CHAPTER 10
TRACEBACKS

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1.0. PURPOSE

This chapter describes Rapid Response Team (RRT) best practices for traceback investigations, in alignment with existing traceback materials identified in the RRT Manual's References section. These best practices can help agencies achieve more consistent gathering and communication of core traceback information and improve overall traceback capabilities.

2.0. SCOPE

This chapter identifies basic components of multi-agency traceback investigations as they involve local, state, and federal agencies. This blends lessons learned from RRTs with existing traceback materials and job aids to describe common elements and unique considerations when conducting traceback investigations.

This chapter does not include details on other related human or animal food investigations, such as traceforward investigations and environmental assessments and investigations. This chapter also does not specifically address the important roles played by all environmental health and food regulatory agencies.

The best practices described in this chapter identify key areas and elements for traceback; but are neither comprehensive nor specific to unique situations. State, local, and federal agencies seeking to improve multi-agency food emergency responses (e.g., States, FDA inspectorate divisions, USDA Food Safety and Inspection Service (FSIS)) may utilize this chapter to assess and improve their response capabilities. Agencies with varying responsibilities (e.g., regulatory, public health, feed/animal health, law enforcement, and/or laboratory) and target response capability levels may differ in how they customize and apply these best practices.

3.0. RESPONSIBILITY

3.1. RRT (or investigatory team, in states without an RRT) Leadership

RRT leadership is responsible for ensuring that personnel assigned to conduct human or animal food traceback investigations have been provided with appropriate training. Examples of important training topics can be found in Chapter 8: Rapid Response Team Training.

3.2. RRT Members (State Partners, FDA inspectorate divisions, etc.)

RRT members are each responsible for playing an active role in maintaining both their subject matter expertise and ability to work effectively in multidisciplinary and multi-agency response teams. For traceback investigations that are part of a multi-state outbreak involving FDA regulated product(s) (i.e., when FDA Office of Coordinated Outbreak Response, Evaluation and Emergency Preparedness [OCORE+EP] is involved), FDA inspectorate divisions are responsible for serving as the point of contact for the RRTs. In these cases, FDA inspectorate divisions receive and distribute information, including records collected, meeting invites, and other documents, from OCORE+EP to RRT members, in accordance with applicable confidentiality agreements. FDA inspectorate divisions are also responsible for submitting traceback investigation findings from the RRT to OCORE+EP. FSIS RRT members are subject matter experts in traceback investigations involving meat, poultry, and processed egg products and serve as a point of contact for RRTs during traceback investigations involving FSIS regulated products.

3.3. FDA (Office of Coordinated Outbreak Response, Evaluation and Emergency Preparedness)

OCORE+EP serves as the traceback experts for investigations requiring FDA involvement and coordinates with state and local public health agencies as well as other federal agencies such as CDC and USDA. OCORE+EP reviews traceback information collected by the RRTs, issues assignments to the FDA inspectorate divisions for information collection, drafts traceback diagrams and timelines, and presents traceback findings to FDA headquarters staff and across agencies.

3.4. FDA (Office of Inspections and Investigations)

The Office of Inspections and Investigations (OII) comprises both headquarters and field staff nationwide. The field will gather information during traceback investigations and will work with their RRTs as appropriate. If the field has any issues on resources or logistical issues, they will work through their management who will work with headquarters to help resolve these issues. OII will work with OCORE+EP, FDA headquarters staff, and others as appropriate during tracebacks.

4.0. DEFINITIONS

The following terms are used frequently in this chapter: traceback. See "Glossary of Key Terms" for definitions.

- **Cluster –** Part of ongoing public health surveillance activities; used to describe a larger number of people than expected with the same illness in a given time and space. "Clusters" of illness occur frequently and may not necessarily be related to a common food source.
- **Consumer Purchase Data –** Records documenting the distribution of products of interest after they leave the facility. Information about the Point of Sale/Service (POS) where food was purchased or served also assists in identification of illness subclusters. Local and state health officials work to obtain specific information about when and where ill people purchased or ate the food item of interest and determine whether documentation of the exposure is available or there is potential cross-contamination at the POS. Examples include shopper cards, loyalty cards, and receipts for products purchased at retail level, and distribution records for processors and distributors. These documents may exist in paper or electronic format.
- **Foodborne illness outbreak** – an incident in which two or more persons experience a similar illness caused by the same pathogen resulting from the ingestion of a common food.
- **Illness Subcluster –** A group of unrelated ill people reported eating or purchasing food from a single establishment (e.g., restaurant, institution, or event) within a larger, more widely-dispersed cluster of illnesses due to the same pathogen.
- **Inventory Control Records –** Records used by investigators to document and assess the degree to which an establishment can link incoming deliveries with outgoing shipments/sales. Examples include Facility standard operating procedures (stock rotation, facility use of commercial codes such as Universal Product Codes (UPC), Stock Keeping Unit (SKU), Price Look Up (PLU) numbers, Global Trade Item Numbers (GTIN) and daily inventory records. These documents may exist in paper or electronic format.
- **Outbreak –** Part of ongoing public health surveillance activities; when an investigation shows that ill persons in a cluster have something in common to explain why they all got the same illness, the group of illnesses is called an outbreak. This could be attributed to food, environmental exposure, animal contact, community events, or person-to-person contact starting from one ill person.
- **Point of Sale/Service (POS)** – The location where an illness subcluster or single ill person reported purchasing or consuming the food being traced (e.g., restaurants, grocery stores).

- **Reference Documents –** Documents that confirm the movement of food from one place to another along the supply chain or can link incoming deliveries with outgoing shipments/sales. Records consist of a wide variety of types, including invoices, purchase orders, bills of lading, production logs, and import documents, if applicable, as well as inventory control records. These documents may exist in paper or electronic format such as spreadsheets.
- **Traceback –** Food product investigations used to determine and document the complete distribution pathway of a contaminated food product, tracking it back to its origin or source. Similarly, as defined by Irvin et. al. (2021) in the Journal of Food Protection, it is also a process of reviewing product supply chain records to identify the origin of food served or sold at a specific Point of Service. In the traceback process, sufficient shipping and receiving documentation are gathered to support regulatory actions, if needed, to ensure adulterated human or animal food is removed from commerce.
- **Traceback Flow Diagram –** A visual reference illustrating each level of the investigation as it branches from the POS to its original source(s).
- **Traceback Timeframe of interest –** The time when contaminated product could have moved through the supply chain. This is often calculated by considering both the shelf-life of the product and the product turnover rate at various points along the supply chain. The following can assist with determining this timeframe: the type of product, product shelf life, onset and length of any associated illness, product rotation practices, among other factors. If it is an FDA traceback, FDA OCORE+EP will determine the timeframe of interest with feedback from subject matter experts. OCORE+EP will include the timeframe of interest in any OCORE+EP issued assignments and all documentation collected by the food safety inspectors for the investigation must include anything produced within the timeframe identified. The timeframe of interest identified can vary across locations. While fewer records may be needed at the point of service (versus further upstream in the supply chain), it is important to collect all information to identify patterns. It is crucial for investigators to find out if there is a "key" that may be needed to decode records.
- **Traceback Timeline –** A visual reference that provides information on the volume and movement of product(s) of interest at various facilities over time. A timeline is a tool used to narrow down the most likely shipments of interest relative to time and exposure/purchase information. Specifically, for each facility and level of distribution of the product of interest, the timeline identifies information such as volume and lots of products in inventory and delivery receipt dates. Attachment A is a traceback example from an existing FDA document.
- **Traceforward –** The determination of where an implicated food product was shipped, sold, or distributed from the location under investigation, starting

with the source and tracing the product forward to the consumer through each point of service. This process is often used during product recall and can be useful in outbreak investigations.

5.0. BACKGROUND

This RRT Manual chapter was developed by a work group of representatives from RRT state public health and agricultural agencies and FDA staff to describe best practices for conducting traceback investigations.

Traceback investigations are conducted to determine the source of contaminated human or animal food that has been implicated by a foodborne illness investigation, laboratory analysis, or routine inspection.

Epidemiological and traceback investigations have historically been viewed as sequential activities, with traceback initiating once an FDA regulated food product is identified. These traceback investigations routinely involve on-site visits, interviews, and collection of records to verify the traceback information.

To reduce the time between outbreak detection and implementation of effective control measures, epidemiologists request assistance from food regulatory partners during epidemiological investigations. Epidemiologists ask regulatory officials to determine whether a food item consumed by multiple case-patients in an illness subcluster, or foodborne illness outbreak has convergence – a point in the supply chain where multiple traceback legs share a commonality, which can include shared facilities, land, water sources, and geographic regions.

It is important that each agency in the response team has a clear understanding of its sister agencies' legal authorities and the evidence (epidemiological, laboratory, and regulatory) these sister agencies require to trigger various responses under those authorities. Documentation collected during traceback investigations may be used to support regulatory or enforcement activities by a state authority or federal agency. Regulatory agencies participating in tracebacks should carefully review their legal authorities and agency policies to ensure that appropriate administrative procedures are followed in case enforcement action is needed. The determination of appropriate regulatory response is made on a case-by-case basis and is often based on several factors, including but not limited to certainty of the evidence, severity of the disease, potential for ongoing exposure, and availability of effective control measures that could prevent additional illnesses and/or deaths.

Epidemiologists and food regulatory officials continue to explore methods to gather traceback data in ways that are accurate, timely, and an efficient use of

regulatory resources. This chapter shares some of the best practices that have emerged to date.

The FDA final rule on Requirements for Additional Traceability Records for Certain Foods (Food Traceability Rule), which was updated in February 2023 and which is codified at 21 CFR Part 1, Subpart S, establishes traceability recordkeeping requirements for persons who manufacture, process, pack, or hold foods included on the Food Traceability List (FTL). Covered entities handling FTL foods will be required to maintain records containing Key Data Elements (KDEs) associated with specific Critical Tracking Events (CTEs) once the compliance date of January 20, 2026, arrives. The rule covers domestic, as well as foreign firms producing food for U.S. consumption, including retail food establishments, restaurants, and farms.

It is anticipated that the Food Traceability Rule requirements could narrow the scope of requested information based on Traceability Lot Codes (TLCs) being carried through the supply chain of FTL foods; additionally, Traceability Plan information would provide an explanation of how required information and records are kept, which could reduce the back-and-forth between regulators and supply chain entities. The rule will also require many covered firms to provide an Electronic Sortable Spreadsheet (ESS) including required information in certain situations, such as an outbreak, recall, or other public health threat. Finally, with TLC/TLC Source (i.e., where the TLC was assigned) information available at the POS, records and information may not necessarily need to be requested from all supply chain partners, which would also allow traceback investigations to be more rapid and efficient.

Additional reference material, one-pagers, templates, translations, FAQs and other information that would assist regulators and industry related to the requirements of this rule can be found at the FDA Food Traceability Rule webpage.

6.0. SAFETY

Agencies must ensure that personnel conducting tracebacks have the training necessary to safely complete their tasks. State partners and FDA inspectorate divisions should communicate the development of safety plans, if a firm identified in traceback investigation may present a safety risk to the investigator.

7.0. INVESTIGATION PLAN AND OBJECTIVES

Traceback investigation activities are an unscheduled workload in addition to agency priorities with pre-existing deadlines such as high-risk inspections and investigations. Epidemiologic and food regulatory agencies should consider resource availability and agency operational constraints, without jeopardizing public health, when developing the investigation plan and objectives.

An investigation to reconstruct the distribution pathways of one or two food items from a single point may require a considerable amount of time depending on the types of information available and the time taken to obtain information. If local or state jurisdictions cannot spare the resources to conduct timely data collection for a particular traceback investigation, several alternatives may be available. For example, state agencies (public health or regulatory) may be able to assist local health departments and/or neighboring states. Federal partners may also be consulted to assist in data collection.

8.0. EQUIPMENT/MATERIALS

Key individuals working on traceback investigations will require access to FoodSHIELD to receive updates on the investigation and share relevant information with other regulatory partners. Equipment and materials needed for specific activities (e.g., graphics software to generate flow diagrams and timelines) should be addressed within each agency's policies and procedures. In addition, portable printer/scanners may assist in collection of records.

9.0. PROCESS DESCRIPTION

9.1. Traceback Process Flow

Traceback investigations are generally not needed when the origin of implicated or suspect foods is known (e.g., clearly labeled processed food with production lot and manufacturer information identified). Specific procedures for conducting traceback investigations are identified in the References and Other Resources section of this chapter. Attachment C is a flow diagram depicting the steps of a traceback process.

9.2. Traceback Investigation

This section provides an overview of tracebacks including triggers, sharing of epidemiologic summaries, coordination, and documentation.

Overview of Traceback Investigation[1]

Tracebacks are an important component of an investigation. The purpose of a traceback is to determine and document the complete distribution and production chain for a product that has been implicated by any of the events listed in the table below. Each point along the farm-to-table continuum must then be examined for opportunities for introduction, survival, or growth of the identified agent. Tracing the source of food items or ingredients through distribution to source of production can be critical to confirming epidemiologic links among cases or ruling them out. For non-branded commodities, such as produce items, the convergence of multiple cases along a distribution pathway may identify the source of contamination. Conversely, failure to identify common suppliers may indicate that the food item in question is not the likely vehicle.

Traceback Triggers

There are various factors that may trigger traceback and related regulatory agency actions. Whenever possible, tracebacks should be closely coordinated with partner agencies. Table 1 (below) outlines situations favoring the initiation of a traceback. In addition to the factors identified in Table 1, there are several conditions that, when some or all occur, indicate that a traceback may be performed:

- Epidemiological subject matter experts designate a suspect food vehicle.
- Cases that can provide a purchase receipt, shopper card information, or at least a definitive date of purchase and purchase location.
- Shipping/receiving documentation must be available from the POS.
- Linked cases occur in multiple locations or jurisdictions (particularly if they occur in multiple states);
- A vehicle cannot be clearly implicated with traditional epidemiologic, laboratory, and environmental investigation methods alone; and
- More information is needed to determine if similar food items from different establishments/stores/firms can be linked to a distributor or processor.

The decision to conduct a traceback investigation should be based on input from both the public health and regulatory agencies.

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[1] Acknowledgement: The information in this section was sourced from the California Department of Public Health/CalFERT Traceback Procedures (with some editing).

Outbreak Epidemiology Summaries for Tracebacks

Before initiating a traceback investigation, RRTs regulatory agencies should review epidemiologic information to determine if a traceback investigation is appropriate, after obtaining a complete understanding of the product and timeframe of interest for the outbreak. Below are examples of items to be shared with regulatory agencies. Communication with the RRT's epidemiological agency or other lead epidemiological agency (e.g., CDC) should be maintained throughout the traceback investigation, in case there is new information or any changes to older information. These changes could affect the relevancy or outcome of the traceback.

- A brief written summary describing the outbreak and cases, including the earliest and latest onsets and points of exposure, symptoms, geographic distribution of cases, etc.
- De-identified case interview forms.
- Results of a preliminary case-control study (if conducted).
- Epidemiologic curve for state cases and multi-state cases (if applicable).
- Information on any cases with product available for testing (with permission from a regulatory agency to contact the individual and obtain samples).
- Product description: Type of food (as specific as possible), brand name, labeling, lot codes, and any other unique identifiers that might be available (UPC, PLU, etc.).
- Purchase date(s) linked to specific retail food locations (try to verify with actual consumer purchase data, if available).
- Identification of all known menu item(s) that included the suspect food item (if purchased from a food service establishment/restaurant).
- Consumption date and menu for the week before illness if the food was eaten at an institution (e.g., long-term care facility, college cafeteria, prison) – to help identify food items/ingredients that may have been served on multiple days.
    - If necessary, a permission form signed by the consumer, allowing their consumer purchase data to be released by the store or chain to investigators – determine if the store or chain has its own form or will accept a generic form.

The following table (Table 1) summarizes the kind of information that the regulatory agencies should consider before initiating a traceback investigation. Additional instructions for collection and evaluation of case information are available in the attached PFP Job Aid (Attachment E).

Table 1: Factors to Determine Appropriateness of a Traceback Investigation for an Outbreak

Factor	Examples Favoring Initiation of a Traceback
Has a potentially severe public health risk been identified with a human or animal food product suspected of being the vehicle of transmission?	Serious health state/conditions, life threatening illness, or death.
How strong is the evidence that illnesses may be related?	1. Epidemiological subject matter experts indicate the illness subcluster/outbreak is significant and has identified a common food item that is most likely to be the vehicle for the outbreak. 2. Cases are laboratory confirmed with indistinguishable genetic fingerprint patterns (e.g., Whole Genome Sequencing [WGS]).
Is there high confidence that the product or ingredient in question was consumed one or more times during the period of interest?	Interviews of case-patients with good food recall history identify very few food items potentially associated with illnesses and no obvious non-food common exposure(s) that can explain the outbreak.
Is/are the consumption date(s) for cases known?	The following types of dates can serve as bases for tracebacks (most preferred type listed 1st): 1. Specific consumption/purchase dates 2. Illness onset dates 3. Isolation dates (when positive laboratory test results were reported).
Is an accurate food/product description available?	Availability of consumer purchase data, product labels or photos.
Is there accurate information regarding the place of exposure/purchase?	Consumer purchase data or invoices.

Traceback Coordination

When coordinating traceback with multiple agencies please refer to the Communications Chapter and ICS Chapter within the RRT Manual.

Traceback Documentation

All traceback investigation documentation should include a summary of the information gathered from the observations, interviews, and records collected at every firm. As documents are updated, they should be shared with FDA partners. This includes:

- A summary of shipment dates and amounts of the implicated food item(s). Verification of record completeness by matching incoming shipments (e.g., volume, dates, lot codes) with outgoing sales where possible.
- A traceback diagram and/or timeline (hand-drawn or computer generated) detailing names, locations, amounts, lot codes, and dates of receipt and shipment.
- A completed questionnaire for each visit (if used).
- Copies of invoices, bills of lading, daily inventories, Hazard Analysis and Critical Control Plans(HACCP), etc.
- Photos of all relevant findings. Note: products on-site at the time of inspection may not be relevant to the time of interest, but photos of these items may still be useful for the investigation.

Copies of reference documents (i.e., invoices, shipping receipts, bills of lading, etc.) or electronic spreadsheets containing relevant data are required from each level of the supply chain and should be included in the report. Daily inventories of the product of interest, if available, will likely be useful. For distributor-level investigations, request documentation regarding any on-site processing, packing and/or repacking of the product of interest. These documents may be faxed and copied several times; therefore, please ensure that the photocopies are legible and complete (i.e., no missing corners/dates) if no electronic data is available.

Specific Procedures

Note: The records, interview questions, and observations are not all-inclusive lists provided in this section but are examples to improve the consistency and effectiveness of traceback investigations.

This section highlights considerations for teams conducting traceback investigations. On-site record collection, interviews, and observations are key tools for gathering traceback information from food establishments. However, the product tracing process needs to be accomplished quickly if it is to be successful. Gathering information by telephone, fax, or e-mail may be faster than sending inspectors to gather records from each establishment.

Agencies should strongly consider use of standardized data collection worksheets or questionnaires to increase the consistency and completeness of

information gathering. Attachment D is a generic worksheet that can be used to gather core information if more specific forms/worksheets/questionnaires have not been developed.

Traceback Key Items

The following practices are recommended when gathering traceback information via telephone:

- Identify most senior food safety professional within the firm's organization (for example, the Vice President of Food Safety and Quality Control). This should be someone that is most knowledgeable about the movement of product through the firm.
- Be prepared to provide a de-identified summary of the current epidemiologic investigation, emphasizing that no specific food item has yet been identified as the source of the outbreak.
- Be prepared to explain how cooperation with this investigation will assist in the identification of the source of the outbreak, or the ruling out of a product of interest.
- Be prepared to cite and provide reference to statutory authority for obtaining records.
- State programs may consider confirming requests via email after telephone conversations have been concluded, so that the specific request is documented. Programs should also be prepared to submit requests on letterhead via fax, if necessary.
- Be prepared to follow up with firms repeatedly via phone, email, fax, or in person, as needed.
- Verify that records or documentation described over the phone or via email are provided (either hard copies or electronic copies).

Establishing deadlines for information requests is critical to the timeliness of the investigation. It is important to convey the urgency of the request to parties who may be unfamiliar with expectations. This will help ensure that the necessary data is available from each point in the trace in a timely manner.

Records Collection

Unless otherwise specified, for tracebacks at POS, consider collecting records beginning two weeks prior to the earliest date of exposure or documented product contamination. Examples of records that typically need to be collected include but are not limited to:

- Invoices;
- Shipping and receiving records;
- Bills of lading;

- Inventory records;
- Identifying information for implicated products;
- Label information;
- Container type, size, description;
- Grade;
- Lot codes;
- UPCs or GTINs;
- Production dates, pull dates, “use by” and/or “sell by” dates;
- Product origin;
- Raw ground beef grinding logs/records;
- Product shelf life;
- Product turn over;
- Advanced ship notices (ASN);

Examination of the delivery frequency at the POS will help determine the timeframe for record collection at facilities further back in the distribution chain.

Verify label and product information with invoices and shipping receipts for the timeframe of interest. Collect product information (labeling, lot codes, etc.) for the product that was used during the outbreak exposure timeframe of interest.

Verify and document any handwritten comments and marks on the reference documents and their meaning and significance.

Interviews and Observations

Determine product ordering practices:

- Identify how and when product is ordered.
- Estimate average daily use.
- Determine alternative sources of product if establishment runs out before another shipment is received (e.g., purchase from grocery store, request more from supplier, etc.).
- Determine how deliveries and receipt dates are recorded.
- Compare the shipping dates to the dates received.
- Determine suppliers during the timeframe of interest, including cash transactions.
- Estimate the transportation time from supplier(s) to the establishment.
- Determine if the product (e.g., fresh produce) was re-packed during distribution.

Determine shipping and receiving practices, making notes of exact receiving dates and times for each shipment. **Do not make assumptions that the date**

on the invoice, bill of lading, etc., is the date of receipt. This is often best determined via interviews with various levels of facility staff (management and frontline employees).

Determine the firm's traceability practices. A firm may use different documents or reference numbers to track a product from receipt through processing and shipment.

Conduct interviews with more than one employee at multiple levels of the organization regarding the implicated product.

Observe and verify that the procedures described by employees are reflected in their work.

Storage, Handling, and Preparation Considerations

Review the standard procedures for stock rotation and how the product is unloaded and added to existing inventory. Determine if first-in-first-out (FIFO) rotation policy is standard operating procedure and, if so, how closely the policy is followed.

Determine if food product storage conditions are in accordance with the manufacturer's requirements (e.g., "keep refrigerated").

Determine if implicated food item is used as an ingredient in the preparation or manufacture of another food item.

Determine how stock inventory is recorded. Determine how partial cases/containers are accounted for, and how and if carryover is recorded. If an inventory record is available for this period, understand how it is used, including its strengths and weaknesses, and determine what time of day the inventory is performed.

Analysis of Traceback Data

Analyze and discuss the data from each level of the supply chain (e.g., retail, distribution, and production) before continuing the investigation to the next level.

Determine which shipments received at the establishment could have been used to prepare the implicated food item.

Farm Investigations and Traceback Procedures

At the farm level, traceback activities focus on verifying the implicated shipments and documenting the system and coding which allows the product to be traced from the field to the next firm in the supply chain (e.g., packinghouse) through loading and distribution. Basic information should include crops, field identification (GPS coordinates if possible), harvest date, harvest crew, lot identification or product code, shipment dates, and customers.

If produce, that is a Raw Agricultural Commodity (RAC) is the food vehicle of interest, and traceback identifies an implicated farm(s), and contamination reasonably likely occurred at the farm level, a farm outbreak inspection may occur. From FDA, OCORE+EP may issue a produce farm outbreak inspection assignment to OII Division of Produce Safety, https://www.fda.gov/food/food-safety-modernization-act-fsma/produce-safety-network. OII Division of Produce Safety is the lead investigations branch from FDA for produce safety on produce farms.

Throughout an outbreak investigation, FDA is coordinating with relevant state partners, including when OII Division of Produce Safety investigates a produce farm. Emergency Response Coordinators (ERCs) are the primary point-of-contact for state partners. When OCORE+EP is issuing an assignment to OII Division of Produce Safety to investigate and collect samples at a produce farm, OII Division of Produce Safety works with the assigned ERC to determine state-level involvement in the assignment. Typically, a produce farm outbreak inspection team consists of OII Division of Produce Safety and state partners with assistance from the OII division. The state partners are often members of the state's RRT and/or State Produce Implementation Cooperative Agreement Program (Produce CAP), https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/grants-and-cooperative-agreements/state-produce-implementation-cooperative-agreement-program-cap.

Table 2: Who Conducts the Produce Farm Inspection?

Cooperative Agreement	RRT State	Not an RRT State
Produce Non-CAP State • State does not have a Produce CAP	OII Division of Produce Safety + RRT • Investigation may be conducted by OII Division of Produce Safety, RRT, or jointly	• **OII Division of Produce Safety** Investigation is conducted by OII Division of Produce Safety - ERC notifies the state, as applicable
Produce CAP Path A State	OII Division of Produce Safety + RRT	• **OII Division of Produce Safety** Investigation is

Cooperative Agreement	RRT State	Not an RRT State
• State has a limited Produce CAP (non-regulatory program)	• Investigation may be conducted by OII Division of Produce Safety, RRT, or jointly • ERC may invite the state Produce CAP grantee	conducted by OII Division of Produce Safety • ERC may invite the state Produce CAP grantee
Produce CAP Path B or C State • State has a full Produce CAP (includes a regulatory program)	OII Division of Produce Safety + RRT + Produce CAP • Investigation may be conducted by OII Division of Produce Safety, RRT, and/or Produce CAP grantee or jointly	OII Division of Produce Safety + Produce CAP • Investigation may be conducted by OII Division of Produce Safety, Produce CAP grantee, or jointly

All members of the outbreak inspection team will have a meeting prior to initiating the inspection at the produce farm. This meeting is to provide an overview of the outbreak, traceback, purpose of the inspection, review of the assignment, and establish roles and responsibilities of team members. This is critical to the success of the inspection.

The purpose of a farm inspection is to gather information and observe and document practices that may have led to the pathogen specific contamination of produce, and that will support regulatory action if appropriate. The focus is on the time and conditions that existed during the growing, harvesting, packing, and holding (as applicable) of the produce implicated in the outbreak. Information is gathered using both traditional fact-finding techniques and the FDA Form 3623 "Farm Investigation Questionnaire", https://www.fda.gov/about-fda/farm-investigation-questionnaire-pdf as the foundation of the investigation.

Inspections of produce-related outbreaks should follow the FDA's "Guide to Produce Farm Investigations" (https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/guide-produce-farm-investigations-1105). Additional information on farm investigations can be found in FDA's Investigations Operations Manual (IOM), Chapter 8 – Investigations, https://www.fda.gov/media/75268/download.

The objectives of a produce farm outbreak inspection assignment are typically:

- Minimize the potential for illness caused by produce that is grown, harvested, packed, and held under insanitary conditions from entering interstate commerce.
- Document possible sources of microbial contamination that may have led to the produce associated outbreak.
- Build a scientific base to assess the relative microbial risk of on-farm practices.
- Refine Agency policy and guidance aimed at reducing foodborne illness related to fresh produce.

The assignment will focus on the pathogen of concern. If the pathogen's only reservoir is humans, then the inspection will then shift to focus on disease prevalence in the community and farm work force, worker hygiene, and contaminated water and sewage inputs. This would apply to pathogens such as hepatitis A virus and the parasite *Cyclospora*. If the pathogen of concern has both a human and animal reservoir, then the inspection will be broader to cover possible animal contamination sources. These bacterial pathogens include, but are not limited to, *Salmonella* and *Escherichia coli* O157:H7.

There are reoccurring challenges related to these farm inspections, including:

- Traceback can be very complex (e.g., often, leafy greens from multiple farms and fields can make up one production lot, making it very challenging to narrow down to a particular farm/fields). Therefore, the assignment may include numerous fields on a farm, including fields in different areas of the region. It is common for an assignment to include coverage of hundreds of acres on a farm in addition to surrounding public land.
- By the time traceback identifies a farm(s) of interest, it is likely the field(s) of interest on the farm are fallow and/or the season is over, so the investigation may be limited.

During a farm investigation, samples may be collected. Samples are a critical part of FDA's regulatory activities and a critical piece to outbreak investigations. During a produce farm investigation, samples may include product samples and environmental samples, which may include water, sediment, soil, soil amendments, air, swabs, and animal feces.

The goal in collecting samples is to determine if the outbreak pathogen is present on product or in the environment at that farm.

Environmental samples play a large role in farm investigations to document how the environment may have contributed to the introduction and transmission of the outbreak pathogen and sources and/or routes that led to product contamination.

While all regulatory actions are considered on a case-by-case assessment of the evidence and findings, the following environmental sampling results are examples of patterns that could lead to FDA consideration of regulatory follow-up.

- A genetic match established by WGS, https://www.fda.gov/food/microbiology-research-food/whole-genome-sequencing-wgs-program, that connects a bacterial strain found in an environmental sample and a bacterial strain from an ill person. When supported by product traceback and/or epidemiological evidence (e.g., a patient food history), this is a scenario where regulatory action may be warranted to protect consumers.
- A genetic match established by whole genome sequencing, that connects a bacterial strain found in an environmental sample and a bacterial strain from a food sample from the same farm. Once again, this is a scenario where regulatory action may be warranted to protect consumers, and food likely to be affected in a similar manner must also be assessed.

9.3. Typical Problems and Potential Solutions

Some typical problems and potential solutions are described in Table 3 (below).

Table 3: Troubleshooting Document Collection

Issue	Problem	Solutions
Firms are slow in providing requested documents	• The firm may not be convinced that the gathered evidence is credible. • The firm may be attempting to gather information that is not needed. • The firm may have limited first-hand experience with foodborne illness outbreaks and potential impacts on their business.	• Provide clear and concise summaries of available epidemiologic, traceback, laboratory, and environmental health evidence to firm decision-makers. • Clearly identify the specific information being requested – timeframe of interest, exact product description, types of records. • Share factual information from recent outbreaks illustrating the potential regulatory, economic, and civil consequences (i.e., class action lawsuits) of delaying identifying the source of the outbreak. • Assign staff to visit the facility, as their presence at the facility often can generate more responsiveness than a request made over the phone.
Inconsistent or incomplete records for some date(s) of interest	• Non-existing records. • Incomplete records. • Poor recordkeeping.	• Gather additional records from before and after the period of missing records (bracketing) to better define usual/typical patterns of receiving, inventory control, and shipping. • Take note of the firm's ordering pattern and confirm that no records are missing. • Request overlapping records (shipping documents to this firm, from their supplier while you request their supplier's receiving records).

Issue	Problem	Solutions
Voluminous paper-based records	• Firm provides requested records in paper-only format. • Firm is providing records that do not pertain to the request.	• Request that firm provide records in an ***electronic sortable spreadsheet*** (or ***sortable spreadsheet***) format, if available. Sometimes firms won't provide records electronically unless directly requested. • If records are not available electronically, the agency should have the capacity to scan the records with Optical Character Recognition (OCR) so that they may be rapidly queried. • Request that the firm provide records for only the product(s) and dates that are requested at this time, however noting your request may expand at a later time.
Agencies lack jurisdictional authority over all entities in the product(s) distribution chain(s)	• Local and state agency regulatory authorities vary significantly from state to state. • Information sharing sometimes requires legally binding agreements.	• Before the next outbreak, contact local, state, and tribal authorities to discuss strategies for collaboration during future outbreak responses. Consider becoming actively involved in your state's Food Safety Task Force and/or other networking mechanisms. • Consider formalizing agreements with a Memorandum of Understanding (MOU) or other written document, when needed.

9.4. Factors to Consider When Determining the Most Appropriate Method(s) for Gathering Traceback Information

Table 4 (below) describes situations where the use of a telephone, fax, or E-mail traceback may be most appropriate to gather information requested by epidemiological and/or environmental health investigators.

Table 4: Traceback Factors

Information Type	Factors Suggesting Telephone, Fax, or E-mail May Be Appropriate
Product Identifying Information	Cases with exposure to common food occur in multiple locations or jurisdictions at the same time (particularly if they occur in multiple states). Firm may be able to provide a description of the product over the phone or with photos via e-mail or fax.

Information Type	Factors Suggesting Telephone, Fax, or E-mail May Be Appropriate
Ordering, Receiving, and Shipping Practices	Firms with a proven record of maintaining accurate, reliable, readily available records could provide information via telephone, fax, or email in a timely manner.
Handling and Storage Practices	Minimal potential for introduction of the contaminant of interest exists (e.g., no on-site packaging, repackaging, or processing of the product). If the product had high potential for introduction of the contaminant, an on-site visit is often in order.
Stock rotation practices	Firms with a proven record of maintaining accurate and reliable inventory management systems and records indicate that they can provide reliable information via telephone, fax, or email in a timely manner. If the firm is unable to provide consistent information, then an on-site visit may be more appropriate.

10.0. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

10.1. Achievement Levels

The following levels described assume that agencies with higher level capacities meet all the elements for lower-level capacities.

Level	Description
1	The agency has processes or procedures for conducting tracebacks.
2	The agency has written traceback procedures and has reviewed the procedures within the past 12 months, including a review for equivalency to a national/multijurisdictional best practices document (e.g., the chapter).
3	The agency has a traceback procedure that is equivalent to a national/multijurisdictional best practices document (e.g., the chapter) that allows the program to complete tracebacks. A scheduled formal review of the document has been established and procedures are updated as necessary.
4	100% of relevant staff have been trained in traceback procedures. Staff receive training within 12 months of updates or revisions of the policy.
5	Within the past 12 months, the program has documented the ability to conduct tracebacks through audits, exercises, or real-world experiences.

10.2. Process Overview

- Review the steps identified in the RRT Food Emergency Response Plan (FERP) Chapter, which are appropriate for agencies interested in developing any RRT capacity.
- Determine what traceback capacity level your agency needs to develop and maintain based on agency objectives, identified risks, past experiences, and the availability of resources.
- Consider how to most effectively use staff training, supervision, jurisdictional authorities, and other resources to achieve desired traceback capacity level. It is often best to accomplish this through agency involvement in a comprehensive process improvement initiative (e.g., enrollment in the Manufactured Food Regulatory Program Standards [MFRPS]).
- Use information from exercises and actual responses to assess the costs and benefits of developing a higher traceback capacity level.

11.0. RELATED DOCUMENTS

Other RRT Manual Chapters: RRT Manual Chapters on Working with Other Agencies, Communication SOPs, Training, and Food Emergency Response Plans.

12.0. REFERENCES AND OTHER RESOURCES

Full citations are in the References Section, “List of Reference Documents,” listed by author.

- Product Tracing in Epidemiologic Investigations of Outbreak due to Commercially Distributed Food Items – Utility, Application, and Considerations - October 2015 (https://cifor.us/downloads/clearinghouse/Product%20Tracing%20in%20Epidemiologic%20Investigations.pdf).
- FDA: Guide to Produce Farm Investigations (http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074962.htm).
- FDA Investigations Operations Manual, Subchapter 8.3 - INVESTIGATION OF FOODBORNE OUTBREAKS 8.3.5.5 - Tracebacks of Foods Implicated in Foodborne Outbreaks (https://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123515.pdf).

- FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods – September 2024 (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods)
- Third Edition of the CIFOR Guidelines for Foodborne Disease Outbreak Response (https://cifor.us/clearinghouse/cifor-guidelines-for-foodborne-disease-outbreak-response).
- Procedures to Investigate Foodborne Illness, 6th Edition 2011, International Association for Food Protection (http://www.foodprotection.org/publications/other-publications/index.php).
- Examples of state procedures, checklists, and guidance documents are available on FoodSHIELD (www.foodshield.org).
- FDA "Guide to Investigation of Eggs and Farms Implicated in Foodborne Outbreaks of Salmonella Enteritidis." (Note: This internal FDA document is available upon request to FDA personnel and commissioned state officials.)
- Irvin K, Viazis S, Fields A, Seelman S, Blickenstaff K, Gee E, Wise M, Marshall K, Gieraltowski L, Harris S. An Overview of Traceback Investigations and Three Case Studies of Recent Outbreaks of Escherichia coli O157:H7 Infections Linked to Romaine Lettuce. J Food Prot. 2021 Apr 9. https://doi.org/10.4315/JFP-21-112.
- Association of Food and Drug Officials (AFDO) Shopper History Outbreak Partnership (SHOP) resources for food purchase history and consumer purchase data (https://www.afdo.org/resources/purchase-history/).
- FDA: LearnED online units, registration required (http://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm119016.htm).
- FDA Training modules

Title	Course Code	Class Type
Traceback Investigations 1: Introduction	CC9030W-1	LearnED
Traceback Investigations 2: Point-of-Service Investigations	CC9030W-2	LearnED
Traceback Investigations 3: Distributor Investigations	CC9030W-3	LearnED
Traceback Investigations 4: Traceback of Eggs and Other Commodities	CC9030W-4	LearnED
Traceback Investigations 5: Concluding the Investigation and Reporting the Results	CC9030W-5	LearnED
ER220: Traceback Investigations	ER220	Classroom
ER321: Produce Farm Investigations	ER321	Classroom

13.0. ATTACHMENTS

- **Attachment A** – Example Traceback Investigation Timeline from FDA's ER220 Traceback Investigations training course
- **Attachment B** – Example Traceback Investigation Flow Diagram FDA's ER220 Traceback Investigations training course
- **Attachment C** – Example Traceback Investigation Master Flow Diagram from FDA's ER220 Traceback Investigations training course
- **Attachment D** –Traceback Information Gathering Worksheet
- **Attachment E** – Partnership for Food Protection (PFP) Job Aid

14.0. DOCUMENT HISTORY

Version #	Status*	Date	Author
1.0	I	9/26/2011	RRT Traceback WG (MI**, Minneapolis District**, MN, CA, Pacific Region, Los Angeles District, Florida District)
1.1	R	2/1/2012	ORA/OP
1.2	R	1/24/2013	ORA/OP
2.0	R	5/26/2017	RRT Traceback Ch. Revision WG (GA, MO, RI, SAN-DO, FDA CORE, FDA Office of Policy & Risk Management, MN**, MIN-DO**)
3.0	R	12/1/2024	ODP-AFDO Compiled Revisions

*Status Options: Draft (D), Initial (I), Revision (R), or Cancel (C)
**Workgroup Lead

Change History
1.1 – Editorial revisions made by ORA for document clearance.
1.2 – Revisions to achievement levels (Section 3) based on recommendations from the RRT 2012 Face to Face Meeting (November 2012).
2.0 – Revised for the 2017 Edition of the RRT Manual by the RRT Traceback Chapter Revision Workgroup.
3.0 – AFDO compilation for 2025 Edition of RRT manual. Updated FDA program names resulting from the 10/2024 FDA reorganization.

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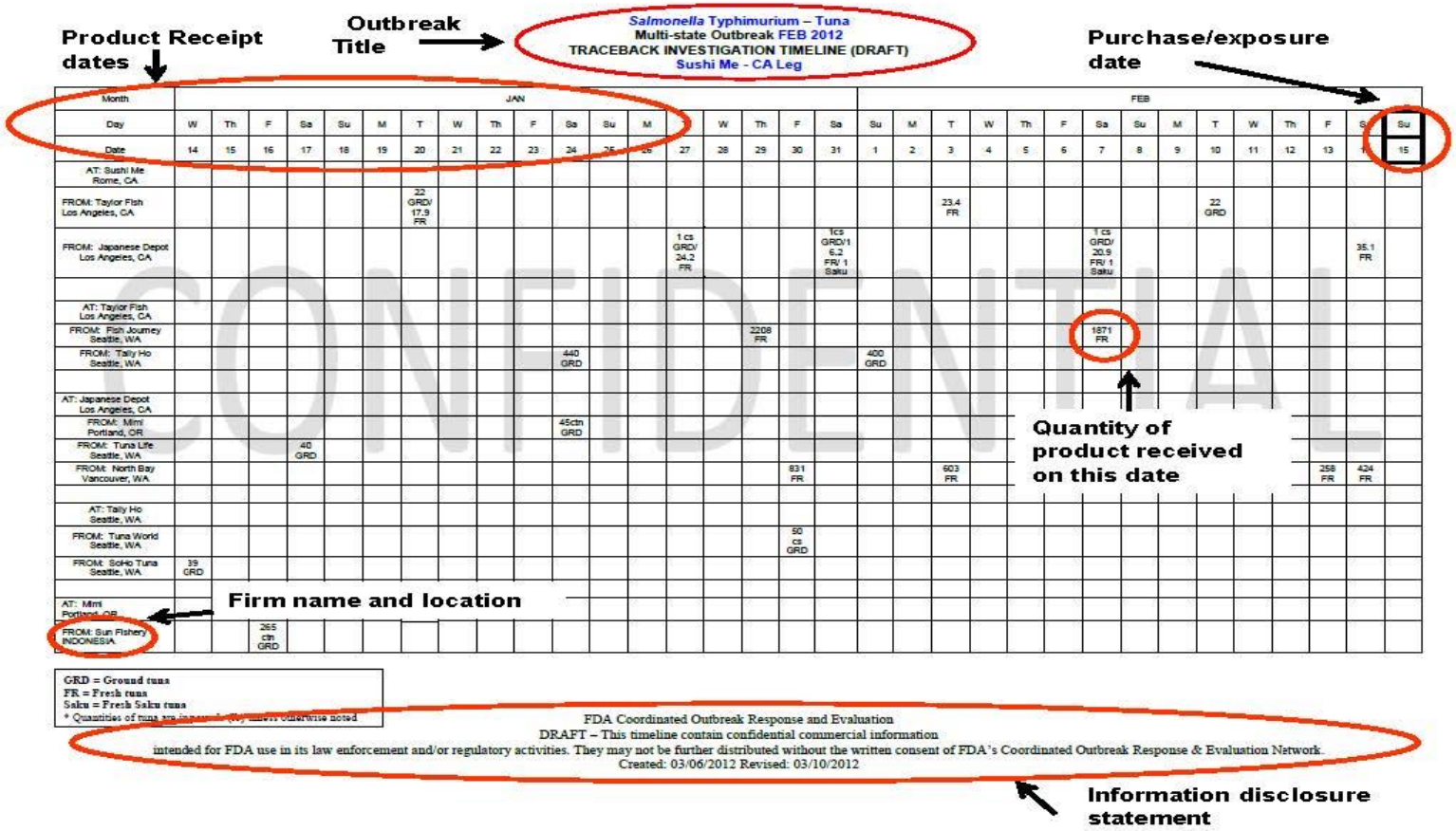
Attachment A – Example Traceback Investigation Timeline from FDA's ER220 Traceback Investigations Training Course

Note: Attachments A-C are examples of FDA documentation; header/footer information (e.g., agency disclosure statement) will depend on the agency drafting the timeline.

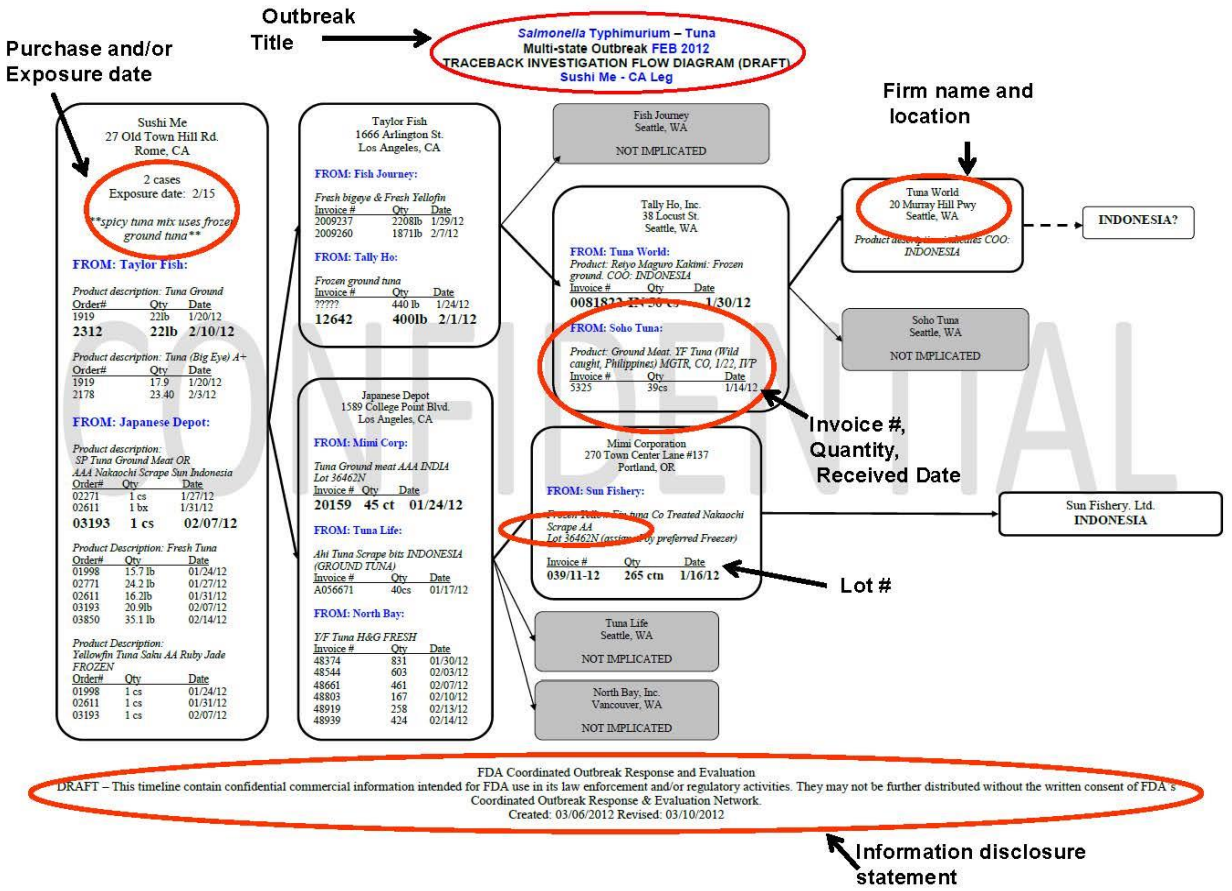


Directions for Completing or Interpreting This Type of Traceback Investigation Timeline:

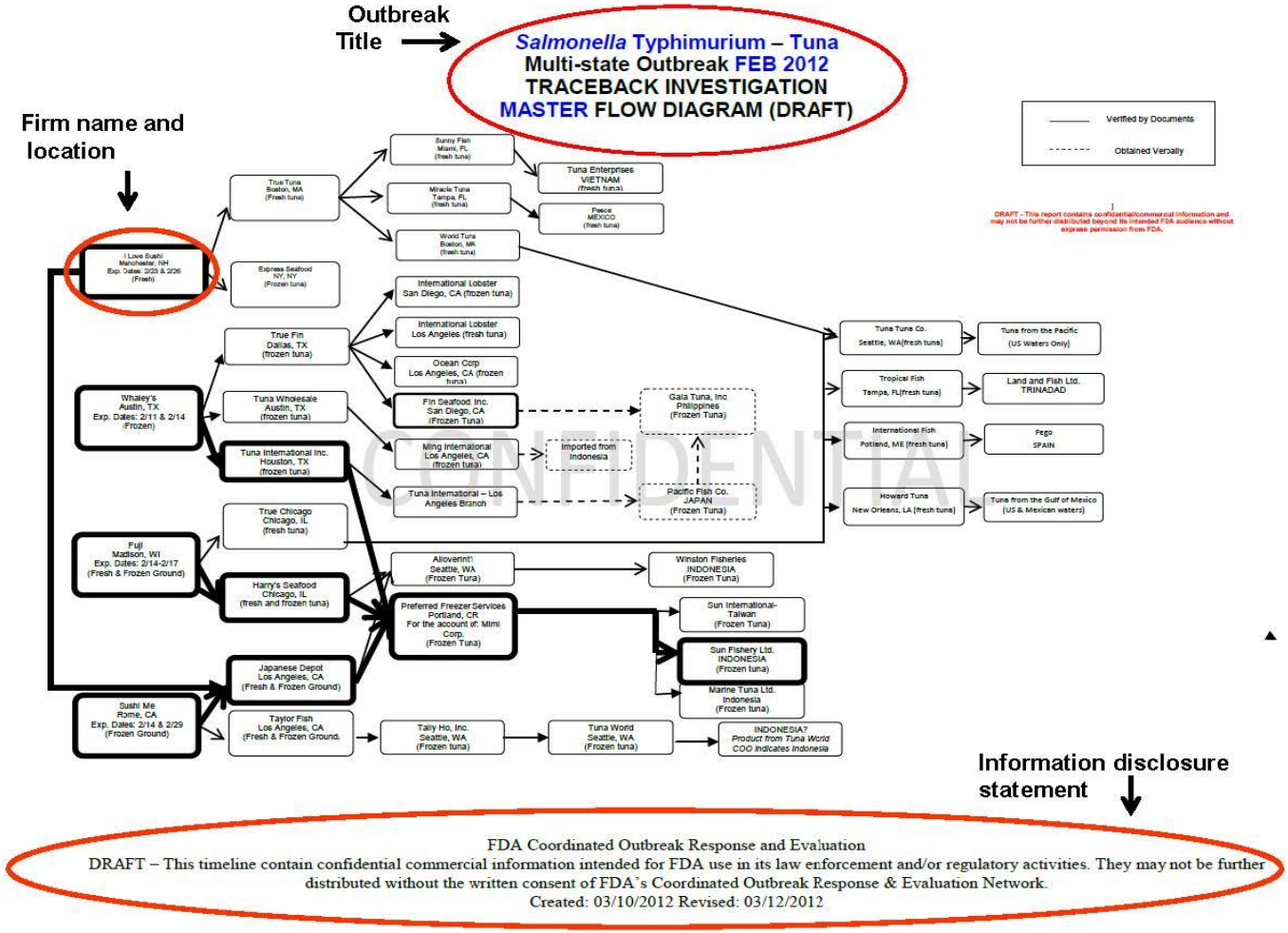
- Label with title of traceback, implicated or suspected product, name of traceback leg, and date(s) of the outbreak(s) (*month and year)*.
- The last date of purchase/exposure should be the furthest, upper-right hand cell. The rest of the dates continue backwards to the left for the entire time frame covering the record collection dates.
- The first left cell on the line under “DATE” contains the POS name, preceded by the word “At.” All suppliers to the POS are listed on a separate line below the POS name and are preceded with the word “From.”
- If there were inventory records at POS, record the inventory under the corresponding dates on the same line as the POS. *Note at the bottom of the timeline if inventory was taken before or after that day’s shipments were received*. If there were no inventory records (or if inventory was not taken on a given day), then line should remain blank (*do not use zero to represent blanks)*.
- Quantity of each shipment should be indicated on the date it was received at POS from the corresponding supplier.
- Implicated shipments will usually be bold or have a bold border.

Attachment B – Example Traceback Investigation Flow Diagram from FDA's ER220 Traceback Investigations Training Course

Most traceback investigations resemble a branching tree because of multiple suppliers throughout the distribution chain. An easy way to visualize the ongoing investigation and shipments of product is to draw a flow diagram illustrating each level of the investigation as it branches from the point of service to its original source(s). Prepare a flow diagram illustrating distribution of the product up through the supply chain currently under investigation. For each implicated distributor, include the following: name, city, state, invoice/purchase order number, date received, quantity, lot number, and Freight/Air Way Bill (AWB) number and date. For non-implicated distributors list only the distributor name and location. If there are numerous shipments involved and the flow diagram would become too complex, just list date received, quantity, and invoice number on the flow diagram, and include other record information in a separate document.



Attachment C – Example Traceback Investigation Master Flow Diagram from FDA's ER220 Traceback Investigations Training Course



Attachment D – Traceback Information Gathering Worksheet

A Microsoft Word file template of the Traceback Information Gathering Worksheet is available upon request to FDA Office of Partnerships (OP.Feedback@fda.hhs.gov) and is posted in the FDA RRT Workgroup in FoodSHIELD (closed workgroup only accessible to RRTs). A screenshot of the file is provided within this attachment.

Traceback Information Gathering Worksheet	
The purpose of these investigations is to identify and document the distribution of implicated foods or foods suspected of contamination. This involves reconstructing past production and distribution events during a specific time period through interviews, observations, and record collection.	
Establishment Name and Address:	
Epidemiological Investigational Information:	**Notes:**
Preliminary product description	
Time period of interest verified (Dates and times product of interest was prepared/served/distributed and consumed at point of service)	
Epi data (to share with industry as needed)–number of cases, association certainty	
Product Identifying Information:	
Product description (Brand, food type, size, container type)	
Include pertinent label information (collect copy or photo if available)	
Document product identifiers (i.e. Lot Codes, Universal Product Codes (UPC), Stock Keeping Unit (SKU), Price Look Up (PLU) numbers, Production/pull dates)	
Manufacturer name and production facility address	
Determine how product is received (i.e. frozen, fresh, shelf stable)	
Identify food items that may contain the product of interest	
Shipping and Receiving Practices (obtain copies of invoices, receipts, bills of lading, etc…):	
Document receiving dates, times, and amounts for each shipment (or transfer) in requested time period	
Determine whether firm wholesales and/or retails product of interest	
Indicate how the dates on the shipping records reflect the date the product was received	
Determine how supplier deliveries are documented or recorded	
Identify firm's suppliers during this time period (include cash transactions)	
Determine or estimate transportation time from supplier to point-of-service	
Handling and Storage Practices:	
Determine if there is any on-site packing, repacking, and/or processing that could have allowed introduction of contamination	
Determine if an environmental assessment/investigation is needed (i.e. to assess cross-contamination opportunities like repacking of fresh produce during distribution)	
Stock Rotation Practices:	
Review the standard operating procedure at the firm	
How is the product unloaded and added to inventory	
Determine if first-in-first-out (FIFO) rotation policy is standard operating procedure and how closely it's adhered to	
Stock Inventory (daily or otherwise):	
Review inventory record (logs) for time period of interest (how records are used by firm, identify record system strengths and weaknesses)	
Determine what time of day inventory is performed	
Identify what each inventory number represents	
Determine how partial cases or containers are accounted for, and how and if carry over is recorded	
Determine if the facility links purchase orders, UPC codes, etc to supplier lot codes	
Ordering Practices:	
Determine how and when the product is ordered	
Determine shelf-life and average daily use	
Identify routine/regular suppliers	
Identify any non-routine suppliers or products used during time period of interest	
Other Information:	

Attachment E – Partnership for Food Protection (PFP) Job Aid

Information Needed to Determine if a Case is a Good Traceback Candidate

(to be completed by investigators at the state/local level during a multi-state outbreak)

This document provides a checklist of information that is helpful when a traceback for a food product of interest is being considered during an outbreak. The information below should not replace your State/local routine process for interviewing case patients, but can be used to supplement your existing agency procedures. Please share answers from this form (and requested attachments) with partners involved in the investigation such as the CDC point of contact (POC) and FDA District POC collecting outbreak information, especially when a traceback is being considered. This information is extremely helpful for FDA to have when FDA is considering embarking on a traceback.

Note: The below table should be filled out for each product of interest. **Product of interest (specify) and case patient identifier (specify):**_____

1. Is the case patient a part of the outbreak cluster (e.g. code assigned by PulseNet), if available?	**Yes** ☐ → Record PulseNet Cluster Code: _____ **No** ☐→Describe cluster of interest: _____ **Unknown** ☐		
2. Residence of case patient?	**Known** ☐→ Document state and city/county of residence: _____ **Unknown** ☐		
3. From what source in the case patient was the pathogen identified?	**Stool** ☐ **Blood** ☐ **Other** ☐→Specify: _____		
4. Case patent illness onset date	**Known** ☐→ Document mm/dd/yy: ____/____/____ **Unknown** ☐→ Enter 99/99/99 if unknown		
5. Is the case a secondary case? A secondary case is a case that became ill from being exposed to another ill case in the outbreak. For example, this can happen within a family, when certain pathogens are involved.	**Yes** ☐→**If "Yes" stop here and do not continue with any of the below questions** **No** ☐ **Unknown** ☐		
6. Is out-of-country travel reported by case during the time frame of interest?	**Yes** ☐→Document location of travel: _____ **No** ☐ **Unknown** ☐		
7. Did the case patient eat the product of interest during the time frame of interest (determined by pathogen)?	**Yes** ☐ **No** ☐→**Stop here and do not continue with any of the below questions** **Unknown** ☐→ **Stop here and do not continue with any of the below questions**		
8. For each instance where the case patient reports eating the product of interest:	**Date case patient reports eating product of interest #1 (mm/dd/yy)** ____/____/____	**Date case patient reports eating product of interest #2 (mm/dd/yy)** ____/____/____	**Date case patient reports eating product of interest #3 (mm/dd/yy)** ____/____/____
A. Is the Point of Service (POS) where the case patient reports eating or buying the product of interest known?	**Yes** ☐ **Possibly** ☐→Explain: _____ **No** ☐→Skip 8A-E and continue 8F onward	**Yes** ☐ **Possibly** ☐→Explain: _____ **No** ☐→Skip 8A-E and continue 8F onward	**Yes** ☐ **Possibly** ☐→Explain: _____ **No** ☐→Skip 8A-E and continue 8F onward
B. What is the type of POS facility where the case patient reported eating/buying the product of interest?	**Retail** (e.g. grocery store) ☐ **Restaurant item** (restaurant) ☐ **Institution** (e.g. cafeteria) ☐ **Other** (e.g. picnic) ☐ **Unknown** ☐	**Retail** (e.g. grocery store) ☐ **Restaurant item** (restaurant) ☐ **Institution** (e.g. cafeteria) ☐ **Other** (e.g. picnic) ☐ **Unknown** ☐	**Retail** (e.g. grocery store) ☐ **Restaurant item** (restaurant) ☐ **Institution** (e.g. cafeteria) ☐ **Other** (e.g. picnic) ☐ **Unknown** ☐
C. Is there information on the name and address of this POS?	**Yes** ☐→Include name, address:_____ **No** ☐	**Yes** ☐→Include name, address:_____ **No** ☐	**Yes** ☐→Include name, address:_____ **No** ☐

D. Is the purchase date for the product of interest at this POS known?	**Yes** ☐→ Include date: mm/dd/yy -verify with receipt and if able attach:_____ **No** ☐	**Yes** ☐→ Include date: mm/dd/yy -verify with receipt and if able attach:_____ **No** ☐	**Yes** ☐→ Include date: mm/dd/yy -verify with receipt and if able attach:_____ **No** ☐
E. Is there documentation confirming the purchase information for the product of interest at this POS (e.g. receipts/shopper card info, bank statement info)?	**Yes** ☐→ Please attach with personal info removed **No** ☐	**Yes** ☐→ Please attach with personal info removed **No** ☐	**Yes** ☐→ Please attach with personal info removed **No** ☐
***F.* Is there product information for the product of interest exposure?** e.g. for meal at POS include menu item consumed containing product interest & name/location POS; for purchase at a grocery store include: store name & location, type of product of interest; brand and variety, product package & description, UPC or PLU#s, lot code, sell-by date/best-by date/use by date if purchased	**Yes** ☐→ Specify: _____ **No** ☐ **Unknown** ☐	**Yes** ☐→ Specify: _____ **No** ☐ **Unknown** ☐	**Yes** ☐→ Specify: _____ **No** ☐ **Unknown** ☐
9. Did this case report exposure at a POS location associated with other cases in this outbreak (case cluster involving same POS location)?	**Yes** ☐→ Document # cases associated with POS, POS name/location, exposure at POS: _____ **No** ☐ **Unknown** ☐		
A. If yes, was cross-contamination at the POS ruled out?	**Yes** ☐ **No** ☐ **Unknown** ☐		
10. Does the case have any commonalities with other cases in the outbreak? (e.g. They share common POS exposure, brand/variety of suspect food product, same geographic area of case)	**Yes** ☐→ Provide details: _____ **No** ☐ **Unknown** ☐		
11. Is the product of interest still available for testing (e.g. in household)?	**Yes** ☐ **No** ☐ **Unknown** ☐		
A. If any of the product of interest is available, is your agency planning on collecting and testing it?	**Yes** ☐ **No** ☐ **Unknown** ☐		
12. Is the case a good candidate for traceback purposes? **Additional comments:** _____	**Yes** ☐→ Explain: _____ **No** ☐→ Explain: _____ **Unknown** ☐→ Explain: _____ *Below are some criteria considered when determining if a case is a good candidate for traceback, reflected in many of the specific questions listed above.* ***The first 5 bullets are all needed*** *to support the case being a good candidate for traceback. The remainder bullets are nice to have but are not always realistic under normal situations.* • ***Case is a confirmed, primary case (seen in above Question 1 and 5) in this outbreak who has a solid onset date (Question 4) and remembers specifically being exposed to the product of interest during the period of interest (Question 7) AND*** • ***He/she is a reliable food historian meaning he/she has a good memory of his/her food exposures and has limited exposures (seen in Question 7, and 8A-F) AND*** • ***Case can provide details about the exposure to the product of interest (Question 8A-F) AND*** • ***The case had only one exposure (or at most very few) to the product of interest, prior becoming ill (Question 7 and 8) AND*** • ***Solid documentation is able to verify case's exposure to product of interest (e.g. receipt/shopper card/bank statement seen in Question 8E)*** • *In this outbreak, the case is part of a case cluster (involving 2 or more cases) associated with the same POS location(Question 9). Ideally the case reported\consuming the product of interest at this POS. Traceback on sporadic cases is not ideal due to recall loss and other such factors.* • *If the case is not part of a case cluster, the case at least has commonalities with other cases in the outbreak such as reporting exposure to the same brand/variety of suspect food product (Question 10).* • *The case is geographically and/or temporally dispersed as opposed to other cases in the outbreak (Question 2) and/or reports exposure at a POS that is unique in nature (e.g. small independent restaurant as opposed to a chain-can be determined in Question 8).Therefore, the case's exposure could identify different distribution pathways leading to a common source.*		

Traceback/Investigational POS Reference Guide

At a minimum, collect the following information during informational traceback effort. Situation-specific information may be added as needed. Please remember to collect information corresponding to the time period of interest leading up to (and including) the date of exposure/purchase. Determining the shelf life of the product will help in bracketing the appropriate time frame of interest. When in doubt, it is always better to collect for a larger time period of interest.

Inspector Information: Inspector's name; phone #; email address, organization/agency; date of informational traceback effort

Observations at POS:

- Facility Type (Restaurant; Grocery Store; Other); name; permit #; address; phone #; manager name
- Any reported employee illnesses during the timeframe of interest? If ill, did they directly handle the product(s) of interest?
- Does the POS have an SOP for disposal of products too old to sell/use or an unwritten practice?
  - If so, please provide specifics on this.
- Were there any maintenance issues (e.g. rodent problems) in the facility during the timeframe of interest?
- Was there any new construction in the facility during the timeframe of interest?
- Has the POS received any reports of illness during the timeframe of interest? If so, please provide details on complaints
- Does the facility perform any environmental swabbing of their facility and product testing?
  - If so, please provide specifics on this, and information on any positive samples.
- Obtain information regarding the POS cleaning schedule and try and obtain SOPs showing when and how they clean.

Product Identifying Information:

- Product Category(Produce; Meat; Grain; Other), product description/ and how labeled at POS.
- Product Brand/Name. Was product(s) of interest renamed or rebranded at POS? If so, please provide details on this.
- Product Origin (if known)
- Product Lot # and code # (if any). Identify if lot # is assigned by POS or supplier/manufacturer
- Product Best Buy Date/ Sell by date and shelf life (if known)
- Product Packaging Type (Box; Bag; Loose; Clam Shell; Can; Other) and containers size/weight
- Can source of suspect product(s) be tracked by the use of a lot number or some other coding system?
  - If so, please describe the traceability process.

Handling and Storage Practices:

- Document storage temperature at POS
- Time and dates prepared, if prepared at POS
- Turn-around time (once received, how long till used/sold)?
- Does the facility have a FIFO policy? Is it closely adhered to? If not, what practice is followed?
- Once at the POS, what is the product(s) of interest used for? In what menu items is it used in and how prepared? Obtain copy of menu and recipes/ingredients.
- Does commingling occur? Does the POS repackage the product?
- Does the facility manipulate the product(s) of interest in any way? If manipulated, provide details regarding when manipulated, how, etc.

Stock Inventory:

- Quantity on site and lot #s available
- What are the stocking practices for the product(s) of interest at POS?
- Is a stock inventory taken at the POS and if so how often and what time day? Consider collecting for timeframe of interest.

Ordering Practices:

- How and when is product ordered? As needed or is there a schedule? Always use same suppliers?
- Did POS order stock from any new firms for product(s) of interest during timeframe of interest?
- Were there cash sales during this time frame for product(s) of interest, due to running out of product? Were these documented?

Shipping and Receiving Practices:

- How does the product arrive at the POS (e.g. diced; whole; shredded; portioned)
- Did POS pick up the order(s) associated with product of interest or was it received directly from the supplier/shipping company?
  - Does the POS have an SOP for truck cleaning or specifications required for suppliers and shipping companies?
- Obtain legible copies of invoices and bills of lading
  - Records received for all shipments of product(s) of interest that POS received starting with day of the patient purchase/exposure at POS, going back to first date of time period of interest. Explain any unusual findings from the record review.
- Product(s) labeling:
  - How is product(s) of interest labeled on the invoices/bills?
- Product(s) receipt dates
  - Are incoming shipments for product(s) of interest initialed or stamped with receipt date? If not, is there a way to determine receipt date at POS, if not on records?
- Were there any holidays or unusual occurrences that would have affected product(s) of interest being received?
- If known, what are the transit times from the suppliers for the product(s) of interest to the POS (if applicable)?
- What are the general delivery times (time of day) that suppliers deliver product(s) of interest to POS (if applicable)?
  - Could product(s) of interest be used/sold same day as it was received?
- How is the incoming product(s) of interest handled upon receipt?
  - Does POS have time/temperature logs for product(s) of interest? Consider collecting.
  - How is incoming product unloaded and added to existing inventory?
- During the timeframe of interest, were there any transfers of the product(s) of interest within the company?
- Shipping company for product(s) of interest: name, address, phone number (if known)
- Distributor for product(s) of interest: name, address, and phone number (if known)
- Manufacturer for product(s) of interest: name, address and phone number (if known)
- Identify role of each of the firms noted in the traceback records and whether these firms actually directly handled product
- Did the POS ship the suspect product(s) to any customers (e.g. other restaurants)? If so, do they have traceability?
- Points in supply chain, if any, where product(s) of interest was manipulated (if known)