UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

# FSIS DIRECTIVE	8080.3	11/17/08

FOODBORNE ILLNESS INVESTIGATIONS

I. PURPOSE

A. This directive instructs personnel from the Food Safety and Inspection Service (FSIS), Office of Public Health Science (OPHS) on the procedures they are to follow when investigating foodborne illnesses potentially associated with FSIS-regulated meat, poultry, or processed egg products. It also instructs personnel from the Office of Program Evaluation, and Enforcement Review (OPEER), the Office of Field Operations (OFO), and the Office of International Affairs (OIA) on the actions they are to take when assisting with an FSIS foodborne illness investigation.

B. This directive supplements, but is not intended to conflict with, procedures of the Consumer Complaint Monitoring System (CCMS) as specified in FSIS Directive 5610.1.

Key Points Covered

- OPHS, Applied Epidemiology Division (AED), Foodborne Disease Investigations Branch (FDIB) procedures for determining when to conduct an FSIS foodborne illness investigation (Section VII).

- Actions that FDIB investigators are to take once an FSIS foodborne illness investigation is initiated (Section VIII).

- Product sample collection and laboratory analyses (Section IX):

  Factors that FDIB and OPHS Microbiology Division, Microbiological Issuances Branch (MIB) are to consider when determining whether to submit a product sample (Section IX. A.)

  OPEER and OFO responsibilities for collecting, preparing, and shipping product samples (Section IX. B.)

- OPEER, OFO, and OIA activities during a foodborne illness investigation: Environmental assessment component (Section X)

- FDIB procedures for analyzing data collected as part of a foodborne illness investigation (Section XI).

- Agency responses to the findings of a foodborne illness investigation (Section XII).

- FDIB procedures for close-out and final assessment of a foodborne illness investigation (Section (XIII) .

- FDIB procedures for conducting continuous activities associated with foodborne illness investigations (XIII).

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.)
Poultry Products Inspection Act (PPIA 21 U.S.C. 451 et seq.)
Egg Products Inspection Act (EPIA 21 U.S.C. 1031 et seq.)

V. BACKGROUND

As a public health regulatory agency, FSIS investigates reports of foodborne illness potentially associated with FSIS-regulated products.

A foodborne illness investigation is a multi-faceted, multidisciplinary undertaking that involves collecting and analyzing data from epidemiologic, laboratory, and environmental assessments. The objectives of an FSIS foodborne illness investigation are to:

1. Determine whether reported human illnesses are associated with an FSIS-regulated product;

2. Identify the source of production, as well as the distribution, of the suspect meat, poultry, or processed egg product;

3. Gather information that FSIS can use to guide its response to the product associated with the reported illnesses;

4. Develop information to guide efforts to prevent further exposure of consumers to the contaminated product;

5. Collect information or evidence that can be used to support or lead to an enforcement action that arises out of the incident in question;

6. Identify contributing factors to the outbreak;

7. Prepare a report on the results of the illness investigation; and

8. Recommend actions or policies to prevent future occurrences.

This directive is organized to reflect the general phases of an FSIS foodborne illness investigation. However, each investigation is unique, and the steps outlined do not always occur in the specified order. The flow of information and data during an investigation is dynamic; consequently, the phases of an investigation may occur almost simultaneously.

This directive is written with a focus on infectious agents causing foodborne illnesses. However the same general steps could be applied to other potential causes of foodborne illnesses.

VI. TERMINOLOGY

Case-patient: An individual with a presumptive or confirmed foodborne illness.

Cluster: Group of case-patients or clinical, food sample, or environmental isolates with indistinguishable pulsed-field gel electrophoresis (PFGE) patterns. A foodborne illness investigation is needed to elucidate whether an association or outbreak exists.

Environmental assessment: Investigation of the factors in the environment including food safety aspects such as product traceback and traceforward, as well as in-plant assessments.

Epidemiology: The study of the distribution and causes of disease in a population.

Foodborne illness investigation: An investigation of a possible association between human illnesses and an FSIS-regulated product that includes epidemiologic, laboratory, and environmental assessments.

Incubation period: The time period between exposure to a pathogen and the onset of signs and symptoms of illness. The incubation period varies depending on the type of pathogen.

Isolate: A pure culture of bacteria; such as *Salmonella*, *Escherichia coli* (*E. coli*) O157:H7, or *Listeria monocytogenes*; isolated from a clinical specimen or food or environmental sample.

Non-intact product: A product with opened packaging or a product that has been removed from its original packaging.

PFGE: An acronym for pulsed-field gel electrophoresis, a DNA-based laboratory method used to determine whether isolates are closely related genetically and therefore could originate from a common source.

Surveillance: The use of systematically collected data to monitor and detect events that may trigger a foodborne illness investigation. The data are continuously analyzed,

including following actions such as a recall or suspension of operations, to incorporate changes that may occur.

Traceback: The actions taken to identify and document the flow of product back to the originating official establishment from other official establishments, retail stores, warehouses, distributors, restaurants, or other firms in commerce.

Traceforward: The actions taken to identify and document product distribution from the originating official establishment to other official establishments, retail stores, warehouses, distributors, restaurants, or other firms in commerce.

VII. DETERMINING THE NEED FOR A FOODBORNE ILLNESS INVESTIGATION: SURVEILLANCE AND INFORMATION MONITORING

A. FSIS conducts foodborne illness investigations in response to situations in which an FSIS-regulated product may be associated with human illness. FSIS may become aware of a potential association between an FSIS-regulated product and human illnesses from the following sources:

1. Notification from local, state, territorial, and international public health officials. If public health officials identify a possible association between human illness and an FSIS-regulated product through surveillance, they typically notify FSIS to report the identified association or to request FSIS assistance with the investigation.

2. Notification from the CDC. If CDC identifies an association between human illness and an FSIS-regulated product, either through surveillance or interaction with public health officials, CDC officials inform the FSIS Liaison to CDC.

3. Notification from other federal agencies. If other federal agencies, such as the Food and Drug Administration (FDA), identify a possible association between human illness and an FSIS-regulated product when conducting their own foodborne illness investigations, they typically notify OPHS.

4. Foodborne illness and hazards surveillance conducted by OPHS. OPHS conducts its own monitoring and surveillance activities driven by the CDC Epi-X system and outbreak reporting listservs, PulseNet, and PFGE clusters involving isolates from positive FSIS laboratory sampling. Surveillance of consumer complaints by CCMS is carried out using procedures outlined in FSIS Directive 5610.1.

5. Information from other sources. FSIS may also become aware of potential associations between human illness and FSIS-regulated product through media reports and other information sources.

B. The OPHS, Applied Epidemiology Division (AED), Foodborne Disease Investigations Branch (FDIB) staff is responsible for evaluating surveillance data or other information gathered by public health officials that points to a potential association between human illness and an FSIS-regulated product.

C. If a public health official outside of FSIS contacts FSIS personnel who work from a program other than FDIB to report information on a potential association between

human illness and an FSIS-regulated product, the program is to inform FDIB and an FDIB investigator is to contact the public health official directly.

D. When FDIB investigators receive information about a potential association between human illness and an FSIS-regulated product, they are to assess the strength of the surveillance data or other information to determine whether there is a plausible basis to support the association and thus initiate an FSIS foodborne illness investigation. FDIB investigators are to consider the following factors:

1. Does the available information suggest a link between FSIS-regulated product and human illness?

2. Are the surveillance, investigative, and laboratory methods being used likely to produce scientifically valid results?

3. Are the preliminary epidemiologic findings plausible?

4. Are the preliminary laboratory and environmental findings consistent with the preliminary epidemiologic findings?

5. Do the published literature and past experiences of the Agency support the preliminary findings?

E. If, based on the factors described above, FDIB investigators determine that the reported human illness may be associated with an FSIS-regulated product; they are to initiate a foodborne illness investigation.

F. When FDIB initiates a foodborne illness investigation, the FDIB Chief is to designate a lead FDIB investigator who will be responsible for the overall coordination of the investigation.

G. When FDIB initiates a foodborne illness investigation, the AED Director is to inform the OPHS Office of the Assistant Administrator (OAA). The OAA will designate an OPHS executive lead for the investigation.

NOTE: Even if FDIB decides not to initiate an FSIS foodborne illness investigation, the Agency may provide technical assistance, investigative support, and guidance to public health officials.

VIII. ACTIONS TO BE TAKEN ONCE A FOODBORNE ILLNESS INVESTIGATION IS INITIATED

A. Alerts and updates

1. Alerts

a. After FDIB initiates an FSIS foodborne illness investigation, the FDIB Chief, FDIB lead investigator, or designee will determine whether to issue an alert. Alerts provide early notification of foodborne illness investigations that will likely necessitate Agency action or resources.

b. If FDIB decides that an alert is warranted, the FDIB chief, lead FDIB investigator, or designee is to enter information about the investigation into the FSIS Incident Management System (FIMS)(formerly referred to as the Non-Routine Incident Management System(NRIMS)). After the information is entered, an alert will be issued through FIMS to an established network of program area contacts selected by program area management.

2. Investigation updates

a. FDIB is to use the FIMS to distribute investigation updates when there are relevant developments in a foodborne illness investigation. The updates will be distributed to the same network of FSIS program area contacts designated to receive alerts. These contacts are responsible for communicating relevant information about an investigation to their program area management, Emergency Management Committee (EMC) representative, and other appropriate personnel.

B. Activation of EMC: should a foodborne illness investigation require involvement of the EMC, FDIB will follow procedure per 5500.2

C. If the FDIB lead investigator or any other FSIS personnel suspect that the situation may involve intentional product tampering or criminal violations of the Acts, they are to notify OPEER/CID Director or designee immediately.

IX. PRODUCT SAMPLING AND LABORATORY ANALYSIS

A. Determining whether to submit product samples for laboratory analysis

1. FDIB investigators are to meet with the OPHS, Microbiology Division (MD), Microbiological Issues Branch (MIB) investigators on a weekly basis and whenever there are new developments in a foodborne illness investigation to discuss issues regarding laboratory analysis.

2. To decide whether to sample and test products potentially implicated in an FSIS foodborne illness investigation, FDIB and MIB staff are to consider the answers to the questions presented below:

a. Do the epidemiologic investigation data, including the reported food history, support a link between illness and FSIS-regulated product?

b. Do the laboratory findings support a link between illness and FSIS-regulated product?

c. Does the environmental assessment support a link between illness and FSIS-regulated product?

d. Is there product available to test meeting FSIS criteria for product identity, chain of custody, and product handling? If not, are there reasons for testing product that may not meet all of these criteria?

e. Has product already been tested by a non-FSIS laboratory with reliable methodology?

f. Can testing be carried out by or in association with FSIS?

3. The FDIB lead investigator and MIB lead investigator are to consult with the AED and MD Directors to consider whether FSIS should analyze non-intact product samples obtained in commerce or from a consumer's home. To determine whether to submit a non-intact product sample for laboratory analysis, FDIB and MIB are to consider the following factors to determine the validity or utility of findings:

a. Was the non-intact product directly handled by the case-patient?

b. Was the non-intact product stored properly to avoid cross-contamination and temperature abuse?

c. Are packaging materials and product labels that identify the non-intact product available? If not, was traceback successful in determining the product identity?

4. If, based on the factors described in sections IX.A.2. and IX.A.3. above, the FDIB lead investigator, MIB lead investigator, and AED and MD Directors,determine that product sampling and laboratory testing are needed to help determine whether there is an association between illnesses and an FSIS-regulated product, the MIB lead investigator is to:

a. Confer with the MD Director or designee to make a science-based recommendation regarding the quantity of product to be collected and tested in order to maximize the chance of detecting contamination,

b. Inform the directors for all FSIS field service laboratories, as well as the Executive Associate for Laboratory Services, of the intent to send samples as part of the foodborne illness investigation and provide them with the number of samples to be tested as well as the priority and urgency of laboratory analysis.

5. If FDIB and MIB determine that FSIS should collect product sampling for laboratory testing, the FDIB lead investigator is to inform both OFO and OPEER personnel of the decision to collect product samples and is to make clear which program personnel, OFO or OPEER/CID, are responsible for collecting the sample and submitting it for analysis.

B. Collecting, preparing, and shipping product samples

1. OPEER/CID investigators and OFO personnel responsibilities: When collecting, preparing, and shipping a product samples for laboratory analyses as part of a foodborne illness investigation, OPEER/CID investigators and OFO personnel are to refer to procedures in FSIS Directive 8010.3.

2. OFO program personnel and OPEER investigators are to contact the MIB lead investigator for the investigation if they have any questions on how they are to collect, prepare, or ship product samples collected as part of a foodborne illness investigation.

3. OFO district office personnel are to notify the affected firm of the Agency's collection of product samples for laboratory analyses.

4. When samples cannot be collected and shipped by FSIS personnel, the MIB lead investigator is to coordinate shipment directly from the State, local or other collecting agency to the appropriate laboratory.

C. Results from non-FSIS laboratories

1. During foodborne illness investigations, non-FSIS laboratories may test FSIS-regulated product. If FDIB and MIB determine that MIB should review the methodology and results of an analysis conducted by a non-FSIS laboratory, the FDIB lead investigator will provide the MIB lead investigator with contact information for the appropriate laboratory personnel. MIB staff are to use the methodology in FSIS Directive 10,000.1 in evaluating whether to accept the laboratory results.

2. If MIB determines that the method chosen by the non-FSIS laboratory is not appropriate, or the sensitivity or specificity is not similar to the FSIS method, MIB may recommend sending samples or isolates to a FSIS laboratory for further analysis. MIB will communicate with non-FSIS laboratory personnel to ensure that they follow acceptable shipping procedures and that they maintain chain of custody.

D. Testing capabilities. If FSIS laboratories do not have the testing capability for the pathogen of concern, the MIB lead investigator may arrange for testing in a government or university research laboratory that MIB has determined has the capability to produce scientifically valid results.

E. PulseNet, VetNet, and PFGE data. All PFGE patterns derived from FSIS foodborne illness investigations and recall related samples are to be uploaded to PulseNet by Outbreaks Section of Eastern Laboratory (OSEL) staff. OPHS staff are to review clusters of illnesses identified by PulseNet. All requests for PFGE, PulseNet, and VetNet data are to be coordinated through MIB and OSEL staff.

X. ENVIRONMENTAL ASSESSMENT: PRODUCT TRACEBACK AND TRACEFORWARD

A. General

1. During a foodborne illness investigation, the FDIB lead investigator is to determine whether the expertise of other FSIS programs, such as OPEER, OFO, or OIA, is needed to assist with the investigation and if so, he/she is to inform the FDIB Chief and AED Director.

2. OFO personnel and OPEER investigators are to work in coordination with one another, and with local, state, and territorial health or agriculture department personnel during domestic traceback investigations. It is imperative that information be shared regularly and promptly to avoid duplicative communication.

3. OFO personnel and OPEER investigators are to collaborate with the FDIB lead investigator regarding traceback/traceforward activities and contribute to the decision-making process. They are to keep the FDIB lead investigator informed of their

activities throughout the investigation and promptly notify the FDIB lead investigator of any new developments

B. OPEER activities during foodborne illness investigations.

1. The AED Director is to request that OPEER/CID assist with a foodborne illness investigation if more information is needed about product that has been distributed in commerce. For example, FDIB may need OPEER/CID to collect traceback/traceforward information about a product, locate or detain the product in commerce, submit samples of product in commerce for laboratory analysis, or conduct other activities to help determine whether there is an association between the product and human illness.

2. If OPEER/CID is needed to assist with a foodborne illness investigation, the AED Director or designee is to document the factual basis for the request for assistance and forward that to the Regional Managers (RM) of the regions where samples of a suspect product are likely to be found.

3. The OPEER/CID RM or designee is to provide the AED Director and FDIB lead investigator with the names and contact information of the OPEER/CID investigators assigned to assist with the investigation and inform the AED Director and FDIB lead investigator of the current status of the OPEER investigator's activities.

NOTE: The OPEER/CID RM or designee should communicate a status back within 24 hours of the initial request describing the decision to provide assistance and current progress. If the OPEER/CID RM has questions concerning a request for OPEER/CID to assist with a foodborne illness investigation, he/she is to immediately contact the AED Director to discuss the request.

4. When conducting activities to assist with a foodborne illness investigation, OPEER/CID investigators are to follow the investigative methodologies described in FSIS Directives 8010.1, 8010.2, 8010.3, 8010.4, and 8010.5. They are to contact the FDIB lead investigator for any questions or clarification they may need about the investigation.

C. OFO activities

1. The AED Director is to request assistance from OFO if more information is needed about product under the control of a federally-inspected establishment. For example, FDIB may need OFO to obtain traceback/traceforward information about a product, obtain information about the establishment's suppliers, locate like- or same-coded product that has not left the establishment, submit product samples for laboratory analyses, collect information about production practices in the plant, perform a food safety assessment (FSA), or conduct other activities to determine whether there is an association between the product and illness.

2. If OFO is needed to assist with a foodborne illness investigation, the AED Director or designee is to document the factual basis for the request for assistance and forward that to the OFO OAA so that he/she can assess and refer the request to the District Manager (DM) of the district where samples of a suspect product are likely to be located.

3. The DM or designee is to provide the AED Director and FDIB lead investigator with the name(s) and contact information of the OFO personnel assigned to assist with the investigation and inform the AED Director and FDIB lead investigator of the current status of OFO personnel's activities.

NOTE: The DAA OFO or designee should communicate a status back within 24 hours of the initial request describing the decision to provide assistance and current progress. If the DAA OFO or designee has questions concerning a request for OFO to assist with a foodborne illness investigation, he/she is to immediately contact the AED Director to discuss the request.

4. When conducting activities to assist with a foodborne illness investigation, OFO personnel are to follow the procedures in FSIS Directive 5100.3 to document their findings. They are to contact the FDIB lead investigator for any questions or clarification they may need about the investigation.

D. OIA activities

1. If traceback investigations suggest a link to product imported into the United States, the AED Director is to inform the Director of the Office of International Affairs (OIA) Import Inspection Division (IID) and provide him/her with relevant information (e.g. product name, country, foreign establishment, shipping marks, production date) from the investigation.

2. The Director OIA IID is to contact the foreign government of the country where the product originated and inform the foreign government of the findings of the investigation.

XI. DATA ANALYSIS AND ASSESSMENT

Data collection, analysis, and assessment of findings are ongoing and occur throughout the entire investigation.

A. During the course of a foodborne illness investigation, the FDIB lead, in consultation with other FDIB investigators, is to assess the entire range of investigative data, including epidemiologic, laboratory, and environmental assessment findings, as they become available, to determine if there is reason to believe that exposure to an FSIS-regulated product may be injurious to health.

B. When assessing the strength of an association between an FSIS-regulated product and human illnesses, FDIB investigators are to use established epidemiologic principles. To help inform their assessment, FDIB investigators are to also consider the factors described below.

C. The following factors are derived from the foodborne illness investigative procedures published by the International Association for Food Protection (International Association for Food Protection, Procedures to Investigate Foodborne Illness, 5th edition, last revised 2007). The factors are not strict criteria for establishing causation. Rather, they are intended to provide a framework for assessing whether the epidemiologic or other investigative evidence collected as part of a foodborne illness

investigation provides a basis for FSIS to conclude that there is reason to believe that a meat or poultry product is causing human illness and is thus likely to contain a pathogen or otherwise be unhealthful. These factors include:

1. Descriptive information

a. What are the characteristics, such as age, race, and socioeconomic status,
of the affected population?

b. Was a majority of the population affected exposed to a common source?

c. Are the illnesses geographically isolated or widespread?

d. Are illnesses spatially associated with the distribution of suspected product?

e. Have the illnesses occurred over a short or long period of time?

f. Are there alternative explanations that have not been eliminated that could possibly explain the illnesses?

g. What was done to characterize them?

2. Time sequence

a. Did the exposure to an implicated food item precede illness onset by a reasonable amount of time, considering the time of exposure and the incubation period for the suspect pathogen?

b. Do the time windows obtained during traceback and traceforward investigations correlate with reported dates of production, distribution, and purchase?

3. Plausibility

a. Is it biologically plausible that the suspected exposure caused the foodborne illness based on laboratory results from patient specimens, testing of food and environmental samples, epidemiologic observations, and environmental assessments?

b. Are the range of clinical signs and symptoms being reported consistent with the presumptive pathogen?

c. Are the characteristics of the pathogen consistent with the suspected source and vehicle of infection?

d. Can investigators develop a rational explanation for food contamination and survival and proliferation of the pathogen? Does the in-plant assessment support the explanation?

e. Do the results of the traceback and traceforward investigations suggest a common source?

f. Are findings consistent with reports of other, similar foodborne illness investigations and Agency historical experience?

g. Could the findings be indicative of an emerging foodborne illness, vehicle, or source?

4. Dose-response

a. Were persons who consumed more food, or consumed food more often, more likely to become ill or have more severe clinical manifestations?

5. Consistency

a. How specific and consistent was the association between exposure and foodborne illness?

b. Did similar exposures result in similar outcomes?

6. Disease confirmation and laboratory analyses

a. If obtained, was the same pathogen isolated both from persons who were ill and from the suspect food?

b. If product testing was conducted, does the PFGE analysis, or other molecular analyses, support an association between clinical specimens and food samples?

7. Analytical studies

a. If an epidemiologic study was conducted, was the study design and method appropriate and sound?

b. Were biases accounted for?

c. How strong was the observed association between exposure and disease? If statistically significant results were observed, were they calculated based on valid statistical models?

D. After considering the factors described above, FDIB investigators are to determine whether there is credible evidence to support an association between an FSIS-regulated product and human illness.

E. If, based on their assessment of the epidemiologic and other investigative data, FDIB investigators determine that there is a basis to conclude that there is an association between exposure to an FSIS-regulated product and human illnesses, the FDIB lead investigator is to inform the AED Director and the OPHS executive lead for the foodborne illness investigation and provide them with a written summary of the findings.

NOTE: FDIB's conclusion may be based solely on the strength of the epidemiologic data.

F. When an association is established between human illnesses and an FSIS-regulated product, FSIS may have a basis to conclude that there is reason to believe that the product is adulterated because it contains a pathogen or is otherwise harmful to human health. The findings of a foodborne illness investigation may lead FSIS to question the adequacy of the producing establishment's food safety system. Although not limited to these situations, findings that are likely to establish a link between human illness and an FSIS-regulated product produced by a specific establishment include:

1. A clearly delineated food history, accounting for time series and environmental findings, that demonstrates an association between human illness and FSIS-regulated product produced by a specific establishment;

2. An appropriately designed epidemiologic study that demonstrates an association between human illness and FSIS-regulated product produced at a specific establishment;

3. PFGE analysis, or other subtyping analyses, from an accepted authority, that supports an epidemiological link between clinical specimens and food samples from a product produced by the specific establishment;

4. Environmental findings from a traceback or traceforward investigation of products consumed by ill persons that provide evidence of a common production source from an inspected establishment;

5. Environmental findings from an in-plant assessment suggestive of product contamination events

XII. AGENCY ACTION

A. If, after reviewing the FDIB's investigative summary, the AED Director and the OPHS executive lead agree that there is a basis for FSIS to conclude that there is reason to believe that an FSIS-regulated product contains a pathogen or is otherwise harmful to human health and the investigation as has identified a specific product that FSIS could recommend be recalled, the AED Director is to contact the OFO Recall Management Staff (RMS) Director and provide him/her with the investigative summary.

B. The RMS Director is to convene the Recall Committee to discuss FDIB's investigative findings and to determine whether the Agency should recommend a recall to prevent further human exposure to the product. The Recall Committee is to consider the factors described in FSIS Directive 8080.1 to determine whether there is a basis to recommend a product recall.

C. If, after reviewing the FDIB's investigative summary, the AED Director and the OPHS executive lead agree that there is a basis for FSIS to conclude that there is reason to believe that an FSIS-regulated product contains a pathogen or is otherwise harmful to human health, but the investigation has not identified a specific product that FSIS could recommend be recalled, (e.g., human illnesses have been linked to the consumption of ground beef but the investigation did not identify a specific brand or

company name), the AED Director is to report the incident through supervisory channels. If appropriate, the situation should be referred to the EMC are provided in FSIS Directive 5500.2. If the situation is referred to the EMC, the EMC will decide whether FSIS should issue a public health alert

D. Other possible Agency actions taken in response to the findings of a foodborne illness investigation will depend on the evidence collected and how strongly human illness is linked to an FSIS-regulated product. Examples of Agency actions other than recommending a product recall that may result from a foodborne illness investigation include, but are not limited to:

1. Increased/enhanced inspection activities;

2. Surveillance review of firms in commerce per Directive 8010.1;

3. Increased frequency of microbial surveillance;

4. Performing an in-plant FSA or intensified verification testing (IVT);

5. Effectuating a regulatory control action, withholding action, or suspension;

6. Issuance of a public health alert;

7. Detention and seizure;

8. Issuance of a notice of intended enforcement;

9. Initiation of a criminal, civil, or administrative action per Directive 8010.5

E. During and following Agency actions, FDIB investigators are to continue ongoing surveillance and information monitoring to ensure that actions are sufficient in scope to prevent additional exposure and human illness. When FDIB determines that further illness is not being reported, it is to initiate procedures to close-out the investigation.

F. FDIB investigators are to communicate Agency actions to public health officials in affected local, state, and territorial health and agriculture departments.

G. OPACE is to lead public communications efforts as described in FSIS Directive 1240.1.

XIII. CLOSE-OUT AND FINAL ASSESSMENT

A. Following the completion of a foodborne illness investigation, FDIB is to convene a group that includes FSIS program area representatives active in the investigation. FDIB will invite other public health agencies on a case-by-case basis.

1. The group is to analyze what occurred to cause the human illness and the corrective and preventive actions taken by the establishment.

2. The group is to assess whether there are changes that the Agency could make in its inspection procedures, regulations or other Agency documents, or in some

other way, that would reduce the possibility of a repetition of the circumstances that led to the Agency action.

3. The FDIB lead investigator is to address any investigative data gaps that remain.

4. The FDIB lead investigator is to coordinate a FSIS close-out call that will include the public health partners involved with investigation.

B. The FDIB lead investigator is to develop a final written summary including potential policy implications for each foodborne illness investigation and provide the summary to the OPHS lead executive, AED Director, FDIB Chief, other program areas involved in the investigations, and to other FSIS entities upon request.

XIV. CONTINUOUS ACTIVITIES—WEEKLY INVESTIGATIONS MEETING; TRACKING AND REPORTING; COORDINATION AND COMMUNICATION

A. Weekly investigations meeting

1. FDIB is to conduct weekly investigations meetings in which representatives from OPHS and other program areas, such as the Office of Food Defense and Emergency Response (OFDER), OFO, OIA, OPACE, OPEER, OPHS, and OPPD, are invited to share information about new and ongoing FSIS foodborne illness investigations. Representatives from the Food and Nutrition Service (FNS) are invited to participate.

2. Representatives from each FSIS program area are expected to participate in the weekly meeting and are to inform their program area management of relevant investigation updates and other pertinent information about new or ongoing investigations.

3. The FDIB moderator for the weekly investigations meeting is to develop an agenda outlining foodborne illness investigations to be discussed and will distribute by e-mail to all of the weekly meeting participants.

4. The FDIB moderator for the weekly investigations meeting is to develop, for each investigation, a list of action items identified during the meeting, and organize these items by program area. Following the meeting, FDIB will distribute the action item list by e-mail to all of the weekly meeting participants.

5. FDIB is to formally close-out all completed foodborne illness investigations in the weekly investigations meeting.

B. Tracking sheets and recordkeeping

1. FDIB investigators are to maintain a foodborne illness investigation database that is also used to create a weekly foodborne illness investigations report spreadsheet.

a. The weekly report spreadsheet is to include information on all open foodborne illness investigations;

b. FDIB is to distribute the weekly report spreadsheet to OPHS management by e-mail;

c. The OPHS leadership team is to discuss the information contained in the weekly report during their weekly meetings.

2. To track the progress of all FSIS foodborne illness investigations, FDIB investigators are to maintain a timeline of events, linelist of case-patients, brief summaries, and other relevant information, such as laboratory testing data.

C. Coordination and communication during an FSIS foodborne illness investigation

1. As the coordinator for an FSIS foodborne illness investigation, the FDIB lead investigator serves as the primary point of contact for external public health officials and for other FSIS program areas that have been assigned to assist with an investigation. OPACE is to be the primary point of contact for inquiries about foodborne illness investigations from consumers, media, and other stakeholders.

2. Coordination with local, state, and territorial public health officials

a. After initiating a foodborne illness investigation, the FDIB lead investigator is responsible for contacting local, state, and territorial public health officials to gather information and to keep those officials informed of FSIS activities related to the investigation. The FDIB lead investigator is to maintain contact with local, state, or territorial public health officials throughout the course of the investigation.

b. To facilitate communication, Agency personnel assisting with a foodborne illness investigation may communicate directly with local, state, and territorial public health officials and each other. However, FSIS personnel outside of FDIB are to inform the FDIB lead investigator of any planned or ongoing direct communications with public health officials outside FSIS.

3. Coordination with CDC

a. The FSIS Liaison to CDC is to serve as the primary Agency point of contact with the CDC. The FDIB lead investigator will continue to be responsible for overall coordination of the FSIS foodborne illness investigation.

b. If the FSIS Liaison to CDC is unavailable, the FDIB Chief, AED Director, or designee will serve as back-up contacts.

c. OSEL staff may communicate directly with CDC PulseNet staff regarding PFGE pattern designations and matches.

d. The FSIS Liaison to CDC is to facilitate FDIB involvement in multi-jurisdictional investigations conducted by CDC and is to serve as the primary coordinator during conference calls.

e. The FDIB lead investigator is to inform the FSIS Liaison to CDC of FSIS activities during a foodborne illness investigation. The FDIB lead investigator may

present information about FSIS activities during conference calls with State or local public health officials.

4. Coordination with other federal agencies

a. FDA, USDA Food and Nutrition Service (FNS), Indian Health Service, and other federal partners. The AED Director or designee is to serve as the primary point of contact with other Federal agencies, but may delegate contact once established. The FDIB Chief or designee will serve as the back-up contact as needed.

b. ARS. During foodborne illness investigations, communication with ARS regarding PFGE interpretation or queries of VetNet will be coordinated through MIB and OSEL staff.

XV. EVALUATION

As noted in Section XIV, the foodborne illness investigation database is used to create a weekly foodborne illness investigations report spreadsheet. OPHS will analyze the data contained in the foodborne illness investigation database. The analysis will confirm that investigations are closed, final statistics are presented, and data are entered correctly. This analysis will be completed quarterly and compiled yearly.

Assistant Administrator
Office of Policy and Program Development

Attachment 1

ROLES AND RESPONSIBILITIES OF FSIS PERSONNEL THROUGHOUT FOODBORNE ILLNESS INVESTIGATIONS

Office of Public Health Science (OPHS)

1. Applied Epidemiology Division (AED), Foodborne Disease Investigations Branch (FDIB)
    - Functions as the Agency lead and principal coordinator for foodborne illness investigations
    - Conducts surveillance and initiates the foodborne illness investigation process
    - Serves as the Agency point of contact for local, state, and territorial public health officials
    - Analyzes epidemiologic and other investigation-related information
    - Assists other program areas to ensure factual, technical, and scientific accuracy in public communications
    - Shares information with other program areas to facilitate effective field investigative activities
    - Coordinates follow-up and close out meetings and compiles information to develop a final FDIB report for dissemination to appropriate Agency entities.

2. AED, Zoonoses and Food Hazards Surveillance Branch (ZFHSB)

    - Conducts consumer complaint surveillance and investigation activities per FSIS Directive 5610.1
    - Coordinates *Salmonella* subtyping and antimicrobial resistance surveillance activities with the Agricultural Research Service (ARS)

3. Microbiology Division (MD), Microbiological Issues Branch (MIB)

    - Coordinates sample collection and transportation and analyses of FSIS samples
    - Evaluates the chain of custody and results of samples from non-FSIS laboratories
    - Communicates and interprets sample results

4. Outbreaks Section of Eastern Laboratory (OSEL)

    - Performs laboratory testing, including PFGE analysis, of investigation-associated samples and isolates
    - Conducts PFGE searches and analyzes PFGE data
    - Coordinates requests for information to ARS VetNet and the Centers for Disease Control and Prevention (CDC) PulseNet

Office of Program Evaluation, Enforcement and Review (OPEER)

- Conducts traceback/traceforward activities to determine product source and locate product in commerce
- Controls adulterated or misbranded product in commerce
- Collects and submits samples of product found in commerce
- Obtains administrative subpoenas for records if necessary
- Investigates situations that may involve criminal activities
- Coordinates investigations involving alleged tampering or terrorist activities with the Office of the Inspector General and other law enforcement agencies
- Assists OFO at official establishments; participates in verification activities and/or product identification and control

Office of Field Operations (OFO)

- Conducts traceback/traceforward activities at official establishments
- Locates and controls product that has not left the official establishment
- Collects and submits product samples collected at official establishments
- Conducts in-plant investigations and actions
- Reviews and verifies inspection records
- Coordinates recall activities

Office of Public Affairs and Consumer Education (OPACE)

- Coordinates media, consumer, trade group, and stakeholder communication

Office of International Affairs (OIA)

- Conducts international traceback/traceforward activities
- Coordinates investigation of foreign establishments

Office of Policy and Program Development (OPPD)

- Assesses policy implications and provides policy-based recommendations
- Reviews investigation data to assess needs for policy clarification or development

Office of Food Defense and Emergency Response (OFDER)

- Collaborates during investigations that may involve food defense issues or emergency response

- Coordinates the activities of the Emergency Management Committee (EMC)
- Manages incidents through the FSIS Incident Management System (FIMS) following FSIS Directive 5500.2

Attachment 2

Surveillance for Human Foodborne Illnesses

Local, state, and territorial health departments require medical providers and laboratories to report certain diseases and conditions; including foodborne illnesses such as salmonellosis, *E. coli* O157:H7 infection, and listeriosis; for investigation. These reports are required by jurisdictional regulations and illnesses reported are typically confirmed by laboratory analysis. Additionally, health departments investigate suspected outbreaks reported by medical providers, consumers, or other sources. Nationally notifiable diseases and conditions, as well as foodborne outbreaks, are voluntarily reported to the CDC.

State public health laboratories are CDC PulseNet partners that conduct PFGE analysis of foodborne pathogens and upload results to the national PulseNet database for analysis to determine relatedness. FSIS relies on the PulseNet database to monitor the PFGE patterns of isolates associated with investigations, FSIS routine sampling, and isolates associated with recall actions.