I. PURPOSE

A. This directive instructs personnel from the Office of Data Integration and Food Protection (ODIFP), Office of Field Operations (OFO), Office of Investigation, Enforcement and Audit (OIEA), Office of Policy and Program Development (OPPD), Office of Public Affairs and Consumer Education (OPACE), and 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 identifies the factors that trigger an FSIS foodborne illness investigation.

B. This directive supplements, but does not conflict with or supersede, instructions related to the Consumer Complaint Monitoring System (CCMS) as specified in FSIS Directive 5610.1, Procedures to Implement the Consumer Complaint Monitoring System.


II. CANCELLATION


III. REASON FOR RE-ISSUANCE

This directive is being reissued in its entirety to reflect changes in organization structures and corresponding changes in responsibilities during a foodborne illness investigation.

IV. BACKGROUND

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

B. A foodborne illness investigation is a multi-faceted, multidisciplinary undertaking that includes, but is not limited to, collecting and analyzing data from epidemiologic, laboratory, and environmental assessments. Roles and responsibilities of FSIS program areas are outlined in Attachment 1. The objectives of an FSIS foodborne illness investigation are to:

1. Determine whether reported human illness is associated with an FSIS-regulated product;
2. Identify the source (slaughter, production, or further processing), as well as the distribution, of suspect meat, poultry, or processed egg product;

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

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

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

6. Identify contributing factors;

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

8. Recommend actions or new policies to prevent future occurrences.

C. 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:
V. TERMINOLOGY

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

Cluster: Group of relatively uncommon events or illnesses in space or time in numbers greater than expected. A foodborne illness investigation is needed to determine whether the cluster represents an outbreak due to the involvement of a common exposure.

Environmental assessment: Investigation of the factors in the environment, such as in-plant assessments.

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

FIMS: An acronym for the FSIS Incident Management System, a web-based system that allows FSIS to manage incident reports of significant incidents.

Foodborne illness investigation: An investigation of a possible association between human illnesses and a food 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 and other factors.

Isolate: A pure culture of bacteria, such as Salmonella, Escherichia coli (E. coli) O157:H7, non-O157 Shiga toxin-producing E. coli, Campylobacter, or Listeria monocytogenes (Lm), isolated from a clinical specimen, food sample, or environmental sample.

MLVA: An acronym for multiple-locus variable-number tandem repeat analysis, a DNA-based laboratory subtyping method. This method, typically used to supplement pulsed-field gel electrophoresis (PFGE), can be useful in discriminating closely related isolates during an illness investigation.

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.

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

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

VI. 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, or international public health officials. If public health officials identify a potential 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 Centers for Disease Control and Prevention (CDC). If CDC identifies a potential association between human illness and an FSIS-regulated product, either through surveillance or interaction with public health officials, CDC officials inform the Applied Epidemiology Staff (AES) Investigations Team Lead or FSIS Liaison to CDC.

3. Notification from other Federal agencies. If other Federal agencies, such as the Food and Drug Administration (FDA), identify a potential 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 foodborne illness 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 become aware of potential associations between human illness and FSIS-regulated product through media reports and other information sources.

B. OPHS/AES 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 in a program other than AES to report information on a potential association between human illness and an FSIS-regulated product, that program is to inform the AES Director or AES Investigations Team Lead. An AES investigator is then to contact the public health official directly for information about the illness and product.

D. When AES investigators receive information about a potential association between human illness and an FSIS-regulated product, they are to begin assessing the strength of the surveillance data or other information to determine whether there is a plausible basis to support the association and initiate an FSIS foodborne illness investigation. At this preliminary stage, information will be classified by AES depending on the level of public health partner engagement and the strength of the potential association. When AES investigators are evaluating the information, they 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, after considering the factors described above, AES investigators determine that the reported human illness may be associated with an FSIS-regulated product, they are to initiate a foodborne illness investigation using the instructions in section VII.

F. When AES initiates a foodborne illness investigation, the AES Director or designee is to designate a lead AES investigator who will be responsible for the overall coordination of the investigation.

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

VII. ACTIONS TO BE TAKEN WHEN A FOODBORNE ILLNESS INVESTIGATION IS INITIATED

A. Notification and coordination

1. After AES initiates an FSIS foodborne illness investigation, the AES lead investigator is to enter information about the investigation into FIMS, creating an incident report (IR) if one does not already exist. The AES lead investigator should ensure that data from the OPHS investigation records database is added to the IR.

2. The AES Investigations Team Lead or designee is to determine whether to issue an e-mail alert. Alerts provide early notification of foodborne illness investigations that will likely necessitate Agency resources or action. The e-mail is to be sent to an established network of program area contacts selected by program area management. It will provide the name and contact information of the AES lead investigator in addition to the IR number. The AES lead investigator is to post the alert in the IR in FIMS.

NOTE: Information in the e-mail alert is confidential and is not to be released outside of FSIS. Health, proprietary, and establishment-specific information is to be carefully reviewed before any further dissemination.

3. The AES Investigations Team Lead is to send update alerts using e-mail when there are relevant developments in a foodborne illness investigation. The updates are to 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. The AES lead investigator is to post this information in the IR in FIMS.

B. Activation of EMC. Should a foodborne illness investigation require involvement of the EMC, AES will follow the procedures of FSIS Directive 5500.2, Significant Incident Response. A significant incident, as discussed in FSIS Directive 5500.2, presents a grave, or potentially grave, threat to public health or threat to the safety of FSIS-regulated product. An example includes life-threatening or widespread human illnesses potentially associated with FSIS-regulated product that led to a foodborne illness investigation.

C. If at any time the AES lead investigator or any other FSIS personnel suspect that the situation may involve intentional product tampering or criminal violations, they are to notify the OIEA Compliance and Investigations Division (CID) Director or designee immediately.

VIII. PRODUCT SAMPLING AND LABORATORY ANALYSIS
A. Determining whether to submit product samples for laboratory analysis

1. AES investigators are to meet with the OPHS Science Staff (SciS) investigators on a weekly basis and whenever there are new developments in a foodborne illness investigation to discuss issues regarding laboratory analyses.

2. To decide whether to sample and test products potentially implicated in an FSIS foodborne illness investigation, AES and SciS staff are to consider the answers to the questions presented below in consultation with OPHS Laboratory Services (LS) staff:
   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 that meets FSIS criteria for product identity, chain of custody, and product handling as outlined in the decision criteria of FSIS Directive 10.000.1, Policy on Use of Results from Non-FSIS Laboratories? 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 AES lead investigator and SciS lead investigator are 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, AES and SciS are to consider the following factors to assess the validity or utility of findings:
   a. Was the non-intact product directly handled by the case-patient? If so, when and under what circumstances was it handled?
   b. Was the non-intact product stored properly to avoid cross-contamination and minimize temperature abuse?
   c. Are packaging materials and product labels that identify the non-intact product available? Does the case-patient have a loyalty or shopper card that would assist with product identity? Was traceback successful in determining the product identity?

4. If, after considering the factors described in sections VIII.A.2. and VIII.A.3. above, the AES, SciS, and LS lead investigators 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 SciS lead investigator is to:
   a. Confer with the SciS 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. Send a proposed sampling plan to AES and SciS Directors, the director of the appropriate FSIS laboratory, and the Executive Associate for Laboratory Services. The sampling plan is to describe the number of samples, the number of test portions, the analytic method, and the priority and urgency of laboratory analyses.
5. If AES and SciS determine that FSIS should conduct product sampling for laboratory testing, the AES Investigations Team Lead is to inform the OFO Deputy Assistant Administrator (DAA) and OIEA/CID Director of the decision to collect product samples and is to make clear which program personnel, OFO or OIEA/CID, are responsible for collecting the samples and submitting them for analyses.

B. Collecting, preparing, and shipping product samples

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

2. OFO program personnel and OIEA/CID investigators are to contact the SciS 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 establishment of the Agency’s collection of product samples for laboratory analyses.

   a. If samples are taken from product that has not moved into commerce, and positive results would support that product is adulterated, OFO district office personnel are to notify the establishment that the sampled lot of product cannot enter commerce (that is, the establishment must hold or control product) until test results are received. This approach is consistent with the Agency’s policy and procedures that require establishments to hold or control product pending certain FSIS test results.

   b. If samples are taken from product that has not moved into commerce and are to be tested for an organism that has not been designated as an adulterant in that product (e.g. Salmonella in raw poultry product), but the product may be associated with or related to product associated with an outbreak, OFO district office personnel are to submit a question to the Risk, Innovations, and Management Staff through askFSIS or by telephone at 1-800-233-3935, as described in section XV, to gain guidance for the establishment related to holding product pending test results.

4. OIEA/CID investigators are to notify the affected retail firm when a product sample in commerce is collected for laboratory analyses.

5. When samples cannot be collected and shipped by FSIS personnel, the SciS 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 AES and SciS determine that SciS should review the methodology and results of an analysis conducted by a non-FSIS laboratory, the AES lead investigator is to provide the SciS lead investigator with contact information for the appropriate laboratory personnel. SciS staff are to use the methodology in FSIS Directive 10,000.1 in evaluating whether to accept the laboratory results.

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

D. Reporting FSIS laboratory results. When analysis is complete, and the release of the results is authorized, laboratory staff are to send a report to an established distribution list as well as to the FSIS staff that submitted the samples. The AES lead investigator is to post this information in the IR in FIMS.

E. Testing capabilities. If FSIS laboratories do not have the testing capability for the pathogen of concern, the SciS and LS lead investigators may arrange for testing in a government or university research laboratory that SciS and LS have determined has the capability to produce scientifically valid results with appropriate chain of custody procedures in place.

F. CDC PulseNet and USDA VetNet. All MLVA and PFGE patterns derived from FSIS foodborne illness investigations and recall related samples by the Outbreaks Section of Eastern Laboratory (OSEL) are to be transferred to PulseNet by OSEL staff. All requests for data from the PulseNet and VetNet databases are to be coordinated by OSEL staff.

IX. ENVIRONMENTAL ASSESSMENT AND PRODUCT TRACEBACK/TRACEFORWARD

A. General

1. Throughout the foodborne illness investigation, the AES lead investigator is to assess whether the expertise of other FSIS programs, such as OIEA or OFO, is needed to assist with the investigation.

2. OFO and OIEA personnel are to work in coordination with one another and with local, state, and territorial health, environmental 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 and OIEA personnel are to conduct traceback and traceforward activities and contribute to the overall decision-making process. They are to promptly notify the AES lead investigator and others working on the investigation of new developments via upload of the information into the IR in FIMS.

4. Information collected during an investigation that contains personal identifiers that can be linked back to case-patients is to be considered confidential and not released to parties outside of FSIS.

B. OIEA activities during foodborne illness investigations

1. The AES Director or designee is to request that OIEA/CID assist with a foodborne illness investigation if more information is needed about product that has been distributed in commerce. For example, OIEA/CID may need to collect traceback or 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 OIEA/CID is needed to assist with a foodborne illness investigation, the AES lead investigator is to document the factual basis for the request for assistance and forward it to the Regional Director (RD) or designee of the appropriate regions and the CID Director and Deputy Director. The AES lead investigator is to post this information in the IR in FIMS.
a. If the foodborne illness investigation suggests a link to product imported into the United States, the OIEA/CID Director or designee will coordinate with the OFO Import Inspection Management Division and OPPD International Relations and Strategic Planning Staff to work with the foreign country’s Central Competent Authority.

3. The OIEA/CID assigned investigator or designee will develop and post an investigative plan and timeline for OIEA activities in the IR in FIMS within 12 hours of receiving the request for assistance. The investigative plan will include the name and contact information of the OIEA/CID investigator assigned to assist with the investigation. The investigative plan and timeline will be updated with information throughout the investigation and posted in the IR in FIMS.

4. When conducting activities during a foodborne illness investigation, OIEA/CID investigators are to follow the investigative methodologies described in FSIS Directive 8010.1, FSIS Directive 8010.2, FSIS Directive 8010.3, FSIS Directive 8010.4, and FSIS Directive 8010.5. They are to contact the AES lead investigator for any questions or clarification they may need about the investigation and provide investigation status updates, as needed, to the OIEA/CID RD, Director, or designee.

C. OFO activities during foodborne illness investigations

1. The AES Director or designee is to request assistance from OFO if more information is needed about product under the control of a federally-inspected establishment. For example, AES 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 AES lead investigator is to document the factual basis for the request for assistance and forward it to the Executive Associates for Regulatory Operations (EAROs) assigned to the districts where the OFO assistance is requested. The EAROs that receive the request are to assess and refer the request to the District Managers (DMs) of the appropriate districts. The AES lead investigator is to post this information in the IR in FIMS.

3. The DMs or their designees are to provide the AES Director and AES lead investigator with the names and contact information of the OFO personnel assigned to assist with the investigation and inform the AES Director and AES lead investigator of the status of OFO personnel’s activities. The AES lead investigator is to post this information in the IR in FIMS.

NOTE: The OFO EAROs or their designees are to communicate a status back within 24 hours of the initial request describing the decision to provide assistance and progress. If the OFO EAROs or their designees have questions concerning a request for OFO to participate in a foodborne illness investigation, they are to immediately contact the AES Director or designee to discuss the request.

4. When conducting activities during a foodborne illness investigation, OFO personnel are to follow the procedures in FSIS Directive 5100.3, Administrative Enforcement Reporting (AER) System, to document their findings. The AES lead investigator is to work with the OFO EAROs and DMs of the appropriate districts to ensure that relevant documents are posted to the IR in FIMS.

X. DATA ANALYSIS AND ASSESSMENT
A. Data collection, analysis, and assessment of findings are ongoing and occur throughout the entire investigation.

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

C. When assessing the strength of an association between an FSIS-regulated product and human illnesses, AES investigators are to use established epidemiologic principles.

D. To help inform their assessment, AES investigators are to consider the factors 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, 6th edition, last revised 2011). 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, poultry, or egg product is causing human illness and is thus likely to contain a pathogen or otherwise be unhealthful. These factors may include:

1. Descriptive information
   a. What are the demographic characteristics 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? What was done to characterize the alternative explanations?

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

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. Consistency

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

b. Did similar exposures result in similar outcomes?

5. 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 analysis, support an association between clinical specimens and food samples?

6. 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?

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

F. If, after assessing the investigative data, AES investigators determine that there is a basis for concluding that there is an association between exposure to an FSIS-regulated product and human illnesses, the AES lead investigator is to inform the AES Director and other program area leads, who are to inform their management, and post the conclusions in the IR in FIMS.

NOTE: Conclusions may be based solely on the strength of the epidemiologic data.

G. When an association is established between human illnesses and an FSIS-regulated product, FSIS may have a basis for concluding that there is reason to believe that the product is adulterated because it contains a pathogen or is otherwise harmful to human health. 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 assessment 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 analysis, from an accepted authority, that supports an epidemiological link between clinical specimens and food samples from a product produced by the specific establishment;

4. 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.

XI. AGENCY ACTION

A. If there is a basis to conclude that FSIS-regulated product contains a pathogen or is otherwise harmful to human health, and the investigation has identified a specific product that FSIS could recommend be recalled, the AES Director or designee is to contact the OFO Recall Management and Technical Analysis Staff (RMTAS) Director and provide him or her with the investigative findings.

B. The RMTAS Director is to convene the Recall Committee to discuss the 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, Recall of Meat and Poultry Products, to determine whether there is a basis for recommending a product recall.

C. If, after reviewing the AES investigative findings, the AES Director believes that there is a basis for FSIS to conclude 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 AES Director is to report the incident through supervisory channels. If appropriate, the situation is to be referred to the EMC as provided in FSIS Directive 5500.2. If the situation is referred to the EMC, the EMC is to decide whether FSIS should issue a public health alert or carry out other activities.

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 or enhanced inspection activities;

2. Investigation at a firm in commerce per FSIS Directive 8010.2;

3. Increased frequency of microbial testing;

4. Performing an in-plant FSA per FSIS Directive 5100.1, Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology or intensified
verification testing (IVT) per FSIS Directive 10,300.1, IVT Protocol for Sampling of Product, Food Contact Surfaces and Environmental Surfaces for Listeria monocytogenes;

5. Conducting an Incident Investigation Team (IIT) review as described in FSIS Directive 5500.3; Incident Investigation Team Reviews.

6. Effectuating a regulatory product control action, withholding action, or suspension (9 CFR 500.3 and 500.4);

7. Detaining or seizing product per FSIS Directive 8410.1; Detention and Seizure; or

8. Initiating a criminal, civil, or administrative action per FSIS Directive 8010.5.

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

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

G. OPACE is to lead public communications efforts as described in FSIS Directive 1240.1, Communicating with External Entities.

XII. CLOSE-OUT AND FINAL ASSESSMENT

A. Following the completion of each foodborne illness investigation, AES is to convene a group that includes FSIS program area representatives active in the investigation. AES is to 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 or enforcement procedures, regulations or other Agency documents, or some other aspect of its regulatory approach that would reduce the possibility of a repetition of the circumstances that led to foodborne illnesses and subsequent Agency action.

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

4. The AES lead investigator is to coordinate an FSIS close-out call that may include the public health partners involved with investigation. This action includes closing the IR in FIMS. The CDC may coordinate separate close-out calls with public health partners in multi-state investigations in which they are the lead agencies. The AES lead investigator will attend these calls to provide FSIS updates.

B. The AES lead investigator is to develop a final written summary, including potential policy implications, for each foodborne illness investigation and provide the summary to the AES Investigations Team Lead, other program areas involved in the investigations, and other FSIS entities upon request. The AES lead investigator is to post a copy of the final written summary to the investigation IR in FIMS.

C. On a quarterly basis or when the OPPD Risk and Innovations Management Staff (RIMS) determines that it is necessary, OPPD/RIMS staff are to lead an assessment of the events leading to a foodborne illness investigation, as well as the FSIS response, to assess whether the Agency can
improve its policies and investigation procedures.

1. OPPD/RIMS is responsible for coordinating the assessment meeting. Participants in the meeting may include, but are not limited to, FSIS program area representatives involved in the foodborne illness investigation.

2. When conducting the assessment, meeting participants are to consider pertinent information within and across program areas such as, but not limited to:
   a. FSA results from the establishment;
   b. Enforcement history of the establishment;
   c. Repetitive positive sampling results;
   d. Reports of consumer illness; and
   e. Any other pertinent information collected during the foodborne illness investigation.

3. After the close of the assessment meeting, OPPD/RIMS is to draft a written summary focusing on the circumstances that led to the investigations and suggesting areas where new policy or policy clarification may be needed. The official that drafted the report is to provide a copy to the RIMS Director and AES Director.

XIII. CONTINUOUS, ONGOING ACTIVITIES—WEEKLY INVESTIGATIONS MEETING; TRACKING AND REPORTING; COORDINATION AND COMMUNICATION

A. Weekly investigations meeting

1. AES is to conduct weekly investigations meetings in which representatives from OPHS and other program areas, such as ODIFP, OFO, OIEA, OPACE, and OPPD, are invited to share information about new and ongoing FSIS foodborne illness investigations. Representatives from the USDA Food and Nutrition Service (FNS) and Agricultural Marketing Service (AMS) are to be invited to participate.

2. Representatives from each FSIS program area are 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 AES 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 AES moderator for the weekly investigations meeting is to develop, for each investigation, a list of action items identified during the meeting and is to organize these items by program area. Following the meeting, AES is to distribute the action item list by e-mail to all of the weekly meeting participants.

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

B. Tracking sheets and recordkeeping

1. AES investigators are to maintain a foodborne illness investigation records 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. AES 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 its weekly meetings.

2. To track the progress of all FSIS foodborne illness investigations, AES 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 AES 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 AES 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 AES 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 AES are to inform the AES 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 AES Investigations Team Lead is to serve as the primary Agency point of contact with the CDC Outbreak Response and Prevention Branch. The AES lead investigator is to continue to be responsible for overall coordination of the FSIS foodborne illness investigation.

b. The AES Investigations Team Lead is to facilitate FSIS involvement in multi-jurisdictional investigations conducted by CDC and is to serve as the primary coordinator during conference calls.

c. The AES lead investigator is to inform the FSIS Liaison to CDC of FSIS activities during a foodborne illness investigation. The AES 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/FNS, USDA/AMS, Indian Health Service, and other federal partners. The AES Director or designee is to serve as the primary point of contact with other Federal agencies.

b. USDA Agricultural Research Service (ARS). During foodborne illness investigations, communication with ARS regarding PFGE interpretation or queries of VetNet is to be coordinated through SciS and OSEL staff.

5. Notification of industry

a. The OFO, OIEA, or OPHS Assistant Administrators or their designees are to inform individual establishments about their potential association with illnesses. They are to notify establishments when the investigation has determined a potential implication of products produced by the establishment. The AES lead investigator is to post the notification in the IR in FIMS.

i. The OFO AA or designee is also to notify the appropriate OFO district office.

ii. The producing establishment is to be informed of its potential association with illnesses or public health risk. It is to be notified when FSIS personnel are to be dispatched to the establishment.

iii. The producing establishment is to be informed that it should be prepared to make available all relevant documents which can assist with traceback and traceforward activities related to the foodborne illness investigation.

XIV. EVALUATION

The foodborne illness investigation records database, referenced in sections VII and XIII, is used to create a weekly foodborne illness investigations report spreadsheet. AES is to analyze the data contained in the foodborne illness investigation database. The analysis is to confirm that investigations are closed, final statistics are presented, and data are entered correctly. AES is to complete this analysis quarterly and is to compile it yearly. Additionally, AES is to provide annual briefings to the Data Coordinating Committee (DCC) and other FSIS personnel and post reports to the DCC SharePoint website.

XV. QUESTIONS

Refer questions regarding this directive to the Risk, Innovations, and Management Staff through askFSIS or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter FSIS Directive 8080.3
Question Field: Enter question with as much detail as possible.
Product Field: Select General Inspection from the drop-down menu.
Category Field: Select Sampling - General from the drop-down menu.
Policy Arena: Select Domestic (U.S.) Only from the drop-down menu.

When all fields are complete, press Continue.

[Signature]
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 Staff (AES)
   - Functions as the Agency lead and principal coordinator for foodborne illness investigations
   - Conducts surveillance and initiates the foodborne illness investigation process
   - Serves as an Agency point of contact for local, state, and territorial public health and agriculture 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 AES report for dissemination to appropriate Agency entities.
   - Conducts consumer complaint surveillance and investigation activities per FSIS Directive 5610.1

2. Science Staff (SciS)
   - 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

3. Outbreaks Section of Eastern Laboratory (OSEL)
   - Performs laboratory testing, including PFGE and MLVA analyses, of investigation-associated samples and isolates
   - Conducts PFGE searches and analyzes PFGE data
• Coordinates requests for information to USDA/ARS VetNet and the Centers for Disease Control and Prevention (CDC) PulseNet

Office of Investigation, Enforcement and Audit (OIEA)

• Conducts domestic and international 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, civil, or administrative activities
• Coordinates investigations involving alleged tampering or terrorist activities with the Office of the Inspector General and other law enforcement agencies
• Coordinates investigation of foreign establishments
• Serves as an Agency point of contact for local, state, and territorial public health and agriculture officials
• Assists OFO at official establishments; participates in verification activities 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 from 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
• Oversees the USDA Meat and Poultry Hotline which serves as a point of contact for the public to report problems or illnesses possibly associated with FSIS-regulated food products

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 Data Integration and Food Protection (ODIFP)

• Collaborates with program areas during investigations that may involve food defense or emergency coordination issues

• Supports investigations by providing data or performing analyses

• Coordinates the activities of the Emergency Management Committee (EMC) as outlined in FSIS Directive 5500.2

• Administrates and manages the FSIS Incident Management System (FIMS) which is used to manage and track incident reports (IRs)

• Oversees and reviews the IRs that may be created due to a foodborne illness investigation

Office of Outreach, Employee Education, and Training (OOEET)

• Provides training on FSIS strategies to address foodborne illness investigations and product traceback/traceforward methodology

• Trains inspection workforce on importance of sample collection techniques, proper documentation, chain of custody, and general food safety issues including HACCP evaluation and product statutes and regulations

• Informs workforce of food safety and biosecurity issues and lessons learned from recalled FSIS-regulated products