

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

<h1 style="margin:0;">FSIS DIRECTIVE</h1>	8080.3 Rev. 2	10/27/17
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FOODBORNE ILLNESS INVESTIGATIONS

I. PURPOSE

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

II. CANCELLATION

FSIS Directive 8080.3, Rev. 1 Foodborne Illness Investigations, 9/4/13

III. 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. The objectives of an FSIS foodborne illness investigation are to:

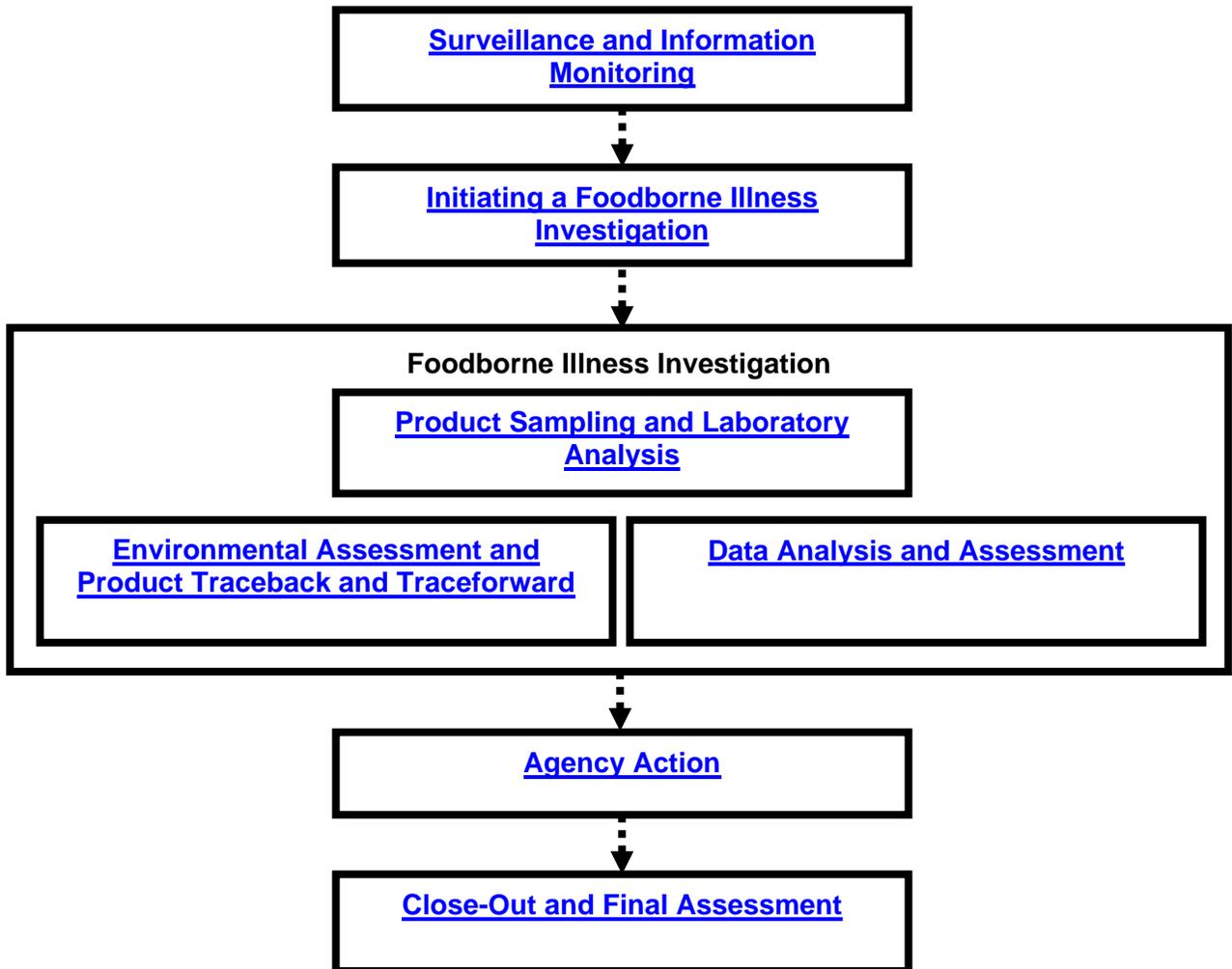
1. Determine whether reported human illness is associated with an FSIS-regulated product;
2. Identify the source and scope, as well as the distribution, of suspect meat, poultry, or processed egg product;
3. Gather information that FSIS can use to guide its response to ensure that the product associated with illness is not available for consumption;
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 recommend the recall of the identified products;
6. Identify contributing factors, including addressing potential system failures;
7. Prepare a report on the results of the illness investigation; and
8. Recommend actions or new policies to prevent future occurrences.

DISTRIBUTION: Electronic

OPI: OPPD

C. Although the focus of the directive is on foodborne illness associated with microbial hazards, the information is applicable for investigation of foodborne illnesses with deleterious substances in food.

D. 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:



E. 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](#).

F. This directive supplements, but does not conflict with or supersede, instructions related to investigation procedures as specified in FSIS Directive [FSIS Directive 8010.1, Methodology for Conducting In-Commerce Surveillance Activities](#), [FSIS Directive 8010.2, Investigative Methodology](#), [FSIS Directive 8010.3, Procedures for Evidence Collection, Safeguarding and Disposal](#), [FSIS Directive 8010.4, Report of Investigation](#), and [FSIS Directive 8010.5, Case Referral and Disposition](#).

G. Some general terms used during outbreak investigations are:

1. Case-patient: An individual with a presumptive or confirmed foodborne illness.
2. 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.
3. Environmental assessment: Investigation of the factors in the environment, such as in-plant assessments.
4. FSIS Incident Management System (FIMS): The web-based application for managing the receipt, monitoring, and follow-up actions of all Incident Reports (IRs) received by FSIS.
5. FSIS foodborne illness investigation: An investigation of a possible association between human illnesses and an FSIS-regulated product that includes epidemiologic, laboratory, traceback activities, and environmental assessments.
6. FSIS foodborne illness watch: An illness cluster with a likelihood of involvement of FSIS-regulated product with traceable information where additional exposures have not been ruled out.
7. Implicated: Evidence from epidemiologic, laboratory, and traceback information or strong evidence from two of the three sources of information, rendering a conclusion about a suspect vehicle.
8. Intact package: A product with unopened packaging or a product that has not been removed from its original primary packaging, by the consumer or other party, as supplied by the producing establishment.
9. 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 or environmental sample.
10. Multiple-locus Variable-number Analysis (MLVA): 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.
11. Non-intact package: A product with opened packaging or a product that has been removed from its original primary packaging, by the consumer or other party, as supplied by the producing establishment.
12. Pulsed-field gel Electrophoresis (PFGE): A DNA-based laboratory method used to determine whether isolates are closely related genetically and therefore could originate from a common source.
13. PulseNet: A national laboratory network headquartered at the Centers for Disease Control and Prevention (CDC) consisting of public health and food regulatory

laboratories that contribute isolate characterization information for sharing across public health and regulatory partners.

14. Surveillance: The use of systematically collected data to monitor and detect events or clusters that may trigger a foodborne illness watch or investigation.
15. 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.
16. 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.
17. Whole Genome Sequencing (WGS): A molecular method that provides high resolution data for identifying and characterizing bacteria and other microorganisms.

IV. ROLES AND RESPONSIBILITIES OF FSIS PERSONNEL THROUGHOUT FOODBORNE ILLNESS INVESTIGATIONS

A. Office of Public Health Science (OPHS)

1. Applied Epidemiology Staff (AES)

- a. Functions as the Agency lead and principal coordinator for foodborne illness investigations;
- b. Conducts surveillance and initiates the foodborne illness investigation process;
- c. Serves as an Agency point of contact for local, state, and territorial public health and agriculture officials;
- d. Coordinates requests for information to and from the Centers for Disease Control and Prevention (CDC) Outbreak Response and Prevention Branch (ORPB) and in coordination with the FSIS Liaison to CDC;
- e. Analyzes epidemiologic and other investigation-related information;
- f. Assists other program areas to ensure factual, technical, and scientific accuracy in public communications;
- g. Shares information with other program areas to facilitate effective field investigative activities;
- h. Coordinates follow-up and close out meetings and compiles information to develop a final AES report for dissemination to appropriate Agency entities;
- i. Conducts consumer complaint surveillance and investigation activities per [FSIS Directive 5610.1](#); and
- j. Coordinate foodborne-related illness root cause assessment with USDA/APHIS as outlined in the MOU between FSIS and APHIS Veterinary Services.

2. Science Staff (SciS)

- a. Designs, coordinates, and leads implementation of intensified sampling or other related sampling activities for outbreak investigations
- b. Coordinates sample collection and transportation and analyses of FSIS samples
- c. Evaluates the chain of custody and results of samples from non-FSIS laboratories per [FSIS Directive 10,000.1](#), *Policy on Use of Results from Non-FSIS Laboratories*;
- d. Communicates and interprets sample results; and
- e. Assists other program areas to ensure factual, technical, and scientific accuracy in public communications

3. Eastern Laboratory Microbial Characterization Branch (MCB)

- a. Performs laboratory testing, including subtyping analyses, of investigation-associated samples and isolates; and
- b. Coordinates requests for laboratory information to and from the CDC PulseNet in coordination with the FSIS Liaison to CDC.

4. FSIS Liaison to CDC

- a. Serves as the primary Agency point of contact with the CDC;
- b. Supports FSIS-CDC interagency investigation coordination and communication; and
- c. Serves as a subject matter expert on foodborne diseases and foodborne illness investigations.

B. Office of Investigation, Enforcement and Audit (OIEA)

1. Conducts domestic and international traceback and traceforward activities to determine product source and locate product in commerce;
2. Controls adulterated or misbranded product in commerce;
3. Collects and submits samples of product upon request;
4. Obtains administrative subpoenas for records, if necessary;
5. Investigates situations that may involve criminal, civil, or administrative activities;
6. Coordinates investigations involving alleged tampering or terrorist activities with the Office of the Inspector General (OIG) and other law enforcement agencies;

7. Coordinates investigation of foreign establishments;
8. Serves as an Agency point of contact for local, state, and territorial public health and agriculture officials to coordinate traceback and traceforward activities; and
9. Assists OFO at official establishments; participates in verification activities or product identification and control.

C. Office of Field Operations (OFO)

1. Conducts traceback and traceforward activities at official establishments;
2. Locates and controls product that has not left the official establishment;
3. Collects and submits product samples from official establishments;
4. Conducts in-plant investigations and actions;
5. Analyses, reviews, and verifies inspection-related data; and
6. Coordinates recall activities.

D. Office of Public Affairs and Consumer Education (OPACE)

1. Coordinates media, consumer, trade group, and stakeholder communication; and
2. 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.

E. Office of Policy and Program Development (OPPD)

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

F. Office of Data Integration and Food Protection (ODIFP)

1. Collaborates with program areas during investigations that may involve food defense or emergency coordination issues; and
2. Supports investigations by providing data or performing analyses;
3. Coordinates the activities of the Emergency Management Committee (EMC) as outlined in [FSIS Directive 5500.2](#), *Significant Incident Response*;
4. Administrates and manages the FSIS Incident Management System (FIMS) which is used to manage and track incident reports (IRs); and
5. Oversees and reviews the IRs that may be created due to a foodborne illness investigation.

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

1. Provides training on FSIS strategies to address foodborne illness investigations and product traceback and traceforward methodology;
2. 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; and
3. Informs workforce of food safety and biosecurity issues and lessons learned from recalled FSIS-regulated products.

V. 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, national, tribal, 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. 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 OPHS AES Senior Epidemiologist embedded in the CDC Outbreak Response and Prevention Branch (ORPB), FSIS Liaison to CDC, or designee; or
3. If other federal agencies, specifically 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, a member of the Coordinated Outbreak Response and Evaluation (CORE) Network, including the FDA Liaison to CDC, notifies AES.

B. OPHS conducts its own monitoring and surveillance activities driven by the CDC Epi-X system, CDC PulseNet, foodborne illness reporting listservs, and illness 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](#).

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

D. 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.

E. If a public health official outside of FSIS contacts FSIS personnel who work in an office other than AES to report information on a potential association between human illness and an FSIS-regulated product, that office is to inform the AES Director or AES Senior Epidemiologist embedded in the CDC ORPB. An AES investigator contacts the public health official, in coordination with CDC ORPB, to gather information about the illness and the affected product. Foodborne illness can also be reported to FoodborneDiseaseReports@fsis.usda.gov.

F. When AES investigators receive information about a potential association between human illness and an FSIS-regulated product, they assess the strength of the epidemiologic data 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 as an FSIS foodborne illness investigation or watch by AES depending on 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?

G. If, after considering the factors described above, AES investigators determine that the reported human illness may be associated with an FSIS-regulated product, they initiate a foodborne illness investigation using the instructions in section VI.

H. When AES initiates a foodborne illness investigation, the AES Director or designee designates an AES lead investigator who will be responsible for the overall coordination of the investigation.

I. 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.

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

A. After AES initiates an FSIS foodborne illness investigation, and if one does not already exist, the AES lead investigator will create an IR in FIMS unless determined otherwise by OFO, OIEA, or OPHS Assistant Administrators. The AES lead investigator will enter information about the investigation into the IR. The AES lead investigator should ensure that data from the OPHS investigation record database is added to the IR.

B. The AES Senior Epidemiologist embedded in the CDC ORPB or designee is to determine whether to issue an e-mail alert. Alerts provide early notification of foodborne illness investigations that will likely necessitate additional Agency resources or action. The e-mail is

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 to the IR in FIMS.

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

D. The AES lead investigator 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, EMC representative, and other appropriate personnel. The AES lead investigator is to post this information to the IR in FIMS.

E. If an FSIS foodborne illness investigation requires involvement of the EMC, AES will follow the procedures of [FSIS Directive 5500.2](#). 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.

F. 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. OIEA will determine if the OIG should be involved as per [FSIS Directive 8030.1](#).

G. If at any time the AES lead investigator or any other FSIS personnel suspect a potential pre-harvest link, they are to notify the AES Director or designee so that a determination could be made regarding coordination of root cause assessment with the USDA Animal and Plant Health Inspection Service (APHIS) as outlined in the [MOU between FSIS and APHIS Veterinary Services](#).

VII. PRODUCT SAMPLING AND LABORATORY ANALYSIS

A. Determining whether to submit case-patient or retail product samples for laboratory analysis:

1. AES investigators are to meet with the OPHS SciS and Eastern Laboratory MCB 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 case-patient or retail products potentially implicated in an FSIS foodborne illness investigation, AES and SciS are to consider the answers to the questions presented below in consultation with MCB:
 - 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 conjunction with FSIS?
3. The AES and SciS lead investigators are to consider whether FSIS should analyze non-intact package product samples obtained in commerce or from a consumer's home. To determine whether to submit a non-intact package product sample for laboratory analysis, AES and SciS are to consider the following factors to assess the validity and utility of findings:
- a. Was the non-intact package product directly handled by the case-patient? If so, when and under what circumstances was it handled?
 - b. Was the non-intact package product stored properly to avoid cross-contamination and minimize temperature abuse?
 - c. Are packaging materials and product labels that identify the non-intact package product available? Does the case-patient have a shopper loyalty card or receipt that would assist with product identity? Was traceback successful in determining the product identity?
 - d. Is the product from an official establishment that has recently been part of a voluntary recall? If yes, was the product produced outside the scope of the recall?
4. If, after considering the factors described in sections VII.A.2. and VII.A.3. above, AES, SciS, and MCB determine that product sampling and laboratory testing are needed to determine whether there is an association between illness 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 types and quantities of samples to be collected and the specific analyses to be performed to maximize the chance of generating data that can inform decision-making.
 - b. SciS is to fill out the "Outbreak-Associated Sample Request" form. This form describes the number and types of samples, the number of test portions, the proposed analyses, and the priority and urgency of laboratory analyses.

B. Investigative sampling: If it is determined that FSIS should conduct investigative sampling at an implicated establishment or at a retail location, SciS will coordinate development of a sampling plan and work with the Laboratory Quality Assurance Staff (LQAS) to develop a

laboratory contract; SciS will develop and implement the sampling in coordination with OFO, OIEA, and OPPD.

C. Collecting, preparing, and shipping product samples:

1. Information regarding product sampling and subsequent laboratory results will be posted to the IR in FIMS.
2. 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](#).
3. OFO program personnel and OIEA/CID investigators are to contact the SciS lead investigator if they have any questions on how they are to collect, prepare, or ship product samples collected as part of a foodborne illness investigation.
4. OFO district office personnel are to notify the affected establishment of the Agency's collection of product samples for laboratory analyses prior to sampling.

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

5. OIEA/CID investigators are to notify the affected retail firm when a product sample in commerce is collected for laboratory analyses.
6. OIEA/CID investigators may coordinate with state or local public health personnel to assist with the collection of samples from a case-patient's residence.
7. OFO district office personnel will notify the official federal establishment when a product sample is collected for laboratory analysis at a retail setting or from a case-patient's home.
8. 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.

D. 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 is 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 an 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. SciS will also coordinate with the MCB personnel to ensure that they are aware of samples being sent to FSIS for analysis.

E. 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, including the AES lead investigator, as well as to the FSIS staff who submitted the samples. SciS will compile data from intensified sampling. OPHS is to post this information to the IR in FIMS.

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

G. CDC PulseNet: All microbiological analysis, including MLVA, PFGE, and WGS data derived from FSIS foodborne illness investigations and recall related samples by MCB are to be transferred to PulseNet by MCB staff. All requests for data from the PulseNet are to be coordinated by MCB staff.

VIII. ENVIRONMENTAL ASSESSMENT AND PRODUCT TRACEBACK AND 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 to 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. All case-patient personally identifiable information (PII) should be redacted.

B. OIEA activities during foodborne illness investigations

1. The AES and SciS Directors or designees are 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 investigative 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 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 Operations Branch and OPPD Import and Export Policy Development Staff; the Office of International Coordination will work and communicate with foreign governments.
3. The OIEA/CID assigned investigator or designee will develop and post an investigative plan and timeline for OIEA activities to the IR in FIMS within 12 hours of the IR approval and include "Investigative Plan was developed and published in the IR" in the comment field of the IR. The Investigative Plan will include the name and contact information of the OIEA/CID investigator assigned to assist with the investigation as described in [FSIS Directive 8010.2](#). The investigative plan and timeline will be updated with information throughout the investigation and posted to 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 Regional Director (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 an official establishment. The request should include the rationale and how the findings will be used in the investigation. For example, AES may need OFO to obtain traceback and traceforward information about a product, obtain information about the establishment's suppliers, or locate like- or same-coded intact package product that has not left the establishment, submit product samples for laboratory analyses, collect information about production practices in the plant, or conduct other activities to determine whether there is an association between product and illness. OFO may identify the need to perform a public health risk evaluation, (PHRE) and/or food safety assessment (FSA), which may yield information relevant to the investigation.
2. The OFO Recall Management and Technical Analysis Division (RMTAD) Director, District Manager (DM), or designee is to provide the AES Director, AES lead investigator, and OIEA investigators with the names and contact information of the OFO personnel assigned to assist with the investigation and inform the AES and OIEA of the status of OFO personnel's activities. The names of the OFO personnel, designated by the OFO DM or designee, assigned to assist with the investigation will be included in the Investigative Plan that is posted to the IR in FIMS.

3. The RMTAD Director, DMs, or designee is to communicate a status back within 24 hours of the initial request confirming the decision to provide assistance. If the RMTAD Director, DMs or their designee has questions concerning a request for OFO to assist 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 RMTAD Director, DMs, or designees of the appropriate districts to ensure that relevant documents are posted to the IR in FIMS.
5. The RMTAD Director or designee is to be included in all email communication between OFO and other internal and external stakeholders.

IX. 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 credible evidence to support an association between an FSIS-regulated product and human illness.

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

C. When an association is established between human illness 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 may 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 or establishments under one corporate umbrella;
2. Findings from a traceback or traceforward investigation of products consumed by ill persons that provide evidence of a common production source at an official establishment;
3. Environmental findings from an in-plant assessment suggestive of product contamination events;
4. 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; or

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

NOTE: Findings may also establish a link between human illness and an FSIS-regulated product from a retail location.

X. 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 RMTAD Director or designee and provide the investigative findings.

NOTE: OIEA provides decision memos as part of the decision making process.

B. The RMTAD Director or designee 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 or designee 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), OPHS may recommend that a public health alert be issued. 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. The 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 or public health alert 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 (intensified sampling);
4. Conduct a PHRE as described in [FSIS Directive 5100.4](#);
5. 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;

6. Conducting an Incident Investigation Team (IIT) review as described in [FSIS Directive 5500.3](#); *Incident Investigation Team Reviews*;
7. Effectuating a regulatory product control action, withholding action, or suspension ([9 CFR 500.3](#) and [500.4](#));
8. Detaining or seizing product per [FSIS Directive 8410.1](#); *Detention and Seizure*; or
9. 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 if one was created for the investigation. OIEA/CID will also provide a written request to close out the IR following an AES recommendation.

F. AES investigators are to communicate Agency actions to public health officials in affected local, state, and territorial health, environmental health, and agriculture departments through established channels, such as the FSIS Resources for Public Health Partners webpage. Release of information specific to an inspected establishment will be cleared by OFO prior to its release outside of FSIS.

G. OPACE is to lead public communications efforts as described in [FSIS Directive 1240.1](#), *Communicating with External Entities*.

XI. 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.
2. The group is to assess whether there are changes that the Agency could make in its inspection or enforcement procedures, regulations, other Agency documents, or some other aspect of its regulatory approach that would reduce the possibility of a recurring circumstance 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 public health partners involved with investigation. The CDC may coordinate close out calls with public health partners in multistate investigations in which they are the lead agency. AES investigators will participate on these calls to provide FSIS updates.
5. An After Action Review (AAR) may be conducted on a case-by-case basis to analyze and assess the investigation to validate best practices, inform process improvements, and provide recommendations for actions that can be implemented immediately and in

subsequent investigations. The AES Director is to designate an AES facilitator to plan and conduct the AAR in addition to developing an AAR report. Factors that may trigger an AAR include:

- a. Issues identified that had an impact on the outcome of the investigation;
- b. Questions that arose during the investigation that were not addressed by existing protocols or procedures;
- c. An unusually complex or difficult investigation or one that was associated with unforeseen challenges; or
- d. New procedures that were implemented during the investigation.

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 Director or designee, 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 IR in FIMS if one was created for the investigation.

C. On a quarterly basis or when the OPPD Risk and Innovations Management Staff (RIMS) determines that it is necessary, OPPD/RIMS staff, in coordination with OPHS, 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. PHRE or FSA results from the establishment;
 - b. Enforcement history of the establishment;
 - c. Historical sampling results, including 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 investigation and suggesting areas where new policy or policy clarification may be needed. The official who drafted the report is to provide a copy to the RIMS and AES Directors along with the attendees from the assessment meeting.

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

A. FSIS Weekly investigations meeting

1. AES conducts 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 watches and investigations. Representatives from the USDA Food and Nutrition Service (FNS), Agricultural Marketing Service (AMS), and APHIS are 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 prior to the meeting.
3. The AES moderator for the weekly investigations meeting is to develop an agenda outlining foodborne illness watches and 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. CDC-FDA-FSIS tri-agency meeting

1. Representatives from OPHS participate in a weekly meeting with CDC and FDA to discuss and review clusters and outbreaks that are of interest to the agencies.

C. Tracking sheets and recordkeeping

1. AES investigators are to maintain foodborne illness investigation data in the investigation record database, which is used to create a weekly foodborne illness investigations report spreadsheet.
 - a. The weekly report spreadsheet is to include information on all open foodborne illness watches and investigations;
 - b. AES is to distribute the weekly report spreadsheet to OPHS management by e-mail;
2. To track the progress of all FSIS foodborne illness investigations, AES investigators are to maintain and include in the IR, if one was created for the investigation, line list of case-patients, brief summaries, and other relevant information, such as laboratory testing data.

D. 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; the AES lead investigator should be kept abreast of all activities associated with the investigation. OPACE is 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 include the AES lead investigator of any planned or ongoing direct communications with public health officials outside FSIS to avoid duplication of effort.

3. Coordination with CDC

- a. The AES Senior Epidemiologist embedded in the CDC ORPB serves as the primary Agency point of contact with the CDC ORPB. The AES lead investigator continues to be responsible for the overall coordination of the FSIS foodborne illness investigation. The FSIS Liaison to CDC serves as the primary Agency point of contact with the CDC.
- b. The AES Senior Epidemiologist embedded in the CDC ORPB 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 and the AES Senior Epidemiologist embedded in the CDC ORPB 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.
- d. CDC-Agency for Toxic Substances and Disease Registry (ATSDR) may participate in an FSIS-led in-plant assessment when epidemiologic data is the key evidence implicating illness to products produced by an establishment and/or when CDC-ATSDR expertise would enhance the assessment as described in the [MOU between FSIS and CDC-ATSDR Regarding Foodborne Health Hazard Assessments Associated with FSIS-Regulated Product.](#)

4. Coordination with other Federal agencies

- a. FDA, USDA/FNS, USDA/AMS, Department of Defense, and other federal partners. The AES Director or designee is to serve as the primary point of contact with other Federal agencies.
 - b. USDA APHIS. Coordinate foodborne-related illness root cause assessment with USDA/APHIS as outlined in the [MOU between FSIS and APHIS Veterinary Services](#).
 - c. OIEA CID Director or designee will notify OIG per [FSIS Directive 8030.1](#) if intentional product tampering is suspected.
5. Notification of industry and industry associations
- 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. A summary of the meeting will be posted to 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 and be prepared to make available all relevant documents which can assist with traceback and traceforward activities related to the foodborne illness investigation. It is to be notified when FSIS personnel are planning to be dispatched to the establishment.
 - iii. When epidemiologic data is the key evidence linking illness to products produced by the establishment, the AES Senior Epidemiologist embedded at CDC ORPB and the FSIS Liaison to CDC will work with CDC and OFO to coordinate conference calls with industry in addition to ensuring proper FSIS representation at the meeting. A summary of the meeting will be posted in the IR in FIMS.
 - b. Factors that may trigger early industry notification include:
 - i. An FSIS-regulated product from the producing establishment has been collected for testing by state or local public health partners as part of the foodborne illness investigation.
 - ii. Preliminary traceback identified multiple producing establishments from the same corporation.
- E. FSIS personnel are to refer to procedures in [FSIS Directive 1450.1](#) if there is a FOIA request regarding a foodborne illness investigation.

XIII. EVALUATION

The foodborne illness investigation record database referenced in sections VI and XII is used to create a weekly foodborne illness investigations report spreadsheet. AES is to analyze the data contained in the foodborne illness investigation record database. The analysis is to confirm that investigations are closed, final statistics are presented, and data are entered correctly. AES will document the completion of this analysis quarterly and yearly. Additionally, AES is to provide annual briefings to the Data Coordinating Committee (DCC) and other FSIS personnel and post reports to the DCC and AES SharePoint websites.

XIV. 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 and at the next screen press **Finish Submitting Question**.

NOTE: Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.



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