario C, Node Breakdown

Node	Response Time	IFT Analysis Time	Breadth, Precision*	Access*	Depth*	System Ranking*
Grower 3	1:01	1:30	High	High	Average	3.00
Grower 4	28:21	0:30	High	High	Average	N/A
Distributor 9	5:15	0:30	Medium	High	Average	3.00
Distributor 8 / Worcester	24:18	2:00	Medium	High	Average	N/A
FS 7	27:22	0:30	Low	High	Above	N/A

*The ways in which these factors were evaluated are described in Chapter 2. System Ranking could only be performed for participants providing information about cost (see Chapter 7)

Scenario D

Scenario D (Figure 11, Table 12) focused on tomatoes delivered to a sandwich shop located inside a retail store. The scenario was set so that illnesses were associated with two stores in two states occurring during a 10 day period. The retailer was asked for information about tomatoes offered for sale over a three-week period, which was traced to a single distributor through 28 POs. The distributor sourced from a re-packer, and the tomatoes of interest were associated with six "lot numbers" as assigned by the distributor to incoming tomatoes based on the purchase order number. The re-packer was able to provide bills of lading showing that the tomatoes were sourced from two growers, one who was not participating in the pilots and another who was a grower in Scenario C. The participating grower included lot numbers on the bills of lading, and information was requested for six lots.

Figure 11. Pilot Scenario D

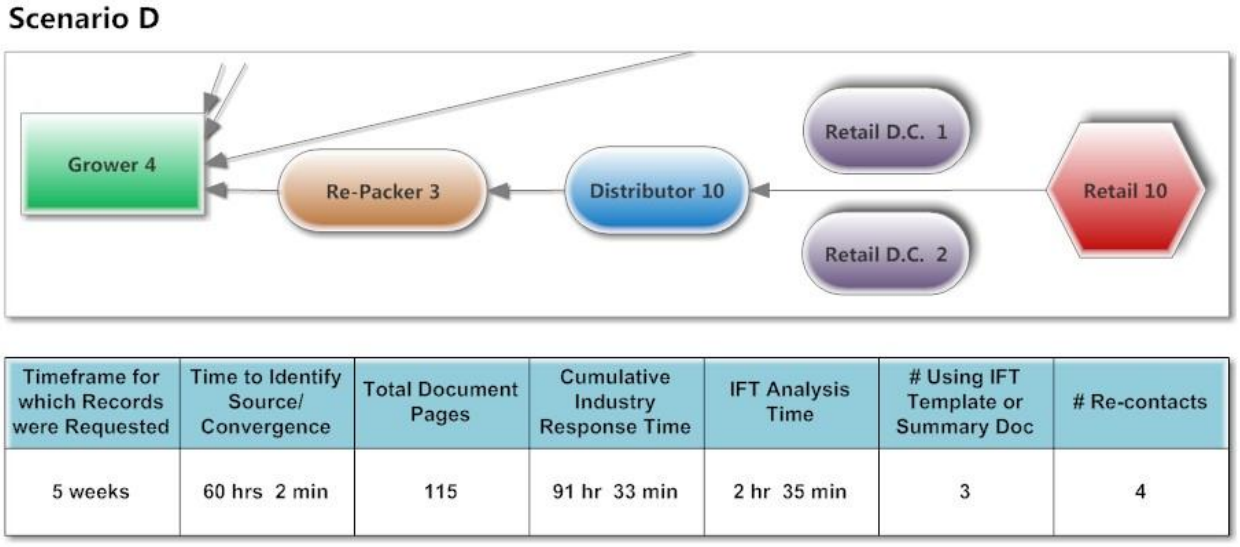


Table 12. Pilot Scenario D, Node Breakdown

Node	Response Time	IFT Analysis Time	Breadth, Precision*	Access*	Depth*	System Ranking*
Grower 4	21:32	0:30	High	High	Average	N/A
Re-Packer 3	4:52	1:05	Medium	High	Average	3.00
Distributor 10	29:10	0:50	Medium	Low	Average	N/A
Retail 10	23:55	0:10	Low	High	Average	1.67

*The ways in which these factors were evaluated are described in Chapter 2. System Ranking could only be performed for participants providing information about cost (see Chapter 7)

Scenario E

Scenario E (Figure 12, Table 13) involved a different retailer, and information was sought for only one retail location. IFT worked with the supply chains before launching the scenarios, to ensure an understanding of the relationships and product movement. However, upon the request for information, records showed that the tomato provider had changed. This resulted in IFT following these tomatoes through a completely unknown path that included a re-packer who sourced from two different providers. Due to the lack of pre-existing relationships, IFT was unable to acquire all information from these two providers (not shown in the diagram below due to their non-participation in the pilots, but who supplied to the re-packer) to allow trace back to the field. One firm indicated that they were owned by a grower and were the exclusive provider of the grower's tomatoes.

Figure 12. Pilot Scenario E

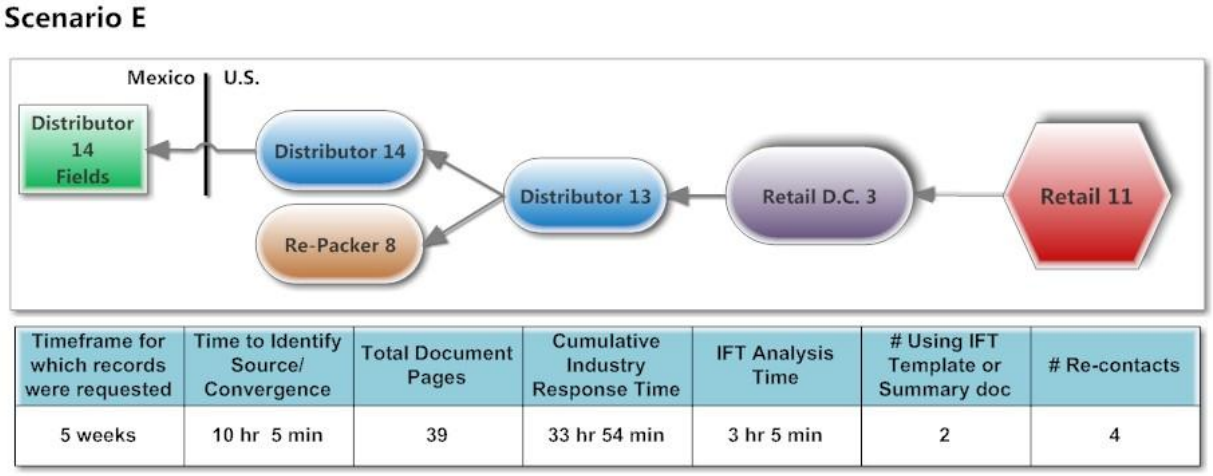


Table 13. Pilot Scenario E, Node Breakdown

Node	Response Time	IFT Analysis Time	Breadth, Precision*	Access*	Depth*	System Ranking*
Grower 11	Contacted; did not participate	N/A	N/A	N/A	N/A	N/A
Re-Packer 8	25:29	0:10	Medium	Medium	Average	N/A
Distributor 13	0:50	0:40	Medium	High	Average	3.00
Retail DC 3 Retail 11	7:35	1:00	Low	Medium	Average	N/A

*The ways in which these factors were evaluated are described in Chapter 2. System Ranking could only be performed for participants providing information about cost (see Chapter 7)

Scenario F

Upon launching Scenario F (Figure 13, Table 14), a foodservice chain responded that they no longer wished to participate. Because the rest of the supply chain was lined up, IFT worked with a distributor to identify another foodservice chain customer to participate. However, when a commitment could not be obtained quickly, IFT and the foodservice distributor agreed to proceed using a slightly modified scenario that began with the foodservice distributor as the initial point of contact, with information sought for three foodservice locations over a one-week period. The impact of this change was that it allowed IFT to contrast the impact of contacting a foodservice chain (as in the other scenarios) versus the distributor. Other scenarios asked for more complete information from the foodservice chains; here the assumption was that the only known information was the distributor (no invoices, receipt dates, etc., were provided to the foodservice distributor).

Figure 13. Pilot Scenario F

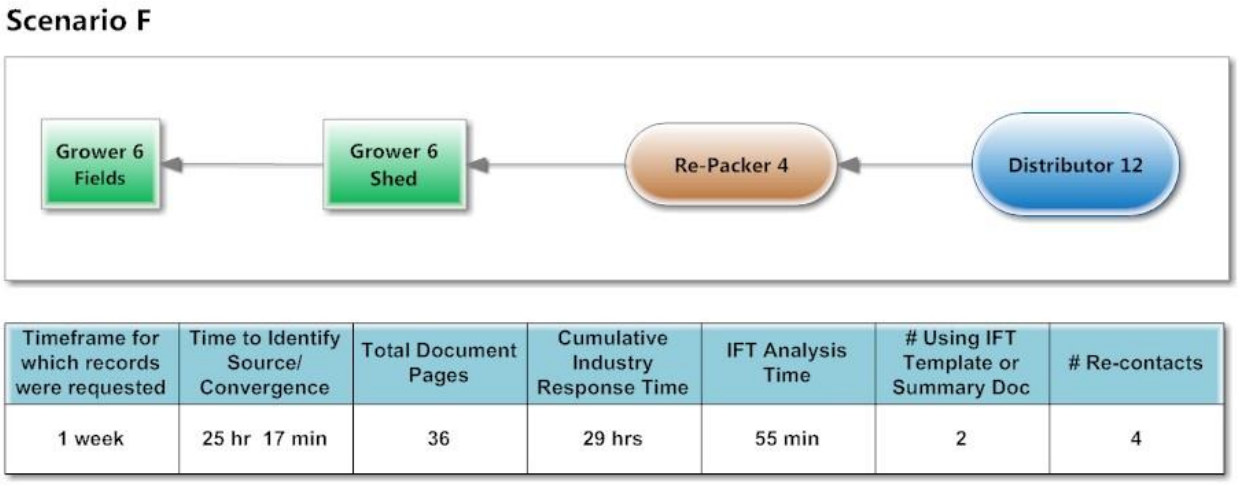


Table 14. Pilot Scenario F, Node Breakdown

Node	Response Time	IFT Analysis Time	Breadth, Precision*	Access*	Depth*	System Ranking*
Grower 6 Fields Grower 6 Shed Re-Packer 4	4:00	0:15	High	High	Average	N/A
Distributor 12	24:57	0:20	Medium	High	Average	2.33

*The ways in which these factors were evaluated are described in Chapter 2. System Ranking could only be performed for participants providing information about cost (see Chapter 7)

Scenario G

Scenario G (Figure 14, Table 15) involved another retail chain who was asked to provide information on tomatoes in three stores (two states) in a scenario nearly identical to Scenario D. Records requested from Retail 14 resulted in bills of lading from Retail DC 5 to Re-packer 5. Re-packer 5 provided a very useful summary document that included all of their suppliers as well as how many cases were shipped to other customers from the same lot. Analysis time for both nodes was very short, despite the very long response time from the retail chain.

Figure 14. Pilot Scenario G

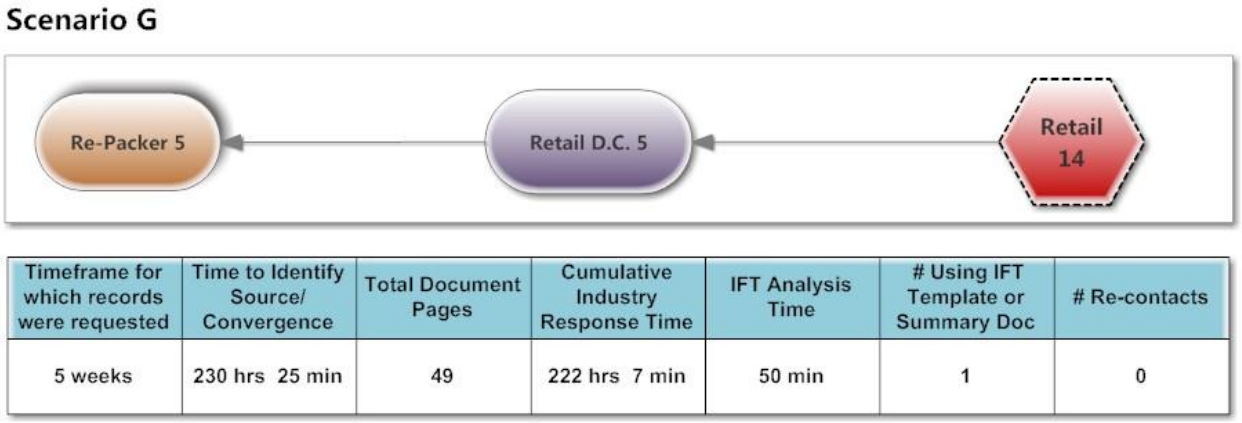


Table 15. Pilot Scenario G, Node Breakdown

Node	Response Time	IFT Analysis Time	Breadth, Precision*	Access*	Depth*	System Ranking*
Re-Packer 5	21:42	0:20	High	Medium	Average	N/A
Retail DC 5 Retail 14	200:25	0:30	Low	Low	Average	2.33

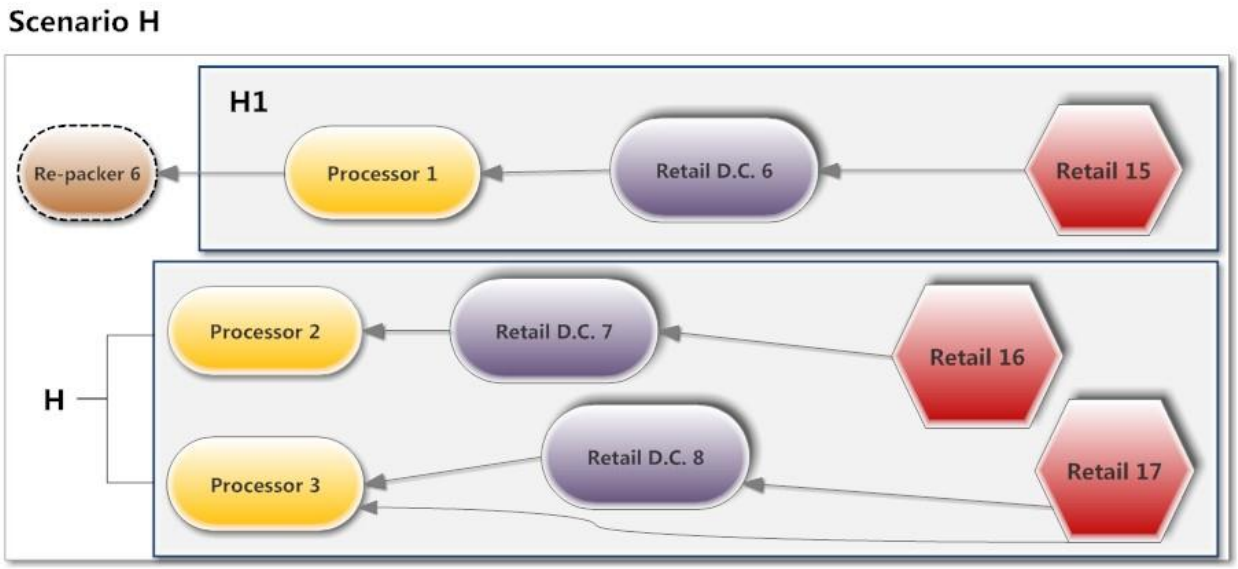
*The ways in which these factors were evaluated is described in Chapter 2. System Ranking could only be performed for participants providing information about cost (see Chapter 7)

Scenario H

The retailer in scenario H (Figure 15, Table 16, Table 17) was known to use three different tomato processors who sliced tomatoes and shipped them to various retail locations (all had agreed to participate; one agreed to work with the re-packer who provided the tomatoes). Several versions of this scenario were launched to engage all participants in this supply chain network. The first scenario launched for this retailer (Scenario H) resulted in tracing 16 POs through one processor, 24 POs through another, and 17 through a third processor. A re-packer who supplied one of the processors was identified and agreed to participate. However, the processor sourced tomatoes from more than one re-packer, and the specific tomatoes that were the subject of the initial scenario happened to not link back

to that re-packer. Therefore an additional scenario was launched (Scenario H1) limited to only one PO number that the processor knew led back to the re-packer.

Figure 15. Pilot Scenarios H and H1



Scenario	Timeframe for which records were requested	Time to Identify Source/ Convergence	Total Document Pages	Cumulative Industry Response Time	IFT Analysis Time	# Using IFT Template or Summary Doc	# Re-contacts
H	5 weeks	5 hr 2 min	7	37 hr 56 min	2 hr 10 min	2	0
H1	5 weeks	1 hr 38 min	3	4 hr 8 min	20 min	2	0

Table 16. Pilot Scenario H, Node Breakdown

Node	Response Time	IFT Analysis Time	Breadth, Precision*	Access*	Depth*	System Ranking*
Processor 2	28:11	1:30	High	High	Average	2.67
Processor 3	7:53	0:30	High	High	Average	N/A
Retail DC 7 Retail DC 8 Retail 16 Retail 17	4:52	0:10	Low	Medium	Average	2.00

Table 17. Pilot Scenario H1, Node Breakdown

Node	Response Time	IFT Analysis Time	Breadth, Precision*	Access*	Depth*	System Ranking*
Processor 1	2:45	0:05	High	High	Average	3.00
Retail DC 6/ CA Retail 15/ San Diego/Santa Maria	1:23	0:15	Low	Medium	Average	2.00

*The ways in which these factors were evaluated is described in Chapter 2. System Ranking could only be performed for participants providing information about cost (see Chapter 7)

Scenarios I and J

These scenarios (Figure 16, Table 18, Figure 17, and Table 19) were similar in that both involved wholesalers (one on a terminal market and one just off the market). Neither wholesaler was "linked" to the pre-existing supply chain (either at the customer end or at the distributor/re-packer/grower end) so the nature of these scenarios was different and focused on internal tracing. Each company was asked to trace tomatoes received on a particular date through their systems to (anonymous) customers.

Figure 16. Pilot Scenario I

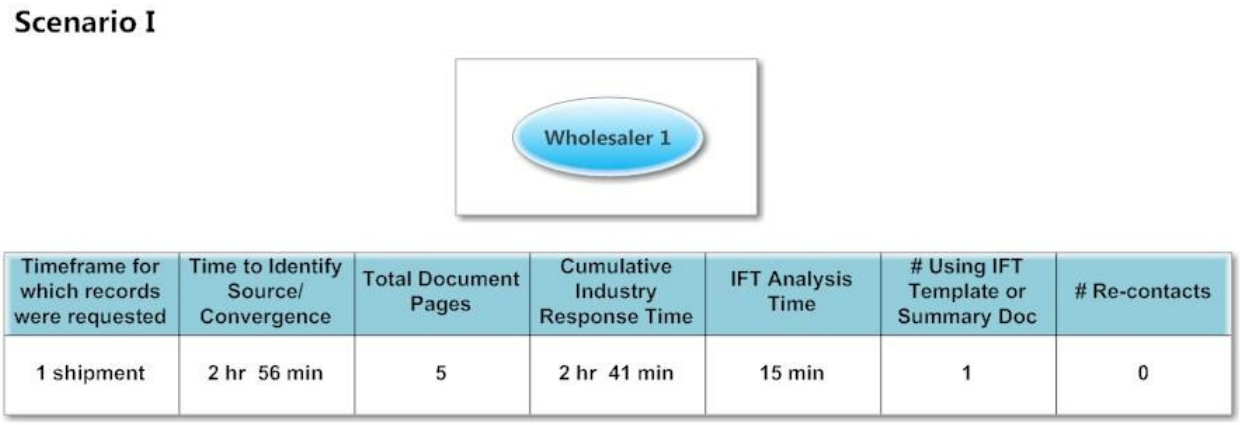


Table 18. Pilot Scenario I, Node Breakdown

Node	Response Time	IFT Analysis Time	Breadth, Precision*	Access*	Depth*	System Ranking*
Wholesaler 1	2:41	0:15	Medium	High	Average	2.67

*The ways in which these factors were evaluated is described in Chapter 2. System Ranking could only be performed for participants providing information about cost (see Chapter 7)

Figure 17. Pilot Scenario J

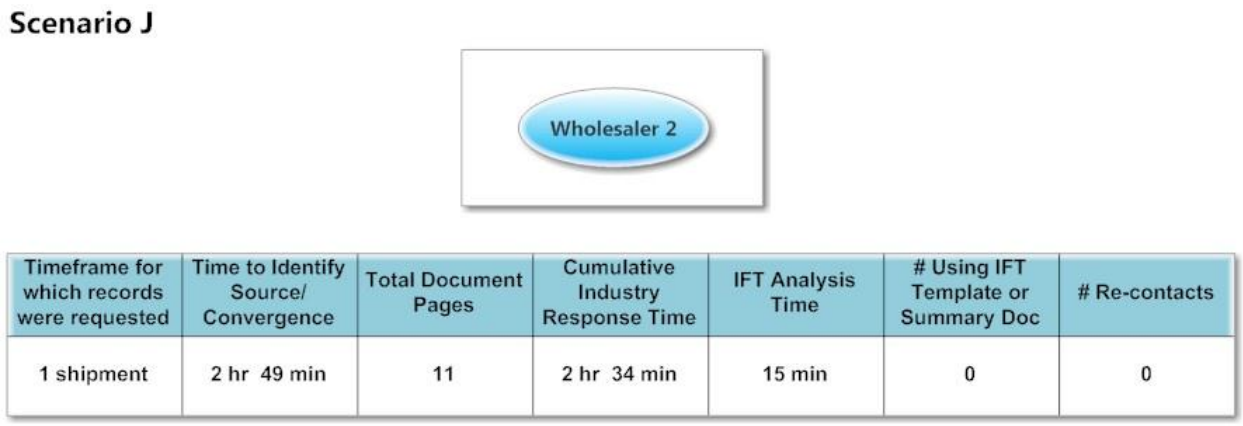


Table 19. Pilot Scenario J, Node Breakdown

Node	Response Time	IFT Analysis Time	Breadth, Precision*	Access*	Depth*	System Ranking*
Wholesaler 2	2:34	0:15	Medium	Medium	Average	N/A

*The ways in which these factors were evaluated is described in Chapter 2. System Ranking could only be performed for participants providing information about cost (see Chapter 7)

Scenarios K and L

These scenarios (Figure 18, Table 20, Figure 19, and Table 21) were also similar to each other in that both involved re-packers who were not otherwise "linked" to the pre-existing supply chain. These scenarios focused on internal tracing with the understanding that the product was being handled through the re-packing process between receipt and subsequent sale.

Figure 18. Pilot Scenario K

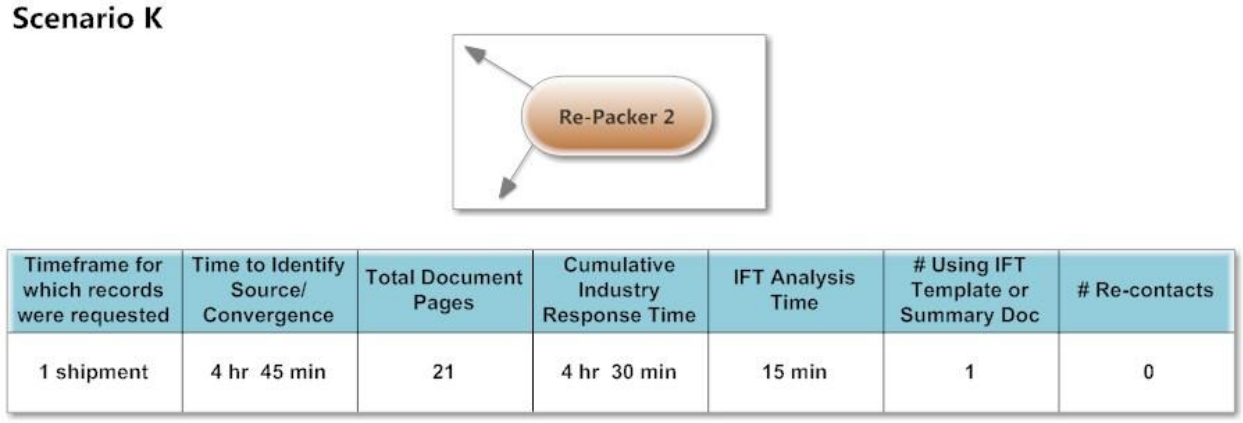


Table 20. Pilot Scenario K, Node Breakdown

Node	Response Time	IFT Analysis Time	Breadth, & Precision*	Access*	Depth*	System Ranking*
Re-packer 2	4:30	0:15	High	Medium	Average	2.67

*The ways in which these factors were evaluated is described in Chapter 2. System Ranking could only be performed for participants providing information about cost (see Chapter 7)

Figure 19. Pilot Scenario L

Scenario L

Timeframe for which records were requested	Time to Identify Source/ Convergence	Total Document Pages	Cumulative Industry Response Time	IFT Analysis Time	# Using IFT Template or Summary Doc	# Re-Contacts
1 shipment	2 hr 38 min	7	2 hr 32 min	10 min	0	0

Table 21. Pilot Scenario L, Node Breakdown

Node	Response Time	IFT Analysis Time	Breadth, Precision*	Access*	Depth*	System Ranking*
Re-packer 1	2:28	0:10	Medium	High	Average	N/A

*The ways in which these factors were evaluated is described in Chapter 2. System Ranking could only be performed for participants providing information about cost (see Chapter 7)

Discussion

The results of the tomato pilot were presented at a meeting of participants, OP members, and other SMEs. Meeting attendees were provided with a number of tables summarizing the data collected through the pilot studies. This included summaries by scenario as well as by firm.

The meeting was preceded by a webinar to familiarize attendees with the scenarios and the types of data that were collected. The meeting was conducted primarily as a breakout session where attendees were asked to evaluate several factors within the data sets provided:

- Is the number of pages of documents related to the number of participants or legs?
- Is the number of participants related to the cumulative “time waiting on firms”?
- Is analysis time related to the use of the IFT template or summary document?
- Are there any trends in types of paperwork provided?
- Does the firm’s role in the supply chain correlate with time to respond or analyze?
- Is there a relationship between business size and practices?
- What seems to “work?”

Comments and observations offered by attendees were then used by IFT and the OP to begin to draw conclusions about the study (described further in Chapter 6) and develop recommendations based on the pilot findings (Chapter 10).

Since there were a large number of scenarios in the produce pilot, many panel participants did not think that they could make connections or correlations between many factors within the data sets. However, two scenarios stood out to the participants because the supply chains were more linear and data from multiple nodes were given to IFT at one time. As in the processed food meeting, participants saw greater value when firms provided summary documents, whether they used the IFT-developed template or an internal template. The meeting participants also believed that firms should be able to determine for themselves how to capture information as long as the information can be shared and easily understood by others. Participants noted that there were very large ranges of "time waiting on firms" and analysis time despite the fact that the supply chains contained similar types of businesses. Participants were impressed by the firms' short response times indicating that some had experienced real tracebacks that took longer than those in the pilots. Findings common to both pilots are presented in Chapter 6.

TOMATO NOMENCLATURE

In the pilot studies, as pointed out in Scenario A, IFT observed that the description of a particular type of tomato occasionally changed between the point of original packing and the receipt at the ultimate retail or foodservice provider, even when re-packing did not occur. Therefore, IFT sought additional information around how tomatoes are sorted and named.

Tomatoes are generally packed in 25-pound boxes, and during this study, there were instances in which the same tomatoes seemed to be described in different ways. Tomatoes were often identified as "#x#." This system indicates the number of rows and number of tomatoes that can fit in a standard case (e.g. 5x6 tomatoes are smaller than 4x4, since you can get more tomatoes and more rows in a box). In some instances, they were just called "25 lb 2 layer." Traceback investigators have previously commented on the confusion caused by the "change" in nomenclature. Even a foodservice pilot participant noted that the same tomatoes seemed to change names from the field through distribution to the restaurant.

There is obviously a continuum in the diameter of tomatoes so that there is a small degree of overlap between sizes. Within a box of tomatoes, even of a specified size, there is still variation, and during the re-packing process, it may be possible to further separate tomatoes by size. As long as inputs and outputs are documented, the "change" in the size of a tomato should not cause confusion. A re-packer also noted that because of the variation in the price of different sized tomatoes, growers or re-packers may preferentially sort tomatoes at the cusp of two sizes—one size versus the other.

A tomato industry representative expressed frustration at regulators' use of the term "red round" tomatoes. This is a very generic term and industry members tend to use more specific terms (based on size) to describe tomatoes. In many instances, IFT heard industry state that they would willingly answer regulators' questions but were wary of offering up additional information. It follows that if regulators ask only for information about "red round" tomatoes, industry will not volunteer the details that FDA really needs to trace products with more specificity. This could be an area where better communication and understanding between regulators and industry could aid in focusing tracebacks.

RE-PACKING

The process of re-packing is often pointed to as one that complicates product tracing. This was the reason that repackers were included in several of the scenarios. IFT sought to determine the complexities introduced into the traceback process, and also gained information from repackers regarding their practices to ensure the ability to trace tomatoes.

Re-packing occurs because tomatoes ripen at different rates and are sold by size. Within a given harvest, tomatoes may have varying degrees of ripeness, and the purpose of re-packing is to create a box of uniform tomatoes—both in terms of size and ripeness—to meet the needs of the customers. For the purposes of the cost analysis, re-packers were considered processors since they are essentially creating a new product from constituent products. This can be considered a transformation event within the context of CTEs (expanded upon in Chapter 6).

Re-packing occurs by physically sorting tomatoes. In IFT's earlier work (McEntire and others 2010), some re-packers reported a recent shift toward limiting the number of input lots that yielded the final re-packed tomato lots. Again, with a different set of participants, IFT observed the same practice. It seems that there is a trend toward re-packing within a lot, and as a consequence, the re-pack runs are smaller. A challenge that has persisted is that the input lot may actually consist of several grower or supplier assigned lots.

Only recently have growers begun to differentiate their assignment of lots on Bills of Lading. While not every grower in the pilot provided this information to their customers, some did, and upon asking, IFT learned that this is a relatively new but growing trend. Limiting re-packing to within a lot (typically a purchase order) improves the precision of a traceback investigation. Limiting re-packing to within a grower-assigned lot would be even more precise.

Chapter Summary

IFT engaged 34 firms involved in the tomato supply chain as growers, shippers, packers, re-packers, distributors, wholesalers, retailers, or foodservice chains. Twelve scenarios were constructed to mimic the traceback investigations and records requests issued by FDA. Twelve mock tracebacks were conducted, and in some cases, firms were asked to provide traceforward information as well. Because the supply chain relationships were generally known, IFT had an idea as to where the supply chain paths would lead. However, there were some unexpected relationships explored: a grower identified the source of tomatoes as another grower which provided a more robust data set to be analyzed by the collaboration platforms (see Chapter 5); some firms decided to opt out; others were new and still participated.

Overarching pilot findings are discussed in Chapter 6. Issues specific to tomatoes, such as the changing name (based on size) as the tomato moved through the supply chain, required additional explanation and investigation. The ways in which re-packing is conducted and how this impacts the ability to trace products was also explored.

Overall, IFT received numerous documents, primarily as PDFs, which needed to be manually analyzed. Surprisingly, the number of documents was not directly related to the number of supply chain nodes in the mock scenario nor was it directly related to the timeframe for which records were requested. IFT found that when firms provided summary-level data (with additional verification documentation), this generally facilitated IFT's understanding of the information. Still, conducting the mock tracebacks was a time-consuming and labor intensive process. In many instances, IFT needed to follow up with firms to clarify information or seek additional information.

CHAPTER 4. PROCESSED FOOD - INGREDIENT PILOT

Finding Participants

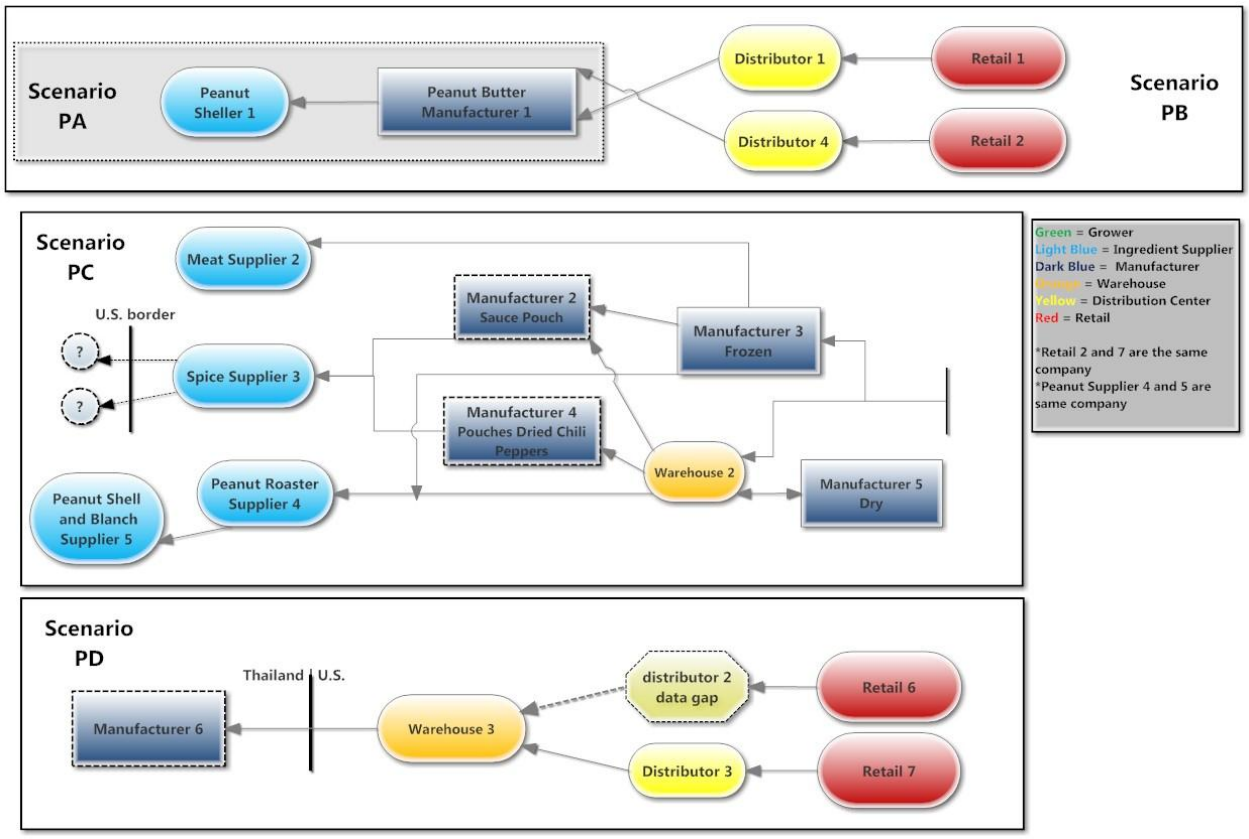
There are a limited number of manufacturers of an Asian style, Kung Pao, or Pad Thai product containing chicken, spices (red or black pepper) and peanut paste/peanuts, whether frozen, dry grocery, or ready to eat (RTE). In addition, after considerable discussion with one large manufacturer, they opted to not participate. In another instance, a retailer who expected to carry this type of product as a new item (and who was willing to engage the supplier) subsequently decided to not carry the product for reasons having nothing to do with the pilots. Another supplier who was an importer (Warehouse 3), after being contacted directly, indicated that they wanted the retailer carrying the product to reach out as a partner. The retailer (Retail 7) agreed and the supplier agreed to work with the overseas manufacturer (Manufacturer 6). However, once the pilots were underway, the importer provided only minimal information and claimed that the firm did not have the resources to fully participate.

However, one manufacturer (Manufacturer 3) expressed immediate interest in contributing to the pilots (even before the products were chosen) and willingly engaged their suppliers. This included the ingredient suppliers of interest (peanut, spice, and chicken). Additionally, this manufacturer indicated willingness to trace two branded products—a frozen skillet-style meal that contained chicken and a dry version in which consumers add meat. This enabled the pilots to explore how ingredients used in complex food products can be traced and also permitted the evaluation of how the use of a co-manufacturer (Manufacturer 5) affects product tracing. In another instance, IFT was introduced to a peanut butter manufacturer (Manufacturer 1) who happened to produce private label product for a grocery chain (Retail 2). Retail 2 had already expressed willingness to participate in the tomato study and agreed to participate with the peanut butter manufacturer as well.

The American Frozen Food Institute (AFFI), the American Peanut Council (APC) and the American Spice Trade Association (ASTA) each provided IFT with useful information about their industries and encouraged their members to participate, although it was clear, particularly for the ingredient manufacturers, that their participation was dependent on the processed food manufacturer engaging them as a supply chain partner.

Figure 20 shows the different participants volunteering to contribute to the processed food - ingredient pilot tests. Note that the prefix “P” before the scenarios was used only to distinguish these scenarios from the tomato pilot.

Figure 20. Flow Diagrams of Supply Chains (Scenarios) of Processed Food - Ingredient Pilot Participants



Scenarios

Thirteen individuals, including two representatives from USDA FSIS, three state traceback investigators, and industry experts spent two hours discussing the details of the scenarios for the processed food - ingredient pilots. Prior to the call, the participants received the supply chain flow diagrams as well as an outline of potential scenarios and situations that could be tested. It was proposed that one of the scenarios focus on a state sampling program identifying an issue with the product so that the traceback was relatively focused. Industry experts provided detailed information about the ingredients used in some of the other products so that scenarios that sought to determine convergence could be appropriately constructed.

A rough draft of the scenarios was provided to the OP members with regulatory experience in conducting tracebacks as well as the FDA. Based on input, the four scenarios were further refined. After the scenarios were finalized, they were mapped to the “key questions” (Appendix L; discussed in Chapter 2) to ensure that as developed the scenarios, in combination with those tested in the tomato pilot, would sufficiently cover all the aspects that the pilot sought to address.

RESULTS

The results of each scenario, including the firm's response and IFT's analysis, were evaluated based on the factors described in Chapter 2, and should be viewed in light of the assumptions and limitations discussed in Chapter 8, particularly that as an opt-in study, participants may be skewed toward those that have better-than-average tracing practices.

Scenario PA

The objective of this scenario (Figure 21, Table 22) was to test how having very specific, granular information about a product influenced the ability to trace it. Unlike the other scenarios, the "timeframe for which records were requested" is not expressed in weeks or months. Here the scenario stated that a particular jar of peanut butter collected at random through a state's testing program was violative. The lot number and location were pre-identified by IFT; IFT found the product at a retail location. Therefore, this scenario began at the level of the manufacturer, with information sought for this one particular lot code identified on the jar of peanut butter. The manufacturer was able to provide information pertaining to the production of the lot. Because peanut butter is produced continuously (as opposed to in batches), the manufacturer provided information on any peanuts that could have been used in the production of the product.

Figure 21. Pilot Scenario PA

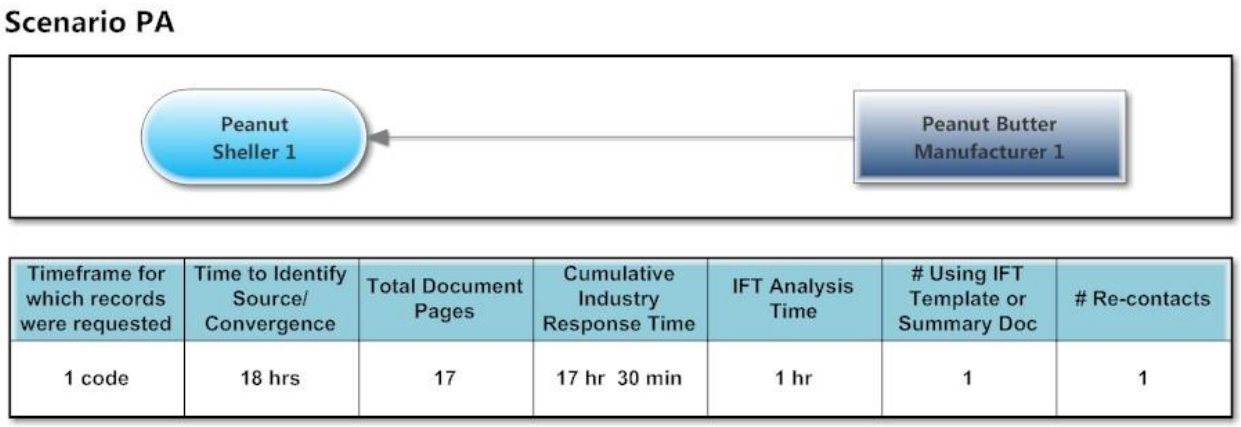


Table 22. Pilot Scenario PA, Node Breakdown

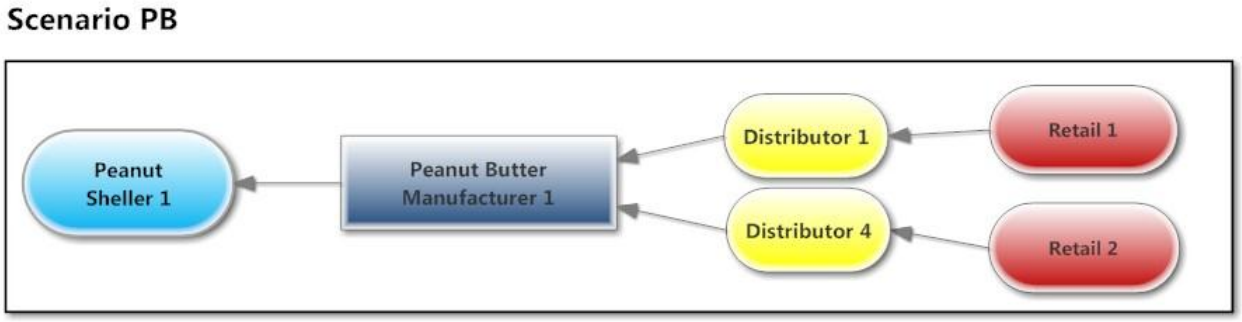
Node	Response Time	IFT Analysis Time	Breadth, Precision*	Access*	Depth*	System Ranking*
Peanut Sheller 1	1:13	0:20	High	High	Average	N/A
Peanut Butter Manufacturer 1	17:45	0:15	High	Medium	Average	2.33

*The ways in which these factors were evaluated is described in Chapter 2. System Ranking could only be performed for participants providing information about cost (see Chapter 7)

Scenario PB

This scenario (Figure 22, Table 23) was constructed to determine the extent to which retail stores could identify or estimate the lots of peanut butter available for sale if the lot number was not provided. Two different retailers who both carry a product produced by the same manufacturer participated. One retailer was provided with shopper card information (for purchases made by IFT prior to launching the scenario). One of the retailers received the product from two distribution centers—one owned by the retailer and one independent. The other retailer received the product from an independent distributor. The distributors were all able to provide the bill of lading for the product, which included hand-written lot number provided by the manufacturer (and quantity, when multiple lots were shipped). However, none of the distributors captured this information or tracked the product by lot as it moved to the retail shelf. In one case, the distributor only recently started carrying the product and had received only one shipment from the manufacturer. Therefore, even though there were several shipments to the retailer in the three-month window, the distributor could say with certainty that they were from a single lot from the manufacturer because that was the only lot received. For the other retailer, the pattern of re-ordering associated with the stores was evaluated. Although the store could not be certain of the lot numbers on the retail shelf during the three-month window, given that the product was re-ordered by stores every few days, it was deemed that the three-month window was adequate. The peanut supplier in this scenario was the same as in Scenario PA. However, given that this scenario sought information for several lot numbers of peanut butter and consequently several lots ofpeanuts, the peanut supplier opted to provide information in summary form to better convey the information.

Figure 22. Pilot Scenario PB



Timeframe for which records were requested	Time to Identify Source/ Convergence	Total Document Pages	Cumulative Industry Response Time	IFT Analysis Time	# Using IFT Template or Summary Doc	# Re-contacts
3 months	27 hr 34 min	130	79 hr 48 min	3 hr 10 min	4	3

Table 23. Pilot Scenario PB, Node Breakdown

Node	Response Time	IFT Analysis Time	Breadth, Precision*	Access*	Depth*	System Ranking*
Peanut Butter Manufacturer 1	28:11	1:00	High	Medium	Average	2.33
Distributor 4	0:25	0:20	Low	High	Average	N/A
Retail 2	2:38	0:20	Low	High	Average	1.67
Distributor 1 Retail 1	24:31	1:20	Low	High	Average	2.33

*The ways in which these factors were evaluated is described in Chapter 2. System Ranking could only be performed for participants providing information about cost (see Chapter 7)

Scenario PC

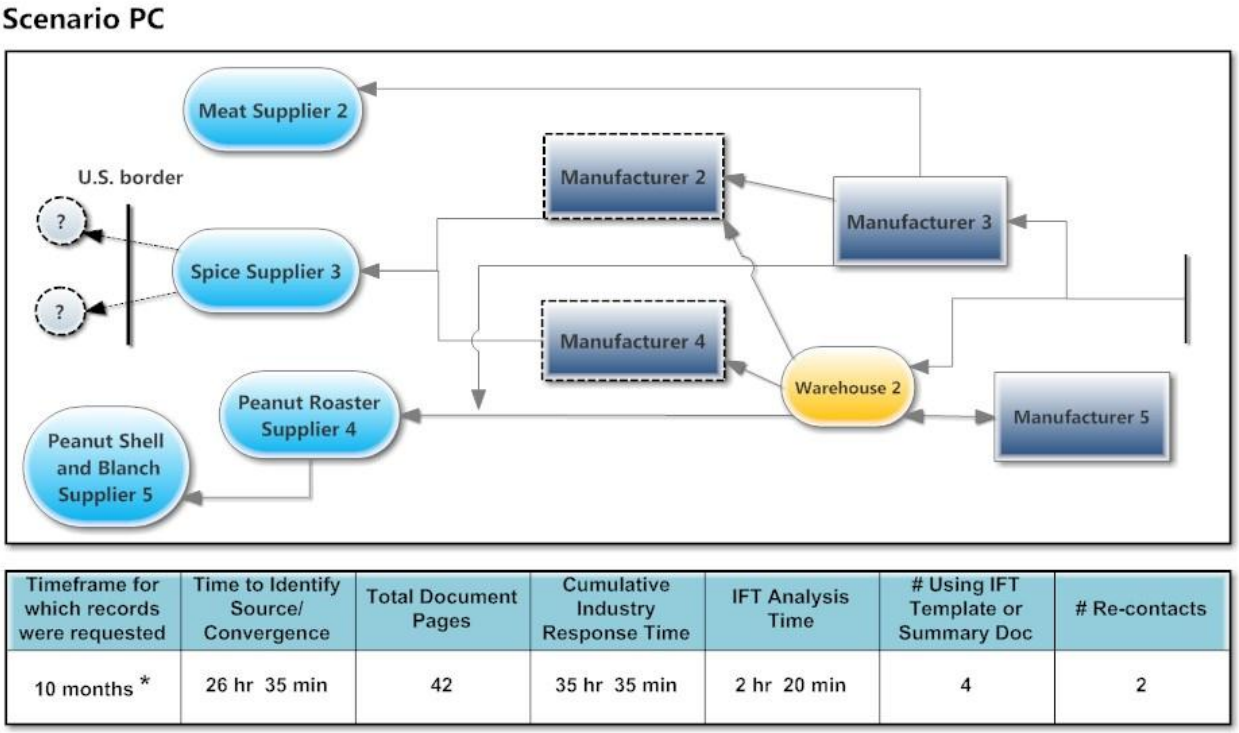
This scenario (Figure 23, Table 24) was by far the most complex scenario tested in the pilot and could arguably have been divided into several different tests. At the core of this scenario were two products marketed under the same brand. One was a frozen product (skillet meal produced by Manufacturer 3) and the other was a dry version in which the consumer would add meat (produced by Manufacturer 5). In discussions with the brand owner, IFT learned that the products were manufactured in two different locations and that the dry product was produced by a co-manufacturer (Manufacturer 5). Additionally, each product contained "pouches" (separate sauce and peanut pouches in each product, and for the dry product, whole chilis) that were manufactured by additional parties (one for the sauce production and one to pouch the whole dried chilis, with the peanuts packaged by the peanut supplier).

The brand owner was able to secure the participation of the co-manufacturer and peanut provider, and IFT had pre-existing relationships with the chicken provider and spice manufacturer (with an overseas joint venture) who provided products to the sauce and chili pouches. Both firms have actively provided thought-leadership in product tracing for many years and may not be representative of "average" firms that typically manufacture these products.

This scenario was unique in that neither the chili poucher nor the sauce manufacturer participated (Manufacturers 2 and 4). This resulted in making assumptions regarding the shipments sent from the spice supplier (and linked to the overseas source) to the non-participants and trying to link these to the pouched products received by the two manufacturing facilities. Had this been a "real" situation, one would expect that the non-participants would cooperate in an investigation, including through FDA's Foreign Inspection Program, but the gaps allowed IFT to test a hypothetical scenario in which a manufacturer (sauce or chili) knew what was received and shipped but was unable to link the ingredients to the finished product.

This scenario also tested the process used to acquire product tracing information, since the brand owner functioned as the hub of information, scheduling three conference calls over the course of two days. IFT participated in these discussions and made the specific information requests. The peanut provider was able to provide information to track back to the raw peanut lots, and the spice supplier was able to track to the overseas supplier, coordinating efforts with their overseas joint venture. Although distribution and retail outlets were not directly part of this scenario, both manufacturers were asked for and able to provide traceforward information to account for the products.

Figure 23. Pilot Scenario PC



Timeframe for which records were requested	Time to Identify Source/ Convergence	Total Document Pages	Cumulative Industry Response Time	IFT Analysis Time	# Using IFT Template or Summary Doc	# Re-contacts
10 months *	26 hr 35 min	42	35 hr 35 min	2 hr 20 min	4	2

* Due to infrequent production; production dates were limited to a few days.

Table 24. Pilot Scenario PC, Node Breakdown

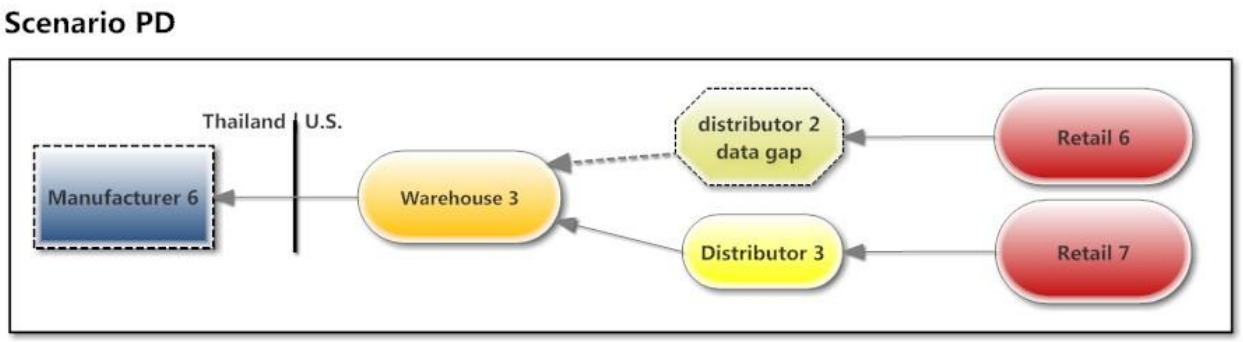
Node	Response Time	IFT Analysis Time	Breadth, Precision*	Access*	Depth*	System Ranking*
Peanut Sheller and Blancher Supplier 5 Peanut Roaster Supplier 4	2:27	0:30	High	High	Average	2.67
Spice Supplier 3	27:30	0:30	High	High	Above	N/A
Manufacturer 2	Did not participate	N/A				
Manufacturer 4	Did not participate	N/A				
Manufacturer 3	1:25	0:30	High	High	Above	3.00
Manufacturer 5 Warehouse 2	1:05	0:30	High	High	Average	N/A

*The ways in which these factors were evaluated is described in Chapter 2. System Ranking could only be performed for participants providing information about cost (see Chapter 7)

Scenario PD

This scenario (Figure 24, Table 25) involved a processed food similar to the dry product in scenario PC, except that it is manufactured overseas, thus emphasizing the significant role of food internationally produced and consumed in the United States. Two retailers who carry the product were asked to provide information on the product during a three-month time frame. One retailer was asked to provide this information for two stores that are geographically close to each other; the other retailer had previously provided data indicating the stores that had sold this particular UPC in the past 13 weeks and the number of sales at each store. That retailer was asked to provide information on two of the stores recognized as having an average of one to two sales of the product per month. Both retailers received the product from distributors. In one case, the distributor agreed to participate; in the other case, the distributor did not want to participate, and this resulted in termination of the traceback as IFT did not hear back from the retailer regarding whether or not the distributor captured the lot codes of the internationally-sourced product. In the leg in which the distributor did participate, the distributor sought lot codes from the importer, but IFT did not receive this information from the distributor. Rather, IFT contacted the importer and requested this information directly. The importer was able to provide PO numbers for the distributor as well as identify the quantity of each foreign sourced lot sent to the distributor on each PO but expressed that he did not have the resources to participate further, and IFT's request for contact information for the actual manufacturer was not met. Therefore, although the product was similar to the one in scenario PC, IFT did not reach the point of the foreign manufacturer for this imported product.

Figure 24. Pilot Scenario PD



Timeframe for which records were requested	Time to Identify Source/ Convergence	Total Document Pages	Cumulative Industry Response Time	IFT Analysis Time	# Using IFT Template or Summary Doc	# Re-contacts
3 months	197 hrs 51 min	9	137 hr 51 min	50 min	3	4

Table 25. Pilot Scenario PD, Node Breakdown

Node	Response Time	IFT Analysis Time	Breadth, Precision*	Access*	Depth*	System Ranking*
Manufacturer 6	Did not participate	N/A				
Warehouse 3	26:10	0:15	High	Low	Average	N/A
Distributor 2	Did not participate	N/A				
Retail 6	9:55	0:05	Low	Medium	Average	2.67
Distributor 3	91:10	0:20	Medium	Low	Average	N/A
Retail 7	10:36	0:10	Low	High	Average	1.67

*The ways in which these factors were evaluated is described in Chapter 2. System Ranking could only be performed for participants providing information about cost (see Chapter 7)

Discussion

The results of the processed food pilot were presented at a meeting of participants, OP members, and other SMEs. Similar to the meeting held of the tomato group, this meeting was structured primarily through breakout discussions and was preceeded by a webinar.

Participants were asked to evaluate several factors within the data sets provided:

- Is the number of pages of documents related to the number of participants or legs?
- Is the number of participants related to the cumulative "time waiting on firms"?
- Is analysis time related to the use of the IFT template or summary document?
- Are there any trends in types of paperwork provided?
- Can the firm's role in the supply chain be correlated with time to respond or analyze?
- Is there a relationship between business size and practices?
- What seems to "work?"

Findings common to both pilots are provided in Chapter 6. With respect to the processed food – ingredient study specifically, overall, participants determined that the number of pages of documents did not relate directly to the number of participants or legs within the scenarios. Participants understood that the greater the number of participants in the scenarios, the longer it would take for IFT to receive all the traceback data. However, some supply chains worked more efficiently and quickly, and so the trend did not exist among all scenarios. Many other factors within the data sets did not correlate directly. Participants saw great value when firms provided summary documents, regardless of whether they used the IFT-developed template or an internal template. Participants in this pilot, particularly in Scenario PC, use ERP systems, and the track and trace information provided to IFT was automatically generated by these systems. However, participants reported that, because the reports contained extraneous information not relevant to the pilots that the firms did not want to share, they expended considerable time removing this information, discussed further in Chapter 6.

Participants strongly believed that firms should be able to capture information however they would like, as long as that information can be easily shared and understood by others. Many also reiterated the limitations of the pilots, noting that the "time waiting on firms" could not always be considered "real world" because not everyone was responding to the pilot scenario requests as they would in a true outbreak scenario. Some participants believed that retailers were a weak link in product tracing since

they do not capture much information from their distributors. The relationships between firms within their supply chain were considered incredibly important. Largely, participants were impressed by the firms' short response times but also recognized that some of the technologies used by participants were more sophisticated than average, and some of the practices which facilitated the mock traceback process (e.g., writing lot numbers on BOL) were not common.

Tracing processed foods is complex because they contain multiple ingredients, and many times those ingredients contain ingredients. Given the scope of the pilot, there are characteristics associated with some processed foods that were not explored in the pilots but should be considered. These include:

- raw materials or other ingredients provided through brokers
- frozen warehouse storage for raw materials
- intentional commingling of raw material commodity items throughout the supply chain to average out variation with key functional factors of the material (e.g., mixing juice concentrates from different regions and times of year to maintain a product with a consistent sugar, acid, and flavor profile year round)
- production processes that normally includes rework/salvage/animal feed

Chapter Summary

IFT engaged 13 firms including an importer, ingredient suppliers, processed food manufacturers, distributors, and retailers. Four scenarios were constructed to mimic the traceback investigations and records requests issued by FDA. The complexity of the scenarios ranged from one in which a single lot code was traced to one which was constructed as an ingredient-driven trace involving two processed food products with several ingredients in common. In some cases, firms were asked to provide traceforward information as well, and IFT found that the number of immediate subsequent recipients was generally high. Additionally, the ingredients were also occasionally used by the manufacturer for products not evaluated in the pilots. The supply chain explored in the ingredient-driven scenario (PC) included two intermediate manufacturers who did not participate in the pilots. This resulted in assumptions being made regarding which lots of ingredients were used in the finished products, which were further evaluated by the collaboration platforms (addressed in Chapter 5).

Overarching pilot findings are discussed in Chapter 6. Issues specific to processed foods and their ingredients, compared to tomatoes, include the use of continuous processing (as opposed to batches that are clearly distinguished from each other) and the use of rework.

Overall, there was wide variety in the types of documents provided to IFT given that there were fewer participants than the tomato pilot. This might be explained by the range of technologies and systems in use in the spectrum of the processed food industry, which uses ERP systems more often than in the fresh produce industry, as well as the need to communicate information related to complex product transformations to a greater extent than produce. The number of documents was not directly related to the number of supply chain nodes in the mock scenario nor directly related to the timeframe for which records were requested, primarily because several manufacturers used ERP systems that extract the relevant data in a succinct fashion. IFT found that when firms provided summary-level data (with additional verification documentation), this generally facilitated IFT's understanding of the information.

Another unique feature of this pilot was the ability to test the utility of holding conference calls between supply chain partners as an alternative to IFT contacting each individually. There was great efficiency gained by this process; and, it also enabled IFT to ask questions regarding how shipments from one supplier linked to those received by the manufacturer. The discussion between supply chain partners also provided learning opportunities: firms saw how their supply chain partners interpreted and used the information provided to them.

CHAPTER 5. EVALUATION OF THIRD PARTY COLLABORATION PLATFORMS

Although the task only charged IFT with evaluating a "collaboration platform" for one study (processed foods - ingredients), IFT determined that there would be benefit to examining the use of these types of technologies in both pilots. A collaboration platform is not a clearly defined term, but from the feedback and clarifications IFT received from the FDA, it was decided that for the purpose of the pilot, a collaboration platform could have one or both of the following characteristics:

- Enable collaboration among multiple food system stakeholders overseas and domestically, including the FDA. This could include any technology that enables improved data sharing, enhanced communication and more effective group analysis among industry, as well as state, federal, and internationally-collaborating regulators. An important distinction here is that these technologies focus on inter-company collaborations as opposed to intra-company (within the four walls) collaboration.
- An electronic platform to allow FDA to better coordinate domestic and global traceback investigations, as well as allow domestic and foreign industry marketing in the United States to better comply with existing regulations and more effectively provide relevant product tracing-related data upon request.

However, to keep the pilots scientific, it was imperative that the inclusion of technology providers into the pilots not be used as a marketing tool to sell more of their services or products. In order to balance the need for voluntary participation and the desire to prevent endorsing a group of technologies, IFT was as transparent and inclusive as possible in the selection process: making a public announcement inviting all technology solution providers to submit an application to be considered, for example. However, IFT blinded the names of the technology companies that would ultimately participate until completion of the evaluation, to respect the confidentiality agreements in place.

Since two pilots were being conducted in parallel, one for produce and one for processed foods containing multiple ingredients, a decision was made (given the limited resources available to manage this part of the study) that up to five technology solution providers would be selected to participate in each pilot, resulting in a total of 9 technologies eventually being selected. This led to less "exclusivity" when it came to participation in the pilots, and allowed IFT to analyze the variability in breadth and depth of capabilities that existed in the marketplace. For the purpose of this study, FDA was considered the end-user of any collaboration platform. IFT did not seek to test how food industry members could use these systems and services directly in or outside the United States. Rather, IFT expected that FDA and other regulators would continue to request data from industry during an investigation, and that these data would be managed and evaluated through a collaboration platform. A key challenge to achieving this goal was the fact that a majority of the solutions target industry as end-users and few had customized their solutions with regulators in mind. So regardless of the approach, there would be some artificiality in how these technologies would be deployed in the United States or overseas, used, and evaluated in the pilots compared with their original intended use (firms submitting their own data rather than collaboration platform providers feeding blinded data into the system).

In addition to these challenges, it was also critical to limit the scope of a collaboration platform study, due to the overwhelming number of technology solutions that exist in the marketplace today or are currently in development. Upon commencement of the pilot projects with FDA, a number of technology solution companies contacted IFT expressing their willingness to be involved. While grateful for such

incredible response and support, IFT decided to solicit stakeholder input to develop the best approach and narrow the list down to a more manageable group of pilot participants.

Stakeholder Input

As described in Chapter 2, IFT held three public stakeholder input sessions to receive recommendations from all stakeholders representing all perspectives. A significant number of attendees (41%) and presenters at these stakeholder input sessions were technology solution providers. IFT received input on how various technologies improve food product tracing, and recommended approaches to selecting a representative set of solution providers for the pilots.

A wealth of information was collected through the oral and written comments received from the stakeholders, which eventually shaped the approach, selection criteria, execution, and evaluation of the technology solution providers. Recommendations received from stakeholders on the characteristics to look for in a collaboration platform, included the following (not an exhaustive list):

- be built using open-source technologies in non-proprietary formats for maximum possible adoption at lowest possible cost
- have built-in communication tools such as messaging or file-sharing
- protect data using encryption technologies similar to those used in banking and finance industry
- use cloud-based computing to be scalable, enable redundancy, and minimize down times
- preserve data ownership such that industry would still own and control their data
- enable role-based permissions, with trading partners having different levels of access to the data compared with regulators
- enable interoperability by implementing non-proprietary import - export capabilities
- provide a mobile user interface to enable field-level or on-the-ground collaboration
- have the ability to handle disparate datasets typically received by the FDA during a traceback investigation
- have the capability to handle structured and unstructured data as well as standardized and non-standardized data
- have analytical capabilities such as search, query, and discover
- have visualization capabilities such as geo-spatial-temporal mapping and network graphs
- be currently in use by an industry, not experimental or a research-based concept

Selection of Technology Providers

Based on the stakeholder input received, a request for information (RFI) was made available on IFT's Product Tracing webpage (http://www.ift.org/traceability) as well as sent to the distribution list of more than 200 contacts from technology companies. The actual RFI is included in Appendix P. This request was made to solicit information about the capabilities of the technologies that exist, to best evaluate their contribution to a collaboration platform and their impact on improving product tracing. The following types of information were requested as a part of this process:

- demographic information for the company and the technology (e.g., name and age)
- number of paying customers; if none then a justification was asked as to why their technology should be selected
- scope of the technology (internal, external, internal to external, or whole-chain)
- data capture, storage and sharing capabilities
- import - export capabilities
- requirement for proprietary versus non-proprietary standards/formats

- data security and control (including encryption)
- willingness to collaborate with other third party technology solution providers to demonstrate interoperability
- demographics of current customers as they relate to the produce and processed food - ingredient pilots. This information was requested to better facilitate the allocation or assignment of the technology solution providers to the appropriate pilot.
- references for the technology (current or previous users)

A preliminary draft of this request for information was made publicly available to receive feedback and fine tune its contents before the final call for information. After adding clarity and content to the draft, a final version was made publicly available with a one-week timeframe for responses. For inclusivity and transparency, late submissions were accepted for up to one week after the date that responses were due. Overall, IFT received 18 responses to this request for information. Two additional vendors (beyond the 18) withdrew from the process once they recognized that their solutions were not a good fit for the objectives of the pilots. Of those two, one was focused purely on internal product tracing (within-the-four-walls) while the other was still under development and not ready for commercial use.

Once IFT had a list of 18 potential technology solution providers who could serve as a part of a collaboration platform activity, the next step was to invite SMEs from the technology sector to review these submissions and make recommendations for selecting technology solution providers. An invitation was sent to five potential reviewers, three of whom agreed to serve as evaluators and signed the confidentiality agreements. All evaluators were required to disclose any conflict of interest and recuse themselves from the study. To further prevent the disclosure of proprietary, non-public information, the content received via the request for information was then blinded to protect the company, product, and technology names from the reviewers. This also prevented any known preconceptions or biases among the reviewers towards the technology solution providers they were reviewing. Reviewers were asked to recommend the selection of at least two and up to 10 technologies based solely on the information collected through the RFI.

Simultaneously, IFT reached out to all the references provided within the RFI to gain a better understanding of the real-world usage of these technologies and get feedback from real-world users. These references were asked the following questions in an informal setting:

- Do you currently use the technology? If yes, how long have you used it? If not, why not?
- What were the selection criteria that you used internally to decide upon the technology?

These contacts were also asked to rank (via a score range of 1 – 10) the following sets of factors:

- professionalism of the technology solution providers' staff
- flexibility of the technology solution to meet the needs of the reference
- ease of use of the solution
- amount of training needed by the reference's staff to use the solution
- amount of support needed on an on-going basis, and nature of the support staff
- relative startup costs to implement or adopt the technology (score range of 1 for most affordable to 10 for most expensive)
- relative ongoing costs to use the technology (score range of 1 for most affordable to 10 for most expensive)
- return on investment through ancillary benefits
- recommended technology, overall

As a result of this evaluation by reviewers, 9 technology solution providers were eventually used as collaboration platforms in the pilots as shown in the Table 26 below. This table lists the number of evaluators who recommended the technology solution provider and the final status of participation for each provider. Each individual evaluator provided a list of technology providers they would recommend for participation in the pilots.

Table 26. Results of the Evaluation for Collaboration Platform Providers

Technology Solution Provider	Number of Evaluators Recommending Participation on Pilots	Final Status
Provider 1	0	Not selected
Provider 2	1	Withdrew
Provider 3	2	Participated
Provider 4	0	Not selected
Provider 5	2	Participated
Provider 6	1	Participated
Provider 7	0	Not selected
Provider 8	0	Not selected
Provider 9	1	Participated
Provider 10	0	Not selected
Provider 11	2	Participated
Provider 12	2	Participated
Provider 13	2	Withdrew
Provider 14	0	Not selected
Provider 15	1	Participated
Provider 16	2	Participated
Provider 17	1	Withdrew
Provider 18	2	Participated

IFT reached out to all technology solution providers that were recommended by at least one of the evaluators, to discuss in more detail their role in the pilots should they choose to participate. Upon further discussion, three withdrew from participation because of one of the following reasons:

- the technology solution did not appropriately meet the needs of the pilot (being a backend technology infrastructure provider)
- the provider was operating in a significantly different time zone making coordination with IFT staff in the pilots a challenge
- the provider did not have enough time/resources to participate

Pilot Collaboration Platforms - Approach

The final 9 technology solution providers agreed to work with IFT on a non-compensated basis on the data-driven part of this study and signed the confidentiality agreements. The pilots were designed to conduct a comparative study on the relative improvements observed when using a collaboration platform to collect and analyze pilot data versus the more manual process of sorting through the paperwork. A team of investigators at IFT was charged with recording the time it took to request data from the supply chain pilot participants versus the time it took to analyze that data using the methods and tools currently used as described in Chapter 2 and provided in Chapters 3 and 4. The technology providers were provided with blinded versions of the data.

The technology providers were given the choice of participating in the produce pilot or the processed food – ingredients pilot, based on the capabilities of the solutions as well as their past experiences. Five solution providers selected the produce pilot while the other five selected processed food – ingredients pilot. Therefore, each technology solution provider within each pilot was independently running the comparative study in parallel, working with the same data, allowing IFT to capture the variability in capabilities and impact on performance. Using multiple technology solutions also allowed IFT to manage the pilot data to determine whether the ability to track and trace is enhanced. These systems were used to establish whether common data elements or data sets and the technology platforms allow for expedited electronic traceback and traceforward.

Supply chain data were blinded to protect company and product names as well as any proprietary information and trading relationships. In order to minimize any external factors being introduced due to this blinding process, the data were blinded in the original format received by IFT from the supply chain participants. For example, if an invoice was provided in PDF format, the blinded version of that invoice was also in PDF format. These blinded data were then shared with the technology solution providers for them to feed it into their systems. IFT also created blinded supply chain flow diagrams to help put the pilot data into perspective for the technology solution providers. Across both pilots, a total of 71 files (7 PDFs, 43 Excel files, 9 word documents and 12 image files) were used or blinded and shared with the technology solution providers through this process (this included redundant or multiple versions of the same file that may have been received from the supply chain participants).

For the purpose of this project, the technology solution providers were asked to record the time it took them to feed these raw blinded data into their systems, as well as any gaps or errors they identified in the data. At the end of the pilot projects, all were asked to provide a list of assumptions they had to make in order to link the pilot data and successfully execute the traceback scenarios. They were also asked to provide a set of recommendations for improving the quality of data they received from the pilots, and how such improvements could benefit product tracing as a whole. Finally, they were asked to enumerate the list of CTEs and KDEs they used from the pilot data and compare them to what they would consider their ideal list of CTEs and KDEs (the ones they would need in order to effectively trace products through their own system).

Near the completion of the pilots, IFT held face-to-face meetings and invited the technology solution providers to conduct demonstrations of their live systems using pilot data. The purpose of the demonstrations was to provide FDA and the supply chain participants and panelists with a proof-of-concept on how a collaboration platform could be used to enhance product tracing, while at the same time, highlighting the challenges and opportunities that currently exist when dealing with incomplete and/or erroneous data. Each of the companies had 45 minutes to explain their process and run queries in front of the pilot groups. Each pilot group consisted of approximately 30 individuals, including some of those who provided supply chain data to the pilots, SMEs, and regulators (both state and federal). Given

that the key intended users of the collaboration platforms were regulators, this portion of the meeting was open to regulators (state and federal) through a web based meeting as well.

Pilot Collaboration Platforms – Results and Discussion

DATA IMPORT

There were several different approaches to dealing with the raw blinded data received by the technology solution providers. Approaches were:

- manual conversion of the raw data into template Excel or XML files prior to importation into the system
- conduction of optical character recognition (OCR) on unstructured data to make sense of the raw data
- fed the data as it was received in the raw format, allowing the import process to fail due to any inconsistencies
- expenditure of a significant amount of time and resources internally to understand the data being sent to them (especially if it was in a non-standard format) and put it in the right context (e.g., in some cases the PO number was transformed into a lot number by a trading partner; such actions were more easily flagged through the use of the collaboration platform compared to manual scanning of the documents)
- use of a lot number or a date range (assuming first in first out) to create linkages across incomplete datasets (most frequent approach)
- voluntary teaming up (by two providers) to demonstrate interoperability; blinded data were stored on the cloud and their individual technology solutions were used to access, visualize and analyze the same dataset; the Electronic Product Code Information Service (EPCIS) model for data exchange and interoperability was used

Each technology company was asked to give the breakdown of the time they spent trying to understand the data (for tasks such as creating master data, linking the data to the scenarios or to ask IFT clarifying questions), time to feed the data into the system (either manual, semi-automated, or fully-automated data entry as well as error handling), and finally time to query or analyze those data for convergence (time to submit a query into the system as well as receive a meaningful response). The breakdown of time spent working with the data from five out of the nine solution providers is listed in Table 27 (the remaining four were unable or unwilling to provide IFT with this breakdown). The final column provides an estimate of the percentage of the total data they attempted to feed into their system. Due to time and capability restrictions, most technology solution providers were unable to feed 100% of the data IFT had supplied to them. There are two important caveats when interpreting this table, however. First, if FDA is the end user of a collaboration platform, they would have more experience and better expertise understanding the data they receive from the industry during a traceback investigation, and the technology providers would not have to assume the role of interpreter. Secondly, these data are self-reported and could not be verified; however, some technology providers were given up to two months to work with the data and were still unable to run a live query showing convergence.

Table 27. Technology Provider Analysis Data Breakdown

Technology Provider	Time to Understand Data	Time to Feed Data	Time to Query/Analyze Data	Percent of Pilot Data Used
1	3 days	4 hours	Within minutes	50%
2	2 days	8 hours	instantaneous	100%
3	7 days	3 days	5 minutes	100%
4	2 days	1 day	10 minutes	33%
5	24 hours	24 hours	Within seconds	100%

DATA MANIPULATION

Once the data were successfully imported into the respective systems, the technology solution providers had to manipulate the data in order to create or fix broken linkages. Observations and experiences during this process were:

- Internal product tracing records were essential to link incoming to outgoing products regardless of the role in the supply chain. This meant recording incoming ingredients and relating them to a finished processed food product at the processor or manufacturer level (including tomato re-packing; records of this nature include a Work Order Number, or Production Run Number that links all input lot numbers used in the creation of a lot number of output), or linking incoming pallets (or cases) to outgoing cases at the distributor level (for example, using a “license plate”). Without accurate internal product tracing records, a traceback either becomes inconclusive, or broadens the scope of the investigation with an increasing reliance on dates.
- The blinding of the data caused some initial confusion that was then cleared upon further discussions with IFT. In reality, this confusion would not exist if FDA was requesting the records and no blinding was necessary.
- Nomenclature turned out to be a big challenge, especially because technology cannot easily distinguish or identify different names being used by different trading partners for the exact same product. For example, red round tomatoes being identified as “5x5 tomatoes” or “tomatoes 5x5” by different trading partners are treated as distinct products by technology.
- Technology solution providers were able to highlight the fact that pilot data consisted of significant data quality issues including several missing, incorrect, misrepresented or inaccurate pieces of data.
- Some providers suggested that using open-ended Excel spreadsheets also results in loss of data integrity due to the potential for manual errors, and recommended using XML-schema based spreadsheets instead. This allows for improved validation of data prior to importation into a collaboration platform.
- Automatic flagging of data inconsistencies helped speed up the data importation process. The reason for the speed up is because if the system was incapable of identifying and flagging inconsistencies, it would fail at a future point or provide inconsistent analysis and results; in either case causing a re-importation of data with the inconsistencies manually removed.

- Some technologies could not accept/import data if the dataset did not contain globally unique product or location identifiers; in these situations, the solution providers created their own fictitious globally unique identifiers and assigned them to the products and/or locations.

Data Visualization

Some of the key data visualization tools demonstrated during the face-to-face meetings in order to better understand the pilot data were:

- querying and reporting tools (e.g., traceback and traceforward searches)
- temporal searches for timeline based queries
- gap analysis to identify inconsistencies in data
- geospatial search for mapping public health data with food product tracing data
- hierarchical and network diagrams to map relationships within the data
- filtering capability to manage the potential for overwhelming amount of data typically collected by the FDA during a traceback investigation
- triangulation used to identify convergence

Data Analysis

Some of the difficulties in working with and analyzing the data, as reported by the technology solution providers, were due to missing or incomplete CTEs and KDEs or issues related to interpretation of information. Issues included:

- Most technology solutions are fairly capable of conducting simple traceback and traceforward from a single node perspective (e.g., from a retailer, distributor, or processor perspective). It was difficult for some to identify common elements that might exist in several supply chain paths.
- Interpretation of data and records collected from the industry is best done by those providing that data since they know their own data best (as opposed to regulators or technology experts). Better communication and understanding of what regulators need and what industry can provide would help manage expectations and make the process of a traceback investigation easier. This highlights the importance of collaboration between the industry and regulators using technology to achieve an effective traceback.
- Changes made to the identification of a product (e.g., sticking a new label on top of an incoming label) without recording or linking the old label to the new one created issues with connectivity (e.g., needing to make assumptions based on FIFO, date ranges, or broaden the scope of the investigation).
- Not all pilot participants provided a batch/lot/serial number for the products they were handling, yet several technology solution providers were able to sort through all the data and provide the links needed between incoming and outgoing products using purchase order numbers (at least up to the nearest transformation point in the supply chain where lot numbers are likely to change).
- Not all pilot participants provided event location identifiers, trading partner location identifiers, or unique item numbers to enable effective tracing.
- It was a challenge to conduct mass balance (for example, reconciling the amount of incoming product compared with amount of outgoing product) when different trading partners used different units of measurements or did not provide quantitative information along with their product tracing records

The technology solution providers attempted to run live queries to find convergence based on the scenarios used in the pilots. There were different approaches to using a technology platform to perform the convergence query. Some solutions were only able to follow one leg of a supply chain at a time, resulting in following the flow of products from retail back to source (farm or ingredient supplier) one query at a time. Some had an incrementally better approach where the queries would be a series of tracebacks and traceforwards in order to find convergence (e.g., a traceback of a product to its source, and then a series of traceforwards of that source to find common retail outlets). A technology provider had built-in capability to input a series of retail locations and run the query to find common lots of convergence that could have been shipped to those retail outlets (this included querying the immediate supplier of products, such as a distribution center, as well as the source supplier of products, such as ingredient suppliers or growers). A few others built new queries based upon the requirements of the pilots to demonstrate that convergence can be found, as well as highlight the fact that their technology platform can be customized to the needs of the end user (in this case, the FDA).

Since technology providers were able to select which pilot they wanted to participate in (tomato or processed food - ingredients), it may not be surprising that those who selected the tomato pilot seemed to have a better grasp of what tests should be performed to demonstrate convergence. Many segments of the produce industry have experienced traceback investigations, and firms that specialize in produce tracing may have a more solid understanding of the issues compared to other food categories.

A combined ideal list of KDEs as defined by the technology solution providers is listed below and was considered by IFT when developing the recommendations in Chapter 10:

- CTE Date
- CTE Time
- Shipping Location
- Receiving Location
- Bill to Location
- Item Code
- Lot/Batch/Serial Number
- Quantity
- Unit of Measure
- Receiving date
- Shipped date
- Best Before date
- Order Number
- Transfer Number (also referred to as freight number)
- Pallet Code
- Case Code (serialized or non-serialized)

Recommendations from Participating Technology Solution Providers

The technology solution providers provided their recommendations on how they envision overcoming the limitations they observed in the pilots and when dealing with the pilot data. Some of these recommendations are:

- The key improvement is in data. Technology and all the analytical tools will only be as good as the underlying data.
- Data integrity (and quality) starts at the transactional level implying that improving the day-to-day recordkeeping practices is the way to improve overall product tracing.

- Having common definitions of terms as well as some standards around the data would help simplify the analysis of the data during an outbreak investigation.
- Use of templates to request data and respond with data resulted in a much easier process of data importation, manipulation, visualization, and analysis.
- Regardless of the eventual technology used by the FDA to aid in traceback investigations, the characteristics of the technology should be amenable to all commodity types, not just for produce and processed food products.
- There are several approaches, including manual entry of data, to allow smaller firms in the food system to contribute to a collaboration platform.
- Business and proprietary data can be protected with encryption and bank-level data security, but still needs to be quickly and easily accessible to the regulators in order to protect public health.
- Education was identified as another key component to an effective trace system. This includes better understanding of internal recordkeeping practices within the industry, improved communication between trading partners, and more effective collaboration between industry and regulators.
- A real-time collaboration platform between state and federal regulators would allow for more rapid dissemination of information, reduced redundancy of data collection efforts, and provide for improved analysis to find points of convergence.

Review of Other Product Tracing Technologies

Although several collaboration platforms were explored in the tracing pilots, there are a number of types of technologies and solutions that may be applicable in product tracing. To ensure that the breadth of solutions was recognized, IFT invited the technology community to provide input on systems, technologies, or processes currently available or in development that should be reported to the FDA. For this purpose, IFT developed another set of questions and issued a RFI to augment the study. The types of questions asked in this RFI were:

- demographics of the company and the technology
- types of users across all industries
- pricing structure and range of costs
- the gap or need that exists in product tracing that the technology is addressing
- unique characteristics of the technology
- stakeholders who would benefit from using the technology

IFT received 26 responses to this RFI. The findings are summarized below.

Figure 25 clearly indicates that a majority (65%) of the companies in the product tracing technology space are fairly new (less than 10 years old). There are at least two possible reasons for this: first, as technology improves and becomes cheaper and more accessible, it has a higher probability for application and adoption within the industry; secondly, with better surveillance methods and an increase in the number of high-profile outbreaks reported in the media during the last decade, the food industry has been actively seeking to improve food safety practices (of which food product tracing is a component), and entrepreneurs may see a market for these types of products.

Figure 25. Age of Responding Technology Companies

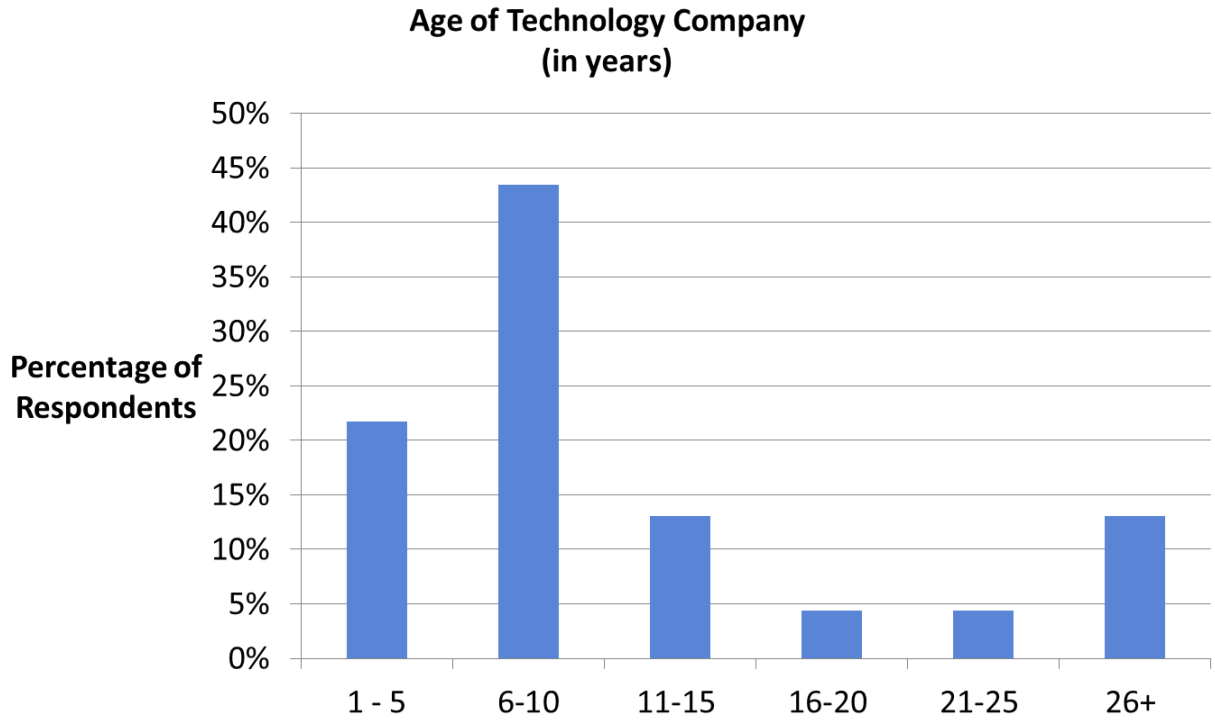
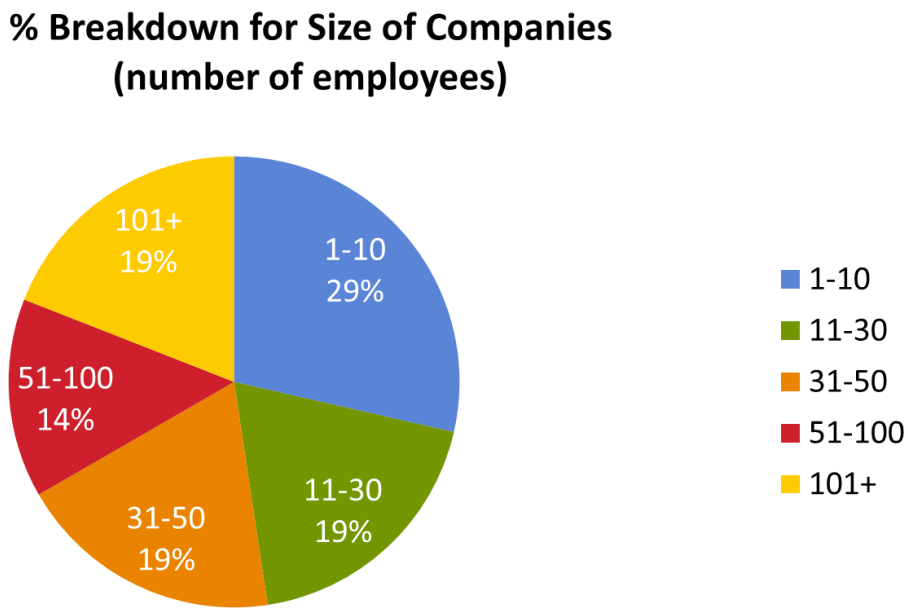


Figure 26. Technology Companies Size Percentage Breakdown



The pie chart in Figure 26 provides a breakdown of the size of the technology companies based on the number of employees. In addition to most companies being relatively new, most companies (29%) have less than 10 employees.

Figure 27 shows the age of the technology solutions (as opposed to the age of the companies shown in Figure 25). This graph is a clearer indicator that there are several relatively new technologies seeking to improve product tracing. The downside to this is confusion in the food industry regarding which technology is the best one for their needs; a problem compounded by the fact that most of these technologies are not truly interoperable (i.e., all members of a value chain would need to subscribe to the same system in order to get the maximum benefit).

Figure 28 shows the distribution of the respondents by the types of users that have adopted their technology solution. For the purpose of this study, there were four categories into which any given technology could fit within: produce industry, processed food industry, industry catering to other foods (when specific foods were not identified), and other industries (e.g., pharmaceuticals, aerospace and automobile); a technology could fit into more than one category depending on function. The technologies varied from specialized product tracing solutions to full-blown enterprise management software such as SAP or WMS systems. Some unique characteristics included web-based and/or mobile integration of consumer access to information on the origin of the foods and/or the ability for consumers to receive alerts for products implicated in an outbreak. Some product tracing technologies were also targeted towards food defense (intentional contamination) and food fraud (including authenticity testing). Finally, ancillary applications of such solutions reported were environmental and time-temperature monitoring and testing.

Figure 27. Age of Technology Solution

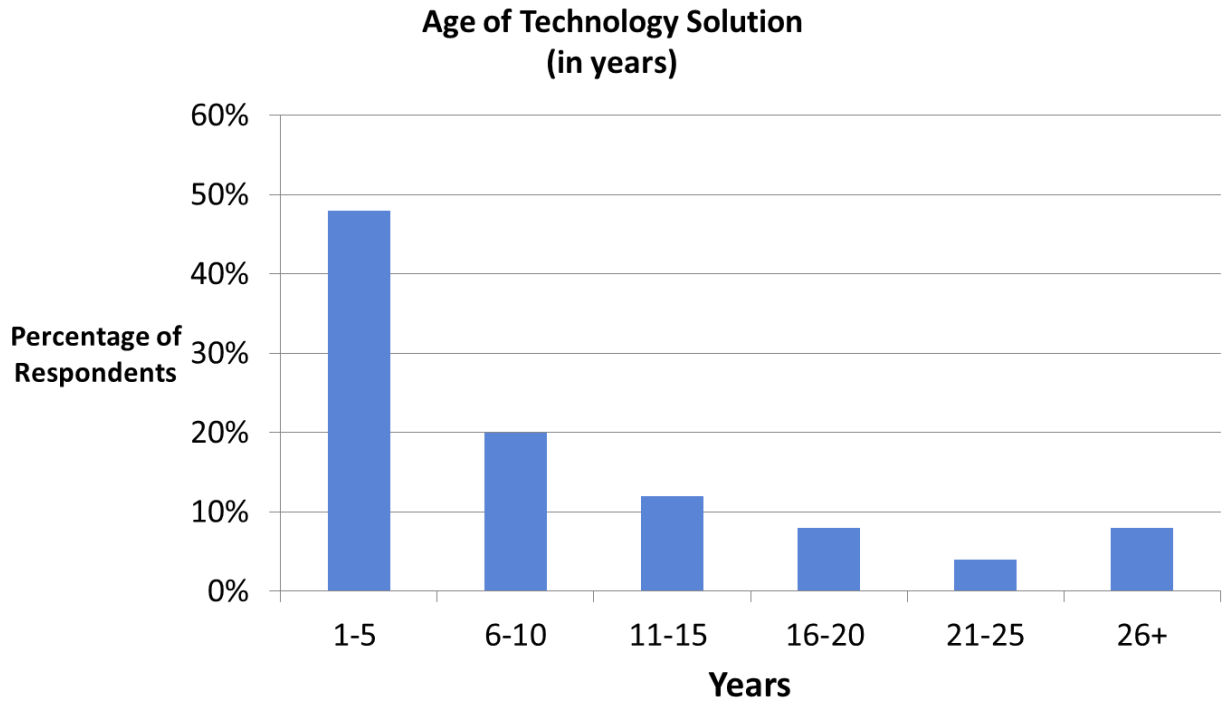
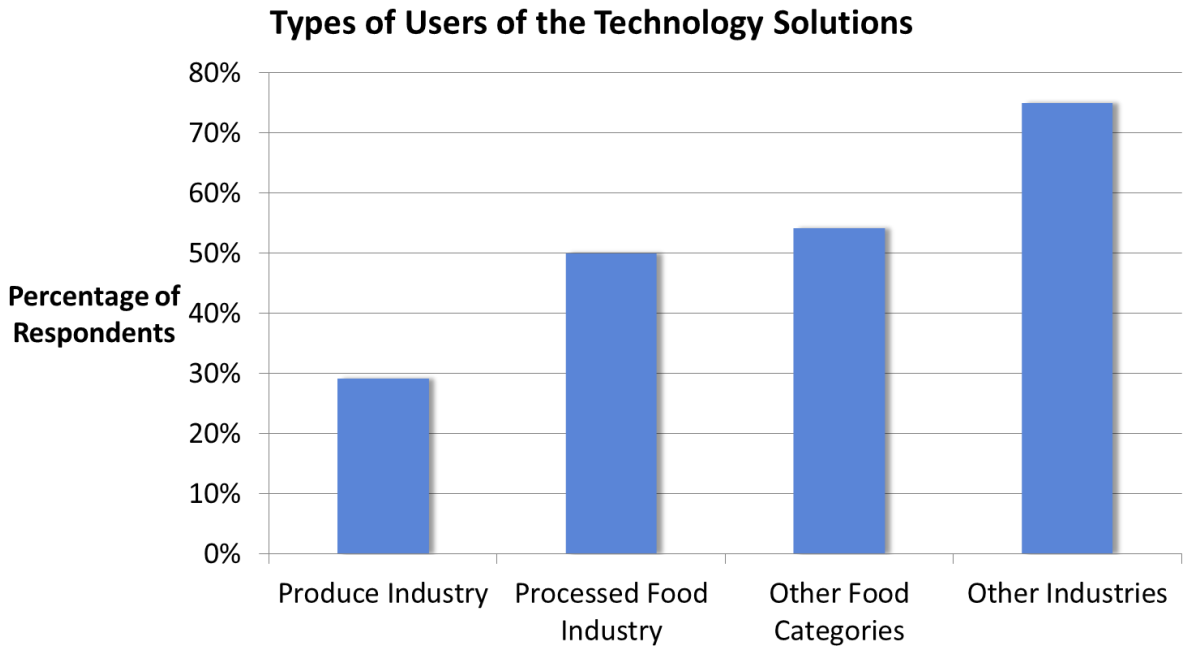


Figure 28. Types of Users of the Technology Solutions



Chapter Summary

Nine technology providers, selected on the basis of peer evaluations of responses to a public request for information published by IFT, participated in the pilots. Four solution providers participated in the produce pilot while the other five participated in the processed food - ingredients pilot. Therefore, each technology solution provider within each pilot was independently running the comparative study in parallel, working with the same data, allowing IFT to capture the variability in capabilities and impact on performance. Near the completion of the pilots, IFT held face-to-face meetings and invited the technology solution providers to conduct demonstrations of their live systems using pilot data. The results of the collaboration platform study highlighted several challenges as well as potential improvements in the data collected through the pilots in the areas of data importation, manipulation, visualization, and analysis. The lessons learned from this study were used to inform some of the recommendations described in Chapter 10.

Recognizing that nine technology solution providers do not accurately represent the breadth of technologies available for product tracing, IFT sought to conduct a qualitative study of "other product tracing systems." For this purpose, another public request for information was published with the intent to learn about the unique capabilities of various technologies as well as their application/use. A total of 26 technology providers responded to this request. The results of this qualitative study indicated a wide range of company and technology demographics (target industry and maturity) as well as variations in pricing structures and unique capabilities.

There are numerous varieties of technology solutions that exist for food product tracing, each with its own capabilities and limitations. Some, but not all, technologies were able to demonstrate convergence during a traceback investigation using the data collected from the pilots. Some were also able to identify gaps in the data, and propose methods to overcome those gaps through improved data capture, visualization, and analytics. Based on the results of this study, FDA should consider using a collaboration platform to manage the volume and quality of data received to ultimately improve the speed and accuracy of traceback investigations.

CHAPTER 6. OVERARCHING PILOT FINDINGS

The pilots substantiated many of the issues identified in the baseline studies. Although there were differences between the tomato and processed food - ingredient pilots, there were similar issues and characteristics that surfaced in several of the mock traces. The pilots examined the following:

- determine how currently available technologies being used within firms impact their ability to respond to track and trace data requests in a way that facilitates the timeliness of the response and the ability to analyze the reported data
- evaluate the types of data needed to follow a product forwards or backwards through the supply chain, including movement within a single facility, as well as the data needed to link product shipped and received between trading partners
- compare how the reporting format or presentation of data impact the ease with which track and trace information can be analyzed by evaluating the usefulness of data provided in native form (e.g., BOL, PO) versus standardized, summary-level data templates
- assess how the data acquisition processes impact the time needed to conduct a traceback, by comparing the stepwise approach currently in use against the use of a collaborative platform

Interpretation of Time to Respond

The tables of results in Chapters 3 and 4, and specifically the times participants needed to respond, needs to be viewed in context. As mentioned in Chapter 4, companies that used technology (such as ERP systems) to auto-generate reports with the information IFT sought in the mock tracebacks and traceforwards reported that removing extraneous data took more time than generating the report. When hard copies (e.g., PDFs) were provided, some firms expended effort in removing information related to costs or de-identifying non-participants. Therefore, the participants wanted to convey that if FDA issued a similar request, the firms would not have removed this information, and the time to respond to FDA would have been shorter for several of the participants. In other words, some firms did not want to share certain information with IFT during these pilots (like non-participating customers and suppliers) but would have shared this information with FDA in response to a request from regulatory officials.

Issues with Definitions/Understanding

After exploring the various definitions offered for a number of terms, IFT provides in this report a glossary of terms in an attempt to provide a platform for discussion. These pilots offered numerous examples of how miscommunication, misinformation, and misunderstanding affected the pilots. A few disparate examples are provided:

- The name and sizes of tomatoes changed through the supply chain, with the grower sizing them as 5x5 and the distributor calling them 5x6. There was no re-packing involved, and when paperwork contained records for several types of tomatoes (e.g., many sizes and varieties) it became difficult to follow which particular tomatoes were of interest.
- When a non-participating manufacturer's product was received by two different firms, in one case it was referred to as "sauce pouch" and in another "Kung Pao Sauce." The difference between these products, if any, is difficult to establish based on the name alone.
- There were several interpretations of the term "supplier assigned lot/batch number" which appeared on the IFT-provided template. In some cases, this was considered to be the manufacturer/grower identification; in some cases it was the way the immediate previous supplier identified the product.

As is often the case, lack of communication—in this case lack of a common vocabulary—was often at the root of these confusions, and IFT benefitted from hearing supply chain partners gain a better understanding of each other's terminology, systems, and expectations at the pilot meetings. Providing a glossary of terms or definitions of important data elements was beneficial to both IFT and the firms involved in the pilot and allowed for common understanding of key data. IFT recommends the creation of a glossary of terms to be shared between industry and regulatory partners, and provides a glossary of terms that are used throughout this document. Further, IFT believes that during an investigation, SMEs could provide explanation to terms that might be specific to a particular industry.

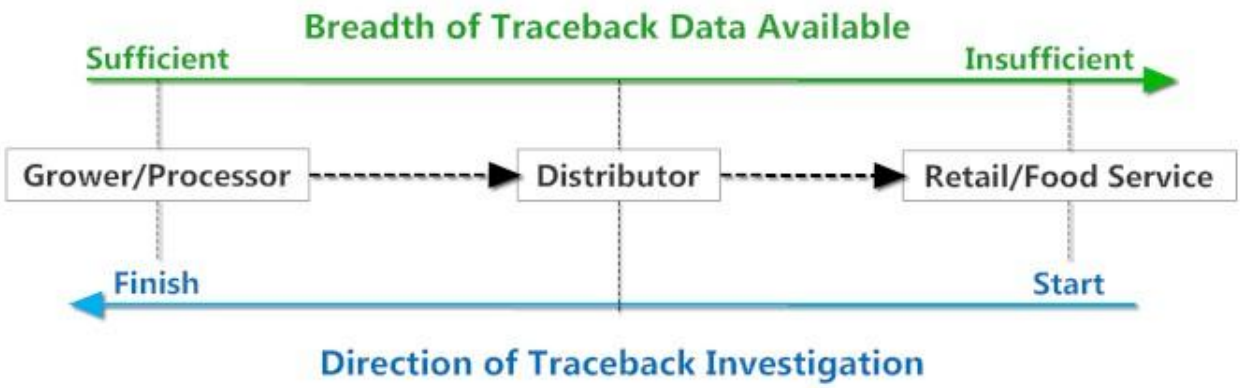
Observations on the Data Captured and Shared

The regulations resulting from the BT Act require records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging. It was evident in the nature of the data provided in the pilots that some in the supply chain did not capture lot information or did not follow intra-company product movement (e.g., from a company-owned warehouse to a retail location). These practices made tracing products more difficult. It is common that those at retail and foodservice expect that their suppliers have a sense of what products were shipped to the retail or foodservice outlet. The ability of the retail or foodservice chain to provide information related to the product(s) in question was highly variable and dependent on the information that their supplier had. It was particularly interesting to observe the response times of retailers, in particular, who participated in multiple scenarios, each with different immediate previous suppliers. It was clear that the response time of the retailer was driven by the immediate supplier's ability to provide information.

Large manufacturing/processed foods facilities (including those manufacturing ingredients) often have robust enterprise resource planning (ERP) systems (further described in Chapter 7), and firms of that category participating in the pilots captured and were able to quickly access and share detailed information related to product inputs and outputs, ingredients, and distribution to customers. These firms also generally provided a mass balance accounting of the product in question. Smaller processors/manufacturers who did not use ERP systems, and who, in some cases used manual processes (especially at the point of batching) still maintained detailed records sufficient for IFT to establish the movement of the product and any ingredients. Similarly, the tomato growers participating in the pilot also collected detailed information, although the resulting identification generally consisted of a long string of digits that needed to be decoded. In some instances the "key" was provided in the first round of the data request; in other cases it was provided after an additional inquiry; in any case, it was clear that a substantial amount of information was being generated and collected.

The extent to which the detailed information collected by the manufacturer or grower was shared with downstream customers varied. In some cases lot numbers were written on BOL. In other cases, this information was kept internal to the company generating the data and was provided upon request. When detailed information was provided to subsequent recipients, it was generally not collected, or not collected in full, by that recipient.

Figure 29. Data Differences at Different Places in the Supply Chain



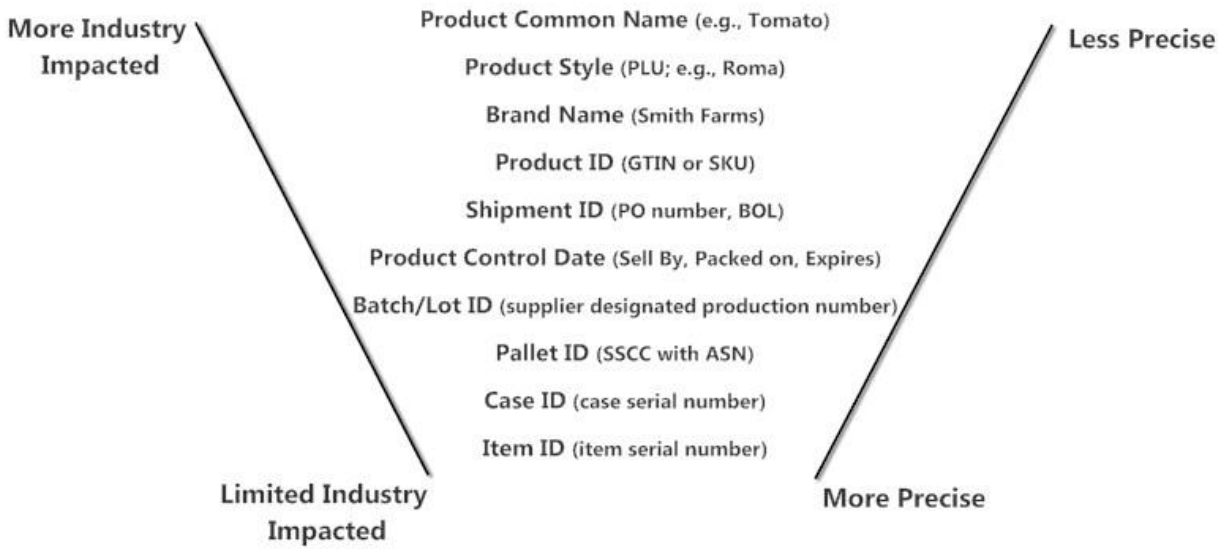
As illustrated in Figure 29, traceback investigations often begin at the retail or foodservice end of the supply chain. The pilots demonstrated that this end of the supply chain lacks the breadth of data needed to efficiently and effectively trace food products. As noted in Chapter 1, the recordkeeping requirements stemming from BT Act exempt farms and restaurants (Section 306) and the resulting regulations and limit the data needed to be captured by retailers (US Congress 2002; FDA 2004). The pilots showed that the amount of information available that aids in product tracing increases as one moves toward the point of production. Thus, data are being lost as the product travels through the supply chain toward the consumer.

Key Data Elements

A key question that the pilots sought to answer was “what data really are necessary to link products through the supply chain”? The answer depends on the level of precision at which one wishes to trace.

As Figure 30 shows, at one extreme, products can be traced to only a general level. This implicates all product and tends to cause economic hardship to an industry. One can then get more specific by naming a brand, a lot of a particular brand, a distribution unit, or consumer level unit. Each step further in the process, as shown in the figure, requires the collection of more information, and a risk management decision needs to be made by regulators as to what level is appropriate. Similarly, companies need to determine how to balance their definition of a “lot size” or the size of their distribution unit against the chance that they may need to trace or recall this amount of product.

Figure 30. Specificity of Information and Impact to Industry



(GTIN= Global Trade Item Number; SKU = Stock Keeping Unit; PO = Purchase Order; BOL = Bill of Lading; SSCC = Serial Shipping Container Code; ASN = Advance Ship Notice)

In the food industry, the level at which food is commonly currently identified by a grower, re-packer, manufacturer or other product originator is the lot level (the size and definition of which varies). As products move through the supply chain this movement tends to be associated with shipments. As shipments are recombined the precision with which food can be traced decreases. As described in Chapter 9, several industry-led tracing initiatives have advocated for continuing to distinguish product at the lot level, with identification applied at the case level.

Given that information related to shipments plays a role in tracing food, in previous deliberations of the IFT Traceability Improvement Initiative (TII) Workgroup (further described in Chapter 9), fields where transformation links would be entered (e.g., a Work Order), where sales documents would be indicated, and where shipping paperwork would be indicated were consolidated to one concept called “Activity” (Hickey, 2012). “Activity ID” and the corresponding “Activity Type” represent the information that is used to link a product between trading partners or link incoming and outgoing products. This required some explanation within the tracing groups, but ultimately the groups agreed that with an understanding of the concept, firms would be able to identify the correct information needed to establish these critical links. Although FDA does not currently require the capture of this information, IFT believes that the pilots demonstrated the value of these data elements and recommends that they be provided to FDA, as applicable, in the future.

Another concept that requires explanation is the lot/batch relevant date. This term is used to represent a marking on a consumer-level product, such as an expiration or “best by” date, when that product lacks the lot/batch number that is present on a case, for example. If testing shows that a product is contaminated, this date must be able to be linked to the originating lot or batch.

While “date” may seem to be an obvious element to record, the pilots showed that it was sometimes difficult to determine how the date could be used to establish the links between shipment and receipt of

product. For example, a document might indicate a shipment date, but the recipient did not necessarily note the date and time the shipment was received. Time is another data element that was seldom provided to IFT. Given that it is advantageous to move product through the supply chain quickly, it was not surprising that IFT found that in some instances, particularly in the tomato pilots, a distributor might receive and ship a product on the same day. For the purpose of a traceback, it is critical to know if a particular shipment could have been received in the morning and shipped later in the day. Date alone are insufficient to make this determination, thus IFT believes that time should also be recorded.

Another area of discussion was around the ways in which product exits the supply chain. This occurs through consumption (whether through sale or donation) or disposal (discarding product, sample analysis, etc.). In the event of a traceforward it is important to account for all products. The pilots did not require firms to perform this kind of reconciliation, but did observe, particularly in the processed food pilots, how firms worked within their companies and with their supply chain partners to ensure all products could be accounted for. In the tomato pilots, upon the request of traceforward information, many participants denoted product that had been discarded. Because these products have a dollar value, IFT sensed that most companies try to account for products so that they can calculate their earnings and profit.

There was considerable discussion over the types of information that should be provided to regulators versus the information that companies should keep that might aid a company in identifying the information that would need to be shared. The Serial Shipping Container Code (SSCC), which links products on a particular logistical unit, was discussed in this context.

The necessity of capturing Carrier ID and Trailer Number was discussed. It was recognized that contamination can occur anywhere in the supply chain, including in distribution. However, there are various modes of transportation and in some instances, Carrier ID and Trailer Number are not relevant. Thus, it was determined that the capture of this information should be deemed “conditional.”

Impact of Tracing by Lot versus Tracing by Shipment

Although it was initially thought that lot/batch numbers should be captured through all stages of the supply chain, the pilot data showed that the Activity IDs could be used to establish these links as well. Recognizing the change in industry practices that would ensue if batch/lot numbers needed to be captured through distribution and retail, IFT sought to validate the pilot findings that Activity IDs could provide adequate, meaningful data that enable the identification of convergence.

Simulation Model Development

A simulation model was developed to test the hypothesis that Activity IDs could enable tracking and tracing products through the supply chain. The simulation consisted of four manufacturers, two distribution centers (DCs) and two retailers. The figures below (Figure 31, Figure 32) show two representations of the supply chains modeled within the simulation. Since the results of the simulation under these two different configurations were similar, this discussion focuses on the simulation of Configuration 1. At the start of the simulation, each manufacturers’ production capacity (number of items produced per day) was set between 100 and 1000 via a random distribution curve. Similarly, the number of lots assigned to those items varied between 1 (entire day’s production assigned to one lot number) and 24 (lot number changes every hour of production). The model was executed over a simulated timeline of 14 days in 1 day increments. Each day, the manufacturers produce new items which are stored in their inventory. Distributors then submit PO requests to each manufacturer who then fulfills each PO using items in their inventory. A similar process continues in which retailers submit PO requests to the distributors and receive shipments of items from the DCs against those POs. Each

shipping and receiving event in the simulation records the lot numbers as well as the PO numbers against which the event occurred. Depending on the quantity of items requested, a PO could be fulfilled with products from a single lot or mixed from multiple lots. An important element of the model is the requirement of a strong link between incoming POs and outgoing POs if tracking at the PO level. This is a stricter requirement than the FIFO relationship based only on timestamps as used at some distribution centers today.

At the end of the simulated second week, queries were submitted to the simulation to mimic the queries during an outbreak investigation. Records were extracted from each modeled retailer about the items they could have received at any given simulated day. The simulation used the information obtained from each retailer to make a similar request of each distributor, asking for the incoming POs which were used to fulfill the list of POs obtained from the retailer. Finally, a query was submitted to the manufacturers requesting a list of lots that were used to fulfill the list of POs obtained from the distributors. To simulate different timeframes of investigations, queries were submitted for records for one day, then over two days, and so on and so forth. The scope of the investigation was incrementally increased one day at a time to analyze the potential impact of two different recordkeeping methodologies as a function of time. The records were extracted at two granularities—one assuming everyone tracked products by the lot numbers assigned by the manufacturer and another assuming everyone tracked products by PO with only the manufacturer tracking at the lot level.

Simulation Model Results

The results of this simulation are shown in Table 28. The results from each day are cumulative and represent the information as if it was gathered at the retail level. The simulation includes transit time between the manufacturer and distributor, and between the distributor and retailer. Therefore, data are only available from the retailer beginning at day 3. Using day 3 as an example, at this point in the simulation, the total number of lots produced by the four manufacturers is 135. If the retailers were asked for information regarding the product they received at day 3, and if both distributors and retailers captured the lot numbers of products provided by manufacturers, investigators would have been provided with 25 lot numbers between the two retailers. In the simulation, five of these lots were common between the two retailers, thus the next column shows that there were 20 unique lots.

If both the distributors and retailers retained PO numbers, but did not record the lot numbers associated with those shipments (similar to the experiences of the mock traceback in the pilots), and assuming that multiple lots could have been associated with each PO at each point in the supply chain, investigators making the same request at day 3 would have traced the POs to reveal 41 lot numbers. However, because of the high number of duplicates (and triplicates) the number of unique lots is still 20. In this example, the “actual” number of lots is 20 in both cases, but when tracing by PO, there is more information that needs to be managed to make that determination. Such duplication could easily be flagged and discounted semi-autonomously through the use of a technology platform.

Tracking by lots is more accurate than tracking by PO number. For example, in the simulation, at day 7, the total number of lots investigators would focus on is 103. However, when tracking by PO, investigators would also be examining five additional lots that happened to be identified by PO numbers but in actuality were not shipped (known because the simulation “knows” that 103 different lots were actually received by the retailers). The total in column 6 (tracking by PO) is always equal to or greater than the total in column 4 (tracking by lot). Surprisingly, this difference is not as great as one would expect, given the uncertainty presumed to exist when multiple lots are associated with an incoming PO and the inability to precisely know which of these lots was shipped on an outbound PO. As one looks down the table, the actual universe of relevant lots is similar across both recordkeeping approaches (lot

level or PO level). It still shows that the narrowest scope of the investigation is achieved by tracking at the lot level; however tracking at the PO level does not significantly increase the scope of the investigation. This theoretical model validates the observations, results, and conclusion from the pilots regarding the ability to track at the PO-level and its relative impact on a traceback investigation compared to tracking at the lot-level.

Simulation Model Assumptions and Limitations

There are a few key points related to the simulation. The first is the recognition that even though tracking by PO yielded relatively few "false positive" lots, in the scenario in which retailers are recording lot numbers, the investigators would immediately know the lots in common between the different retailers. In the situation where POs are relied upon, the identity of the lots is obscured, and thus the investigation may be delayed, until the manufacturer is able to identify the lots associated with specific POs. Thus, although the accuracy associated with tracking by PO is only slightly lower than tracking by lot, the accessibility of information is very different. That said, if any transformations have occurred that result in the assignment of a new lot number (e.g., a contaminated ingredient used in multiple finished products), there would still be different lot numbers at retailers, and investigators would still need to follow these lots through the supply chain before being able to identify a common source. Tracking by lot number through the retail level therefore does not necessarily mean that investigators will be able to instantly determine common product lots.

Another consideration relates to the assumption that contamination occurs only at a manufacturer or grower. Some pilot contributors suggested that if the retail/foodservice segment of the supply chain captured lot numbers, investigators would be able to bypass other supply chain members and investigate the cause of the issue more readily. The pilots sought to trace products through the supply chain as far as possible without speculating as to the reason for the inquiry. Given that food safety breaches can occur at any point in the supply chain, it is important that all members participate in a product tracing system.

Finally, although the accuracy of tracking by PO number rather than lot number may yield similar results, it must be recognized that tracking by PO numbers yields substantially more data that need to be managed. By comparing columns 3 and 5 in Table 28, one can see that although the non-duplicated lots in columns 4 and 6 are comparable, the total amount of information is not. With each passing day, the amount of information—much of which is duplicative—increases substantially when tracking by PO. Discerning and distilling this information is a laborious process when done manually (as demonstrated in the mock tracebacks).

In some of the pilot scenarios, distributors were involved in sequential series, similar to Figure 32. The pilot groups deliberated whether a more complex supply chain, with more distributors in series, would alter the results of the simulation described above. The only difference observed when a similar exercise was modeled using Configuration 2 was that the raw number of relevant lots expanded more rapidly. This means that the sheer volume of data to be managed was larger, but the accuracy was comparable to Configuration 1.

Simulation Model Summary

In summary, when the collaboration platforms showed that Activity IDs such as purchase orders could be used to identify points of convergence when firms maintained solid relationships between products shipped and received, IFT conducted additional work modeling the difference between tracking by lot number versus Activity IDs. While tracking by lot number offers several advantages over tracking by Activity ID (information immediately accessible to regulators, less information to sort through), Activity

IDs, particularly when used in conjunction with a system to analyze data, can provide meaningful information to aid in product tracing investigations when firms also maintain good internal tracing.

Figure 31. Simulation Model Supply Chain Configuration 1

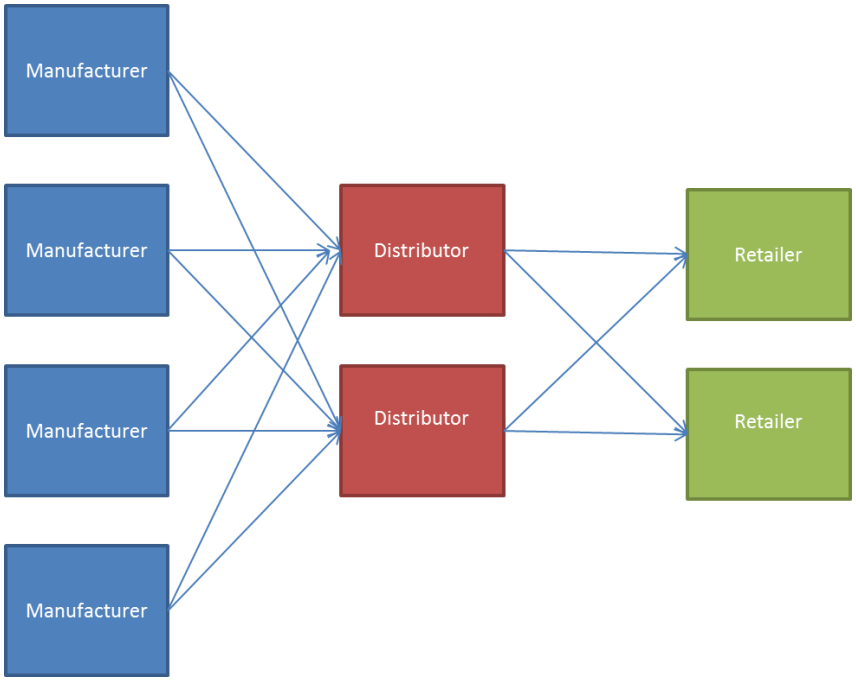


Figure 32. Simulation Model Supply Chain Configuration 2

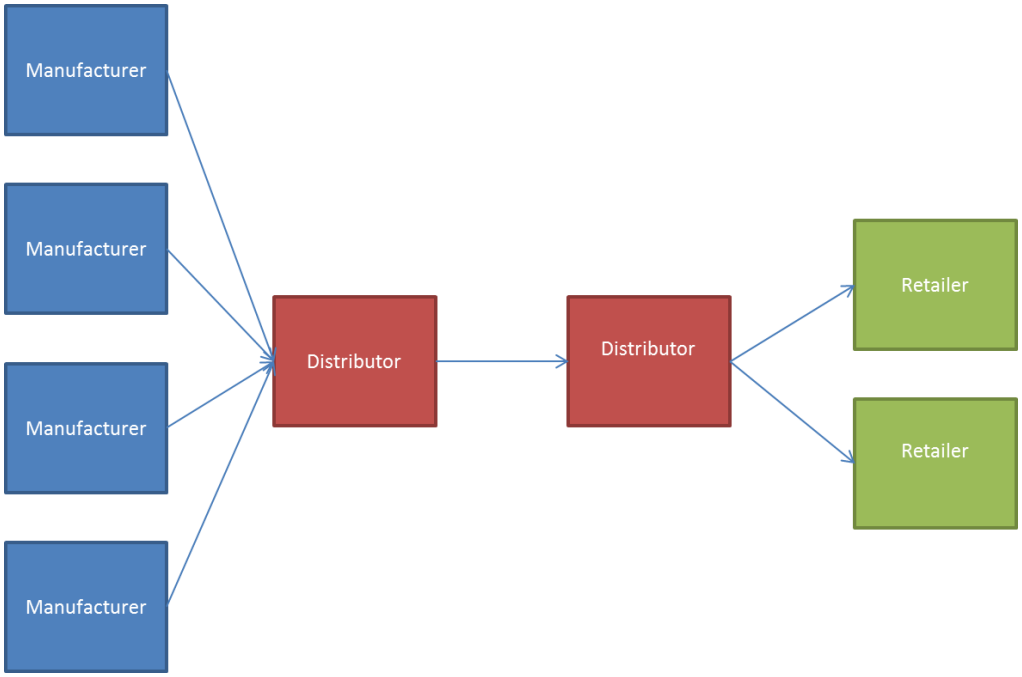


Table 28. Simulation Model Output Comparing Recordkeeping at Lot-Level versus at Purchase Order-Level

Simulation Day	Total Lots Produced by Manufacturer (cumulative over days)	Raw Number of Lots at Retailers when Tracking at Lot Level	Actual Number of Lots at Retailers when Tracking at Lot Level	Raw Number of Lots at Retailers when Tracking at Purchase Order Level	Actual Number of Lots at Retailers when Tracking at Purchase Order Level
Description of columns	The sum of the number of lots produced by all four manufacturers	Assumes the traceback includes all lots recorded by retailers; each lot counted separately	Same as previous column, except duplicate lots are removed	Assumes the traceback includes all lots potentially associated with all POs; each lot counted separately	Same as previous column, except duplicate lots are removed
1	45	0[1]	0	0	0
2	90	0	0	0	0
3	135	25	20	41	20
4	180	56	46	104	56
5	225	83	66	166	67
6	270	116	78	239	86
7	315	148	103	310	108
8	360	188	121	399	130
9	405	215	139	453	143
10	450	248	153	516	155
11	495	284	170	597	174
12	540	315	188	665	190
13	585	347	204	737	208
14	630	380	219	801	222

[1]During the first two simulation days, the supply chain relationships are still being established and no products exist at the retail level (products are in transit). Each day represents the accumulation of lots from the previous days (e.g., results from day 7 represent a request for data spanning all 7 days from the time of production).

Identification of Key Data Elements and Critical Tracking Events Recommended to FDA

Upon consideration of the pilot results, results of modeling the impacts of tracing by shipments (based on POs, BOLs, etc.) versus by lot number (as identified on a case or pallet), and substantial discussion of these findings, IFT determined the KDE at each CTE that IFT feels FDA should consider as guidance and/or regulations pertaining to product tracing and recordkeeping. These are provided in Table 29.

In reviewing the proposed KDEs, it was recognized that current statutes and regulations, namely the BT Act and associated rules, already require many of these data. However, the pilots showed that the "Activity Type" and corresponding "Activity ID" were also instrumental in establishing links, particularly between trading partners. Thus, Table 29 is divided to identify the KDEs that are currently generally required by FDA versus those that IFT recommends also be considered important in a product tracing investigation, particularly to establish the links needed to follow product movement. This table does *not* represent what is required today. Rather, items denoted as "R" (required) represent the data elements that IFT feels FDA *should* require in the future. These recommendations are further expanded upon in Chapter 10, recommendation 2.

Table 29. IFT's Recommendations Regarding Key Data Elements as Related to Critical Tracking Events

CTEs	Transportation (exchange of goods) - Shipping	Transportation (exchange of goods) - Receiving	Transformation (creation / manipulation of products) – Input	Transformation (creation/manipulation of products) – Output	Depletion (exit from system) – Consumption	Depletion (exit from system) – Disposal
Currently Required KDEs						
Event Owner (firm submitting information)	R	R	R	R	R	R
Date/ Time	R	R	R	R	R	R
Event Location	R	R	R	R	R	R
Trading Partner [1]	R	R	R			
Item (the good)	R	R	R	R	R	R
Lot/Batch/Serial#	BP*	BP*	R	R	BP	BP
Quantity	R	R	R	R	R	R
Unit of Measure	R	R	R	R	R	R
Linking KDEs						
Activity Type (e.g., PO, BOL, Work Order)	C*	C*	R	R		
Activity ID (number associated with PO, BOL, Work Order)	C*	C*	R	R		
Transfer Type[2]	C	C				
Transfer Number[2]	C	C				
Lot/Batch Relevant Date[3]	C	C	C	C	BP	BP
Carrier ID	C	C				
Trailer Number	C	C				

R = Required Field

C = Conditional Field; the need for this field would be determined by business circumstances, and in the instance of transport events that do not capture batch/lot numbers, this field may be required (*)

BP = Best practice is to capture the batch/lot number or relevant date whenever possible; however, in recognizing the current difficulty in capturing this information for transport and depletion events, Activity ID or other KDEs that provide links, as identified in the table, must be provided (*) as the industry prepares to meet a future requirement to capture lot/batch numbers

[1] In the event of a shipping CTE, the trading partner is the immediate subsequent recipient of the shipment; in the event of a receiving CTE, the trading partner is the immediate previous supplier of the product; in the event of a transformation CTE, the trading partner is the supplier of the input into the transformation

[2] If the Activity Type and ID are not linked to a particular shipment of a product (e.g., a purchase order that is fulfilled by multiple shipments over time), then the Transfer Type and ID are used to indicate the particular shipments that are linked to the Activity Type and ID

[3] If there is a different lot/batch designation on a consumer-level product, such as a "best by" date, it must link to the manufacturer-assigned lot number

Once the groups were comfortable with the recommendations relating to data, it was suggested that IFT compare how the data provided by the pilot participants were or were not a match to those recommendations. Such a comparison would provide an indication of the records currently available compared to records that would need to be kept. IFT selected two representative scenarios, one from the produce pilot (Scenario C) and one from the processed food - ingredient pilot (Scenario PB), and evaluated how the data provided for one item/shipment compared to the recommended data identified in Table 29.

There were several challenges that complicated this exercise. As mentioned earlier in this chapter, time was not indicated in the records provided to IFT. Another field that was difficult to enter into the spreadsheet was date. As conceptualized, "date" should be the date of that event, be it shipping, receiving, etc. However, this information was not nearly as straightforward as one would expect. For example, at the point of "receiving," a firm would provide a BOL to show receipt. However, the BOL might only contain the "ship date" rather than the date of the receiving event.

In some cases, it was difficult to discern how the information was used by the firm. For example, when transformation data were provided, it was not clear until speaking with the firm that the "input" lot number was the PO on which the tomatoes were received. The re-packer created a new identity after tomatoes were re-packed, consistent with the requirements of a transformation event. The inputs (based on PO) and outputs were captured. In this case, the tomato supplier provided the re-packer with the lot number. A better practice would have been for the re-packer to associate that lot number, rather than the PO, with the transformation event. This is dependent on the communication of the grower lot number which, while provided in this case, was found to be inconsistently provided in other pilot scenarios.

Templates and Data Summaries

Participants responded to the requests for data in many ways. The variety of types of documents on which key data resided included sales orders, BOL, invoices, etc. Many firms summarized track and trace information, either on the IFT-provided template (Appendix M) or using their own formats.

As previously mentioned in Chapter 2, the IFT template was built on the basis of IFT's previous work in identifying CTEs and KDEs, which was further improved upon by the mpXML group (a not-for-profit meat and poultry data standards group also seeking to advance tracing in their segment), carefully considered by the IFT TII Workgroup, and further refined by contributors to this task order. Each pilot group met separately to deliberate the data that FDA should "require" of firms to link products. After the pilots, the templates and the utility of the data captured within them was discussed to inform IFT's recommendations provided in Chapter 10.

In the produce pilot, the template was used 14 times out of a possible 36, including one re-packer who used the "transformation" tab to denote what re-packed lots were derived from the input lots. While the template was often used by those in retail and foodservice, it was also used by the variety of other participants. In the processed food - ingredient pilot, it was used three times out of a possible 16, and each use was by a retailer.

When IFT received the templates, it was occasionally difficult to figure out what was meant by "supplier assigned lot/batch number." In some instances, this was the number assigned by the grower/manufacturer/re-packer, regardless of the number of supply chain steps the product might have gone through. In other instances, this was the number assigned by the immediate previous supplier. IFT found that the template was helpful in deciphering accompanying paperwork, but was difficult to use independently of the backup documentation. In a few instances IFT also found typing errors (missing or

transposed digits, errors in dates, etc.) that needed to be checked on. Some of these errors existed in the data, while others were introduced during the filling of the templates. There was also inconsistent use of “trace product shipped” and “trace product received,” depending on whether people read this as “trace product I shipped” or “trace product shipped to me;” however, this was usually easy to figure out.

At the meetings of the individual pilot groups, those that used the templates reported that they too, found some of the fields confusing and found that filling them out could be cumbersome. This supports the notion that definitions for data fields will be helpful in ensuring that industry understands what information is (or is not) useful to trace food products.

IFT requested that firms provide the documents necessary to trace the products, and in several instances, firms chose to provide IFT with what we collectively termed a “summary document.” In some cases, the summary documents were Word documents that provided an explanation of the subsequent documents (e.g., exhibit “A” shows that lot xyz was provided on January 1 from supplier 3.). In other cases, the “summary document” contained the summary of all the relevant data needed to trace the products. In many instances this included internal and external links that would not have otherwise been obvious. In those cases, IFT generally sought to understand how the firm was able to establish those links. In the produce pilot, a summary document was provided six times (out of a possible 36), often by growers and sometimes by distributors and re-packers. In the processed food pilot, a summary was provided nine out of a possible 16 times.

IFT found the summary documents to be incredibly useful and in general, the fields identified by the firms as being necessary to link information about a product seemed appropriate to the firms’ practices. In a few instances, IFT did not understand the meaning of a field and sought clarification, but in general, IFT found that these documents enabled more rapid tracing of the products in question.

Supply Chain Attributes Considered in the Pilots

Although the pilots were by definition limited in scope, the studies were able to include a number of characteristics that exist in food supply chains.

> **Direct Store Delivery (DSD) Network:** There are three main ways in which a retailer can receive product to stock their shelves. Many larger retailers have their own distribution center. Some receive products from independent distributors. Finally, some products are sent directly from the manufacturer (DSD) or a distributor to the store shelves. IFT was able to include a DSD distribution network which serviced a small retailer. In this type of the supply chain, trucks deliver directly to the stores and stock the shelves, as opposed to products being received at a retail distribution center, sent to stores, and unpacked by store employees. One participating retailer noted a concern that when the shelves are stocked directly by the drivers making the deliveries, the retailer has no opportunity to record information associated with the shipment, because the store staff does not open or handle those cases. The retailer also reported that their distributor prefers this method of delivery since it is more expeditious than waiting for the grocery staff to “check in” the product, checking for quality and verifying quantity against paperwork.
>
> The DSD distribution system had an impact on the pilot scenario, since the retail store did not receive the product in a way that facilitated the capture of information related to the product. Rather, the retailer needed to work with the distributor (who did not participate in the pilots) to identify the manufacturer, which was a very time consuming process. There may be instances in which DSD processes record which products are delivered to which stores, but these were not observed in the limited scope of the pilot.

- **Commingled Lots:** The pilots explored the issue of bulk commingling in a few different scenarios, namely in the ingredients traced in the processed food - ingredient pilots. Peanuts supplied by two different companies were both commingled at various stages of production, as well as by the peanut butter company that roasted the peanuts. Crushed red pepper was also commingled. The process of commingling makes it nearly impossible to pinpoint the origin of a specific peanut (or grain of wheat, or glass of milk). Commingling should be considered a transformation event within the lexicon of CTE, with the input and outputs being tracked. In the pilots, IFT was forewarned that it would be impossible to trace the peanuts, for example, back to the farm. However, in the pilots, both peanut suppliers maintained records of the suppliers of raw peanuts.
- **Continuously Produced Product:** When products are produced by a batch process, akin to using one large mixing bowl, distinguishing different batches, and the ingredients that comprised that batch, is fairly straightforward. However, many food products are not produced through a batch process, but rather through a continuous flow operation. In this system, "lot" is often defined by time (e.g., all product produced in a 24-hour period). Clearly, products manufactured minutes apart, even technically on different days, likely have similar ingredients. Two processed food - ingredient pilot scenarios involved peanut butter, which is produced continuously. In one mock traceback, the peanut butter manufacturer was provided with the date code associated with a specific jar of peanut butter. In this pilot, the manufacturer provided information for all products manufactured the day before and day after (based on the calculated throughput of ingredients and providing for a safety buffer).
- **Shopper Card Data**
  Another component of traceback investigations explored in the pilot was the use of shopper card data. In one scenario (PB), IFT arranged to have the pilot product purchased in advance of the launch of the scenario. IFT provided one retailer with the shopper card number and the general type of product of interest (peanut butter). The retailer was able to quickly identify the type, brand, and date of purchase of the product. In the processed - ingredient group meeting there was discussion around whether or not the retailer, if provided with shopper card information for several people, would have been able to identify any common items purchased using most or all of the shopper cards. Because the information is stored electronically, the sense was that this could be done, although the extent to which retailers have analyzed data in this way was unknown. In the event that an outbreak was driven by a contaminated ingredient present in multiple products, it would be difficult to readily identify a common product purchased by several shoppers since the specific ingredients are not associated with the shopper card data, only the SKU/UPC of the purchased product.

It is important to recognize that the prevalence and popularity of shopper cards varies between retailers and within different parts of the country. Additionally, even when stores offer shopper cards, there is no requirement that they be used. One retailer provided data indicating that approximately 75% of customers use their shopper card when making purchases. In the pilot, shopper card data helped identify the specific product and date of purchase, which could be helpful in both the epidemiological and traceback components of an investigation.

Chapter Summary

There were several lessons learned by conducting the mock tracebacks. A precursor to accurate data capture is a clear understanding of terminology. IFT found several examples in which terms were used by different supply chain partners in different ways. This impacted the utility of the IFT-provided data summary template. Still, the template was useful in being able to understand the relevance of

information in accompanying documents. Company-generated summaries were also incredibly useful in being able to more rapidly determine how pieces of information were connected to each other. Some of the summaries were auto-generated by the technology systems already in place within a firm. Some were provided as electronic spreadsheets which could be readily fed into a collaboration platform; others were auto generated by the firm's software system, but could only be provided as a PDF. The specificity of information provided generally increased as IFT moved from the point of retail/foodservice toward the point of origin/manufacture.

Through the analysis of the types of documents provided, IFT was able to identify KDEs that IFT believes are necessary to track and trace the movement of products through the supply chain including movement within a single facility, as well as the data needed to link product shipped and received between trading partners. Many of these data elements are already captured by many pilot participants. Additional data that IFT believes would aid in increasing the effectiveness of a tracing investigation include the capture of time, specifically the time that CTE occurs (be it shipping, receiving, transformation, etc.). Although dates are often provided on documents, these dates may not always match the date of an event. For example, the date on a BOL indicates the date of shipment. However, if this document is used by the recipient as a record associated with a receiving CTE, the date of receipt also needs to be indicated.

The KDEs that were subject to the greatest debate were Activity Type and ID (e.g., Work Order, PO, BOL) and lot/batch/serial number. Associating lot number with product movement provides greater accuracy than following Activity IDs. However, the difference was surprisingly minimal. This was demonstrated first through the use of collaboration platforms which were able to successfully trace product movement and identify convergence when Activity IDs were relied upon, and was then verified by the use of a simulation model. Although accuracy is not substantially compromised, the accessibility of lot numbers is decreased since investigators need to reach the source able to reveal lot numbers. Additionally, the amount of information that needs to be aggregated and analyzed is substantially increased. This can be managed through the use of a collaboration platform.

The pilots were able to explore several situations common within the food industry, including DSD, batch versus continuous process operations, and the use of shopper card data. Given the limitations inherent with a pilot, IFT was able to identify areas where systems and technologies in current use can be better utilized to aid in the tracing process, and also identify the data and records that are needed to trace food products.

CHAPTER 7. COST - BENEFIT EVALUATION

All stakeholders want to understand how the benefits of improved product tracing compare to the costs incurred. The FSMA requires FDA to ensure that the public health benefits of additional recordkeeping requirements outweigh the costs associated with such requirements. As such, FDA tasked IFT with conducting an in-depth review of the costs and benefits associated with the adoption and use of several product tracing technologies, including those used in the mock traceback/traceforward activities. Specifically, FDA asked IFT to look at costs including, but not limited to those for:

- capital equipment improvements,
- additional recordkeeping, and
- harvesting, processing, and point-of-sale improvements.

As an overall charge, FDA specifically requested that IFT "assess the costs and benefits of the methods for rapid and effective tracking and tracing of the selected foods and key ingredients." IFT employed a multi-pronged approach to address this portion of the task, including:

- subcontracting to Auburn University to conduct a literature review,
- identifying and analyzing non-published cost and benefit information,
- working with Deloitte Consulting (who provided pro bono support) to determine the costs incurred and benefits realized by pilot participants,
- obtaining cost information related to the use of several technologies, and
- reaching out to small businesses to ensure the economic feasibility of the recommendations within this population.

Deloitte also expected to use information derived from a proprietary survey conducted by the consulting firm of its clients and contacts; however, a report was not developed due to the low response rate.

As previously noted in Chapter 2, IFT sought stakeholder input to inform several aspects of this task, including the cost-benefit evaluation. Most stakeholders felt that IFT should consider the ancillary benefits of product tracing in the evaluation; but there were no offers of existing sources of data to perform either the cost or benefit calculations, other than the general benefits of using specific technologies made by the vendors of those systems.

In addition to a public posting on IFT's website requesting input for costs and benefits, targeted outreach was conducted, summarized in Table 30, to obtain cost and benefit information (including emails, phone calls and/or site visits) to:

- pilot participants
- industry members (involved in the pilots as SMEs as well as other contacts)
- trade associations
- technology companies
- small businesses

Table 30: Targeted Outreach for Costs and Benefits Data

Costs and Benefits Outreach	Number of Individuals / Companies Contacted
Stakeholder Input	140
Pilot Participants	45
Pilot Panelists	34
Trade Associations	7 trade associations with more than 5739 members combined
Technology Companies	175
Small Businesses	24
Total	**425**

IFT also took into consideration the comments offered by the approximately 50 individuals attending the final pilot meeting who, upon review of the draft report, expressed their sense that the preliminary data could be augmented through an aggressive, active outreach effort.

While IFT was not charged with conducting a complete regulatory economic impact analysis, it was IFT's aim to provide FDA with as much useful information as possible related to the costs and benefits of the adoption of various systems and technologies to improve recordkeeping and ultimately improve the traceback process. Antle (1999) reviewed the concepts and methods that can be used to quantify the benefits and costs of food safety regulations. Antle (1999) suggested that the costs of statutory regulations are the result of design and performance standards. Design standards specify the technology that a firm must use, without specifying the outcome that must be achieved by a firm. Antle (1999) indicates that a performance standard imposes a requirement that a firm must achieve a specified goal or objective without specifying the technology the firm must use to achieve the standard. Based on Antle's definition, the current recordkeeping requirements resulting from the BT Act can be considered a performance standard, since no stipulations are made as to how this standard should be achieved. Antle (1999) added that some regulations will combine elements of both performance and design standards. The recommendations made by IFT begin to encompass design standards, for example, with the recommendation that FDA develop standardized, structured, and electronic reporting mechanisms for industry to provide CTE and KDE product trace data (all recommendations are discussed in Chapter 10). In fact, as further explained below in the section titled "Cost - Benefit Determination," in order to obtain cost estimates from pilot participants, IFT needed to specify various design options which began to suggest the "how to" means of reaching the desired objectives.

Literature Review

APPROACH

Dr. Mark Clark at Auburn University led the literature review, which focused on two main areas: (1) understanding the costs and benefits associated with food product tracing based on the published literature, and (2) collecting and assessing industry-specific information for the four foods (tomatoes, poultry, peanuts, and spices) explored in the pilot studies. Within these four food categories, the three main topics addressed were: (a) the supply network, (b) current product tracing efforts specific to these sectors, and (c) segmentation including data relating to size and location. Much of the background information on these industries appears in Appendices J, K, and R.

FINDINGS: COST

While a number of authors discuss the costs involved in food product tracing, Mejia and others (2010) specify the potential associated costs and also provide a literature review and case studies associated with product tracing costs. They report that the costs for product tracing initiatives are generally in one of two categories: fixed costs and variable costs. The fixed costs include the one-time initial purchase and installation costs, while the variable costs include the on-going operating costs. Mejia and others (2010) go on to define the specific costs that should be considered by a firm. These costs include:

- capital equipment and software,
- costs for identifying, designing, or implementing the system (including external consulting),
- training costs associated with using the system,
- labor costs for operating the system,
- additional materials for operating the system, and
- the effects the product tracing system might have on the line speed or the efficiency of operations.

Mejia and others (2010) also explain that the costs need to be estimated for each type of firm in the supply chain. The firm could then be placed in a category of similar firms that most closely matches its operations, size, location, etc. Then, the costs could be multiplied by the total number of similar firms in each category to reach an industry-wide cost estimate.

Much of the peer-reviewed, published information available focuses on product tracing costs and benefits in a more qualitative or categorical nature as opposed to quantitative nature. The quantitative information found was focused on very specific case studies which were not applicable to the industry as a whole. These focused studies were informative but the tailored nature and limited scope does not allow the information to be applied across industry.

Chryssochoidis and others (2009) addressed a case that involved the conversion of a paper records system to an electronic (computerized) records system for a bottled water company in a South European country. The company was composed of 30 employees that produced roughly 30,000,000 liters of water per year which translates to about 18,000 liters of water per day.

The company experienced several initial investment costs as well as some ongoing costs. The company reported that it was able to make the transition without any additional computers; however, its custom software development costs were €600 ($942 USD) per day and the license cost was €150 ($235 USD). The company incurred costs associated with training that equaled time for two people over half a day each, and the cost for data conversion for input purposes was €1,100 ($1,727). The company's ongoing cost was limited to the monthly license cost of €105 ($165) per month.

Although the company could not attach a dollar amount to the cost savings, company officials perceived that there was a reduction in transaction errors, better tracking of product, and logistics assets. The company officials also perceived an increased ability of the company to handle recalls with a much narrower scope. They believed they could improve their demand forecasting, and were in a better position to collaborate with the company's customers. Inventory was easier to track, and they were able to reduce shrinkage through a more visible supply chain. They believed that they were able to increase the level of product quality, and improve customer trust through the company's ability to react to a possible recall more quickly. Overall, the company officials perceived that the company's conversion to an electronic system enhanced its ability to make better decisions.

In 2004, Can-Trace, the Canadian public-private partnership working to improve the ability to trace Canadian food products, conducted a pilot that explored tracing in the produce sector (as well as beef and poultry). As part of this pilot, Can-Trace sought to develop a business case detailing:

- incremental costs and accrued benefits, with results organized by company size and supply chain segment,
- industry recommendations surrounding how costs for the implementation of traceability (product tracing) will be allocated,
- other issues pertaining to the cost implications for domestic product vs. imported product, and
- the creation of templates for individual participants to use in assessing their benefits and costs.

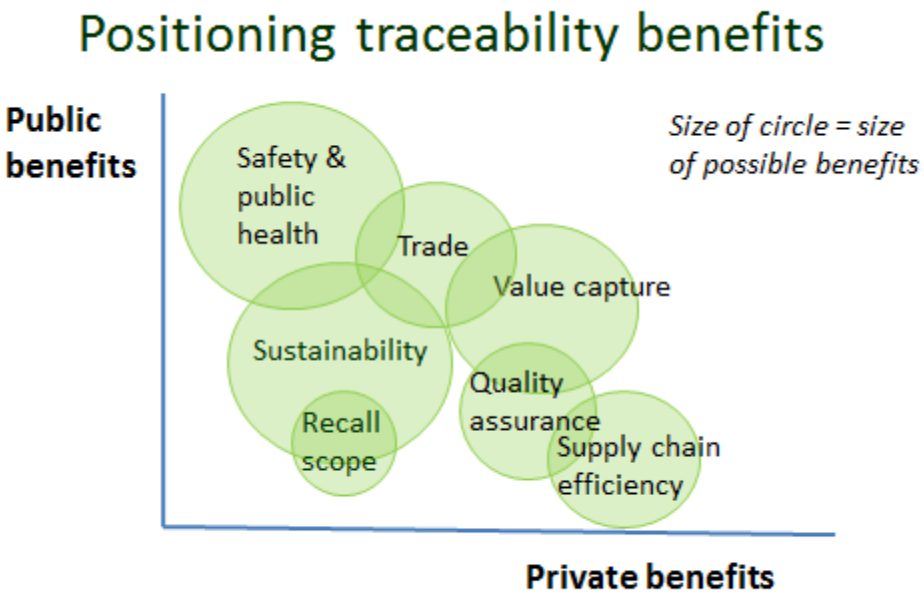
However, the report concluded that the business case could not be developed due to the inability or unwillingness of firms to provide financial data (Can-Trace 2004a). The group did, however, create a robust, comprehensive template spreadsheet to help individual companies quantify their costs and benefits. This template and the accompanying document provide an excellent starting point for firms seeking to understand and quantify costs and benefits (Can-Trace 2004b).

FINDINGS: BENEFITS

In general, the benefits of improved product tracing are more difficult to quantify and assign than the costs associated with system upgrades. The costs of product tracing improvements are usually expended by the firm that engages in the installation of equipment and the annual maintenance of the equipment. Some will argue that this cost is usually passed onto the consumer, but initially, the costs can be assigned to the firm along the supply chain. One of the complicating factors of quantifying the benefits of product tracing is that several entities benefit: the firms, consumers, and the public sector (or regulatory agencies), as illustrated in Figure 33. According to Sparling and others (2011) and as shown in this figure, benefits to safety and public health are deemed to be the most substantial benefits resulting from improved product tracing practices, and these are primarily public benefits as opposed to private (industry) benefits. The size of each circle indicates the relative magnitude of the benefits compared to the other circles. As illustrated in the figure, the greatest public benefits are from increased public health protection and the greatest industry benefits are from improved supply chain efficiencies. The other categories of benefits were:

- trade: increased ability for cross-border collaboration, visibility, and accountability from food imports and exports,
- value capture: market advantages that can be made by being able to trace products to a particular source (e.g., making claims about organic, wild-caught),
- sustainability: the ability for improved product tracing to prove/validate a claim of sustainable agriculture/processes,
- recall scope: the ability to reduce the number of products implicated or recalled through improved product tracing practices, and
- quality assurance: enhancements along with improvements in product tracing due to better accountability, inventory management, and order filling.

Figure 33. Positioning Traceability (Product Tracing) Benefits, Public vs. Private



From Sparling and others (2011). Used with permission.

Alfaro and Rabade (2009) explain that food product tracing can provide an image of food safety. Many firms use their product tracing systems as a promotional device in order to show the reliability of their food safety procedures. Others (Latouche and others 1998) have reported that some consumers demand greater transparency of food safety information and are willing to pay for it, thus increasing the margin for the suppliers.

Cheng and Simmons (1994) conclude that a good product tracing system will provide information to the supply chain so that the correct amount of product is at the right place at the right time. Alfaro and Rabade (2009) suggest that another benefit of improved product tracing is that it is a tool for significant differentiation among firms.

In another study, Buhr (2003) surveyed six firms in the meat and poultry industries with one primary question: Why is electronic supply chain traceability (product tracing) adopted? Other than the previously stated benefits such as labor reductions, information accuracy and the avoidance of human error, Buhr (2003) found that an overriding benefit is the reduction of information asymmetry along the supply chain.

Sparling and others (2006) surveyed 130 companies primarily in the Canadian dairy industry. They found that the perceived benefits were categorized into two areas: benefits that motivate implementation, and benefits that were realized after implementation. Prior to implementation, firms were driven based on risk factors such as product liability and recalls. However, after implementation, firms perceived the benefits to be much more about how others perceived their company.

In a discussion of tort and statutory liability in Canada, Manes (2009) submits that improved product tracing "helps producers legally defend their products and business reputations" despite the fact that at

first glance, some food producers may prefer the anonymity associated with inability to trace food products.

There are a few published studies which quantify the industry benefits associated with improvements in product tracing; few attempt to quantify public health benefits. In addition to providing a literature review on industry benefits associated with product tracing, Mai and others (2010) described the conversion experience from a bar code system to RFID tracking system for two companies in the fish industry. One firm is a seafood processor while the second company is considered a wholesaler. The first company is located in Iceland and has roughly €10,000,000 (about $15 million) in annual sales and employs about 50 people. It handles products weighing approximately 450 tons (approximately 1 million pounds) of product per day, and it decided to track to the box level, which has a weight of approximately 1 kg (2.2 pounds). The wholesaler is located in Iceland as well and has 70 employees with about €400,000,000 (about $600 million) in annual sales. Both companies were using a paper-based system prior to the conversion to RFID.

Mai and others (2010) were able to estimate the conversion costs for each of the companies while using passive RFID tags. The total five-year cost for the processing company was €845,000 (about $1.3 million), with the major cost being for the tags, which were €776,200 (about $1.2 million). The next largest cost was the RFID readers which were estimated to cost €45,000 (about $70 thousand). For the wholesale company, the total cost was estimated to be €800,900 (about $1.2 million), with the next largest cost being €87,800 (about $137 thousand) for the replacement of lost tags. The readers were next with an estimated cost of €22,500 (about $35 thousand).

Mai and others (2010) provided expected benefits during the five year period for two categories. The first category considers a higher rate (0.25) of recalls and the second category a lower rate (0.10) of recalls. For the processing company, when considering the higher rate of recalls, there were no benefits and there was actually an expected net loss over the course of five years of €749,400 (about $1.1 million). However, in the case of the lower recall rate, the benefits were positive with a total five-year present value benefit of €491,700 (about $771 thousand). For the wholesale company, the benefits were positive for both categories of recalls. The benefits were estimated to be €56,615,400 (about $88 million) and €94,892,900 (about $150 million) for the higher and lower recall rates, respectively. For the wholesale company, it appeared that the benefits of the product tracing system far outweighed the costs.

Karkkainnen (2003) presents a case study of an RFID implementation in a grocery retailer (Sainsbury) in Finland. Although a pilot study was actually performed, the total implementation cost was expected to be £18 to £24 million (about $24 - $38 million). The RFID readers were expected to cost between £6,000 and £8,000 (about $9 - $13 thousand) and the tag cost was between 30p and 65p (about 50 cents to a dollar) each.

The total benefits associated with the implementation were £130,000 (about $204 thousand) in inventory control improvement, £294,000 (about $461 thousand) in reduction of store receiving costs, £2,556,000 (about $4 million) in reduction of stock/code checks, £1,425,000 (about $2.2 million) in improvement of replenishment productivity, and £4,117,000 (about $6.4 million) in prevention of stock loss of short shelf life products. The implementation was expected to have a three-year payback period, showing benefits similar to those reported by others (Dursun and others 2007).

Additionally, Alfaro and Rabade (2009) suggested that there are efficiencies to be gained by a good product tracing system within a company. They report that in a study of a Spanish vegetable firm, a computerized food product tracing system provided many benefits as it relates to efficiencies in production, warehousing, and distribution. They report that the system helped increase (almost double)

production with the same number of workers, reduce disruption in production by 90%, reduce indirect cost by 20%, increase warehousing capacity by as much as 15%, and reduce safety stock by as much as 30%. The study reports factors that could influence a "reduction in indirect costs" are "increased rate of production, increased productivity, increased efficiency, and subcontracting of smaller warehousing spaces."

The literature reviewed showed that while firms and society can expect to realize many benefits from improved product tracing, only a few published studies quantify these benefits. Further, the questions asked of firms generally pertain only to how the information obtained through better recordkeeping systems improves operations within the firm, and do not extend to how this information or technology systems can benefit public health during traceback investigations. For example, the speed with which records can be accessed and provided to regulatory agencies is seldom mentioned.

Non-Peer Reviewed Information

Approach and Outreach

When the literature review showed that the extent of published work was limited, IFT used several mechanisms to secure information not available from the published literature. This included working with some of the pilot advisors, some of whom participated in the pilots (a foodservice distributor and food processor) and one who did not (a food processor), to provide additional information on studies they had conducted internally. During the course of the task, IFT gave presentations to the PTI Leadership Council twice, and in the second presentation, asked for firms to volunteer the costs incurred as they implemented the PTI or made other enhancements to their product tracing systems. PMA and UFPA actively sought and provided additional cost information that they gathered from their members. Some members of the OP also used their network of contacts to obtain additional insights into specific costs of product tracing systems. Additionally, standards organizations and technology solution providers were also asked to volunteer any cost-related information they had as it related to implementing their technology (or adopting their standard) in the food industry.

Findings: Cost

Through the course of many discussions IFT heard anecdotal opinions that the cost to improve product tracing systems is "high." IFT urged these firms to quantify "high" and reached out all stakeholders (pilot participants, non-pilot participants, through trade associations, standards organizations, technology solution providers and other SMEs) to request and collect information from anyone willing to share costs of implementing or upgrading a product tracing system. This section discusses some of the non-published references and non-peer reviewed literature collected through this effort and where appropriate compares these findings to published studies.

Consistent with the literature, IFT found that firms generally divided their costs between the "one time" costs and the ongoing costs associated with labor and materials. In a 2011 white paper, Bunsey commented on the specific challenges associated with the ability of small firms, particularly small processors/manufacturers, to trace products internally (Bunsey 2011). In his assessment, the ongoing labor costs associated with applying and scanning bar codes will exceed the cost for software, but this assertion was based on the assumption that software providers will identify the needs of small firms that are using paper-based systems and develop cost-effective electronic solutions to address them.

IFT learned that many firms relate cost to other types of challenges (beyond product tracing), stating that a major reason they are not willing to make an investment is because they don't believe that the

resource expenditure is justified. Firms believe that their supply chain partners need to improve their systems as a prerequisite, primarily to provide meaningful, discernible information that can then be captured. Investing in things such as bar code scanners is useless if the incoming products lack bar codes, for example.

While IFT is not advocating the use of bar codes as the only or preferred method for communication of information on cases, "scanning labels" were presented to pilot participants as an area for which cost information was sought (further described below), because many industry-led initiatives (discussed in Chapter 9) specify the use of bar codes. Therefore, IFT believes it is appropriate to include additional information obtained about the current status of the use of bar codes within the food industry.

As with RFID tags, bar codes are data carriers. There are several types of bar codes available which can carry varying amounts of data. Bar code data that are static (e.g., company identifier, item identifier) can be pre-printed, either on labels or on shipping materials such as cases. When data are dynamic (e.g., lot codes that change frequently), bar codes generally need to be printed on labels as part of an in-line or in-production process (i.e., not pre-printed). Thus, if a firm decides to include a lot number within a bar code, they may need to "upgrade" the type of bar code they are using as well as change where in the process the bar code is generated and applied. More sophisticated bar codes, such as the GS1-128 (Figure 34) contain relatively more information and require more advanced printers to achieve the necessary resolution compared with a simpler bar code (which contains relatively less information), such as the ITF-14 bar code (Figure 35). A more detailed description of bar codes can be found in McEntire and others (2010).

Figure 34. GS1-128 Bar Code

Figure 35. ITF-14 Bar Code

In one internal study of the use of bar codes, one major manufacturer worked with a retail partner's distribution center in 2011 to survey the nature of the markings on dry grocery products. The survey included more than 100 cases, and represented nearly 100 brands produced by more than 60 manufacturers.

- More than 90% of dry grocery cases used a type of bar code (for example, ITF-14) which cannot support coding of batch/lot number.

- Almost 25% of cases used inkjet in-line printers for printing bar codes which do not produce the quality needed for more sophisticated bar codes (for example, GS1-128) which allow the inclusion of dynamic data (e.g., batch/lot code).

A major foodservice distributor conducted a similar study in 2011, looking at the types of bar codes present on more than 500 cases of a variety of products.

- More than 25% of cases (132/511; all products) had no bar code at all, especially products held in cold storage.
    - More than 80% of produce cases (53/65; only produce) lacked a bar code (any type).
- Of those with a bar code, less than 20% had the type of bar code that can include lot/batch numbers (e.g., GS1-128).

While there may be other ways to improve recordkeeping, the use of bar codes, particularly those that can contain more robust data, will require producers/manufacturers to invest in new labeling solutions (i.e., phasing out pre-printed bar codes and inkjet printing and moving to higher quality, higher cost label-base print and apply). As is reiterated later, bar code printers cost approximately $14,000 - $20,000 according to pilot participants. Mejia and others (2010) estimated the cost of printers at less than $1000; software and support for bar codes were identified separately. Pilot participants estimated scanner hardware costs at about $50,000 - $75,000; Mejia and others (2010) reported hardware costs of $2750 with an additional "bar code system integration average cost" of $50,000. Hand-held scanners were reported by pilot participants to cost about $20,000, which is evenly split between hardware and software costs. Mejia and others only reported the hardware cost for hand-held scanners, estimating a cost of $400 per reader. The cost for the labels themselves is approximately ½ cent per label, which is consistent with the report by Mejia and others (2010). Mejia and others (2010) provide substantial additional detail regarding implementation costs of bar code and RFID systems.

Another distributor reported that the cost to scan bar codes of each incoming and outgoing case would amount to $300,000 in additional labor per facility on an annual basis. Additionally, the firm estimated a need to expand the size of each warehouse in order to better segregate products (e.g., add additional storage slots) which would require a fixed cost expenditure of several million dollars.

Findings: Benefits

From July – November, 2011, IFT hosted three Traceability Research Summits from which a working group grew. This diverse cross section of stakeholders divided product tracing benefits into two categories: the direct benefits that result from the ability to execute faster and more targeted product recalls, and the indirect supply chain efficiency and productivity gains (Bhatt and others 2012). However, the group did not quantify the extent or relative magnitude of these benefits.

Sparling and others (2011) developed a white paper based on a meeting of a cross section of 160 Canadian stakeholders, including farmers, processors, distributors, government officials, and others. About 45% of growers and 55% of processors saw opportunities to increase the marketing and branding of their products based on improved product tracing. In this survey, about 60% of both growers and processors felt that the greatest benefit to improved product tracing was "faster, more reliable, and more precise product recalls" with only a handful of farmers and no processors indicating that the primary benefit related to supply chain efficiencies or increased market access.

IFT received information from a produce shipper who recently upgraded their product tracing system to include bar code scanning. This company was able to improve individual accountability of who packed each box, which reduced overall quality claims and increased employee pride in their work.

Another produce shipper upgraded their product tracing system to enable real-time visibility of what products were actually field packed; thereby reducing daily overselling and/or underselling. This system also allowed for real-time tracking from field to coolers which was used to prioritize loads going into the coolers based on when products were picked.

A produce buyer invested in RFID scanning of inbound shipments which increased accuracy and productivity for this company. Through this implementation, the system also supported the integration of receiving and quality inspection functions resulting in additional cost reductions.

Case Study: Produce Traceability Initiative (PTI)

To better illustrate real-world costs and benefits of improving product tracing policies, procedures and technologies, IFT worked with PMA and UFPA to collect information from 18 companies (of which four were pilot participants) related to the costs and benefits of implementing the PTI. While PTI is being used as an example of some quantitative data on industry costs and benefits, this is not an endorsement or critique of this particular approach to improving product tracing. This section is aimed at reporting the costs and benefits as reported by food companies that are participating in PTI and who volunteered to share data.

Prior to presenting the costs incurred for compliance and benefits received from implementation, it is important to put them in context of the requirements of PTI. The PTI is described in more detail in Chapter 9, but briefly, seven milestones were outlined by PTI (PMA 2012). Depending on the point in the supply chain, firms may only need to perform some of the milestones (i.e., a distributor would not need to encode information in a bar code). The seven milestones are:

Milestone 1: obtain company prefix

Milestone 2: assign GTIN numbers to every case configuration

Milestone 3: provide GTIN information to buyers

Milestone 4: show human-readable information on cases

Milestone 5: encode information in a bar code

Milestone 6: read and store information on inbound cases

Milestone 7: read and store information on outbound cases

Company-specific information related to the costs and benefits of implementing the PTI follows.

Company 1 (Processor, Distribution Center, Food Service)

This company volunteered the cost and benefit information they recorded while implementing PTI during a five-year period. The company has retail and food service operations as well as a processing and distribution center (DC). They assign approximately 1000 GTINs to their brand-owned products in addition to handling other suppliers at their DC. They decided to implement a new WMS for which one of the secondary benefits was compliance with PTI. At this point, they have reached milestone 6—reading and storing information on inbound cases. It took the company five years from planning and implementation through refinement for the WMS upgrade, at the cost of $1 million in capital investment. This capital investment does not include the cost of labor and training.

However, they reported several observing benefits upon completion of their technology upgrade, including:

- The number of errors in order filling and product tracking were reduced by 25% during the five-year timeframe. This reduction in errors translated to $500,000 per year in savings due to more accurate order filling.
- Once the technology upgrade was complete, the automated labeling and scanning equipment put in place resulted in an increased rate of production of five cases more per hour. Based on their annual sales figures, this resulted in $200,000 additional revenue per year.
- By moving from a paper-based to a paperless system, they were able to reduce clerical staff in their back offices. They eliminated two office/clerical positions, resulting in $60,000 savings per year
- Having a paperless system in place, they reduced their use of paper which in turn resulted in $20,000 in savings per year.

Company 2 (Food Service)

Upon exploring the economics of equipping 20,000 foodservice restaurants with the tools necessary to scan incoming cases, one major foodservice chain calculated that the costs for a web-based software-as-a-service (SaaS) model, necessitating a handheld computer device, software, device cell coverage and helpdesk support amounted to $1.25 per day per store in addition to a one-time cost of $3 million (during three years). These costs do not include the cost of labor or training, which was estimated at $100/store, nor the costs of archiving and sharing the data through a supply chain.

Company 3 (Grower)

A small Mexican produce grower shipping 100,000 cases per year implemented bar-code labeling and scanning in accordance with PTI guidelines. In the first year, the cost for hardware, software, and labor amounted to $5,500. Additionally, the firm needed to purchase 100,000 labels at ½ cent each. The firm projects ongoing annual costs of $1,500 after the first year and additional costs of ½ cent per label. This equates to a cost of $.026 per case.

Company 4 (Grower)

This company has 50,000 acres over a large cross-boundary region which produces 40 items and ships 18 million cases each year. Consolidating their carton runs into larger batches by eliminating the need for a wide range of special cartons saved them $0.01 per case which translated into $90,000, assuming at least half of the total cases shipped each year were labeled accurately. The company estimates they spent $0.02 to $0.03 per case to implement PTI; however these costs seem to be offset by the savings noted above, as well as through improved productivity, accuracy gains in ensuring that the right products are sent to the right customers, and back office billing efficiencies by being able to more easily determine the recipients of products.

Company 5 (Grower, Shipper, Packer)

This company owns 30,000 acres and handles 10 million cases each year. They decided to upgrade their labeling and product tracing practices to comply with PTI at a cost unknown to IFT. A reduction in waste and labor costs resulted in a savings of $100,000 each year.

Company 6 (Grower, Shipper, Packer)

This company produces, grows, imports, packs, and ships 10 million cases of 55 commodities each year. When they improved the ability to trace cilantro, they were able to pinpoint the product associated with a recall to 12% of their total cases in stores. Prior to the technology upgrade; they would have had to recall 100% of the cases. The company reported that the improvements saved them “thousands of dollars” in recall expense (GS1US 2012a).

Company 7 (Distributor)

This firm began requiring GTINs in late 2011 and was motivated primarily by the ability to prove that deliveries had been made. They sought to reduce their delivery errors from 1/150,000 to 1/250,000 and ultimately expect to reach zero when the system is fully implemented. The ongoing cost associated with scanning bar codes on cases was estimated at 13 cents/case, which was considered minimal by the firm.

Company 8 (Shipper)

This company upgraded their product tracing systems to use bar-code labeling on cases to replace manual tracking of:

- who packed each case,
- how many cases were packed, and
- when the cases were packed.

Because they were able to determine who the packer was, it resulted in a reduction in quality claims from more than 5% to less than 1%. This alone paid for entire cost of PTI implementation. They were also able to reduce expenses by eliminating one payroll clerk from their staff.

Company 9 (Re-packer)

This firm has been applying GTINs for roughly one year. As re-packers, they needed to purchase a total of 10 automatic packing machines with the ability to print labels for bar codes. Some of the machines also have the ability to print labels from desktop computers. The cost to implement the system was $350,000 and they expect to incur an ongoing labor cost of $40,000.

Company 10 (Distributor)

The ability to scan bar codes at the case level required an initial investment of $80-90,000, and the firm estimates that their total expenditure has been roughly $300,000.

Company 11 (Shipper)

An upgrade of this company's product tracing capabilities allowed it to eliminate pre-printing country of origin labels on cardboard boxes resulting in more than $100,000 per year in savings. This company had used manual processes to record harvest and lot information. They had no visibility to actual harvest quantities until product was received at cooling facilities. They implemented PTI with label printing in the field and electronic recordkeeping of harvest and lot information. Real-time visibility of what was actually field packed has also reduced daily overselling and/or underselling of products.

Company 12 (Shipper)

This company accomplished 100% accurate shipments (order filling) by scanning case labels as pallets are assembled in order to create hybrid pallet tags. Upgrading their systems allowed them to use hybrid pallet tags in place of pallet license plates in coolers.

Company 13 (Distributor)

This firm spent $350 - 400 thousand to implement a warehouse management system, including upgrading computers, software, and hardware, purchasing scanners, applying bar codes on the slots (e.g., specific locations where products are stored) in the warehouse, and training. This company is also using the services of a consultant. The firm is expecting to achieve a 15 - 20% improvement in productivity. Errors relating to the selection of products for customers will decrease from 1/1500 to 1/5000. The firm expects to achieve a return on investment within 24 months.

Company 14 (Buyer)

For this company, scanning cases at time of order assembly has increased accuracy from 99.5 to 99.99+%.

Company 15 (Grower, Packer, Importer, Shipper)

This company ships a wide variety of fruits and vegetables totaling 36 million cases with annual sales of $500 - $600 million dollars for an average cost of $15 - $16 per case.

Upgrading their food product tracing system resulted in a one-time cost of $1,416,000 with implementation rolled out in one year to achieve PTI milestones 1 to 6. Additional costs are broken down into the following expenses:

- $0.094 per case annual increased operating cost
    - $0.0105 per case for systems
    - $0.0295 per case for labels
    - $0.0536 per case for labor

Company 16 (Produce Wholesaler/Re-packer)

This company ships six million cases with annual sales of $90 - $95 million dollars for an average cost of $15 - $16 per case. They ship dozens of produce items and over 400 processed food items.

Upgrading their food product tracing system resulted in a one-time cost of $500,000 and an annual increase in operating cost by $0.0042 per case. This company rolled out their implementation in one year and achieved PTI milestones 6 and 7.

Company 17 (Retailer)

This large retailer ships 400 million cases for annual sales of over $10 billion, primarily in produce, fresh meat, and deli items. Implementing radio frequency scanners to allow for scanning at time of receiving in the produce distribution centers and software upgrades to track and store GTIN and lot number was a one-time investment of $3,200,000. The annual incremental costs of $0.0125 per case shipped are incurred as a result of additional receiving labor.

Company 18 (Grower, Packer, Shipper)

This company ships 85.7 million cases per year with an estimated annual sales in excess of $1 billion dollars. An improvement in its product tracing capabilities resulted in a one-time cost of $183,000 with annual incremental cost of $0.0075 per case.

Summary of PTI Case Study

Table 31 summarizes the information gleaned from the various firms described above to paint a more comprehensive picture of the costs associated with the implementation of bar code scanning in accordance with the PTI guidelines (the source of these data are individual companies who agreed to volunteer information about their participation on PTI, either directly with IFT or anonymized through a trade association).

Table 31. PTI Case Study

Company	Segment *	Annual Number of Cases Handled	Number of products	Technology	PTI Milestone	Investment ($)	Benefit
1	Pr, D, FS	N/A	100000 GTINs	Internal WMS with bar coding	6	1M capital investment/ 5 yr	$780K/yr
2	400 D; 50 suppliers ; 20,000 FS	N/A	N/A	N/A	N/A	3M	N/A
3	G	100,000	N/A	Bar code printing and scanning	1-6	6000 year one; 2,600 annually	N/A
4	G; 50,000 acre	18M	40 items	Bar code scanning	N/A	360-540K/yr	$90K/yr
5	G/S/Pa; 30,000 acre	10M	N/A	Bar code scanning	N/A	N/A	$100K/yr in reduced waste and labor cost
6	G/S/Pa	N/A	55 commodities	Bar code scanning	N/A	N/A	Limit scope of recall to 12% cases vs 100% before PTI
7	D	N/A	N/A	Bar code scanning	N/A	13 cents/case	Reduce delivery errors from 1/150,000 to 1/250,000
8	S	N/A	N/A	Bar code scanning	N/A	N/A	Reduce quality claims from 5% to 1%; reduce 1 payroll clerk
9	Rp	N/A	N/A	Bar code scanning	N/A	350K year one; 40K annual in labor	N/A

Company	Segment *	Annual Number of Cases Handled	Number of products	Technology	PTI Milestone	Investment ($)	Benefit
10	D	N/A	N/A	Bar code scanning	N/A	80-90K one time; 300K total	N/A
11	S	N/A	N/A	In-field label printing and electronic recordkeeping	N/A	N/A	$100k/yr
12	S	N/A	N/A	Bar code scanning including hybrid pallet tags	N/A	N/A	100% accurate order filling/ shipment
13	D	N/A	N/A	WMS including bar code scanning	N/A	350-400K; ROI expected in 24 months	Increase productivity 15-20%; decrease selection errors from 1/1500 to 1/5000.
14	Buyer	N/A	N/A	Bar code scanning at time of order assembly	N/A	N/A	Accuracy increase from 99.5 to 99.99%
15	G/S/Pa/I	N/A	~50 commodities	N/A	1-6	1.416M	N/A
16	W, Rp	6M	6 commodities + 400 processed foods	N/A	6, 7	500K one-time; 25K annual	N/A
17	R	100M	N/A	N/A	N/A	3.2M one-time; 5M annual	N/A
18	G/S/Pa	85.7M	N/A	N/A	N/A	183K one-time; 650K annual	N/A

* D= Distributor; FS= Foodservice; G = Grower; I= importer; Pa= Packer; Pr= Processor; Rp= Re-packer; R= Retailer; S= Shipper; W= Wholesaler

Cost - Benefit Determination

Approach & Outreach

In addition to using information gathered through the literature review and other previous work, IFT collected data for this portion of the task in a variety of ways. IFT worked with Deloitte Consulting to obtain quantitative estimates of costs and benefits from pilot participants. IFT also obtained information related to the costs of technologies: IFT advertised a request for input from vendors of product tracing-specific solutions, and IFT contacted several providers of more comprehensive software solutions (e.g., WMS, accounting). Additionally, IFT contacted small businesses to identify costs and resource needs related to product tracing improvements.

Cost and Benefit Data from Pilot Participants

Based on the discussions with the pilot participants and other industry stakeholders, IFT identified several ways in which firms were able to provide track and trace data. Ultimately, the way in which data could be readily accessed and transmitted to IFT in the pilots was dependent on the systems and processes in place within a firm to capture, store, and report this information. IFT identified nine potential ways in which product tracing recordkeeping could be improved.

The first four improvement options revolve around data capture as part of recordkeeping. IFT believes that capture of the right data, regardless of format, is a prerequisite to any substantial improvements in product tracing. The first four options explore different ways that the same data could be captured using different types of technologies (e.g., spreadsheets and ERP systems, as further described in this chapter as part of technology costs). For reasons described below, the KDEs included in the options presented to pilot participants did not include lot/batch number.

The first four recordkeeping improvement options (for which questions were asked about costs and current capabilities) related to the ability to:

- capture KDEs (Supplier ID, Product ID, PO Number, Quantity-pack size, Receipt date) by **writing on paper**
- capture KDEs (Supplier ID, Product ID, PO Number, Quantity-pack size, Receipt Date) by **writing on paper and later entering into a database/spreadsheet**
- capture KDEs (Supplier ID, Product ID, PO Number, Quantity-pack size, Receipt Date) by **scanning labels** (e.g., bar codes)
- capture KDEs (Supplier ID, Product ID, PO Number, Quantity-pack size, Receipt Date) by **electronic message**

IFT observed that some segments of the distribution chain do not generally record the grower/producer-assigned lot number (which is not required by FDA regulations for some segments and is required only if lot numbers exist for others). Therefore, as noted above, lot/batch number was not included as a data element in the four options above, but was treated as its own question. The remaining five options related to the use of standards, communicating data forward to customers, and the use of a summary data sheet. They were the ability to:

- capture incoming quantity by received lot number, assuming a lot number is provided
- link incoming and outgoing product, whether there is transformation (e.g., ingredients into a finished product) or not (e.g., relating lot numbers received to lot numbers shipped)
- use non-proprietary standards (e.g., GTIN, GLN, state-issued plant/registration number)
- Send KDEs electronically to customers

- provide a data summary sheet (or template such as the one IFT provided) that highlights the links between KDEs for the products of interest

Deloitte Consulting, with input from Dr. Mary Muth (RTI International) and Dr. David Sparling (University of Western Ontario), worked with the pilot participants to determine costs associated with the nine identified options, as well as the types of benefits they had realized from their investments.

All 45 pilot participants were asked to indicate whether they had systems in place to perform each of the nine improvements, and if they did, provide an estimate of the cost to establish the system to attain that goal; if they did not, they were asked to estimate the resources needed to reach the goal. Each of the respondents also provided background information on their firm (Appendix R).

Deloitte also assessed, with IFT, the current product tracing system maturity for pilot participants. Three separate metrics were used to compare and contrast system rankings across the pilot participants:

- Self-Reported Product Tracing System Rankings – The pilot participant questionnaire asked each firm to rank its system on a scale of 1 (non-existent) to 10 (very sophisticated) with 5 representing the industry average. Firms were asked to provide a self-ranking for both their current system and their system as it was five years ago.
- Pilot Performance Rankings – This metric was based on the results of the scenarios from the pilot studies.
- Tracing System Sophistication – This metric quantitatively used the pilot participant questionnaire to determine a **high, medium,** or **low** ranking for a firm's product tracing system capabilities based on equal weighting of three categories:
    - self-reported product tracing system ranking
    - responses to nine improvement options
    - system-type rating based on the ability to automate data capture and effectively link products within a facility and between trading partners

The pilot participant questionnaire was also used to capture industry benefits. When possible, the pilot participants provided a quantitative number associated with benefits; however, the vast majority of the results were qualitative and some firms did not respond at all.

Questions were asked relating to benefits in the following eight areas, which were consolidated from the benefits identified by others (Can-Trace 2004b, USDA-ERS 2004, Bhatt and others 2012):

- Improved Brand Reputation — Firms investing in product tracing technologies can benefit from opinions related to a firm's brand and in some instances can be used as a form of capital to justify price premiums for goods and services.
- Increased Consumer Confidence — Improved product tracing can increase optimism that consumers feel about the overall state of the food industry because of investments in product tracing technologies.
- Expanded Markets — Investments in product tracing technologies represent an attractive opportunity for some to offer their products to a wider section of the industry. The issue of product tracing has become so important in the food industry that many firms have their own product tracing standards in order to establish business relationships.
- Improved Supply Chain Management — Firms can expect enhanced capability in the visibility of raw materials, work in process, and finished goods from the point of origin to the point of consumption with improvements in product tracing.
- Decreased Insurance Cost — Lowered risk exposure to disruptions in operations due to product recalls.

- Increased Supply Chain Confidence — Related to the expectation shared by trading partners in the ability to conduct product tracing activities (for example, in the event of a recall).
- Decreased Spoilage — Investments in product tracing are closely related to investments in inventory management, which is a significant issue for food items that deteriorate to a point where it is not edible by consumers due to reduced quality.
- Improved Business Processes — Firms improving product tracing often gain improvements in existing business processes and many of these improvements lead to increased profits, reduced costs, and accelerated production schedules.

Responses for the pilot benefits were compiled according to the pilot participant's North American Industry Classification System (NAICS) segment. Responses were not separated according to size because of the small number of responses from which to draw conclusions.

Discussions with Participants

IFT identified 17 firms with which to have in-depth discussions in order to provide qualitative insights on costs and benefits in the absence of quantitative data. Firms were identified as candidates for the telephone discussions based on commodity type, business model, degree of vertical integration, size, and other practices as determined by IFT based on the initial outreach efforts conducted prior to commencing the pilots. After the first round of telephone calls was conducted (nine firms agreed to participate), IFT invited all pilot participants to provide additional cost information and context to Deloitte through additional conversations.

Pilot Participant Segmentation

For the purpose of understanding how the costs for the different options varied by point in the supply chain, pilot participants were categorized according to their NAICS code as presented in the 2007 Economic Census Report (USCB 2007). Many of the firms participating in the pilots are assigned multiple NAICS codes; the code used in the segmentation in this report was selected to correspond to the role the firm played in the pilot (e.g., if the primary NAICS code of a firm was a grower, but in the pilot the role of the firm was a tomato processor, the firm was classified as a processor).

FDA tasked IFT with evaluating the impact of changes in product tracing on small and very small businesses. The guidelines outlined by the U.S. Small Business Administration (SBA) in the "Table of Small Business Standards Matched to North American Industry Classification System Codes" were used to define small firms; all other firms not meeting the SBA guidelines are classified as large firms (SBA 2012). One limitation of the census data is that it may not accurately reflect the number of small businesses (estimates suggest the census could overlook less than 4% of total sales nationwide, many of which could be small businesses). Although Dun and Bradstreet data have been used for this type of segmentation for other studies, IFT did not have ready access to this information for this study. Additional outreach efforts towards small businesses are further discussed in the next section below.

The segmentation approach for the pilot participants resulted in four primary segments: growers, processors, distributors, and retailers (For more information on the characteristics of each segment, refer to Appendix Q). Table 32 outlines the NAICS codes used to define each primary segment:

- Growers are comprised of establishments, such as farms, orchards, groves, greenhouses, and nurseries primarily engaged in growing crops, plants, vines, or trees and their seeds (NAICS Definition for 111) as well as firms primarily engaged in animal production. Additionally, the processed food pilot project included chicken as one of the ingredients which falls under animal production.

- Processors are comprised of establishments that transform agricultural and livestock into products for intermediate or final consumption (NAICS Definition for 311).
- Distributors are comprised of establishments that sell nondurable goods to other businesses (NAICS Definition for 424).
- Retailers are comprised of establishments that prepare meals, snacks, and beverages to customer order for immediate on-premises and off-premises consumption (NAICS Definition for 722) as well as other food and beverage stores, convenience stores, and warehouse clubs and superstores.

Table 32. Segmentation of Pilot Participants Based on NAICS Codes and SBA Guidelines

Segment	Included NAICS Codes	SBA Guideline	Number of Non-SBA Firms*	Number of SBA Firms*	Percent Sales-Non-SBA*	Percent Sales-SBA*	Number of Non-SBA Pilot Participants	Number of Small Businesses in Pilots
Grower	111 – Crop Production	Under $750k in annual revenue	85,898	2,118,895	66	34	7	1
Processor	311 – Food Manufacturing	Under 500 employees (excluding limited exceptions)	555	21,036	77	23	5	5
Distributor	4244 – General Line Grocery Merchant Wholesalers	Under 100 employees	26,198	1,275	73	27	13	7
Retailer	445 – Food and Beverage Stores	Under $7 million in annual revenue (excluding Supermarkets-$30M and Convenience Stores-$27M)	7,087 (over all retailer segment codes)	585,687 (over all retailer segment codes)	68 (over all retailer segment codes)	32 (over all retailer segment codes)	6 (over all retailer segment codes)	1 (over all retailer segment codes)
Retailer	452910 – Warehouse Clubs and Superstores	Under $27 million in annual revenue	7,087 (over all retailer segment codes)	585,687 (over all retailer segment codes)	68 (over all retailer segment codes)	32 (over all retailer segment codes)	6 (over all retailer segment codes)	1 (over all retailer segment codes)
Retailer	722 – Food Services and Drinking Places	Under $7 million in annual revenue (excluding Limited-Service Restaurants-$10M, Cafeterias Grill Buffets and Buffets-$25.5M, and Food Service Contractors-$35.5M)	7,087 (over all retailer segment codes)	585,687 (over all retailer segment codes)	68 (over all retailer segment codes)	32 (over all retailer segment codes)	6 (over all retailer segment codes)	1 (over all retailer segment codes)

* Source: USCB (2007).

Outreach to Small Businesses

In addition to the costs reported by the small businesses who participated in the pilots, IFT sought additional information on costs and challenges to small businesses. IFT contacted 24 small growers, processors, and distributors, primarily by telephone, to learn more about their current capabilities and expectations of costs. North American Perishable Agricultural Receivers (NAPAR) also provided contacts who offered their insights.

Cost Associated with Third Party Tracing Technology Providers

As part of the exploration of other firms offering product tracing solutions specifically (as opposed to WMS, for example), IFT requested information related to the general costs of these systems and how the fees are structured. Specifically, any firms interested in sharing more about their systems were asked to provide:

- pricing structure for adoption of technology (for example, software as a service, on-going subscription fee, one-time fee)
- range of costs for adoption of technology (minimum for very small businesses and maximum for large businesses)

Cost Associated With Systems Used or Mentioned by Industry Participants

Many firms reported that improvements in technology were necessary to reach the desired qualities with respect to recordkeeping. A variety of technologies are currently employed in the food industry, and the utility and functionality of these technologies were explored in the pilots.

IFT reached out to eight solution providers that some pilot participants reported using to manage recordkeeping (and often for other functions). The goal of reaching out to these solution providers was to understand the cost drivers for similar technology options. Specifically, they were presented with the three "sample" firms and asked:

1. What are the fixed costs to implement your system (e.g., installation, activation, engineering analysis and specification)?
2. For the profiles listed below, what would typical total fixed costs be? Providing a range is fine.
3. On average, approximately what percentage of your total costs typically represents fixed costs?
4. What are the typical variable costs of your system (e.g., number of licenses/users, modules, level of service)?
5. What are the cost drivers of the variable costs (e.g., number of licenses versus type of license)?
6. For the profiles listed below, what is the range of common variable costs associated with your product?
7. For the profiles listed below, what is the typical range of annual recurring operations and maintenance costs?

The profiles of "sample" firms are described in Table 33 below.

Table 33 - Profiles of "Sample" Firms

Attributes	Profile A	Profile B	Profile C
Business description	commercial grower that markets multiple produce products throughout the United States	vertically integrated food manufacturer and marketer of fresh and fresh-cut fruit and vegetables.	foodservice distributor of food items in North America
Size	mid-sized (revenues $.25M - $2M)	mid-sized (below $30M)	mid-sized (below $30M)
Warehouse distribution	operates one regional distribution center	operates two manufacturing plants, one distribution, and one warehousing facility	operates three distribution centers in the United States and Canada
Facility size	20,000 sq ft	15,438 sq ft	17,664 sq ft
Number of users	85	98	123
Business segment	Grower	Food Manufacturing	Merchant Wholesaler, Non-Durable Goods
Vertical integration	Crop Production Merchant Wholesaling	Crop Production Merchant Wholesaling Food Manufacturing	Crop Production Merchant Wholesaling
IT staff	0	1	1
Current implementation	QuickBooks Enterprise Edition	Legacy enterprise solution from small software publisher	Custom in-house solution
Third-party support	No	Yes	No

Calculation of Public Health Benefits

The key benefit to improved product tracebacks is the protection of public health. Therefore, IFT worked with Deloitte Consulting and others to estimate the impact that reductions in traceback time have on public health using eight case studies. This approach to public health benefit analysis could be replicated and expanded given a richer data set with the relevant outbreak database information to provide a more accurate picture of the benefits of improved product tracing.

To effectively provide estimates for the public health benefit, assumptions were made to guide and structure the analysis. The assumptions were:

- Improved product tracing can reduce the time between identification of an implicated food causing an outbreak and the identification of the specific product, and recall and removal from commerce. The reduction in disease incidences will be proportional to the time reduced through effective whole supply chain product tracing.
- Holding all else constant, a perfect product tracing system across the food industry would result in a near "instantaneous" identification of a food source and the initiation of a product intervention to remove it from commerce and stop public exposure (e.g., recall). This instantaneous traceback is not a reality but does represent the theoretical maximum possible reduction in illnesses.
- Each pathogen has an individual incubation period or range. Therefore, even when the exposure to the contaminated food is stopped, there may be some individuals who were already exposed but are in the incubation period and are not yet symptomatic. Therefore, benefits calculated by illnesses reduced due to earlier food vehicle identification and intervention need to take this incubation period into consideration.

The public health analysis approach uses the following data to develop the calculations:

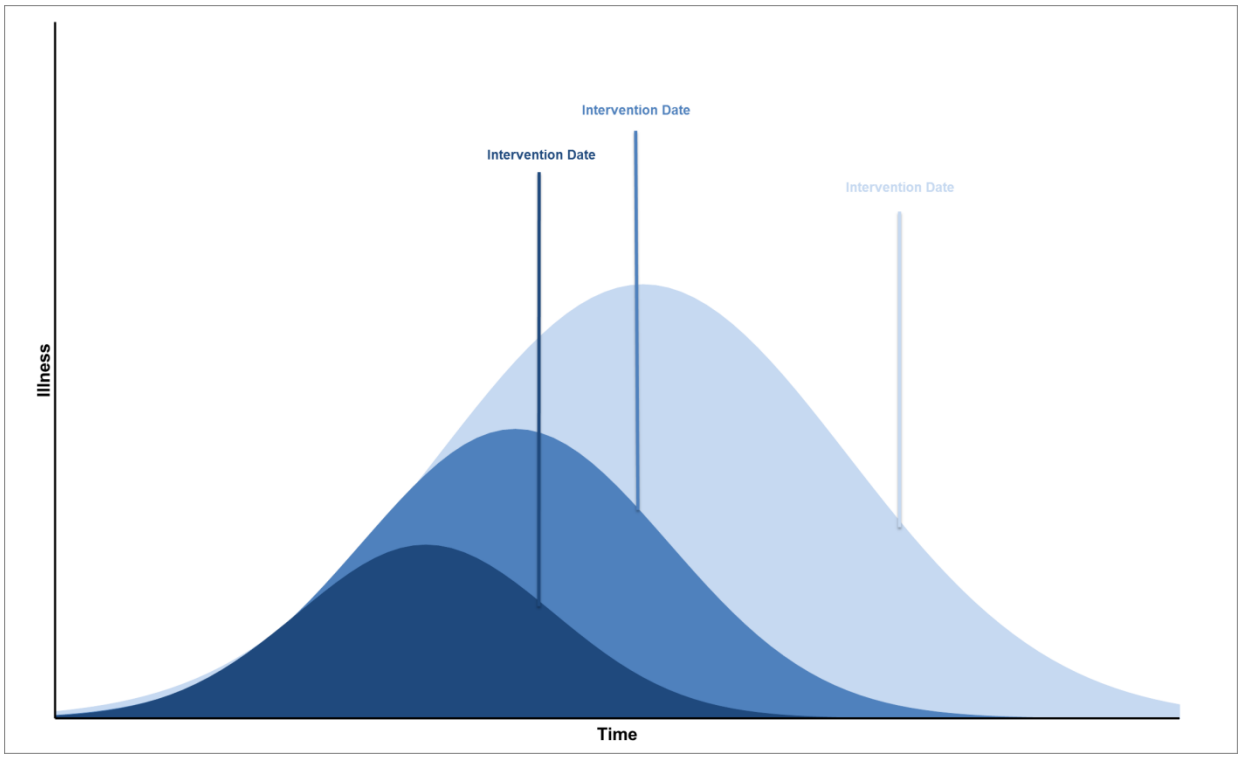
- eight outbreak case studies focused on two pathogens (*Salmonella* and *Listeria monocytogenes*)
- epidemic curve data for each outbreak (i.e., number of new illness cases by day)
- economic cost per case of particular pathogen (from FDA and USDA regulations)

EPIDEMIC CURVE DATA

Public health improvements can be illustrated by shifting the epidemic curve ("epi curve") to indicate a reduction in the number of illnesses from a contaminated product. As stated by the CDC, an epi curve shows the progression of an outbreak over time (CDC 2008a). As depicted in Figure 36, the horizontal axis in an epi curve represents the date when a person became ill, also called the date of onset, and the vertical axis is the number of persons who became ill on each date. (For the purposes of this analysis, the epi curve will represent the number of those who became ill with either *Salmonella* or *Listeria* as a result of a food-related outbreak.)

Figure 36 below shows that the epidemic curve can be shifted to the left if there is an earlier intervention that prevents the occurrence of additional illnesses. In this case, the intervention would represent the identification of the contaminated product and initiation of a recall or other efforts to remove the product from commerce.

Figure 36. Shifting of the Epidemic Curve through Improved Product Tracing



To monetize the reduction of illness that results from shifting the epi curve, an economic cost benchmark for each pathogen was estimated. These benchmarks provide an economic cost per case. The benchmarks selected were based on FDA and USDA regulations that factored in all or most of the relevant economic costs (i.e., the health care costs of mild illnesses, the health care costs of severe illnesses, and loss of value of life due to death) (FDA 2012b). Table 34 summarizes the benchmarks selected for this analysis, the source for each benchmark and the types of costs incorporated into the standards.

Table 34. Economic Cost Benchmarks for Salmonella and Listeria Analysis Process

Pathogen	Economic Cost Per Case Benchmark	Agency	Source	Types of Economic Costs Incorporated into Benchmark
Salmonella	**$17,900**	FDA	Salmonella Shell Egg Rule (2010)[1]	• mild Illnesses • moderate Illnesses • severe Illnesses • death • loss of productivity
Listeria	5% of cases are moderate and costs = **$10,300** 95% of cases are severe = **$28,300**	USDA	Listeria in Ready-to-Eat Meat and Poultry Products Rule (2003)[2]	• moderate Illnesses • severe Illnesses

To conduct this public health benefit analysis, a set of formulas and variables were developed to produce calculations of the public health impact of improved product tracing.

Maximum reduction in illnesses due to reduced time between food vehicle identification and intervention to control the product responsible (100% Improvement in Traceback Time)

This analysis addresses the potential reductions in the number of cases of illness from reductions in traceback time from the identification of the food vehicle to the identification and recall (or other intervention) of specific food products. For each outbreak studied, the following process and variables were used:

d = pathogen associated with outbreak

GF = date that the general implicated food was identified

R = intervention date

Id = average incubation period for the pathogen identified in the outbreak

Xi = number of illness incidence occurring on day i

M = maximum potential reduction in cases for the outbreaks studied that could be achieved by reducing the time between identifying the food vehicle and actual source identification and recall (or other intervention); sum of all illnesses occurring between GF+ Id and R+Id occurring on the epi curve.

$$M = \sum_{\mathrm{i=GF+Id}}^{\mathrm{R+Id}} Xi$$

[1] Prevention of *Salmonella* Enteritidis in shell eggs during production, storage, and transportation; final rule. 74 Fed. Reg. 33,030, (July 9, 2009) (codified at 21 C.F.R. pt.118).

[2] Control of *Listeria monocytogenes* in ready-to-eat meat and poultry products. 68 Fed. Reg. 34,252, (June 6, 2003).

ADR = M/(R-GF) = average daily reduction in incidences

Maximum Economic Benefit

C = total expected economic loss per infection (as explained and identified in Appendix S)

M (C) = maximum economic impact for the potential reduction in infections for a particular recall

ADR (C) = average economic impact per day of reduced time for a particular recall

Because there is a range of incubation periods for different pathogens, the average of these ranges was used when applicable. The stated range of incubation, the average incubation period used in the calculation and the sources for the two pathogens are provided in Table 35.

Table 35. Average Incubation Period Used for *Salmonella* and *Listeria*

Pathogen	Range of Incubation	Average Incubation Used in Calculations	Source
Salmonella	6 - 48 hours	24 hours	"What You Need to Know About Foodborne Illness-Causing Organisms" FDA[3]
Listeria	9 - 48 hours for gastro-intestinal symptoms, 2 - 6 weeks for invasive disease	24 hours (based on gastrointestinal symptoms)	"What You Need to Know About Foodborne Illness-Causing Organisms" FDA[3]

Range of Improvement in Product Tracing (25%, 50%, and 75% Improvement in Traceback Time)

For the purpose of analyzing the eight outbreak case studies, a percentage range of improvement was used to calculate different public health benefits during the traceback period. Increments of 25% were used in the calculations (25%, 50%, and 75%). A 100% improvement assumes an instantaneous traceback with the point of convergence and/or source location of the contamination identified as soon as the type of implicated food is identified.

To calculate the economic impact of a percentage improvement, the potential reduction in illnesses was calculated by assuming various percentage improvements of the time between identifying the general food vehicle and the traceback (actual source/site of contamination identification and recall).

PI = percentage improvement (e.g., 25%, 50%, 75%)

Period of Time to Calculate Reduction of Illnesses = ((GF+Id)-(R+Id))*PI

[3] (FDA 2008).

Economic Benefit from Percentage Improvement in Traceback Time = sum of illnesses on the epi curve during the period of time identified in the equation above multiplied by the total economic loss per infection

COSTS STUDY RESULTS

Pilot Participants

Twenty two pilot participants (out of 45) provided some information pertaining to costs and benefits (however, it should be noted that not all 22 firms answered all the questions about costs and benefits). Nine of these firms provided additional details through phone conversations. The information obtained from pilot participants should be viewed with the following limitations in mind:

- **Limited Scope of Pilots** – The two pilot studies focused on tomatoes and processed foods and their ingredients; these products may not be representative of every other type of food product.
- **Focus on Products Previously Associated with Outbreaks** – FSMA stipulated that the pilot studies focus on foods associated with "significant outbreaks" in the recent past. In response to these issues, these industry segments may have improved traceback capabilities compared with those who have not experienced significant outbreaks or recalls associated with the products they handle.
- **Voluntary Participation** – The pilot studies relied on voluntary industry participation and therefore those who felt their systems were inadequate may not have participated.
- **Participant Firm Size** – Fewer small firms volunteered to participate compared to large firms, especially in the grower and retail segments.
- **Small Sample Size** – The two pilot studies were limited to a small sample size (n = 45) and the number of industry participants responding to the cost and benefit questionnaire (n = 22) also limited the scope of results.

The following tables provide a high-level summary of the cost analysis results from the pilot participants and observations about key cost drivers.

Table 36 contains an observation for each size segment based on the pilot participant questionnaire and follow up conversations. The recordkeeping improvements for each segment are suggestions from the observations which appear to be applicable to most of the segment. A qualitative cost magnitude measure is also associated with each improvement. This cost magnitude measure is designed to help indicate the size of the cost and change associated with an improvement. These improvements may not be applicable to every firm in each segment, but they are intended to give segment specific suggestions to improve product tracing from the results of the cost analysis.

IMPROVEMENTS

Table 36. Summary of Respondent Observations and Improvements based on Pilot Discussions

	Observations	Recordkeeping Improvements
Large Grower	Participants were much larger than average farms in this segment and have made significant improvements to their tracing systems in the past five years	$$$ - Implement system with automated data capture $$ - Use a standardized naming convention if not already built into system $ - Electronically provide outgoing information to customers if automatic data capture already performed
Small Grower	Not enough data provided through pilots	N/A
Large Processor	Generally use more advanced Enterprise Resource Planning systems across the whole company not specifically designed for product tracing	$$$ - Implement system with automated data capture $$ - Link incoming ingredients with finished products in a more accurate and efficient way
Small Processor	Systems tend to be very specific to the company's operations and transitions to systems with automated data capture have the potential for significant costs	$$$ - Implement system with automated data capture $ - Implement niche or customized system
Large Distributor	Warehouse management systems are key for operations in this segment and many capabilities are built into these systems but it is vital to define the KDEs and CTEs necessary to capture	$$$ - Implement warehouse management system with automated data capture $ - Implement warehouse management system with some manual data capture $ - Expand capabilities to accept and send information electronically with trading partners
Small Distributor	Wide range of systems are currently in use and the investment level appears to be directly related to capabilities	$$$ - Implement warehouse management system with automated data capture $ - Implement warehouse management system with some manual data capture
Large Retailer	Current systems used for product tracing appear to be separated across company operations although there appears to be significant current investment in improving these systems	$$$ - Implement system with automated data capture $$ - Capture incoming information in an automated and consistent manner $$ - Link product receipt at distribution center to receipt at retail location in a more accurate and efficient way
Small Retailer	Not enough data provided through pilots	N/A

Cost Magnitude Key
$$$ - Significant investment requiring changes to current processes and operations and a long term business decision
$$ - Investment with potential for significant changes but relies on current system
$ - Minimal investment or change utilizing current system capabilities

The percentage of pilot participants within each segment that have invested, in the areas listed below, to improve their product tracing systems in the past five years is shown in Table 37.

Table 37. Pilot Participant Investment Areas in Past Five Years

Investment Area	Description	Grower[1]	Processor[1]	Distributor[1]	Retailer[1]
Fixed Software Costs	• Licenses • Implementation • Training and change management				
Fixed Capital Expenditures	• Tracking equipment • Manufacturing and processing equipment • Training and change management				
Fixed Costs for Changes to Current Processes	• Implementation • Training and change management				
Fixed Compliance Costs	• Policy development • Training and change management				
Annual Ongoing Software Costs	• Operations and maintenance • Additional full time equivalents				
Annual Ongoing Capital Expenditures	• Operations and maintenance				
Annual Ongoing Costs for Changes to Current Processes	• Additional logistics • Additional full time equivalents				
Annual Ongoing Compliance Costs	• Additional full time equivalents				

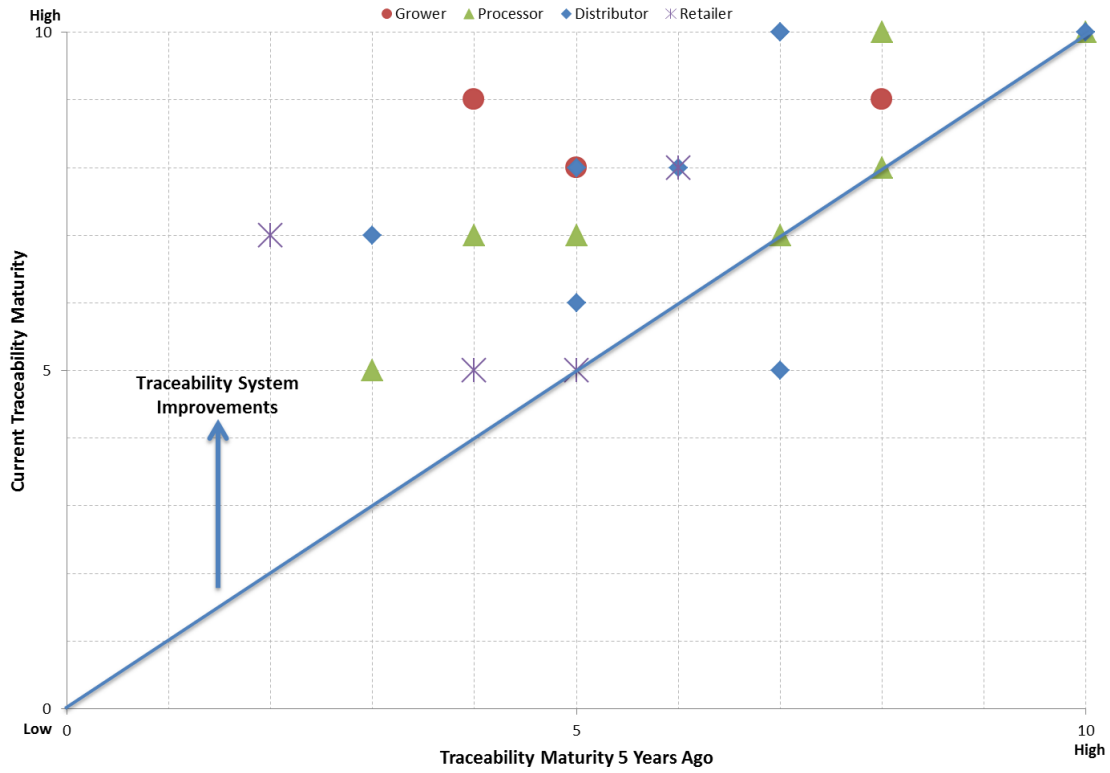
[1]Shaded areas (in blue) represent % that reported investment

Self-reported product tracing system rankings of the pilot participants comparing their current capabilities to their status five years ago are shown in

Figure 37. The chart indicates that the pilot participants currently rank their product tracing systems better than their systems that were in place five years ago. This result implies that the pilot participants have invested in and improved their systems during the previous five years. The current self-reported rankings also show that the pilot participants rate themselves at or above the industry average (a rank of

5), which is not surprising, given that this was an opt-in exercise. The attributes or capabilities of the "industry average" may vary by supply chain node (e.g., the "average" in the grower community may be different than the "average" in the retail community, although the "average" for both is 5).

Figure 37. Self-Reported Tracing System Rankings



The percentage breakdown of tracing maturity of the pilot participants by segment, based on the three factors described in the approach (self-reported ranking, evaluation of technology sophistication, and pilot performance) is shown in Figure 38. The results show that system maturity varies by segment, with those closer to production having more mature tracing systems.

Figure 38. Product Tracing Maturity by Segment

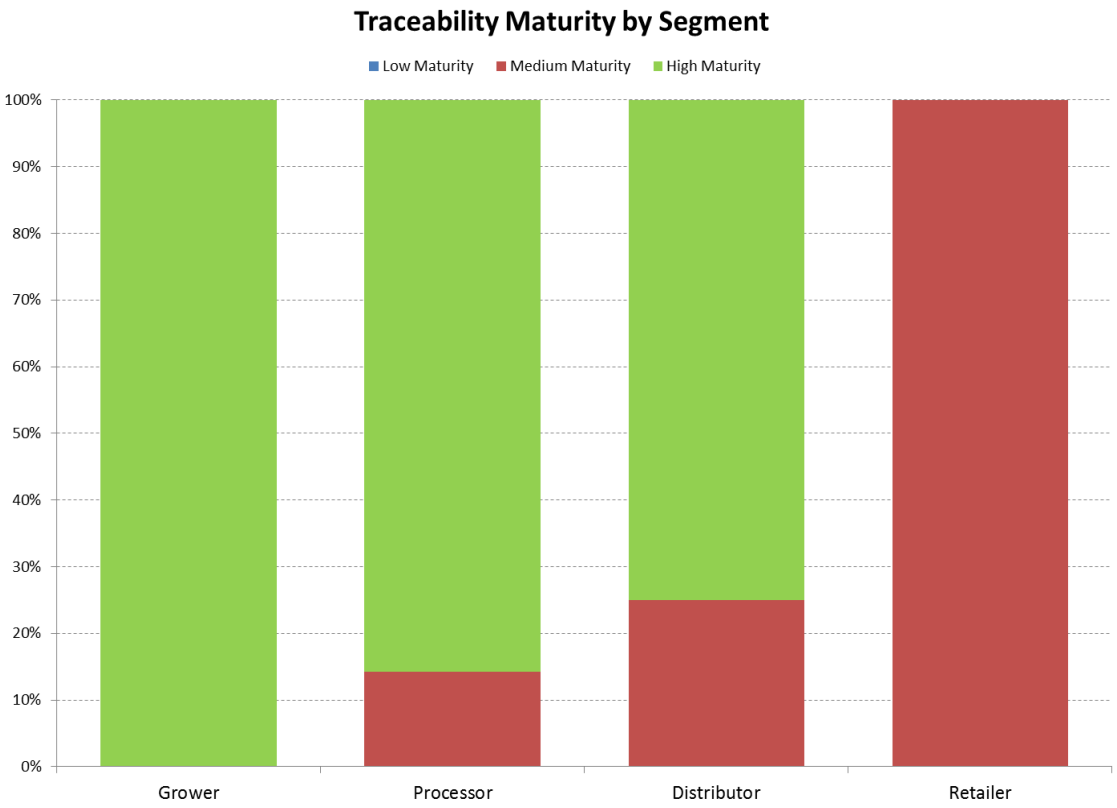


Table 38 shows qualitative detail on the cost drivers from the discussions with pilot participants. For each segment, the table provides detail about what types of changes are characterized as "Capital Expenditures and Software" or "Changes to Current Processes." Because product tracing relies on recordkeeping, cost drivers associated with additional recordkeeping are not identified as a single option. Instead recordkeeping is a part of both, the capital expenditures and software as well as changes to current processes.

Table 38. Qualitative Cost Driver Observations

Segment	Capital Expenditures and Software	Changes to Current Processes
Grower	• Scanning equipment to automatically read labels with bar codes • Upgrade computer system to capture scanned bar code information	• Invest in additional labor to put labels with bar codes on every box • Moving from tracking pallets to cases requires additional scanning capabilities (different process) and additional scanning events
Processor	• Enterprise resource planning systems require a significant company-wide investment; may not specifically be designed for product tracing • Appropriate information technology staff to support systems used • User licenses and service contract for system • Upgrade computer hardware and systems to support changes • Printers for bar codes can be $14–20K to add to a processing line • Scanner hardware can be in the $50–75K range	• Any enhancement for enterprise resource planning system requires training and maintenance • Add radio frequency identification pallet tags/bar codes to automate process; efficiency gains led to reduced staff • For continuous processes there needs to be set standards and rules to perform effective tracing • Less space to store paper records when automated • Some processors audit suppliers for recordkeeping information meeting U.S. Food and Drug Administration and U.S. Department of Agriculture standards
Distributor	• Cost mainly based on number of users for system and service level for support • Appropriate information technology staff to support systems used • Upgrade computer hardware and systems to support changes • Pallet to case level can require finger scanner requiring $10K in hardware plus $10K in software	• Moving from tracking pallets to cases requires additional scanning capabilities (different process) and additional scanning events • Place label/bar code sticker on every incoming unit to be scanned • Train employees how to use new systems • If re-packing product, new lot numbers assigned and tracked
Retailer	• Enterprise resource planning system used to integrate disparate systems across whole company. • Software to collect data from across company	• Integrate data from multiple sources across company into one place

The percent of total pilot participants (22 total participants represented in the table) in each size segment that can currently perform the nine improvement options that IFT identified (as discussed above in the approach section of this chapter) is shown in Table 39. This information shows the current capabilities of the pilot participants and a snapshot of their product tracing system's capabilities. Note that the pilot participants tend to have more advanced systems than the industry average, as indicated by their self-rankings as well as IFT's expectation that the population willing to participate in pilots is more confident in their systems than average. It is also important to note that just because a firm

reported the capability to meet this goal, it does not necessarily mean that they are performing these functions today.

Table 39. Percent of Pilot Participants with Current Capabilities

	Improvement Options	Large Grower	Large Processor	Small Processor	Large Distributor	Small Distributor	Large Retailer
Capture KDEs*	KDEs manual only	100%	100%	100%	100%	100%	100%
Capture KDEs*	KDEs manual data input to electronic system	100%	100%	100%	100%	100%	100%
Capture KDEs*	KDEs scanning	100%	100%	33%	100%	50%	50%
Additional Capabilities	Incoming KDEs by electronic messages	66%	50%	33%	100%	25%	50%
Additional Capabilities	Incoming lot number information*	66%	100%	100%	100%	75%	0%
Additional Capabilities	Link product from receipt to production to shipping*	100%	100%	100%	75%	75%	25%
Additional Capabilities	Standardized naming	66%	75%	66%	100%	75%	0%
Additional Capabilities	Outgoing KDEs electronic to customers (advance ship notifications)	66%	50%	66%	100%	75%	75%
Additional Capabilities	Data summary	100%	100%	100%	75%	50%	100%

* Note that for the purpose of this assessment, lot/batch number was not included in the identified KDEs and is instead assessed as two separate items, relating first to the capture of incoming lot numbers, and also to the ability to follow product through the facility and to the next supply chain recipient.

The following series of tables provides the results of the cost analysis from the data the pilot participants provided through the questionnaire responses and discussion. There are two size segments – small growers and small retailers – for which no data were available.

The results for each segment include:

- comparison of broad segment characteristics to pilot participant characteristics
- summary of the cost range and qualitative responses to the improvement options
- written summary of respondent observations

The first two context boxes compare characteristics of the entire segment (based on the census segmentation explained in the approach) to the characteristics of the pilot participants who responded to the request for cost information. This comparison is important because it shows how representative the pilot participants are compared to the industry segment as a whole.

The results tables (Table 40, Table 41, Table 42, Table 43, Table 44, and Table 45) summarize the cost range associated with each improvement option as well as qualitative system observations from the analysis. The results tables have two main elements: “Cost to Capture KDEs” and “Incremental Cost for Additional Capabilities.” The range of costs for the systems currently in use to capture the information and key data elements (KDEs) is found in the “Cost to Capture KDEs” rows. The second main element of the results tables provides the cost ranges for additional capabilities, which would require incremental costs on top of the system used to capture the KDEs (with the exception of lot numbers).

If the cost range includes a $0 dollar estimate, it indicates this additional capability can be included in the system used to capture the KDEs so there may not be an additional cost to the company. For example, an ERP system may have built-in capabilities to accept ASN’s electronically from suppliers so there would not be an additional cost to add this capability. If the cost range provided is “Unknown,” then the pilot participants did not provide enough information to determine an informed cost range but qualitative observations are provided.

It is important to note each segment may not have a cost for each improvement option identified. The ability for growers to capture incoming data elements electronically from suppliers, for example, represents an option that is not applicable to growers and is therefore not included on the summary of results for the grower segment. Also, all firms responded that they were capable of capturing the KDEs identified using a manual paper-based process, so this option was not included in the summary of results.

Finally, the respondent results include a written summary of the main points from the cost analysis. Together, these three parts of the results section provide the context with which to view the results as well as cost ranges and qualitative observations focused on each segment’s current product tracing systems.

Large Grower Respondents: Summary of Observations

Industry Segment Characteristics	Pilot Participant Characteristics
▪ Approximate number of firms: 85,898 ▪ 2% of all U.S. farms have revenues exceeding $1 M ▪ Value of production: 66% of U.S. total ▪ Average full time equivalent: 8 – 12 ▪ Operating margin: 24.4% - 25.7% ▪ SBA Guidelines: Greater than $750,000 Source: 2007 Census Data, SBA Guidelines	▪ Sample size: 3 firms ▪ Revenue: $60 M - $150 M ▪ Full time equivalents: 200 - 350 employees ▪ Average product tracing maturity five years ago: 6 out of 10 ▪ Average current product tracing maturity: 9 out of 10 Source: Pilot Participant Data

Table 40. Large Grower Respondents: Summary of Observations

	Industry Improvement Options	Reported Cost Range to Implement	Key System Observations
Cost to Capture KDEs	KDEs scanning	$350K – $4.5M	• Scanning capabilities generally involve printing labels at a case or pallet level • Significant costs can occur to transition a system from tracking at a pallet level to a case level • Requires sticker/bar code on every product tracked as well as scanning and printing hardware
Incremental Cost for Additional Capabilities	Incoming KDEs by electronic data messages	Unknown	• Automated data capture is key • Capabilities can also be built into enterprise resource planning system • May not be applicable if company is first point in supply chain
Incremental Cost for Additional Capabilities	Supply chain link	$0 - $65K	• Can be integrated into system implementation costs • Could require additional full time equivalents
Incremental Cost for Additional Capabilities	Standardized naming	$0 - $500K	• Requires labeling equipment configured for standardized naming conventions if not already built into system • Need a standard procedure for when to assign a standardized name
Incremental Cost for Additional Capabilities	Outgoing KDEs electronic to customers (advance ship notifications)	$2-$5K	• Generally capabilities are built into systems but requires customers able to receive information and setting ability to share across systems • Need additional information technology resources to set up communication capabilities
Incremental Cost for Additional Capabilities	Provide data summary	Unknown	• Can be integrated into system capabilities • Need information technology resources to set up reporting capabilities

The large grower segment consisted of seven pilot participants, with three responding to the inquiry. The firms participating in the pilot projects were much larger than most growers. Pilot participants in the grower segment generated sales in excess of one million per year, which places them in the top two percent of the industry. The results within this segment are only from the larger growers so they may not be applicable to the broader grower industry. The firms that responded had scanning capabilities enabling tracing products at either the case or pallet level using labels with bar codes. These systems allowed the large growers to be able to implement many of the improvement options that the pilot

studies identified. A significant improvement has been realized by these firms in the past five years, as indicated by their self-ranking evaluations (6 to 9 score on the scale) and the current capabilities in place.

Another important consideration for the grower industry is the granularity at which companies are tracking their product. Depending on the operations, growers track their product at either the pallet or case level. If a system is only tracking at the pallet level there could be significant costs to requiring tracking cases.

A standardized naming convention has the possibility to add significant costs if it is not already built into a grower's current system. Some growers currently use some form of naming conventions, but if a system is not in place to use a particular type of naming convention then it may require installing additional labeling equipment or related capabilities. One area to improve upon for this segment is utilizing large growers' capabilities to provide outgoing information to customers. If growers and their customers have the ability to exchange information it will make product tracing much easier across the supply chain.

Small Grower Respondents: Summary of Observations

IFT did not have access to enough data to provide a summary of observations for this segment of pilot participants.

Large Processor Respondents: Summary of Observations

Pilot Participant Characteristics	Industry Segment Characteristics
▪ Sample size: 4 firms ▪ Revenue: $500 million - $30 billion ▪ Full time equivalents: 300 – 100,000 employees ▪ Average product tracing maturity five years ago: 7 out of 10 ▪ Average current product tracing maturity: 8 out of 10 Source: Pilot Participant Data	▪ Approximate number of firms: 555 ▪ Total receipts: $456 B ▪ Total employees : 958,194 ▪ Average revenue per firm: $822 M ▪ Average employees per firm: 1,726 ▪ SBA Guideline: greater than 500 employees Source: USCB (2007), SBA (2011).

Table 41. Large Processor Respondent Summary of Observations

	Industry Improvement Options	Reported Cost Range to Implement	Key System Observations
Cost to Capture KDEs	KDEs scanning	$500K-$1.2 million	• Range of systems includes radio frequency scanning and enterprise resource planning systems • Systems in place have multiple business functions and not specifically designed for product tracing • Scanning equipment required at product receiving locations
Incremental Cost for Additional Capabilities	Incoming KDEs by electronic data messages	Unknown	• Some participants accomplish this by in house programing or through enterprise resource planning systems
Incremental Cost for Additional Capabilities	Incoming lot number information	$0-$60K per year	• Firms with enterprise resource planning systems appear to have this capability built in, but for others there are additional costs • Some firms have implemented ways to receive information from suppliers • Some firms use scanning equipment and software to track incoming products
Incremental Cost for Additional Capabilities	Supply chain link	$0-$60K per year	• Wide variety of methods to link products, including manual methods, using scanning systems in place, enterprise resource planning systems, or time inference • Standard internal process required to follow product through company operations • Some firms use scanning system in place to capture transfer of product from incoming, to WIP, to finished good
Incremental Cost for Additional Capabilities	Standardized naming	Unknown	• Current systems appear to capture standardized naming conventions through modification of software and business processes
Incremental Cost for Additional Capabilities	Outgoing KDEs electronic to customers (advance ship notifications)	Unknown	• Able to send advance ship notifications to customers although not all customers are able to receive them
Incremental Cost for Additional Capabilities	Data summary	$0-$2K	• Current systems in use have summary report capabilities

The large processor segment contained five firms, and provided information on costs. Within the results, two of the firms compare well to the segment average in terms of revenue and number of employees. The other two firms consist of very large processors at the top end of the industry in terms of size. As indicated by the tracing maturity self-rating, these firms generally have more advanced systems when compared with other segments across industry. The systems that these firms currently have in place range from scanning, labels, and RF capabilities to complete ERP systems used across the entire firm. Each respondent indicated the ability to scan products and capture the necessary information to trace products automatically.

The technology systems in use do not appear to be designed with product tracing as a primary or fundamental part of their architecture, but as an additional feature that is optional. In calculating costs of complying with a regulation, it is often difficult to separate out the costs of a technology that are associated specifically with compliance – such as product tracing versus those that are associated with an entire system that serves multiple purposes. Table 41 shows that many of the improvement option capabilities may already be built into the system, so there is no additional cost; or the cost may be unknown because it is not able to be separated from the system implementation. For example, firms with ERP systems appear to already be able to capture incoming lot number information, thus there is no additional cost; other systems may require an additional investment typically estimated by pilot participants to cost around $60,000. This segment also currently appears to have systems in place that are able to implement standard product naming conventions such as GTINs, which is not true for most other segments. Another interesting note was some processers' ability to send advance ship notifications (ASN's) to customers and their willingness to do so if the customer was able to receive this information. Some of the systems currently in place have the capability to electronically interact with supplier and customer systems but other firms do not seem to have adopted this feature into their systems.

The processor respondents submitted a wide range of responses when asked about their ability to maintain the link between incoming and outgoing product tracing data within the firm's operations. The way these links are currently established varies from manual methods to ERP systems using time inference. Because processing steps can be very complicated and many inputs can be used to create a finished product, a firm's ability to link ingredients with finished products is critical. Continuous flow processes may need to employ different processes to establish these links compared to products that result from defined batch operations.

Small Processor Respondents: Summary of Observations

Pilot Participant Characteristics	Industry Segment Characteristics
▪ Sample size: 3 firms ▪ Revenue: $25 - $75 million ▪ Full time equivalents: 50 – 200 employees ▪ Average product tracing maturity five years ago: 6 out of 10 ▪ Average current product tracing maturity: 8 out of 10 Source: Pilot Participant Data	▪ Approximate number of firms: 21,036 ▪ Total receipts: $134 B ▪ Total employees : 481,072 ▪ Average revenue per firm: $6.3 M ▪ Average employees per firm: 23 ▪ SBA Guideline: less than 500 employees Source: 2007 Census Data, SBA Guidelines

Table 42. Small Processor Respondents: Summary of Observations

	Industry Improvement Options	Reported Cost Range to Implement	Key System Observations
Cost to Capture KDEs	KDEs manual data input to electronic system	$250-$350K	• Niche solutions require investment in fixed up front costs, license fees for users, and annual maintenance requirements. • Customized solutions are built in house and would require some information technology staff.
Cost to Capture KDEs	KDEs scanning	$350-$800K	• Upgrading to a system with scanning capabilities requires significant investment in new processing equipment able to print bar codes and scanners for automated information capture.
Incremental Cost for Additional Capabilities	Incoming KDEs by electronic data messages	Unknown	• Can be integrated into system capabilities • May require scanning capabilities and software changes to capture information
Incremental Cost for Additional Capabilities	Incoming lot number information	$0	• Firms appear to have this capability already built into their system
Incremental Cost for Additional Capabilities	Supply chain links	Unknown	• Firms appear to have this capability already built into their system but the method varies between systems. • Some firms still rely on partially manual processes to link product movement and automating would require changing how their system captures data.
Incremental Cost for Additional Capabilities	Standardized naming	Unknown	• Can be integrated into system capabilities but may also require additional costs for systems without this capability
Incremental Cost for Additional Capabilities	Outgoing KDEs electronic to customers (advance ship notifications)	Unknown	• Can be integrated into system capabilities but may also require additional costs for systems without this capability
Incremental Cost for Additional Capabilities	Data summary	$0	• Current systems in use have summary report capabilities • Upgrades to software required for companies without these capabilities

The small processor segment had five pilot participants of which three firms responded to the questionnaire. The pilot participants who responded are on the larger size of SBA guidelines and the results are not likely to be representative of very small processors (SBA guidelines are discussed above in the approach section of this chapter). Small processors are characterized by the operations in relation to the pilot scenarios as opposed to their primary NAICS code. Two firms in the small processor segment have a primary NAICS code of a distributor but their operations for the tomato pilot project more closely related to processors since they transformed the product through re-packing operations. The typical system for a small processor is more likely to consist of a customized solution as opposed to a manual system or to an advanced ERP solution found in the large processors. The responses indicated a significant cost to move to a system capable of scanning bar codes which would require investment in printing and scanning equipment.

Similar to the large processors, many of the improvement option costs for the small processors appear to be included in system implementation costs. Customized solutions appear to provide most of the necessary information for an efficient food tracing system as long as the proper information is captured. Also, this segment has a variety of methods to link incoming and outgoing products.

There is a significant cost for this segment in making the transition to a more automated way of capturing information. Current systems are fairly customized to a firm's operations and anytime the decision is made to move to an automated system there is a potential for significant costs. However, automatically capturing key information could improve product tracing.

Large Distributor Respondents: Summary of Observations

Pilot Participant Characteristics	Industry Segment Characteristics
▪ Sample size: 4 firms ▪ Revenue: $50 million - $20 billion ▪ Full time equivalents: 120 – 24,000 employees ▪ Average product tracing maturity five years ago: 6 out of 10 ▪ Average current product tracing maturity: 8 out of 10 Source: Pilot Participant Data	▪ Approximate number of firms: 1275 ▪ Total receipts: $470 B ▪ Total employees : 524,892 ▪ Average revenue per firm: $369 M ▪ Average employees per firm: 412 ▪ SBA Guideline: greater than 100 employees Source: 2007 Census Data, SBA Guidelines

Table 43. Large Distributor Respondents: Summary of Observations

	Industry Improvement Options	Reported Cost Range to Implement	Key System Observations
Cost to Capture KDEs	KDEs manual data input to electronic system	$50-$200K	• Warehouse management systems are key for operations in this segment • Software can be customized for a company's operations
Cost to Capture KDEs	KDEs scanning	$125K-$1M	• Firms in this segment appear more likely to use niche solutions • Requires investments in software and scanners for automated information capture • Business decision needed for tracking at pallet level vs. case level
Incremental Cost for Additional Capabilities	Incoming KDEs by electronic data messages	Unknown	• Firms of this size appear to be able to accept electronic data interchange or advance ship notifications from customers • Information technology staff needed to set up ability to accept information electronically
Incremental Cost for Additional Capabilities	Incoming lot number information	$0	• Information capture built into some warehouse management systems • Information can be captured by accepting advance ship notifications from suppliers
Incremental Cost for Additional Capabilities	Supply chain links	Unknown	• Built into some systems • Software updates may be required to track information in a way to establish supply chain links • Every product requires labeling/bar code to follow through company operations
Incremental Cost for Additional Capabilities	Standardized naming	$0-$80K	• Built into some warehouse management systems but other systems require upgrades to labeling machines • Smaller suppliers may not use standardized naming limiting this capability at distributor level
Incremental Cost for Additional Capabilities	Outgoing KDEs electronic to customers (advance ship notifications)	$0	• Built into some warehouse management systems • Information technology staff to update software capabilities if sending information electronically required
Incremental Cost for Additional Capabilities	Data summary	$0	• Built into some warehouse management systems but may require information technology staff to build new reports

The large distributor segment was the largest in the pilot studies and contained 13 participants. Only four of these participants responded to the questionnaire and each firm was a very different size. This segment is more likely to use customized software solutions tailored to their operations. More advanced systems appear to allow large distributors to perform many of the improvement options with no additional cost. Based on the responses of pilot participants, this segment appears to have shown significant improvement in product tracing maturity over the past five years, moving from an average of 5 to 8, as indicated by self-rated responses.

One key consideration reported by distributors when implementing a product tracing solution is whether to track products at the pallet level versus the case level. Some systems currently in place track product only at the pallet level and transitioning to case level tracking could require significant changes to business operations and results in increased costs. Moving to case level tracking would require additional events to capture information leading to increased labor costs and time. Currently, the level at which product is tracked is a business decision based on internal costs and benefits for a company.

Warehouse management systems (WMS) are a key component of distributor operations so many of the product tracing improvement options are built into the systems used by this segment. The WMS in place for large distributors appear to have the capabilities to capture incoming KDEs and lot number information automatically as well as send outgoing information to customers. An area for improvement in this segment would be expanding and utilizing these capabilities within the supply chain partners the distributors deal with. Another key aspect to this exchange of information is defining the KDEs in a consistent manner.

Small Distributor Respondents: Summary of Observations

Industry Segment Characteristics	Pilot Participant Characteristics
▪ Approximate number of firms: 26,198 ▪ Total receipts: $172 B ▪ Total employees : 243,450 ▪ Average revenue per firm: $6.5 M ▪ Average employees per firm: 9 ▪ SBA Guideline: less than 100 employees Source: 2007 Census Data, SBA Guidelines	▪ Sample size: 4 firms ▪ Revenue: $30 - $50 million ▪ Full time equivalents: 40 – 100 employees ▪ Average product tracing maturity five years ago: 7 out of 10 ▪ Average current product tracing maturity: 8 out of 10 Source: Pilot Participant Data

Table 44. Small Distributor Respondents: Summary of Observations

	Industry Improvement Options	Reported Cost Range to Implement	Key System Observations
Cost to Capture KDEs	KDEs manual data input to electronic system	$40-$70K	• These systems are typically customized or developed in house for the business needs • Requires investment in computer system to track data
Cost to Capture KDEs	KDEs scanning	$200K-$1.5 million	• These systems appear to be based on niche or enterprise resource planning solutions • Requires scanning equipment and software to support automated data capture • Enterprise resource planning system implementation requires training and transition period from previous systems
Incremental Cost for Additional Capabilities	Incoming KDEs by electronic data messages	$0-$15K	• Requires software modifications to current systems if capability not already built into system
Incremental Cost for Additional Capabilities	Incoming lot number information	$0-$150K	• Information may already be captured for scanning or enterprise resource planning systems • Other systems may require additional costs and process changes
Incremental Cost for Additional Capabilities	Supply chain links	$0-$150K	• Information may already be available if using scanning or enterprise resource planning systems • Other systems may require additional costs, process changes, or manual steps
Incremental Cost for Additional Capabilities	Standardized naming	$5-$150K	• If using a scanning system this information only needs to be added in the database but for other systems there are additional costs • Not every supplier uses standardized naming limiting this capability at distributor level
Incremental Cost for Additional Capabilities	Outgoing KDEs electronic to customers (advance ship notifications)	Unknown	• Generally already built into systems
Incremental Cost for Additional Capabilities	Data summary	$0-$10K	• Added costs for advanced reporting capabilities include software updates

The small distributor segment consisted of seven pilot participants of which four responded to the questionnaire. The pilot participants who responded represented larger-than-average distributors in this segment who fall very close to the SBA guidelines at 100 employees. This segment has a wide variety of systems in place – from customized solutions built in house to advanced ERP solutions.

The same decision faced by large distributors regarding the granularity at which to track products (pallet versus case level) is also faced by small distributors. Currently it is a business decision each company makes to optimize their operations. This segment is a good example in which the investment level in product tracing corresponds to the capabilities of each company. The investment level of the pilot participants in this segment was tied to their product tracing system maturity as indicated by the pilot results.

As with the large distributors, WMS are important to distributor operations. Many of the improvement option capabilities can be built into WMS implementation. However there are additional costs if a customized solution does not have the option already built into the system. Because there is a wide range of systems, the investment a small distributor uses for a WMS is directly related to the capabilities available from each system. If information is captured in an automated manner then the system generally has more advanced product tracing capabilities.

LARGE RETAILER RESPONDENTS: SUMMARY OF OBSERVATIONS

Pilot Participant Characteristics	Industry Segment Characteristics
▪ Sample size: 4 firms ▪ Revenue: $0.5 - $90 billion ▪ Full time equivalents: 3,000 – 160,000 employees ▪ Average product tracing maturity five years ago: 4 out of 10 ▪ Average current product tracing maturity: 6 out of 10 Source: Pilot Participant Data	▪ Approximate number of firms: 7,087 ▪ Total receipts: $1 T ▪ Total employees : 7,147,928 ▪ Average revenue per firm: $152 M ▪ Average employees per firm: 1,009 ▪ SBA Guideline: Varied ($7-$35 M) Source: 2007 Census Data, SBA Guidelines

Table 45. Large Retailer Respondents: Summary of Observations

	Industry Improvement Options	Reported Cost Range to Implement	Key System Observations
Cost to Capture KDEs	KDEs manual data input to electronic system	Unknown	• Many firms appear to have separate systems across operations that are not fully integrated
Cost to Capture KDEs	KDEs scanning	Unknown	• These participants were able to scan product at their distribution centers although the stores are not as automated • Systems and capabilities can differ at distribution centers and retail stores
Incremental Cost for Additional Capabilities	Incoming KDEs by electronic data messages	Unknown	• Firms of this size appear to be transitioning to enterprise resource planning systems from separate systems across operations • Changes to software may be required to integrate this capability
Incremental Cost for Additional Capabilities	Incoming lot number information	Unknown	• Systems do not currently appear to capture incoming lot numbers and would require process changes to do so • Some firms indicated relying on suppliers for pieces of information
Incremental Cost for Additional Capabilities	Supply chain link	Unknown	• Currently products are linked through manual processes • Firms can implement enterprise resource planning "traceability" module add-on to enable products to be linked from receipt to shipment • Some firms may need process changes to capture additional information
Incremental Cost for Additional Capabilities	Standardized naming	Unknown	• Current efforts are being pursued but are not operational

The large retailer segment consisted of six pilot participants and four responded to the questionnaire. The participants in this segment were hesitant to share specific cost information which is why the cost ranges are unknown in

Table 45. The responding firms are significantly larger than average firms in this segment. The pilot respondents also rated themselves much closer to an industry average both five years ago and today. The current technology infrastructure of large retailers appears to be a collection of independent applications. However, some large retailers appear to be in the process of implementing ERP systems.

Based on information obtained from the retailers, the large retailer segment currently does not seem to have the capability to perform many of the improvement options identified through the pilot results. It appears incoming information, including lot numbers, is not being captured nor transmitted electronically through EDI, in a way that enables retailers to effectively document the specific products received and subsequently track their movement. Also, some retailers indicated relying on suppliers for information necessary for product tracing. This is consistent with the pilot results. According to the responses from this segment many retailers perform product tracing through manual processes due to separate systems across operations. Focusing on improving how incoming information is captured and maintained is necessary to improve product tracing in this segment.

One aspect of the large retailer segment is a distinction between separate systems at internal distribution facilities and systems at the store level. Many of the changes observed in responses from this segment focused on implementing a system that would have disparate systems interact with each other in order to more readily access information. Transitioning from separate systems across a firm to one integrated system should continue to be a focus and area of improvement for the large retailer segment.

Small Retailer Respondents: Summary of Observations

IFT did not have access to enough data to provide a summary of observations for this segment based on pilot participation.

Small Business Costs

Of the 25 small businesses contacted, IFT spoke with nine on the telephone and six agreed to provide information. Most of those contacted felt that their current ability to trace products was sufficient and felt that additional product tracing solutions would be costly with minimal benefits. A few other businesses thought that more regulations on product tracing would cause their products to double in price, and therefore go out of business. Additionally, small growers believed that it would be too costly to invest in smartphone applications linked with their product tracing systems, but the percentage that use smartphones within this group is not known.

Small growers who are part of Pro*Act began using GS1 standards under the PTI (described in more detail in Chapter 9, with a case study in this chapter). Pro*Act is a trading network that began with foodservice distributors forming a group to consolidate marketing and networking. They have since become “America’s leading distributor of fresh produce to the foodservice industry” and have approximately 50 distributors and 70 distribution centers in North America that source 50 million cases of fresh produce annually (Pro*Act 2012). The growers indicated that the switch to GS1 was expensive, but facilitated trade, relationships, and markets with their customers. Some growers said that their customers started to require the use of GS1 nomenclature on the products sold to them.

One auction house said that they tag a majority of the boxes of produce that come into their facilities, assigning each different grower a different "lot number" that is attached to their produce. They indicated that they have plans to start labeling all boxes of produce, and did not foresee a significant cost burden to implement this practice.

A small produce wholesaler reported that it would be easier to capture incoming lot information (provided by growers or re-packers) compared to capturing lot information as products were assembled for customers. The firm currently uses a custom-built software system for inventory control. Upon receipt of products, the firm applies their own "lot number" and felt that linking this to the original lot number would require some modification of their software system but be achievable. The challenge reported by this firm related to process changes that would occur in the selection of outbound products. As a wholesaler on a terminal market, the firm allows customers to arrive at the location and in some cases, the customers are permitted to select their own cases of product. A foreman checks the products before they leave the facility. The wholesaler realizes that the capture of KDEs of outgoing products will need to occur at the warehouse level, before the involvement of the foreman. This will require training of the warehouse staff, a change in the operation of the business (eliminating the option for self-loading), and the purchase of hand-held scanners. Additionally, 30% of the transactions for this firm are cash-based. The other 70% of transactions are associated with specific customers within the software system. "Cash" is recognized as a customer in the software system. While there is a field to add detail (e.g., the name of the cash customer), in 10 - 20% of the cash-based sales, the customer is not known.

TECHNOLOGY COSTS

Implementing technology to help perform tracebacks requires an investment. For example, the system implementation cost to perform product tracing using a manual system and an electronic spreadsheet is very different than the system implementation cost to install an ERP solution with scanning capabilities. Each of these options requires different levels of investment.

The spectrum of technology solutions used by the pilot participants to maintain records include Enterprise Resource Planning, Niche, Hosted, Customized, and Off-The-Shelf Solutions. In relating these technology solutions to the nine options presented to pilot participants, it should be noted that some but not all of the options would require the use of technology. However, most of the options can be accomplished with very low-tech solutions.

Enterprise Solutions

ERP solutions are applications that integrate information systems by managing the flow of data across the entire organization. This often results in a more efficient, streamlined and cohesive set of business units. Although each department within the organization has its own set of software applications, each department would be linked together and run off a common database. Some of the most prominent ERP applications include SAP, Oracle, and i2 Technologies.

Niche Solutions

Niche solutions are a class of IT solutions designed specifically for an industry segment or niche (e.g., Famous Software, Produce Pro, etc.). For the purposes of this project, these solutions are defined as those designed and targeted towards specific food industry segments.

Hosted Solutions

Hosted solutions are software applications that are delivered to the customer by a third-party from a remote location using a model called SaaS. These solutions manage not only the application but also the

customer's data. As examples, Microsoft and IBM offer hosted solutions for various business-to-business applications.

Customized Solutions

Firms may also decide to design product tracing solutions themselves. There were several instances in which firms have relied on custom-built applications to meet their product tracing needs. Custom software is often developed by an in-house development group or contracted to a software development firm.

Off-the-Shelf Solutions

Other solutions include commercially available off-the-shelf software applications not specifically designed with product tracing or supply chain management in mind (e.g., Quickbooks Enterprise, MS Excel).

Many of the firms that participated in the pilots approached recordkeeping (and therefore product tracing) in a piece-meal manner as opposed to a comprehensive system. This included large, complex IT infrastructures augmented by tedious manual processes tied to hand written recordkeeping. While the above are the five general types of technology solutions identified from the pilots, this list is not exhaustive of all the types of systems available to the food industry to improve their product tracing capabilities, and IFT found that a single company would often use several types of systems.

Of the eight "niche solution" companies contacted, IFT received information on the costs of the systems from four firms. The main cost driver for these services was the number of users for the system. This was by far the highest variable cost associated with adopting one of these technologies. As with any variable cost, the number of users is tied to the size of the company. This was the main factor in the ranges indicated below.

- The least expensive options for these types of technologies had an estimated annual cost of $5,000 - $8,000. This type of solution appears to be applicable to small distributors (around $1 million in annual revenue) or small growers with only one harvesting crew.
- For typical growers or distributors with annual revenues in the range of $10 - $25 million, the technology firms estimated an upfront fixed cost investment in hardware and software of $15,000 - $50,000. The annual cost (dependent on the number of users) was then estimated to be in the range of $5,000 - $20,000.
- Companies larger than $25 million in annual revenue can expect to invest $75,000 - $100,000 in fixed costs to implement a solution similar to the services provided by the four technology firms. The annual cost is also dependent on the number of users and needs to be considered. One solution provider indicated companies with more than $100 million in annual revenue typically see large benefits from ERP type systems and if a company has more than $150 million in annual revenue they will have their own IT staff and departments. This indicates niche solutions may not always be scalable to the largest companies in the food industry.

Product Tracing Specific Solutions

Twenty-six firms responded to IFT's request for additional information on solutions specific for product tracing. As shown in Figure 39, Figure 40 and Figure 41 below, there is a wide variability in the pricing structure of these technology solutions. Very few (4%) respondents reported providing their technology only as SaaS model. A SaaS model typically allows the user to pay per use (scalable cost structure with low throughput small businesses paying less than large throughput operations). SaaS also typically has low start-up costs since the software is delivered via the internet and requires minimal hardware purchases (it requires access to computers and the Internet, however). A larger portion (13%) of the

respondents reported providing their software with as one-time only fee. Technology companies offer their software for a one-time fee or software as a service for costs ranging from minimal (zero or close to zero) to one million dollars. As a point of reference, Mejia and others (2010) estimated SaaS fees to range from $6,000 - $25,000.

Finally, a larger proportion (26%) of respondents reported providing their software on a subscription basis only. This could be a monthly or an annual subscription pricing model in which future updates are received for free, as long as the subscription is valid. Some solution providers reported a monthly minimum subscription cost of zero, making the use of these technologies more accessible to very small businesses. The maximum monthly subscription cost reported was approximately $3000; however, based on the data collected, it was not possible to infer total implementation costs (including start-up as well as on-going capital expenditures). Another interesting observation was the spread of costs reported by the technology providers when targeting small through large businesses. Some solutions were sold at a fixed cost regardless of client size, while some ranged from a few hundred to a few thousand dollars depending on firm size.

Figure 39. Various Pricing Structures Reported by 26 Technology Solution Providers

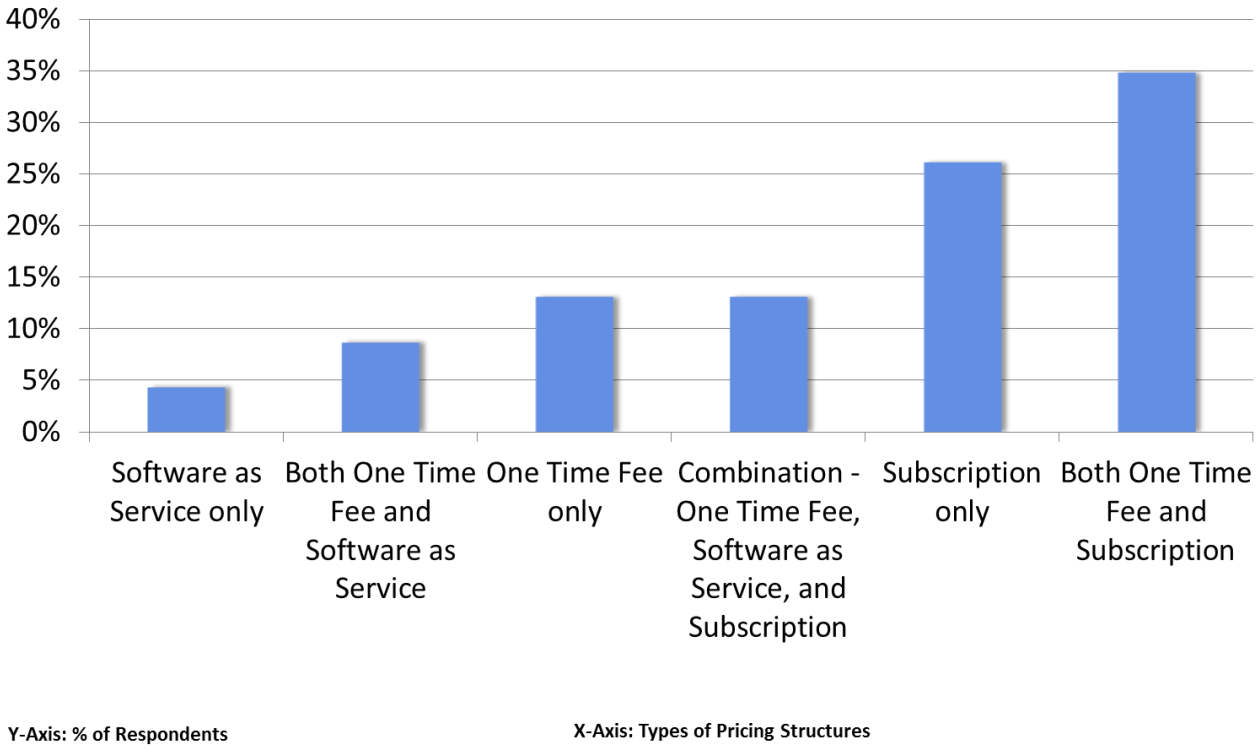
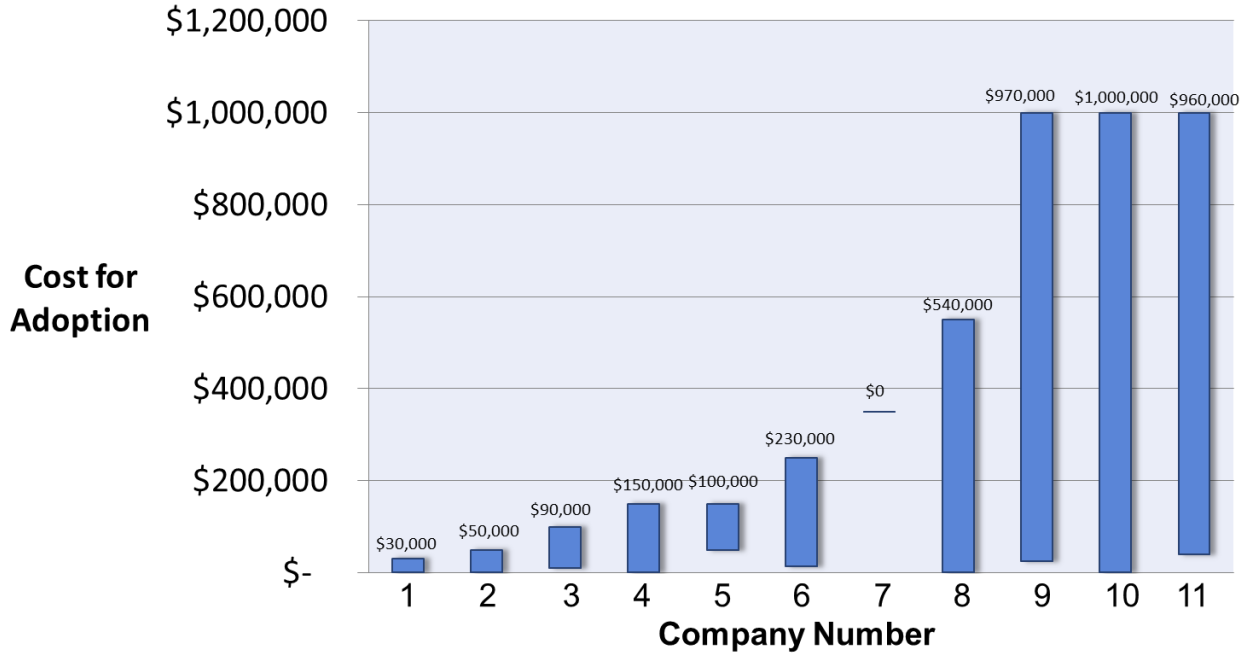
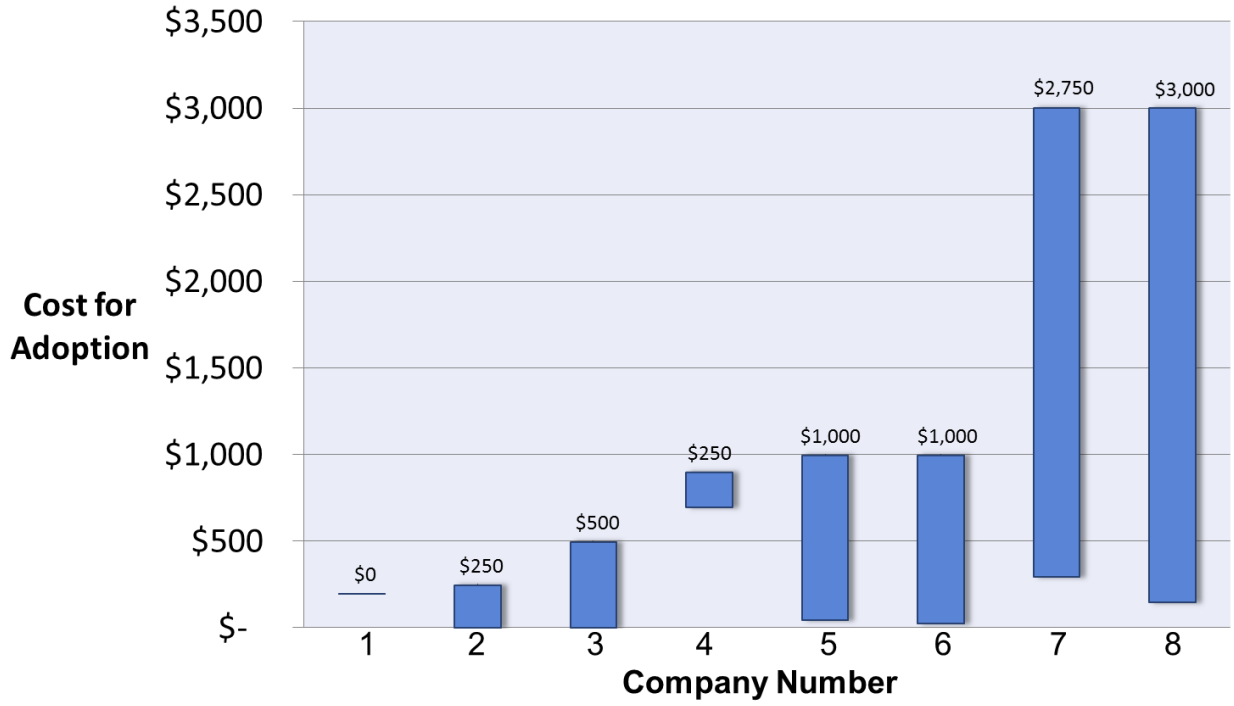


Figure 40. Range of Costs Reported for Technologies Offered as One-Time Fees or Software as a Service



*Dollar range (height) shown on the top of each bar

Figure 41. Range of Costs Reported for Technologies Offered as Monthly Subscriptions



*Dollar range (height) shown on the top of each bar

One solution provider offered more detailed estimates of the costs associated with the use of their product. In a previous pilot project, working with supply chain partners, this firm implemented its software to improve product tracing capabilities. The project aimed to develop tracing capabilities for inbound, slotted (stored in a specific warehouse location), and outbound product to increase process efficiencies.

The costs included the following:

- Web-based software: $1800 per year
- Installation fee: $1000 per day (no more than an afternoon for installation is most cases)
- Training cost: $1000 per day (suppliers require 4 - 6 hours of training at approximately $625).
    - Processors and distributors require 2 - 3 days (at approximately $2,500) due to an increased number of processes such as receiving, picking requirements (selecting products for a specific customer order), and shipping.
    - Retailers and food service companies require one day per location, but this can vary considerably based on the size of the organization and how effectively multiple trainings can be administered in a central location.

Warehouse management system enhancements for the retail operations included a full infrastructure adjustment, software, hardware, individual GTIN assignment, and line personnel training and support for a large packing shed with multiple lines for approximately $75,000.

BENEFITS STUDY RESULTS

Pilot Participant Benefits

Many pilot participants found it difficult to quantify the benefits realized from improved product tracing. Some pilot participants quoted benefits in dollar value while others quoted benefits in improved supply chain efficiencies (e.g., better pick rates). As mentioned by several pilot participants, product tracing technologies are a subset of supply chain management technologies and are closely related to inventory management, asset management, inventory forecasting, inventory visibility, quality management, replenishment, and/or demand forecasting technologies. Investments in product tracing technologies often lead to incremental improvements in related supply chain management areas and often lead to optimal inventory levels.

Table 46 qualitatively explains general benefits from improved product tracing for all four segments combined. In the sections below the table, segment-specific results are discussed along with segment-specific tables summarizing the percent of pilot respondents who reported realizing each benefit.

Table 46. Key Observations of Pilot Participants Benefits

Benefits	Key Observations
Improved Brand Reputation	• Product tracing systems support decisions impacting brand reputation. Improving product tracing improves decision making ability.
Increased Consumer Confidence	• While product tracing may be considered a normal cost of doing business, not having these capabilities negatively impacts consumer confidence and customer loyalty for many of the firms.
Expanded Markets	• Many firms have become increasingly concerned with their exposure to recall and traceback risks and require trading partners to meet minimum tracing standards. • One pilot participant estimated that their investment in improved product tracing allowed then to establish a business relationship worth an estimated $4 million.
Improved Supply Chain Management	• Improved product tracing allows firms to become more efficient and realize benefits including increased inventory accuracy and visibility that allow firms to meet customer demand in an improved way. • One pilot participant estimated the financial benefit of increased visibility at $200,000.
Insurance Cost Reduction	• Some insurance providers require product tracing capability in order to underwrite certain insurance policies for firms within the food industry.
Supply Chain Confidence	• Firms who improve product tracing often benefit from more efficient recalls. As a result, supply chain participants increasingly requiring improved product tracing performance from trading partners.
Decreased Spoilage	• Improved product tracing often results in better inventory management. Better inventory management allows firms who deal in nondurable goods to realize decreased shrinkage costs. • One pilot participant estimated the shrinkage cost savings at $3,000 a week.
Process Improvement	• Improvements in product tracing often results in decreased error rates, improved selection accuracy, and improved document management. • One pilot participant was able to more effectively manage and maximize their work flow. Some distributors have estimated increased sales of $500,000 - $600,000.

Grower Segment

Growers who have achieved improved product tracing capabilities that allow them to distinguish their products from their competitors, benefit by avoiding disruptions in their operations during an outbreak if their product is not directly implicated. Avoiding disruptions is not only important operationally, but also important in improving brand reputation.

Processor Segment

Much of the benefit experienced by processors participating in the pilots is related to improvements in workflow. In one instance where improving product tracing required upgrades in related systems, one pilot participant described a cost-savings benefit of 3 – 5 employee wages. Another pilot participant described an unintended benefit in document management. This benefit can be measured by improved access to data or the square footage no longer being occupied by physical documents.

Distributor Segment

The pilot participant questionnaire revealed important insights about the distributor segment. Many firms have become increasingly concerned about their exposure to recall risks and require trading partners to meet minimum product tracing standards. One firm estimated that their investment in improved product tracing allowed them to establish a new business relationship worth an estimated $4 million.

Distributors are sensitive to downstream demand from supermarkets and grocery stores. Improvements in product tracing offer enhanced inventory management capability, allowing better information for sales forces, improved pick rates, and decreased inventory shrinkage. One of the pilot participants estimated a combined cost savings and sales increase of $500,000 - $600,000.

Retailer Segment

Retailers reported achieving better inventory management results from improvements related to improved tracing, including increased inventory accuracy, selection efficiency, and visibility.

Percentage of Pilot Participants with Realized Benefits

From the pilot participant questionnaires and discussions, IFT was able to get a sense of which supply chain nodes realize certain benefits from investments in improved product tracing. Table 47 details the results from that analysis and shows the difference across the supply chains:

Table 47. Percentage of Pilot Participants with Realized Benefits

Recordkeeping Benefits	Growers (n=2)	Processor (n=6)	Distributors (n=8)	Retailers (n=4)
Improved Brand Reputation	100%	33%	62%	50%
Increased Consumer Confidence	0%	67%	75%	25%
Expanded Markets	50%	33%	50%	25%
Improved Supply Chain Management	50%	67%	62%	100%
Insurance Cost Reduction	50%	33%	12%	0%
Supply Chain Confidence	0%	83%	75%	25%
Decreased Spoilage	50%	67%	75%	25%
Process Improvement	100%	33%	100%	100%

Percent of Pilot Participants Identifying the Recordkeeping Benefit *If the response to an individual benefit was left blank, it was treated as a "does not identify this benefit" answer in the calculations above.

Small Business Segment

Special outreach was conducted to small growers and other small businesses. The intangible benefits of improved product tracing were seen as better market access, increased consumer confidence and supply chain confidence by these small growers. One small business sourced their products from local farms and delivered them directly to consumers' homes. This company indicated the farm of origin of each product on the customer's receipt. This practice started as a marketing tactic, so customers would have a better connection to the origin of the food that they received. The business eventually saw benefit in collecting and sharing this information for the purposes of product tracing and quality.

Many small businesses saw the implementation of better tracing systems as beneficial, citing several benefits that larger companies cited, including improved pick rates, fewer errors (both in product selection and deliveries), and better control of their product inventory. The quantifiable benefits of improved product tracing were seen as a possible decrease in related insurance costs and/or limitation of direct litigation liability exposure. The most important quantifiable benefit of improved product tracing was seen as the ability to provide customers with specific, real time information that could quickly and accurately ensure proof of exclusion from both a suspected outbreak area and a recall. The ability to respond to both types of investigations was deemed to be equally important. Smaller businesses enjoy very deep direct business-to-consumer relationships with their customers and often need to field a range of questions and concerns directly. The ability to precisely demarcate the boundaries of their specific supply chain/supply constellation from a potential national/regional food scare, even if one step removed to a local store front or food service operation, was seen as a strong incentive to proactively comply with timely demands for compiled internal data during an early stage/informal product tracing investigation.

Public Health Benefits

The public health analysis focused on eight outbreaks described below. For each outbreak, information is provided on:

- the pathogen associated with the outbreak
- investigation description

- potential improvement range from the estimated date of the initiation of the traceback to the estimated date of recall or other intervention
- total illnesses and deaths for the duration of the outbreak.

While this is only a small set of the total number of foodborne outbreaks with a corresponding product intervention, these outbreaks represent a variety of food sources and at least two pathogens for which there is reliable epidemiological data.

With six of the outbreaks illustrated here, the identified food vehicles and the resulting tracebacks focused on a single commodity. For two of them, there were complicating situations that further exacerbated the complexity of the traceback.

For the “peppers and tomatoes” outbreak, the epidemiologic evaluation initially identified tomatoes as a possible food vehicle, so a traceback was initiated for the tomatoes, with a public notification. As the illnesses were continuing after the public notification and the tomato traceback efforts were not yielding clear convergence, other possible food vehicles were considered and tracebacks initiated on jalapeno and serrano peppers (CDC 2008a). FDA has stated there were challenges in the tomato traceback which made it difficult to discern whether these challenges meant a single convergence couldn't be found due to problems with the industry-provided trace data and records or that there was another and/or other food vehicle involved. This demonstrates the importance of both the confidence needed in the traceback but also shows that tracebacks, using quality data and records with linkages, can greatly inform the epidemiology in identifying the possible food vehicles.

In another situation, in which the initial food vehicle identified is a complex or multi-ingredient food, the traceback(s) can take on additional complexity. The initial traceback can identify the complex food and a recall or intervention of that specific complex food can be initiated. If illnesses continue post-intervention, then the source of the contamination must be identified from among the ingredients, as a contaminated ingredient in one complex food may well also be distributed to other locales and used in other complex foods. This is the case with the “red and black pepper spice” outbreak below. The initial epidemiologic and traceback work identified the salami and salami products from a specific processing facility as the implicated food vehicle. The further investigative and traceback efforts to identify which ingredient in the salami product was the cause of the contamination (red and black pepper) added additional time to the public health intervention necessary to remove the contaminated food from commerce and reduce public exposure.

Outbreak Case Study Results for Public Health Analysis

Table 48 shows the results of the public health analysis for eight food outbreak case studies. This information provides a range of associated with each outbreak regarding the average economic impact per day reduction, and maximum economic benefit. For details on how these were calculated, please refer to the Approach and Outreach section above. A sample calculation is also provided in Appendix S.

Table 48. Public Health Benefit Results for Selected Outbreak Case Studies

Case Study	Pathogen	Maximum Illnesses Prevented	Percent of Total Illnesses Prevented	Average Economic Impact per Day Reduction	25% ↓ Time	50% ↓ Time	75% ↓ Time	Maximum Economic Benefit (+100%)
Peppers and tomatoes (2008)	*Salmonella* Saintpaul	790	55%	$277,275	$8M	$12M	$13.6M	$14M
Cantaloupe (2008)	*Salmonella* Litchfield	1	2%	1,053	$18K	$18K	$18K	$18K
Raw alfalfa sprouts (2009)	*Salmonella* Saintpaul	73	31%	$23,758	$465K	$806K	$1.2M	$1.3M
Red and black pepper spice (2010)	*Salmonella* Montevideo	47	17%	$16,496	$286K	$573K	$716K	$841K
Unspecified Mexican food (2010)	*Salmonella* Baildon	2	3%	$1,377	$0	$0	$18K	$36K
Shell eggs (2010)	*Salmonella* Enteritidis	120	3%	$268,500	$537K	$1.1M	$1.6M	$2.1M
Ground turkey* (2011)	*Salmonella* Heidelberg	17	13%	$16,016	$72K	$125K	$179K	$304K
Fresh cantaloupe (July 2011)	*Listeria monocytogenes*	28	19%	$153,440	$219K	$384K	$493K	$767K

*FSIS regulated product

As shown in Table 48, the public health benefit realized by improvements in product tracing is dependent on the particular outbreak. The estimated maximum number of illnesses that could be prevented from rapid tracebacks ranged from 1 to nearly 800 across the eight case studies. This reduction in illnesses represented 2 – 55% of the total illnesses reported for each outbreak. For those illnesses that could be reduced, the estimated costs savings (or average economic impact reduction as titled in the table) was calculated for each day of reduction in traceback time. This per day estimate was then used to calculate a 25, 50, 75 and 100% improvement in the estimated time it took to conduct the traceback investigations for each outbreak above. For example, if a traceback investigation lasted an estimated 4 days, a 25% improvement would imply the traceback took 1 day less to complete. This resulted in a maximum economic benefit ranging from $18K - $14 million. In some outbreaks, such as the 2008 cantaloupe outbreak, there was only one case of Salmonellosis that could have been avoided by a more rapid traceback. In contrast, in the 2008 outbreak involving tomatoes and peppers, more than half of the illnesses occurred after the estimated date of traceback initiation.

When considering the public health benefits stated in the table, it is important to realize that the cost per day is constant at $17,900 for cases of salmonellosis and $27,393 for cases of listeriosis as identified in Table 34. A further refinement would have been to calculate the health outcomes specific to each case associated with each outbreak on each day of the outbreak. Also, the total number of illnesses for which costs (health care costs of mild illnesses, health care costs of severe illnesses, and loss of value of life due to death) are assigned is limited to those illnesses reported through the public health system. That is, the table does not consider illnesses which were not reported. Scallan and others (2011) estimate that for every reported case of Salmonellosis, there are approximately 30 that are not

reported. Therefore, the true public health benefit is larger than indicated in the table. Even without this multiplier, it is clear that great gains in public health can be achieved by improved traceback processes.

Cost of Recommendations

IFT's recommendations to FDA to improve product tracing are discussed fully in Chapter 10. A key recommendation is to require firms to capture KDEs at CTEs. Discussions with pilot participants, as well as IFT's previous work (McEntire and others 2010), show that the ability to capture this information (much of which is already required by BT Act and Perishable Agricultural Commodities Act and their related regulations) already exists and therefore the cost for a basic level of compliance will be minimal.

All 22 pilot participants responding to information on cost indicated that they already have a system in place to capture most of the information, even if this is paper-based. The literature review and PTI case study showed that as technologies are employed to automate data capture and store information in a way that makes it more accessible, costs increase. These costs are related to the size of the firm as well as their role in the supply chain.

Firms creating new products through transformation (and therefore generating new information) include growers, food processors, re-packers, etc. When firms transform or create products, they will need to determine how to relate inputs to outputs. This can be done by paper-based batch logs, whether entered into a spreadsheet later or not, by scanning ingredients used (either bar code or RFID), or through ERP systems. Each of these has a different associated cost, with paper being the least expensive and the implementation of ERP systems being the most expensive.

Firms that handle products but do not transform them (e.g., distributors) need to capture information related to inbound products, track those products as they are stored in a facility and selected for distribution to customers, and capture information related to what is sent outbound. Again, there are various ways for firms to capture and store information.

The costs related to product tracing are generally proportional to the size of the firm; the more product handled by a firm, the more information there is to capture and communicate. For firms that transform products, fixed costs are related to the hardware and software needed to generate and capture track and trace information. Hardware costs may be dependent on firm size, since the more lines of production that exist, the more hardware (e.g., printers to generate bar codes with dynamic data) is needed. Ongoing costs related to labor and materials (e.g., labels for bar codes) are generally proportional to throughput of the facility.

Pilot participants reported that the cost associated with transitioning to a system capable of scanning information (e.g., bar codes) ranged from $125,000 - $4.5 million. This is consistent with the experience reported by firms implementing PTI (which requires the use of GS1 128 bar codes); the reported range of costs was generally from several hundred thousand to a few million dollars.

IFT is not suggesting that FDA mandate that firms must capture track and trace information electronically, but is recommending that when FDA requests information as part of tracing investigations, that firms provide it electronically. IFT does not anticipate that firms will incur any costs to retrieve this information because they are already required to provide this information to FDA as part of the regulations resulting from the BT Act, although the regulations do not specify how the information should be provided or presented to the Agency. However, firms will likely spend additional time sorting through documents and querying systems to extract and compile the appropriate KDEs. There may also be additional time required by a firm to submit this information if a reporting system is developed by FDA. The amount of time required to perform these additional functions (extracting and compiling KDEs and submitting a report to FDA) will depend on the amount of information that FDA has

requested. For example, responding to a request pertaining to one shipment requires less effort than responding to a request related to several months' worth of production.

IFT also recommends that FDA require firms to develop, implement and exercise a product tracing plan. Most firms already have some components of a product tracing plan in that they have documented plans around recalls and crises, and often conduct mock recalls. Additional effort will be required to augment this plan with information specific to traceback, and will likely require the input of quality assurance, information technology, supply chain, procurement, sales, legal, and others within a firm. Resources will also be required to exercise the plans on a regular basis. The amount of time firms invested to participate in the pilots varied. Depending on the scenario, participants reported spending between 4 - 8 total hours, generally involving several individuals within the firm, responding to the IFT requests. However, firms who received more complex requests (e.g., a restaurant chain needing to assemble information for several restaurants) reported expending more effort. In the pilots, IFT planned the scenarios; in a firm-led exercise this planning time would also need to be considered.

IFT also proposes that FDA accept summary-level data. In the pilots, IFT received summary information 15 times (out of a possible 52 times). Pilot participants who were food processors most often provided custom summaries; those in retail and foodservice more commonly used the IFT-provided template. When pilot participants were asked about the cost to provide KDEs in summary form, most firms responded that this would require little additional cost; the highest estimate offered was $10,000.

Comparison with Benefits

FSMA requires that "the public health benefits of imposing additional recordkeeping requirements outweigh the cost of compliance with such requirements." Scallan and others (2011) estimate that there are 48 million cases of foodborne illness annually in the United States. About 5% of cases (2.4 million) are estimated to be associated with outbreaks. Improvements in product tracing have the potential to impact cases associated with outbreaks. IFT explored the benefits to public health by using eight case studies in which data were available allowing the determination of the traceback time (not the total outbreak investigation time, but the time specifically spent on traceback, which IFT feels can be reduced by the implementation of the recommendations in Chapter 10) and the additional illnesses which occurred in that timeframe. The benefits from a 50% reduction in traceback time ranged from $0 - $12 million. Each day's improvement was valued at between $1053 - $277,275 depending on the scale of the outbreak. These sum of these case studies clearly undervalue the public health benefits to product tracing, since many more outbreaks occur than were evaluated. Additionally, Scallan and others (2011) recognize that reported cases (on which the case studies relied) underestimate the total number of cases by a factor of 30 for Salmonella. For these outbreaks, one could arguably multiply the values by 30 to obtain a more realistic view of the real public health benefit.

Challenges and Limitations of Cost Benefit Evaluation

This report is limited by the confines of the pilot environment and relatively minimal access to other industry cost data. Recognizing these limitations, IFT provides this information with the understanding that it would be more refined if there were access to more data and a more robust dataset that provide for larger representation of the food industry supply chain. This report also doesn't consider the benefit to FDA from better tracebacks as this is something FDA can calculate by assessing the resources consumed from previous traceback investigations.

Few firms exclusively invested in improved product tracing as the primary objective. More commonly, firms made more comprehensive or adjacent investments improving supply chain management where product tracing was a byproduct. The limitations in the data provided resulted in the benefit analysis focused on a qualitative assessment around benefits observed from improved product tracing. Industry members who were contacted (either due to their participation in the pilots, as part of the outreach to small businesses, or through other networks such as trade associations) reported difficulty in providing quantitative estimates of costs and benefits because:

- They did not record the costs and/or benefits from recent improvements to their product tracing capabilities.
- They were unable to tease apart the costs and/or benefits specifically related to product tracing from upgrades to their technology.
- They (or their lawyers) did not want the company to go on record with any quantitative costs and benefits data.
- They had some ideas on the costs and benefits received from improving their product tracing system but did not have any quantitative data to justify or backup those claims.

At the same time, there were several reasons why IFT could not summarize the data received from the industry, in a concise table expressing costs and benefits for each segment. These reasons included:

- IFT received qualitative or anecdotal data that was non-numeric.
- IFT received marketing materials instead of actual data.
- IFT was unable to verify or validate the data received through follow up emails or conversations.
- IFT was unable to provide sufficient scientific justifications or explanations for some of the data received.
- Costs and benefits quantified by other researchers and summarized in the literature review were limited in scope and not directly related to IFT's recommendations to FDA.

Summary of Costs and Benefits

Charged by the FDA to "assess the costs and benefits of the methods for rapid and effective tracking and tracing of the selected foods and key ingredients," IFT conducted significant outreach for this study. IFT sought stakeholder input and worked with Auburn University, Deloitte Consulting, and ~50 other panelists to bring in SMEs, pilot and non-pilot industry, several trade associations including PMA, FMI, UFPA, IDFA, NFI, and GMA, technology companies and small businesses.

A literature review was conducted to analyze previously published studies on the costs and benefits of improving recordkeeping and product tracing capabilities. However, there were very few studies that published quantitative costs or benefits. Instead, they described more qualitative characteristics in their observations and analysis. For example, the costs associated with improvements include fixed and variable costs, such as capital equipment, software, consulting, design and implementation, training, labor, materials and impact on speed of business operations. The qualitative benefits associated with

improvements include protection of public health, improved trade, sustainability tracking, limited recall scope, increased market access, quality assurance and supply chain efficiencies. Due to the limited availability of published studies, IFT collected more data through the use of non-peer reviewed case studies and white papers including data from technology solution providers and standards organizations.

IFT identified nine improvement options and asked pilot participants to estimate costs associated with meeting those goals. The first four improvement options revolve around 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.

In terms of the costs needed to reach the goals identified above, the 22 firms who provided data reported the ability for some form of data capture. For those capturing data by hand or who had invested to convert manually captured data to spreadsheets, the cost of this capability ranged between $40 - $350K. In contrast, capturing the same types of data, but doing it by scanning (e.g., a bar code) was reported to be roughly an order of magnitude more expensive, ranging between $125K - $4.5M. This is consistent with the experience reported by firms implementing PTI (which requires the use of GS1 128 bar codes); the reported range of costs was generally from several hundred thousand to a few million dollars.

Many firms reported the ability to capture incoming lot numbers (assuming they were provided), however, the pilot demonstrated that even if this capability exists, it is more likely to be used by processors, especially of multi-ingredient products, compared to others in the supply chain. Therefore, while the estimate to reach this capability ranged from $0 - $150K, IFT expects that implementation of this practice would be more costly, although a focused effort would be required to quantify these costs.

Of all the options presented, the development of a data summary, whereby industry would present the KDEs in a logical fashion that illustrates the internal and external links, was deemed the easiest to achieve in terms of expenditures. Firms generally reported this capability, and where resources were required were never reported to be in excess of $10K annually.

Questions were asked of the pilot participants in an attempt to collect quantitative benefits information in the following eight areas: improved brand reputation, increased consumer confidence, expanded markets, improved supply chain management, decreased insurance costs, increased supply chain confidence, decreased spoilage and improved business processes. The public health benefits were calculated based on an analysis of eight past outbreaks and the ability of improved product tracing to reduce the time for tracebacks, thereby reducing the number of illnesses reported. The cost savings (driven by reductions in illness) resulting from reducing traceback duration by 25, 50, and 75% were calculated. The range of the public health benefit per outbreak spanned $18K to $14M depending on the characteristics of the outbreak.

CHAPTER 8. ASSUMPTIONS AND LIMITATIONS

By definition, a pilot is a test and cannot be inclusive of all factors or circumstances that influence food product tracing. IFT is pleased with how in-depth these pilots were, and recognizes the tremendous effort of everyone involved in the task. Assumptions needed to be made in order to execute the pilots within the given timeframe and budget. Although IFT believes the pilot approach was sound (given that the approach was formulated considering stakeholder input as well as input from the panels), there are very real limitations which must be recognized when considering the results. It is important that the limitations of the pilots are clearly articulated, so that gaps can be filled by researchers in the future.

Assumptions

A key assumption made at the outset was that IFT would be able to secure willing participants who currently comply with the recordkeeping requirements of the BT Act's related regulations. While it can be expected that there are firms that are not keeping adequate records as required by current law, IFT did not attempt to quantify the extent of current non-compliance nor assess the impact this had on the current ability to trace products. Rather, IFT assumed that participants were currently in compliance. Another assumption was that participating firms would follow their normal product tracing practices for the pilot and would communicate to IFT ways in which the response to IFT during the tests differed from their response to regulators. It was important, in the assessment of response time, analysis time, and other factors, that the results be as close as possible to what FDA currently experiences during outbreak investigations and IFT instructed participants to respond as if they were responding to a request from regulatory officials. In a follow up, most firms indicated that they provided a similar response, although some took additional time to remove irrelevant or proprietary information. Others requested extensions due to scheduling conflicts. IFT also assumed that the supply chains identified and firms expressing willingness to participate would provide IFT with requested data upon the launch of the scenarios. However, in a few instances this was not the case, and the individual scenarios describe when these differences occurred.

Limitation: Participants

Given the voluntary, opt-in nature of the pilots, there are necessary limitations to the conclusions that can be drawn. The pilots represent an artificial view of reality, since not every size and type of firm participated, and the pilot environment was not strictly controlled. Participants were actual firms conducting day-to-day business, which may have impacted their ability to participate. Participation was voluntary, which could have biased the results. Those who opted to participate could have been those with greater confidence in their product tracing systems, and may not be representative of the breadth of practices. Certain supply chain segments were under-represented or were not represented at all. Although brokers were identified as supply chain partners by some participants, this occurred very late in the process and brokers were not engaged. Small operators, especially small, independent restaurants, did not participate. Distributors and wholesalers were asked if any of their small retail/foodservice customers would participate but these participants did not agree to participate.

Limitation: Known, Predictable Supply Chains with Advance Knowledge

The supply chains in the pilots were generally known. Although there were some surprises as the pilots were conducted, IFT had advance knowledge of who supply chain participants were and who the "one back" firm should be. The correct contact persons within the food companies were known. Again, due to the fact that IFT had worked extensively with most participants to get them to agree to participate and

understand their practices, when IFT needed to reach through the supply chain, IFT already knew the appropriate company contact, and in many cases had several. This is in stark contrast to the situation that traceback investigators, especially at the federal level, are generally in.

Limitation: Limited Industries, Supply Chain Characteristics Explored

The pilots were more focused and narrow in scope than during an outbreak investigation when the item is not known. With an item unknown, a traceback would likely include several products/SKUs and identify multiple potential raw materials with different lots to further investigate. Additionally, in accordance with the task, the pilots focused more on traceback rather than traceforward. Particularly in the event of ingredient-driven investigations, the traceforward component can be substantial and complex. In some scenarios, IFT requested traceforward information to determine the breadth of distribution of products of interest; however, the recipients were rarely participants in the pilot and IFT generally received only the number of customers or shipments, rather than the actual contacts that would have permitted the pursuit of a comprehensive traceforward.

Because FSMA Section 204 restricts FDA from requiring additional records for foods not designated "high risk" (which has not yet been determined) and because FSMA specifies that the pilots focus on foods that were the subject of significant outbreaks, FDA should consider how the foods ultimately identified as "high risk" may differ from those explored in the pilot with respect to challenges in product tracing. IFT is aware that in some instances, brokers may purchase foods or ingredients from several different suppliers, but not convey the information about the original supplier when the material is sent to the manufacturer. IFT received other reports that brokers served an important function in maintaining product tracing information and generally took that responsibility seriously. Nevertheless, brokers were perhaps the most notable type of supply chain participant absent from the pilots.

In the pilots, none of the scenarios had rework/salvage in the implicated product. This is not applicable in the instance of tomatoes but it is highly relevant in the world of processed foods and ingredients. Based on IFT's previous work (McEntire et al 2010), most firms reported treating and tracking rework as a separate ingredient. Still, this can make the traceback to the original lot more complicated and implicate multiple lots.

Limitation: Identifying Convergence

Limited participation limited the opportunities for convergence. The purpose of a traceback investigation is to find a common supply chain point from the path of point of sale/service toward the grower/raw material source. In these pilots, although numerous companies participated, they were not generally related to each other in such a way that enabled IFT to probe multiple, unrelated restaurants and grocery store chains and identify a single common source of product to these locations. Although this was explored to a limited extent in the pilots (both in identifying convergence of tomatoes initially assumed to be provided by two different growers, and identifying a common lot of crushed red pepper in two different processed food products), it was thought that a rigorous evaluation of recordkeeping practices and information sharing, and improvements in these areas, would by definition allow for more rapid convergence during an investigation (if convergence did indeed exist).

Collaboration Platform Limitations

Since these were only pilot projects, there are several limitations and assumptions that were made during the evaluation of the collaboration platforms. These are:

- Nearly all technology solution providers in the quantitative study had developed their solutions with industry as an end-user. However, the pilots required them to tweak their systems to enable FDA as an end-user of the system. This created some challenges when dealing with data security and sharing of relevant information across the entire supply chain (if seen from the industry perspective).
- Due to a tight timeline, the technology solution providers had limited time to work with the blinded raw data and feed it into their system. Realistically, they would have more time to establish protocols with the FDA on data import and access.
- The voluntary nature of participation in the pilots caused the collaboration platforms to identify significant gaps in the supply chain. In some cases, these gaps should not be misconstrued as poor recordkeeping practices within the industry, but as gaps in participation in the pilots.
- While about 44 technology companies were evaluated between the two studies (qualitative and quantitative), IFT acknowledges that there are many more which exist that may not be well represented within the sample.
- The studies were intentionally designed to extract themes and characteristics from the participating technology solution providers. The goal was not to compare one against another in an effort to prevent the perception of endorsement or critique of a select few technologies.
- IFT hopes that based on the observations and recommendations within this section of the document, FDA has a much clearer roadmap on how best to include the use of a collaboration platform in traceback investigations. Clearly there are several approaches to meeting the same objectives. IFT has attempted to be less prescriptive in the recommendations presented, to enable a more flexible approach to adoption.

Small Business

As mentioned, the pilots compiled data taken from a very small sample size which did not accurately reflect the makeup of the industry, and did not include a sufficient number of small growers to properly represent the potential challenges in the landscape.

Operations within some small businesses can include constellations of independent contractors or loose “dotted line” entity relationships bound together by operating agreements (or handshakes). Accordingly, recordkeeping accountability is dispersed over several nodes and pre-emptive measures can prove challenging due to the lack of transparency and reporting.

Cost and Benefit Calculation Limitations

As noted in Chapter 7, this report is limited by the confines of the pilot environment and relatively minimal access to other industry cost data. There are surprisingly few reports of the costs and benefits associated with product tracing that are applicable to these pilots; those in existence are generally very narrow in scope and consider very specific technology changes.

This report provides results in the form of ranges and estimates for specific costs and benefits associated with particular types of systems or technology options for improving product tracing. This report does not provide average industry-wide costs or benefits and should be viewed as information that offers baseline context for future analyses and detailed discussions of cost drivers and benefit factors.

The public health benefit analysis is similarly limited due to a lack of available data to accurately extrapolate results to society beyond the limited range of illnesses selected for analysis. Recognizing these limitations, IFT provides this information with the understanding that there may be an opportunity

for further refinement given access to more data and more robust datasets that provide for larger representation of the food industry supply chain participants.

While it was difficult to convince participating firms to provide cost information, it was virtually impossible for most firms to assign dollar values to the benefits derived from improved recordkeeping.

Chapter Summary

By definition, a pilot is a test and cannot be inclusive of all factors or circumstances that influence food product tracing. For example, IFT did not attempt to quantify the extent of current non-compliance nor assess the impact this had on the current ability to trace products. The pilots represent an artificial view of reality, since not every size and type of firm participated, and the pilot environment was not strictly controlled. Another limitation was that the supply chains in the pilots were generally known by IFT prior to the initiation of the pilots. This is in stark contrast to the situation in a traceback investigation by FDA. Similarly, the pilots were more focused and narrow in scope than during an outbreak investigation when the violative food item is not known. There was also limited participation by certain segments of the industry, such as brokers and small businesses. In these pilots, although the number of participants was vast, they were not generally related to each other in such a way that enabled IFT to look for convergence by probing multiple, unrelated restaurants and grocery store chains and identify a single common source of product to these locations. When it came to the evaluation of collaboration platforms, IFT attempted to be less prescriptive in our recommendations to enable a more flexible approach to adoption. This part of the pilot project was intentionally designed to extract themes and characteristics from the participating technology solution providers. There are also surprisingly few reports of the costs and benefits associated with product tracing that are applicable to these pilots; those in existence are generally very narrow in scope and consider very specific technology changes.

CHAPTER 9. CURRENT DOMESTIC AND GLOBAL TRACING INITIATIVES AND PRACTICES

Although the number of participating firms exceeded the number engaged in most "pilot" endeavors, it still represents an extremely limited view of the "food industry", as noted in the chapter above. The pilots focused on very specific foods, and as part of IFT's charge in this task, IFT explored and evaluated other domestic and international product tracing practices. This was done by both visiting a number of facilities and by examining the product tracing initiatives in existence and in development in the United States, as well as those that have a global scope.

Site Visits

In support of the task, IFT and IFT representatives visited several facilities, including both companies who actively participated as pilot participants, as well as those who did not. In many cases these visits were "add-ons" to existing travel in order to maximize efficiency and economy. Table 49 lists the nature of the visits, which provided first hand insight into how tracing is practiced.

Through these visits IFT 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 the those studied in the pilots.

Table 49. IFT and IFT Representatives Site Visits

Date	Establishment type	Key findings
12/9/11	Retail distribution center	Making major, long term investment in inventory management system
12/13/11	Produce distributor	N/A
1/10/12	Ingredient manufacturer, importer	Very sophisticated tracking systems in use
1/11/12	Produce wholesalers	Other food safety concerns take priority over tracing issues
1/11/12	Produce fresh cut processor	Applies own bar codes and uses them to associate product input with output
1/17/12	Produce distributor	Applies and tracks internal pallet identification system
1/18/12	Grower, Packer	Ability to track till the field level using internal coding systems. Ability to link incoming to outgoing at packing house
1/18/12	Produce distributor	Visibility to their farms by two different tracing systems
1/19/12	Food service retailer	Visibility and control over supply chain; requires DC to maintain records
1/19/12	Produce distributor	N/A
1/19/12	Produce distributor	N/A
1/19/12	Grower, Packer	Internal batching/coding system; not linking incoming to outgoing
1/20/12	Distribution Center	Small quantities, deals in cases not pallets, FIFO, uses technology/software to maintain link between incoming to outgoing
1/27/12	Foodservice DC	N/A
2/6/12	Fluid milk and juice processing plant	Consumer unit containers labeled with date; cases use bar code but often fall off
3/7/12	Tomato re-packer	Uses commercial software with paper backup to track re-packing-only repacks within lots, even if small runs. More specific lot info provided by most growers than captured at receipt

Grain and Animal Feed

IFT also sought information on parts of the food system identified as potentially facing other tracing-related issues, such as bulk grains and animal feed. FDA's authority to regulate both human and animal foods is increased by FSMA. The 2010 IFT study (McEntire and others) sought input on tracing practices from three members of the animal feed industry. In this study, IFT again sought to determine the state of tracing in this industry, and in fact, considered whether an animal food product should be evaluated through the pilot. In 2007 the risks associated with pet food reached the public view when melamine (combined with cyanuric acid) was used to give the appearance these products contain a higher level of protein than they actually do for economic benefit (FDA 2010b). More recently, a number of other hazards, including *Salmonella*, have resulted in recalls (CDC 2011d).

IFT was proactively contacted regarding product tracing issues associated with animal food and feed. A university working with the grain industry sought information regarding the pilot methodology and will be conducting a pilot related to bulk grains. Bulk grains and other bulk products pose a difficult issue in product tracing, because multiple sources and lots of ingredients are commingled, commonly in very large containers. The ingredients in these containers can be used for many months, making it difficult to determine exactly which lots were used in all outgoing products. The bulk grain industry sees the need for collaboration and sharing of "best practices" in product tracing. Many firms in this industry are putting an emphasis on educating their staff on the importance of recording product tracing data and emptying tanks as often as possible. Emptying holding tanks can be very beneficial for product tracing since it provides a definitive point indicating whether or not a specific lot of ingredients was in the tank on certain dates.

A company that manufactures both human food and animal feed also contacted IFT to gain insights into how product tracing could be managed and to share information regarding some of the unique challenges associated with the animal feed industry.

The U.S. animal food industry is very diverse. FDA's BSE inspection database lists approximately 6,600 feed mill, protein blenders, and rendering facilities (FDA 2012c). In addition there are hundreds of other facilities that supply ingredients to the industry. The companies involved range from those that operate single locations to others that have multi-national operations.

The National Grain and Feed Association (NGFA) has made extensive efforts to inform their members within the grain and feed industry about FDA's recordkeeping requirements established under the Bioterrorism Preparedness and Response Act of 2002. The NGFA FDA Recordkeeping Bioterrorism Guidance document provides comprehensive guidance on how the recordkeeping requirements apply to companies involved in grain handling, grain processing and feed manufacturing (NGFA 2012). The association indicated that they will be updating the document in the near future to reflect the recent changes in FDA's authority to access food records. It is felt that there is a good level of knowledge within the industry about the recordkeeping obligations. In addition to the efforts made by trade associations to ensure members are informed as well as the information provided by regulators during inspections (many feed mills produce medicated feeds and are regularly inspected), commercial demands made by customers arguably have been the biggest driver in promoting knowledge about recordkeeping requirements. When entering into purchase agreements and commercial contracts, buyers want assurances from their suppliers that they have recordkeeping systems in place that meet legal requirements and provide the ability to accurately trace information about products in the event of a food safety incident. However, just like within any industry sector, there likely are some firms that need more awareness and education.

Grain and feed products are handled in bulk and are commingled by nature. Because of this, there typically are multiple sources of inbound products that are represented within a given outbound shipment of finished product. Under the Bioterrorism Act's recordkeeping requirements, firms must be able to identify the immediate previous sources and the immediate subsequent recipients of food, including packaging. The regulations within 21 CFR Part 1, Subpart J, section 1.345(b) indicate that records must include "reasonably available" information for the specific source of each ingredient used to make every lot of finished product (FDA 2004). However, tracing across entire supply chains, especially where commingling occurs at multiple facilities and at various steps in the manufacturing process, is complex, as the scope of potential ingredient sources in a finished product can be very broad.

Like many manufactured human foods, animal feed may contain many ingredients. In addition to vitamins and grains, animal feed may also contain rendered products as well as ingredients that are diverted from human food streams. This introduces a great deal of complexity.

Like other food industries, firms handling grain and feed are establishing and maintaining required records in a variety of ways. Some firms manually create paper records, maintain electronic records or use a combination of both methods. Others utilize software systems to help trace products. In addition, many firms have implemented management practices to help limit the scope of "immediate previous sources" that could be present within an outbound shipment should there be a potential food safety-related issue. Some of these management practices include: 1) enhanced documentation of the flow of commodities from bins to holding tanks to shipping bins to conveyances; and 2) keeping records of when specific bins are emptied, which establish a "reset" point for the immediate previous sources that may be present within the given bin.

For animal feed facilities that also handle inbound products in packaged form, some companies are using bar coding systems to track the packaged ingredients that are represented in final products. In addition, there is generally high awareness within the feed industry about the obligation to be able to identify the lot numbers of ingredients (if they exist) to the lots of finished products produced. As previously mentioned, some firms establish and maintain these records through software and technology systems, manually create and maintain paper records or use a combination of both methods.

Tracing Practices within Small Firms

In addition, because the task required IFT to consider the practices, needs, and limitations of small businesses, IFT conducted targeted outreach to this community. There was a common overall sentiment that small businesses understood that product tracing was important, and that they should be accountable for their products so as not to "break the chain." However, some a few small growers did not feel any pressure to capture track and trace information and did not think that their suppliers believed that this information was important.

Small growers who went through the process of becoming certified as organic commonly had more mature systems for inventory and product tracing. Lot numbering was very important to their company, and they were able to easily assign lot numbers to their products based on physical block and product variety. Blocks were regularly picked all at one time by variety. The way that lots are indicated on the products ranged greatly, with companies using handwritten codes, stickers, scan-able bar codes, and other methods. Some small growers indicated that using less mature lot identification facilitated their change in starting to capture and record lot numbers. Some of these growers also indicated that they had previously tracked product on their farms by block to determine what fields had good yield and

good product quality, for future growing. Thus, there were business drivers to being able to associate products with a particular area of harvest.

Sometimes small distributors stated that they do not capture the lot numbers that are provided to them from their suppliers, but did not feel inclined to do so because they only used one supplier per item. Similarly, some small growers did not feel the need to include certain information (pick dates, field numbers, etc.) because they work with such a small amount of product or acreage.

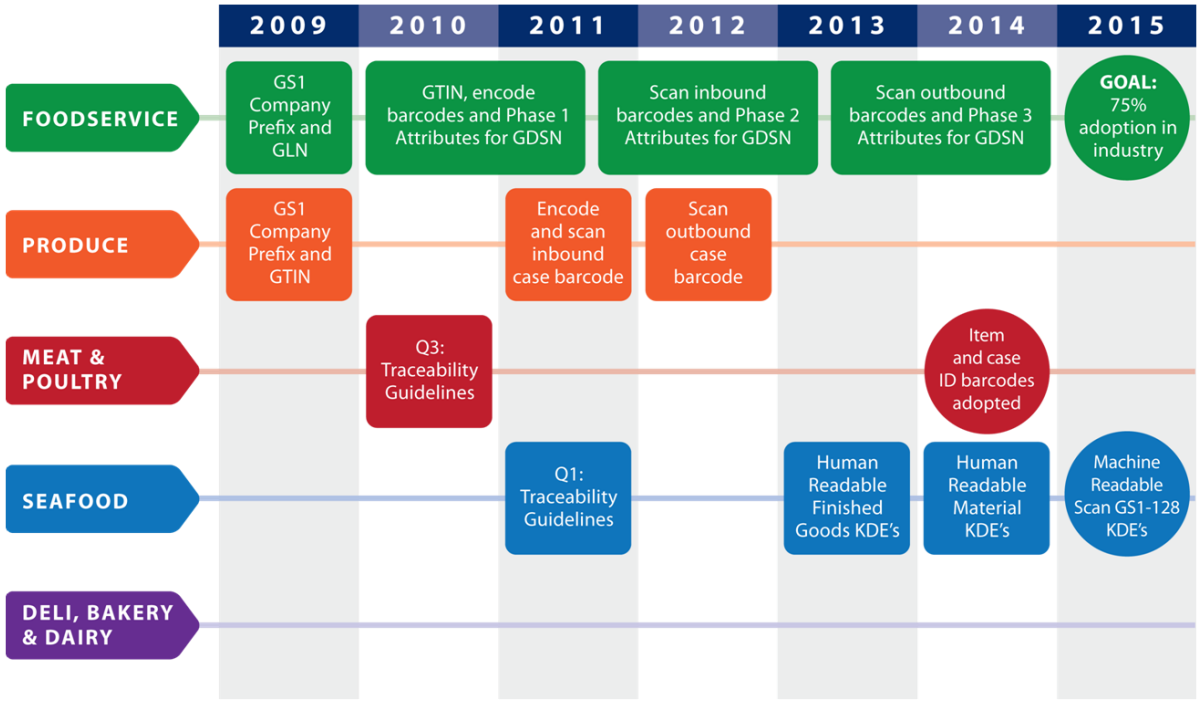
Domestic Tracing Initiatives

Several sectors within the food industry in the United States are proceeding on independent yet parallel paths toward improving product tracing in their supply chains. One common element in these various product tracing efforts is the use of GS1 Standards—the most widely used system in the world, with 1.5 million businesses using the standards to identify, capture and share product information within their own facilities and as products move from trading partner to trading partner to consumer (GS1 2012).

The need for standards is often mentioned when barriers to product tracing are discussed. While several systems of standards exist, and IFT reported on the various types of standards that could be used to express individual key data elements (McEntire and others 2010), the detail provided about GS1 Standards is necessary because so many segments of the food industry have already committed to the use of some of the GS1 standards. Currently GS1 US has approximately 103,500 member companies within the food industry (GS1 2012).

Figure 42 identifies the various industries that have programs in place and summarizes their key implementation milestones. It should be noted that just because milestones are identified, they are not always hit. In fact, when evaluating the adoption of the various initiatives by different segments of the supply chain, IFT often hears that the industry is hesitant to move forward due to the concern that FDA requirements will ultimately be inconsistent with these initiatives. Each initiative is discussed in more detail below.

Figure 42. US Industry-Specific Programs for Product Tracing (GS1 2012)



Integrating product tracing across the food industry is attainable based on the processes already in place and used by many supply chain participants in fresh food categories, foodservice, as well as consumer packaged goods and retail. While these efforts are largely centered in the United States, they incorporate global processes and organizations and are designed for global adoption and use.

To achieve product tracing throughout the supply chain, trading partners must be able to link products with locations and times through the supply chain. For this purpose, the work led by the Institute of Food Technologists (McEntire and others 2010) described two foundational concepts: Critical Tracking Events (CTEs) and Key Data Elements (KDEs).

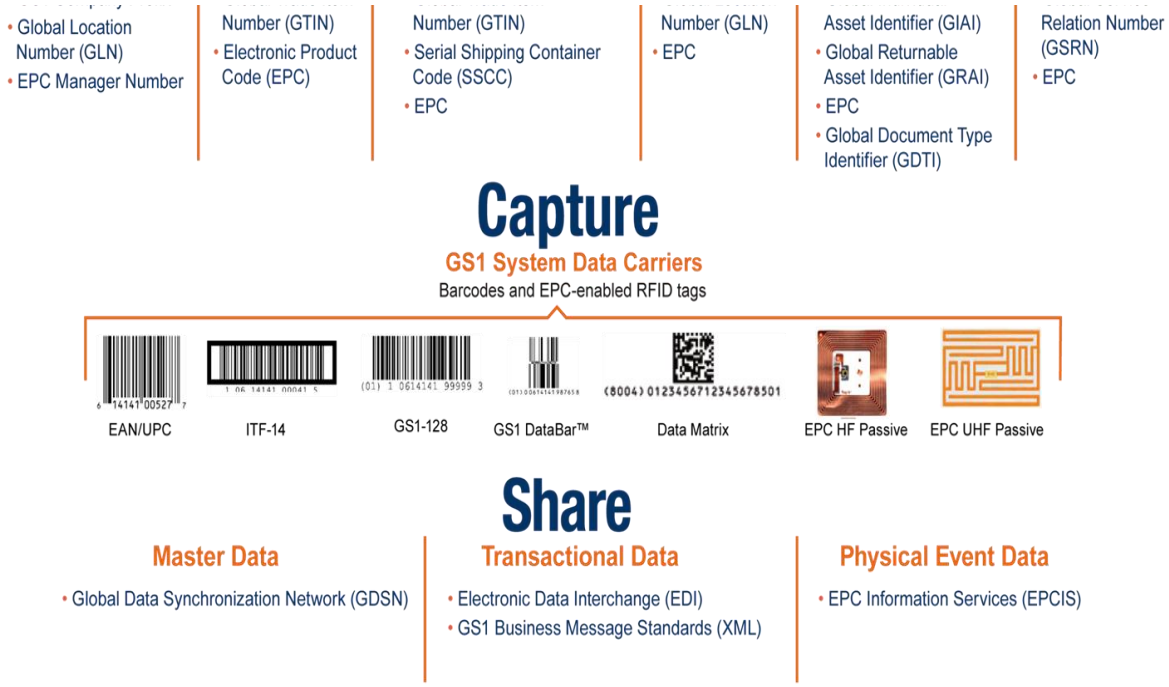
To most efficiently identify, trace and track CTEs and KDEs and share this information with multiple parties, businesses are already using a single, global, open system of supply chain standards. The GS1 System is an integrated suite of global standards that provides supply chain visibility through the accurate identification, capturing and sharing of information regarding products, locations, assets and services, as shown in Figure 43 (GS1 2012). Using GS1 identification numbers, companies and organizations around the world are able to globally and uniquely identify physical entities like trade items, physical locations, assets and logistic units as well as less-tangible things like corporations or a service relationship between a distributor and an operator. This provides the foundation for solutions and tools and allows interoperability by using a common language between trading partners in the global supply chain.

Each of the industry initiatives leverages this GS1 identification system to share standardized information such as product master data, transactional data and/or physical event information, so that

the connection is made between these physical or less-tangible items and the information the supply chain needs about them. These are the foundational elements supporting CTEs and KDEs.

It's a powerful three-step process. First, companies must identify products and locations using a standardized numbering system. Second, companies must capture the standardized identification in a common approach, that is, bar codes and/or electronic product code (EPC)-enabled radio frequency identification (RFID) tags. Third, once companies are using a common language to identify and capture product data, they can share the information in a standardized format, ensuring data completeness and accuracy.

Figure 43. GS1 System of Standards (GS1 2012)



PRODUCE TRACEABILITY INITIATIVE (PTI)

The Produce Traceability Initiative (PTI) is the most wide-reaching voluntary industry initiative working towards case-level product tracing and improved food safety (PMA 2012). It is governed by a 34-member Leadership Council representing all facets of the produce supply chain. The PTI promotes and facilitates whole-chain tracing by developing best practices in a collaborative environment to help supply chain participants link their internal tracing processes with external systems. The work is carried out by volunteer-led working groups in the areas of implementation, master data, technology, and communications and is administered by the Canadian Produce Marketing Association (CPMA), the Produce Marketing Association (PMA), the United Fresh Produce Association (UFPA), and GS1 US (PMA

2012). The original PTI group convened in 2007, reaffirmed its goals in 2009, and set a 7-step milestone schedule to guide the produce industry move towards its product tracing goals (PMA 2012). Again, adoption has not been universal as the industry weighs the costs against the expected federal regulations.

Companies following PTI recommendations track products at the lot level with identification at the case-level. The GS1 Global Trade Item Numbers and corresponding Batch/Lot Numbers are encoded into bar codes (GS1-128) for case identification to ensure consistency and accuracy, and to prevent errors caused by cross referencing and/or translation. PTI chose GS1 Standards as the common language for product identification, data capture and sharing, since GTINs and their corresponding Batch/Lot Numbers are used ubiquitously across other fresh food categories as the key to product tracing. Having the ability to identify potentially harmful products by GTIN and Batch/Lot Numbers has been shown to reduce cost for suppliers in case of product withdrawals and recalls.

Step by step, the produce industry is moving forward by allowing trading partners to tie their internal product tracing systems to an external system with standardized data and supply chain processes. That said, adoption has not been universal as the industry weighs the costs against the expected federal regulations.

A large majority of industry participants have their GS1 Company Prefix (Milestone 1) and have created GTINs (unique identification) for their case configurations (Milestone 2). Relative to communicating GTINs to trading partners (Milestone 3), the initiative recommends sharing this data via a spreadsheet at the start, given that a higher percentage of industry readiness is needed to be able to communicate with synchronization tools.

Many growers/shippers have most of the information needed for printing human readable information onto cases (Milestone 4).

All of the larger grower/shippers have Milestone 5 completed which prescribes encoding GTIN and Batch/Lot Numbers in a bar code (GS1-128). As of April 2012, PTI is in the process of conducting a survey to help gauge implementation levels. A study by a major foodservice distributor in the last year found that over 80% of produce cases did not have any kind of bar code. Industry consensus is that more and more suppliers are ready to move forward as soon as the buyer community signals their readiness. Similarly to the previous milestone, reading and storing inbound case information (Milestone 6) is expected to speed up once the buyer community communicates to the supplier community that case labels are needed. The same is true for the final milestone of PTI which requires reading and storing inbound case information.

FDA regulations and buyer/government requirements are believed to be the most powerful forces influencing even broader adoption of product tracing standards in the produce industry. It is anticipated that produce companies will speed up adoption once FDA publishes its new regulations, provided that they are in concert with the PTI requirements. Buyer requirements for using case labels will also go a long way in extending the reach of PTI.

Note that the produce industry is behind in supply chain efficiencies compared to consumer packaged goods. While the cost of implementation is always a concern, there are inexpensive systems available today to aid with adoption. In addition, the PTI has been able to demonstrate many benefits in efficiency improvements, cost reductions and even improved opportunities for higher sales and better brand recognition for products, suppliers, and retail stores. Some of these examples are described in the PTI case study provided in Chapter 7.

PTI working groups have compiled a significant repository of best practices and key learnings that are readily available to the entire produce industry. These educational and reference materials are helping companies proceed along the milestones with expert guidance and industry-tested advice in a collaborative environment of information sharing. Other fresh food categories consider the PTI approach—which is based on GS1 Standards and the interoperability they provide—as a good example and model for product tracing implementation and a feasible way to improve food safety along the supply chain.

Seafood

In March 2011 at the International Boston Seafood Show, the National Fisheries Institute released "Traceability for Seafood, US Implementation Guide" (NFI 2010). The purpose of the Guide is to provide a framework to the seafood industry on information and processes to support product tracing based upon industry identified best practices. The Guide is intended primarily as a product tracing tool that can be used for both food safety and sustainability. NFI affirmed the requirements of the Bioterrorism Act but prepared a document that allows for a broader approach to product tracing throughout the supply chain, especially in light of anticipated regulations from FDA. The document, which NFI has made available free of charge to members and non members, has been downloaded over 900 times.

The NFI document was patterned after the "mpXML," "Traceability for Meat and Poultry, US Implementation Guide (MPXML 2010)" and endorses the use of GS 1 standards. The document quickly became a valued reference on product tracing by the Institute of Shortening and Edible Oils (ISEO), Fisheries Council of Canada, Fisheries and Oceans (Government of Canada), and the International Dairy-Deli-Bakery Association.

NFI's goal is for its members to be compliant in the GS 1 Global Trade Identification Numbers (GTINs) for finished goods by early 2014 and for raw materials and packaging by early 2015. Because of the global nature of seafood procurement, NFI expects the Guide to be adopted by overseas suppliers.

Meat and Poultry

Within the US meat and poultry supply chain, industry coordination of product tracing has been led by the Meat and Poultry Business Data Standards organization, known as mpXML. In June 2010, this non-profit data standards organization defined key product tracing concepts and implementation guidance for the US supply chain by issuing the "Traceability for Meat and Poultry U.S. Implementation Guide (MPXML 2010)." The guide, endorsed by numerous meat and poultry associations, was developed by industry representatives from the US meat and poultry supply chain to document minimum and best practices for product tracing. Because the development of the guide was undertaken by mpXML members and industry supply chain experts, the USDA Food Safety Inspection Service was not an official participant in the development process.

The Traceability for Meat and Poultry U.S. Implementation Guide provides guidance for enabling product tracing from supplier to the grocery retail point of sale. The document addresses both human readable and electronic information capture of key product attributes and endorsed the Critical Tracking Events approach to managing product tracing. Adoption of common product tracing standards is emphasized for the timely and accurate communication of product tracing information. The meat and poultry industry is a very fragmented industry comprised of small independent companies and large corporations. Therefore, the need to define consistent practices for identifying products, labelling packages, and sharing product tracing data that can be managed by all companies regardless of size is critical for effective product tracing.

The guide reflects the US meat and poultry industry's clear preference for using GS1 logistical standards to facilitate the adoption of product tracing processes and procedures. GS1 standards are used for product and location identification, encoding key product tracing data on package label bar codes for hand-gun scanning, and for creating electronic EDI messages to send product tracing data to trading parties. The use of the X12 EDI Advance Ship Notice (856) was encouraged as a best practice for electronically sharing product tracing information. The use of GS1 bar codes at the consumer points of sale was also encouraged as a best practice. The guide notes that in January 2014, a new GS1 DataBar™ bar code format will provide for expanded data to be captured at point of sale, such as the GTIN, batch/lot number, and product expiration dates. With the DataBar, retailers will be able to automate the capture of all critical product tracing data for the consumer sale transaction event.

Members of the meat and poultry supply chain are now aware of the requirements needed to design and implement product tracing processes and systems. Some mpXML members have already leveraged this guidance to develop their own internal product tracing systems and are positioned to capture, store, and share the critical product information necessary to support one up and one down product tracing. Implementation milestones have not been established for meat and poultry as they were by the produce supply chain, in part because the standard business practices of meat suppliers already comply with minimum requirements for product tracing. Further definition of CTEs and KDEs is necessary before defining implementation milestones for the entire meat and poultry supply chain, including products created or sold by suppliers, processors, distributors, foodservice operators, and grocery retailers.

As a consequence of needing defined CTEs and KDEs to establish implementation milestones and the global nature of the meat supply chain, mpXML is working with GS1 US, GS1 Canada, and GS1 Mexico to expand implementation guidance on the precise use of critical tracking events and key data elements for all of North America. Drafting of this North American guide has begun, with a planned release date in 2013.

Dairy, Deli and Bakery

The FDA Food Safety Modernization Act (FSMA) has brought the need to align all fresh food categories in terms of product tracing to the forefront for the entire food industry. The International Dairy, Deli & Bakery Association (IDDBA), the International Dairy Foods Association (IDFA) and GS1 US are working closely together to help move these fresh food sectors to broader adoption of standardized product and location identification, data capture and information sharing processes—with the ultimate goal of further enhancing food safety for consumers. These three organizations representing all supply chain roles are collaborating to produce a Product tracing Guide for the Dairy, Deli, & Bakery industries in the United States with an anticipated publication date of June 2012.

Inspired by the progress already made in other fresh food categories, the product tracing work in the dairy, deli and bakery segments aims to build on the foundational principles of Critical Tracking Events and Key Data Elements as defined by the Institute of Food Technologists. In addition to incorporating regulatory requirements and taking into account best practices from other segments (i.e.Produce Traceability Initiative, mpXML for meat and poultry, National Fisheries Institute for seafood), this industry effort also emphasizes the already proven and potential industry benefits of product tracing. These include enhancing consumer confidence, improved inventory management, and increased order accuracy (IDDBA 2008).

In the process of developing the guide, the three organizations are soliciting industry input and feedback to help define the various supply chain roles necessary to validate business processes, product flow, and product data needed for exchanging product tracing information up and down the supply chain. The main objective of the document is to aid in the adoption of consistent business practices to effectively

manage product tracing for the Dairy, Deli, & Bakery industry in alignment with other fresh food categories and the broader food industry. It will provide additional detail referenced in *Industry Roadmap: Building the Fresh Foods Supply Chain of the Future* (IDDBA 2008).

The new guide is expected to address product tracing practices from the processing facility to the point of consumer sale or consumption; including all U.S. distribution channel participants, processors, suppliers, importers, exporters, wholesalers, distributors, food retailers, foodservice operators, and 3rd party providers. Industry stakeholders already agree that the recommended guidance will be based on GS1 global standards for supply chain management and product identification. These standards are already used successfully in other fresh food categories, and the dairy, deli, and bakery segments are poised to build on existing knowledge and experience and identify their own best practices in alignment with the rest of the food industry with benefits to all stakeholders.

FOODSERVICE

GS1 US launched the Foodservice GS1 US Standards Initiative in October 2009 in partnership with the International Foodservice Distributors Association (IFDA), the International Foodservice Manufacturers Association (IFMA), and the National Restaurant Association, along with 55 leading manufacturer, distributor, and operator companies (GS1US 2012b). Their goal was to drive waste out of the foodservice supply chain, improve product information and establish a common foundation for food safety through better product tracing. Today, with more than 80 foodservice manufacturers, distributors, operators, associations, and others as members leading the Initiative, over 1900 trading partners are not subscribers to Global Data Synchronization Network (GDSN), representing 55 percent of the foodservice industry's manufacturers (by revenue) and 45 percent of distributors (by revenue) currently implementing GS1 Standards to meet these goals.

The FDA Food Safety Modernization Act (FSMA) and other related regulations —plus a growing consumer demand for more and better nutritional and allergen product information—are all driving the foodservice sector to use a standards-based system for accurate and timely product information. Stakeholders in the foodservice supply chain are seeing multiple benefits from using the GS1 System of Standards for product and location identification and data sharing processes, much like the grocery and retail industries have realized from using the same in their operations for decades.

The implementation of GS1 Standards improves product tracing, from the operator all the way back to the distributor, manufacturer, processing plants and ultimately, the farm. With GS1 Standards, restaurant owners and managers are able to maintain more accurate, comprehensive records of their purchases, deliveries and inventories. This is an important element in being able to react faster to recall and outbreak situations. If a recall occurs, restaurants can look back at their own systems to verify if they received the potentially harmful product or not.

The Initiative—with the use of GS1 Standards—provides a common platform for structuring and sharing product information globally. GS1 Standards used in the foodservice industry include Global Location Numbers (GLNs) for location identification, Global Trade Item Numbers (GTINs) for product identification, the use of bar codes (GS1-128) for data capture and the utilization of the GDSN for the sharing of product data attributes. The number of foodservice companies subscribing to the GDSN has grown tenfold since the start of the Initiative–from 191 in 2009 to 1,924 today (GS1US 2012b).

To guide adoption and usage of standards that support product tracing, the Initiative through several working groups has developed foodservice-specific implementation guides, identified foodservice workflow scenarios within the GDSN, and defined key product data attributes relevant to the foodservice industry.

IFT Traceability Improvement Initiative

In summer 2011, the Institute of Food Technologists (IFT) initiated its Traceability improvement initiative (TII) to leverage its leadership position to bring together all stakeholders and discuss challenges and opportunities in food product tracing. TII is funded by BASF The Chemical Company at the gold level, Underwriters Laboratories (UL) at the gold level and the National Fisheries Institute (NFI) Fisheries Scholarship Fund at the silver level.

Through TII, IFT held three product tracing research summits in fall 2011, where representatives from the industry, trade associations, non-profits, consumer groups, academia, technology solution providers, standards organizations as well as federal (FDA, USDA FSIS and AMS) and state regulatory agencies exchanged ideas and knowledge through their own perspectives. The first summit focused the discussions on what the vision for product tracing should be, in an effort to bring consensus around the goals and objectives of a real product tracing system. Before delving into a discussion on how to achieve the vision identified in the first summit, the second summit sought to provide an overview of all the current on-going product tracing initiatives across multiple food sectors and stakeholders. An in-depth discussion around multiple approaches to improving the current state of product tracing highlighted the costs and benefits of each approach, along with a real sense of the feasibility of adoption and expectations from the industry and regulators to work collaboratively. Following the second summit, a working group composed of some members of the summit attendees took upon themselves the task of refining product tracing-related critical tracking events (CTE) and key data elements (KDE) that would be shared with the regulators in the event of an outbreak. The concept of CTEs and KDEs evolved from IFT's product tracing report to the FDA in 2009, which was consequently codified by mpXML and widely accepted by the industry. The third summit presented the refined CTE and KDE tracking template with the larger group of attendees and sought feedback on further improvements. Another important accomplishment from the third summit was the development of a glossary of terms to ensure all stakeholders were referring to the same concepts using the same terminologies and prevent any miscommunication. Recognizing FDA's authority under FSMA to require additional recordkeeping for high-risk foods, the summit participants felt strongly that the food industry should coordinate efforts to take a leadership role and be positioned to contribute and respond to any rules or guidance around product tracing.

The Initiative also partly funds a National Center for Food Protection and Defense (NCFPD) grant that is evaluating the characteristics and capabilities of food product tracing technology solutions. More specifically, it is recognizing the need for technology solutions to have the ability to interoperate – in other words – the ability to share product tracing-related data with one another in the event of an FDA investigation. Interoperability becomes especially important with the reality that there will never be one technology solution provider that will collect and store the product tracing data of the global food system. This study, slated to be completed in the fall 2012, is a forward thinking exercise since it does not bind the technology solution providers to existing regulatory structures, but rather encourages them to use technology to demonstrate a proof of concept on how food product tracing can be significantly enhanced without compromising confidentiality and privacy demanded by the food industry. TII also funds the creation and dissemination of publications and articles to provide food system stakeholders with access to cutting-edge research and trends. A special Product Tracing Supplement will be published in the Journal of Food Science towards the end of 2012 that will compile all the work conducted within the Initiative under one roof (Bhatt 2012, Hickey 2012, IFT Forthcoming 2012). More information on IFT's Traceability improvement initiative as well as its other product tracing related efforts can be found at the following URL: IFT's Product Tracing Webpage (http://www.ift.org/traceability).

Global

Internationally, product tracing must be considered in the context of what has been agreed upon by governments as an international standard through Codex Alimentarius, the regulatory requirements of other parts of the world, and the standards that have been agreed to by companies around the world.

International Regulatory Requirements

Codex Alimentarius

Codex Alimentarius latest, "Principles for Product Tracing/Product Tracing as a Tool within a Food Inspection and Certification System, CAC/GL 60-2006" outlines the scope, definitions, principles, rationale, design, and application of a product tracing tool in two pages (CA 2006). The principles described here are focused entirely on product tracing tools and what should be expected of these systems, such as transparency, being aware and accommodating to developing countries, and not allowing importing countries to force exporting countries to use the same tool. It is designed to help implement and use a product tracing tool to protect consumers from foodborne problems and fraudulent product.

European Union

Although the task did not require IFT to delve into country specific regulations, IFT did deem it important to note regional tracing requirements, such as the European Community Regulation 178/2002 'General principles and requirements of food law.' Enacted 28 January 2002, and in force from 1 January 2005, this regulation requires:

> *"The ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution."*

Requirements like these work to aid the EU's Rapid Alert System for Food and Feed (RASFF), which is a tool they use to communicate about problems with the food supply allowing for quicker response time and more coordinated efforts (ECDGHC 2012).

Global Industry Standards

FSMA requires that FDA "consider international efforts, including an assessment of whether product tracing requirements… are compatible with global tracing systems." IFT previously reviewed international efforts in the area of product tracing (McEntire and others, 2010). The current report provides an update on some of these efforts, and provides information on global influencers related to product tracing not reviewed in the 2010 publication.

GS1

GS1, previously referenced in this chapter, is a not-for-profit standards setting body that is heavily involved with product tracing initiatives around the world from farm to retailer. GS1 is a global organization with over 100 member organizations, such as GS1 US, around the world. GS1 US has been actively working with many different industries like meat and poultry, dairy deli and bakery, fresh produce, foodservice, seafood and others, some of which are described in more detail below. Through the use of a common set of standards, a common language and identifiers are used to track product throughout the supply chain (GS1 2012). Their system is based on creating specific identifiers for every

KDE, CTE and logistics units like pallets that are involved in a supply chain. Provided is a list of GS1 Identification Keys (SQFI 2012) to use as a model to create each identifier along with recommended GS1 Data Carriers and GS1 Communication Standards (GS1 2012).

In July 2009, 12 GS1 offices, including the global office, GS1 US, and GS1 China published the GS1 Product tracing for Fresh Fruits and Vegetables - Implementation Guide recommended minimum data set required to ensure product tracing between trading partners (GS1 2009). This consists of:

- Logistic unit identifier (SSCC)
- Commodity name and, where applicable, variety name
- Trading partner/buying party (GLN)
- Ship from location identification (i.e. GLN of shipping location)
- Ship to location identification (i.e. GLN of receiving location/trading partner)
- Date of despatch/shipment
- Grower records details related to growing/production (e.g. field, seeds, details of production
- inputs)
- Additional grower information (e.g. harvest crew, date of harvest) to enable batch/ lot
- assignment by the trading partner (packer)
- Each product tracing Partner (company) must be able to identify the direct source (supplier) and direct recipient (customer) of traceable items. This is the "one step up, one step down" principle.
- Each logistics label should provide the following data in human-readable format:
    - Unique logistics unit identifier (e.g. SSCC)
    - Commodity name and, where applicable, variety name
    - Your company's unique identifier
    - Additional grower/harvest information

Underwriters Laboratories

In 2012, Underwriters Laboratories expects to publish UL 2757, *Food and Food Product Audit Guidance Document* (UL 2012). This document is intended to provide a means for auditing the implementation and operation of internal food and food product tracing programs, external food and food product tracing programs, and/or the connections between the two. Select members of the food industry have been consulted for their input and comments throughout its development.

UL has notified ANSI of its intent to develop UL 2757 into an American National Standard. Once the current draft is published, UL will work through its ANSI-accredited standards development process with the goal of creating an American National Standard for food product tracing.

ISO

ISO 22000 is widely recognized as the standard for industry food safety management systems (ISO 2009). ISO 22005, first published in 2007, provides the standard for product tracing (ISO 2010). The revised standards specify which data elements must be recorded for each link in the production chain — fishing boat or farm, fish processing company, transport company and wholesaler and retailer.

ISO 22005, entitled Product tracing in the feed and food chain – General principles and basic requirements for system design and implementation, touches on terms and definitions, principles, design and implementation, training, monitoring, and by offering helpful general principles and things to consider when designing a product tracing system such as:

- principles
    - "Product tracing systems should be; verifiable, applied consistently and equitably, results oriented, cost effective, practical to apply, compliant with any applicable regulations or policy, and compliant with defined accuracy requirements."
- key terms and definitions
- design and implementation
- objectives;
- regulatory and policy requirements relevant to product tracing;
- products and/or ingredients;
- position in the feed and food chain;
- flow of materials;
- information requirements;
- procedures;
- training, documentation, monitoring and review.
- documentation;
- feed and food chain coordination

The document states that product tracing systems should be able to document the history of the product and/or locate a product in the feed and food chain, addressing at least one step forward and backward, but leaving the door open for more than one step if there is agreement that greater visibility is needed. The scope of the supply chain includes production/origin through processing and distribution. The standard states that product tracing systems contribute to the search for the cause of nonconformity and the ability to withdraw and/or recall products if necessary, and that these systems can improve appropriate use and reliability of information, effectiveness and productivity of the organization. The document recognizes that there are both technical and economic challenges that need to be addressed (Sansawat and Muliyil 2011).

GFSI

The Global Food Safety Initiative (GFSI) has gained worldwide momentum as the basis for which many audits are conducted (GFSI 2012). Upon benchmarking against the GFSI Guidance Document 6, an audit "scheme" becomes recognized by GFSI. GFSI Guidance 6 sets a certain standard that everyone must adhere to. When an audited food company has been audited against a GFSI recognized scheme, this certification includes standards for product tracing that each benchmarked scheme has addressed. All of the schemes require that a firm have methods of identifying products from receiving to recipient and frequently test and document their way of doing this. "All schemes require procedures to be in place to identify all lots of raw materials and packaging from receipt through in-process status to finished product and, at minimum, to the next level of distribution. Product tracing requires testing annually with results documented and used to improve the process when results do not fall within acceptable tolerance levels. All schemes require the organization to have effective prerequisite programs (PRPs) in place, with regularly scheduled monitoring, documented corrective actions in response to non-conformities and verification of activities key to food safety control (Sansawat and Muliyil 2011)."

Product tracing and recall procedures are one of the PRPs listed here and “most PRP requirements are common to all food processor schemes approved by the GFSI.”

Product tracing requirements of two of the more commonly accepted schemes in the processed food industry, BRC and SQF, are described in more detail:

BRC

The BRC global standard is one of the food safety schemes recognized by GFSI (BRC 2011). BRC (2011) defines product tracing as: the ability to trace and follow a food, feed, food-producing animal, or raw material that is intended to be, or expected to be, incorporated into a food, through all stages of receipt, production, processing and distribution.

BRC’s issue 6 came into effect on January of 2012. Product tracing is discussed in section 3.9, which is considered “fundamental,” meaning that failure to comply leads to non-certification or withdrawal of certification.

In issue 6, the only change with relation to product tracing compared to issue 5 is the addition of a four hour record retrieval guideline. “One up, one down” requirements apply along with testing of the tracing system throughout a product lifecycle “including quantity check/mass balance” at all points in their processes. On product tracing, the standard in this scheme is:

“The company shall be able to trace all raw material product lots (including packaging) from their supplier through all stages of processing and despatch to their customer and vice versa.”

The 3 clauses are:

- 3.9.1 - Identification of raw materials, including primary and any other relevant packaging and processing aids, intermediate/semi processed products, part-used materials, finished products, and materials pending investigation, shall be adequate to ensure product tracing.
- 3.9.2 - The company shall test the product tracing system across the range of product groups to ensure product tracing can be determined from raw material to finished product and vice versa, including quantity check/mass balance. This shall occur at a predetermined frequency and results shall be retained for inspection. The test shall take place at least annually. Full product tracing should be achievable within four hours.
- 3.9.3. - Where rework or any reworking operation is performed, product tracing shall be maintained.

SQF

Safe Quality Food (SQF) certifies food safety companies on a global level. Within SQF there are three levels to which a company can be certified; levels 2 and 3 are recognized as GFSI schemes. In June of 2012 SQF is beginning to audit to its 7th Edition, and also publishes a guidance document to accompany the documents outlining the requirements (SQFI 2011). In the guidance document, it states, with respect to product tracing:

- Product is clearly identifiable during all stages of receipt, production, storage and dispatch; and
- Finished product is labeled to the customer specifications and or regulatory requirements.
- Finished product is traceable to the customer (one up) and provides traceability through the process to Raw materials, food contact packaging and materials and other inputs (one back)
- The effectiveness of the product identification system should be tested at least annually.
- You are required to retain records of all product dispatched. Both the details of the product, and where and to whom it was dispatched must be recorded.

A general guide is to include the following on the label:

- Identification of Supplier or distributor;
- Name, type and variety of product in the package (include method of preservation);
- Count, size or weight;
- Code to facilitate traceback, which may be a date code
- Cooking/handling instructions (where applicable);
- Country of origin as required by legislation.

IUFoST

In March 2012 the International Union of Food Science and Technology (IUFoST) published a scientific bulletin entitled Food Traceability which covers recent updates to global tracing legislation and voluntary schemes (IUFoST 2012). They also describe common product tracing challenges such as multi ingredient foods, recordkeeping inconsistencies and the compounding time each node takes to respond to investigators. There are some initiatives covered in more depth within this report but there are other interesting global updates:

- Agriculture and Rural Development Department (ARD) of the World Bank working with infoDev to use new tools in improving food safety and product tracing in agriculture.
- GS1 Australia and others including key government agencies working together to "establish a portal for all product recalls and withdrawals."
- China is beginning a pilot to test a new cloud computing method to aid in food product tracing.
- Food product tracing advancements in India and updates about Korea's beef product tracing system.

The article highlights the Critical Tracking Event approach to effective and speedy product tracing systems. IUFoST concludes that:

"Food product tracing based upon OUOD (one up one down) is not likely ever to satisfy speed requirements necessary for rapid and precise food recalls. A relatively new food product tracing concept known as Critical Tracking Events simplifies data collection and standardization while providing for extremely rapid supply chain elucidation during traceback investigations as well as rapid outbreak source identification and precise food recalls."

Chapter Summary

In addition to the focused work of the mock tracing exercises, IFT sought to learn how other industries and segments of the food system are currently viewing product tracing. This included initiatives in the United States as well as the exploration of global factors that should be considered as FDA proceeds in implementation of FSMA Section 204.

Consistent with the observations reported in IFT's 2010 report (McEntire and others, 2010), there are numerous processes, methods, and technologies used to enable recordkeeping within food firms within the United States. Product tracing is an area of concern for many segments of the food industry, as evidenced by the increase in the number of industry-led initiatives that have developed over the past few years. Many of these initiatives are still in the early stages of adoption and the extent to which they will be fully implemented may be dependent on the actions taken by FDA over the next several months and years.

IFT wanted to ensure that several parts of the food system were explored as part of this task, including foods for animal use. Given the relationship between human and animal foods, and the outbreaks and recalls that have been associated with animal foods, it is not surprising that the issue of product tracing is of concern to this industry. Additionally, there are complexities associated with the production of foods for animal use that could be further explored.

Although IFT included some small businesses in the pilot studies (Chapters 3 and 4) and conducted targeted outreach to small businesses to acquire information related to cost (Chapter 7), IFT wanted to ensure that small business perspectives were reflected in the current work and therefore sought to learn more about recordkeeping practices. In some ways, product tracing was more straightforward for smaller firms, for example, if distributors only sourced from a single supplier or a produce item was harvested from a specific field.

As FDA considers the recordkeeping requirements and product tracing systems associated with FDA-regulated products, FDA must be aware of the international efforts underway. Internationally relevant product tracing/traceability standards published by Codex Alimentarius and ISO are rather broad. Global industry drivers, such as the audit schemes associated with GFSI, have slightly more detail and are likely more visible to food industry members, although they lack a regulatory component.

CHAPTER 10. RECOMMENDATIONS

FDA is challenged by the need to be both expeditious and accurate during the investigation of foodborne outbreaks. If FDA is not accurate, public health is at risk, there is no public health benefit, and the industry and international trade are damaged. The following recommendations are intended to improve the: (a) quality and accuracy of the information provided by the food industry, which will increase FDA's ability to be accurate; or (b) manner in which industry can provide data or FDA can accept data for more rapid analysis. The pilots demonstrated that improvements in product tracing are achievable, given existing technologies, and IFT recommends that FDA should proceed with rulemaking as proposed in FSMA.

IFT Recommendations

In addition to one overarching recommendation pertaining to the food products that should be able to be traced and the types of firms that should be expected to keep records, there are two recommendations that IFT hopes FDA will consider as part of rulemaking (i.e., requiring the capture of KDEs at CTEs, and requiring firms to develop and exercise tracing plans). IFT identified several other areas of improvements to the way in which FDA currently interacts with the food industry and the way that the Agency collects and analyzes records, which could improve the speed and accuracy of investigations. Additionally, collaboration with partners is a theme in several of the recommendations. While these recommendations are actions FDA can take, those in the food supply chain should view these recommendations in the context of the nature of improvements that may be expected of them.

Recognizing that the FSMA limits FDA's requirement of additional recordkeeping to only those foods identified as "high-risk," IFT submits the overarching recommendation that:

1. **FDA establish a uniform set of recordkeeping requirements for all FDA-regulated foods, and not permit exemptions to recordkeeping requirements based on risk classification. Further, IFT recommends that FDA issue guidance documents defining these requirements.**

In a rare showing of unanimity, the pilot participants and advisors agreed with IFT's 2010 (McEntire and others 2010) recommendation to FDA that there is a need to trace all food product categories in the supply chain, regardless of the risk they are perceived to have today. It is widely recognized that several foods and ingredients previously identified as "low-risk" have been associated with recent outbreaks, and that by requiring additional recordkeeping for only "high-risk" foods, FDA will inevitably find itself investigating outbreaks associated with "non-high-risk" foods. Additionally, it is noteworthy that high-risk ingredients can be used in lower risk products, and vice versa.

Moreover, the definition of "high-risk" could change with time in response to future outbreaks or other circumstances, and it would be difficult for firms to quickly and easily comply with new regulations if one or more of the products that they produce or handle were suddenly reclassified as "high-risk." IFT urges FDA to consider the confusion and difficulty that could be expected to ensue by asking firms to follow two different recordkeeping requirements based on the risk classification of the food that they produce, distribute, or sell. Thus, IFT recommends that FDA establish a single set of recordkeeping requirements. If FDA can only require increased recordkeeping for certain foods, IFT encourages FDA to recommend that all firms in the food supply chain meet these standards as a best practice.

Further, IFT recommends that FDA create guidance or educational programs for small businesses including produce terminal market vendors, growers, producers, manufacturers, distributors, wholesalers, independent retail stores, farmers markets, and others. IFT recognizes that certain segments of the food industry experience unique challenges, and IFT encourages FDA, in concert with

industry implementation forums, to assist these segments in understanding their critical role in traceback investigations. FDA should develop guidance or other educational programs to facilitate the understanding, capacity, and adoption of globally effective product tracing practices.

In future rulemaking:

2. **IFT suggests that FDA require firms who manufacture, process, pack, transport, distribute, receive, hold, or import food to identify and maintain CTE- and corresponding KDE-related records, as defined by FDA based on input from the food industry.**

There are various points in a supply chain, termed CTEs, at which data capture is necessary to follow product movement. These include shipping from one facility to another (Transport), receipt at another facility (Transport), and changes that occur as products are manufactured or transformed during processing (Transformation). Traceforward requires an accounting of all suspect product; therefore, it is important for firms to also record the ways in which products exit the supply chain through depletion events (Depletion). At each CTE, KDEs must be captured to enable tracking and tracing of product movement through the supply chain; it is critical that the data establishing these links be maintained.

The concepts of CTEs and KDEs were proposed by IFT in 2009 (McEntire and others, 2010), and considerable effort has been expended over the years by at least 100 stakeholders to clearly identify which data elements need to be provided to regulators in order to effectively trace food products throughout the supply chain.

FDA should require companies involved in the food supply chain to capture and maintain internal trace records based on the IFT-recommended CTE and KDE framework described below. This framework provides information on the what, where, and when with respect to food products that traverse the supply chain. While each firm must maintain these records internally, these data establish the links needed to connect supply chain partners. IFT also encourages cross-sector collaboration to assist industry in sharing best practices and identifying a consistent implementation approach to product tracing for growers, producers, distributors, retailers, and foodservice operators.

The clear definition of CTEs and KDEs, along with guidance to facilitate understanding and implementation will allow individual supply chain companies to correctly identify the CTEs that they are responsible for and ensure that KDEs for each CTE are captured and available for reporting as needed based on a specific request from regulatory officials.

IFT believes the following concepts are useful in defining CTEs, and suggests that the IFT-identified KDEs be considered a minimum standard which should be validated by FDA.

Transport Events: Those events that typically support external product tracing between supply chain locations resulting from the physical transport of product by air, truck, rail, or ship from one supply chain location to another supply chain location. The “To” and “From” locations may be separate companies within the supply chain or two separate custodial locations within the same corporate entity and possibly within several countries.

- **Receiving CTE:** The event at which traceable product is received at a defined location from another defined location. Receiving CTEs typically occur in response to earlier Shipping events. Typically, this event occurs when a traceable product is received at a location after being transported by air, truck, rail, or ship from one supply chain company to another supply chain company, although it can also be between two separate locations within the same company.
- **Shipping CTE:** The event at which traceable product is dispatched from a defined location to another defined location. Shipping CTEs are typically followed by subsequent Receiving events. Typically, this event occurs when a traceable product is sent by air, truck, rail, or ship from one

supply chain company to another supply chain company, although it can also be between two separate locations within the same company.

Transformation Events: Those events that typically support internal product tracing within the four walls of a supply chain company. Examples of transformation events are when product ingredients from one or more suppliers or sources are combined, or when a product is further processed such as by cutting, cooking, or repackaging.

- **Transformation Input (T1) CTE:** The event at which product ingredients from one or more suppliers or sources are combined and/or processed to produce a new traceable product that enters the supply chain. The objective is to capture the supplier, product ID, and production unit of all ingredients used to create the new traceable product.
- **Transformation Output (T2) CTE:** The event at which a new traceable product is created and packaged for entry into the supply chain. The objective is to capture the supplier, product ID, and lot/batch number (or equivalent) of the new output product and to ensure this information is available for capture in subsequent transformation input events, transport events, and depletion events.

Transformation information may be consolidated to levels that the manufacturer feels are adequate to fully link traceable product being utilized during the transformation process for the new traceable product being produced. Traceable product produced as an internal-use-only item during the transformation process but then immediately utilized during a subsequent step may not need to be recorded if adequate records are maintained that link the initial traceable product utilized and the final traceable product created.

Depletion Events: Those events that capture how traceable product is removed from the supply chain, and importantly, when, and where that product becomes available to consumers.

- **Consumption CTE:** Those events at which a traceable product becomes available to consumers. Examples of a consumption event are when a case of fresh produce is opened and placed in bulk self-service bins at a retail grocery store, a packaged traceable product is sold at a point-of-sale register at a retail grocery store, or a case of seafood product is opened for use in preparing menu items in a foodservice restaurant. The objective is to capture the supplier, product ID, and batch/lot number (or equivalent) of the traceable product and associate those with the location, date, and time that the product became available to consumers, recognizing that this is difficult to achieve today.
- **Disposal CTE:** Those events at which a traceable product is destroyed or discarded or otherwise handled in a manner that the product can no longer be used as a food ingredient or become available to consumers. An example of a disposal event is when a case of unopened fresh produce or other traceable product at a foodservice restaurant or grocery retail store reaches its expiration date and is properly discarded. The objective is to capture the supplier, product ID, and batch/lot number (or equivalent) of the traceable product and associate those with the location, date, and time that the product was removed from the supply chain without becoming available to consumers. While not used in a traceback investigation, the Disposal CTE is important for reconciliation during a traceforward/recall investigation.

Table 50 is divided between those data elements that are currently required by FDA (although they may not be required for each firm or for each type of CTE specified) and additional data IFT believes are needed. The bottom half of the table (linking KDEs) represents the CTEs that IFT believes should be captured to establish the links needed to trace product movement through the supply chain. While lot/batch/serial number, in combination with date/time and location can be used to link product

shipments, IFT found that lot/batch/serial numbers were seldom communicated through some parts of the supply chain particularly as product moved downstream toward consumers. In the absence of such information, other documents can be used to establish these links within a supply chain. One data element that is of particular relevance and is not required by current regulation is an “Activity ID” which is an identifier associated with an “Activity Type” such as a PO or invoice number that can be used to link products between supply chain partners. Another type of Activity ID is a specific Work Order, which links ingredients with finished products. The pilot showed that Activity IDs were a key piece of information used to follow the path a product takes through the supply chain. Table 50 illustrates the data elements that IFT believes are needed for tracking and tracing the movement of food. The table is a mixture of elements that are required as part of the regulations resulting from the BT Act and some that are not currently required. Thus the table does not reflect the overall current state of requirements but reflects IFT’s recommendation to FDA regarding the KDEs that FDA should require or encourage at each CTE, as well as those that may be required depending on the circumstances and their applicability (termed Conditional). While Activity Type and ID are listed as conditional, they should be required if lot/batch/serial numbers are not indicated on documents shared between supply chain partners, since they then serve as the critical link connecting product shipments.

While IFT feels strongly that the data elements suggested below are well developed, supported by the pilot findings, and warrant serious consideration, IFT recommends that FDA continue to work with industry to refine these data requirements, and create a flexible structure which will allow for changes as the capability of the industry to trace products evolves. IFT does not believe that the need for further input and refinement is a reason for delay in implementation progress.

Table 50. IFT Suggested Key Data Elements (KDE) for Capture and Recordkeeping at Critical Tracking Events (CTE)

CTEs	Transportation (exchange of goods) - Shipping	Transportation (exchange of goods) - Receiving	Transformation (creation / manipulation of products) – Input	Transformation (creation/manipulation of products) – Output	Depletion (exit from system) – Consumption	Depletion (exit from system) – Disposal
Currently Required KDEs						
Event Owner (firm submitting information)	R	R	R	R	R	R
Date/ Time	R	R	R	R	R	R
Event Location	R	R	R	R	R	R
Trading Partner [1]	R	R	R			
Item (the good)	R	R	R	R	R	R
Lot/Batch/Serial#	BP*	BP*	R	R	BP	BP
Quantity	R	R	R	R	R	R
Unit of Measure	R	R	R	R	R	R
Linking KDEs						
Activity Type (e.g., PO, BOL, Work Order)	C*	C*	R	R		
Activity ID (number associated with PO, BOL, Work Order)	C*	C*	R	R		
Transfer Type[2]	C	C				
Transfer Number[2]	C	C				
Lot/Batch Relevant Date[3]	C	C	C	C	BP	BP
Carrier ID	C	C				
Trailer Number	C	C				

R = Required Field

C = Conditional Field; the need for this field would be determined by business circumstances, and in the instance of transport events that do not capture batch/lot numbers, this field may be required (*)

BP = Best practice is to capture the batch/lot number or relevant date whenever possible; however, in recognizing the current difficulty in capturing this information for transport and depletion events, Activity ID or other KDEs that provide links, as identified in the table, must be provided (*) as the industry prepares to meet a future requirement to capture lot/batch numbers

[1] In the event of a shipping CTE, the trading partner is the immediate subsequent recipient of the shipment; in the event of a receiving CTE, the trading partner is the immediate previous supplier of the product; in the event of a transformation CTE, the trading partner is the supplier of the input into the transformation

[2] If the Activity Type and ID are not linked to a particular shipment of a product (e.g., a purchase order that is fulfilled by multiple shipments over time), then the Transfer Type and ID are used to indicate the particular shipments that are linked to the Activity Type and ID

[3] If there is a different lot/batch designation on a consumer-level product, such as a "best by" date, it must link to the manufacturer-assigned lot number

IFT believes that the capture of at least the required KDEs as products travel through the supply chain will improve the ability to trace products. IFT found that these data, particularly the PO number and

BOL, were useful for identifying product transported between trading companies when supplier-established lot information was not available. IFT recommends that the capture of certain "linking" information be required for all transformation events and for those transport and depletion events when product batch/lot information is not available. For all other events, the use of linking information is encouraged, even when batch/lot information is available.

Because there are a number of barriers to implementing in the near term the capture of batch/lot/serial numbers for all depletion and transport events, further described below, initially the capture and reporting of these data for these events should be encouraged as a best practice and the Activity ID and Type should be required to be recorded. The pilot showed that Activity IDs could be used to trace products, although not quite as accurately as if batch/lot numbers were captured throughout the supply chainv (Chapter 6). However, using Activity IDs to trace products results in much more data (compared to using batch/lot/serial numbers) and, thus, is only efficient when used in conjunction with a collaboration platform by the regulators (see recommendation 9 below). Further, following products through a string of Activity IDs obfuscates the manufacturer- (or other transformer-) assigned lot numbers until they are revealed by the manufacturer (or transformer). Clearly, capturing lot numbers along the supply chain would provide investigators with instant access to the lot numbers assigned at the most recent transformation event. For these reasons, IFT recommends that FDA consult with the industry and then establish a reasonable effective date when the capture and reporting of the batch/lot/serial number (or equivalent) will be required for all CTEs.

While the FSMA does not permit FDA to specify certain systems, processes, and technologies that industry uses in support of their internal product trace initiatives, the FDA should be aware that many firms will be faced with incremental costs to develop new product trace capability that could introduce significant change to current operational practices. Recognizing the significant change and investment that may be required by industry in order to comply with new product trace requirements, IFT recommends that the FDA consider extending a ramp-up period that will allow industry time to implement appropriate changes to internal systems and processes. For additional justification for this recommendation, please refer to Chapter 6.

Additionally:

3. IFT recommends that FDA require that each member of the food supply chain develop, document, and exercise a product tracing plan.

IFT is aware of and encouraged that several industry pilot participants have already changed their internal processes as a direct result of their participation in the pilots. Several firms have noted changing their processes to record trace data so that they are more accessible. This information was previously kept, but difficult to retrieve in a timely manner; by going through the pilot exercise firms identified ways to improve their overall processes. These lessons provide evidence that having a "Product Tracing Plan" at each facility in the food system, from production to food manufacturing to retail/foodservice, will improve communication between the industry and regulatory agencies, raise awareness of the responsibilities of the industry during an investigation, and catalyze more effective traceback and traceforward (recall) investigations. The development and documentation of a company product tracing plan and regular exercise of such a plan will increase the speed with which a firm can respond and reduce the likelihood of errors. The plan can be internal to an establishment, or voluntarily span more than one supply chain node. Unlike a HACCP plan, a tracing plan could be established for use across each facility; a separate plan for each product or line would not be necessary, although all CTEs and KDEs would need to be documented. Firms should expect their plan to be reviewed by regulatory agencies upon request, including during a domestic or foreign inspection.

The plan should contain the following elements:

- identified CTEs and KDEs
- identification of how information is recorded and linked
- identified authorized point(s) of contact
- metrics for trace data reporting response times
- frequency of trace plan exercises
- frequency of trace plan review

Recognizing that FDA is limited in its authority to access individual company trace records, IFT recommends that FDA seek volunteers willing to test their trace plans, including communication of trace data through standardized and structured reporting solutions provided by the FDA, in order to test integration with any collaboration platforms that the FDA may choose to implement.

4. IFT recommends that FDA encourage and support industry-led initiatives for the development of implementation guidelines and seek stakeholder input by issuing an Advance Notice of Proposed Rulemaking (ANPR) or using other input mechanisms

Many parts of the food industry (produce, meat/poultry, seafood, dairy/deli/bakery, and foodservice) have developed guidelines, generally building upon each other, to improve product tracing in these supply chains (described in Chapter 9). While these segments of the food industry have aligned on an approach that they believe will standardize the way product trace information is communicated between supply chain partners, IFT has heard countless times that a major reason that firms are delaying implementation of these voluntary guidelines is because they fear that forthcoming FDA requirements will be inconsistent with the industry-led guidelines.

As in IFT's previous report to FDA on product tracing (McEntire 2010), IFT maintains that FDA should not prescribe the specific means that industry uses to meet FDA's objectives recommended by IFT. Several industry groups have begun identifying ways in which industry can improve product tracing capabilities, and IFT recommends that FDA support these efforts. IFT believes that FDA's support for these industry-led implementation initiatives will enable real-world adoption of improved product tracing capability at a more rapid pace than would otherwise be possible and avoid costly and time-consuming company and industry-led "resets" that would result from disruption of these initiatives.

FDA incentives directed toward industry-led initiatives to develop and share actionable implementation guidelines will help facilitate faster acceptance and adoption by industry. Incentives may include participating as a consultant to industry work groups, drafting implementation guidance and sponsoring cross-industry work group meetings, technology exploration for in-plant pilot tests, and development and communication of project plans, training materials, etc. that will allow industry supply chain leaders to better disseminate best practices.

IFT recognizes that FDA has conducted extensive outreach and sought input from stakeholders in multiple ways with respect to product tracing. However, much of this information was obtained prior to the passage of FSMA. Given the opportunities and limitations provided in FSMA, IFT feels that through an ANPR or other mechanism to gain input, FDA can present stakeholders with specific questions and seek targeted input. Since the public meetings in 2009, the product tracing and technologies landscapes have evolved, and FDA is encouraged to provide an opportunity for the food industry to show how the steps that certain segments have proposed can meet FDA's objectives of more rapid and effective tracebacks.

5. IFT recommends that FDA clearly and more consistently articulate and communicate to industry the information needed during a product tracing investigation.

IFT encourages FDA to provide context to a request for product tracing records to help the food industry in determining the appropriate records that contain information that may aid in an investigation. For example, the investigator might consider explaining whether a sample of a product tested positive for an adulterant, or an epidemiological investigation had identified the product as a potential suspect vehicle. This may enable the firm to identify records or other types of information of which FDA might not have been aware.

The FDA Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations (FDA 2001) should be updated so that investigators are directed to request the appropriate information (based on CTEs and KDEs), with firms being responsible for identifying the appropriate documents which contains that information. While the FDA Guide currently acknowledges the variety of types of paperwork on which KDEs might be found, there has been past emphasis on invoices. The pilots showed that while invoices could be used, POs and BOL documents were more useful in many cases.

Individual firms should be responsible for identifying the appropriate records that provide internal and external linking information, and investigators should clearly request the specific pieces of information (e.g., supplier names, lot numbers) that are necessary for the investigation to proceed (as opposed to the specific types of documents, such as invoices and bills of lading that may or may not contain all the needed information). The Guide may also benefit from a glossary which explains how the different documents are used by the industry (e.g., BOL versus invoices).

Additionally, IFT believes that industry would respond positively to an investigation if firms were able to participate as a partner with a role in protecting public health as opposed to a suspect in an investigation.

6. IFT recommends that FDA develop standardized, structured, and electronic mechanisms for industry to provide the Agency CTE and KDE product tracing data when requested during a specific food safety investigation.

A number of key lessons from the pilots highlighted the importance of developing standardized, structured, and electronic reporting mechanisms for CTE and KDE data.

- The pilot studies showed that while the reporting template developed for the pilots did not meet the needs of all firms, it was useful in facilitating the rapid collection and analysis of information by IFT when firms used it.
- Several firms chose to provide self-defined summary documents which also proved to be useful in understanding the supporting documentation.
- Manual entry of information that was communicated via paper-based and PDF documents exposed issues with data accuracy and integrity and highlighted the increased time required before data is available for analysis.

The pilot findings confirm that standardized, structured, and electronic reporting of CTEs and KDEs increases the speed by which product trace data can be collected, compiled, and analyzed and indicate that any structured reporting templates will need to vary based on the needs of specific industry segments (e.g., grower, supplier/packer, distributor, foodservice operator and retailer), and possibly commodity categories (e.g., seafood, produce). Most importantly, industry guidance will be needed on appropriate universal references for parties, products, and locations. Having globally unique, structured references for consistently defining the who, what, and where of each event will prove essential for a rapid and efficient product mapping and discovery process.

IFT believes that guidance can be developed with illustrative examples to highlight how a standardized and structured reporting approach can be tailored to specific industry segments to better relay

information to the FDA. IFT expects that a few standard reporting formats could be developed to meet the needs of industry and the FDA. With this goal in mind, IFT recommends that the FDA consider that a number of companies across different industry segments have already given substantial thought to how to best to summarize and convey product trace information, and invite the industry to share these examples and provide other input to the FDA in order to achieve maximum benefit.

In accordance with provisions in the FSMA, IFT also recommends that firms be allowed to maintain their internal records using the systems and processes currently in place, including paper-based recordkeeping systems. IFT recommends that these records only be required to be transposed to the standardized and structured reporting format when data are being requested in relation to a specific request from regulatory officials. IFT also recommends that any standardized and structured reporting format be adapted to appropriate data communication vehicles, including spreadsheet, web-based portal or EDI electronic message, to accommodate the varied needs and capabilities of large and small firms alike. FDA may find value in working with global standards organizations to develop standardized message formats (e.g., xml, EDI) as one of the reporting options. In accordance with OMB guidance, FDA should support the use of voluntary consensus driven standards that are already in use in the food industry to meet FDA objectives (OMB 1998).

7. FDA should accept CTE and KDE data sent in summary form through standardized and structured reporting mechanisms and initiate investigations based on this data.

In order to expedite traceback investigations to protect public health and limit impact on industry and individual brands and products, FDA should request summaries of CTEs and KDEs from firms and use this information to quickly "rule in or out" products or supply chains that may or may not be associated with a specific food safety concern. IFT recognizes the risks associated with relying on un-authenticated data, and particularly the risk of following the "wrong path." IFT found, through the pilots, that when summary information was provided that could help expedite the identification of subsequent points in the supply chain, there were occasional errors (both in transcription and in the native data) that could compromise the ability to be "right." On the other hand, when the detailed data arrived and confirmed the summaries, immediate action was possible, saving time. IFT expects that a firm will be able to generate a summary document quickly, within 24 hours, since a firm would be able to interpret and summarize their own data/records much faster than FDA. The time needed for FDA to learn and understand each firm's system (as FDA did in past outbreak tracebacks) can be reduced. The general data needs should be similar in most traces, enabling firms to develop processes and systems in advance of a traceback that could automatically generate summary information when needed.

While FDA has increasingly adopted this approach, IFT believes that in concert with clearly defined CTEs and KDEs, the communication of the information via standardized and structured reporting solutions, and technology-enabled analysis of the data, this approach can be used to a greater extent in the future.

IFT is not suggesting that FDA rely exclusively on summary data; rather IFT encourages FDA to continue the practice of collecting "hard copy" supporting information (e.g., Invoice, PO, BOL) from firms associated with products that are not readily excluded from an investigation. While this process may add an extra step by asking industry to provide a summary, and then later to provide more detailed documentation, this process will have the benefits of enabling FDA to quickly obtain information and focus investigation on public health, and provide industry more time to collect hard copy records in advance of a possible subsequent verification request.

8. If available, FDA should request CTE and KDE data for more than one up - one down in the supply chain.

IFT found that in both produce and processed food - ingredient pilots, there were some companies who are quasi-vertically integrated or who otherwise have strong control (and therefore visibility) through their supply chains and can provide information more than one step back. Thus, in such instances, FDA should request and act on this information for the sake of public health; and as a second priority, should verify information with the individual firms in a supply chain who may have handled the product. During the pilots, there were instances where several supply chain partners shared and analyzed product tracing data through teleconference calls. Firms should consider inviting regulators to participate in these discussions and FDA should be open to collaborating with industry on such discussions in order to rapidly gain meaningful information. During the pilot IFT noted that availability of more than one back trace data from any one firm was more the exception than the norm. In some instances, firms reporting more than one level of information do not keep this information themselves as a part of regular operations, but can readily access the information via supply chain partners. In such instances, it would be important to minimize duplicative requests coming from both supply chain partners and regulatory agencies. This recommendation is based on the availability of information from capable supply chain partners and is not recommended as a requirement for all supply chain partners.

9. **IFT recommends that FDA pursue the adoption of a technology platform to allow the Agency to efficiently aggregate and analyze data reported in response to a specific request from regulatory officials. The technology platform should be available to regulatory counterparts.**

One nationwide retailer reported that up to 23 different agencies request similar information during an investigation. An FDA-managed information system for collecting requested information would decrease the resources required by the industry to respond (e.g., submitting information once rather than in response to multiple requests from state and federal regulators) and would decrease redundant efforts of local, state, and federal governments by granting public health and regulatory partners secure access to the information system during an investigation. State and local regulatory agencies should be involved in the development and implementation of such a system, and should have equal access to any "technology platform" to the extent permitted by law.

FDA should seek to integrate any new systems with existing reporting systems including the Reportable Food Registry, as well as industry recall systems (e.g., GS1 Rapid Recall Exchange), to avoid data input redundancy and minimize data integrity issues that can result from redundant manual entry of information.

IFT does not advocate the establishment of a common "cloud"-based repository as a continuously standing collection of all CTE and KDE data captured across the supply chain. The information system that IFT envisions would be managed and hosted by FDA and collect only CTE and KDE data related to past or current outbreak investigations. An FDA portal type of access could meet both the security concerns of industry and the need to have consistent data for regulatory analysis. Adapting existing technology to meet the specialized needs of an FDA platform would allow investigators to aggregate the specific data received and then allow secure access for use by any agencies for analysis.

IFT notes that the utility of an FDA-managed platform for collaboration with public health partners is completely dependent on the submission of accurate, complete event data. Technology should not be expected to compensate for poor recordkeeping.

10. **IFT recommends that FDA coordinate traceback investigations and develop response protocols between and among state and local health and regulatory agencies using existing commissioning and credentialing processes. Further, FDA should formalize the use of industry SMEs to address FDA's general questions about the characteristics of a particular supply chain at the outset of an investigation.**

IFT recommends that FDA continue to collaborate with state and local counterparts to ensure that investigations proceed rapidly and with minimal duplication of efforts. Data should be shared and available in near real-time. Existing Memoranda of Understanding should be reviewed and improved if needed to better promote collaboration and coordination between all agencies involved in traceback investigations. The FSMA also calls for FDA to build capacity within state and local agencies. Such capacity building will also improve the speed and accuracy of outbreak investigations and their related tracebacks.

The establishment of the CORE network within FDA was an important step in coordinating efforts internal to FDA, and IFT encourages the Agency to identify, train, and field deploy a select group FDA staff in response to traceback investigations, similar to the way in which "rapid response teams" function at the state level. These investigators could be housed at CFSAN or embedded within the districts, but would be the lead point of contact in the field during traceback investigations. This "ownership" of the investigation would potentially reduce response time, duplication of requests, and grant a more complete picture of the investigation to CORE and CFSAN.

IFT recommends that FDA ensure that any internal processes which identify the agency's actions in an investigation, and collaboration with other agencies, as well as any interagency agreements, are reviewed to ensure consistency with any implemented recommendations.

IFT also encourages FDA to pre-identify SMEs (regulatory, academia, industry) in a variety of food product-commodity areas as well as those representing diverse portions of the supply chain, who can advise the Agency during the early stages of investigations regarding general practices, product flow (including as relates to seasonality, regionality), terminology, etc. in a given industry segment.

Summary of Recommendations

Table 51 summarizes how the ten recommendations proposed by IFT affect the ability to conduct tracebacks more rapidly, more accurately, or both.

Table 51. Steps to Improve Accuracy and Speed of Product Tracing

Steps	Improve Accuracy	Improve Speed
Establish Uniform Recordkeeping Requirements	X	X
Maintain CTEs and KDEs	X	N/A
Require Industry "Traceback Response Plans"	X	X
Support Industry-Led Initiatives	N/A	X
Communicate Needed Information	X	N/A
Develop Standardized, Electronic Reporting Templates	X	X
Accept CTEs and KDEs in Summary Form	N/A	X
Request more than One up – back	N/A	X
Use Technology to Share and Analyze Data	X	X
Coordinate with State and Local Counterparts, and Use Industry SMEs as appropriate	X	X

Barriers to Implementation of Recommendations and Potential Solutions

Effecting change is a difficult task, and an ongoing process. In conceptualizing an ideal state of product tracing, IFT previously identified several categories of challenges financial, business/operational, cultural/human, and policy (Bhatt and others 2012). In considering the recommendations proposed as a result of the pilot studies, there are several barriers, real and perceived, that may result in resistance to the recommendations proposed in this report.

The Value of Capturing Batch/Lot Numbers at Distribution and Retail/Foodservice

The most contentious recommendation was around data requirements, and specifically, the feasibility of collecting lot/batch numbers through distribution and at retail and foodservice. There were a number of factors that drove IFT to ultimately recommend that lot/batch numbers should be collected during transport CTEs and consumption CTEs as a best practice, with a requirement for the recording of "Activity IDs" such as PO numbers in the absence of the collection of lot/batch numbers.

- As long as there was a definitive link between receipts and shipments whereby the Activity ID at receipt could be tied to the Activity ID of the shipped product, the collaboration platforms were able to successfully identify points of convergence in the supply chain
- IFT developed a model (described in Chapter 6) to quantify the impact of relying on POs (which may contain more than one lot) versus knowing the lot numbers. While the number of potential lots was always greater when POs were used, the model showed that the increase in the

number of lots was generally less than 5%. In other words, relying on POs did not increase the number of suspect lots by more than 5% in most cases, so the impact on accuracy was minimal. However, the impact on the total amount of data that needed to be analyzed was substantial. The use of technology to analyze data would aid in this aspect.

It is important to note that product traceback and traceforward depend on different CTE events. Effective traceback depends first on consumption events to rapidly identify the supplier, product, and production unit of suspected products associated with locations of illness outbreaks and depend then on transformation events to identify the ingredients of those suspected products. Once the product source(s) of the outbreaks have been identified, the traceforward or recall process begins, which depends on transport events (shipping and receiving) to determine the distribution of implicated product and then on depletion events (consumption and disposal) to account for all implicated product.

For this reason, it is essential that product packaging available at the time of consumption events be clearly marked with product ID and batch/lot numbers or batch/lot relevant date information. With the effective capture of KDE information at consumption events, investigators will know immediately which suppliers and production units to focus on, and the capture of batch/lot numbers for transportation events becomes less critical to effective traceback, assuming the issue did not occur during the transportation process. With the consistent capture of supplier, product, and production unit information for consumption events, the capture of batch/lot information for transportation events can be accepted as a best practice rather than a requirement until industry evolves to increase the capability to readily capture batch/lot information for every transportation event.

The accuracy associated with tracking by PO, BOL or other Activity ID as opposed to lot depends on the number of lots present in that PO, for example. Obviously, the fewer lots within a PO, the less impact tracking by PO has. In the pilots, IFT observed that on some occasions products were tracked by the pallet. Reducing the number of lots associated with a pallet has a similar benefit. To further explore this issue, in 2011 Tyson Foods, which distinguishes lots based on the hour of production, conducted research examining how many different lots were found in more than 1400 pallets of a proprietary customer's product line. More than 80% of the pallets contained just one lot, nearly 20% contained two, and less than a half percent contained three lots. Had Tyson expanded their definition of a lot to include one day's production, then more than 99% of the pallets would contain product from a single day, and none of the pallets would contain product from more than two days. The role of distributors is to break larger quantities, such as pallets, into smaller quantities, such as cases, for delivery to customers. Picking and recording the product shipped from the pallet would provide an efficient means to capture the batch/lots shipped without tracking the lot numbers applied to cases. An added benefit of tracking in this manner rather than by PO, BOL or Activity Number, is the potential of reducing the number of lots shipped on an outgoing customer order. This could be an initial step toward being able to track to a batch/lot level. Bhatt and others (2012) further discuss issues related to the selection of logistical units.

Prerequisites to Efficient Data Capture and Sharing

Data can be communicated through the supply chain through physical markings on the product (e.g., cases, pallets) as well as on the paperwork that accompanies transactions (e.g., POs, invoices). Effective product tracking requires that product cases or other containers be clearly labeled to indicate the supplier, product identification, and production unit for use by supply chain companies and, when consumer packaged, that similar information be available for use by the ultimate household consumer. This issue should not be confused with "product tracking to the case level" which implies serialization, yielding the ability to track each case of product, as is done in some parts of the food industry such as red meat cuts.

The rapid capture of KDEs likely necessitates the use of some types of technology aids. However, there are several current challenges that limit the ability to rapidly and accurately capture this information. Shipping and receiving of full pallets containing a single batch/lot would allow batch/lot to be provided on a BOL document or provided at the pallet level on the product itself, although even at the level of the manufacturer this is not always possible. Shipping and receiving of less than full pallets, as is common with distributors and retailers, would likely require batch/lot to be provided in a machine readable way (e.g., GS1-128 bar code described in Chapter 7) on the product at the case level. Current industry case labeling practices are not well positioned to support the inclusion of batch/lot numbers. The concern over this issue is highlighted by the fact that food companies are actively researching the challenges and potential solutions.

One major manufacturer worked with a retail partner's distribution center just over a year ago to survey the nature of the markings on dry grocery products. The survey included more than 100 cases representing nearly 100 brands produced by more than 60 manufacturers.

- More than 90% of dry grocery cases used a type of bar code (ITF-14) which can carry a generic product identifier (GTIN) but cannot support coding of additional information (e.g., batch/lot number).
- More than 65% of cases used pre-printed bar codes (corrugate or labels) which will not support dynamic data (e.g., batch/lot code).
- Almost 25% of cases used Inkjet line printers for printing bar codes which do not produce the quality needed for more sophisticated bar codes (GS1-128) which allow the inclusion of dynamic data (e.g., batch/lot code).
- About 65% of cases had bar codes printed with black ink on brown corrugate which limits contrast and will not support GS1-128 bar codes with dynamic data.
- More than 10% of the cases did not convey lot/batch numbers in a human readable form.

A major foodservice distributor conducted a similar study in 2011, looking at the types of bar codes present on more than 500 cases of a variety of products.

- More than 25% of cases had no bar code at all, especially products held in cold storage.
    - More than 80% of produce cases lacked a bar code.
    - Seafood products were most likely to have some kind of bar code.
- Of those with a bar code, less than 20% had the type of bar code that can include lot/batch numbers (GS1-128).
    - When a bar code was present, meat (>80%) and poultry (>50%) were most likely to have this more sophisticated bar code.
- In the overall study, 40 cases had a GS1-128 bar code that included information that could be tied to a specific unit of product (e.g., lot/batch number, pack date, production date, "best before" date), with only six having the lot/batch encoded in the bar code.

This suggests that a requirement to track batch/lot number by all supply partners (producer, distributor and retailer) could require producers to invest in new case labeling solutions (i.e., phasing out preprinted bar codes and inkjet printing and moving to higher quality, higher cost label-base print and apply). This change would present a significant investment of time and capital that could legitimately take several years to accomplish.

A 2002 study by Tyson Foods was initiated to determine the value of transitioning from the use of pre-printed labels to applying labels in-line, enabling the inclusion of dynamic data such as lot number in a bar code. In the study, Tyson evaluated 140 pallets from their largest distribution center which received

product both from facilities that were applying bar codes and scanning as well as those using preprinted labels with batch numbers indicated in human readable form. Each pallet was audited, comparing the product physically on the pallet to the paperwork (which included the batch number) associated with the pallet as generated by ERP systems. When comparing the two populations the difference in the level of accuracy in tracking between the two types of labels was minimal (4% variance) and was essentially equivalent when taking into consideration the margin of error for the test. When there were discrepancies, 93% of the time they were errors in quantity within a batch (which could result in errors in trying to reconcile and account for product during an actual traceforward investigation, but would not impact the ability to find convergence). This study was conducted three times and did not validate a statistical advantage that would justify the capital expenditure necessary to dynamically label cases with in-line labels rather than using pre-printed labels.

Thus, while there is technology available that enables the full implementation of IFT's recommendations, some of this technology is not currently being utilized by large segments of the food industry. Additionally, it is clear that there are multiple ways of meeting the data capture objectives, and IFT encourages those firms who have found achievable solutions to share those findings and approaches with firms struggling to overcome barriers. A thorough evaluation of the costs and benefits should be used in determining the appropriate solutions for each segment of the food industry and each individual firm.

Lack of Standards Results in Fragmented Requirements

In considering all the data and all the stakeholder input offered, IFT believes that issues related to product tracing will remain in a state of perpetual flux until FDA provides clearer definitions for data requirements and begins to share with industry the Agency's vision of an effective product tracing system. Currently, there are several industry initiatives underway which seem to be working in concert (Chapter 9), but there are also numerous customer requirements that challenge food supply chain members.

With time, as adoption and capability evolve, FDA could work with industry to drive consistency with a more unified set of product tracing requirements across all segments of industry. It is important that the ends of the supply chain closest to consumers are not faced with needing to accommodate numerous systems with different requirements; similarly, it is important that manufacturers are not forced to provide different types of tracing information on different products based on the requirements of their customers, as is the case today.

Limitations in Global Connectivity

There was clear recognition over the course of the pilots that when information is available electronically, the ability to analyze the information is greatly enhanced. However, the communication of such data is still somewhat limited in some parts of the world, including some parts of the United States. The implementation timeframe for the FSMA should accommodate parallel communications/joint initiatives with telecommunication carriers, the Federal Communications Commission, and appropriate state and local authorities who manage planning and implementation of rural infrastructure. In particular, high-speed broadband in key growing areas should be considered with a view to parallel economic/community development in disadvantaged areas with quantifiable grower communities. Any ambition to require electronic traceback data submission to FDA must accommodate these real-world structural limitations.

In the case of smaller growers, there are several issues related to electronic submission, primarily lack of access to technology due to hardship, lack of in-house staff, training, or gaps in rural infrastructure.

These barriers should be accommodated in the timing of any proposed implementation of FSMA. Information technology access may be minimal among smaller operators. Although minimal, there are some confidentiality and privacy issues associated with sharing not only one's own data but data that relate to supply chain partner transactions over insecure channels (e.g., the local town library) that should be recognized.

While not related to technology, another challenge in global connectivity is language. When the mock tracebacks led to tomato growers in Mexico, some documents provided to IFT were in Spanish. This increased the difficulty in determining how these documents related to other documents.

Education and Culture

Increasing awareness of the requirements of a product tracing system will be a continual challenge given the low barrier to entry in many food-related businesses. The evolving demographics of the United States population also presents challenges to communicating requirements. Small growers are often first generation immigrants due to their differentiating depth of hands-on specialist growing experience gained in horticultural skills-based economies. Definitions of "acceptable practices" may vary due to these societal differences. Language and communication norms often mean that training is best conducted verbally. Written communication can be viewed as a barrier to doing business. It is important to carefully consider the nuances in how related training is provided at the small business level in order to accommodate these cultural differences.

Chapter Summary

IFT identified ten recommendations that, if implemented, should increase the speed, accuracy, and overall efficiency of product tracing investigations. These recommendations include some process changes regarding the way in which FDA currently conducts investigations, and also includes some changes that will affect how industry interacts with the Agency to provide product tracing information. IFT believes that a clear understanding of terms will enable industry to more readily provide FDA with the data needed to track and trace product movement, and that combined with the use of technology and increased collaboration amongst all stakeholders, product tracing efforts will be improved to be more protective of public health.

Change is not expected overnight. While there are barriers and challenges to immediate implementation of all of IFT's recommendations, IFT is confident that through increased education and collaboration, innovative solutions can be identified that will enable the food industry to meet FDA's objectives.

CHAPTER 11. NEXT STEPS

The pilots identified several areas for additional work that could provide great value, both to industry and to regulators.

Develop Educational Materials

IFT has found it useful to distinguish tracebacks from recalls and the need continues to better educate the food industry on the goals, objectives, starting points, and ending points of traceback investigations. This task focused more on traceback rather than recall (traceforward). Since the traceback and traceforward steps could be well served by implementation of the CTE and KDE concepts, future pilots should evaluate which data are best utilized for tracebacks that rapidly identify the point of convergence, investigation and traceforward. A thorough regulatory investigation accounting for all steps in the supply chain may demand a different set of KDEs compared with those which allow for rapid identification of convergence and those needed for an effective recall.

Develop Industry and/or Supply Chain Node-Specific Guidance

FSMA limits FDA to enacting additional recordkeeping requirements to "high-risk foods." However, outbreaks during the last several years reinforce the fact that foods previously considered "low-risk" can quickly find themselves on the "high-risk" list. Therefore, IFT suggests that FDA take the opportunity to advise the entire food industry, segment by segment, on the "best practices" for recordkeeping through the use of guidance documents. The pilots suggest that different people interpret the phrases "product tracing" and "traceability" differently depending on their role in the supply chain and providing additional information and education will enable industry to better understand how their practices and processes can impact an investigation.

Examine Alternatives to One Up - One Back

A key lesson from the recent pilots suggests that rapid identification of points or nodes of "convergence" in the supply chain would greatly accelerate investigations. Future work might consider alternatives to the one up - one back approach to identify convergence more rapidly. The process of identifying nodes of convergence is part of the "traceback" function. Once point(s) of convergence are identified, in-depth documents and on-site investigations are used to identify the source of the issue. Once a source of the issue is determined and/or if situations warrant, a recall or "trace-forward" is used to remove suspect products. Additional work could be performed exploring not only the technology required to determine convergence more quickly, but also the data security, and social and economic issues associated with increased data visibility.

Develop Workshops and Tools to Help Supply Chain Partners Better Understand Each Other's Data

The concept of "standardization" means different things to different people. The pilots exposed two types of standardization involving data field names and data structures. Results from pilots suggest that data field standardization is very important and data structure is much less so although some collaboration platform providers required the use of a standard data structure (Chapter 5). Future pilots might include "data field mapping sessions" between immediate neighbors in the supply chain. These mapping sessions would serve as an immediate channel of communication between supply chain partners enabling each to understand which data connect them for the purpose of product tracing. It is

likely that after these exercises, industry members would better understand, and be able to convey, how to trace products.

Distinguish and Define How Technology Aids the Food Industry and Regulators

The pilots suggest that the term "collaboration platform" does not properly define what is needed to execute food product tracing queries and investigations. "Collaboration" needs to be separated into what is needed for data producers and data consumers. Supply chain participants produce data and health officials/regulators consume data. Producers need tools to collect, secure, and store data, and to make data available as they choose to do so in terms of access/transmit permissions, etc. Investigators need systems capable of querying, receiving, and making sense of distributed data. Future pilots should seek to focus attention on these different needs rather than attempting to compare systems that promise to provide a complete solution capable of doing everything for everyone.

Create and Support a Product Tracing Alliance

Improving our ability to track, trace, and more efficiently recall foods in the supply chain may help to reduce foodborne illness, the volume of food recalled, instances of improperly recalling or otherwise implicating safe and wholesome foods, negative impacts to valuable brands, and costs associated with investigating outbreaks. As industry, government, and academia struggle to understand immediate costs and regulatory impacts of changing recordkeeping and other product tracing practices, the coordinated effort to properly evaluate the application of existing practices and technologies, explore alternatives, identify technological gaps and report on findings, is insufficient.

Product tracing guidelines, standards, and regulations will impact virtually every aspect of the food supply chain. In addition to unbiased analysis of approaches, there is a need for a neutral entity, ideally a public-private partnership, to coordinate standards, guidelines, and best practices. While a variety of existing for-profit and not-for-profit entities have attempted to step into this role, none has been able to gain sufficient authority to be able to bring the various stakeholders together to develop clear actionable guidelines. A government-supported tracing alliance will simultaneously provide the necessary collaborative platform from which to evaluate and report on existing and novel approaches to food product tracing, while providing a platform from which to publish guidelines, and best practices, and to assist in drafting new science-based product tracing information.

By supporting a collaborative body for investigating real world, workable implementation guidelines, FDA could provide the mechanism that allows industry to begin taking steps now to meet future regulations and help lead the ongoing work toward further optimizing supply chain practices for recordkeeping and reporting.

Identify Resources Needed for Small Operators Producing "High-risk" Foods

As FDA solidifies the categories of food types subject to additional recordkeeping, the Agency may be able to take a more targeted approach in further studying the resources needed (including guidance, training, etc.) for small and very small businesses. This could include the exploration of a financial assistance program for very small businesses to assist with compliance-related tasks (along the lines of the organic program). USDA could serve as a resource for best practices on implementation.

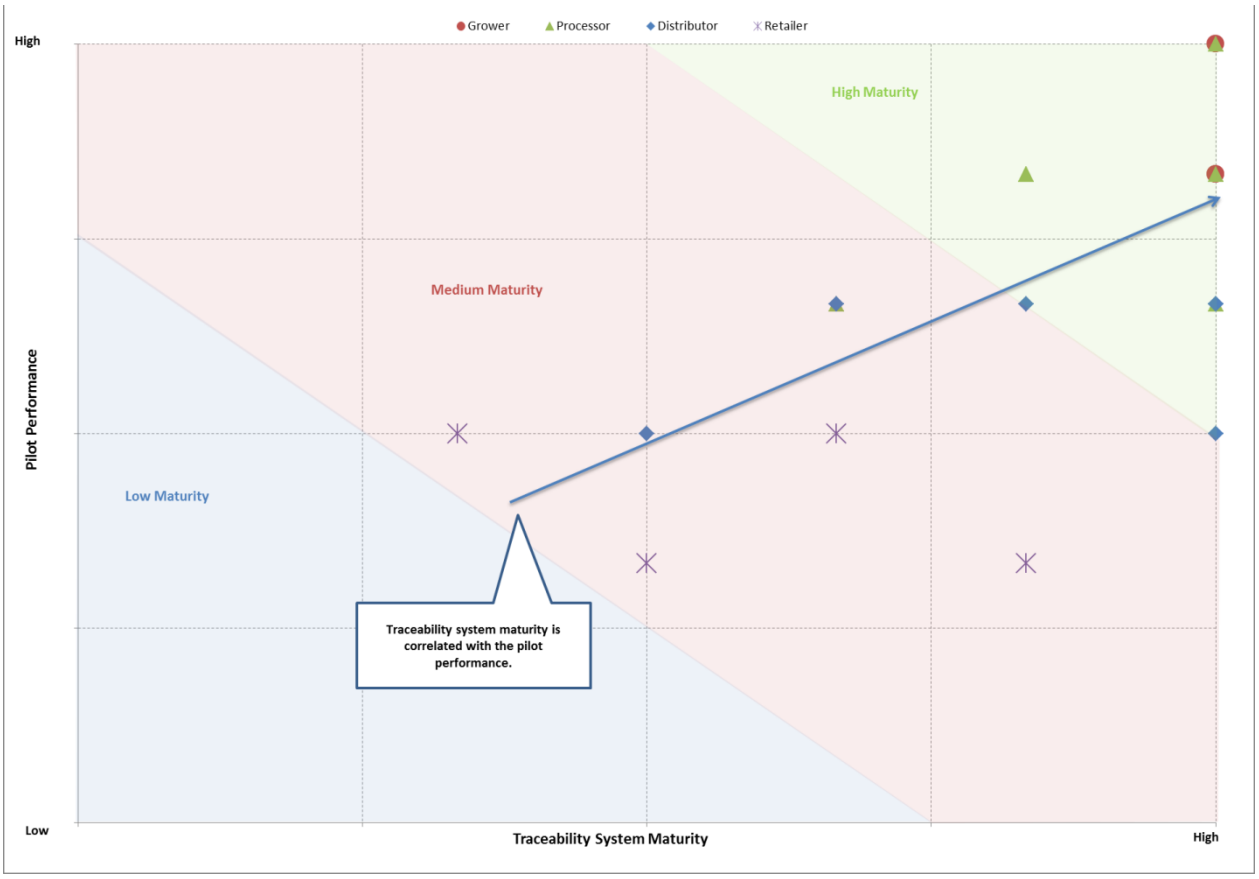
Refine Cost Calculations

The cost and benefit analysis performed in the pilot projects is the first step that can lead to additional studies in this particular subject area. From the results of the literature review, this type of in-depth analysis is fairly unique and provides a starting point for similar analyses that can build this knowledge area. As many more firms make the decision to invest in product tracing technologies, there will be a richer dataset that could provide additional insights into perceived costs and benefits. While this investigation is limited in approach and scope, there is ample room for an improvement in methods and opportunity for future studies that will offer a spotlight on this critical issue.

CHAPTER 12. CONCLUSIONS

The product tracing pilots—including 12 mock tracebacks involving tomatoes, two involving peanuts and peanut butter, and two involving several ingredients as components of processed food products—provided a number of lessons that can aid FDA in recommending or requiring changes that will result in more rapid and effective tracebacks. The pilots provide a snapshot of how the practices and systems used by firms directly correlate with their ability to provide IFT with records that enabled a mock traceback (Figure 44).

Figure 44. Pilot Performance vs. Tracing System Maturity



There were several specific issues which confounded or aided the mock traceback process. While many of these have been identified previously (Can-Trace 2004; McEntire and others 2010) the pilots provided an independent study to substantiate these claims. The pilots identified multiple ways in which improvements in product tracing can be realized. Achieving these improvements, however, will require a change in mindset and in operational procedures, which FDA will need to drive.

Table 52 lists the variety of recordkeeping factors within the pilots that either delay/confuse tracebacks or aid/facilitate tracebacks. These factors were present in many firms within the pilot studies and are applicable to all food industries.

Table 52. Factors that Delay/Confuse and Aid/Facilitate Traceback

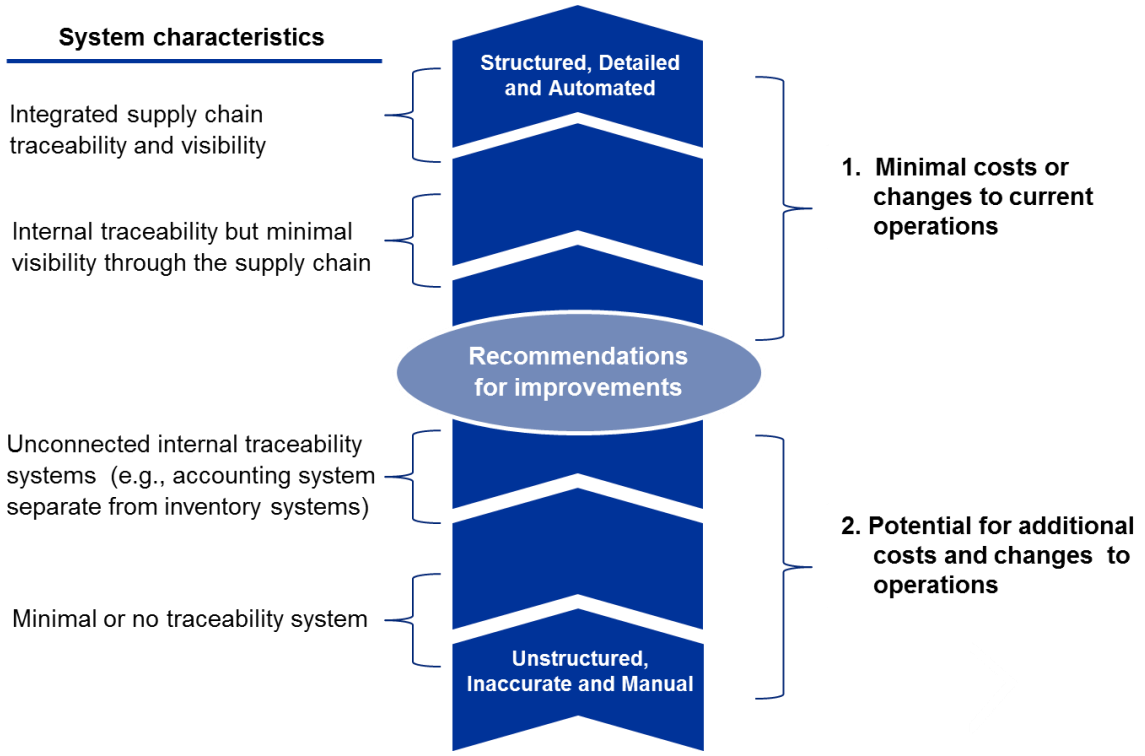
Delays/Confuses Traceback	Aids/Facilitates Traceback
Hard-copy paperwork that needs to be deciphered	Summary documents
PDF/hard copies of documents	Electronic documents that can be used by collaboration platforms or otherwise searched and sorted
General information on bills of lading	Lot information on bills of lading
First in First out inventory management based on time windows	Internal tracking that relates incoming with outgoing product
Errors within documents or hand-written notes on documents	Clearly organized documents that can be verified by cross referencing with corresponding supply chain members documents
Inconsistent use of terminology (e.g., when a PO number is later referred to as a lot number)	Consistent use of terms that enables immediate recognition across different documents

Figure 45 illustrates the relationship between the diversity of product tracing practices observed in the pilots and the associated cost to change practices. In some sectors, the investment will be minimal, as these firms already employ practices, systems, and technologies that enable product tracing. The challenge exists when a supply chain partner to these "best in class" firms lacks the practices, systems and technologies that enable tracing that product and is a weak link in the supply chain. These firms, depicted toward the bottom of the figure, will likely require the greatest investment (Figure 45).

Based on the pilot findings and discussion with stakeholders, IFT identified several types of information (KDEs) that FDA should expect industry to maintain for the purposes of tracking and tracing. The types of data are dependent on the nature of the event occurring (CTEs), shipping and receiving events, product transformations, and the ways in which products exit the system (through sale, donation, or disposition) and each require different pieces of information in order to link the movement of products. Many of these KDEs are already required to be kept by firms through the BT Act requirements and implementing regulations. The pilots showed that other pieces of information, such as PO or BOL, were incredibly valuable in establishing the links between what was shipped by one firm and received by another.

Neither the BT Act nor FSMA specifies the way in which firms should record or communicate information. IFT believes that firms should be able to continue to capture data according to the methods appropriate for the business, but does believe that at the point that FDA requests the information as part of a tracing investigation, the track and trace information should be provided using a standardized, structured, electronic reporting mechanism. The costs incurred by firms to meet IFT's recommendations are dependent on their current capabilities as well as the business decisions they make when considering the ancillary benefits achieved when using more sophisticated technology (e.g., improved inventory control).

Figure 45. Relationship Between the Diversity of Product Tracing Practices Observed in the Pilots and the Associated Cost to Change Practices



The technology systems that firms use are generally not focused on product tracing alone and often achieve product tracing as a result of another system capability. For example, warehouse management systems designed primarily for inventory can be used to capture KDEs. Decisions on which systems make the most sense for a particular firm should be made on a case-by-case basis. An ERP system has many benefits, but may not be a realistic solution if a business is not large enough to justify the cost. As recommended in this work, there needs to be standard definitions and guidelines on what information is most important and what information needs to be captured across industry.

Benefits related to improved product tracing are primarily related to public health, but firms should not ignore the benefits they will realize as well. Discussions with pilot participants and other stakeholders reinforce information available in the literature, which suggests that if a firm improves their ability to trace products, the firm can expect to also achieve improved business processes, increased supply chain confidence, and expanded markets. Many firms in the food industry consider product tracing a subset of the supply chain operations and product tracing may not be a dominant consideration when making investment decisions. However, the threat of not having product tracing capabilities in the event of a foodborne illness outbreak represents significant risks to an implicated firm.

Data from the public health analysis support the concept that if there is an improvement (reduction) in the number of days required for traceback then there can be a quantifiable benefit from the reduction of the number of illnesses associated with an outbreak. From the eight outbreak case studies analyzed, the estimated reduction in economic impact per day ranges from $1,053 to more than $277,000; the

number of illnesses that could be avoided ranges from 1 - 790; and the maximum economic benefit per outbreak ranges from $36,000 - $14 million. These case studies are limited in scope, but the data from the more severe outbreaks indicate that there would be a significant public health impact if improved product tracing systems are implemented. These results must be viewed within proper context and should not be viewed as the total public health impact, which would be higher. This analysis is just a starting place for future investigation and demonstrates one concept for measuring the public health benefits resulting from the reduction of illnesses for a particular outbreak.

Outbreaks continue to demonstrate that the public health impact is amplified when inadequate recordkeeping practices through a supply chain cause delays in identifying the source of contamination, and subsequently hinder the ability to determine the forward distribution of potentially contaminated products. Product tracing is not something that exists within a single firm—it is the product of accessible, detailed records at each point in a supply chain that relate to the records at the previous or subsequent supply chain points, enabling regulators to track the movement of food. It would be naïve to assume that there will be 100% compliance with any requirement and yet the ability to trace products relies on each supply chain member providing accurate data in a timely manner. For this reason, IFT suggests that extensive outreach and education around future regulations and expectations be offered. IFT expects that the recommendations contained herein will not only help protect consumers, but also help protect the brands and reputations of those firms who are committed to providing safe and abundant food, contributing to healthier people everywhere.

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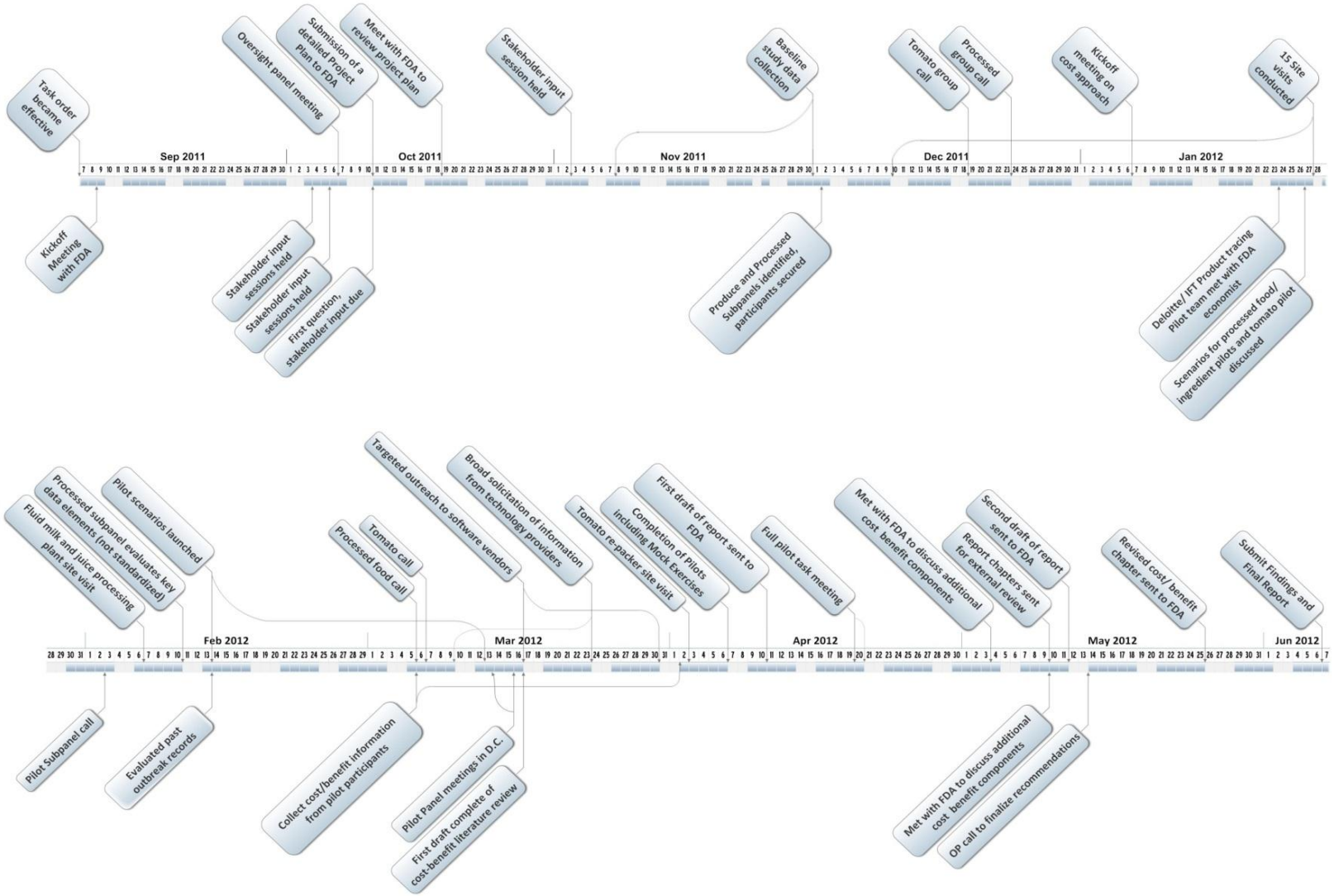
APPENDIX A. PILOT DELIVERABLES TIMELINE

Figure 46. Pilot Deliverables: Description, Dates Due, and Dates Delivered



APPENDIX B. RULES AND REGULATIONS IMPACTING PRODUCT TRACING

The FDA Food Safety Modernization Act ("FSMA") is the third law in the past 10 years to implement product tracing and reporting requirements for food. Two key legislative precursors are product tracing systems contained in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act") and the Food and Drug Amendments Act of 2007. These two laws contained the essential recordkeeping and reporting elements that are enhanced by FSMA's product tracing and related provisions discussed below. These laws inform the structure of the pilots and future programs created by FSMA.

The Bioterrorism Act's "one-up/one-down" product tracing. 21 USC §§ 350c & 374.

The Bioterrorism Act of 2002 (BT Act) provided the U.S. Food and Drug Administration (FDA) with authority to require large segments of the food industry to keep records of the "immediate previous sources and the immediate subsequent recipients of food." Section 414 of the Federal Food, Drug, and Cosmetic Act ("FFDCA") (21 U.S.C. § 350c(b)). Known as "one-up/one-down" product tracing, the system provides outbreak investigators with information on a food item that links it back or forward from a point in the supply chain (as long as it's not exempt). FDA issued final regulations to implement this provision in 2004. For more information see 69 Fed. Reg. 71562, Dec. 9, 2004, (21 C.F.R. § 1, Subpart J1 and § 11.1).

There were a number of shortcomings that quickly became apparent. The BT Act exempted farms and restaurants, and limited access to records, both of which can provide essential information in an outbreak investigation. The BT Act also failed to require tracking the movement of products through a single warehouse, so identification can be lost during an investigation. In 2007, the FDA proposed changes to the records access provisions in section 414 of the FFDCA and began public hearings to gather input on how it could improve its ability to trace food. Additionally, several members of Congress introduced legislation to require a more comprehensive product tracing system. Some of these proposals became the building blocks for product tracing provisions incorporated into the FSMA.

Reportable Food Registry and Essential Trace Information 21 U.S.C. § 350f.

The Food and Drug Amendments Act of 2007 added the reportable food registry ("RFR") which is closely linked to the recordkeeping and one-up one-down product tracing system established by section 414 of FSMA. Under its provisions, a responsible party must be able to provide notice to its immediate prior sources and immediate subsequent recipients of a reportable food.

The RFR requires a responsible party to file a report through the RFR electronic portal when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals (FDA 2010a). Such foods are "Reportable Foods."

Whereas the BT Act regulations require persons who manufacture, process, or pack food to record the lot, code or other identifiers (to the extent this information exists), the RFR adds more extensive identifying information such as use-by dates and names of manufacturers, packers, or distributors normally found on packaging. The RFR also requires information on the nature of the adulteration.

Improvements made by the RFR addressed some shortcomings in the one-up – one-down system, but did not fundamentally alter the overall product tracing system's focus on moving link-by-link through relationships between commercial entities. The FSMA provides FDA with broader authority and includes an opportunity to advance product tracing and its application to protect consumers from contaminated food.

FSMA Product Tracing Provisions § 204

Section 204 of FSMA requires FDA to take two actions designed to enhance its ability to trace foods. Subsections (a), (b), and (c) require the agency to study product tracing systems and technologies and establish an improved product tracing system based on its findings. FDA, under subsection (d), is to establish new recordkeeping requirements for foods that the agency identifies as high-risk.

Enhancing product tracing § 204(a), (b), and (c)

Under subsection (a), FDA is to conduct at least two pilot projects in coordination with the food industry to explore and evaluate methods to rapidly and effectively identify recipients of food. At least one pilot will focus on processed food and one on fruits or vegetables that are raw agricultural products. The pilot projects were to commence no later than 270 days after enactment of the FSMA with a report on findings and recommendations due 18 months after enactment. Subsection (b) provides for a data gathering program to review the feasibility of various tracing technologies. Subsection (c), provides authority to establish a product tracing system, considering the results of the pilots, that improves FDA's capacity to trace food. Notably, these provisions do not modify BT Act provisions in section 414 of the FFDCA, which will continue in effect, as a minimum standard for product tracing.

High-risk product tracing § 204(d)

Subsection (d) defines how FDA is to proceed in establishing additional recordkeeping requirements to aid in tracing high-risk foods. Within one year after enactment of the FSMA, the agency is to designate the foods that will fall under the high-risk food product tracing provisions and, within two years of enactment, must issue a proposed rule. In addition, the agency is required to conduct at least three public meetings in diverse geographical locations during the comment period on the proposed rules. Several provisions are prescriptive of agency authority. For example, the agency must ensure costs to industry don't outweigh public health benefits, scale the requirements to the affected facilities, and not require significant duplication of records.

The high-risk product tracing system is intended to go beyond the one-up – one-down product tracing system under section 414 of the FFDCA. Among its provisions is an allowance for FDA to require each person in the supply chain to maintain a more extensive history on the sources of a high-risk food. Although the FDA cannot require a full pedigree or a record of the complete previous distribution history from the point of origin (§ 204(d)(1)(L)(i)), the FDA is able to require recordkeeping that goes deeper than the immediate previous sources. The only limit is that requirements must relate to information that is reasonably available and appropriate, and meet cost-benefit criteria. However, there is an explicit prohibition on requiring records of recipients of a food beyond the immediate subsequent recipient—one up.

A major difference in the high-risk program is its application to farms. Cast as limitations, the program nonetheless requires farms to have identity-preserved labels that display the address and phone number of the farm or else fall under the recordkeeping provisions. Exemptions apply to certain fishing vessels, certain comingled raw agricultural commodities, food intended for further processing (if designated by the FDA) and certain farms. This last exemption applies to farms selling product directly to

consumers (or a grocery store). Product tracing in that instance is covered by a requirement for the grocery store to maintain records of the farm where the food originated. A separate provision in subsection (f) requires farms regardless of their exempt status to produce records that identify subsequent recipients (other than consumers) for an outbreak investigation.

Report and recommendations by GAO

Section 204 concludes with several housekeeping provisions. Subsection (e) requires the Government Accountability Office to report on the high-risk product tracing system and make recommendations, if warranted, for improving its effectiveness at protecting public health. The recommendations can extend to applying recordkeeping requirements to restaurants and other foods. Subsection (i) phases-in compliance for small and very small businesses and requires FDA to issue a small business compliance guide for complying with the high-risk recordkeeping requirements. Finally, subsection (j) provides for enforcement through the FFDCA's prohibited acts (section 301) and import refusal of admission provisions (section 801).

A review that only examined section 204 of FSMA would overlook the full impact of the new law on product tracing. As noted above, a number of sections affect product tracing recordkeeping or support stronger tracing capacity.

Records Access § 101

Section 101 of the FSMA expands FDA's authority to access records as part of an investigation. It permits FDA to access records in a food facility for articles of food that are related to the food under investigation. Previously, FDA could only obtain the records for articles of food under investigation but not for other foods produced in the same facility. Section 101 also provides a new avenue for gaining access where there is a reasonable probability an article of food will cause serious adverse health consequences or death. Under the older provision, FDA had to have a reasonable belief the food was (1) adulterated and (2) presented a threat of serious adverse health consequences or death. FDA testified in 2008 that this two-step proof hampered its investigation of the outbreak caused by melamine in pet food because the agency had clinical evidence of which food was causing illnesses but lacked clear evidence of specific adulteration.

Capacity building traceback report § 110(f)

Section 110 of the FSMA requires FDA to engage in a series of capacity building programs at the state and local levels for improving domestic food safety. Not later than two years after enactment of the FSMA, the agency is to report to Congress on programs and practices that promote safety and prevent outbreaks. Included in the report is an analysis of the FDA's performance in foodborne illness outbreaks involving fruits and vegetables during the five-year period preceding enactment. Among other requirements, the report must recommend enhancements to product tracing. The report also has to address communication and coordination issues related to outbreak identification and traceback.

Mandatory recall § 206

Although recalls are generally a post-trace activity, the FSMA's section 206 on mandatory recall authority includes notification requirements that dictate better product tracing recordkeeping. The provision requires a responsible party to notify its supply and distribution chain to cease distributing an article of food if ordered. (A "responsible party" is a term within the FFDCA which, in general, refers to the person who submits a food facility registration under section 415 of the FFDCA.) Where a recall addresses food that may not be sufficiently identifiable by a warehouse-based third-party logistics provider, the responsible party must include additional information to aid in its identification. This

provision protects warehouse operators from potential liability, but rules of construction in the provision state it does not exempt them from the requirements to keep records under section 414 of the FFDCA.

The mandatory recall provisions require notice to consumers and retailers who may have received the article of food. This provision bridges a gap in the product tracing system. Retailers are not required to keep records on their customers. As a result, the only means of warning consumers, who may have a dangerous product in their home, is through public notices. The section opens the door to better communication with consumers by directing the FDA to review the USDA's policy of publishing a list of retail consignees in Class I recalls. The list allows consumers to determine whether their grocer carried a recalled product.

IMPROVING CONSUMER NOTIFICATION UNDER THE REPORTABLE FOOD REGISTRY § 211

Section 211 of the FSMA builds on this base to address the shortcoming in the product tracing system referenced above. To reach consumers with information about a potential hazard, the FSMA requires the responsible party to submit a description of the food that consumers can use to identify it. This includes universal product code (UPC), stock-keeping unit (SKU), or lot/batch numbers. The FDA is then required to publish a notice on its website for grocery stores to download and post in conspicuous locations. This adds a new aspect to requirements for product tracing records by making the information on the container consumer-accessible. In doing so, it takes the supply chain product tracing system outside of its focus on products moving between commercial entities to directly warn the consumers the system is intended to protect.

Collectively, the FSMA contains a more comprehensive set of provisions related to product tracing than those appearing only in section 204 on enhancing tracking and tracing of food and recordkeeping. While that section is the only one dedicated specifically to product tracing reform, scattered throughout the Act are records access, capacity building, reporting, and recall provisions that support product tracing. Any consideration of how the FSMA changes product tracing requires a review of more than the modifications it contains to the existing foundation of one-up – one-down recordkeeping.

USDA Product Tracing Approach

USDA FSIS

The U.S. Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) follows directive 8080.3 (USDA-FSIS 2008). FSIS uses a centralized system to house information as it is shared. Investigators work collaboratively to gather traceback/traceforward information in commerce and/or at federally-inspected establishments. Information gathered is shared with epidemiologists; a timeline is established showing the progress made that day and identifying areas that need follow up.

USDA AMS

In the produce industry, recordkeeping requirements are often discussed in the context of the Perishable Agricultural Commodities Act (PACA), established in 1930. According to the USDA Agricultural Marketing Service (AMS), "any person who buys or sells more than 2,000 pounds of fresh or frozen fruits and vegetables in any given day is required to be licensed under the PACA. Wholesalers, processors, truckers, grocery wholesalers, and food service firms fit into this category (USDA-AMS 2006)." Section 499i specifies "every commission merchant, dealer, and broker shall keep such accounts, records, and memoranda as fully and correctly disclose all transactions involved in his business (Perishable Agricultural Commodities Act, 1930)."

State Product Tracing Approaches

In the US, there are approximately 3,000 state and local agencies with some regulatory responsibility for food safety. Many of these agencies also have their own epidemiology / disease surveillance programs and public health laboratories. This system creates challenges when foodborne disease surveillance, detection, investigation and response are conducted, as there often is a lack of clarity over roles and responsibilities and decision-making authority. Staff who conduct these investigations usually have many responsibilities in addition to foodborne disease surveillance. Epidemiologists are conducting surveillance for many diseases and often have multiple investigations they are juggling at the same time. Federal food safety agencies depend on under-funded state and local agencies to identify and investigate outbreaks linked to products that they regulate.

Some States also may have rules, sometimes commodity specific, that are relevant to product tracing and recordkeeping. In Florida, for example, tomato growers and packers, including re-packers, are required to comply with the Tomato Good Agricultural Practices (T-GAP) and Tomato Best Management Practices (T-BMP) as defined in the Tomato Best Practices Manual (FDACS 2007). Sections “o” through “s” touch on recordkeeping and lot identification, and place limits on what re-packers may commingle.

In Ohio, the Ohio Produce Marketing Agreement Program was established in 2010 (OPGMA 2010); product tracing is one of the four core standards. This requires the generation of lot numbers (using whatever format is determined to be appropriate by the firm).

The Institute of Food Technologists (IFT) did not conduct an exhaustive search of product tracing requirements or commodity requirements in each state, but these examples illustrate that some states specify their expectations of product tracing systems, which is important given the role that state and local governments play in traceback investigations.

APPENDIX C. SUMMARY OF 2009 FDA OIG REPORT ON PRODUCT TRACING

The Office of Inspector General (OIG) conducted a study in 2009, and reported how the product tracing system performed in certain supply chains for a pseudo-random sample of foods. They discovered that the capability of some in the supply chain to accurately report "the one-up, one-down" information was lacking for a significant number of participants (Levinson 2009). It could be argued that the experimental sample size was too small and the items selected might not have been completely random. However, the results could show the level of capability among the points in the different supply chains. All the information which is summarized in this section was taken from the 2009 OIG report.

The OIG study was based on two primary data sources: (1) a product tracing 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 product tracing exercise, 40 food products were purchased from different retail stores and OIG attempted to trace them through each stage of the food supply chain back to the farm(s) or the border. The supply chain partners who had handled the products were asked for information about their sources, recipients, and transporters, which were used in an effort to trace the product.

As a result of the information that was collected, the OIG was able to trace 5 of the 40 products through each stage of the food supply chain. For 31 of the 40 products, the inspectors were able to identify the facilities that likely handled the products as they moved through the value chain. Most facilities that handled these products did not maintain lot-specific information and could only provide a range of dates that the products might have been delivered. As a result, the inspectors were not able to trace these specific products through each stage of the food supply chain. For four products, the inspectors 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.

The OIG's study report suggested that several factors limited the inspectors' 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 if they exist, as required by the regulations implemented in response to the BT Act; (2) other types of facilities not maintaining lot-specific information because it is not required by the BT Act or related regulations; (3) retailers receiving products not labeled with lot-specific information; and (4) the mixing of products from a large number of farms. The inspectors concluded that these factors also affect the speed with which the FDA can trace specific food products through the food supply chain.

The second part of the OIG study was a structured survey of managers at food facilities that handled the selected food products. Fifty-nine percent (70 of 118) of the food facilities 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.

The survey found that the 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.

While the survey was conducted without an outbreak as an impetus for the investigation, it demonstrates some of the recordkeeping issues often cited by regulators as impacting the ability to trace products.

APPENDIX D. PREVIOUS PRODUCT TRACING PILOTS

Most published studies of food product tracing are peripheral to the types of pilots required by Congress in the 2011 FDA Food Safety Modernization Act.

Some pilot studies have focused on internal product tracing, exploring inventory and other efficiencies achieved by a single firm. Others have explored the use of different data carriers, such as radio frequency identification (RFID) tags, to hold information. Some other sectors of agriculture have performed studies akin to the pilots described herein, looking at the flow of data through supply chains (Bhatt, 2012).

In 2004, Can-Trace published the results of a product tracing pilot (Can-Trace 2004a) which evaluated recalls (not tracebacks) in the beef, pork, and produce industries. Seven firms participated in the produce pilots, which took roughly two months to complete. Two recall scenarios were evaluated, each limited to three supply chain nodes (grower and packer/shipper distributor in the first scenario, and importer, distributor, retail/foodservice in the second scenario). The lack of a unique identifier used throughout the supply chain and the variations in nomenclature were identified as challenges to a rapid traceback.

The study most relevant to the pilots conducted in the present work involved tomatoes. A task issued to the Institute of Food Technologists (IFT) in 2009 built upon work initiated by Harvard University in the summer of 2008 that included Microsoft, TIBCO, tomato associations, state and federal regulators, and a tomato supply chain (grower, distributor, foodservice chain). The study centered on the benefits of collaboration, and explored how existing data, converted to electronic format, could be used to conduct a mock traceback/traceforward aided by visualization software. This work sought to evaluate the following: ease of participation and use for industry to submit and store data and for government to use these data; whether and how, using available data and visualization software, industry working with government could, upon request, illuminate designated supply chains; whether or not this process could expedite product tracing investigations, or what else might be needed to support such efforts and; how industry and government collaboration might improve the traceback process.

The statement of work charged IFT to:

“Organize and implement a mock traceback/traceforward exercise, in which FDA and other subject matter experts would participate, utilizing:

- a collaboration platform to share data from various sectors of the tomato industry
- establish whether the data sets and technology platform would allow for expedited electronic traceback/traceforward of tomatoes.

In this work, over 25,000 records of transactions associated with tomatoes were acquired. The firms who supplied these data did so through a spreadsheet template. Historical data covering a two week timeframe was used but were not collected in response to a particular situation. Rather, the data were pooled and then queried to illuminate supply chain paths.

The data collection process was iterative, since additional supply chain participants were identified after the initial work was begun. Additionally, the data deemed necessary to trace products continued to evolve so some firms needed to provide different pieces of information over time to ensure that the supply chain links could be established. This work was conducted before IFT proposed the critical tracking event (CTE) and key data element (KDE) concepts, but the data collection process in the pilot validated the 2010 recommendation for clarity around data requirements. The current pilots have built upon, tested, and further refined these data elements.

Table 53 shows the data that were ultimately captured in this work.

Table 53. Data Needs of Mock Tomato Traceback

Grower	Packing House:	Re-packer	Distributor	Point of Service
Name	Name	Name	Name	Store Number
Address	Address	Address	Address	Address
City	City	City	City	City
State	State	State	State	State
Blue Book Number	Blue Book Number	Blue Book Number (if any)	N/A	N/A
Lot ID	Lot ID	Input/Output Lot Number	Input/Output Lot Number	Input Lot Number
N/A	N/A	Repack Number	Repack Number	N/A
Harvest Date	Pack/Ship Date	Ship Date	Ship/Receive Date	Receive Date
N/A	Product Description	Product Description	Product Description	Product Description
N/A	Product Code	Product	Product	Product
N/A	Quantity Shipped	Quantity	Quantity	Quantity
N/A	Pounds	Pounds	Pounds	Pounds
N/A	N/A	Shrink	Shrink	Shrink

Before the visualization software system was functional, the data needed to be reviewed for accuracy and errors. While the analysis generally only took minutes, it took months of "prepping" the data before the analysis could be conducted. Errors included the identification of ship dates that occurred after the product was reported received, discrepancies in quantities shipped versus received, etc. Further, several data fields in the spreadsheet needed to be standardized, including date, quantity, and address.

The mock traceback/traceforward demonstrated there was value in industry and government working in collaboration, sharing data, and achieving faster, visual traceback/traceforward results. The potential exists to expedite tracebacks by visualizing supply chains to find points of commonality based on data availability, capture, and readiness. The 2009 tomato pilot tested a limited data set. Real time data, other food products, a broader geographical region, import data, and a complete supply chain were not tested to their full extent.

While not a pilot, IFT's initial work in the product tracing area involved outreach to 58 food companies, including those involved in produce, animal feed, and ingredients (McEntire and others, 2010). In this study, IFT coined the terms "Critical Tracking Events" and "Key Data Elements" which are now in ubiquitous use in food product tracing. It was evident that across industries, firms generally were comfortable with their abilities to trace products through their facilities. All firms believed that they were in compliance with the recordkeeping requirements stemming from the BT Act, and yet it was

clear that they often relied on their trading partners for critical pieces of information during a traceback investigation. IFT believed that there were critical events that occurred through the supply chain in which data capture was necessary to be able to establish the path a product took. These events, termed "Critical Tracking Events" encompassed both events that enabled tracking within a company (internal tracing) as well as those in which product moved between supply chain partners (external tracing).

The report recommended that product tracing data be provided in a standardized, electronic format, and identified several candidate standards in existence at that time.

This task also required IFT to conduct a cost evaluation, which was difficult. So few published studies existed that IFT took the approach of identifying the types of costs that could be expected to be incurred by firms, as well as the types of benefits companies could reap by improving their ability to trace products.

APPENDIX E. FOOD PRODUCT SELECTION MATRIX

Table 54. Food Product Selection Matrix

	Leafy lettuce	Leafy spin	Tomatoe	Hot pepper	Sprout	Cilantro	Cantalo-upe	Berries	Peanut paste	Chicken pot pie ***	Spice	Frozen pizza ***	Seafood ***	Nutmeg almond
Imported														
Geo diverse region														
Dist complexity														
Packaged /UPC**														
Multiple														
no label at retail**														
Bulk ingredient														
Commingled-same product														
Nomenclature issues														
Prod, ingr complexity/ transformation														
Assc w out-breaks 2005-10														
Use as an ingredient-tomato in salsa														
Inc small business														
Retail*														
Foodservice*														

- *Issue here is whether the contaminated product is provided both at retail and foodservice (illness at both locations)
- **issue here is whether the same product diverges and appears in both packaged and unlabeled form (both can cause illness)
- ***excluded due to causative vehicle being an FSIS regulated product (pot pie and pizza) or because processed products are rarely associated with severe illness (seafood)
- Import: high = >50% product is imported throughout the year; med = 25 - 50% is imported, depending on time of year; low = less than medium; or zero
- Geographically diverse region: high = >6 states in several time zones; med= >3 states in two time zones; low = two states or zero
- Small businesses: please describe the points in the supply chain that have high small business presence
- Associated with outbreaks: high - >2 outbreaks AND high number of cases, severe illness; med - > two outbreaks OR high number of cases

APPENDIX F. FREQUENTLY ASKED QUESTIONS

Frequently Asked Questions about the Product Tracing Pilots

How can individuals be involved and find out more about the pilots?

There are many variables with respect to conducting the pilots, and IFT hopes to gain stakeholder input during the process. There are several areas in which IFT is seeking specific input. After posting these questions, IFT hopes stakeholders will take advantage of opportunities to provide oral feedback (tentatively scheduled for October 3, 2011 in Seattle, WA, October 5 in Washington, DC, and November 2 in Chicago, IL; other locations TBD) and/or written feedback (by December 1). Exact dates and locations, and additional information, will be available at www.ift.org/traceability shortly. Caitlin Hickey is the IFT point of contact for inquiries (chickey@ift.org).

Why was IFT chosen by the FDA to lead these pilots?

IFT was competitively awarded a 5-year contract with FDA in 2009. This was IFT's third competitively awarded contract. Within the five year period, FDA asks IFT to perform specific "tasks". In the last contract, tasks focused on issues such as food defense, allergen labeling, and product tracing. Results from the most recent product tracing tasks can be found at www.ift.org/traceability under '2009 IFT Report Findings and Recommendations to FDA: Product tracing (Product Tracing) in Food Systems'. The most recent task requires IFT to execute the product tracing pilots that FDA is required to perform as part of the FDA Food Safety Modernization Act.

How will this all come together?

Three IFT food scientists (one Ph.D, and 2 MS), along with support staff, will work with a group of 8 "oversight panelists". Although the pilot tests are the main component of the task, IFT staff must also conduct related work to inform the final report to FDA. Oversight panelists have been invited. They include Douglas Bailey from the USDA Agricultural Marketing Service, Benjamin Miller from the MN Department of Agriculture, Bruce Welt from the University of Florida, Brenda Lloyd from UFPC/Yum! Brands, Jack Guzewich, IFT's Food Safety Strategist, Thomas Breuer from Deloitte Consulting, and Caroline Smith DeWaal from the Center for Science in the Public Interest. In addition, IFT expects to enlist a number of participants, potentially including state traceback investigators, food industry members, and others, for actual pilot tests. Both the produce and processed food studies will consist of at least two tests. Finally, IFT is charged with evaluating the costs and benefits associated with the pilots and other tracing technologies. IFT expects to issue a subcontract to Auburn University to support their cost- benefit research efforts on this task. Stakeholder input sessions, described below, will also take place.

Is IFT accepting additional sources of funding to complete the work?

No. Although IFT has recently launched a Traceability improvement initiative which is privately funded, that Initiative is not supporting the pilots (the Initiative is augmenting an award from the National Center for Food Protection and Defense to study interoperability of product tracing technology providers). IFT will not accept additional funds to support the pilots. However, IFT has been encouraged by the in-kind support offered by technology providers, food industry members and others. IFT does not expect that the budget will allow IFT to reimburse all participants for all time expended on this task, and is appreciative of the effort that may be volunteered. A team from Deloitte Consulting will be leading the cost- benefit evaluation (with Auburn University) pro bono.

How will the pilots be conducted?

First, gaining stakeholder input is critical and will help shape details around how the pilots are conducted. Second, it is important to clarify that Congress required pilots to evaluate product tracing, not recalls. A traceback investigation seeks to identify points of convergence, beginning with many downstream points in a supply chain and potentially including a number of different types of products.

IFT will work with a group of state traceback investigators to evaluate some historical data to determine a "baseline" for the time and effort involved in various investigations (including produce and processed food(s)), as well as the factors that seem to influence the ability to trace products.

IFT does not expect that the first pilot test will use any kind of technology solution. Rather, IFT will evaluate industry practices and will test how these processes, practices, and systems can be modified to improve the speed and accuracy of a traceback investigation. This might include testing Critical Tracking Events, Key Data Elements, standardization, and data formats.

Once the data requirements and food industry practices have been evaluated, IFT will explore how collaboration platforms (likely third party technology solutions) can be used to further enhance traceback capabilities.

Is IFT going to create a new product tracing solution to test in the pilots?

No. Over the past several years IFT has learned about so many commercially available technologies, as well as those in development, that it did not seem economical or efficient to develop a new system for this task.

If the pilots are supposed to test technology providers, how will they be selected?

As stated above, examining the effect of using a technology platform is only one aspect of the task. Given the scores of technology providers in existence, many of whom have already contacted IFT requesting to be involved, how participants will be selected is a very difficult question to answer. IFT seeks considerable input regarding the characteristics of the platform(s) that should be involved, and how to fairly select participants. IFT does not expect that all technology providers who wish to be involved will serve as "the" collaboration platform or have ready access to the data used in the pilots. Consistent with FSMA provisions, FDA will be engaged in rulemaking with regard to product tracing. Consequently, **all data and documents used or generated as part of this task order will be provided to FDA** and may become part of a public record in the rule making process. Data and documents may also become public if a request is made under the Freedom of Information Act. IFT **will not** remove any company-identifying information. FDA will redact any documents or data that are to be made public, in keeping with the applicable laws and regulations governing disclosure.

If only a few technology providers will be involved in the pilots, how can other providers let FDA know of their capabilities?

FDA must hold 3 public meetings as they proceed in rule making related to product tracing. In addition to providing input directly to FDA, individuals and companies are also encouraged to provide input directly to IFT for consideration by the oversight panel. This information may be evaluated and compiled for inclusion in IFT's report to FDA.

How will food industry participants be selected and what is expected of them?

IFT is interested in input regarding the food products to be evaluated. Once selected, IFT will seek participants. Consistent with FSMA provisions, FDA will be engaged in rulemaking with regard to product tracing. Consequently, **all data and documents used or generated as part of this task order will be**

provided to FDA and may become part of a public record in the rule making process. Data and documents may also become public if a request is made under the Freedom of Information Act. IFT **will not** remove any company-identifying information. FDA will redact any documents or data that are to be made public, in keeping with the applicable laws and regulations governing disclosure.

How will the stakeholder input meetings be run?

At the meetings, there will be a 15 minute overview by IFT on the task. There will be no other formal presentations. The rest of the time will be divided based on the number of stakeholders requesting time. Each person will get at least 5 minutes, depending on the number of individuals requesting time to speak. We will schedule people in the order that they register until all spots are full. Because of space limitations, preference will be given to those wishing to speak versus attend or listen. We expect an audio recording will be available for a limited time after the meetings.

Can an individual speak at more than one stakeholder input meeting?

Individuals may speak at more than one session, pending space. Priority will be given to those who are not speaking at another input session. IFT will be giving the same presentation at all input meetings.

APPENDIX G. STAKEHOLDER INPUT CORRESPONDENCE AND QUESTIONS

Background information:

The Institute of Food Technologists (IFT) will lead two pilot programs for the U.S. Food and Drug Administration (FDA) designed to test and study various product tracing systems. The purpose of these pilots will be to identify methods to rapidly and effectively trace food products throughout the supply chain so that, during a food-related outbreak, products can be quickly identified and removed from the marketplace, which will ultimately help minimize the number of consumers affected by a contaminated product.

IFT is seeking input on the following questions. Please visit http://www.ift.org/traceability and FDA's Product Tracing Webpage (http://www.fda.gov/Food/FoodSafety/FSMA/ucm270851.htm) for more information on the pilots.

Written responses can be sent to Caitlin Hickey at chickey@ift.org.

Three stakeholder input sessions have been scheduled:

Table 55. IFT Stakeholder Input Sessions, Date, Location and Times

Date	Location	Time Window	Please Respond by	Receive confirmation
Oct 3, 2011	**Seattle, WA**	8am-12pm	Sept 26, 2011	Sept 28, 2011
Oct 5, 2011	**Washington, DC**	12pm-5pm	Sept 26, 2011	Sept 30, 2011
Nov 2, 2011	**Chicago, IL**	8am-2pm	Oct 18, 2011	Oct 24, 2011

Please register at: http://www.surveymonkey.com/s/LN6QXDD

Input needed:

1. *FSMA requires that the pilots examine foods associated with outbreaks between 2005-2010.
    a. How should the products evaluated in the pilots be selected? Which products are best for evaluation?
    b. How heavily should each of the following factors be weighted in selecting the products?
        i. willingness of supply chain partners to participate;
        ii. distribution complexity, including number of "points" in the supply chain, inclusion of very small & small businesses and crossing of international boundaries;
        iii. food product complexity, including number of ingredients, commingling, etc;
        iv. processing/harvesting conditions that may increase the likelihood of contamination

2. Several segments of the food industry, such as produce and seafood, have encouraged the adoption of a method to trace products (e.g, PTI). To what extent should these initiatives and other industry-led pilots and projects be considered by IFT?
3. A two phased approach to the pilots was proposed, focusing first on enhancing practices already in place in the food industry, and then on determining the impact of using collaboration platforms to analyze data. In the first phase, IFT proposed to explore how defining Critical Tracking Events and focusing on Key Data Elements might improve the ability to trace products. To what extent should the pilots seek to:
    a. test which points in the supply chain (internal and external) need to capture data, the level of granularity needed, and the logistical unit to be tracked.
    b. test the data that are needed to link ingredients and finished products as well as shipments between trading partners
    c. explore how standardizing data formats (e.g., a common system to identify locations) could facilitate product tracing?
4. The intent of the FSMA is to improve product tracing beyond the BT Act requirements. Several points in the supply chain are exempt from the BT Act recordkeeping requirements. To what extent should the pilots include those who are exempt from the BT Act requirements (e.g., those at the beginning and ends of the supply chain, brokers, overseas sources, etc.)
5. Should the pilots consider paper-based information (batch logs, bills of lading, etc.) or should the focus be on information that is available in electronic form only? To what extent should we consider data carriers such as bar codes and RFID tags?
6. Should the pilots leverage defined industry logistical standards and practices for defining and marking information on product packaging or should new standards and tracking systems be given equal consideration?
7. IFT was charged with using a “collaboration platform” (which will likely be done in the second phase of the pilots). IFT will not be developing a “collaboration platform” as part of this task.
    a. Given that scores of technology and service providers exist, how should the “collaboration platform” be selected?
    b. To what extent should proprietary systems be considered? Should systems that are not yet commercially available be used? If only one or a limited number of systems is used, how can the results of the study be applied broadly, rather than just to the firm providing the platform?
8. IFT must conduct a cost/benefit analysis. Many benefits reported by industry are the result of using data that may be “above and beyond” what is needed to simply trace products. To what extent should tangential benefits be quantified?
9. All processors and industry stakeholders have expenses related to capture of information that is relevant to product tracing. In some cases, this information is included as ancillary in procurement and invoicing systems. To what extent can IFT gather data and segregate the current cost of collecting product tracing information in existing industry systems?

*Responses to question 1 must be delivered by October 10, 2011

APPENDIX H. MEETINGS FOR STAKEHOLDER INPUT ON APPROACH FOR FDA PILOTS

Table 56. Meetings at which IFT Collected Stakeholder Input or Presented on Approach for FDA Pilots

Date	Location	Approximate Number of Attendees	Key Questions/Concerns/Input
Sept 20, 2011	**International Foodservice Distributors Association, Tysons, VA**	18	Against case level tracking - would slow system; feel that knowing supplier is more important than tracking lot number on cases
Oct 2, 2011	**ISSC, Seattle, WA**	~35	Asked if data provided would be subject to enforcement action; curious if shellfish could be part of pilot (and if not could one be done with FDA); concern that tracing at retail is poor and pilot should focus there
Oct 3, 2011	**United Fresh Produce Association, Food Safety & Technology Group, Washington, DC**	40	Concern that findings from one pilot/one product cannot be applied to other produce items; question whether this includes bagged produce; how will PTI be part of study; difference or overlap between epidemiological and regulatory trace
Oct 4, 2011	**North West Food Processors Association, webinar**	13	Association with outbreaks and food product complexity should drive product selection; industry initiatives should be considered; pilot should include paper and electronic records; all in supply chain should participate; collaboration platform should be commercially available and have customers; ancillary benefits should be considered
Oct 6, 2011	**Underwriters Laboratories Inc. Meeting, Chicago, IL**	20-25	Need to consider food contact packaging as an "ingredient" in the processed food pilot because it adds a whole new level of complexity to outbreak investigation and traceback. Consider evaluating the need/benefits for having standards to audit product tracing systems and their effectiveness. Need to consider how FDA would interface/interact with the collaboration platform being evaluated in the pilots.
October 12, 2011	**Produce Product Tracing Initiative Leadership Meeting, Atlanta, GA**	~30	Standardized key data elements needed for industry wide adoption; standards need to be identified and required by FDA. Education, outreach and training should also be a component of an effective product tracing system. Collaboration platform should include how FDA and state and local public health officials would collaborate with the industry using the system.
October 20, 2011	**Food Marketing Institute, Washington, DC**	26	Foreign suppliers deemed important in the pilots; requested a retail expert on the oversight panel. Had very strong opinions towards one of the pilots that it includes tomatoes, especially 'red round' or 'number five' tomatoes. Did not like the idea of using sprouts, based on comparative simplicity of supply chain.

Date	Location	Approximate Number of Attendees	Key Questions/Concerns/Input
October 26, 2011	**Flavor and Extract Manufacturers Association, Jersey City, NJ**	~130	Few questions; only question pertained to consistency between audits for product tracing
November 16, 2011	**SINTEF Fisheries and Aquaculture, Oslo, Norway**	~35	Few questions; questions regarded FSMA deadlines and Electronic Product Code Information Services (EPCIS) inclusion within pilots.
December 8, 2011	**American Peanut Council Winter Conference, Washington, DC**	~30	Concern on negative publicity, some questions about how the pilots will run.
December 1, 2011	**Food Policy Impact Conference, Washington, DC**	~40	N/A
January 4, 2012	**Western Growers, webinar**	102	N/A
Feb 1, 2012	**Washington DC section IFT, Washington, DC**	~50	Questions regarding the cost-benefit analysis, inclusion and applicability to retail and foodservice
Feb 1, 2012	**Pew Charitable Trust, Washington, DC**	~50	N/A
March 1, 2012	**Global Midwest Alliance Meeting, Chicago, IL**	~50	N/A
April 12, 2012	**3rd Annual Food Defense Strategy Exchange, Washington, DC**	40	N/A
April 18, 2012	**Food Safety Summit, Washington, DC**	~100	N/A
May 2, 2012	**Produce Traceability Initiative Leadership Conference, Dallas, TX**	N/A	N/A
May 2, 2012	**Association of Official Agricultural Chemists (AOAC) / American Association of Cereal Chemists (AACC) Annual Meeting, Long Beach, CA**	~25	N/A
May 8, 2012	**Food Safety Technology, Chicago, IL**	~60	N/A
June 6, 2012	**GS1 Connect, Las Vegas, NV**	~45	N/A
June 6, 2012	**Trans Atlantic Consumer Dialogue (TACD) Conference**	~60	N/A
June 14, 2012	**New Zealand Seafood Industry Traceability Workshop**	~30	N/A

Date	Location	Approximate Number of Attendees	Key Questions/Concerns/Input
June 27, 2012	**IFT Annual Meeting, Las Vegas, NV**	N/A	N/A
July 24, 2012	**International Association for Food Protection, Providence, RI**	N/A	N/A
Oct 11, 2012	**National Restaurant Association Quality Assurance Executive Study Group Meeting, Nashville TN**	N/A	N/A

*In each case, there was either no travel or travel costs were covered by the meeting host. Therefore, the only charge to the task was for time (generally less than one hour per meeting). IFT or Leavitt Partners is absorbing the cost for time to give presentations after the task concludes on June 6, 2012. The purpose of these presentations was to either collect stakeholder input or be transparent in the process and approach IFT was undertaking on the pilots. There was no discussion of the results of the pilots at any of these venues (for future venues, results will not be discussed without prior FDA approval)

APPENDIX I. IFT - FDA PRODUCT TRACING PILOTS BASELINE STUDY

Discussions were held with the following individuals based on the following information provided to them in advance of the phone call:

List of investigators:

Debbra Callan, Texas Department of State Health Services

Karla Clendenin, Florida Department of Agriculture and Consumer Services

Shaun Cosgrove, Colorado Department of Public Health

Diane Eckles, Arizona Department of Agriculture

Steve Fuller, Washington Department of Agriculture

Lisa Hainstock, Michigan Department of Agriculture

Sandi Hanson, U.S. Food and Drug Administration (FDA) Coordinated Outbreak Response and Evaluation (CORE)

Rita Johnson, Florida Department of Agriculture and Consumer Services

Ernest Julian, Rhode Island Department of Health

Pat Kennelly, California Department of Public Health

Thomas McLean, FDA

Ben Miller, Minnesota Department of Agriculture

Carrie Rigdon, Minnesota Department of Agriculture

Randy Robertson, U.S. Department of Agriculture (USDA) Food Safety Inspection Service (FSIS)

Nicole Yuen, FDA San Francisco District Office

Ingrid Zambrana, FDA

(contact was also made with Utah, Virginia, Missouri, and Kansas but was unable to conduct the discussions with them)

Individuals were provided with the following information prior to the discussion:

The FDA contracted with the Institute of Food Technologists (IFT) to execute the product tracing pilots required by the FDA Food Safety Modernization Act (FSMA). In order to determine which variables to test in the pilots, IFT need to determine the factors that make an investigation “easy” or “difficult.” We wish to speak with you and other traceback investigators to establish a baseline so that we can determine, in the pilots, the extent of improvements.

Please consider the questions below with respect to any of the following outbreaks which you worked on. Ideally, our conversation will focus on one - two outbreaks that you felt were easy to trace and one - two that you felt were difficult to trace. We will also ask you to identify one or two additional outbreaks not listed that are memorable to you as being particularly easy or difficult, and discuss the attributes that aided or hindered your ability to trace.

To the extent possible, we would like to quantify factors such as time and resources so that we can test potential improvements that will increase the speed and accuracy of traceback investigations.

If you have any questions about the pilot study, please contact the Project Director, Jennifer McEntire at *jennifer.mcentire@leavittpartners.com* 301-551-3601. Questions for FDA may be directed to Sherri McGarry *sherri.mcgarry@fda.hhs.gov*.

Outbreaks

- 2010 – 11, hazelnut
- 2010, *Salmonella* Montevideo, pepper
- *E. coli* O157:H7, Nestle cookie dough
- 2009, *Salmonella* St. Paul, tomato/pepper
- 2006, *E. coli* O157:H7, spinach
- *Salmonella* Baildon, associated with taco bell, unsolved
- *Salmonella,* pet food
- 2009, *Salmonella* Typhimurium, lettuce
- *Salmonella* St Paul, sprouts, Nebraska
- *Salmonella,* Peter Pan peanut butter
- 2009, *Salmonella,* PCA

Questions for Discussion:

In the past (2) years, how many tracebacks has your agency attempted? How many were successful (determined the source of the outbreak or resulted in adulterated product being removed from the marketplace)?

Do you wait until there is an epidemiologically implicated vehicle until you start a traceback?

From the regulatory trace perspective, was this an easy or difficult trace? Was it successful or unsuccessful?

How many different products were traced as part of this investigation?

How long did it take from the time you or your office was alerted to the issue to the time that you had traced the product as far back as you could? Were there external factors (political, etc) that influenced the speed at which the investigation was conducted?

What were the average person-hours of active pursuit (active time does not include waiting for industry response to data requests) required to complete the traceback?

Is this expenditure of resources a concern in conducting tracebacks in general? Do you limit your traceback activities based on resource allocation or constraints?

What were the key factors that facilitated this trace (e.g., “good” records- what makes them “good”)?

What were the key factors that made this trace difficult (e.g., a number of suspect ingredients, missing data)?

What kinds of resources were used to complete the “easy” trace, in terms of labor hours, total expense etc.?

What kinds of resources were needed to conduct the more difficult traces?

Is this expenditure of resources a concern in conducting tracebacks in general? Do you limit your traceback activities based on resource allocation or constraints?

Fill in the blank: If _____ had happened/existed, it would have made this traceback easier in the following way_____, and this could have had the following impact _____

Results

Based on the discussions, IFT was able to gain a picture of the issues faced by traceback investigators during an investigation.

Initiating a Traceback

The start of a state traceback investigator's role in an investigation is heavily reliant on the information gathered by the epidemiology team. Several state investigators reported having a relationship with the epidemiological staff, and were therefore aware of the multiple food items identified as possibly being responsible for a foodborne illness outbreak. State investigators seldom wait for a single food to be implicated, and will start tracing the supply chains of a few items to look for convergence. If the implicated product is branded, state investigators may wait a bit longer to determine the correct product/brand before proceeding with the traceback and traceforward. In some instances, investigators reported becoming involved after the the FDA or another state identified a potential segment of a supply chain being investigated that resided in that state. The FDA field offices differ in when they become involved in traceback investigations, primarily based on their relationships with the state health and agriculture departments. FDA traceback investigators commonly become involved in an investigation once the FDA and Centers for Disease Control (CDC) determine clusters of illnesses that are deemed actionable.

Timeline and Resources

State traceback investigators indicated that most "easy" traceback investigations are started within one day of notification. Time until the completion of the trace varies depending on many factors, including the type of product implicated, the approach to traceback, the number and quality of records, the number of trips that were needed, the cause of the end of the traceback (convergence found vs. not found), etc. "Easy" investigations are reported to last between a few days up to two and a half weeks. Tracebacks deemed "difficult" were started between one and five days within notification. The additional time before starting the traceback is commonly associated with the inability to determine with enough specificity the likely suspects in food contamination. "Difficult" investigations can last up to two months or more. There are many factors associated with determining when to conclude an investigation, including available resources, the shelf life of the product, the amount of new information being gathered, and the prevalence of continuing illnesses.

Investigations deemed "easy" had between 4 and 20 person hours associated with completing the traceback/traceforward. "Difficult" investigations ranged from 8 to 240 hours or more, with a large range of total employees working on the trace.

Inter-Agency Collaboration

Often, investigations start at the local and state levels, with FDA headquarters as well as the regional and district FDA offices becoming involved in multi-state traceback investigations. Sometimes the FDA will verify the information that state traceback investigators have gathered, essentially duplicating the work done. However, the FDA noted that when this occurs, it is not duplicative, but rather an effort to

fill data gaps or better understand and interpret the data provided. The FDA noted that when states have collected much of the needed information, the investigations proceed much more smoothly. Some state investigators noted that the FDA did not share with the state level traceback investigators all the information they had, hindering the work that could be done; however, FDA is legally restricted from sharing commercial confidential information, needing to ensure that such information is provided pursuant to written confidentiality agreements or to state officials who have been commissioned by FDA. There were concerns that some at the state level were not commissioned by FDA and that there would be benefit in increasing the pool of investigators who could collaborate. In addition, state agencies felt that in some instances they knew first-hand about the quality of data based on previous interactions with the firms in their states, whereas the FDA may have more difficulty in assessing whether data provided to the Agency were accurate. It was clear from discussions with state investigators that they sought increased collaboration with the FDA to aid in traceback investigations. Similarly, traceback investigators at the FDA noted the importance of articulating the purpose of their traceback activities to those they are collaborating with; and one investigator suggested standardizing the questions that are asked of firms between the state and federal level investigators.

Number of Supply Chain Nodes/Extra Trips

Generally, when traceback investigators spoke about cases, they noted that most investigations included contact with three or more nodes within the supply chain. Although more nodes can commonly make an investigation more difficult, the state investigators that IFT spoke with said some “difficult” tracebacks have had a minimal number of nodes. Data collection is performed very differently between states, with some physically taking trips to the different locations for collecting information, and others collecting information by phone or email. All investigators noted that follow-up with the supply chain nodes was necessary and common within a traceback investigation. It is also common for records to be incorrect, lacking information, or containing information that cannot be read or easily understood. This necessitates multiple visits or calls to a single company to obtain additional or clarifying information.

Qualities That Make Traceback Easier

Consumer, Epidemiological, and Product Identification Factors

Some qualities that can help facilitate a traceback start with the epidemiological investigation. It is beneficial when the state health departments have been actively collecting stool samples from sick patients, and when patients can accurately recall their consumption history. In addition, it is useful when clusters of illness form for investigators to start working with. It is easiest for traceback investigators when a minimal number of implicated food items are possible, and is especially easier if the foods were somehow branded or labeled. This was generally the first factor mentioned by the state or federal investigators. The more information on the packaging of the foods, the easier it generally is to track the product back to a common source. Point of purchase recordkeeping, such as shopper cards can also help facilitate retail facilities and consumers in determining what products were purchased and may have been consumed. Ideally, a suspected product will be available for testing to match the product with the outbreak strain.

Supply Chain Qualities

The easiest traceback investigations occurred when data elements were well documented within supply chain nodes, and when definitive relationships were established between these nodes. Many traceback investigators believe that internal inventory and product tracing systems, as well as linkages between products moving in and out, are imperative for a successful trace. It was also seen as beneficial when

two trading partners had a standardized way of requesting and sharing information with each other so that the shipping/receiving transactions could be readily verified.

Other Positive Qualities

The fewer points in a supply chain that the traceback investigators work with, the easier it is for them to manage the data they receive. Electronic records are preferable to paper records, because they are easily read and they can sometimes be shared more quickly. Implicated products with a long shelf life make it easy for investigators to obtain some of these products, as they may still be present in consumer's homes. When there is a single manufacturer that supplies a branded product to retail facilities, it can be much easier to determine the likely source of contamination.

Qualities That Make Traceback More Difficult

Consumer Qualities

Tracebacks can be difficult because consumers cannot recall what they have consumed, or incorrectly report their consumption habits, naming the wrong brand names for products or wrong food items entirely. Determining the cause of a foodborne illness outbreak can be difficult when there are different exposure locations which may or may not be connected. It can also be difficult if the exposures themselves include similar products, many of which have the same set of ingredients. In this case, it is difficult to determine which ingredients could be likely culprits since many ingredients cannot be ruled out. One state traceback investigator said that there needs to be enough heterogeneity of exposures for triangulation, but not so much data that there is too large of a supply chain web to analyze.

Product Qualities

State traceback investigators find that "difficult" tracebacks often include produce and/or commingled products. Products without labeling, branding, or coding all limit the investigators' chance for a successful trace. In addition, products that have been manipulated, such as products that are diced, may be more difficult to trace. Products that have a wide distribution result in a large amount of data, which can be overwhelming to analyze. Certain food items may also lend themselves to nomenclature issues. The items may not be referred to as a singular name at different points in their supply chain, including at the consumer level. Products with a short shelf life are also difficult to trace, as the food items have been either consumed or thrown out in a short amount of time. In such scenarios, it is difficult to find a contaminated food product still in the store or home, so the microbiological link to a specific food product can be hard to establish.

Supply Chain Qualities

The manner in which different supply chain partners collect and store data, as well as which data are stored, can vary greatly. Most food handling facilities do not track which lots are shipped to which locations. Some facilities do not house their records at their facility, but need to access this information through a separate source. Invoices may not always correspond with correct shipments, and some might not document changes to orders. There are other circumstances that are also difficult, such as tracing foods to food banks, charities, or salvors, because of a lack of documenting information. Also, there are times at which farms will source foods from smaller farms when needed, but no transactions will be kept as to the incoming foods. It is not always readily apparent how product moves between supply chain partners, and which numbers (e.g., invoices, purchase orders) should be used to establish the links.

Other Negative Qualities

Paper records can be difficult to read, and can take longer to locate and share with state officials. Some records may not always be in English. Some food industries reuse boxes and containers without proper relabeling or documentation. Sometimes clerical support for the food industry may enter data instead of those working with the products directly, which can lead to errors in data entry.

Coordination Issues

There is a lack of structure associated with data collection and sharing between local, state, and federal agencies, as well as points within the supply chain. Information sharing and protocol is not standardized between different states. Different states have different methods for assimilating data, with some, in certain instances, volunteering to collect data from all states in a central hub for analysis. Some states have good working relationships with the FDA, but there is no widespread standard for data capture or sharing. FDA needs to "marry" the data collected by state and local health departments and agriculture departments, generally working with data collected by several states. The disclosure laws of some states are recognized to limit the extent of confidential information that can be shared. If implicated products go into certain jurisdictions within a state, the current investigators may not have regulatory authority and will need to start to facilitate dialogue and coordination with other agencies to continue with the traceback.

Resources

Most states do not track resources involved with doing a traceback, so it is difficult to quantify the total expenses to the agencies and consumers. Until recently, the FDA only tracked the time spent visiting firms, but not the time (which could be substantial) compiling data from various states from both the public health-led investigations (retail and foodservice) and agriculture-led investigations (distributors and manufacturers). Resources influence how or whether to proceed in an investigation in many instances. Resources are a limiting factor for most agencies, with many state departments having only one or two people assigned to conducting tracebacks. In some cases, field inspectors are tasked with collecting records instead of conducting their normal duties. A lack of resources also impedes the ability to work on traceback investigations simultaneously with other investigations and can pull these investigators from their other daily activities. If an implicated food has a short shelf life and illnesses are no longer being reported, investigators reported difficultly in justifying continuing some investigations since their limited resources are not prioritized for outbreaks that are not causing further illnesses. In some instances, frustration was expressed at the duplication of efforts between different agencies, given limited resources.

External Factors

In some traceback investigations, external factors played a large role. Media coverage of a recall may result in more consumers coming forward, which will give epidemiologists more information about the outbreak. However, the limited staff working on an investigation may be distracted from their work to take media calls or host press conferences. Media attention also leads political figures to put pressure on the traceback investigators to quickly reduce consumer risk from the current investigation. If the food item publicized to the public is wrongly implicated, the corresponding food industry can unnecessarily suffer significant financial loss. In addition, a lot of time can be wasted in following the wrong lead by the investigators due to such external factors.

APPENDIX J. BACKGROUND ON FRESH PRODUCE AND THE TOMATO INDUSTRY

Dimitri (2003) reported that from 1987 to 1997 the number of fresh produce items in retail stores increased from 173 to 345. Per capita consumption of fresh fruits and vegetables increased 6% per year between 1987 and 1995, and 8% between 1995 and 2000.

On the other hand, Porter and others (2011) reported that the Alliance for Food and Farming had published the results of a recent investigation in which of all the cases in which a successful source was identified, only 2% of the outbreaks and 6% of the illnesses were confirmed as problems associated with growing, packing, shipping, or processing fresh produce. According to the same study, 65% of the illness outbreaks associated with the produce was attributed to restaurant mishandling, 14% to mishandling at community levels, and 13% to mishandling at home.

McLaughlin (1999) reported that of the $75 billion fresh fruits and vegetables consumed, roughly $40 billion was purchased at retail grocery stores while about $34 billion was provided through food service organizations.

Golan and others (2004) reported that approximately 12% of the produce grown by U.S. farmers goes to shippers, 2% is sold directly to consumers through farmers markets and the remaining 86% is sold to processors. Golan and others (2004) also report that 50% of the consumption is through the food service industry and about 48% through retailers. Porter and others (2011) reported slightly different percentages in that 32% of the produce consumption passes through the food service industry while 66% is sold through retailers.

Other candidates for the produce pilot were cantaloupes, leafy greens, and sprouts. Although the cantaloupe supply chain may appear simpler than the others, cantaloupes can be grown domestically or can be imported. Additionally, there are opportunities to reprocess (e.g., to fruit salad) which may complicate the supply chain and therefore a traceback/traceforward. Feedback from the Michigan Department of Agriculture indicated that we might want to consider other melons such as watermelons.

With respect to leafy greens, the OP felt that a lettuce such as romaine could be a good candidate. The growing region is slightly more diverse, and the likelihood that it is imported is slightly higher than a leafy green such as spinach. Additionally, compared to spinach, romaine is more likely to be sold both packaged with a label as well as in an unprocessed form without a label at retail. However, input from a state public health department noted that the while there is still variation within practices between firms, the California Leafy Greens Marketing Agreement has had a positive impacte on the ability to trace products in California.

The Florida Department of Agriculture and Consumer Services agreed with the proposal of tomatoes, cantaloupes, and leafy greens, and offered that cilantro would be another suitable candidate, given the regular outbreaks associated with *Salmonella*.

After IFT gave a presentation to the PTI leadership council, a group of about 35 trade associations and produce industry members, the group provided IFT with the following written recommendations and rationale:

First Choice: Tomatoes

- Product distribution path is one of the most complex in the industry and your previous experience and understanding of the tomato industry may be of great value.
- Could leverage some of the work previously done by IFT; product is grown year round in the United States; includes major grower-shippers and small local farms. Substantial imports from Mexico, Canada.

Second Choice: Cantaloupes

Distribution path is extensive, as exhibited in the recent incident with cantaloupes from a Colorado grower.

- Product is timely due to *Listeria* recall; multiple U.S. growing regions; includes major grower-shippers and small local farms; substantial imports from Mexico and Central America.

Third Choice: Cilantro

Distribution path is extensive; smaller volume, doesn't move as whole truckloads, but more of an "add-on" item with other purchases; also more likely a "stealth ingredient" in many partially fresh foods, e.g. salsas, or as garnish at restaurants.

After IFT presented FDA with the results of the stakeholder input and other information, the Agency directed IFT to pursue tomatoes as the produce item to be evaluated in the pilot project.

Tomatoes are an important agricultural commodity in the United States:

- The US is the second leading tomato producer in world (China is leading producer)
- Tomato varieties are bred for requirements of fresh or processing markets; processing tomatoes accounted for 89% of market in 2008
- Florida and California account for 66 - 75% of commercially produced, fresh market tomatoes; Virginia ranks third in fresh tomato production (Levine 2011).

Table 57. Fresh Vegetables Consumed in the Past Seven Days

State	N	Statistic	Green onions (scallions)	Leeks	Avocado (for guacamole)	Any homegrown fresh tomatoes (eaten raw)	Any store-bought fresh tomatoes	Any tomatoes on a sandwich or burger
CA	564	n	281	34	306	107	365	307
CA	564	%	49.8	6.0	54.3	19.0	64.7	58.5
CO	904	n	323	37	414	204	581	574
CO	904	%	35.7	4.1	45.8	22.6	64.3	61.3
CT	915	n	248	47	167	210	583	522
CT	915	%	27.1	5.1	18.3	23.0	63.7	58.9
GA	931	n	215	25	146	291	535	508
GA	931	%	23.1	2.7	15.7	31.3	57.5	57.7
MD	929	n	244	29	163	257	530	528
MD	929	%	26.3	3.1	17.5	27.7	57.1	58.1
MN	928	n	215	19	149	241	458	496
MN	928	%	23.2	2.0	16.1	26.0	49.4	56.0
NM	904	n	304	26	470	244	607	585
NM	904	%	33.6	2.9	52.0	27.0	67.1	67.6
NY	933	n	176	24	87	232	532	487
NY	933	%	18.9	2.6	9.3	24.9	57.0	53.8
OR	898	n	370	37	381	228	563	549
OR	898	%	41.2	4.1	42.4	25.4	62.7	61.3
TN	923	n	236	14	109	359	508	558
TN	923	%	25.6	1.5	11.8	38.9	55.0	65.4
Total	8829	n	2612	292	2392	2373	5262	5114
Total	8829	%	29.6	3.3	27.1	26.9	59.6	59.9

Source: FoodNet Population Survey, Atlas of Exposures, 2006-2007 Virginia Department of Health

Table 57 illustrates that in a given week, more than half the surveyed population (n= 8829) consumed store-bought tomatoes as well as tomatoes as part of a sandwich or hamburger (FoodNet 2007).

The domestic source of tomatoes in January and February, the time periods when the pilots were being conducted, barring a freeze event, came from the areas around Palm Beach, Homestead/Florida City and Immokalee/Naples areas in Florida. Product may also be sourced from a few greenhouses (hot houses) in California, or can be imported from Mexico. Table 58 shows the importance of imported tomatoes. For the timeframe captured below, the least amount of tomatoes was imported in September, still contributing over 76,000 metric tons. The greatest amount of tomatoes was imported in January (over 173,000 MT). Additionally, imports generally account for roughly 50% of the fresh tomato supply over the course of the year (Beckman, 2011 personal communication).

Table 58. U.S. Imports of Fresh Tomatoes (Metric Tons) by Harmonized System Code and Country, July 2010 to June 2011

Harmonized System Code / Country	Total
Total Imports (All products and countries)*	**1,401,779.20**
0702004010 - GRHS TM7/15-8/31	**54,282.60**
Canada	29,283.50
Mexico	24,673.10
Costa Rica	247
Dominican Republic	42
Netherlands	33.8
Guatemala	3.3
0702002010 - GREENHOUS TOM 3/	**361,206.70**
Canada	93,175.20
Mexico	262,404.70
Costa Rica	222.5
Netherlands	205.8
Dominican Republic	1,523.90
Guatemala	3,584.20
Israel	42.4
New Zealand	15.5
United Kingdom	32.6
0702004098 - TM, NS 7/15-8/31	**16,746.20**
Mexico	14,387.60
Canada	2,285.60
Guatemala	66.9
Dominican Republic	6.1
0702002099 - TOM, NS 3/1-7/14	**90,250.80**
Mexico	83,714.10
Guatemala	5,580.80
Canada	529
Colombia	2.1
Dominican Republic	308.2
Israel	21
Netherlands	0.5
New Zealand	95.1
0702006010 - GRENHOUS TOM 11/	**203,486.60**
Canada	8,605.70
Costa Rica	55.4
Dominican Republic	902.1
Guatemala	1,860.60
Israel	18.2
Mexico	191,906.50
Netherlands	48.2
New Zealand	89.8
0702006099 - TM NS 11/15-2/28	**86,434.50**
Colombia	5
Costa Rica	16
Dominican Republic	86.9
Guatemala	4,076.90
Israel	14.7
Mexico	82,190.00
New Zealand	45

*Total includes cherry, grape and Roma (not shown in table)

Data provided by Ed Beckman, formerly of California Tomato Farmers

According to the 2007 U.S. Census of Agriculture, California and Florida are the largest producers of tomatoes, representing roughly 85% of the total tomatoes grown in the United States. However, these states represent just more than 8% of the total tomato farms in the United States. The top six states represent almost 89% of the acres harvested, but only 31% of the number of farms in operation. See Table 59.

Table 59. Tomatoes Grown by State (Number of Farms and Acres Harvested)

	Total Farms	Total Farms	Total Acres	Total Acres	Processing Farms	Processing Farms	Processing Acres	Processing Acres	Fresh Farms	Fresh Farms	Fresh Acres	Fresh Acres
United States	25,809	N/A	442,225	N/A	1,761	N/A	319,549	N/A	24,630	N/A	122,675	N/A
California	1,782	6.9	335,133	75.8	490	27.8	297,357	93.1	1,344	5.5	37,726	30.8
Florida	339	1.3	40,437	9.1	16	0.9	560	0.2	329	1.3	39,877	32.5
New York	1,407	5.5	2,876	0.7	95	5.4	509	0.2	1,368	5.6	2,367	1.9
North Carolina	1,429	5.5	3,726	0.8	107	6.1	55	0.0	1,365	5.5	3,671	3.0
Ohio	1,351	5.2	7,368	1.7	127	7.2	4,805	1.5	1,272	5.2	2,563	2.1
Pennsylvania	1,737	6.7	3,458	0.8	98	5.6	1,470	0.5	1,670	6.8	1,988	1.6
Total	**8,045**	**31.2**	**392,998**	**88.9**	**933**	**53.0**	**304,756**	**95.4**	**7,348**	**29.8**	**88,192**	**71.9**

Source: US Census of Agriculture 2007

Although California grows 93% of the processed tomatoes, Florida produces slightly more fresh tomatoes in terms of acres planted. The six states that are listed in Table 59 represent the six largest fresh tomato-producing states. These six states produce roughly 72% of the fresh tomatoes on approximately 30% of the nation's tomato farms.

Since the pilot project will contain fresh tomatoes, a more extensive review of the fresh tomato market was performed. Table 60 shows the results of the findings for the fresh tomato growers in the six states listed in Table 59.

Table 60. Fresh Tomatoes Grown by Farm Size (Number of Workers)

	CA #	CA %	FL #	FL %	NY #	NY %	NC #	NC %	OH #	OH %	PA #	PA %
Hired Farm Labor -Farms	29,661	NA	10,081	NA	9,273	NA	12,284	NA	14,057	NA	11,722	NA
Hired Farm Labor -Workers	448,183	NA	115,306	NA	59,683	NA	77,400	NA	58,271	NA	60,721	NA
Hired Farm Labor -Payroll (k)	5,015,513	NA	1,208,631	NA	583,051	NA	623,130	NA	411,941	NA	590,891	NA
1 worker - Farms	7,051	24 %	2,892	29 %	2,294	25 %	3,678	30 %	4,895	35 %	3,818	33 %
1 worker - Workers	7,051	NA	2,892	NA	2,294	NA	3,678	NA	4,895	NA	3,818	NA
2 workers - Farms	5,262	18 %	2,192	22 %	1,921	21 %	2,545	21 %	3,225	23 %	2,471	21 %
2 workers - Workers	10,524	NA	4,384	NA	3,842	NA	5,090	NA	6,450	NA	4,942	NA
3 or 4 workers - Farms	5,033	17 %	1,915	19 %	1,870	20 %	2,506	20 %	3,050	22 %	2,426	21 %
3 or 4 workers - Workers	17,286	NA	6,535	NA	6,409	NA	8,618	NA	10,365	NA	8,273	NA
5 to 9 workers - Farms	4,950	17 %	1,533	15 %	1,758	19 %	1,957	16 %	1,952	14 %	1,843	16 %
5 to 9 workers - Workers	32,127	NA	9,743	NA	11,321	NA	12,547	NA	12,235	NA	11,651	NA
10 workers or more - Farms	7,365	25 %	1,549	15 %	1,430	15 %	1,598	13 %	935	7%	1,164	10 %
10 workers or more - Workers	381,195	NA	91,752	NA	35,817	NA	47,467	NA	24,326	NA	32,037	NA

Source: US Census of Agriculture 2007

In California, there are as many farms with one or two workers as there are with five or more workers. However, in every other state, there are more farms with one or two workers than there are with five or more workers. In fact, in Florida, 51% of the farms have two or fewer workers.

Table 61 provides similar information at the state level, but provides information segmenting the industry by farm size.

Table 61. Tomatoes Grown by Farm Size (Number of Acres Harvested) Source: 2007 US Census of Agriculture

State	Farm Type	Unit	Tomatoes in the open	0.1 to 0.9 acres	1.0 to 4.9 acres	5.0 to 14.9 acres	15.0 to 24.9 acres	25.0 to 49.9 acres	50.0 to 99.9 acres	100.0 acres or more
CA	Total Harvested	Farms	1,782	740	348	82	21	38	49	504
CA	Total Harvested	Acres	335,133	200	620	607	392	1,351	3,644	328,320
CA	Harvested for Processing	Farms	490	-	-	3	3	12	31	441
CA	Harvested for Processing	Acres	297,357	-	-	18	60	484	2,237	294,558
CA	Harvested for Fresh Market	Farms	1,344	740	348	79	19	26	21	111
CA	Harvested for Fresh Market	Acres	37,776	200	620	589	332	867	1,406	33,762
FL	Total Harvested	Farms	339	170	66	15	10	12	10	56
FL	Total Harvested	Acres	40,437	43	109	108	173	430	632	38,942
FL	Harvested for Processing	Farms	16	6	3	-	2	-	2	3
FL	Harvested for Processing	Acres	560	1	7	-	(D)	-	(D)	(D)
FL	Harvested for Fresh Market	Farms	329	164	65	15	8	12	9	56
FL	Harvested for Fresh Market	Acres	39,877	42	102	108	(D)	430	(D)	(D)
NC	Total Harvested	Farms	1,429	1,052	284	56	15	11	5	6
NC	Total Harvested	Acres	3,726	307	441	473	277	333	298	1,598
NC	Harvested for Processing	Farms	107	85	19	3	-	-	-	-
NC	Harvested for Processing	Acres	55	18	23	13	-	-	-	-
NC	Harvested for Fresh Market	Farms	1,365	990	282	56	15	11	5	6
NC	Harvested for Fresh Market	Acres	3,671	289	417	460	277	333	298	1,598
NY	Total Harvested	Farms	1,407	830	461	95	9	7	4	1
NY	Total Harvested	Acres	2,876	249	873	710	(D)	241	269	(D)
NY	Harvested for Processing	Farms	95	45	40	8	-	-	1	1
NY	Harvested for Processing	Acres	509	10	49	(D)	-	-	(D)	(D)
NY	Harvested for Fresh Market	Farms	1,368	806	448	94	9	7	4	-
NY	Harvested for Fresh Market	Acres	2,367	239	824	(D)	(D)	241	(D)	-
OH	Total Harvested	Farms	1,351	899	358	39	12	6	12	25
OH	Total Harvested	Acres	7,368	257	610	265	207	218	816	4,995
OH	Harvested for Processing	Farms	127	49	29	14	-	4	11	20
OH	Harvested for Processing	Acres	4,805	10	37	69	-	(D)	(D)	3,828
OH	Harvested for Fresh Market	Farms	1,272	862	348	37	12	3	2	8
OH	Harvested for Fresh Market	Acres	2,563	247	574	196	207	(D)	(D)	1,167
PA	Total Harvested	Farms	1,737	1,179	475	51	12	7	7	6
PA	Total Harvested	Acres	3,458	336	747	354	220	272	414	1,116
PA	Harvested for Processing	Farms	98	50	19	4	9	5	7	4
PA	Harvested for Processing	Acres	1,470	8	16	26	(D)	(D)	414	646
PA	Harvested for Fresh Market	Farms	1,670	1,141	471	49	4	2	-	3
PA	Harvested for Fresh Market	Acres	1,988	328	731	328	(D)	(D)	-	470

The average yield per acre was provided by the U.S. Department of Agriculture Economic Research Service. This information is found in Table 62.

Table 62. Fresh Tomato Average Yield

State	Acres Harvested	Average Yield (Cwt/acre)	Average Yield (tons/acre)
CA	37,726	300	15
FL	39,877	385	19.25
NY	2,367	180	9
NC	3,671	290	14.5
OH	2,563	210	10.5
PN	1,988	210	10.5

Source: Compiled from US Census of Agriculture 2007 and the ERS. Cwt = hundred weight

Tomato Metrics

In October 2008, an effort was made to implement a new food safety program in the fresh tomato industry through "*The Food Safety Programs and Auditing Protocol for the Fresh Tomato Supply Chain* (UFPA 2008)." The initiative provides a framework for growing, packing, and shipping tomatoes free of harmful pathogens, in addition to specifying a protocol for auditing these activities for harmful violations of the best management practices. Safety programs and protocol were developed for greenhouse production as well as open field production. Further down the supply chain, programs for packing and re-packing were developed. Along with each protocol, checklists were developed so that audits can be performed in a uniform way. Although most of the initiative addresses safety issues, the initiative contains procedures for product tracing as well (Retrieved from UnitedFresh.org).

For fresh tomatoes specifically, there are approximately 20 shippers that handle 90% of the production (Beckman 2011, personal communication).

Census data does not contain exact matches for the shipping and packing function, however, nation-wide data for the Farm Product Storage and Warehousing sector are available. Table 63 provides the nation-wide data segmented by revenue, and Table 64 provides the nation-wide data segmented by number of employees. Although this data might include some of the produce shippers and packers, all shippers and packers are not represented in this data.

Table 63. Farm Product Storage and Warehousing Firms (by Total Revenue)

Firm Size (annual revenue)	Number of Firms	Number of Establishments	Total Revenue (Millions)
All firms	451	705	$762,840
Firms operated for the entire year	395	649	$748,717
Less than $100,000	149	225	$1,396
$100,000 to $249,999	43	44	$7,568
$250,000 to $499,999	39	41	$13,893
$500,000 to $999,999	38	48	$26,626
$1,000,000 to $2,499,999	60	87	$103,811
$2,500,000 to $4,999,999	32	80	$112,424
$5,000,000 to $9,999,999	17	28	$116,185
$10,000,000 to $24,999,999	11	35	D
$25,000,000 to $49,999,999	6	61	D
Firms not operated for the entire year	56	56	$14,123

Source: US Census of Agriculture 2002

Table 64. Farm Product Storage and Warehousing Firms (Number of Employees)

Firm Size (number of employees)	Number of Firms	Number of Establishments	Total Revenue (Millions)
All firms	451	705	$762,840
Firms operated for the entire year	395	649	$748,717
Less than 5 employees	139	143	$54,637
5 to 9 employees	94	112	$119,937
10 to 19 employees	56	82	$87,168
20 to 49 employees	54	107	$144,022
50 to 99 employees	23	71	D
100 to 249 employees	21	103	D
250 to 499 employees	7	23	D
500 to 999 employees	1	8	D
Firms not operated for the entire year	56	56	$14,123

Source: US Census of Agriculture 2002

Table 65 and Table 66 provide information on the wholesale and retail trade for produce in the 2007 census publications.

Table 65. Fresh Fruit and Vegetable Merchant Wholesalers (by Number of Employees)

Area Name	Paid Employees	Annual Payroll ($1,000)	Total Firms	1 - 4	5 – 9	10 - 19	20 - 49	50 - 99	100 - 249	250 - 499	500 - 999	1000 or more
Alabama	526	18,438	25	10	4	6	1	2	2	0	0	0
Alaska	141	5,631	5	1	1	0	2	1	0	0	0	0
Arizona	2,419	90,006	150	62	25	27	26	6	4	0	0	0
Arkansas	243	11,586	16	4	2	6	4	0	0	0	0	0
California	21,037	1,036,112	1,030	428	207	157	124	64	45	4	1	0
Colorado	2,010	68,691	58	18	6	7	14	9	3	1	0	0
Connecticut	684	30,883	33	16	5	3	5	2	2	0	0	0
Delaware	0-19	Withheld	3	1	2	0	0	0	0	0	0	0
DC	178	5,904	10	1	4	1	4	0	0	0	0	0
Florida	9,644	315,370	539	300	87	57	43	27	21	4	0	0
Georgia	3,494	128,004	136	66	22	21	15	4	7	0	0	1
Hawaii	921	29,745	46	13	12	7	9	4	1	0	0	0
Idaho	2,106	51,264	49	12	9	3	9	10	6	0	0	0
Illinois	2,470	139,618	187	92	30	31	27	4	3	0	0	0
Indiana	1,273	47,974	40	23	7	0	6	1	2	1	0	0
Iowa	477	18,987	12	3	2	1	2	2	2	0	0	0
Kansas	334	17,054	17	6	6	2	2	0	1	0	0	0
Kentucky	1,091	45,072	31	15	3	5	4	0	3	1	0	0
Louisiana	250-499	13,532	24	10	4	2	6	1	1	0	0	0
Maine	229	9,205	26	12	5	7	2	0	0	0	0	0
Maryland	2,571	103,679	67	29	13	9	4	4	6	2	0	0
Massachusetts	2,285	134,764	151	60	26	37	21	5	1	1	0	0
Michigan	1,994	98,323	136	56	27	16	30	5	2	0	0	0
Minnesota	1,779	75,744	63	26	7	10	10	4	5	1	0	0
Mississippi	300	9,795	24	8	5	6	4	1	0	0	0	0
Missouri	677	28,794	45	17	13	5	8	1	1	0	0	0
Montana	250-499	Withheld	6	4	1	0	0	0	1	0	0	0
Nebraska	161	3,158	7	2	1	0	3	1	0	0	0	0
Nevada	777	27,152	23	7	4	3	3	2	4	0	0	0
New Hampshire	96	2,912	9	4	1	3	1	0	0	0	0	0
New Jersey	3,392	162,887	174	91	30	27	10	8	6	2	0	0
New Mexico	100-249	6,501	22	8	9	5	0	0	0	0	0	0
New York	5,515	265,604	519	296	89	63	50	14	6	1	0	0
North Carolina	1,765	53,590	98	38	17	21	12	7	3	0	0	0
North Dakota	200	4,894	12	3	1	5	2	1	0	0	0	0
Ohio	2,576	106,305	103	35	21	19	18	4	4	2	0	0
Oklahoma	1,222	40,520	30	12	4	5	2	4	1	2	0	0
Oregon	2,685	97,433	80	30	9	10	17	6	6	2	0	0
Pennsylvania	3,992	155,932	217	82	49	43	26	7	8	2	0	0
Rhode Island	228	7,788	16	5	5	3	2	1	0	0	0	0
South Carolina	496	17,319	31	13	6	5	5	1	1	0	0	0
South Dakota	0-19	Withheld	3	2	0	1	0	0	0	0	0	0
Tennessee	1,633	60,235	50	17	8	10	7	3	3	2	0	0
Texas	8,592	258,942	326	133	55	48	54	16	16	3	0	1
Utah	259	11,101	20	8	2	6	4	0	0	0	0	0
Vermont	100-249	Withheld	4	0	1	1	1	0	1	0	0	0
Virginia	1,008	33,764	52	24	7	8	7	5	1	0	0	0
Washington	6,652	233,192	168	56	24	26	26	15	17	4	0	0
West Virginia	136	4,015	8	2	2	2	1	1	0	0	0	0
Wisconsin	755	36,804	43	15	7	9	8	4	0	0	0	0
Wyoming	20-99	Withheld	6	4	2	0	0	0	0	0	0	0

Source: US Census of Agriculture 2002; Number of Establishments, by Employment-size class

Table 66. Fruit and Vegetable Markets (Retailers) (by Number of Employees)

Area Name	Paid Employees	Annual payroll ($1,000)	Total Firms	1 - 4	5 - 9	10 - 19	20 – 49	50 - 99	100 - 249	250 - 499	500 – 999	1000 or more
Alabama	316	3,923	33	20	4	1	8	0	0	0	0	0
Alaska	0-19	N/A	2	2	0	0	0	0	0	0	0	0
Arizona	1,017	18,034	44	21	5	5	3	10	0	0	0	0
Arkansas	25	480	9	7	2	0	0	0	0	0	0	0
California	3,195	69,247	427	239	104	55	20	8	1	0	0	0
Colorado	20-99	974	17	13	2	2	0	0	0	0	0	0
Connecticut	212	4,457	58	42	8	6	2	0	0	0	0	0
Delaware	108	2,494	20	15	4	0	0	1	0	0	0	0
DC	0-19	N/A	2	1	1	0	0	0	0	0	0	0
Florida	1,777	35,638	242	158	38	24	15	6	1	0	0	0
Georgia	466	9,659	44	27	9	4	2	0	2	0	0	0
Hawaii	113	1,650	21	12	6	2	1	0	0	0	0	0
Idaho	43	481	15	11	3	1	0	0	0	0	0	0
Illinois	1,668	36,799	123	60	17	13	27	5	1	0	0	0
Indiana	168	3,793	37	26	7	1	3	0	0	0	0	0
Iowa	20-99	N/A	12	7	3	1	1	0	0	0	0	0
Kansas	20-99	N/A	9	4	3	2	0	0	0	0	0	0
Kentucky	281	4,176	26	12	7	2	5	0	0	0	0	0
Louisiana	447	5,314	24	9	4	3	5	3	0	0	0	0
Maine	17	358	10	9	1	0	0	0	0	0	0	0
Maryland	440	17,455	53	35	11	4	2	0	1	0	0	0
Massachusetts	1,292	34,663	100	54	14	14	15	1	1	1	0	0
Michigan	1,438	28,710	124	79	19	7	5	13	1	0	0	0
Minnesota	131	2,760	19	11	3	2	3	0	0	0	0	0
Mississippi	65	1,527	18	13	4	1	0	0	0	0	0	0
Missouri	106	2,173	37	29	6	1	1	0	0	0	0	0
Montana	0-19	141	5	5	0	0	0	0	0	0	0	0
Nebraska	0-19	N/A	6	5	1	0	0	0	0	0	0	0
Nevada	20-99	N/A	4	3	0	0	1	0	0	0	0	0
New Hampshire	140	2,843	12	3	6	0	3	0	0	0	0	0
New Jersey	1,721	40,968	241	166	33	25	12	2	3	0	0	0
New Mexico	20-99	1,117	16	13	2	1	0	0	0	0	0	0
New York	2,663	55,867	653	516	88	29	17	3	0	0	0	0
North Carolina	398	6,840	87	68	9	6	4	0	0	0	0	0
North Dakota	0-19	N/A	2	2	0	0	0	0	0	0	0	0
Ohio	828	12,223	106	64	20	8	13	1	0	0	0	0
Oklahoma	20-99	396	10	9	0	1	0	0	0	0	0	0
Oregon	205	3,909	49	31	9	9	0	0	0	0	0	0
Pennsylvania	1,442	21,967	179	93	34	31	19	2	0	0	0	0
Rhode Island	163	3,751	19	11	2	3	3	0	0	0	0	0
South Carolina	151	1,819	40	30	8	1	1	0	0	0	0	0
South Dakota	0-19	N/A	2	2	0	0	0	0	0	0	0	0
Tennessee	250-499	5,116	50	32	8	7	3	0	0	0	0	0
Texas	887	16,759	106	67	18	11	4	6	0	0	0	0
Utah	67	1,055	12	8	2	0	2	0	0	0	0	0
Vermont	25	675	13	11	2	0	0	0	0	0	0	0
Virginia	197	3,785	51	35	10	6	0	0	0	0	0	0
Washington	451	11,528	82	57	16	6	2	0	1	0	0	0
West Virginia	92	1,159	16	11	1	3	1	0	0	0	0	0
Wisconsin	146	2,772	26	18	3	3	2	0	0	0	0	0
Wyoming	0-19	N/A	1	1	0	0	0	0	0	0	0	0

Source: US Census of Agriculture 2002; Number of Establishments by Employment-size Class

APPENDIX K. BACKGROUND ON PEANUT INDUSTRY

Unlike the selection of the produce item, few stakeholders had input on what type of product should be chosen for the processed food pilot. Peanuts were identified early on by the U.S. Food and Drug Administration as a product of interest, and considerable information is available on the peanut industry.

In the United States, peanuts are used domestically or may be exported, primarily to Canada, Japan, the European Union and Mexico. Worldwide, India, Vietnam, and China also grow peanuts. Americans consume six pounds of peanuts annually, which is worth more than $2 billion dollars at the retail level.

The vast majority of the peanuts grown in the United States are grown in only seven states (Table 67). Forty-one percent is grown in the state of Georgia alone. In these seven states, there are four varieties of peanuts which are sorted into three quality categories (12 distinct combinations) after they are delivered to market. These categories are typically referred to as Segment I, Segment II, and Segment III. For example, the higher quality nuts (Seg I) are used for edible products, whereas the lower quality nuts (Seg II and III) are used for products such as cooking oil. Historically, the proportion of peanuts categorized as Seg 1 has been above 90%, however, the quality is dependent on a number of environmental factors such as rainfall and temperature during the growing season and is variable from year to year.

The bar chart in Figure 47 provides the distribution of the top ten producing states, while Figure 48 provides the distribution for the number of farms by the number of acres harvested (USCB 2007).

Table 67. Peanut Growers by State, by Number of Acres Harvested (Source: U.S. Census Bureau. c2007)

State	1 – 24 acres	25 – 99 acres	100 – 249 acres	250 – 400 acres	500 – 999 acres	>= 1000 acres	Total
Alabama	84	219	192	122	64	23	704
Georgia	350	943	817	422	189	41	2762
Texas	49	198	305	140	71	21	784
North Carolina	177	215	210	73	18	6	699
Florida	69	122	107	48	48	29	423
South Carolina	70	73	106	59	17	2	327
Virginia	25	61	72	20	2	-	180
Oklahoma	20	65	49	11	3	-	148
Mississippi	35	7	12	19	9	3	85
New Mexico	-	5	14	4	2	4	29
Tennessee	19	-	-	-	-	-	19
California	11	-	-	-	-	-	11
Louisiana	4	1	1	2	-	-	8
Missouri	1	-	-	-	-	-	1
Arkansas	-	-	1	-	-	-	1
Arizona	1	-	-	-	-	-	1

Figure 47. Number of Farms, by State

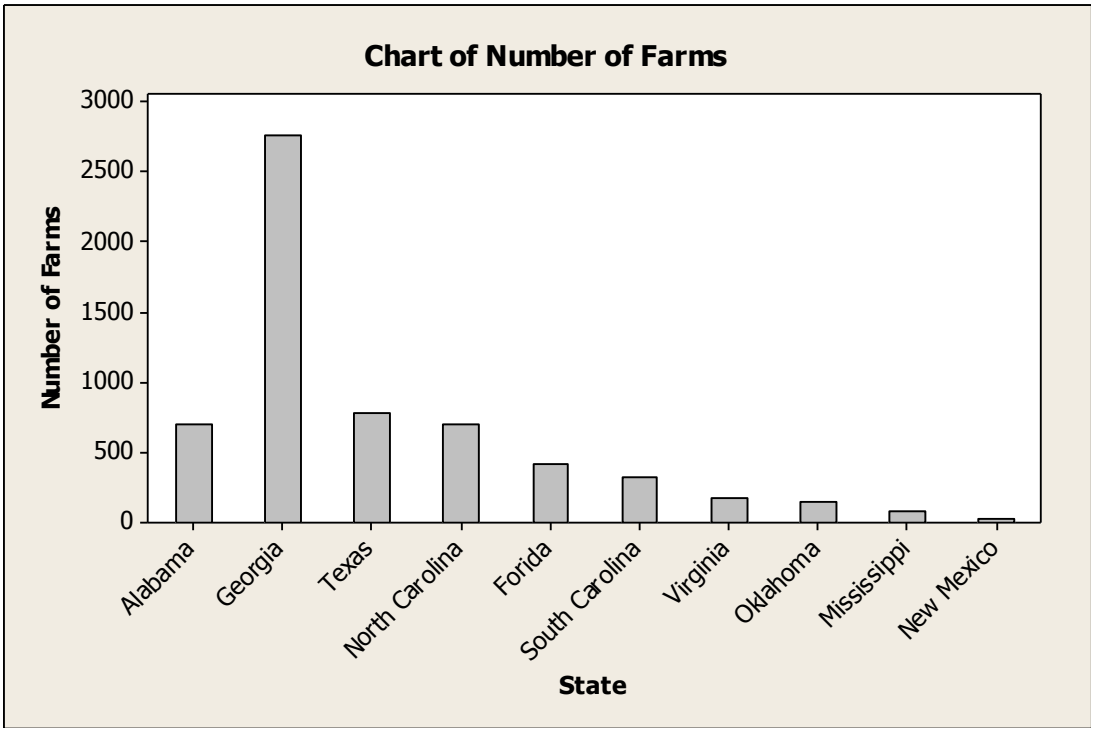


Figure 48. Distribution of the Number of Farms by the Number of Acres Harvested

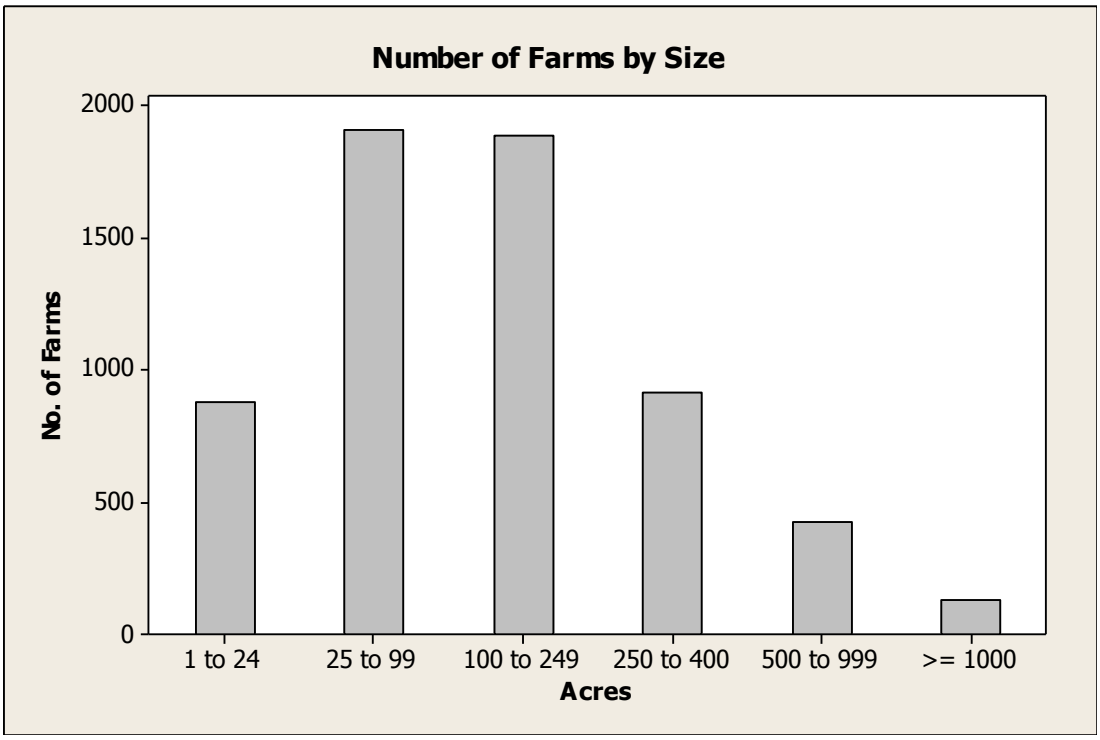


Table 68 and Table 69 provide the number of buying points and shelling facilities by state. Establishments could not be segmented based on tons or employees, but general information on the capacity of these entities was available. The buying points range in size from 1,000 tons to 25,000 tons; however all of them are relatively small based on the number of employees (<50). The average capacity of a shelling operation is roughly 75,000 tons. (Archer, 2012)

Table 68. Number of Peanut Buying Points per State

State	Number of Buying Points per State
Alabama	42
Arkansas	1
Florida	23
Georgia	160
Mississippi	1
North Carolina	62
New Mexico	4
New York	1
Oklahoma	14
South Carolina	8
Texas	50
Virginia	33

Source: American Peanut Buying Point Association

Table 69. Number of Peanut Shelling Establishments per State

State	Number of Shelling Facilities per State
Georgia	12
Alabama	3
Florida	1
North Carolina	6
Virginia	1
Texas	4
Oklahoma	1
New Mexico	2

Source: American Peanut Council

As mentioned previously, the first FSIS quality inspection process sorts the peanuts into three quality categories. If the peanuts are not Seg I, then they will fall in one of the remaining two categories. The Seg II is based largely on visual characteristics: color, general peanut damage, and the amount of foreign debris such as stems, rocks, etc. Peanuts are placed in Seg III if there is any visual evidence of mold, known as Visual Aflavous (VAF).

Once the peanuts are segregated based on variety and quality, the peanuts are usually held in storage until transported to one of 30 shelling operations. Due to the different combinations of quality and variety, and the limited number of warehouses, peanuts are often shipped from the buying point to another warehouse location. Once the peanuts are shelled, FSIS performs an Aflatoxin test involving very specific sampling plans being followed. Once the test is complete, the shelled peanuts are placed in 2,000 lb. tote bags and an FSIS label is applied to the bag. The bags are then shipped to the food manufacturer (Cowart).

According to the 2007 U.S. Census of Manufacturing, there are about 215 firms that process peanuts or other nut products, as shown in Table 70. It is unclear which of these processors is transformative or pass-through. Of the number of processors in the country, the State of California has the most with 57, which is about 27% of the total number of firms. These 57 firms employ 5,267 of the 13,873 employees in this industry segment, which is about 38% of the total.

Table 70. Number of Processors and Employees, by State

State	Number of Employer Firms	Employer Sales, Shipments, Receipts, Revenue ($1,000)	Annual Payroll ($1,000)	Number of Paid Employees
United States	215	6,795,099	507,114	13,873
Alabama	4	D	D	e
Arkansas	3	D	D	f
California	57	2,466,202	180,690	5,267
Connecticut	1	D	D	c
Georgia	12	D	40,273	1,155
Hawaii	4	D	D	e
Illinois	7	D	D	1,044
Indiana	2	D	D	c
Iowa	2	D	D	e
Kentucky	5	449,205	29,063	612
Maryland	2	D	D	c
Massachusetts	7	141,862	10,169	210
Michigan	3	D	D	c
Minnesota	9	149,675	15,653	477
New Jersey	4	47,188	D	c
New Mexico	3	D	4,215	124
New York	6	79,348	6,311	153
North Carolina	7	D	17,110	558
Ohio	9	D	12,830	330
Pennsylvania	5	86,448	5,424	116
Texas	16	D	18,487	533
Virginia	7	D	22,433	525
Wisconsin	5	D	4,435	131

Key: D – withheld to avoid disclosing data of individual companies; S – Withheld because estimates did not meet publication standards; N – data not available or not comparable; c – 100 to 249 employees; e – 250 to 499 employees; and f – 500 to 999 employees.

The 2007 U.S. Census of Manufacturing also provides information on the peanut processing firms that have more than 20 employees. Of the 215 peanut processing firms, approximately half (105) have more than twenty. The value added for the firms is shown in Table 71.

Table 71. Number of Processors with more than 20 Employees per State

State	Number of Firms	Firms with 20 Employees or More	Number of Employees	Value Added ($1,000)	Total Cost of Materials ($1,000)	Total Value of Shipments ($1,000)	Total Capital Expenditures (New and Used) ($1,000)
Alabama	4	2	e	D	D	D	D
Arkansas	3	2	f	D	D	D	D
California	57	35	5,267	989,737	1,506,689	2,466,202	60,789
Connecticut	1	1	c	D	D	D	D
Georgia	12	10	1,155	D	496,063	D	D
Hawaii	4	1	e	D	23,964	D	D
Illinois	7	5	1,044	D	243,980	D	5,425
Indiana	2	1	c	D	D	D	D
Iowa	2	2	e	D	D	D	D
Kentucky	5	3	612	141,439	308,705	449,205	8,757
Maryland	2	2	c	D	D	D	D
Massachusetts	7	3	210	39,636	100,406	141,862	981
Michigan	3	1	c	D	D	D	D
Minnesota	9	4	477	D	D	149,675	1,376
New Jersey	4	2	c	17,223	33,266	47,188	1,180
New Mexico	3	2	124	D	D	D	D
New York	6	3	153	24,365	53,961	79,348	1,789
North Carolina	7	6	558	D	293,608	D	9,924
Ohio	9	5	330	D	D	D	450
Pennsylvania	5	2	116	26,617	61,070	86,448	1,978
Texas	16	7	533	D	D	D	4,216
Virginia	7	3	525	S	D	D	5,875
Wisconsin	5	3	131	16,344	D	D	D

Key: D – withheld to avoid disclosing data of individual companies; S – Withheld because estimates did not meet publication standards; N – data not available or not comparable; c – 100 to 249 employees; e – 250 to 499 employees; and f – 500 to 999 employees.

Table 72 provides information on the peanut processing firms by number of employees. This table also provides the value added to the products versus the value of the raw materials.

Table 72. Number of Peanut Processing Firms, by Number of Employees and Average Value-Added

Firm Size by Number of Employees	Number of Firms	Number of Employees	Value Added ($1,000)	Total Cost of Materials ($1,000)	Total Value of Shipments ($1,000)	Total Capital Expenditures (New and Used) ($1,000)
All	215	13,873	2,222,899	4,599,615	6,795,099	157,143
0 - 4	55	136	27,653	55,634	85,152	1,438
5 - 9	29	189	34,310	62,925	91,058	2,539
10 - 19	19	270	36,473	72,763	109,026	1,878
20 - 49	46	1,495	235,693	495,441	726,191	19,786
50 - 99	28	1,937	330,508	522,138	832,212	20,167
100 - 249	25	3,839	587,383	1,353,321	1,937,034	50,589
250 - 499	9	2,668	231,940	1,189,282	1,430,827	30,274
500 - 999	4	3,339	738,939	848,111	1,583,599	30,472
1000 - 2499	0	0	0	0	0	0
> 2500	0	0	0	0	0	0
Covered by administrative records	65	280	49,173	106,444	155,617	3,895

APPENDIX L. KEY QUESTIONS TO BE ADDRESSED BY PILOTS

The objective of this task is to improve the speed and accuracy of product tracing, and evaluate the costs and benefits associated with various practices as identified through pilot studies involving tomatoes and processed foods containing spices, chicken and/or peanuts. Each supply chain path will be subjected to one or more "tests" based on hypothetical scenarios which require a traceback and/or traceforward. In order to evaluate the tests in a quantitative fashion, the scenarios constructed should answer some key questions (Table 73, Table 74,Table 75, Table 76, and Table 77).

IFT is required to evaluate the following aspects of product tracing systems:

Breadth, depth, precision, accuracy (objective); impact on system overall (subjective)

Breadth: the amount of information the product tracing system records

Depth: how far upstream or downstream in the supply chain the system tracks

Precision: the degree of assurance with which the system can pinpoint a particular product's movement or characteristics

Access: the speed with which track and trace information can be communicated to supply chain members and the speed with which requested information could be disseminated to public health officials during food related emergencies

Table 73. Key Questions Addressed by Pilots: Breadth

	Issue	Question	Measurements	Hypothesis	Cost impact	Outcome
B1	Industry captures and FDA collects a lot of information, some of which is likely necessary and some of which is not.	What data are typically captured by industry? What data are requested by FDA? What data are necessary to link products through the supply chain, internally and externally?	Compare data provided (regardless of form) and relate to ability to trace. What is essential, useful and irrelevant?	The key data elements identified on the Critical Tracking Event/Key Data Element spreadsheet are all that are needed to trace. Some data submitted will be superfluous and will need to be weeded out.	Cost can only be calculated by assuming that FDA could "require" specific data elements	They types of data, or at least the way the data are described varied. Due to lack of lot numbers through most of the supply chain, Purchase Order numbers or other numbers on paperwork were used
B2	Although records may be provided, some may need a "key" or other way to decipher such records	How are data organized and maintained? Is there interpretation needed or a legend? Are they in different systems?		Depending on how data are organized, the inclusion of data that are not relevant may or may not impede tracing efforts.	No viable cost impact, try to quantify resources needed to extract, compile and provide explanation	Experienced this in Scenario E, in which a re-packer reported that "traceback number" starts with 5 it is repacked; 1 if not) and Scenario A grower:- block ID translates to year, grower, field, product
B3	Current requirements are for one up - back but some types of operations may know information beyond one up - back and knowing this information could help an investigation move more rapidly	Do the records identify beyond one step forward or back? Is this restricted to certain segments of the supply chain, and is it inclusive of internal traceability?	Ability to rapidly link product in the supply chain (see previous comments on this too)	Being able to acquire information more than one step in the supply chain at a time will save time and resources	Cost could be calculated – would need to specify test	In scenarios A and B, the foodservice chain acquired information more quickly, but still through a one back process; in Scenario PC, the manufacturer had knowledge more than one back

	Issue	Question	Measurements	Hypothesis	Cost impact	Outcome
B4	In manufacturing a processed food, ingredient lots may change within a code lot of finished food. Ingredients may even come from different suppliers.	Do manufacturers identify ingredient lot changes that occur in production of a lot code of finished product, or by other means, and if so, how? How and where are the data captured?	Ability to rapidly link product in supply chain	Data elements that link product (see comments) internally and externally provide more rapid and targeted tracing	Cost should be able to be calculated – at least an estimate	All processed food scenarios showed that manufacturers link incoming ingredients with finished product by lot or pallet number, but this may be captured on a paper log

Depth- in the pilots we are including all participants in the supply chain to the extent possible (point of production to point of sale/service)

Table 74. Key Questions Addressed by Pilots: Depth

	Issue	Question	Measurements	Hypothesis	Cost Impact	Outcome
D1	BT Act limits who needs to keep one up - back records	Would it be helpful for those currently exempt from BT Act requirements to maintain records that enable product tracing?	Include point of sale/service all the way back to grower/origin and identify where it would be useful to have product tracing information	Expanded recordkeeping will improve the ability to trace products.	Cost impact unclear at this stage.	Records were kept by growing operations despite their exemption. In fact, these were often the most detailed records. The fewest records were kept by retail/foodservice
D2	Some technologies allow individual products to be traced by the consumer	What information must be associated with the identifier to aid in tracing through the supply chain?	Measurement may not be in the pilot itself but can be discussed/explored/overlaid		Ability to assess cost will depend on specifying somewhat precise process or technology changes.	Not assessed through scenarios
D3	Some technologies, such as shopper cards can allow individual products to be traced to the consumer if the data are scanned	How can information associated with consumer purchases be used to aid in investigations	Purchase one of the products and provide shopper card data to the retailer		Ability to assess cost will depend on specifying somewhat precise process or technology changes.	Explored in Scenario PB and effective at identifying product

Table 75. Key Questions Addressed by Pilots: Precision

	Issue	Question	Measurements	Hypothesis	Cost Impact	Outcome
P1	During a traceback, if the "one back" is not provided or misidentified, it can impact an investigation. Some technology providers purport that their algorithms are strong enough to "jump" a step in the process to identify likely supply chain partners.	Can a "collaboration platform" help identify likely sources/recipients when there are unknown players/gaps in the supply chain?	Use collaboration platform when a retailer is known but immediate supplier of a branded product is not.	Some algorithms may be able to jump a supply chain node.	Use of a collaboration platform can be tested and a cost estimated, both for industry and FDA.	Some providers were willing/able to make assumptions that allowed them to bypass gaps; others did not.
P2	In many cases products that do not change in composition undergo changes in identification (breaking a 1:1 relationship).	Can the use of globally unique product values minimize the impact of unreported transportation events?	Measure the ability to track product across "gaps" for those instances in which a standardized item identifier and lot batches are used to identify product compared to instances where product is reported by stock-keeping units or with generic terms.	When globally unique product, firm, and shipment information is used a complete one-up – one-down thread is not required to locate product across the supply chain.		Lot/batch information was rarely provided and could not be tested.

	Issue	Question	Measurements	Hypothesis	Cost Impact	Outcome
P3	Commingling and/or re-packing is often identified as a challenge in pinpointing the exact source of a product.	How does commingling impact ability to successfully conduct a traceback with precision?	Compare supply chains that do and do not have tomato re-packer (if different lots* are repacked); peanut sheller, nut receiving stations, etc.	Commingling may generally make tracing more complex but this is dependent on the handling/segregation practices in place.	Evaluate cost of changing practices to limit these issues.	Scenarios D, F, K, G, H PA; PC; In the case of tomato re-packing, some firms have moved to only re-packing within the incoming "lot" (e.g., Purchase Order - not the grower assigned lot). Commingling of nuts and the volumes commingled make it impossible to trace to a farm level.
P4	For some products there may be a positive sample that can be tied to a specific lot code, sometimes there is an association with a specific brand but not an identifier, sometimes there is simply an association with a food item.	What is the information present on the consumer article that provides useful information to the traceback?	Compare results of tomato (unbranded) and processed food (branded) scenarios, accounting for other variables.	The more information is known about the consumer-level product, the easier it is to narrow the focus of the investigation. Immediate knowledge of the manufacturer or supplier, even if lot number is unknown, will aid in tracing the product and will positively impact public health since consumers can be directed to avoid the brand.	No viable cost impact – would require "mandating" information on consumer articles to effectively estimate cost.	The association with a brand made it easy to quickly narrow the scope and identify the manufacturer/source.

	Issue	Question	Measurements	Hypothesis	Cost Impact	Outcome
P5	"Lot" is an often-used term that is undefined.	How does lot size definition impact the precision, scope and depth of the trace and the resulting effort and time needed to complete the task?	Monitor the quantity/products associated with a "lot" as it moves/morphs throughout a supply chain.	The more defined a "lot" is, and the greater the extent a 1:1 external tracing relationship is maintained, the more precisely product can be traced.		Each supply chain node used the term "lot" to identify products. In many cases, this included multiple "lots" as assigned by the previous supplier.
P6	Some industry initiatives have case-level scanning as a focus.	How does the focus on tracing by the consumer unit compared to the case unit or pallet unit impact the precision of a trace exercise?	Evaluate how the unit assigned a number is able to be precisely tracked.	This may relate to the definition of "lot"—and whether mixed "lots" are present on a pallet, in a case, etc.		Not addressed in pilots but IFT obtained data regarding the number of lots on a pallet.
P7	When information is hand written or transmitted to electronic systems through data entry, there is a possibility for errors to occur. Additional opportunities for error also exist and can cause misdirection and confusion in product tracing.	How can data errors be identified, and how are data errors/inconsistencies most readily identified? What procedures are used to minimize data entry errors and verify correct entries? Perhaps try to evaluate nature of the error.	"Flag" inconsistencies in manual process (in "raw" data as well as templates); determine which collaboration platforms identify these inconsistencies.	A collaboration platform will more rapidly identify inconsistencies in data and will identify more inconsistencies than are evident through the manual process.	Use of a collaboration platform can be tested and a cost estimated, both for industry and FDA.	Most errors observed occurred when people manually filled out spreadsheets or other summary documents. These included missing digits and transcriptions. The collaboration platforms did not demonstrate the ability to catch errors.

	Issue	Question	Measurements	Hypothesis	Cost Impact	Outcome
P8	The lack of precision in product, lot, shipment, or party identification reported does not allow for rapid links along the supply chain or for common points of convergence to be rapidly detected.	What information is particularly critical in identifying and isolating product movement through a complex supply chain? What harmonized formats or global standards exist that could be readily used by companies to effectively provide precise information?	Note which data elements critically support product tracing and would benefit most from the use of precise information values. Look at information reported to determine the extent to which globally consistent, structured data is already in use by the trade.	Globally unique product and company data element values and the consistent use of data formatting allows for faster detection of points of convergence than regional or company-specific data values or unstructured, free-form data element values.	Cost can be evaluated.	Few pilot participants used standards. Various numbers were used to establish links, and points of convergence could not be established until reaching the point of origin (grower or ingredient supplier).
P9	Many use a first in first out inventory process, but in some instances this can be overridden.	How do differences in inventory rotation practices (i.e., first in first out vs. last in first out and cross docking) impact the precision of a trace exercise?	Compare inventory management procedures with the ability to narrow or focus the product in question.			First in First Out at distribution resulted in the inability of some collaboration platforms to determine the product pathway. In Scenarios PB and PD the inventory at retail was unknown and therefore the date ranges for longer shelf life products was expanded.

Table 76. Key Questions Addressed by Pilots: Access

	Issue	Question	Measurements	Hypothesis	Cost Impact	Outcome
A1	The manual assimilation of data (especially data that are not in electronic form) is a time consuming process.	Would an electronic message (e.g., spreadsheet) allow for the rapid import and export of traceability data among trade, government, and proprietary information systems?	Evaluate how data are provided, and when provided electronically, the formats through which information is transmitted.	A data message standard is the most neutral and efficient means of sharing data between traceability systems as standardization occurs through the adoption of a common domain standard and not through a specific technology or system.	Evaluate various costs with the generation of electronic data.	The IFT templates were useful but there was hesitation in relying on them because of differing use of some fields. It was easier for collaboration platforms to "read" this information than PDFs.
A1a	The manual assimilation of data (especially data that are not in electronic form) is a time consuming process.	Would a standard electronic (e.g., XML) message definition allow for the rapid import and export of traceability data among trade, government, and proprietary information systems?	Evaluate how data are provided, and when provided electronically, the formats through which information is transmitted.	A data message standard is the most neutral and efficient means of sharing data between traceability systems as standardization occurs through the adoption of a common domain standard and not through a specific technology or system.	Evaluate various costs with the generation of electronic data.	Standard electronic messages in this sense were not provided and therefore not tested.

	Issue	Question	Measurements	Hypothesis	Cost Impact	Outcome
A2	The manual assimilation of data (especially data that are not in electronic form) is a time consuming process.	Can a collaboration platform increase the speed with which convergence is determined?	Use collaboration platform that is pre-loaded with industry-supplied data.	Data analysis through an electronic system will greatly increase the speed with which points of convergence are identified.	Use of a collaboration platform can be tested and a cost estimated, both for industry and FDA.	The input of non-standardized data into the collaboration platforms was a time-consuming process, but once input, convergence was quickly identified in most systems that had the functionality to find convergence.
A3	The Bioterrorism Act regulations specify which records need to be kept by which supply chain members. As investigations proceed, missing data elements may slow or complicate an investigation.	If supply chain nodes are known, but one or more key data elements (about the product, shipment, etc.) are missing at one or more nodes, how does it impact the speed of building a tracking tree?	Compare the speed through which supply chains are illuminated when all data are provided vs. when some data (e.g.. lot number) are missing.	The time required to identify supply chain participants (trading partners) will not differ if data details are missing, however if the data cause the identification of several potential suppliers (versus the specificity of identifying with confidence the sole supplier) investigation time may increase as the “potentials” are ruled out.	Could estimate cost of requiring industry to capture specific data elements across all nodes.	The earlier in a scenario that manufacturer-assigned lot numbers were provided (scenario PB), the easier it was to pinpoint the scope of potentially affected product. When this information was not provided (scenario PD) it was extremely difficult to trace.

	Issue	Question	Measurements	Hypothesis	Cost Impact	Outcome
A4	The one up –one down system relies on each supply chain member providing information in a timely fashion in order for an investigation to proceed. Some have purported that in some instances there may be alternate ways to more readily obtain information.	How does the investigative process impact the ability to identify supply chain partners?	Identify questions the FDA/states currently ask and then compare them to the questions the pilot participants wish they would ask regarding who to speak to, how to access others in supply chain etc.	Communicating with industry corporate headquarters for the brand (whether manufacturer, retailer, or foodservice) will be more effective than communicating with individual establishments if data are centrally housed or managed.	No industry cost impact; could estimate cost to FDA/ states of re-training, etc., but may be difficult to obtain cost estimate.	In Scenario PC 3, conference calls were convened which allowed each party to share information and ask questions. This was a very efficient way to gain a great deal of information quickly.

	Issue	Question	Measurements	Hypothesis	Cost Impact	Outcome
A5	Data are provided to regulators in a variety of formats which need to be deconstructed in order to understand the information being shared.	How does the presentation of data in a structured format, such as a template, impact the speed with which supply chain links can be established? Can a universal template be developed that can be provided to those in the supply chain to obtain the desired data more efficiently? How can the information in the template be verified for regulatory purposes? What level of confidence will be given to the data provided?	Compare data provided on the "template" with data provided in the "raw" form (e.g., invoices, bills of lading, etc.). Measure speed with which "investigators" can establish links versus amount of additional industry effort to fill out template. Assume data in template are correct (errors are addressed in another question).	Companies understand their own information and can more readily transfer pertinent information to the template; the use of the template will result in faster data analysis.	Cost can be estimated for use of a standard template.	A single universal template may not be appropriate. Sharing data on a template/summary was very useful in better understanding verification documentation. Industry time to fill out the template depended on the complexity of the scenario and complexity of their operation. Many found it cumbersome and confusing to use the IFT template but easily created customized templates.

	Issue	Question	Measurements	Hypothesis	Cost Impact	Outcome
A6	It is often reported that issues arise at 5:00 pm on a Friday. Accessibility to the right people at the right times is critical.	How does the location of supply chain members in different time zones impact the speed of a trace exercise?	The tests will be conducted during "normal business hours" and participating firms know they are participating. Still this issue should be noted.			Scenario A - was sent at 4:45 pm. Scenario H sent when the contact was on travel. Other scenarios were sent during off hours/Friday afternoons and in some scenarios participants asked for additional time as a result.
A7	There is an assumption that "data are data" regardless of international boundaries, yet investigations that cross borders can present unique challenges.	How does language and cultural presentation of data impact the speed of a trace exercise?	Both pilots include participants outside the United States (Mexico, Thailand). The nature of records and process used to acquire information will be evaluated.			In some tomato scenarios, documentation was provided in Spanish which provided some challenges. In Scenario PD the trace stopped at the importer; we were not able to make contact with the Thai manufacturer.

Table 77. Key Questions Addressed by Pilots, Other

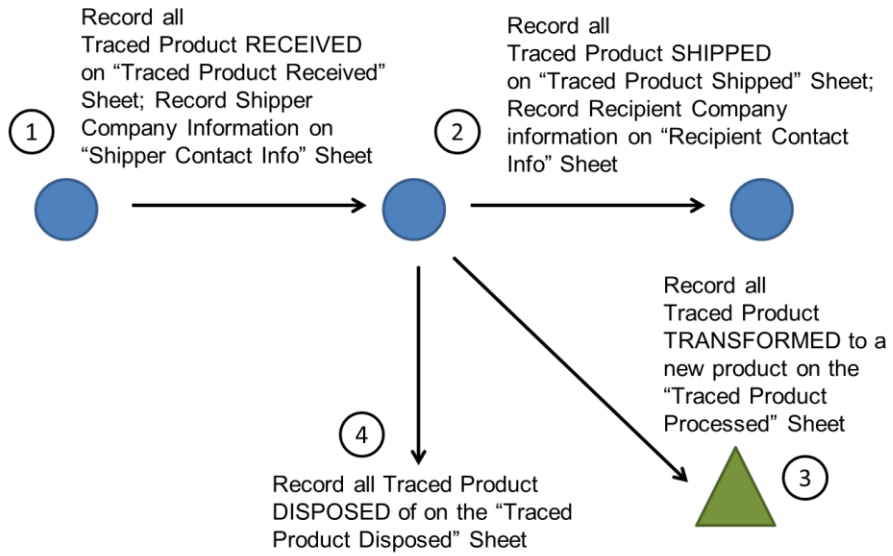
	Issue	Question	Measurements	Hypothesis	Cost Impact	Outcome
O1	At the outset of an outbreak investigation, the causative food vehicle is not known and could be a USDA or FDA regulated product. Additionally, some outbreaks have been linked to products regulated by FSIS that contain FDA regulated ingredients which were the source of contamination. The agencies must work together but different laws may govern their traceback practices.	Explore how FDA and FSIS tracebacks differ; possibly how different state laws impact tracing (e.g. FL sunshine laws)	Examine how both agencies trace in a jointly regulated product; if possible, examine regulations related to tracing			Scenario PC traced both USDA and FDA regulated products, but this did not have a noticeable impact on the nature, quality, or format of the information provided by the firms.
O2	Lengthy outbreak investigations cause harm to an industry as consumers often avoid a product category.	How does the time between the identification of an outbreak and resolution (identification of convergence) impact industry/brand reputation	Use case studies to relate tracing time with industry/market impact	The more rapidly a situation is resolved, the less financial damage will be incurred by the affected industry/brand	Can estimate brand resilience for segments of the industry, but not for the industry as a whole; brand resilience will be a factor in cost-benefit analysis of tangible tests.	This could not be explored in the pilots but was modeled using case studies determining the public health impact of more rapid investigations.

	Issue	Question	Measurements	Hypothesis	Cost Impact	Outcome
O3	It typically takes a few weeks before outbreaks are identified and a regulatory traceback begins. Depending on the shelf life/turn of a product, a contaminated product may have exited the supply chain. That said, there is great benefit in determining the root cause of the outbreak in order to prevent a similar recurrence.	How does the turn rate of the product (rate at which it exits the supply chain) impact the ability to impact public health?	Document epi assumptions and develop expected "date of illness onset" curves for products with high and low turn rates; calculate public health gain when time to trace is decreased by a set number of days	The time to identify an outbreak for a short shelf life/high turn product may mean that illnesses have stopped before the traceback begins, making the immediate impact on public health minimal		The public health case studies included a variety of products/ingredients with varying shelf lives.

APPENDIX M. IFT TEMPLATE

STEPS TO COMPLETE THE TRACE-FORWARD SURVEY FORM

Complete the "Responding Company Info" Sheet.
Then, for each product item of interest identified, take the following steps:



PRODUCTS OF INTEREST				
BRAND OWNER (Name of Supplier Company)	ITEM NAME or number	SUPPLIER-ASSIGNED LOT/BATCH ID	OTHER LOT DESCRIPTION (e.g., SELL BY DATE, PO #)	PRODUCT DESCRIPTION

RESPONDING COMPANY INFORMATION

Instructions:

The objective of this sheet is to gather basic and company contact information about your firm.

NOTE: The inclusion of the "company identifier" is optional and WILL NOT be used in this study. We are curious if firms tend to have these numbers and hope to speculate about how this information could be used by authorized individuals during an investigation

Responding Company Name	
Corporate Address	
City	
State	
Zip	
Contact name	
contact phone number	
contact email	
backup contact name	
backup contact phone number	
backup contact email	
Company identifier (FDA facility registration number, Duns number, GS1 Global Location Number, etc)	
Identifier type (FDA facility registration, Duns, GLN, etc)	

RECEIPT OF TRACEABLE ITEMS/SHIPMENTS

Instructions:

On this sheet, please provide information about the receipt of the items/shipments designated to be of interest to the invesitigators.

NOTE: If you received product from a supplier that is *not* participating in this study, please denote this as "supplier 1", "2", 3" etc. We would like to capture the complexity of the traceback tree.

The Product Received should be one of the Products of Interest listed on the INSTRUCTIONS sheet.

There are some definitions of terms that appear below.

RECEIPT OF PRODUCT(S) OF INTEREST																		
Report line#	BRAND OWNER (Name of Supplier Company)	ITEM NAME or number	SUPPLIER-ASSIGNED LOT/BATCH ID	DESCRIPTION (optional)	QTY received	Unit of measure	Date received	Time received	Receiving location	Internal/assigned number (if any)	SHIPPER NAME	Ship from location	ORDER # (eg PO#)	Order Type (eg PO)	Transfer #	Transfer type (e.g bill of lading)	Other necessary information
1																	
2																	
3																	
4																	
5																	
6																	
7																	
8																	
9																	
10																	
11																	
12																	
13																	

Order Number	identification reference number number for an order that can be used to associate all elements of a Critical Tracking Event together. For instance a Purchase Order Number may be used for a shipment, a Sales Order Number may be used to process a customer sale, and a Processing Order Number may be used for a Transformation
Order Type	This will be a code to represent the Type of Order Number associated with a CTE such as a Purchase Order or a Production Order Number.
Transfer Number	A number that can be used to fully identify a shipment to both partners. For instance for a shipment by a carrier a Bill of Lading number may be used.
Transfer Type	A code to specify the type of Transfer Number included with the CTE such as Bill-of-Lading or Overnight Tracking Number

SHIPPER CONTACT INFORMATION

Instructions:

The objective of this sheet is to gather contact information about suppliers of ingredients/products listed on the "incoming products" sheet

	Shipper # 1	Shipper # 2	Shipper # 3
Shipper Company Name			
Corporate Address			
City			
State			
Zip			
Contact name			
contact phone number			
contact email			
Notes/Remarks			

Add more columns as necessary if more than 3 shippers

SHIPMENT OF TRACEABLE PRODUCT ITEMS

Instructions:

On this sheet, based on the items/shipments of interest communicated to you, please provide information regarding who received this product (by lot, date, etc based on the IFT inquiry).

NOTE: If you sent product to a firm that is *not* participating in this study, please denote this as "recipient 1", "2", 3" etc. along with quantity. We would like to capture the complexity of the traceback tree.

The Product Shipped should be one of the Products of Interest listed on the INSTRUCTIONS sheet.

There are some definitions of terms that appear below row 20.

SHIPMENTS OF PRODUCTS OF INTEREST															
Report line#	BRAND OWNER (Name of Supplier Company)	ITEM NAME or number	SUPPLIER-ASSIGNED LOT/BATCH ID	DESCRIPTION (optional)	QTY shipped	Unit of Measure	DATE shipped	Time shipped	Ship from location	RECEIVER NAME	Ship To Location	ORDER # (eg PO#)	Order Type (eg PO)	Transfer #	Transfer type (e.g bill of lading)
1															
2															
3															
4															
5															
6															
7															
8															
9															
10															
11															
12															
13															

Order Number	identification reference number number for an order that can be used to associate all elements of a Critical Tracking Event together. For instance a Purchase Order Number may be used for a shipment, a Sales Order Number may be used to process a customer sale, and a Processing Order Number may be used for a Transformation
Order Type	This will be a code to represent the Type of Order Number associated with a CTE such as a Purchase Order or a Production Order Number.
Transfer Type	A code to specify the type of Transfer Number included with the CTE such as Bill-of-Lading or Overnight Tracking Number

RECIPIENT CONTACT INFORMATION

Instructions:

The objective of this sheet is to gather contact information about the recipients of the items/shipments listed on the "Outgoing Product" sheet

	RECEIVING COMPANY # 1	RECEIVING COMPANY # 2	RECEIVING COMPANY # 3
Receiver Company Name			
Corporate Address			
City			
State			
Zip			
Contact name			
contact phone number			
contact email			
Notes/Remarks			

Add more columns as necessary if more than 3 recipients

NEW PRODUCTS CREATED FROM A PRODUCT OF INTEREST

Instructions:

The purpose of this sheet is to document when a product of interest (as listed on the INSTRUCTIONS Sheet) is used to create a new product.

NOTE: If you are a distributor/wholesaler/grower/ or other who does not create new products by way of manufacturing, repacking etc, this sheet does not apply to you.

The "Input Product" should be one of the Products of Interest listed on the INSTRUCTIONS sheet.

The definition of transformation appears below.

PRODUCTS OF INTEREST USED TO CREATE NEW PRODUCTS												NEW PRODUCTS CREATED FROM PRODUCTS OF INTEREST				
Report line#	BRAND OWNER (Name of Supplier Company)	ITEM NAME or number	SUPPLIER-ASSIGNED LOT/BATCH ID	QTY Used	Unit of Measure	Transform-ation location	Transform-ation date	Transform-ation time	Other necessary informatio n	TO CREATE New Product on Reference line #		NEW PRODUCT Reference line #	NEW PRODUCT Supplier Name	NEW PRODUCT Item Name or number	NEW PRODUCT Supplier-Assigned Lot/batch ID	Other nec
1												N1				
2												N2				
3												N3				
4												N4				
5												N5				
6												N6				
7												N7				
8												N8				
9												N9				
10												N10				

Transform ation	. The act or result of changing the item such as combining ingredients to make a finished product or repackaging a product such as producing a tray-packed product for consumer sale from cased ingredients. Transformation can be production, aggregation, grouping, splitting, mixing, packing and repacking traceable items.

TRACED PRODUCT DISPOSED INFORMATION

Instructions:

On this sheet, based on the items/shipments of interest communicated to you, please provide information regarding product that was destroyed.

The Products Disposed should be one of the Products of Interest listed on the INSTRUCTIONS sheet.

PRODUCT(S) OF INTEREST DESTROYED									
Report line#	BRAND OWNER (Name of Supplier Company)	ITEM NAME or number	SUPPLIER-ASSIGNED LOT/BATCH ID	DESCRIPTION (optional)	QTY disposed	Unit of Measure	DATE Disposed	Time disposed	Comments/Remarks
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									

APPENDIX N. BACKGROUND ON PILOTS PROVIDED TO TRADE ASSOCIATIONS AND POTENTIAL PARTICIPANTS

Participants Sought for Product Tracing Study

What: The Institute of Food Technologists, working under contract with FDA, is conducting product tracing pilots for produce and processed foods

Produce item: tomatoes

Processed food: Asian style RTE or non-RTE (including frozen) dish containing chicken, peanut products, and spices, examples of which could include Pad Thai or Kung Pao.

When: Food industry supply chain partners who will participate in the pilots need to be secured by November 30. Data collection and the mock traceback tests will be conducted in the first quarter of 2012. IFT must provide FDA with the final report by June 6, 2012.

Who: Many supply chain partners, spanning raw material providers/growers through all points in the supply chain through to retail and foodservice. This may include: transporters, brokers, foreign suppliers, etc. The pilots are not limited to those required to keep records under the Bioterrorism Act of 2002. **IFT is currently seeking volunteers for these pilots.** Interested companies should engage their supply chain partners. IFT will provide all interested firms with additional information, including a more detailed timeline, and will answer any questions companies may have regarding participation. It is important to construct complete supply chains (i.e., a string of trading partners through whom product flows). IFT will work to include as many interested companies as possible who handle the aforementioned products (and in the case of the processed food, the spices or peanut ingredients that will be traced).

The two pilots will be run separately, but concurrently. The approach, execution, and analysis of the results/findings will be developed primarily by panels (one for produce and one for processed foods) consisting primarily of pilot participants, select trade association representatives, and other stakeholders. These panels have not yet been assembled. All food companies participating in the pilot studies will be invited to be represented on the respective panel, however, panel participation is not mandatory. Those choosing to participate in the panels will need to commit more time to this project than companies who participate in only the studies. The panels will have at least one face-to- face meeting and many conference calls/web meetings over the course of three months. Some panelists will be asked to participate in a final meeting in April 2012.

At this time, IFT is not actively seeking participants from the 3rd party technology community. The request for this type of participant will be issued in early December, 2011, along with a list of the criteria by which interested technology companies will be evaluated and an explanation of the process for selecting these types of participants.

How: IFT is currently working with a group of state and federal traceback investigators to develop a baseline study, evaluating historical investigations to determine aspects of product tracing that tend to help or hinder an investigation.

IFT's task, which includes the pilots as well as additional work, will be conducted by several panels working collaboratively, including the traceback investigator panel, the produce panel, the processed food panel, the cost panel, and an oversight panel. The oversight panel consists of seven individuals: Jack Guzewich, Tom Breuer, Caroline Smith DeWaal, Benjamin Miller, Douglas Bailey, Brenda Lloyd and

Bruce Welt. These individuals have already helped collect and analyze input into how the task should be conducted. The “produce” and “processed” panels, led by IFT, will determine the exact specifications for the pilot tests. The proposed approach is as follows:

Between now and early December, shortly after participants have been selected, IFT will spend at least one hour with each participant to understand their operation. We would love to conduct some “field trips”. Each participant will be asked questions regarding data collection, capture, and sharing, how internal and external product tracing are managed, and other records-related questions, as well as about the product of interest (rough estimates of batch sizes, # distribution units/batch, “shelf life” and expected flow through the supply chain, etc.).

Based on some of the issues identified in the baseline study, and some work being done independently to specify Critical Tracking Events and Key Data Elements, IFT will divide participants into at least two groups based on their reported recordkeeping practices: those that seem to follow practices that would facilitate product tracing, and those where improvements could have the maximum impact Within the “improvement” group, depending on the nature and extent of areas for improvement, and in consultation with the panels, IFT may request volunteers to make minor changes to their recordkeeping or other practices in order to test hypotheses regarding the factors that improve product tracing. Due to time and budget constraints, it is expected that modifications requested will be reasonable, and the panel will help determine the best approaches to conduct the tests.

Firms will be asked to collect data (in many cases, this will be in a similar fashion to current practices) over a finite period (likely a few weeks, depending on the product/ingredient), and provide these records to IFT for analysis by IFT, FDA, and the panel during the test demonstrations. Hypothetical outbreak scenarios will be developed by the panel and traceback investigators. A mock traceback will first be conducted in a manual fashion (analyzing and sorting records essentially “by hand” to establish links between ingredients and finished products, and between supply chain partners). In this stage we will seek to identify the data attributes and other industry practices that enable or prevent linking of supply chain data. In a second stage, the information will be analyzed using one or more collaboration platforms. Again, these have not yet been selected, and a separate notice will be issued in December 2011.

Important Considerations

FDA has indicated that firms participating in the study will *not* be subject to enforcement action as a result of the information provided. This study does not seek to point a finger at any particular firm or industry for deficiencies in recordkeeping. Rather, IFT and the panels will look for themes—processes or practices employed by various firms—that contribute to the ability to trace products. Ultimately we seek to identify ways to improve the speed and accuracy of product tracing, and quantify the cost and benefits associated with these improvements.

IFT will *not* remove any company-identifying information from materials supplied by companies in connection with the study. The FDA will redact any documents or data that are to be made public in keeping with the applicable laws and regulations governing disclosure.

Why Participate?

The results of these pilots will form the basis of FDA's report to Congress, due July 2012. While participants will not be permitted to discuss the results of the study (including the data that are collected, the firms participating, the scenarios applied in the tests, etc.) and the recommendations put forward as a result of the work, they will certainly have first hand insight into the process and will be key to the process itself. Participation also provides an opportunity to better understand how a company may improve it's current operations, and for some, perhaps showcase their current systems. IFT understands the perceived risk associated with participating. However, with or without *your* company's participation, the pilots will be conducted. We hope firms will see the benefit of proactive participation.

For more information

Contact Caitlin Hickey at 202-330-4984; chickey@ift.org

APPENDIX O: BASIC LETTER TO PILOT PANEL MEMBERS

Thank you for your interest in serving on a pilot panel for the IFT-led product tracing pilots. We greatly value the expertise you have to offer, and hope that you will agree to serving on the panel after reading more about roles, responsibilities, and expectations.

The panel, currently around 20 members, consists of a blend of food company pilot participants (those who will be providing their traceback data for the study) as well as individuals with expertise and insight into this industry, experience in other industries that we can learn from, and/or product tracing practices. This is a diverse group with many perspectives represented, and it will be important to maintain a professional, cooperative attitude.

We expect that there will be difference of opinion within the panel, and this group is encouraged to use the oversight panel – a neutral body who is overseeing all aspects of the task—to discuss major issues for which consensus is not easily reached. The oversight panel will also be reviewing the approach recommended by this group to ensure that that all aspects of the task are covered, and they, along with IFT, reserve the right to make adjustments that are in the best interest of the project, using an open, transparent process.

The panel serves three main functions:

- Assist in fine-tuning the approach for the pilot
- Participate in the execution of the pilot
- Evaluate the results and help develop draft portions of the report to FDA

We hope to schedule conference calls in December and early January. The panel will meet either via a web meeting or face to face in early-mid March, and potentially in mid-April.

IFT has a very limited amount of funding to subsidize travel to the meeting(s). Priority for funding will be given to those food companies volunteering data for the pilots. We are able to fund travel for roughly 5 individuals. Requests for travel support should be submitted to me along with agreement to protect non-public information, and I will inform you of the ability to cover your travel costs in early January.

FDA has continually stressed to IFT the need to be transparent and inclusive of all stakeholders during the design phase of the pilots. However, FDA has also emphasized that once the pilot studies are underway and the results are assessed, it is critical that panel members and other participants keep deliberations confidential. **Under no circumstances should details of the results or recommendations be shared outside the panel**. Individuals violating this policy will be immediately removed from the task. IFT is not permitted to share results or publish the report without approval of FDA. Once the final task report becomes public, this restriction will be lifted. If there are any questions about what can or cannot be shared at any time, please let me know.

If you have any questions, please don't hesitate to contact myself or Caitlin Hickey (chickey@ift.org; 202-330-4985).
Again, I look forward to working with you.
Best regards,

Jennifer McEntire, Ph.D.
Project Director/ IFT Tracing Pilots
Jennifer.mcentire@leavittpartners.com
301-551-3601

APPENDIX P. TECHNOLOGY REQUEST FOR INFORMATION

The Institute of Food Technologists (IFT) has been charged with conducting the Food and Drug Administration pilots as required by the FDA Food Safety Modernization Act (FSMA) of 2011. The two products selected by the FDA are: tomatoes and frozen or ready to eat processed food product containing spices, peanuts and chicken. The pilots are required to evaluate the effectiveness of using a "collaboration platform" during these pilots. This document outlines the initial request for information from all interested technology solution providers who may be a part of the collaboration platform. Significant stakeholder input and guidance was received and used to develop this selection criteria. While there are several aspects of the pilot still to be determined, data collected through this document will be used to identify a short list of potential candidates based upon our needs in the pilots, who will be further evaluated. You will be notified of your status by December 15, 2011. A minimal (non-exhaustive) set of requirements include:

- References from currently paying customers in the food industry (preferably from the products selected for the pilots)
- Interoperable; willingness to sharing of data with other solutions
- Ability to import and export data in a non-proprietary formats
- Ability to work with other 3rd party solutions to create a collaboration platform
- Openness to new ideas, concepts and strategies to improving traceability through the use of technology

Please complete and return this document to Tejas Bhatt (tbhatt@ift.org) **by Friday, December 9th, 2011.** The completion of this document does not constitute your agreement to participant in the pilot studies. Information received via this request will not be shared by IFT with the FDA, but may be shared (under non-disclosure agreements) with the panel members responsible for ultimately selecting the technologies to be used on the pilots. You do not need to respond to all questions; however, the more information IFT has regarding your technology, the easier it will be for us to evaluate your capabilities with respect to pilot participants. Please see the attached tentative timeline for the progression of the pilots, keeping in mind that it's flexible and subject to change. We expect the participating solution providers to have about two weeks to upload data and another two weeks to test and respond to scenario-based queries on that data during the months of February and March of 2012.

1. Please provide the following statistics for your company:
    a. Name of your company:
    b. Year company established:
    c. Size of your company (number of employees):
    d. Number of paying clients in the food industry currently supported
2. A preference will be given to those who currently have paying customers in the food industry. Please provide the name and contact information for one to three references. If you do not have currently paying customers, please justify why your technology should be considered. IFT may contact your customers to gain their perspective on the use of your technology.
3. Since these pilots are being conducted from farm to fork, IFT is looking for solutions that have the ability to capture, store and share data across the entire supply chain. Is your solution specifically designed for internal (within the four walls) traceability, external (connecting trading partners) traceability or whole chain traceability (both internal and external)?

4. Your solution is applicable for which of the following broad –based areas (select all that apply):
    a. Data capture (labeling, radio frequency identification (RFID), bar-coding etc.)
    b. Data storage (Warehouse management services (WMS), Enterprise resource planning (ERP) etc.)
    c. Data sharing (cloud-services, web-services, others)
5. Which of the following ways can traceability related data/ records be imported into your solution (select all that apply)
    a. Manually
    b. Through batch uploads (at the end of a shift/day etc.)
    c. Extracted from existing information technology (IT) systems like ERP, WMS or financial/accounting systems
6. IFT is looking for a collaboration platform that is able to import and export data in a variety of formats and may not use a collaboration platform or system that either cannot import/export data or that requires the use of a specific system. Is your solution able to import and export data using non-proprietary formats like text, comma separated values (CSV) or extensible markup language (XML)?
7. IFT is going to evaluate the use of structured standardized as well as unstructured non-standardized data in the pilots and may not use a solution that cannot handle both types. Does your system require the use of only proprietary / standardized data fields/formats?
8. Data security is critical. Does your solution use any form of encryption when storing or transmitting data? If yes, please specify the type/level of encryption (for example, 128-bit SSL).
9. A collaboration platform will be evaluated as a means for multiple trading partners to share data as needed. It is IFTs expectation that at least one test for the collaboration platform will be on interoperability. Is your solution capable of interoperability (currently implements connecting with and sharing of traceability related data with another 3rd party solution provider)? If yes, please provide the name and contact of the 3rd party solution provider(s) you have worked with to demonstrate this. If not, please indicate your willingness to collaborate.
10. With the inclusion of international suppliers/importers, IFT may give preference to solutions that support multiple languages. What languages does your system support (on the client side)?

One approach suggested by stakeholder input was to invite those solutions already in use today in the product sectors selected for the FDA pilots. We also encourage you to reach out to your customers and ask them to participate in the pilots enabling you to demonstrate the effectiveness of your technology. Regardless of the approach used, we may use the following 2 tables below to appropriately slot the scope and reach of your solution in the pilots.

11. Within the tomato sector of the food industry, please mark an "X" in all the cells in the table below where you currently have paying customers:

Your customer's company size as determined by number of employees →	Very Small (1 – 19 employees)	Small (20 – 99 employees)	Medium (100 – 499 employees)	Large (500 or more employees)
Greenhouse Growers				
Field Growers				
Foreign Growers				
Importers				
Brokers				
Packing Houses				
Re-packers				
Re-graders				
Processors				
Wholesalers				
Distributors				
Retailers				
Terminal Markets				

12. Within the selected processed food (a frozen or ready to eat product containing spices, peanuts and meat) sector of the food industry, please mark an "X" in all the cells in the table below where you currently have paying customers:

Your customer's company size as determined by number of employees →	Very Small (1 – 19 employees)	Small (20 – 99 employees)	Medium (100 – 499 employees)	Large (500 or more employees)
Spice Importer				
Spice Supplier				
Chicken Supplier				
Peanut Supplier				
Processor (of selected food for the pilots)				
Chicken Processor				
Peanut Paste Processor				
Distributor				
Retailers				

APPENDIX Q. INDUSTRY PROFILES BASED ON BUSINESS SIZE

The following series of charts (Figure 49, Figure 50, Figure 51, and Figure 52) illustrate the relative size of firms within the four industry segments analyzed: retailers (including foodservice), processors, distributors and growers. The bar charts below show the distribution of total number of firms as well as revenue across a segment. The X axis on each bar chart divides each segment into six buckets according to relative firm size. Both the distributor and the processor segments' SBA guidelines are defined by employee size but growers and retailers are defined based on a total amount of sales; this was accounted for in the underlying analysis and is shown in the bar charts. When applicable the SBA guideline is also added to the bar charts if it is consistent for the entire segment. If the SBA line is not included, then the guidelines differed between subsectors within the segment or the census data was not grouped in the same manner as the SBA guidelines. In the bar charts, the Y axis shows both total revenue (above the center line representing $0) and total number of firms (below the center line representing 0). This visualization allows the observer to compare the total number of firms to how much revenue the firms produce across a whole segment.

Figure 49. Grower Segment Characteristics, Distribution of Firms and Associated Sales, by Size

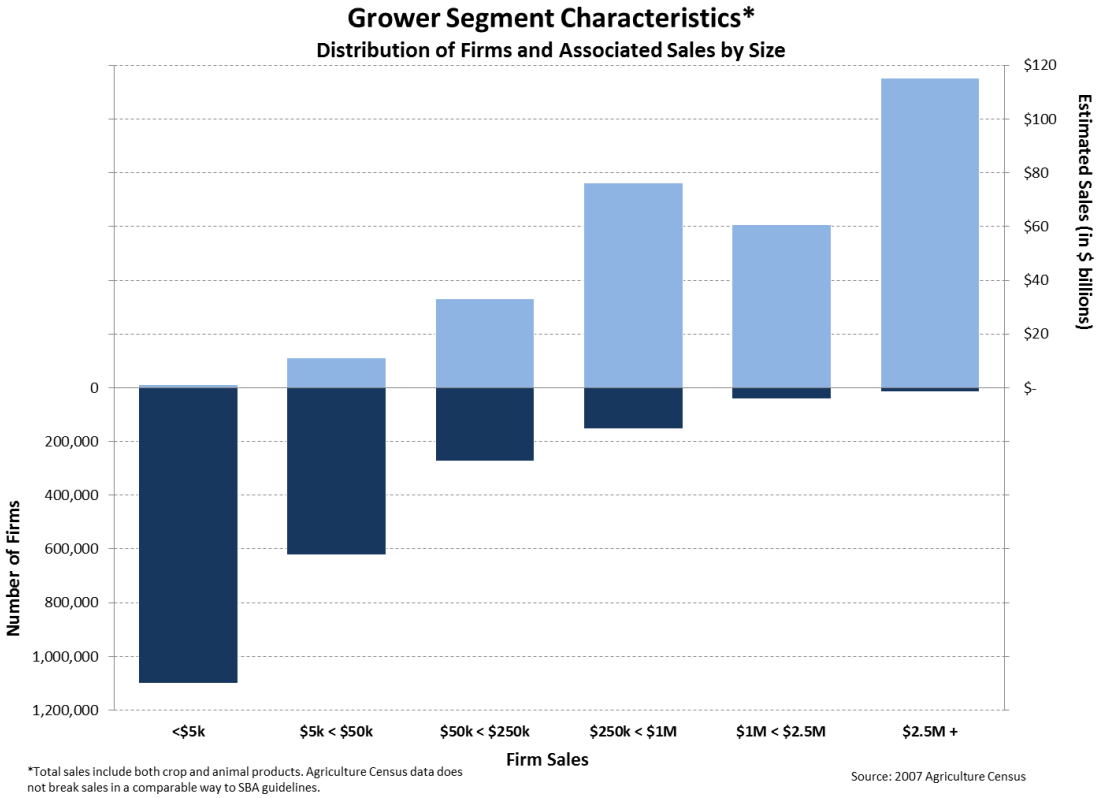


Figure 50. Distributor Segment Characteristics, Distribution of Firms and Associated Receipts, by Size

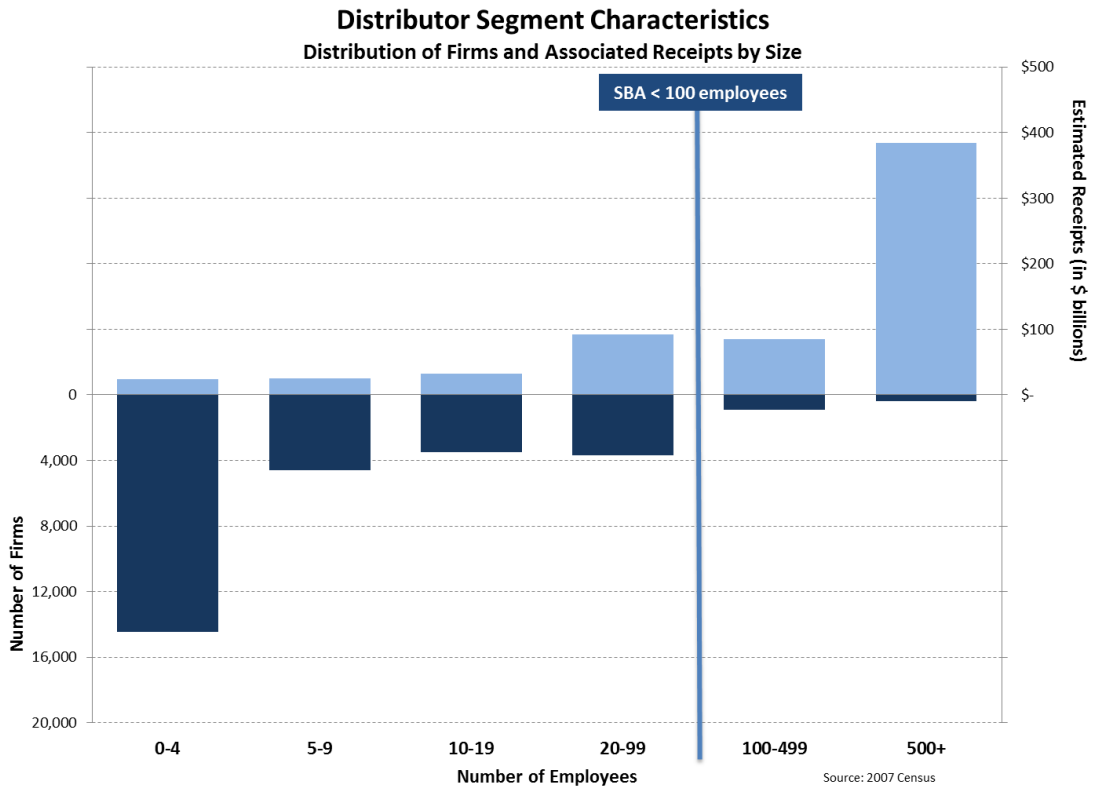


Figure 51. Processor Segment Characteristics, Distribution of Firms and Associated Sales, by Size

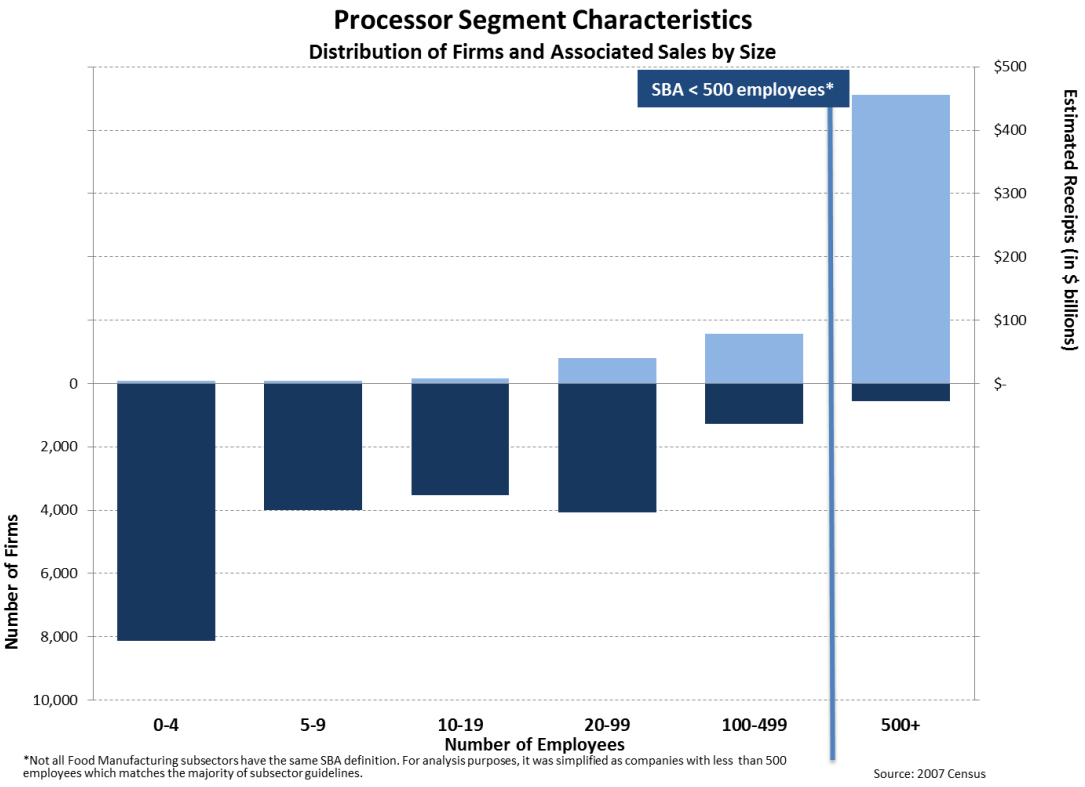
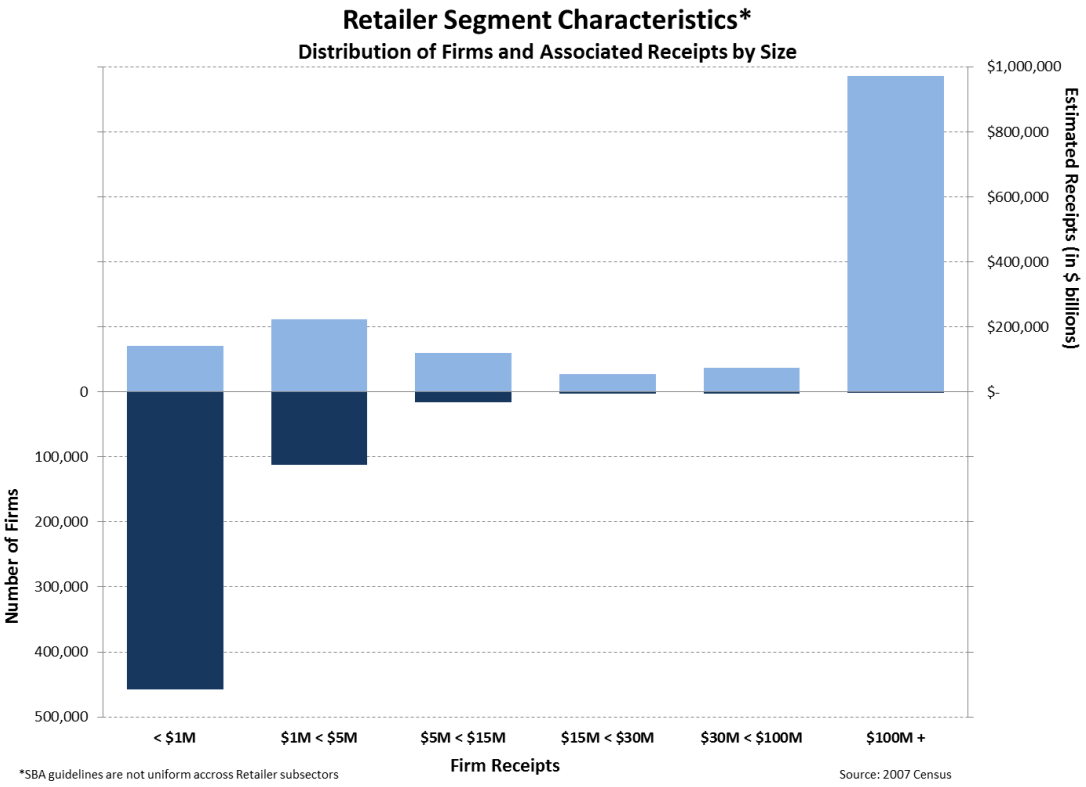


Figure 52. Retailer Segment Characteristics, Distribution of Firms and Associated Receipts, by Size



APPENDIX R. COST ANALYSIS QUESTIONNAIRE

Pilot Participant Cost Analysis Questionnaire

Background Information	
(A) First Name	
(B) Last Name	
(C) Position/Title	
(D) Email	
(E) Company	

(F) Company operations size

Annual sales in $US millions:	
Number of full time equivalent (FTE) employees:	

(G) Number of facilities owned

Grower:	
Processor:	
Distributor:	
Retailer:	
Other:	
If you selected "Other", please specify:	

Possible Industry Improvements	

(1) On a scale of 1 (Non-Existent) to 10 (Very Sophisticated), with 5 representing the industry average:

(a) How would you characterize your current product tracing system?	
(b) How would you characterize your product tracing system 5 years ago?	

(2) Did you use the template provided by IFT in your responses to the pilot scenarios?	

(3) If you used the template provided by IFT in your response to traceback scenarios please respond to the following questions:

(a) How many additional employee hours did it take to respond using the template?	
(b) How much estimated additional cost ($US) is necessary to respond using the template (including the value of extra employee time)?	
(c) Please describe any changes compared to your normal response in order to respond using the template:	

Industry Improvements

For the following questions below, the pilot scenarios have identified a few key traits of traceability systems. For each of these traits we have described a goal for a company's traceability system to obtain. Please answer the following questions based on if your company's current traceability system can perform the goals as stated.

Goal - Capture key data elements (Supplier ID, Product ID, Purchase Order Number, Quantity-pack size, Receipt Date) by writing on paper

(4) Can your company's current traceability system achieve the above goal?	

Goal - Capture key data elements (Supplier ID, Product ID, Purchase Order Number, Quantity-pack size, Receipt Date) by writing on paper and later entering into a database/spreadsheet

(5) Can your company's current traceability system achieve the above goal?	

Goal - Capture key data elements (Supplier ID, Product ID, Purchase Order Number, Quantity-pack size, Receipt Date) by scanning labels

(6) Can your company's current traceability system achieve the above goal?	

Goal - Capture key data elements (Supplier ID, Product ID, Purchase Order Number, Quantity-pack size, Receipt Date) by electronic message

(7) Can your company's current traceability system achieve the above goal?	

Goal - Capture incoming quantity by received lot number, assuming a lot number is provided

(8) Can your company's current traceability system achieve the above goal?	

Goal - Linkage between incoming and outgoing product, whether there is transformation (e.g., ingredients into a finished product) or not (e.g., relating lot numbers received to lot numbers shipped)

(9) Can your company's current traceability system achieve the above goal?	

Goal - Use a non-proprietary standardized product naming system, including item identification (e.g., GS1, GTIN, GLN, state-issued plant/registration number, etc.)

(10) Can your company's current traceability system achieve the above goal?	

Goal - Send key data elements electronically to customers

(11) Can your company's current traceability system achieve the above goal?	

Goal - Provide a data summary sheet (or template like the one IFT provided) that highlights the links between key data elements for the products of interest

(12) Can your company's current traceability system achieve the above goal?	

Data Capture

Incoming Ingredients/Products/Materials

(13) Which of the specific information is captured at your facility for Incoming Ingredients/Products/Materials?

(Select all that apply)

	Supplier
	Date
	Location
	Product Identifier
	Product description
	Batch/Lot
	Quantity
	Lot Control Date
	Source (Name, address, facility, etc.)
	Storage Location
	Seal Verification
	Other (please specify below)

(14) How are these data captured for Incoming Ingredients/Products/Materials?

(Select one which best represents your system)

	Manually (paper based)
	Manually and input to electronic system
	Electronically
	Other (please specify below)

Transformation Points

(15) Which of the specific information is captured at your facility for Transformation Points?

(Select all that apply)

	Date
	Location
	Ingredient Identifier
	Ingredient Batch/Lot
	Ingredient Quantity
	Ingredient Lot Control date

	Finished Product Identifier (Description)
	Finished Product Batch/Lot
	Finished Product Quantity
	Finished Product Lot Control Date
	Other (please specify below)

(16) How are these data captured for Transformation Points?

(Select one which best represents your system)

	Manually (paper based)
	Manually and input to electronic system
	Electronically
	Other (please specify below)

Distribution of Finished Products

(17) Which of the specific information is captured at your facility for Distribution of Finished Products?

(Select all that apply)

	Customer
	Date
	Location
	Destination Name and Address
	Shipment Number
	Finished Product Identifier (Description)
	Finished Product Batch/Lot
	Finished Product Quantity
	Finished Product Lot Control Date
	Other (please specify below)

(18) How are these data captured for Distribution of Finished Products?

(Select one which best represents your system)

	Manually (paper based)
	Manually and input to electronic system
	Electronically
	Other (please specify below)

Business & Economic Considerations

(19) In the following table please indicate any applicable cost areas your company has invested in the past 5 years as well as your best estimate of the total cost associated to improve your product tracing system.

Cost area	In the past 5 years I have invested in this area? (Y/N)	Estimated total cost in $US in thousands
Software		
Licenses		
Implementation		
Training and Change Management		
Operations and Maintenance		
Additional FTEs		
Tracking Equipment		
Manufacturing and Processing Equipment		
Training and Change Management		
Operations and Maintenance		
Changes to Current Processes		
Implementation		
Training and Change Management		
Additional Logistics		
Additional FTEs		
Compliance		
Policy Development		
Training and Change Management		
Auditing and Analytical FTEs		
Other		
(please indicate)		

(20) In the following table please indicate any applicable benefits your company has been able to realize and what the estimated annual monetary benefit is for any improvement in your product tracing system?

Benefits	Has your company realized these benefits? (Y/N)	Estimated annual monetary benefit in $US in thousands
Increased Brand Reputation		
Increased Consumer Confidence in Industry		
Expanded Markets (market access)		
Improvement in Just In Time inventory, Supply Management		
Decrease in Liability/litigation		
Insurance Cost Reduction		
Supply Chain Confidence		
Decreased Spoilage/Storage		
Process Improvement		
Other (please indicate below)		

APPENDIX S. BACKGROUND ON PUBLIC HEALTH BENEFIT CASE STUDIES AND SAMPLE CALCULATION

Table 78. Descriptions for the Eight Outbreak Case Studies

Case Study	Pathogen	Investigation Description	Potential Improvement Time	Total Illnesses for Entire Epi Curve (Deaths)
Peppers and Tomatoes (2008)[4]	Salmonella Saintpaul	The investigation showed that initially tomatoes were the suspect food vehicle. The tomato traceback was initiated based on the epi evidence. When public notification and recall did not reduce the numbers of illnesses, and traceback convergence was not clear, further efforts to identify the food vehicles and contamination site were initiated. Subsequently, Jalapeño peppers were found to be a major source of contamination and that Serrano peppers also were a source. Jalapeño peppers were traced back to distributors in the United States that received produce grown and packed in Mexico.	51 days	1,442 (2)
Cantaloupe (2008)[5]	Salmonella Litchfield	Collaboration with public health officials in multiple states across the U.S. and the FDA investigated a multi-state outbreak of Salmonella Litchfield infections. An investigation that used interviews comparing foods eaten by ill and well persons showed that cantaloupe from Honduras was the likely source of the illnesses.	17 days	53 (0)
Raw Alfalfa Sprouts (2009)[6]	Salmonella Saintpaul	On February 26, 2009 a notice about a cluster of case-patients with *Salmonella* Saintpaul infection among residents of Nebraska was distributed to US State public health officials. Interviews showed that five of 14 Nebraska case-patients patronized a common restaurant chain and that nine had recently consumed alfalfa sprouts. Identifying the alfalfa sprouts was fairly quick (1 day traceback) but the alfalfa seeds were determined to be the source of the contamination resulting in the longer traceback period.	55 days	235 (0)
Red and Black Pepper Spice (2010)[7]	Salmonella Montevideo	During January 16-21, 2010, CDC and public health officials in multiple states conducted an epidemiologic study which suggested salami as a possible source of illness by comparing foods eaten by 41 ill and 41 well persons. Ill persons (58%) were significantly more likely than well persons (16%) to report eating salami. Further investigative and traceback work was initiated to identify the source of the contamination in the salami products. The variety packs and deli trays all included salamis made with black pepper, which was added after the lethality step. Red and black pepper were implicated and the tracebacks to identify the pepper sources were conducted, so the pepper could be removed from commerce.	51 days	272 (0)
Unspecified Mexican Food (2010)[8]	Salmonella Baildon	Analysis indicated that the outbreaks were associated with eating at a Mexican-style fast food restaurant chain. Restaurant Chain A, was associated with some of the illnesses. Among persons eating at Restaurant Chain A, no specific food item or ingredient was found to be associated with illness for either outbreak.	26 days	80 (0)

[4] CDC (2008a).
[5] CDC (2008b).
[6] CDC (2009a).
[7] CDC (2010a).
[8] CDC (2010c). No specific food was recalled and the case was unsolved. At the time of the 8/4/2010 press release outbreaks returned to baseline levels.

Case Study	Pathogen	Investigation Description	Potential Improvement Time	Total Illnesses for Entire Epi Curve (Deaths)
Shell Eggs (2010)[9]	Salmonella Enteritidis	Epidemiologic investigations conducted by public health officials in 11 states since April 2010 identified 29 restaurants or event clusters where more than one ill person with the outbreak strain had eaten. Data from these investigations suggested that shell eggs were a likely source of infections in many of these restaurants or event clusters and a single egg supplier was identified for 15 of these 29 restaurants or event clusters.	8 days	3,578 (0)
Ground Turkey (2011)[10]	Salmonella Heidelberg	Collaborative investigative efforts of state, local, and federal public health and regulatory agencies indicated that ground turkey was the likely source of this outbreak. Among the 94 ill persons with available information, 51 (54%) reported consuming ground turkey. A sample of leftover unlabeled frozen ground turkey was collected by public health officials from the home of an ill person infected with the outbreak strain of Salmonella Heidelberg in Ohio. This retail sample originated from a meat processing establishment in Arkansas.	19 days	134 (1)
Fresh Cantaloupe (2011)[11]	Listeria monocytogenes	Collaborative investigations by local, state, and federal public health and regulatory agencies indicated that the source of the outbreak was whole cantaloupe grown at a farm in Colorado. Among the 140 ill persons with available information on what they ate, 131 (94%) reported consuming cantaloupe in the month before illness onset. Source tracing of the cantaloupes that ill persons ate indicated that they came from Jensen Farms, and were marketed as being from that region.	5 days	146 (30)

Sample Calculation for Salmonella in Shell Egg Outbreak Case Study

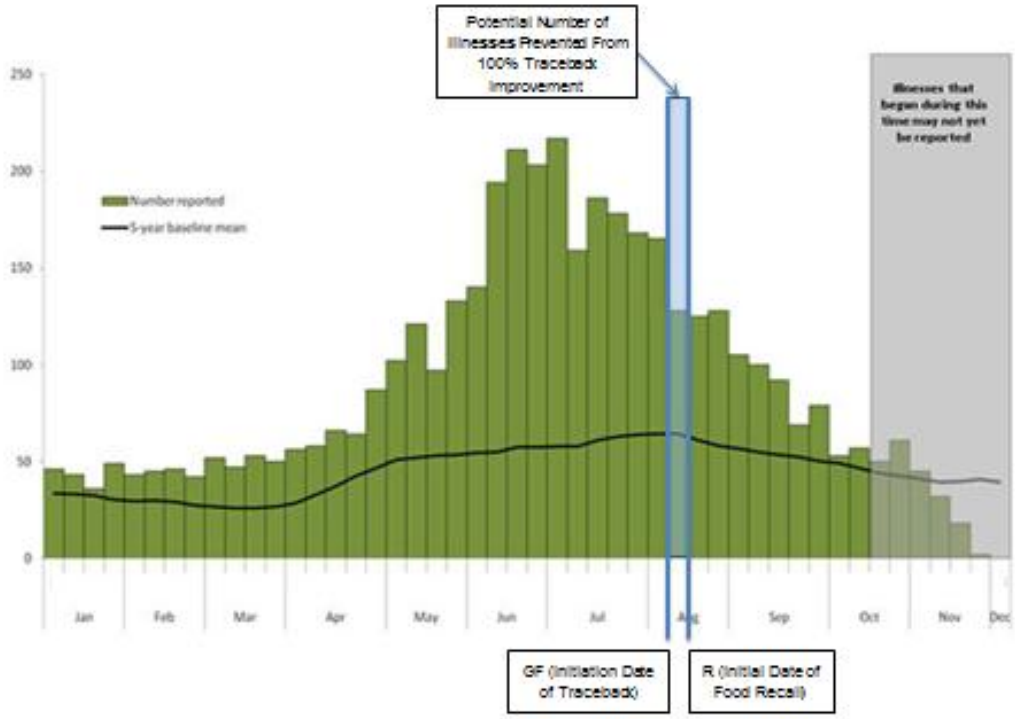
To demonstrate the analytical process and the applicability of this analysis, below are the calculations for the *Salmonella* in shell eggs case study from 2010. The calculations for the remaining case studies were not provided but followed a similar process.

Epidemic Curve for Shell Egg Outbreak Case Study

For the epidemic curve data[12] for the shell egg cases, first the potential improvement time between the initiation of the traceback and the initial intervention date must be located on the curve to provide the bounds for the calculation of the maximum potential number of illnesses that could be prevented. This portion of the curve is the maximum number of illnesses that could be prevented if the traceback time was reduced to 0 days (Figure 53).

[9] CDC (2010d).
[10] CDC (2011a).FSIS Regulated Product.
[11] CDC (2011b).
[12] CDC (2010d).

Figure 53. Epidemic Curve Analysis for Shell Egg Outbreak



CALCULATIONS FOR SHELL EGG CASE STUDY

Ti = Total Number of Illnesses on Entire Epi Curve = **3,578 cases**
GF = **Provided by FDA**
R = **Provided by FDA**
Id = 1 day
GF-R = **8 days**
M = **120 cases**
ADR = M/GF-R = 120 cases /8 days = **15 cases per day**
C = **$17,900 per case**

Average Economic Impact Per Day of Reduced Time = ADR*C = 15*$17,900 = **$268,500**

Maximum Economic Impact = M*C = 120*$17,900 = **$2,148,000**

Percentage of total illness prevented for recall (assuming max product tracing improvement) = M/Ti = 120 cases /3578 cases = **3%**

25% Improve Traceback

25% Number of Days = (GF-R)*.25 = **2 days**
25% Reduction of Illnesses = **30 cases**
25% Economic Benefit Impact = 30*$17,900 = **$537,000**

50% Improve Traceback

50% Number of Days = (GF-R)*.50 = **4 days**

50% Reduction of Illnesses = **60 cases**

50% Economic Benefit Impact = **60***$17,900 = **$1,074,000**

75% Improve Traceback

75% Number of Days = (GF-R)*.75 = **6 days**

75% Reduction of Illnesses = **90 cases**

75% Economic Benefit Impact = 90*$17,900 = **$1,611,000**

GLOSSARY

The following glossary is offered to provide context to the terms *as they are used in the report.* Definitions in other contexts may vary. References are provided as available and as relevant.

Term	Description
Access	The speed with which track and trace information can be communicated to supply chain members and the speed with which requested information can be disseminated to public health officials during food-related emergencies.
Activity ID	The characters that constitute an identifier (e.g., abc123) that can be used to link multiple Critical Tracking Events to fully track and trace a product. For transformation events, this can be the identifier on a process or Work Order, or some other identifier to relate the inputs to the outputs of a production process. For shipping and receiving, this can be the identifier on a purchase order, a sales order or some other identifier that will relate shipments to receipts.
Activity Type	An indication of the type of identifier that is present in the Activity ID field (e.g., Purchase Order, Work Order).
Agency	A governmental body with the authority to implement and administer particular legislation.
Batch/Lot Number	A batch number is a unique coded identifier that unites products/items that have undergone combination, transformation, or manipulation of one or more products. The lot number is an identifier that corresponds to a specific grouping/composition of the product. "Batch" and "lot" are considered synonyms by some firms.
Bill of Lading (BOL)	A document that establishes the terms of a contract between a shipper and a transportation company. It serves as a document of title, a contract of carriage and a receipt for goods.
Breadth	The amount of information recorded by the product tracing system.
Carrier ID	A number used to identify the company or individual responsible for conveyance of goods from one party to another.
Collaboration Platform	An electronic platform to allow FDA to better coordinate traceback investigations, as well as allow industry to better comply with existing regulations and furnish relevant traceability-related data upon request.
Commingled Products	Any commodity that is combined or mixed after harvesting but before processing. Does not include types of fruits and vegetables that are raw agricultural commodities for which the Secretary has determined that standards promulgated under section 419 of the Federal Food, Drug, and Cosmetic Act would minimize the risk of serious adverse health consequences or death. FDA Food Safety Modernization Act § 204(d)(6)(D)(ii), 21 U.S.C. § 2223(d)(6)(D)(ii) (2012).[13]

[13] This is definition of "commingled raw agricultural commodity" in section 204 of the FDA Food Safety Modernization Act.

Term	Description
Consumption Event	A Critical Tracking Event that involves the transfer of custody of a product to the final point in the supply chain with the expectation that the item will subsequently be consumed. (This could be the sale of an item at retail, the consumption of an item for a finished plate in food service, the movement of samples to the final party, or the donation of goods.)
Convergence	In food traceback (product tracing) investigations, the process of determining the origin of contaminated food by following the food distribution channel back through multiple nodes from the point of service of the food to its point of origin (field, packing house, estuary, farm, manufacturer/processor, distributor). When the pathways for two or more independent traces that began at different points of service cross, a point of convergence has been discovered. The more independent traces "legs" or "branches" that reach that common point of convergence, the stronger the confidence that this was the point where the food became contaminated.
Critical Tracking Event (CTE)	Points in the supply chain where product is moved between premises or is transformed, or is determined to be a point where data capture is necessary to maintain the ability to trace products. This includes any occurrence involving an item within the supply chain at a specific location and time that is associated with collection and storage of data which is useful for associating an item or related items to the specific occurrence at a later time and is determined to be necessary for identifying the actual path of an item through the supply chain.
Depletion Event	A Critical Tracking Event that comprises the final point in the supply chain for any item through a Consumption Event or a Disposal Event.
Depth	How far upstream or downstream in the supply chain the system tracks.
Disposal Event	A Critical Tracking Event to denote the destruction of an item and removal from the supply chain in a manner making it unfit for consumption.
Distributor	A wholesaler, jobber, or other manufacturer or supplier that sells chiefly to retailers and commercial users.
Economic Cost Benchmark	The economic cost per case associated with an illness caused by a particular pathogen (e.g., *Salmonella* and *Listeria*). These selected benchmarks are provided in the regulatory impact analysis contained within previous FDA or USDA regulations. The economic costs include a calculation that factors in the following types of costs: mild illnesses health care costs, severe illnesses health care costs and loss of value of life due to death.
Electronic Reporting	An online (web-based) reporting mechanism that allows industry to provide their CTE/KDE data as needed based on a specific request from regulatory officials.
Electronic Traceback and Traceforward	The ability to electronically trace the movement of a food product forward or backwards through its supply chain.
Event Owner	The firm responsible for reporting Key Data Elements (KDEs) for Critical Tracking Events (CTEs).
External Traceability	The data exchange and business processes that take place between trading partners to accurately identify (track/trace) product.

Term	Description
Facility	Any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Food, Drug, and Cosmetic Act § 415(c)(1), 21 U.S.C. § 350d(c)(1) (2012)[14]
First In First Out (FIFO)	In a FIFO system, the first items that enter a system are the first ones that exit the system. In other words, the items are removed in the same order they are entered.
Firm	The association by which persons are united for business purposes.
Grower/Producer	A person who engages in growing and harvesting or collecting crops (including botanicals), raising poultry or animals used in producing food (including fish, which includes seafood), or both. Prior Notice of Imported Food, 21 C.F.R. § 1.276(b)(7) (2011).
GS1 System	A portfolio of specifications, standards, and guidelines administered by GS1. GS1 is dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility of supply and demand chains globally and across sectors.
High-risk	A food exhibiting the characteristics identified in section 204 of the FDA Food Safety Modernization Act and designated as high-risk by the Secretary of Health and Human Services. FDA Food Safety Modernization Act § 204(d)(2), 21 U.S.C. § 2223(d)(2) (2012).
IFT Template	A form provided to pilot participants as a multi-tab spreadsheet requesting contact information for the party providing the information, the immediate previous supplier(s) or subsequent recipient(s) as appropriate, and the data for shipping, receiving, and transformations. Two versions of the template were produced: one specific to tracebacks and one for traceforwards.
Implicated Product	A product identified during an investigation as being the source of contamination.
Internal Traceability	The ability to follow the path of a specified unit of a product and/or batch upon receipt, through internal processes, and until shipment from within one company or company unit.
Key Data Elements (KDEs)	The essential data values captured for a Critical Tracking Event to identify and maintain a chain of custody for an item as it is transformed through the supply chain.
Leg	The documented path of a product starting at the point of exposure where consumers purchased or ate the product suspected of causing illness. The objective of tracing a particular "leg" is to follow the product through that distribution chain to determine if it connects with other "legs" at a common convergence point in the supply chain.
Location	A place where a traceable item was, is, or could now be located [ISO/CD 22519]. A place of production, handling, storage and/or sale. (See also Premises)

[14] The term "facility" is not specifically defined in section 204 of the FDA Food Safety Modernization Act. FDA in 21 C.F.R. § 1227 defines the term "facility" more generally and then provides exclusions to bring the regulation in line with the statutory requirement for registering. Also FDA in 21 C.F.R. §1.328 uses the term facility more generically. This is the regulatory implementation of 21 U.S.C. § 350c(b), which is relevant as the statutory basis for one-up/one-down recordkeeping.

Term	Description
Logistic Unit	An item of any composition established for transport and/or storage that needs to be managed through the supply chain.
Lot/Batch Relevant Date	A date that is associated with a specific group of products/items that have undergone the same transformation processes. This date may be used in managing the product and could include production dates, "use by" dates or "best by" dates. For example, If there is a different lot/batch designation on a consumer-level product, such as a "best by" date, it must link to the manufacturer-assigned lot number
Node	An exit or entry point for food items in the distribution system.
Outbreak	The occurrence of two or more cases of a similar illness resulting from the ingestion of a certain food. FDA Food Safety Modernization Act § 205(a), 21 U.S.C. § 2224(a) (2012)
Party	A business entity or specific shipping/receiving location at the discretion of the reporting business entity.
Point of Convergence	The common node or point within the supply chain identified after tracing food from two or more independent points downstream, for the purpose of identifying the causative food vehicle (a common source of contaminated food).
Point of Origin	The node where food enters the food distribution system.
Precision	The degree of assurance with which the system can pinpoint a particular product's movement or characteristics.
Processor	Any person engaged in commercial, custom, or institutional processing of [a food product], either in the United States or in a foreign country. Hazard Analysis and Critical Control Point (HACCP) Systems, 21 C.F.R. §§ 120.3(k) (2011).[15]
Product ID	A reference value, typically numeric, to a static set of product formulation and packaging characteristics assigned to a product by the product supplier. Examples include a Stock Keeping Unit (SKU) and a Global Trade Item Number (GTIN).
Product Tracing	The ability to follow the movement of a food product and its constituents through the stages of production, processing, and distribution, both backward and forward
Production Unit	A set of product continuously produced over a defined period of time under similar circumstances and labeled to retain its identity by the product supplier. Examples of a production unit identifier include a batch/lot number, a serial case number, a production date, or a "sell-by" date.
Purchase Order Number	A reference number issued by a buyer to reference a transaction to purchase goods from a supplier.
Quantity	A precise number of articles, pieces or units. Used in conjunction with Unit of Measure.
Recall	A firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery. Enforcement Policy, 21 C.F.R. § 7.3(g) (2011).

[15] The FDA Food Safety Modernization Act defines "processing" for purposes of the provision on tracing "commingled raw agricultural commodities" as meaning "operations that alter the general state of the commodity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization. 21 U.S.C. § 2223(d)(6)(D)(ii)(III).

Term	Description
Receipt Date	Date/time upon which the goods were received by a given party.
Receiving	The act of accepting a shipment of a trading good from another trading partner.
Retailer	A person who makes direct sales to consumers. Food Labeling, 21 C.F.R. § 101.9(j)(1)(i) (2011); cf. Registration of Food Facilities, 21 C.F.R. § 1.227(b)(11) (2011) (Retail food establishment means an establishment that sells food products directly to consumers as its primary function.)
SSCC (Serial Shipping Container Code)	The 18-digit number comprised of an extension digit, GS1 company prefix, serial reference, and check digit.
Ship Date	The date on which goods were shipped or dispatched by a supplier.
Ship from Location	Identification of the site from which goods will be or have been shipped.
Ship to Location	Identification of the site to which goods will be or have been shipped.
Shipment	An item or group of items delivered to one party's location at one moment in time that have undergone the same dispatch and receipt processes.
Shipping	The act of releasing a shipment from one trade partner to another.
Small Business	A business entity as defined by the Secretary of Health and Human Services under section 103 of the FDA Food Safety Modernization Act. FDA Food Safety Modernization Act § 204(i), 21 U.S.C. § 2223(i) (2012)[16] For the purpose of the cost analysis, SBA guidelines were used
Supplier	A person engaged, directly or indirectly, in the business of making a product available to consumers.
Supply Chain	The system of organizations, people, activities, information and resources involved in producing and/or moving a food product to the consumer.
Technology Solution Provider	One who can develop or apply existing solutions to solve challenges. In the context of this report, it primarily refers to a software vendor that has developed a commercial third party system for product tracing (including systems used as collaboration platforms).
Traceability	Multiple definitions and uses; sometimes used synonymously with product tracing; sometimes refers to tracing within a single firm; internationally may mean the ability to genetically distinguish products
Traceback Investigation	Begins at the end of the supply chain nearer to consumers or the point-of-purchase and traces the distribution of the product in the direction of the source/farm.
Traceforward Investigation	Begins at the end of the supply chain nearer to the source/farm or manufacturer/distributor and traces forward toward the consumer.
Trading Partner	Any supply chain partner that has a direct impact on the flow of goods through the supply chain. Examples include third party logistics providers, manufacturers, processors, retailers, wholesalers, distributors, operators, and growers.
Trailer Number	A number associated with a specific trailer used to transport goods from one trading partner to another.

[16] FDA has typically defined small business as a business with fewer than 500 employees. See, 21 C.F.R. § 120.3(b)(1). For analysis purposes, small business is defined according to the guidelines outlined by the US Small Business Administration (SBA) in the "Table of Small Business Standards Matched to North American Industry Classification System Codes".

Term	Description
Transfer Number	A number that can be used to fully identify a shipment to both partners. For instance, for a shipment by a carrier, a Bill of Lading number may be used.
Transfer Type	A code to specify the type of Transfer Number included with the Critical Tracking Event such as Bill-of-Lading or Overnight Tracking Number.
Transformation	The act or result of changing the item such as combining ingredients to make a finished product or repackaging a product such as producing a tray-packed product for consumer sale from cased ingredients. Transformation can be production, aggregation, grouping, splitting, mixing, packing and re-packing traceable items.
Transporter	The party that handles, conveys and/or temporarily stores the traceable item, solely for the sake of transportation from one point to another without transforming the item. The Transporter may only have “possession, custody, control” of a traceable item, as distinct from ownership.

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