

**Minnesota Department of Agriculture
Food and Feed Safety Division**

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Title: Traceback and Traceforward Investigations SOP	

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1. PURPOSE

The purpose of this document is to outline the procedure for staff conducting traceback and traceforward investigations. This document identifies common elements and unique considerations for regulatory tracebacks, informational tracebacks, and regulatory traceforward investigations.

2. SCOPE

This procedure applies to Rapid Response Team (RRT) staff and Manufactured Food and Retail Food Program Staff within the Food and Feed Safety Division (FFSD) of the Minnesota Department of Agriculture (MDA) conducting traceback and traceforward investigations. Regulatory and informational tracebacks and regulatory traceforwards are addressed in general terms that complement existing guidance materials that are identified in the “References” section. This procedure does not address other related food or feed investigations, such as environmental assessments or root cause analyses, or the use of the Incident Command System (ICS).

3. BACKGROUND

This procedure is based on content from the RRT Best Practices Manual, a document developed by state food regulatory agencies, U.S. Food and Drug Administration (FDA) District Offices, and FDA Centers as a part of FDA’s RRT Cooperative Agreement Initiative.

Traceback investigations are conducted to determine the source(s) of contaminated food identified through an epidemiological investigation, laboratory analysis, or by routine inspection. Epidemiological investigations and traceback investigations have historically been viewed as sequential activities, with a traceback initiated following the implication of a food product via an epidemiological investigation. Regulatory tracebacks routinely involve onsite visits with interviews, inspections, and record collection to verify the traceback information.

However, in an effort to reduce the time from outbreak detection to implementation of effective control measures, epidemiologists are increasingly requesting assistance from regulatory partners during epidemiological investigations. Food regulatory officials are asked to determine whether a food item consumed by multiple case-patients in a cluster or outbreak has a common source of distribution or a point of convergence linking multiple clusters. Because they are time-sensitive and exploratory in nature, “informational tracebacks” (also called “epidemiological” or

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“investigational tracebacks”) may not always include the collection of all records or onsite inspections typically conducted during regulatory tracebacks. Informational tracebacks are frequently used by RRTs in outbreak investigations when the source of an outbreak has not been definitively identified. Sometimes, as informational tracebacks progress, increasingly convincing evidence is gathered regarding the source of a contaminated product. For example, all known cases may be linked to a single source or point in the distribution chain.

Traceforward investigations are similar to tracebacks in that they are collecting food supply chain documentation, but they trace contaminated food from the source of contamination (e.g. at the manufacturer, farm, etc.) *forward* through the supply chain to the final consumer. Traceforwards are regulatory in nature since they begin with a confirmed contaminated food product and take place as part of recall response actions. Their purpose is to identify all product types that potentially became contaminated from the original source and where these contaminated products were distributed and sold. The ultimate goal is to remove contaminated products from the marketplace and notify consumers about the products. Traceforwards may happen in conjunction with a traceback investigation if a source is identified and a recall is initiated, or may happen independently when a contaminated food is identified.

FFSD traceback and traceforward investigations often involve communication and collaboration among multiple agencies, including MDA’s delegated agencies, FDA Minneapolis District Office (MIN-DO), and the Minnesota Department of Health (MDH). Specific communication procedures during response are outlined in *RESP.50.05 – RRT Communications SOP*.

4. RESPONSIBILITY

Response, Training and Outreach (RTO) Supervisor – The RTO Supervisor will oversee RRT staff in completion of traceback and traceforward investigations. The RTO Supervisor also provides guidance and subject matter expertise during the process.

RRT Coordinator – The RRT Coordinator will be responsible for completion of traceback and traceforward investigations, identifying staff to complete onsite data collection, recording of all documentation associated with the investigations, and sharing information with relevant agencies.

RRT Investigator/Analyst – The RRT Investigator/Analyst will be responsible for assisting the RRT Coordinator with completion of traceback and traceforward investigations, particularly the recording of all documentation associated with the investigations.

Food Supervisor – The Food Supervisor will identify staff to complete onsite data collection and oversee completion of document collection by FFSD Inspector as a part of a traceback or traceforward investigation.

Food Inspector – The Food Inspector will assist in conducting document collection as a part of a traceback or traceforward investigation.

5. DEFINITIONS

Hazard: Any biological, chemical, or physical agent in food that is reasonably likely to cause illness or injury in the absence of its control.

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

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include: facility standard operating procedures including 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 a paper or electronic format.

Informational Traceback (also known as epidemiological or investigational traceback): Food or product investigations conducted to support epidemiological investigations by determining whether food items consumed by multiple case-patients in a cluster or outbreak have a common source or distribution point. This type of traceback can be helpful during the preliminary stages of an investigation, and involves gathering data about product distribution from at least one of the companies involved in the suspected flow of product from its source to the point-of-sale. The information can help show product distribution or patterns; however, it is often incomplete and does not verify the chronological order of shipments through verified documentation at each point in the distribution chain. This may sometimes be referred to as an epidemiological traceback. While informational tracebacks progress rapidly, results should be confirmed by regulatory traceback prior to use as regulatory evidence.

Receiving Records: Records documenting the source(s) of products or ingredients of interest during the time period of interest. Examples include: purchase orders, bills of lading, and invoices. These documents may exist in a paper or electronic format.

Regulatory Traceback: Food product investigations used to determine and officially document distribution of a contaminated food product from points of exposure to its best identifiable common source. Sufficient documentation is gathered to support additional regulatory actions, if needed, to ensure adulterated food and/or feed is removed from commerce through a trace forward or recall.

Sales/Shipping Receipts: Records documenting the distribution of products of interest after they left the facility. Examples include: shopper cards at retail level, and distribution records for processors/distributors. These documents may exist in a paper or electronic format.

Traceback Flow Diagram: A visual reference illustrating each level of the investigation as it branches from the point-of-service to its original source(s). Attachment B is an informational traceback example that combines both timeline and flow diagram elements into a single document.

Traceback Investigation (also spelled “trace back”):

(a) Method used to determine the source and scope of the product/processes associated with an outbreak and document the distribution and production chain of the product that has been implicated in a foodborne illness or outbreak. (Multistate Foodborne Outbreak Investigations Guidelines for Improving Coordination and Communications, National Food Safety System Project, Outbreak Coordination and Investigation Workgroup, February 2001)

(b) Process by which the origin or source of a cluster of contaminated food is identified. (see Council to Improve Foodborne Outbreak Response (CIFOR) Guidelines for Foodborne Disease Outbreak Response.)

Traceback Timeframe: For a traceback investigation, a timeframe of interest will be determined depending on the type of product, product shelf life, onset and length of any associated illness,

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among other factors. If it is an FDA traceback, the FDA Coordinated Outbreak Response Evaluation (CORE) Network will determine the timeframe with feedback from the FDA district offices and the CDC. CORE will issue these start-end dates in any related assignments and all documentation collected by the food safety inspectors for the investigation must include anything produced within the timeframe. While fewer records may be needed at the point of service (versus further in the supply chain), it is important to collect all information to identify patterns. The investigators are crucial for finding out if there is a “key” that may be needed to decode records.

Traceback Timeline: A visual reference that provides information on inventories on given dates, as well as the receipt and/or shipment dates of deliveries made to each level of distribution of the product(s) of interest. Attachment A is a regulatory traceback example from an existing FDA guidance document.

Traceforward Investigation (also spelled “trace forward”): Method to determine the distribution and disposition of contaminated product from the source of the contamination forward through the food supply chain. A traceforward investigation begins with the source/farm or manufacturer/distributor and traces forward to the consumer.

6. PROCEDURES

6.1 Initiate an INFORMATIONAL TRACEBACK Investigation – RRT Coordinator

- 6.1.1** Determine if an informational traceback investigation should be initiated. Consider the questions and factors outlined in Table 1. Factors to Determine Appropriateness of a Traceback Investigation of an Outbreak:

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

Factor	Examples Favoring Initiation Of A Traceback
Has a potentially severe public health risk been identified with a food/feed product suspected to be the vehicle of transmission?	Irreversible health state/conditions, life threatening illness, or death of humans or animals.
How strong is the evidence that the cases of illness may be related?	1. Epidemiological subject matter experts indicate the cluster/outbreak is significant. 2. Cases are laboratory confirmed with indistinguishable genetic fingerprint patterns (e.g. Pulsed-Field Gel Electrophoresis (PFGE), Whole Genome Sequencing (WGS), or Multi-Locus Variable-number tandem repeat Analysis (MLVA)).
Is there a high confidence that the product or ingredient in question was consumed one or more times during the time period of interest?	Interviews of case-patients with good food history recall identify very few food items potentially associated with illnesses and no obvious non-food common exposure(s) that can explain the outbreak.
Are the consumption dates for cases known?	The following types of dates can serve as basis for tracebacks (most preferred type listed first): 1. Specific consumption dates 2. Illness onset dates 3. Isolation dates
Is an accurate food/product description available?	Availability of receipts, shopper card information, product labels or photos.
Is there accurate information regarding the place of exposure/purchase?	Receipts, shopper card information, credit card receipts, invoices.

6.1.2 If the criteria to initiate an informational traceback investigation are met, contact appropriate MDA staff and involved agency(ies). If the traceback is in response to a foodborne illness outbreak, provide the following epidemiological background information:

- a. Brief written summary describing the outbreak and cases, including the earliest and latest points of exposure, symptoms, geographic distribution of cases, and whether cases have leftover product of interest;
- b. De-identified line list of cases;
- c. Results of preliminary case-control study (if conducted);

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- d. Epidemic curve for Minnesota cases and for multi-state cases (if applicable);
 - e. Description of the product of interest, including type of food (as specific as possible), brand name, label description, lot codes, and any other unique identifiers that may be available (UPCs, PLUs, etc.);
 - f. Purchase date(s) linked to specific retail food locations verified with receipts or shopper card information, if possible (note that it may be necessary to request documented permission from the case requesting that their shopper card history be released by the store to investigators);
 - g. Menu item that included the food item of interest, if purchased from a food service establishment or restaurant;
 - h. Consumption date and menu for the week before illness if the food was consumed at an institutional facility (e.g. long-term care facility, school cafeteria, prison);
 - i. Information on any cases with product available for testing (with permission for regulatory agency to contact the individual and obtain samples);
 - j. If necessary, a permission form allowing their shopper card history 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.
- 6.1.3** If there are multiple exposures of interest, prioritize the exposures to trace. High-priority exposures often meet the following criteria:
- a. Clear, documented details are available;
 - b. Exposure is shared by two or more case-patients (e.g. ate at the same restaurant, shopped at the same grocery store, report the same brand or variety of the suspect food item);
 - c. The geographic and/or temporal dispersion of exposures indicate the exposures are related.
- 6.1.4** Determine whether a telephone or onsite traceback is most appropriate using Table 2. Factors to Consider When Determining the Most Appropriate Method(s) for Gathering Informational Traceback Information. If conducting a telephone traceback, follow 6.2. If conducting an onsite traceback, skip to 6.3.
- 6.1.5** If the traceback must take place at a Minnesota Department of Health (MDH) regulated facility, share the required *Traceback Information Gathering Worksheet* with the lead epidemiologist for the investigation. Multiple worksheets may be required if multiple food items are being traced. The worksheet(s) will be shared with the MDH inspection staff and supervisor responsible for the facility. Reference the *MOU with the Minnesota Department of Health* for additional guidance on interactions with MDH.

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Table 2. Factors to Consider When Determining the Most Appropriate Method(s) for Gathering Informational Traceback Information.

Information Type	Factors Suggesting Telephone/Email 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). Note: If all cases can be linked to a single point in a distribution or production chain, an on-site environmental assessment or investigation of that common point should be conducted to assess the potential for on-site introduction of contamination.
Ordering, Receiving, and Shipping Practices	Firms with a consistent track record of maintaining accurate and reliable shipping and receiving records indicate that they can provide electronic or hard copies of requested information. If certain data elements cannot be clarified over the phone (e.g., the meaning of dates on invoices or bills of lading) or if it is important to assess exceptional events (e.g. special sales, emergency orders purchased with cash), then an on-site visit may be necessary.
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). Otherwise, an onsite environmental assessment or investigation is often in order.
Stock rotation practices	Firms with a proven track record of maintaining accurate and reliable inventory management systems and records indicate that they can provide electronic or hard copies of requested information. If inconsistent information is provided, then a close examination of stock rotation practices during an onsite visit may be required.

6.2 Conduct an INFORMATIONAL TRACEBACK via telephone or email – RRT Coordinator

6.2.1 Identify the most senior food safety professional within the firm's organization (e.g. the Vice President of Food Safety and Quality Control) if a telephone or email traceback is determined to be appropriate. Contact information for previously-contacted personnel is located in the *Industry Investigation and Traceback Contacts* list located on the RRT SharePoint site. Contact can be made via telephone or email. Provide the following information:

- a. If associated with an illness outbreak: basic, de-identified summary of the current epidemiological investigation (pathogen name, number of cases, range of onset dates) emphasizing that no specific food item has been identified as the source of the outbreak;
- b. Reference to the statutory authority for obtaining records;

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- c. Deadlines for the receipt of requested information.
 - 6.2.2 Request documentation for traceback, including date range of interest and detailed description of the food items of interest. Use the Traceback Information Gathering Worksheet to standardize data collection for consistency and completeness of information gathering. Examples of records to be collected include, but are not limited to:
 - a. Invoices
 - b. Shipping and receiving records
 - c. Bills of lading
 - d. Inventory records
 - e. Label information
 - f. Container type and size
 - g. Lot codes
 - h. UPCs, GTINs, PLUs, and/or SKUs
 - i. Production or pull dates
 - j. Product origin
 - k. Other identifying information for the implicated product (e.g. color, grade, etc.)
 - 6.2.3 If traceback is discussed via telephone, follow-up the call with an email summarizing the information listed in 6.2.1 and 6.2.2.
 - 6.2.4 Consult Table 3. Solutions to Common Problems during a Traceback Investigation for solutions to common issues or obstacles during traceback investigations.
- 6.3 Conduct an INFORMATIONAL TRACEBACK onsite – RTO Supervisor, RRT Coordinator, RRT Investigator/Analyst, and Food Inspector**
- 6.3.1 In coordination with Food Program Supervisors, identify staff who will visit the facility if an onsite traceback is determined to be appropriate. Staff may include the RTO Supervisor, RRT Coordinator, RRT Investigator/Analyst, and/or the facility inspector. If RTO/RRT staff is unavailable, provide background and data request information to the facility inspector before the onsite visit.
 - 6.3.2 Provide the following information to the facility's point of contact while onsite:
 - a. If associated with an illness outbreak: basic, de-identified summary of the current epidemiological investigation (pathogen name, number of cases, range of onset dates) emphasizing that no specific food item has been identified as the source of the outbreak;
 - b. Reference to the statutory authority for obtaining records;

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- c. Document/records request, including date range of interest and detailed description of the food items of interest;
 - d. Deadlines for the receipt of requested information.
- 6.3.3** Conduct the record collection.
- a. During an onsite informational traceback, collect documents and observe processes that are identical to a regulatory traceback.
 - b. Use the *Traceback Information Gathering Worksheet* to standardize data collection for consistency and completeness of information gathering.
 - c. Examples of records to be collected include, but are not limited to, the list outlined in 6.2.2.
 - d. After the onsite visit, send an email to the facility of interest summarizing the information discussed in 6.3.2 and 6.3.3.
- 6.3.4** If the traceback must take place at a Minnesota Department of Health (MDH) regulated facility, share the required *Traceback Information Gathering Worksheet* with the lead epidemiologist for the investigation. Multiple worksheets may be required if multiple food items are being traced. The worksheet(s) will be shared with the MDH inspection staff and supervisor responsible for the facility. Reference the *MOU with the Minnesota Department of Health* for additional guidance on interactions with MDH.
- 6.3.5** Consult Table 3. Solutions to Common Problems during a Traceback Investigation for solutions to common issues or obstacles during traceback investigation:

Issue	Problem	Solutions
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Firms are slow in providing requested documents	<ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> Cite Minnesota Statutes 17.984 and 31.04. Provide clear and concise summaries of available epidemiologic, laboratory, and environmental health evidence to firm decision-makers. Clearly identify the specific information being requested – time period 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	<ul style="list-style-type: none"> Non-existent records 	<ul style="list-style-type: none"> 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.
Voluminous paper-based records	<ul style="list-style-type: none"> Firm provides requested records in paper only format. 	<ul style="list-style-type: none"> Request that firm provide records in a <i>searchable</i> electronic format, if available. Sometimes firms will not 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.

Table 3. Solutions to Common Problems during a Traceback Investigation.

6.4 Initiate a REGULATORY TRACEBACK Investigation – RRT COORDINATOR

- 6.4.1** Determine if a traceback investigation should be initiated. Consider the factors in Table 4. Potential Triggers of Regulatory Tracebacks and Regulatory Agency Actions:

Table 4. Potential Triggers of Regulatory Tracebacks and Regulatory Agency Actions

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Events that may trigger Regulatory Traceback	Actions of Regulatory Agency			
	Contact Firm	Issue Consumer Advisory/Press Release (Typically for situations warranting Class 1 Recalls)	Recall Required	Initiate Regulatory Traceback
(1) A specific food/feed item is associated with foodborne illnesses or found to be adulterated by laboratory testing (contains a HAZARD) or routine inspection and...				
(1a) Food item is still in commerce or available for consumption	Inform firm and share epidemiological evidence (include epidemiologic agency) Firm should submit RFR (if it qualifies as a Class I Recall).	Inform firm of the need to notify public through consumer advisory (coordinate with epidemiologic agency)	Recall required; firm to contact the appropriate FDA District Office and make notifications up and down their distribution.	Collect necessary distribution documents. Determine if additional lots or ingredients may be contaminated.
(1b) Food item is NOT in commerce or available for consumption	Inform firm and share epidemiological evidence (include epidemiologic agency)	No consumer advisory required unless additional lots/ingredients identified. Consider including summary of outbreak/investigation in annual summary (coordinate with epidemiologic agency).	Recall may be required on other products if regulatory traceback identifies other potentially contaminated lots or ingredients.	Collect necessary distribution documents. Determine if additional lots or ingredients may be contaminated.
(2) Report of contamination has been made to the Reportable Food Registry (RFR) (firm has identified a HAZARD)				
	Firm should already be aware; request additional information if necessary.	Consumer Advisory may be necessary if product is in commerce or available for consumption AND firm hasn't issued press release	Recall required if food item still in commerce or available for consumption; firm to contact FDA District Office	Collect necessary distribution documents. Determine if additional lots or ingredients may be contaminated. Contact epidemiologic agency to determine if any associated illnesses have been reported.

6.4.2 If the criteria to initiate a regulatory traceback investigation are met, contact appropriate MDA staff and involved regulatory agency(ies) and provide the following epidemiological background information:

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- a. If associated with an illness outbreak: brief written summary describing the outbreak and cases, including the earliest and latest points of exposure, symptoms, geographic distribution of cases, laboratory testing;
- b. If associated with an illness outbreak: de-identified line list of cases;
- c. Results and design of epidemiological studies (if conducted);
- d. Description of the product of interest, including type of food (as specific as possible), brand name, label description, lot codes, and any other unique identifiers that may be available (UPCs, PLUs, etc.).

6.4.3 Determine whether a telephone or onsite traceback is most appropriate using Table 2. If conducting a telephone traceback, follow 6.5. If conducting an onsite traceback, skip to 6.6.

6.5 Conduct a REGULATORY TRACEBACK via telephone – RRT Coordinator

6.5.1 Identify the most senior food safety professional within the firm's organization (e.g. the Vice President of Food Safety and Quality Control) if a telephone traceback is determined to be appropriate. Contact information for previously-contacted personnel is available in the *Industry Investigation and Traceback Contacts* list located on the RRT SharePoint site. Contact can be made via telephone or email. Provide information summarized in 6.2.1. If contact is made via email, use the *Traceback Information Request Template* to draft the email.

6.5.2 Request documentation for traceback, including date range of interest and detailed description of the food items of interest. Use the *Traceback Information Gathering Worksheet* to standardize data collection for consistency and completeness of information gathering. Note that documentation must be provided for all steps in the flow of the food item from consumer to source for a complete regulatory traceback. Examples of records to be collected include, but are not limited to the list outlined in 6.2.2. If traceback is discussed via telephone, follow up phone call with email communication summarizing the information listed in 6.5.1 and 6.5.2, using the *Traceback Information Request Template*.

6.6 Conduct a REGULATORY TRACEBACK onsite – RTO Supervisor, RRT Coordinator, RRT Investigator/Analyst, and Food Inspector

6.6.1 Identify the staff person or people who will visit the facility if an onsite traceback is determined to be appropriate in coordination with food supervisors. This may include the RTO Supervisor, RRT Coordinator, RRT Investigator/Analyst, and/or the facility inspector. If RRT staff is unavailable, provide background and data request information to the facility inspector before the onsite visit.

6.6.2 Provide the following information while onsite:

- a. Basic, de-identified summary of the current epidemiological investigation (pathogen name, number of cases, range of onset dates)

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emphasizing that no specific food item has been identified as the source of the outbreak;

- b. Reference to the statutory authority for obtaining records;
- c. Document/records request, including date range of interest and detailed description of the food items of interest;
- d. Deadlines for the receipt of requested information.

6.6.3 Conduct record collection. Use the *Traceback Information Gathering Worksheet* to standardize data collection for consistency and completeness. Examples of records to be collected include, but are not limited to the list outlined in 6.2.2. Determine product-ordering practices:

- a. How and when the product is ordered,
- b. Average daily use,
- c. What is done if the establishment runs out of product before another shipment is received (e.g., purchase from grocery store, request more from supplier, etc.),
- d. How deliveries and receipt dates are recorded,
- e. Shipping dates and dates received,
- f. Suppliers during the time period of interest, including cash transactions,
- g. Transportation time from supplier(s) to the establishment,
- h. Repacking of product during distribution,
- i. How the product is unloaded and added to existing inventory,
- j. If implicated food item is used as ingredient in preparation or manufacturer of another food item,
- k. How stock inventory is recorded,
- l. How partial cases/containers are accounted for,
- m. How and if carryover is recorded,
- n. If an inventory record is available for the time period of interest, and
- o. Standard procedures for stock rotation (i.e. how product is unloaded and added to existing inventory) and if first-in-first-out (FIFO) rotation policy is standard operating procedure and how closely it is adhered to.

6.6.4 Follow up the onsite visit with email communication summarizing the information discussed in 6.6.2 and 6.6.3.

6.6.5 Consult Table 3 for solutions to common issues or obstacles during traceback investigations.

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6.6.6 If the traceback must take place at a Minnesota Department of Health (MDH) regulated facility, share the required *Traceback Information Gathering Worksheet* with the lead epidemiologist for the investigation. Multiple worksheets may be required if multiple food items are being traced. The worksheet(s) will be shared with the MDH inspection staff and supervisor responsible for the facility. Reference the *MOU with the Minnesota Department of Health* for additional guidance on interactions with MDH.

6.7 Complete a TRACEBACK INVESTIGATION – RRT Coordinator

- 6.7.1** Upon receipt of requested traceback documentation, construct a traceback diagram and/or timeline to visualize the flow of product and help identify points of convergence. The diagram should detail names, locations, amounts, and dates of receipt and shipment. See Appendix B for an example of a traceback diagram.
- 6.7.2** If product(s) of interest are linked to a common source or other distribution point, consider conducting an environmental assessment to identify and assess contributing factors (e.g. cross contamination, ill food workers, and other onsite sources of contamination) and environmental antecedents.
- 6.7.3** Create a summary of information gathered from observations, interviews and records collected from every firm. This includes:
- a. Summary of shipment dates and amounts of the implicated food item(s) that will allow items in invoices to be visualized.
 - b. A completed traceback questionnaire (if used). See Appendix D.
 - c. Copies of invoices, bills of lading, daily inventories, HACCP plan(s), etc.
 - d. Photos of relevant finding, including process flow and traceability elements (unique identifiers or codes).
 - e. If onsite traceback takes place, a complete inspection report detailing the type and nature of records requested and supplied.
 - f. A completed questionnaire for each visit (if used).
- 6.7.4** Include copies of paperwork from each level of the distribution system (as possible) in the report if a regulatory traceback is completed. For distributor-level investigations, request documentation regarding any onsite processing, packaging, and/or repacking of implicated product.
- 6.7.5** Verify label and product information with invoices and shipping receipts for the time period in question. Collect product information (labeling, lot codes, etc.) for the product that was used during the outbreak exposure time period.
- 6.7.6** Verify any hand written comments and marks on the documents and their meaning/significance.

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6.7.7 Share traceback information with all involved agencies, including FDA. FDA is responsible for sharing with federal partners, including CDC.

6.8 Conduct Traceback Analysis – RRT Coordinator

6.8.1 Analyze and discuss the data from each level of the investigation (example: retail, distribution, production) before continuing the investigation to the next level.

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

6.8.3 Share traceback analysis with all involved agencies, including FDA. FDA is responsible for sharing with additional federal partners, including CDC.

6.9 Initiate a TRACEFORWARD INVESTIGATION– RRT Coordinator

6.9.1 Initiate a traceforward investigation when the source of contamination is identified. Note that a traceforward investigation may be initiated prior to completion of a traceback, though this is not routinely advised.

6.9.2 If the traceforward investigation is occurring as part of a recall follow-up or recall effectiveness check assignment, follow procedures in *FOOD.30.06 – Inspection Recall Removal SOP* or *RESP.50.15 – Recall Effectiveness Check SOP*, respectively.

6.9.3 Work with Food Program Supervisors and Food Program Management to identify the staff person or people who will visit the facility if any onsite traceforward actions are determined to be appropriate. This may include the RRT Coordinator, other RRT staff, and/or the facility inspector. If RRT staff is unavailable, provide background and data request information to the facility inspector before the onsite visit.

6.9.4 Collect records for the timeframe of interest, which should include the timeframe that the contaminated product was being distributed. Examples of records to be collected include, but are not limited to the list outlined in 6.2.2.

6.9.5 Determine product-ordering practices as outlined in 6.3.3.

6.10 Complete a TRACEFORWARD INVESTIGATION – RRT Coordinator

6.10.1 Create a summary of information gathered upon receipt of requested traceforward documentation. This includes the list summarized in 6.7.3.

6.10.2 Analyze and discuss the data from each level of the investigation (example: retail, distribution, production) before continuing the investigation to the next level.

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

6.10.4 Identify all product types that potentially became contaminated from the original source and where these contaminated products were distributed and sold.

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6.10.5 Share traceforward information with all involved agencies, including FDA. FDA is responsible for sharing with additional federal partners, including the CDC.

6.11 Traceback and Traceforward Investigations – RRT Investigator/Analyst

6.11.1 Assist the RRT Coordinator with completion of traceback and traceforward investigations. By request of the RTO Supervisor or RRT Coordinator, this may include, but is not limited to the following:

- a. Create summaries of the outbreak or investigations,
- b. Organize and recording documentation collected during a traceback or traceforward information,
- c. Provide information to inspectors conducting onsite traceback or traceforward data collection (including the *Traceback Information Gathering Worksheet*),
- d. Visit the firm with other FFSD or RRT staff to complete an onsite traceback or traceforward,
- e. Conduct telephone traceback or traceforward,
- f. Develop traceback diagram (*Attachment A*) and/or timeline, and
- g. Assist in analysis of data from each level of the investigation.

6.12 Traceback and Traceforward Investigations – RTO Supervisor

6.12.1 Serve as the main contact for traceback or traceforward investigations in the absence of the RRT Coordinator.

6.12.2 Provide guidance and subject matter expertise to the RRT Investigator/Analyst and RRT Coordinator throughout traceback and traceforward investigations. This may include, but is not limited to the following:

- a. Assist in determining if traceback should be initiated,
- b. Assist in determining if an informational or regulatory investigation should be conducted,
- c. Assist in determining if a telephone or onsite trace is most appropriate,
- d. Assist in identifying appropriate staff to conduct onsite traceback or traceforward work,
- e. Assist in prioritizing products to trace, and
- f. Provide guidance during analysis of data from the investigation.

6.13 Traceback and Traceforward Investigations – Food Inspector

6.13.1 Assist RRT Coordinator and/or RRT Investigator/Analyst during onsite traceback or traceforward investigations. This may include, but is not limited to the following actions:

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- a. Visit the firm with other FFSD or RRT staff to complete an onsite traceback or traceforward,
- b. Provide information to the firm about the investigation as provided by the RRT Coordinator, and
- c. Conduct record collection using the *Traceback Information Gathering Worksheet*, as requested by the RRT Coordinator.

6.14 Traceback and Traceforward Investigations – Food Supervisor

- 6.14.1** Work with the RRT Coordinator to identify the staff person or people who will visit the facility if any onsite traceback or traceforward actions are determined to be appropriate in coordination with food supervisors and program managers. This may include the RTO Supervisor, RRT Coordinator, RRT Investigator/Analyst, and/or the facility inspector.
- 6.14.2** Oversee completion of document collection by FFSD Inspector as a part of a traceback or traceforward investigation.
- 6.14.3** Provide guidance and subject matter expertise throughout traceforward and traceback investigations.

7. RELATED DOCUMENTS (includes References, Attachments)

Attachment A – Example of Traceback Product Flow Diagram

FOOD.30.06 – Inspection Recall Removal SOP

RESP.50.05 – RRT Communications SOP

RESP.50.15 – Recall Effectiveness Check SOP

Industry Investigation and Traceback Contacts list

MOU with the Minnesota Department of Health

Traceback Information Gathering Worksheet

Traceback Information Request Template

FDA Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations - June 2006

FDA Investigations Operations Manual, Subchapter 8.3 – INVESTIGATION OF FOODBORNE OUTBREAKS – April 2016

“Product Tracing in Epidemiologic Investigations of Outbreaks due to Commercially Distributed Food Items – Application, Utility, and Considerations” by Smith, K., Miller, B., Williams, I., et al, 2010.

Council to Improve Foodborne Outbreak Response (CIFOR) Guidelines for Foodborne Disease Outbreak Response (Section 5.2.4.1.6)

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Procedures to Investigate Foodborne Illness, 6th Edition 2011, International Association for Food Protection (IAFP)

RRT Best Practices Manual (January 2013 Edition)

8. EQUIPMENT/MATERIALS NEEDED

Microsoft Visio, PowerPoint, or similar software to generate process flow diagrams.

Adobe Acrobat Pro or similar software to search and organize scanned documents.

9. SAFETY

All MDA employees must follow the personal protective equipment requirements and field safety guidelines outlined in the initial and annual Food Inspector safety training. Never enter an area or perform any job task that you think will result in injury or illness. If you do identify any unsafe conditions – STOP the inspection immediately and consult with the facility management or your supervisor regarding a corrective action for the hazard(s). Lastly, stick to the specific focus of your position and as always – THINK SAFETY!

Food inspection staff must follow the Verbal and Physical Assault of State Agriculture Inspectors Policy. If the firm's operators have a history of hostile behavior, speak with your supervisor before conducting inspection. Before performing an inspection, ask firm about any physical or chemical safety issues in the firm. If the inspector has concerns about in-facility safety, please contact supervisor.

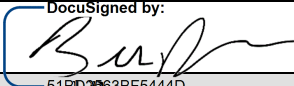
10. CIRCULATION

This document will be circulated to the following groups: FFSD Manufactured Food and Retail Food Program Inspectors, FFSD Manufactured Food and Retail Food Management and Supervisory Staff, and RRT staff including RTO Supervisor, RRT Coordinator, and RRT Investigator/Analyst. This document will also be made available upon request to other local, state, and federal agencies that participate in traceback and traceforward investigations. The current version will be stored electronically on the FFSD document control site.

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11. APPROVAL/DOCUMENT HISTORY

Document History		
Version #	Status (I, R)	Change History
1	R	Previous version FOOD.50.08 – Traceback and Traceforward Investigations SOP transferred to RESP.50.08. Updates made to reflect division structure changes from DFID to FFSD and responsibility changes within the SOP.
1.1	R	Removed DRAFT watermark from the document and added reporting to the CDC in sections 6.7.7, 6.8.3, and 6.10.5.
2	R	Addition of hazard, receiving records, sales/shipping records, and traceback timeframe to the definitions section; changes reflected in the 2016 RRT Best Practices Manual Traceback Chapter; updated Informational Traceback definition; updates to tables; removed Attachments A, D, and C; removed CalFERT Questionnaires from related documents and added Traceback Information Gathering Worksheet and Traceback Information Request Template.
DocuSigned by: 		12/23/2016
Approved By:		Date
Approved By:		Date

I = Initial document; R = Revised document

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Attachment A – Example of Traceback Product Flow Diagram

