GUIDE TO INVESTIGATION OF EGGS AND FARMS IMPLICATED IN FOODBORNE OUTBREAKS OF *SALMONELLA ENTERITIDIS*

This Inspection Guide is intended to provide guidance and instructions to FDA staff for obtaining information to help fulfill the Agency's plans regarding follow-up to findings of Salmonella Enteritidis in Eggs. The Inspection Guide does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations. It is intended for FDA personnel and is available electronically to the public.

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INTRODUCTION

In the 1980's, *Salmonella Enteritidis* (SE) infections in humans increased on both sides of the Atlantic Ocean. The World Health Organization (WHO) Salmonella surveillance data for 1979-87 suggested that SE was increasing on the continents of North America, South America, and Europe. Although the reason for the global increase was not clear to researchers, investigations in individual countries suggested it was related to consumption of eggs and poultry that harbored the organism. In 1986, foodborne illness outbreaks involving SE were first associated with the consumption of Grade A eggs. Since then research has shown that SE infects the ovaries of hens and contaminates the eggs before the shell forms. In a letter to the Council of State and Territorial Epidemiologists, dated October 1, 2001, CDC reported 50 outbreaks of *Salmonella Enteritidis*, with a total of 861 cases, 2 deaths and 151 hospitalizations. Of these 50 outbreaks, 28 had a suspect vehicle that contained eggs.

Under the authority of the FD &C Act, the Food and Drug Administration (FDA) shares responsibility for the regulation of producers of shell eggs with the states (usually the state's Department of Agriculture). FDA also has jurisdiction over restaurants, institutions, food manufacturing plants, and similar establishments that break and serve eggs, or use them in their products. The Egg Product Inspection Act (EPIA) also gives FDA additional authority to detain eggs in violation of EPIA, even without interstate commerce. The United States Department of Agriculture (USDA) has jurisdiction over the quality of the eggs and commercial egg breaking facilities under the (EPIA).

FDA, in cooperation with other public health and agriculture officials, is focusing their efforts on achieving the reduction and eventual eradication of egg-related SE illnesses in humans. One way this is being done is by conducting traceback and farm investigations in order to determine the source of the eggs and the contamination.

EGG TRACEBACK PROCEDURES

An egg traceback is the method used to determine and document the distribution chain and the source of the eggs that have been implicated in a foodborne illness investigation. An egg traceback involves good interviewing techniques, a complete record review, and

timely reporting to meet its intended purpose. A subsequent source investigation may be conducted at the farm(s) identified in the traceback investigation.

The tools and interviewing techniques outlined in these instructions will help identify possible shipments, suppliers, and the source(s) that supplied the implicated eggs.

INITIATING AN EGG TRACEBACK INVESTIGATION

Some outbreak investigations have relied on the historical association between SE (or Salmonella Group D_1) and eggs as sufficient information to implicate eggs as the source of an SE outbreak; and based on this association, initiate or request an egg traceback. This is not sufficient evidence for FDA to initiate a traceback investigation. In most circumstances, FDA will not initiate an outbreak-related traceback without a review of the state/local investigational findings. The findings from an investigational study must support a scientifically sound association between the consumption of shell eggs (or a product containing shell eggs) and human illness.

FDA Office of Crisis Management/Emergency Operations Center (EOC) HFC-160, should be notified when a District Office is aware of a SE foodborne outbreak or when a state/local agency initiates an egg traceback that may involve interstate commerce.

The District Offices must refer all requests for FDA to participate in, or to conduct an egg traceback investigation to EOC (301-443-1240). EOC in turn will provide early alerts to the affected District Offices and FDA Center for Food Science and Applied Nutrition (CFSAN) when an egg traceback investigation has been requested and/or may be assigned in the near future. FDA encourages state agencies to conduct egg tracebacks in their jurisdiction using FDA procedures.

Prior to initiating an egg traceback, EOC will ask the District to obtain the following information from the state/local agencies: a written epidemiological summary, a hazard analysis or environmental and inspection reports (including a food preparation review), laboratory results, implicated egg cartons (if available), and copies of any invoices and distribution information already collected by the state/local agencies. If The Center for Disease Control (CDC) conducted or coordinated the epidemiological investigation, EOC will request the information from CDC.

Other factors that will be considered by the EOC and CFSAN prior to initiating an FDA traceback include evidence of interstate commerce, disease severity, the risk of ongoing exposure, the availability of shipping records, reliable exposure data, the size and scope of the outbreak(s), and the availability of resources to conduct the investigations. Timing is also a major factor in determining the appropriate response to an egg-related outbreak.

Only the EOC can generate egg traceback assignments. All traceback assignments including inter-district traceback work requests will be assigned in Field Accomplishments and Compliance Tracking System (FACTS) by the EOC, under Program Assignment Code (PAC) 03R264 – *Salmonella Enteritidis* in Eggs Emergency.

TRACEBACK COORDINATION

When a traceback investigation has been assigned to you (the investigator) in FACTS, you must contact the EOC to discuss the assignment. Your District may wish to include your supervisor or other designated person(s) on this initial call. You will have frequent communication with the EOC coordinator throughout the investigation.

Upon completion of each traceback step, you must contact the EOC coordinator to discuss the data analysis and the next stage of the traceback. The District may choose to have other individuals participate in these ongoing discussions, for training or other reasons. After each firm visit, a copy of the records you collected must be faxed to EOC (301-827-3333). If there are a large number of records, they may be sent by overnight mail to FDA Emergency Operations Center, HFC-160, 5600 Fishers Lane, Room 12A-55, Rockville, Maryland 20857.

There are several reasons why this communication and coordination with EOC is a critical component of traceback investigations. The EOC coordinator will be the main communication point, receiving and analyzing data that will help to guide the investigations. This central coordination will allow earlier notification to the District Offices of assignments, provide the District management with greater flexibility in assigning traceback work, provide training opportunities for investigators, eliminate repetitive or unnecessary work, and improve FDA's overall response time.

PRODUCT SAMPLES

If any of the original eggs (same shipment date, code, size, color, type, etc.) or food prepared with the eggs from the implicated meal(s), or the egg carton from these eggs is available, it should be collected. Unless otherwise directed, eggs and labels from later shipments should not be collected.

USE OF FDA REPORTS AND FORMS IN TRACEBACK INVESTIGATIONS

FDA 463A – Affidavits are not required to be used in a traceback investigation. All pertinent information and discrepancies that are noted during the investigation should be explained in the memo. The following are examples when you ***may*** chose to use an affidavit during a traceback investigation:

1) to provide an explanation of inaccurate shipping records or written mistakes on records that cannot be verified or documented using other records but can be explained by an employee.
2) to describe the personal knowledge or belief of an employee regarding the shipping and/or handling of the implicated product which is not supported by other documents or other interviews and would have a direct bearing on the analysis of the records.

FDA 482, Notice of Inspection - an FDA 482 should be issued to each firm that is visited in the course of the traceback investigation. *Memo* - if you conduct a food preparation review at the point of service, this information can be reported in a memo. *FDA 483 List of Observations, Establishment Inspection Report, and FMD 145 Post-inspection Letter* - if you conduct a domestic establishment inspection as a result of a traceback investigation, the procedures regarding these inspections and forms are outlined in the IOM and should be followed.

A traceback assignment is an investigation. It is not necessarily an inspection and it is not solely a record collection activity. Your management may decide that they want you to conduct an inspection while you are there. If that is the case, due to the nature of the traceback investigation (response to foodborne illnesses), the traceback work will take priority over any inspectional work. A FDA-482 Notice of Inspection, will be issued to each firm that is visited during a traceback investigation regardless if a standard inspection is planned.

TRACEBACK REPORTS

You will be responsible for generating a final report for the portion of the traceback investigation that was assigned to you. The traceback report consists of a FACTS cover sheet with your supervisor's endorsement, the Freedom of Information (FOI) statement (see next section), a timeline and flow diagram **and for each firm** you visited, the following items are to be included:

- FDA 482
- Invoices, inventory records, shipping/receiving records (including records and information obtained from other agencies).
- A memo summarizing the information gathered from the observations and interviews at the firm, including explanations of the data analysis (i.e., how receipt dates were determined).
- Affidavits (if used).

In addition to the flow diagram that you received from EOC at the completion of your assignment, EOC will also send a final flow diagram to you when the entire investigation is complete.

Your final traceback report is to be maintained in your District Office and a copy sent to EOC, HFC-160. The EOC copy does not need to include a copy of the shipping records, as these have already been mailed or faxed to EOC. This final traceback report is not an Establishment Inspection Report (EIR) and is separate from the EIR for a Farm Investigation. EOC will send the final traceback packet to CFSAN for their review.

If an inspection is conducted at a firm visited as part of the traceback investigation, an EIR will be written in accordance with standard procedures. This EIR is a separate report from the traceback report (memo and records) and does not replace the traceback report.

REQUESTS FOR INFORMATION

FOI Requests

You must include the following statement in your final traceback report: "All FOI requests or other inquiries for release of foodborne outbreak and traceback investigations should be referred to EOC (HFC-160)." It is recommended that this statement be in bold lettering at the bottom of the cover page and may be included as part of your supervisor's endorsement. Some of the information collected in the course of these investigations is non-public, e.g., commercial confidential information and is not to be released even after the investigation is closed.

Release of Information to FDA Commissioned Officers

Prior to releasing any foodborne outbreak and traceback documents to a state or local official who is a FDA Commissioned Officer, you should contact EOC. EOC will work with the Division of Federal-State Relations (DFSR) to verify the status of the commission and the 20.88 Certification Commitment form to determine what information can be released. Any information and records collected *jointly and in-person* with state/local investigators may be shared with their agency without concern.

Partnership Agreements

Some states have an existing partnership agreement with FDA. EOC will work with DFSR regarding the identification of the appropriate state official and the

release of information to that official under existing partnership agreements.

TRACEBACK RESPONSIBILITIES

You, the investigator, are responsible for completing the following tasks:

1. If requested, obtain the following information from the state/local agencies (if available) and provide a copy to EOC (See detailed Checklist in Attachment 1 for specific items to request):
    - Epidemiological data
    - Environmental inspection
    - Preliminary traceback and distribution information
    - Implicated product name and any available packaging, labeling, color, size, grading, and packing
2. Obtain the following from EOC:
    - Coordinator name and contact number(s)
    - Dates for record collection
    - FACTS Assignment Number
    - Traceback Event Code
    - Timeline
    - Flow Diagram
3. Review the background information with EOC prior to visiting a firm.
4. Coordinate with state and/or local investigators. In coordination with DFSR & EOC a courtesy call should be made to both the state health and state agriculture representative when a traceback is initiated in a state.
5. Conduct an investigation and record collection at each implicated firm, in the order it is assigned.
6. Analyze the data. Fax (or overnight) a copy of the records to EOC after each firm is visited. Discuss analysis and next steps with the EOC Coordinator before proceeding to the next implicated firm.
7. Repeat Steps 5 and 6 until either a potential farm(s) is identified or an implicated firm is located out of your area of responsibility.
8. Summarize each firm investigation in a memo.
9. Send EOC (HFC-160) a copy of the traceback report.
10. Lead or participate in farm investigations, if requested.

The EOC Coordinator is responsible for completing the following tasks:

1. Obtain a written summary of all available epidemiological, environmental and laboratory data from the District Office(s) or CDC (if applicable).
2. Generate FACTS assignments and Traceback Event Codes.
3. Conduct a conference call with investigator to discuss and share the background information on the outbreaks and the assignment. Provide the dates of the 30-day record collection period.
4. Maintain regular contact with the investigator.
5. Review traceback records and data analysis.
6. Conduct or assist with data analysis, as needed.
7. Provide training to investigators, as needed.
8. Update and distribute the timeline and flow diagram to the investigators throughout investigation.
9. Issue Inter-District traceback assignments in FACTS.
10. Compile a final report for EOC that includes each investigator's report and the final timelines and flow diagrams.
11. Communicate findings to the District Investigators and CFSAN. Provide a final flow diagram to all of the Districts that participated in the investigation and CFSAN when the traceback(s) are complete. Using appropriate confidentiality agreements, release findings to other agencies (i.e., CDC, USDA, State agencies) when requested and approved by EOC management.
12. Work with District management and CFSAN to identify investigators to lead and participate in domestic farm investigations.
13. Complete FOI requests using guidelines pertaining to release of Commercial Confidential Information (including Q & A for disclosing traceback data). EOC Management should review the documents prior to release of information.

METHODS AND ANALYSIS

POINT-OF-SERVICE (POS) INVESTIGATION

In a traceback investigation, the Point-of-Service (POS) is understood to be the point-of-sale to the consumer. Although the consumers are exposed to the food at home or other locations, it is the retail establishment (e.g. restaurant, caterer, grocer) that is the usual starting point of the records collection. You will be given specific instructions as to where to begin your traceback investigation.

The goal of the point-of-service (POS) investigation is to determine and understand the firm's ordering, receiving, stock rotation, inventory, and food preparation procedures and to obtain the appropriate records and documentation. By understanding how the eggs are received, recorded, rotated and prepared, you will be able to determine which shipments were available and most likely consumed at the implicated meal.

In addition to the record collection and review,

interviews and observations are key parts of a traceback investigation. It is not possible to do a thorough traceback investigation over the telephone. You will need to conduct the interviews, make observations, and collect records in person.

POS Interviews

If the POS is someone's home or a non-traditional place of business, the exposure data and other product information will be collected and verified by the state health agency and reviewed by FDA prior to the initiation of the traceback. In these instances, the place the consumer(s) purchased the food will be considered the point of service (e.g., grocery store, or caterer).

Conduct interviews with more than one employee at multiple levels of the organization (e.g., chef, kitchen manager, line cook) to determine the following information:

- Product Identifying Information- The firm may be using a different type of egg or a different supplier than what was used at the time of the outbreak. Only collect carton and label information for the product that was used during the outbreak exposure time period.

Include the following information in the description of the implicated eggs:

a) Shell or pasteurized
b) PackType: ½ or full case or other (basket)
c) Packing method: Loose or carton
d) Size: Jumbo, X-large, Large, Medium, Small
e) Color: White or Brown
f) Grade: AA, A, B, Nest run
g) Brand
h) Plant code and/or lot number on carton (if available)

- Shipping and Receiving Practices - Determine the receiving dates and times for each shipment in the 30-day requested time period. Indicate how the dates on the shipping records reflect the date the eggs were received. Determine how supplier deliveries are documented or recorded. Determine the firm's suppliers during this time period, including any cash transactions. Determine or estimate the transportation time from the supplier to the point-of-service.
- Handling and Storage Practices - Interview employees regarding receipt and preparation of the implicated eggs for the implicated meal, if this information hasn't already been provided by state, local authorities, or CDC.
- Stock rotation practices - Review the standard operating procedure at the firm. Determine how the eggs are unloaded and added to existing inventory. Determine if a first-in-first-out (FIFO) rotation policy is standard operating procedure and how closely it is adhered to.
- Daily (or otherwise) stock inventory - If an inventory record is available for this time period, understand how it is used, including its strengths and weaknesses, and determine what time of day the inventory is performed. Understand what each inventory number represents. Determine how partial cases or containers are accounted for, and how and if carry over is recorded.
- Ordering practices – Determine how and when eggs are ordered. Determine average daily use.
- Repacking or repackaging – If either of these occur at the POS upon receipt from a distributor, then the practice and polices used by the firm should be fully explained and understood. Determine if any of the packaging material is re-used. NOTE: Changing from grade AA to A is often reflected on invoices because distributors lump these two grades together. If you suspect this may have occurred while reviewing the records or observing practices, try to clarify how and when this occurs.

POS Observations

Observe and verify that the procedures described by employees are reflected in their actual work. Whenever possible, have the employees who regularly perform each of the tasks demonstrate their procedure. You should be able to describe the flow of the product through the firm. Walk through the receiving and shipping process and follow a shipment of eggs physically through the firm and compare it with the records (written and computerized). This information will be critical for the analysis.

POS Record Collection

Obtain a copy of all invoices, shipping and receiving records, bills-of-lading, inventory records and any other records regarding the implicated eggs that are available for the **30-day period** (beginning at the earliest date of exposure/purchase and counting backwards) and any additional records to cover the entire exposure period if it is more than one day. If the state initially conducted this portion of the traceback and did not collect the records for the time period requested, you will need to go to the POS and collect the missing records.

You will want to review the records on site. There will often be many dates and handwritten notes on the records. Determine or estimate the date of receipt. The person who is responsible for receiving the product should be able to assist in this. The shipping date, the invoice date, and/or the order date may be

the same as the receipt date or they may be used to determine the receipt date. Do not make assumptions regarding the dates on the records. Be sure to ask for an explanation of all dates on the records.

Interview the employees and determine the date and time shipments are received. Determine the transit time from the distributor shipping the product to the POS. You will need to clearly document in the memo how the receipt date was determined or estimated and how it relates to the dates on the records. You should be able to read and understand all items on the records. If the quantity printed on the record is difficult to read, it may be calculated using the unit price and total price. Be aware of the use of "dozen" or "carton" when using the unit price. Some suppliers may be reluctant to disclose pricing information. If the quantity is legible, there is no reason why FDA needs the pricing information. If the supplier prefers to redact the pricing information before releasing the records, that is acceptable and will not affect FDA's investigation.

You may encounter resistance when requesting records. Take the time to explain the reason for this investigation, including a summary of the outbreak, the number of illnesses, and the importance of identifying the source of the product. Be prepared to volunteer to go through the firm's files to locate the records, assist clerical help in doing so, make the copies (on-site or off-site), and go to other locations where the records may be located.

If you are unable to obtain the records immediately, be persistent in obtaining them as quickly as possible. If you are not able to get the records in a timely manner (1-2 days), notify the EOC Coordinator immediately. Many states have laws that require these shipping records to be provided to the state health and regulatory authorities upon request. If the firm will not provide the requested records, you may need to ask for assistance from these agencies.

If you have determined, with great certainty, that you have the actual egg carton that contained the implicated eggs, notify EOC before proceeding any further.

Analysis of Point-of Service Data

You will need to analyze the first level of data before continuing the investigation at another firm. If you are being trained or would like assistance with the analysis, contact your EOC Coordinator. EOC will provide an electronic timeline or other tools for you to use in your analysis. You will need to follow these steps in order to analyze the data.

Step 1. Determine what type of egg is implicated in the outbreak and separate out all the records relating only to that type of egg with respect to size, color, and grade. Label the timeline with the following:

- Title, Date, Event Code, Product
- Dates of Record Collection
- POS Firm name

Step 2. Fill in Receipt Dates.

- Add the names of the suppliers under the POS, one per line.
- If an inventory list is available, place the quantity on the POS line corresponding to the appropriate date. You will need to note in the memo how and when inventory is taken.
- Place the quantity of each shipment in the cell corresponding with the date it was received at the POS from the corresponding supplier.

Step 3. Review the pertinent information collected during the interviews and observations.

- How the receipt date is determined
- How inventory is handled
- Delivery receiving times
- Serving and preparation times
- Stock rotation practices

Step 4. Implicate shipments and suppliers. Using the information from the interviews and observations, determine which shipments received at the POS may have been available and could have been used in preparing the implicated food item. This will tell you which firms supplied those shipments. (For an example of the analytical decision making process, refer to the Guide to Tracebacks of Fresh Fruits and Vegetables, April 2001, Attachment 2).

Step 5. Contact EOC. Fax (or overnight) a copy of the invoices to EOC (301-827-3333).

- Discuss the analysis with the EOC Coordinator. You will need to share the information you have added to the timeline. You may fax this or communicate the information by phone.
- If the implicated firm is in your district, you will continue the traceback at the implicated supplier (if it is assigned to you). EOC will add the firm to the FACTS assignment.
- EOC will provide an updated electronic copy of the timeline and flow diagram to you.

Do not write the traceback report until you have completed all of the implicated firms assigned to you. You may only have the POS firm located in your district. If that is the case, then the report can be written at this time. However, if the implicated suppliers are in your District, the continuation of the traceback investigation must not be put on hold while a report for the POS firm is written. When the

traceback investigation is completed, EOC will send the final flow diagram(s) to CFSAN and to each investigator who participated in the traceback.

DISTRIBUTOR INVESTIGATIONS

The goal of the investigations at the implicated suppliers or distributors is similar to the goal at the POS. You will not need to determine preparation procedures and serving times at this level. You will need to verify all previously collected shipping information from the distributor to the POS. The same process should be followed when going to the next level of distribution (distributor to distributor sales). Also collect new information on all incoming receipts of product to this distributor from other distributors or producers. Interviews, observations and record collections must be done in person. You may or may not have conducted the POS investigation. It is important for you to review the POS analysis and shipping receipts prior to beginning the investigation at a distributor.

There are several types of distributors and other firms that may be encountered during the traceback investigation: distributors that supply to the POS (which is used as the example in the following instructions), distributors that supply product to other distributors, and brokers who may never physically handle the product, only the paperwork. Use the following procedure for the distributor (omitting what is not applicable).

Distributor Interviews

You must conduct interviews with more than one employee at multiple levels of the organization (e.g., floor manager, loading dock personnel, shipping clerks, drivers, etc.) to determine the following information:

- Product Identifying Information – Verify that all information that is collected pertains to the implicated eggs (same color, size, and grade). Check product descriptions. The firm may be using a different supplier or supplying a different type of egg than was shipped during the time frame under investigation.
- Grading designation – Some distributors or retail/wholesalers use tracking systems (some computerized) which do not distinguish between grades of eggs or they combine grades. Review the invoices to determine if the firm's practices maintain the grading distinctions. Describe the firm's practices if grade distinctions are not maintained.
- Shipping and Receiving Practices - Determine the receiving dates and times for each shipment in the requested time period. The time period will cover same 30 days as the POS and may include additional days to cover the time period that includes 30 days from the date of the last shipment from that distributor to the POS. Indicate how the dates on the shipping records reflect the date the product was received. Determine how supplier deliveries are documented or recorded. Determine the firm's suppliers during this time period, including any cash transactions. Determine or estimate the transportation time from the supplier to the POS.
- Stock rotation practices - Understand the standard operating procedure at the firm. Determine how the eggs are unloaded and added to existing inventory. Determine if a first-in-first-out (FIFO) rotation policy is standard operating procedure and how closely it is followed.
- Daily (or otherwise) stock inventory - If an inventory record is available for this time period, understand how it is used, including its strengths and weaknesses, and determine what time of day the inventory is performed. Understand what each inventory number represents. Determine how partial cases or baskets are accounted for, and how and if carry over is recorded.
- Ordering practices – Determine how and when product is ordered. Determine average daily use or turnover.
- Product Handling and Storage Practices - Interview multiple organizational levels regarding receiving, repackaging, and/or handling of the implicated eggs prior to delivery to the point-of-service or the next distributor. Report on relevant unloading, storage, loading or other pertinent conditions.
- Repacking or repackaging - Changing from grade AA to A is often noted on invoices, as it is common for distributors to lump these two grades together. Determine if this occurs and review the records and observe practices to try and clarify how and when this occurs. If the implicated product is repackaged or handled in any way, the practices and policies used by the firm must be fully explained and understood and included in the report memo. Determine if any packaging material is reused.

Distributor Observations

Observe and verify that the procedures described by employees are reflected in their actual work. Whenever possible, have the employees who perform each of the tasks demonstrate their procedure. You should be able to describe the flow of the product through the firm. Walk through the process and follow a shipment of eggs physically through the firm and compare it with the written (and computerized) records. This information will be critical for the analysis.

Distributor Record Collection

Obtain a copy of all invoices, shipping and receiving

records, bills-of-lading, inventory records and any other records regarding the implicated eggs that are available for the time period that was requested. Only collect records for the implicated eggs using size, color, grade and packaging/label information provided by the POS. If the state conducted this portion of the traceback and did not collect records covering the requested time period, you will need to collect the missing records.

You will need to verify that the shipment information collected at the POS from this distributor is both accurate and complete. This will involve looking at all outgoing shipments from this firm to the POS firm. You do not need to recopy these records. If a previously unidentified shipment is found, copy that record. You do not need to collect information on **outgoing** shipments from this firm to firms other than the POS, unless directed to do so. You will need to collect and review all receiving records for all **incoming** shipments of the implicated eggs over the time period requested. Refer to the POS investigation section for additional guidance on record collection and review.

Analysis of Distributor Data

You will need to analyze this data before proceeding to the next level of distribution. If you are receiving training or would like assistance, contact the EOC Coordinator. The analysis will be described in this section.

Step 1. Collect and review all records with the same type (size, color, grade) of shell egg that is implicated in the outbreak and separate out all the records relating only to that type of egg. The timeline should be updated with the following information:

- Add the names of the suppliers under the distributor, one per line.
- If an inventory list is available, place the quantity on the distributor line corresponding to the appropriate date. You will need to note in the memo how and when inventory is taken.

Step 2. Fill in Receipt Dates. Place the quantity of each shipment in the cell corresponding with the supplier and the date it was received at the firm.

Step 3. Review the pertinent information from interviews and observations

- How the receipt date is determined
- How inventory is handled
- Stock rotation practices
- Time and dates eggs are received and shipped

Step 4. Implicate shipments and suppliers.

Using the information from the interviews and observations, determine which shipments received at this distributor may have been available and could have been used to fill the implicated shipments.

Step 5. Contact EOC (301-443-1240).

- Fax (or overnight) EOC a copy of the invoices (301-827-3333).
- Discuss the analysis with the EOC Coordinator. You will need to share the information you have added to the timeline. You may fax this or communicate the information by phone.
- If the implicated supplier is in your district and is assigned to you, you will continue the traceback.
- EOC will update and provide an electronic copy of the timeline and flow diagram to you.

Do not write the traceback report until all of the investigations of implicated firms assigned to you are completed. You may have more than one distribution firm located in your District. If additional implicated suppliers are in your District and assigned to you, the continuation of the traceback investigation should not be put on hold while a report is written. Once you have completed all the assigned firm visits, the report should be written and a copy sent to EOC. Do not include another copy of the records, since these have already been faxed to EOC. When the traceback investigation is completed, EOC will send the final flow diagram to each investigator that participated in the traceback and a final investigation report, including a copy of all records will be sent by EOC to CFSAN.

EGG PROCESSOR / PACKER INVESTIGATIONS

If the processor owns or contracts flocks, this investigation will be conducted as part of the farm investigation. If not, at the processor/packer you are to determine when the implicated eggs may have been processed and packed. Review the inventory and all records. These records may include grading sheets, rail sheets or some other form of record keeping. These may be kept for each house, supplier, or processing line and may help eliminate a potential farm source. Fax or mail the records to EOC. EOC and CFSAN will review the data with the investigator.

FARM INVESTIGATIONS

TEAM SELECTION

In most cases, a multi-disciplinary team will conduct a farm investigation. A FDA investigator from the home district will lead the team. It may include individuals from CFSAN and state agencies with expertise in such disciplines as veterinary medicine, microbiology, and epidemiology. Division of Field Investigations (DFI), EOC, the District office, and CFSAN will discuss the exact make-up of these teams on a case-by-case basis. CFSAN will issue a FACTS

assignment for the farm investigation.

INVESTIGATION PLANNING

Once the team is selected, CFSAN will issue a FACTS assignment to the home district. The team leader will be responsible for recording the time in FACTS for all of the FDA investigators. Pre-planning conference calls will be held. The team will be briefed on the outbreak investigation, including the epidemiological findings, the traceback results, and any microbiological background data. The team members' roles and responsibilities will be discussed. Team leader responsibilities are outlined in IOM 502.4. Other items that will be discussed include coordination, communication, equipment needs, samples, and laboratory analysis. The Division of Field Science (DFS) and CFSAN will discuss the number of samples, and determine the appropriate laboratory analysis and lab facility. The laboratory supervisor and DFS should be kept informed and may want to participate in the planning calls. The lab must be informed about the number of possible samples, when they will be sent, and who should be notified of the results. The laboratory will be updated as the inspection progresses if there are any changes.

CONDUCTING THE INVESTIGATION

The team will coordinate their arrival and activities with the home district office. The team will meet and organize supplies and plan activities prior to arriving on the farm.

On the farm, present credentials and ask to talk with the most responsible person (e.g. owner or senior management). Issue a FDA-482-Notice of Inspection. Explain the SE outbreak in general terms and the farm's involvement. You will need to review the specific invoices of the egg shipments for the farm and obtain and review the information in order to determine which houses or sites could have supplied the eggs. For example, if brown eggs were implicated, then only brown laying hens and houses would be considered for sampling. If a white medium egg was implicated all white egg laying houses in production at the time would be sampled unless there are records that prove no medium eggs were produced at that time (sampling procedures are found in Attachments 3 & 4). The records used to determine this would be actual grading records not weight records. If there is a mixed bird house then the entire house is sampled. You will also need to determine the general procedures followed by the farm. For example you will want to determine if they are on an egg safety plan and if they test or monitor the hens, houses and/or eggs. The review of these procedures, safety plans, etc. is usually delayed until after the sampling of the houses in order to get samples to the laboratory in a timely manner.

BIOSECURITY

Of paramount importance is maintaining good biosecurity, which includes wearing protective clothing for the safety of the chickens as well as the investigators. Each team member will change protective clothing between houses and use all available footbaths. See IOM Section 504-Inspectional Precautions, 519-Inspection Procedures at Growers-Producers, & 141.4-Respiratory Protection.

Plan the order of the sample collection by the age of the birds in each house, beginning with the house containing the youngest birds and ending with the house containing the oldest birds, unless there are other circumstances such as illnesses or multiple sites. Enter houses from the outside rather than by crossing between houses on common hallways. Footwear should be disinfected or changed between houses. If the farm has additional biosecurity measures in place, follow them. Personnel safety should be considered at all times but especially when sampling fans and high manure piles. Walkways on the upper levels of the houses can be dangerous and have loose or rotted floorboards.

Respirators with an ammonia and particle cartridge and goggles should be used where needed. See IOM 141.4. Hardhats with lights may be used in the manure pits as needed.

FARM INVESTIGATION REPORTING

The FDA lead investigator is responsible for submitting the EIR to CFSAN.

ATTACHMENT 1: OUTBREAK INVESTIGATION CHECKLIST

STEPS IN AN OUTBREAK INVESTIGATION - POS

1) Epidemiology
   a) What is the implicated food?
   b) How was the implicated food determined?
   c) Was a case control study done? (Include a copy of the study.)
   d) Were attack rates determined?
2) Were stool samples collected from the patients? (Include results)
3) Were food samples collected? (Include results)
4) Were stool samples collected from the food workers? (Include results)
5) Has the food preparer or any of his or her family members been ill in the week before preparation of the implicated food? Month before?
   a) If yes, what were the symptoms?
      i) What was the onset date of symptoms?
      ii) Were stool samples or blood samples collected?
6) Stool samples should be collected from anyone involved in food preparation, anyone who may have come in contact with the food, or anyone within the room during preparation of the implicated food.
7) Food Preparation Review
   a) What are the ingredients of the implicated food and amounts of each ingredient?
   b) Date and starting time of preparation of the implicated food.
   c) What were any distractions during the food preparation time (time during which the food or ingredients may have sat unrefrigerated e.g. power outages, etc.)?
   d) Number of servings prepared?
   e) If eggs were used, what were their size and color?
   f) Were raw whole eggs or pasteurized eggs used?
   g) Were individual eggs used or were they mixed (pooled) in a container? How many pooled
   h) Were pooled eggs carried over from one day to the next?
   i) How are the eggs normally stored prior to use? Was this also the case in this instance?
   j) Were there any other ingredients in the food that may have contributed to the illnesses?
   k) What time was preparation completed (not including cooking time)? And at what time did preparation began?
   l) What were the exact cook time and temperature for this specific batch of food?
8) Cross contamination possibilities during preparation:
   a) Were there any other high-risk foods prepared at the same time (poultry, other meats, cheese, etc.) for this function or another?
   b) Were the same utensils or food contact surfaces used for preparation of other high-risk foods?
9) Storage of prepared food (at the food preparation facility):
   a) How was the prepared food stored (refrigerator, ice chest)?
   b) Was the prepared food stored covered?
   c) Was there the possibility for cross-contamination from other foods while in storage?
   d) How long was the prepared food in the storage facility?
10) Food transport (finished product)
   a) Was the prepared food refrigerated while in transport? How? At what temperature?
      i) What was the elapsed time in transport?
      ii) What was the temperature of the prepared food upon arrival?
      iii) How long prior to consuming did the food arrive at the event?
      iv) How was the prepared food stored at the event? What was the temperature?
11) Was the prepared food heated prior to consumption?
   a) List the time and temperature of heating.
   b) Was the food kept in its original container?
12) Was there the possibility of cross contamination prior to, during, or after heating or cooking (use of common utensils of high-risk foods heated at the same time)?

13) Food Served
    a) Was there the possibility of cross contamination with other foods during serving (common serving spoons, etc)?
    b) What were the foods in immediate proximity of the implicated food at the time the food was served?
14) Preparation of implicated food - (cook a test batch)
    a) Visit the food preparation site and have the same person prepare the same food (maybe smaller amounts) under the same conditions to extent possible.
15) Is the food preparation site a private home or a business?
    a) If a business is it government regulated? Past history (last inspection report)
        i) If it is a business complete a food facility inspection.
    b) If it is a private residence visit and note the general condition of the kitchen.
        i) Do you see any refrigerated food stored unrefrigerated?
            (1) Any eggs stored unrefrigerated?
16) Record temperature of refrigerator thermometer.
17) Record temperature using inspector's thermometer.
18) Record the actual temperature of the oven at the cook setting.
    a) Record the following measurements of the finished product (cooked food):
        i) Temperature
        ii) pH
        iii) Water activity
    b) Length, width, and depth of the pan the food was cooked in
    c) Upon completion of the cook is food cooked throughout (runny)?
19) Traceback Information
    a) Source of Raw Ingredients of Implicated Food:
    b) For each ingredient of the implicated food, list:
        i) Product brand
        ii) Container size
        iii) Normal site of purchase
        iv) Alternate site(s) of purchase
        v) Date(s) of purchases within the last 30 days
    c) Where were the eggs purchased? Is this where eggs are normally purchased?
    d) Were eggs from only a single purchase used in the implicated food, or eggs from a previous purchase as well?
    e) What was the date(s) of purchase of eggs used in preparation of implicated food?
    f) How many packages were purchased?
    g) Do you have a store receipt, or credit card receipt?
    h) Do you have the original packages of the eggs were purchased in?
    i) What was the package size (18, 12, or 6 eggs)?
    j) Do you recall labeling or package color?
    k) Do you buy a specific brand?
    l) What is the distance and travel time from store to site?

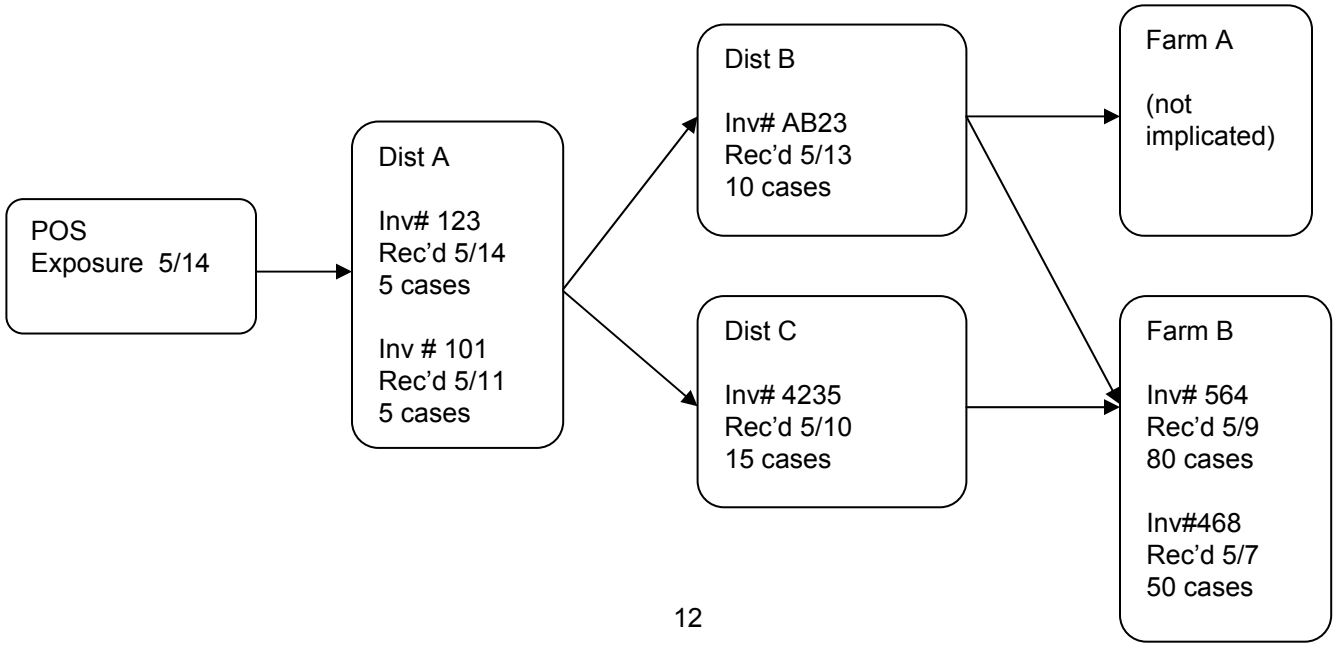
ATTACHMENT 2: EGG TRACEBACK TIMELINE AND FLOW DIAGRAM

Timeline: This is an example of a 15-day timeline. You will be provided with a timeline to cover the 30-day record collection time period. For additional examples, refer to *"Guide to Traceback of Fresh Fruits and Vegetables, April 2001."*
Exposure date = 5/14

Date of Receipt

Firm Name	4/30	5/1	5/2	5/3	5/4	5/5	5/6	5/7	5/8	5/9	5/10	5/11	5/12	5/13	5/14
At POS															
From Dist A			5			5			5			5			5
At Dist A															
From Dist B		10						10						10	
From Dist C					15						15				
At Dist B															
From Farm A															50
From Farm B								50							
At Dist C															
From Farm B				80						80					

Flow diagram: This example of a flow diagram represents the suspected shipments that are highlighted in the timeline above. You may find it helpful to include the information on the implicated shipments in the flow diagram boxes, but it is not necessary to do, particularly if there are a large number of implicated shipments. You may list the information separately and include it in your memo.



ATTACHMENT 3: EQUIPMENT LIST FOR FARM INVESTIGATIONS

- Hair nets
- Goggles
- Respirators
- Dual Ammonia and Hepa cartridges (ammonia and particle)
- Hard hats with lights
- Disposable Coveralls (Tyvek suits)
- Disposable Gloves (Sterile)
- Disposable Boots Covers
- Boots for working in the pits
- Coolers with gel packs
- Whirl-paks (estimate 4 per bank/ row plus feed, fans, egg belts)
- Sterile bottles & sterile bottles with sodium thiosulfate for water collection (see IOM426.3)
- Large Garbage bags
- Sterile 4 x 4, 12-ply gauze pads
- Sterile Drag swabs
- Canned evaporated milk (skim milk preferred)
- 70% ethyl alcohol
- 2 pair of scissors
- 2 can openers
- Permanent felt tipped marker
- Masking tape (1” or 2”)
- Brown paper bag or appropriate container for sample storage in house
- Bucket and Brush with disinfecting solution (not needed if using disposable boots)
- Sprayer with Clorox
- Plastic pan to contain equipment
- Additional Whirl-paks
- Overnight mailers and shipping containers for samples, if needed
- Kneeling pads (not knee pads)
- Seals
- Labels
- Camera and film
- Paper towels or utility wipes
- Fly strips (discuss use during planning meetings with CFSAN)

ATTACHMENT 4: SAMPLE COLLECTION

SAMPLE COLLECTION
The general procedures are outlined below, followed by sections for specific styles of houses. A list of equipment required for environmental sampling can be found in Attachment 3.

Control Samples –See IOM Section 426.5
- Sterile gloves, (one pair of each size)
- Sterile drag swab, open and unopened
- Sterile gauze pad, open and unopened
- Sample collection containers, open and unopened
- Can of evaporated milk (whole or skim)
  If the can is from the same lot, you only need one can and then you may reference this control sample for any additional sampling. If more than one lot of evaporated milk is used, one can from each lot should be collected as a control.

. Submit the controls as subs of the first investigational samples, or with related samples, as appropriate.

Standard sample collection procedures for a layer house
1) Put on all protective clothing (Tyvek suit, hairnets, boot covers) and bring hard hats, goggles, and respirators.
2) Follow biosecurity practices of the farm if they are more stringent than FDA's procedures.
3) Bring all sample collection material into the house and find an area in the house to organize equipment.
4) Use a plastic garbage bag to cover work area and arrange materials on the bag.
5) Use additional garbage bags for trash. Do not take used garbage bag into another house.
6) Shake the cans of milk and pour alcohol on can top and wipe excess with sterile gauze pad and cover top of can with another sterile gauze pad.
7) Disinfect the can opener and scissors by pouring enough alcohol into a plastic cup to cover the ends of the scissors and can opener. Place can opener and scissors into cup. Store in cup when not in use.
8) Use the can opener to open the can of milk after shaking excess alcohol off of opener.
9) Open one sterile swab at a time as needed for sampling or (using gloved team member) open the number of swabs needed in an area of the house and place into a whirl pak at one time.
10) Put on sterile gloves in a surgical manner.
11) Follow Aseptic Sample Collection procedures. See IOM 426.

Note: Each house will be assigned a separate sample number and all manure, egg belt, water, feed or other environmental collection from that house will be sub samples of the assigned sample number and reported as such on the CR reports. (For purposes of this written example, only, each sub sample is below is referred to as a sample.)

Manure sampling
1) Open the drag swabs pack (4x4-gauze 12-ply package), making sure the swabs/gauze remain sterile.
2) Moisten the swabs/gauze with canned evaporated milk.
3) If using a pole, tie the string that was attached to the swab in the sterile pack to the pole that the team brought, or hold it so that the drag swab makes contact with the manure under the row/bank being sampled.
4) If drag swabs cannot be used, use 4x4, 12 ply gauze, moistened with canned evaporated milk.
5) Follow the specific procedures listed below that correspond to the style or type of house. BE CAREFUL and AWARE of any water leaks that may have created pools in deep manure piles.
6) When finished with each row or procedure as directed, place the swab/gauze in a Whirl-pak bag with no more than 15-30 mls of the same milk, sufficient enough to keep it moist in transit. Use only one drag swab/gauze per bag. Note: Drag swabs and gauze pads are usually dirty and frayed after dragging.
7) Clean poles with 70% ethyl alcohol between rows/banks.
8) Repeat process until all samples are collected.
9) Before leaving the house, collect all material, including garbage bags and sample bag. Place used disposable items in garbage bag (e.g., used gloves, empty milk cans). Leave the house

by the same entry door. Outside of the house, remove protective clothing and place all used suits and boots in the house garbage bag. Place sample bag in secure area. Disinfect equipment carrier and restock with needed material. Disinfect boots, if not using disposable covers.

10) Repeat these procedures until all implicated houses on the farm are sampled. Arrange for same day pickup or next morning pickup of the samples. Submit the samples to the laboratory as soon as possible and definitely within 24 hours.

Collection of manure samples will depend on the type of house. The following describes the most common styles of houses and methods of sampling them.

Deep Pits (high rise)

Collect two swabs at a time by having one person on each row/bank walk up and back the same side of manure beneath a row/bank of cages, using a pole with two drag swabs. Drag one swab over the right side of the manure pile and one swab over the left side of the manure pile. Use of a pole helps placement of the swabs on the left and right side of the row/bank. If a pole is not available or the manure is too high, then drag one swab up and back the manure pile. Do one swab for each side of every row.

One story with scrapers (shallow pit)

Walk up and back the same side of the row/bank of cages or attach the swab to the scraper, if in operation. Repeat for the other side of the row/bank and for all rows/banks.

One-story without scraper (or California-style houses)

Walk up and back the same side of a row/bank of cages, dragging the swab over the manure on that side of the row/bank under the cages. Repeat for the other side of the row/bank and for all rows/banks.

One-story scraper with lagoon (water flushing under cages)

Walk up and down the same aisle between cages, dragging the swab between the cages if the water is running. Otherwise, follow the procedure for the one story house without scrapers.

Houses with liquid pits

Lower the swab down into the pit area where there is an opening in the wire barrier, if access can be obtained. Use one swab per side of row/bank. Repeat for all rows/banks. Drag a swab down each aisle between rows/banks.

One-story house with single-tier rows

Drag the swab under the cages, starting on the left side and going down the full length of cages. With the same swab, come back up the right side of that same row of cages. Repeat for all rows/banks.

One-story house with manure belts

Using a moistened 4x4 gauze, swab all scraper bars across the belt at the end where the manure is removed. Swab the belts within the vicinity of the bars on all rows. Use one 4x4 gauze for the left and one for the right side of each row/bank. Repeat procedure for all rows/banks.

Egg belt sampling

Collection of egg belt samples will depend on the type of egg collection system in the house.
The following describes the most common egg collection systems and the appropriate methods to be used. Gloves should be changed after each sample. Use a 4x4-gauze pad, moistened with canned evaporated milk (whole or skim) as previously instructed. Place each gauze in a Whirl-pak bag with sufficient milk for transit (no more than 15-30 mls).

Automated egg belts

For all tiers on a side of a row/bank, periodically swab the egg belt within the first 30 feet of the escalator. Areas on the belt showing egg yolk/white should be swabbed in addition to the periodic swabbing. If the row/bank has eight tiers of cages, sample all tiers as high as one can reach. With the same gauze pad, periodically, swab all

escalators on this side of the row. Repeat the procedure for the left and right sides of all rows/banks.

Non-egg belt houses; hand collected houses

Going up and back one side of a row/bank, periodically swab an area of the egg rollout area, including any water pipes under the cages. Dropboards are another potential area for sampling. Repeat the procedure for the left and right sides of each row/bank.

Non-egg belt house; hand collected with single-tier houses

Walk down the entire length of the left side and swab periodically. Using the same swab, return on the right side and swab periodically.

Common egg belt

Periodically swab areas of the common egg belt, including areas of egg residue. If belt is running, sample belt as it passes by. If belt is not running, swab area with access.

Fans

Samples should be obtained in houses with fans in the pits, on the sides, or in the back. Using a 4x4 (12 ply) gauze pad, moistened with canned evaporated milk as previously instructed, swab the fan blades (if they are not moving) and the inside of the fan housing of at least two fans per sample. Obtain two samples per house. Side ledges may be used for open-sided houses with no fans. Place each gauze pad in a Whirl-pak bag with sufficient canned evaporated milk for transit (no more than 15-30 mls).

Feed sampling

Obtain two separate feed samples from the feed hoppers from two separate rows prior to the feed getting into the feed trough. Sample size per a Whirl-pak bag should fill a 5 x 4-inch area.

Water sampling

For hen houses supplied by a well, surveillance water samples should be collected. Water samples, which are investigational samples only, should be collected in accordance with IOM section 426.3. Ideally, the samples should be collected from a point located somewhere along the distribution system prior to where the water enters the hen houses. If that is not possible, water samples should be collected from two separate rows in each house and directly from the water nipples located in a cage. Prior to water collection, clean the nipples thoroughly and then wipe with an alcohol swab. You should determine from the firm's management if they chlorinate their well water. If they do chlorinate, you will need to dechlorinate samples using sodium thiosulfate per IOM 426.3.