Frequently Asked Questions about the Product Tracing Pilots

General FAQs

In September 2011, the U.S. Food and Drug Administration (FDA) tasked the Institute of Food Technologists (IFT) with leading two pilot programs designed to test and study various product tracing systems. The purpose of these pilots was 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.

What is food product tracing?

In general, food 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 or foodservice outlet. Product tracing encompasses traceback and traceforward. In the United States, people often use the terms product tracing and traceability interchangeably, although the terms may have different meanings in other parts of the world and in other contexts.

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 previous product tracing tasks can be found at www.ift.org/traceability. The most recent task required IFT to execute the product tracing pilots that FDA is required to perform as part of the Food Safety Modernization Act.

How did this all come together?

Three staff food scientists (one Ph.D., and 2 MS), along with support staff, worked with a group of 7 “oversight panelists.” Although the pilot tests were the main component of the task, IFT also conducted additional related work to inform the final report to FDA. Oversight panelists included the following individuals:

- Douglas Bailey from the USDA Agricultural Marketing Service
- Benjamin Miller from the Minnesota 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
- Caroline Smith DeWaal from the Center for Science in the Public Interest
In addition, IFT enlisted a number of participants, including state, local and federal traceback investigators, food industry members, and others, for actual pilot tests. Both the produce and processed food / ingredients pilots consisted of multiple tests. Finally, IFT was charged with evaluating the costs and benefits associated with the pilots and other tracing technologies. IFT worked with Deloitte Consulting and Auburn University to facilitate the cost-benefit research efforts on this task. Three stakeholder input sessions, described below, also took place.

**Did IFT accept additional sources of funding to complete the work?**

No. Although IFT previously launched a Traceability Improvement Initiative which is privately funded, that Initiative is not providing funding support to the pilots (the Initiative is augmenting an award from the National Center for Food Protection and Defense to study interoperability of traceability technology providers). IFT did not accept additional funds to support the pilots. However, the work benefitted from the voluntary participation of technology providers, food industry members and others. The budget did not allow IFT to reimburse all participants for all time expended on this task, and IFT is appreciative of the tremendous effort that was volunteered by all stakeholders. A team from Deloitte Consulting and Auburn University led the cost-benefit evaluation pro bono.

**How were the pilots conducted?**

First, gaining stakeholder input was critical and helped shape details around how the pilots were 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 worked with a group of state, local and federal traceback investigators to evaluate some historical data to determine a “baseline” for the time and effort involved in various investigations (including produce and processed foods / ingredients), as well as the factors that seem to influence the ability to trace products.

The pilot tests involving the food industry did not use any specific technology solutions. Rather, IFT evaluated industry practices and tested how these processes, practices, and systems can be modified to improve the speed and accuracy of a traceback investigation.

Once the data requirements and food industry practices were evaluated, IFT explored how collaboration platforms (third party technology solutions) could be used to further enhance traceback capabilities. Further detail on technology providers can be found below. Overall, IFT sought to determine what features would be useful for regulatory agencies to use to aggregate and analyze traceback data.

**Did IFT create a new traceability technology 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. Rather, existing commercially available products were used as described below, although this represented only a portion of the total pilot work. Identifying opportunities for the food industry to
improve recordkeeping processes and practices, independent of technology solutions, was also a main component of the task.

What foods were a part of the pilots?
With input from a variety of stakeholders, the following types of foods were selected for the pilot projects:

- Tomatoes, grown in fields and greenhouses; whole and sliced; and distributed to restaurants and other institutions like hospitals, schools and nursing homes, and through grocery stores. We looked at tomatoes because they have been involved in a number of significant and repeat outbreaks. Tomatoes represent a complex food supply chain and were identified by most industry associations as a top candidate for the produce-related pilot;
- Frozen Kung Pao-style dishes that contain peanut products, red pepper spice, and chicken were chosen because they contain multiple ingredients involved in significant outbreaks. They also offer a variety of supply chain distribution channels, and, like tomatoes, can involve both domestic and imported products.
- Jarred peanut butter and dry, packaged peanut/spice were added to the pilot projects to enhance the complexity of the pilots.

How were food industry participants selected?
IFT gathered stakeholder input surrounding which foods should be evaluated in the pilots. After reporting this information, FDA decided on the two foods (although the processed food/ingredient pilot consisted of several foods and ingredients). Once selected, IFT sought volunteer participants in those supply chains. Volunteers were encouraged to ask their suppliers and customers to participate as well to increase the probability of evaluating entire supply chains through these pilots. IFT posted notices regarding the opportunities and worked extensively through trade associations to identify volunteers.

How were the technology providers selected for the pilots?
Many technology providers contacted IFT requesting to be involved. IFT sought considerable input regarding the characteristics of the platform(s) that should be involved, and how to fairly select participants. IFT then posted a public request for information (RFI) open to all prospective technology providers; information received through this RFI was then peer-reviewed by an expert panel. Ten providers were chosen; five for each pilot. Nine technology providers eventually worked with blinded pilot data to showcase their capabilities.

Why didn’t you test technologies that could really improve traceability, like RFID?
There are several reasons why the pilots were conducted using the process described in the report. The greatest limitation in conducting the studies was time. IFT essentially had 5 months to identify and secure participants, conduct the tests, and analyze the results. IFT is aware that several in the private sector and academic community are exploring RFID, and felt that tests of this nature were better conducted by those operating with more generous timeframes. Additionally, FDA is restricted by FSMA from prescribing specific technologies and is charged with limiting the extent to which changes to recordkeeping cause a change in business practices. The implementation of RFID systems falls outside the scope based on the statement of work provided to IFT by FDA (and the limitations put in place by
Finally, IFT firmly believes that the first step in improving product tracing involves the collection of the correct information, in a form that is understandable throughout the supply chain. RFID is a data carrier but does not resolve the fundamental issue of determining the appropriate data that need to be captured, stored and shared.

**If only a few technology providers were involved in the pilots, how did other providers let FDA know of their capabilities?**

FDA must hold 3 public meetings as they proceed in rule making related to product tracing where all stakeholders will have an opportunity to share information with FDA. In addition to providing input directly to FDA, individuals and companies provided input directly to IFT for consideration by the oversight panel. This information was evaluated and compiled for inclusion in IFT’s report to FDA. Some technologies were not a good fit for the pilot studies, but the report details other technologies that currently exist in the realm of product tracing.

**If participation in the pilots was opt-in, then how relevant are the findings to the rest of the industry?**

This is an inherent limitation in the pilot. Neither IFT nor FDA could force any company to participate. It can be expected that firms who felt their practices were deficient would probably not choose to participate. This is part of the reason IFT conducted the baseline study, through which IFT gained insight into how the traceback of a “real life” outbreak unfolds. Many of the elements of the baseline study were reinforced through the pilots, even though the self-selection of participants (as well as their self-reported tracing abilities) would suggest that they may represent firms who perform better than average. A pilot study cannot be expected to include every exception, and IFT encourages firms to test their product tracing abilities and provide additional insight to FDA during the public comment period.

**You acknowledge that small businesses were under-represented. Why weren’t more involved?**

IFT made substantial efforts to engage small businesses. Ultimately, of the 45 participants, fourteen are defined as small businesses by the SBA guidelines. IFT reached out to the Delaware Growers Association, NAPAR, NWFPA and others to encourage the participation of a diversity of firms. IFT also contacted 25 small growers and receivers to further understand their current tracing practices, capabilities, and hurdles with respect to implementation of the recommendations.

**Why was this a boardroom-based exercise? Why weren’t firms asked to provide data in real time?**

- In the case of the processed food/ingredient pilot, the shelf life and distribution/sale pattern of the finished product and limited time of production resulted in IFT using historical data spanning a period of one year. The spices and peanuts that were ingredients in the product also have long shelf lives, and records needed to be obtained going back to 2010.
- The objective of traceback is to find convergence (the point where different paths cross). In the case of the pilot, it was important to know in advance how the product flowed through the supply chain and where possible points of convergence might exist. The boardroom based exercise enabled this exploration where the assembly of data in real time might not.
- Finally, because of the passage of time before an outbreak is recognized, FDA and state/local investigators are relying on historical data. They are not capturing data in real time.
There are several firms that offer to house and manage industry tracing data. Why weren’t firms asked to use these in the pilots?

IFT worked within the specifications of FSMA and knew that FDA could not require adoption of a particular service. Again, IFT feels that the first step to improve product tracing is providing the food industry with a clear requirement on data that enable supply chain links to be established and easily followed. IFT would encourage food companies to explore whether the tracing technology solution providers assist the industry in determining “how”. IFT focused on “what” in this task.

**Recommendations FAQs**

The pilots demonstrated areas in which improvements can be implemented to reduce traceback time and ensure the accuracy of information. 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. Below are the numbered recommendations, with some additional FAQs:

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.**

   *Doesn’t FSMA impose limitations on recordkeeping requirements? What about small businesses?*

   FSMA does impose limitations on recordkeeping requirements, but 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, “high-risk” foods can be ingredients of “low-risk” foods, and the definition of “high-risk” may change. Many stakeholders believed that the FDA should establish a single set of recordkeeping requirements. The number of basic requirements is likely low, and all businesses should be able to comply. IFT also recommended that FDA create guidance or educational programs specifically for small businesses. More information on product tracing within FSMA can be found at [http://www.fda.gov/Food/FoodSafety/FSMA/ucm247548.htm#SEC204](http://www.fda.gov/Food/FoodSafety/FSMA/ucm247548.htm#SEC204)

   *Was this recommendation highly debated by the pilot panels?*

   After some discussion about this recommendation, the group as a whole agreed that this should be a recommendation to FDA. A variety of industry participants in the pilot groups believed that all firms should have the same recordkeeping requirements, and that the product tracing within an entire supply chain is only as good as its “weakest link.” Consumer group participants thought this recommendation would best protect public health, and traceback investigators thought it may minimize confusion in working with industry.

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.**

   *What are CTEs and KDEs? Where can I find them?*

   There are various points in a supply chain, termed Critical Tracking Events (CTEs), where data capture is necessary to follow product movement. These include transportation, transformation and depletion
events. Key Data Elements (KDEs) are the data elements that should be captured at each CTE for product tracing. Please refer to the table found in the final report for specific CTEs and KDEs.

How were CTEs and KDEs developed?

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. IFT held a Traceability Improvement Initiative which presented the refined CTE and KDE tracking template with a large group of attendees and sought feedback on further improvements. Participants in the pilots had the opportunity to further refine the CTEs and KDEs before they were agreed upon and published in the report.

You recommend that lot number should be a Key Data Element. Doesn’t FSMA prevent FDA from requiring firms to track at the case level?

IFT believes that these are two separate issues. Tracking at the case level would require serialization of cases (i.e. identifying what went into case 1 versus case 2). This is different from tracking at the lot/batch level where the primary granularity of interest is the lot. This lot identifier can then be used to label pallets, cases or individual products, as needed (i.e. lot A went into 100 cases or 2 pallets).

<table>
<thead>
<tr>
<th>Critical Tracking Events</th>
<th>Transportation (exchange of goods)</th>
<th>Transformation (creation/manipulation of products)</th>
<th>Depletion (exit from system)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Shipping</td>
<td>Input</td>
<td>Output</td>
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<tr>
<td>Currently Required KDEs</td>
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<td>Date/ Time</td>
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<td>Event Location</td>
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<td>Trading Partner ¹</td>
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<td>Item (the good)</td>
<td>R</td>
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<td>Lot/Batch/Serial#</td>
<td>BP*</td>
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| Linking KDEs             | C*                                 | C*                                                | R                           |
| 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                           | BP | BP |
What is an activity type?
A descriptive label for the type of identifier that is present in the Activity ID field (e.g., Purchase Order, Work Order).

What is an 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 IDs were recommended as required for capture in the absence of batch/lot information. Batch/lot information, however, is preferable.

What is a transfer type?
A descriptive label for the type of identifier that is present in the Transfer Number field (e.g., for a shipment by a carrier, a Bill of Lading transfer type may be used).

What is a 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.

What is a 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.

What is a 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. This could include non-monetary transactions like donations or samples.

Where can I find more information on this table?
Additional glossary terms can be found in the Glossary section of the final report, and more explanation on the table can be found in the Recommendations section of the report.
3. 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.

Is there a difference between a recall plan and a product tracing plan?

Yes. Companies commonly have recall plans and conduct mock recalls, in which they have specific information on the products of interest. Tracebacks are distinct from recalls in that the details of the product of interest are not known. Product tracing encompasses both recalls and tracebacks. Although many of the records to conduct them are similar, the questions and approaches are different enough that IFT felt that firms should plan for both. 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.

Are product tracing plans required today?

Product tracing plans are not required by federal agencies today. Some companies may have these as a best practice, or customers may require them of their suppliers. Companies involved in the pilots commonly did not have official tracing plans in place.

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.

Is IFT saying that FDA will require industry to follow existing industry initiatives?

Not necessarily. IFT believes that FDA should not prescribe the specific means that industry uses to meet the FDA objectives (and/or those recommended by IFT). However, several industry groups have begun identifying ways in which the industry can improve product tracing capabilities, and FDA should support these efforts where they are aligned with FDA’s thinking. IFT acknowledges that FDA’s recommendations may be different from those listed in the report by IFT. Many current domestic and international industry-led initiatives are profiled in Chapter 9 of the IFT report to FDA.

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

How does this differ from a recall? What information does IFT think is important?

In a recall, regulatory agencies offer specific information on the products that need to be recalled or disposed of as reported to them by the food industry. In a product tracing investigation, FDA may be trying to determine the product of interest, and may give industry a more general request. IFT recommends that FDA 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).

Did pilot participants give suggestions for how FDA could achieve this?

Some industry participants indicated that they had been asked for specific types of paperwork by regulatory agencies during an outbreak investigation but could have provided additional information if they had a better understanding of the issue that was being investigated. IFT believes that FDA should focus on the data that they would like to obtain as opposed to the types of documents that may or may
not house these data. Participants also found that traceback investigations worked best when they understood the nature of the issue and were treated as partners in finding a resolution.

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.**

*Does this mean that industry will have to collect information in electronic format?*

No. Although IFT believes that collecting and sharing data in electronic format is ideal, industry would not have to collect their data in electronic format to satisfy this recommendation. However, industry might have to provide data in a standardized and structured way to the regulatory agencies during an investigation. The pilot results confirm that standardized, structured, and electronic reporting of CTEs and KDEs increases the speed by which product tracing data can be collected, compiled and analyzed. IFT also recommended that FDA take other steps to accommodate the varied needs and capabilities of large and small firms alike.

*What is currently required by the FDA during an investigation?*

Current recordkeeping requirements do not specify the format of records. Through the baseline study, IFT found that most traceback information sent to regulatory agencies is not in electronic form, and is commonly faxed documents that can have both printed and handwritten information on them. During the IFT pilots, most information was sent in Adobe Acrobat PDF format. Records submitted in electronic formats that cannot be analyzed in a structured and standardized way do not satisfy this recommendation (for example, a PDF of a scanned handwritten note does not satisfy this recommendation).

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.**

*What does a summary look like?*

Different companies sent different types of summary documents which varied based on the types of processes they employed. Some companies within the pilots sent IFT summary documents (e.g. Excel spreadsheets) along with “hard copy” supporting information (e.g., Invoice, Purchase Order, Bills of Lading). These summary documents included explanation of the movement of their products. IFT found it extremely helpful to have summary tables with tracing information, or to have descriptions of the codes and numbers used within the “hard copy” documents. Although it may be difficult to develop a universal summary document, IFT feels that providing templates and examples will provide the food industry with the useful components of summary documents.

*Does this mean that industry will only have to provide a summary document?*

No. Regulatory agencies will likely ask for “hard copy” supporting information in addition to a summary document for validation purposes. In the pilots, summary documents were shown to be very useful for quickly analyzing the “hard copy” information, and with these documents, regulatory agencies would be able to go forward with their traceback investigation at a faster rate.

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

*Doesn’t FSMA dictate that FDA cannot ask for more than one up- one back?*
Regulations stemming from the Bio Terrorism Act of 2002 state that a company must have information for the products coming in from their suppliers, as well as the product being sent to their customers. FSMA states that FDA cannot require firms to know more than their immediate subsequent recipient. IFT recommends that FDA could ask for records for more than one back, in hopes that the firm might have them. In the pilots, some firms had great visibility up their supply chain, and were able to quickly access information for their suppliers. Although IFT then verified information at each suppliers’ firm, a more holistic picture was visible quickly with this additional information. The IFT 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.

Why is this platform needed?

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.

Does this mean that industry will have to continuously upload their data to FDA?

IFT does not advocate the establishment of a repository that is continuously collecting all CTE and KDE data captured across the entire food industry. 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.

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.

What would the SMEs do?

IFT 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 it relates to seasonality and geographic distribution), terminology, etc. in a given industry segment. These SMEs could be useful in quickly guiding the FDA in the beginning of their traceback investigations.

Other FAQs

Aren’t the recommendations biased because industry had a hand in writing them?

FDA continually stressed the importance of stakeholder input during this task, and IFT was inclusive of the variety of stakeholders, including food industry members, but also including not-for-profits, small businesses, consumer groups, members of the technology community, academics, and state and Federal
regulators. Each of these stakeholders was represented in the groups that deliberated the recommendations, and IFT relied on a 7-member oversight panel (of which one member was from the foodservice industry) to advise on the final recommendations, which IFT made final decisions on.

*Will implementing the recommendations increase the cost of food?*

IFT recognizes that any change has an associated cost, and that given the slim profit margins in the food industry, it is likely that some or all of these costs may be passed on to consumers. That said, some pilot participants who recently changed their systems to improve product tracing found benefits that offset these costs. The cost to benefit ratio will be dependent on the segment of the supply chain and specific to the firm. There is also an undeniable public health benefit, and the potential to shift the epidemiological curves to prevent illness and death through more rapid product tracing should be recognized by consumers and policy makers.

*After reading the ~50pp on costs and benefits, it’s not clear to me, as an industry member, how much these recommendations would cost me.*

Unfortunately, the answer is: it depends. Although the pilots collected data for a limited number of firms, it was clear from these conversations and from the pilot results that different segments of the food industry have different capabilities. As a generalization, we would suggest that the closer (in the supply chain) firms are to providing food to consumers, the more resources will be needed to improve their current capabilities. Of course, within any segment of the industry, there are a diversity of practices and systems, as documented in this study. Early adopters may not incur additional cost, having already made improvements to their systems. Adoption of new practices and technologies by “the masses” are traditionally associated with decreasing technology costs.

IFT also sought to provide industry clear direction of the “what” rather than the “how”. The flexibility afforded in how firms choose to meet the recordkeeping requirements recommended by IFT should foster the development of creative solutions and encourage competition to develop cost effective methods to meet the objectives.

*Why aren’t there any recommendations about the epidemiological investigations?*

In the statement of work on the pilot projects, IFT was tasked with a focus on the traceback investigation, after a food may be considered “suspect.” Although some information was given to IFT about epidemiological investigations in the baseline study, the pilots concentrated on the traceback investigations themselves.