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

FSIS DIRECTIVE

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FOODBORNE ILLNESS INVESTIGATIONS

I. PURPOSE

This directive provides personnel from the 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), Office of Planning, Analysis, and Risk Management (OPARM), Office of Public Health Science (OPHS), and Significant Incident Preparedness and Response Staff (SIPRS) 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. The Agency is reissuing this directive to reflect changes in organization structures, laboratory methodology for microbial characterization, and responsibilities during a foodborne illness investigation.

II. CANCELLATION

FSIS Directive 8080.3, Rev. 2 Foodborne Illness Investigations, 10/27/17

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 involves collecting and analyzing data from a variety of sources. Epidemiologic, laboratory, environmental, and traceback information helps guide the short-term response and long-term preventive actions. The objectives of an FSIS foodborne illness investigation are to:

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

2. Identify the source, scope, and distribution of suspect meat, poultry, or processed egg products;

3. Gather information that FSIS can use to guide its response to ensure that the product associated with reported illnesses is not available for consumption to prevent further consumer exposure;

4. Collect information and evidence that can be used to support or lead to an enforcement action or recommend the recall of the identified products;

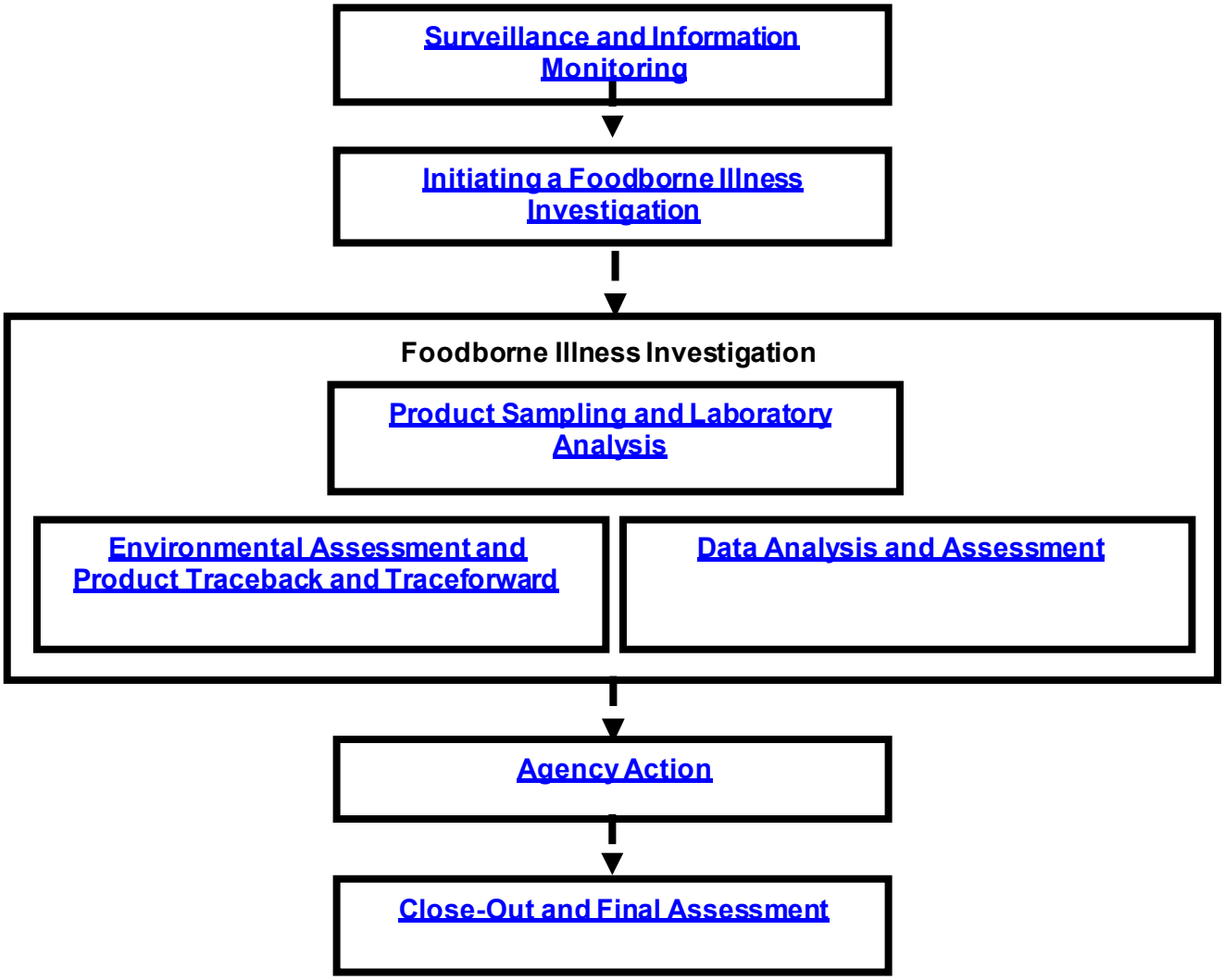
5. Identify contributing factors, including addressing potential system failures;

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

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

C. Although this directive focuses on foodborne illness associated with microbial hazards, the same process is generally applicable for investigation of foodborne illnesses with other deleterious substances in food.

D. This directive is organized to reflect the general phases of an FSIS foodborne illness investigation (see diagram below). 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 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 5500.3, *Incident Investigation Team Reviews*, 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*, FSIS Directive

8010.5, *Case Referral and Disposition*, and FSIS Directive 8080.1, *Recall of Meat and Poultry Products*.

G. Some general terms used during outbreak investigations are:

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

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

3. Environmental assessment: Investigation of the factors in the environment, such as in- plant or in-commerce 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 investigation: An illness cluster with a strong likelihood of involvement of FSIS-regulated product that may necessitate additional Agency resources.

6. FSIS 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. FSIS extended watch: An illness cluster with a likelihood of involvement of FSIS-regulated product; case count continues to increase over an extended period of time and a common product type or source has not been identified.

8. Implicated: Evidence from epidemiologic, laboratory, environmental, and traceback information or strong evidence from two of the three sources of information, rendering a conclusion about a suspect vehicle.

9. Intact package: A product with unopened packaging or a product that has not been removed from its original primary packaging, as supplied by the producing establishment, by the consumer or other party.

10. 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.

11. Non-intact package: A product with opened packaging or a product that has been removed from its original primary packaging, as supplied by the producing establishment, the consumer or other party.

12. 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.

13. Surveillance: The use of systematically collected data to monitor and detect events or clusters that may trigger a foodborne illness watch or investigation.

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

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

16. Whole Genome Sequencing (WGS): A molecular method that provides high resolution data for identifying and characterizing bacteria and other microorganisms used to determine whether isolates are closely related genetically and therefore could originate from a common source.

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

A. 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 CDC Outbreak Response and Prevention Branch (ORPB) and in coordination with the OPHS Epidemiologist or Liaison at 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. Coordinates meetings with internal and external partners to discuss epidemiologic, traceback, and other evidence to determine next investigative steps;

   h. Shares information with other program areas to facilitate effective field investigative activities;

   i. Coordinates follow-up and close-out meetings and compiles information to develop a final AES report for dissemination to appropriate Agency entities;

   j. Facilitates after-action reviews (AAR) with public health partners to identify, share, and apply lessons learned with public health, industry partners, and consumers to help prevent future illness and improve response;

k. Conducts consumer complaint surveillance and investigation activities per FSIS Directive 5610.1; and

l. Coordinates foodborne-related illness root cause assessment with USDA Animal and Plant Health Inspection Service (APHIS) as outlined in the Memorandum of Understanding (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 collection, transportation, and analyses of FSIS samples;

c. Evaluates the chain of custody and results of sample tests from non-FSIS laboratories per FSIS Directive 10,000.1, *Policy on Use of Results from Non- FSIS Laboratories*;

d. Communicates and interprets sample test results; and

e. Assists other program areas to ensure factual, technical, and scientific accuracy in public communications.

3. The Field Service Laboratories (FSLs) (Eastern Laboratory (EL), Western Laboratory (WL), and Midwestern Laboratory (ML))

a. Performs laboratory testing, including subtyping analyses, of investigation-associated samples and isolates; and

b. EL's Microbiology Characterization Branch (MCB) coordinates requests for laboratory information to and from the CDC PulseNet in coordination with the OPHS Epidemiologist or Liaison at CDC.

4. OPHS Epidemiologist or Liaison at 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. OIEA

1. Conducts traceback and traceforward activities to determine product source, product distribution, and product location 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 in coordination with AES; and

9. Assists OFO at FSIS-regulated establishments by participating in verification activities or product identification and control.

C. OFO

1. Conducts traceback and traceforward activities at FSIS-regulated establishments;

2. Locates and controls product that has not left the FSIS-regulated establishment;

3. Collects and submits product samples from FSIS-regulated establishments;

4. Conducts in-plant investigations and actions;

5. Coordinates information requests between AES and District Offices;

6. Analyzes, reviews, and verifies inspection-related data; and

7. Coordinates potential recall activities.

D. OPACE

1. Coordinates communication with media, consumer and trade groups, state, and Federal partners, and other stakeholders;

2. Drafts, clears, and publishes FSIS recall notices and public health alerts; and

3. 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. OPPD

1. Assesses policy implications and provides policy-based recommendations; and

2. Reviews investigation data to assess needs for policy clarification or development.

F. OPARM

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.

G. SIPRS

1. Coordinates the activities of the Emergency Management Committee (EMC) as outlined in FSIS Directive 5500.2, *Significant Incident Response;*

2. Administrates and manages FIMS which is used to manage and track IRs; and

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

H. Office of International Coordination (OIC)

1. Serves as the Agency's point of contact during foodborne illness investigations that involve foreign imported product or exports to other foreign markets; and

2. Coordinates international activities related to foodborne illness investigations.

V. 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 illness 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;

    a. 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 Epidemiologist or Liaison at the CDC, or designee; or

    b. 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.

2. Notification from the OPHS MCB review of FSIS isolates through routine testing and comparing the isolates to other clinical and nonclinical isolates uploaded to the National Center for Biotechnology Information (NCBI) database.

NOTE: If a public health official contacts FSIS personnel 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 Epidemiologist embedded in the CDC ORPB. An AES investigator will contact the public health official, in coordination with CDC ORPB, to gather information about the illness and the affected product. Foodborne illness outbreaks can also be reported to FoodborneDiseaseReports@usda.gov.

B. OPHS conducts its own monitoring and surveillance activities driven by the CDC PulseNet, foodborne illness reporting listservs, media reports, 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. 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.

D. When AES investigators receive information about a potential association between human illness and an FSIS-regulated product, they assess the strength of evidence 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 potential link between an 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 all 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.

F. 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.

G. 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 is to ensure that data from the investigation record database is added to the IR.

B. The AES Director 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.

1. The e-mail is sent to an established network of program area contacts selected by program

area management. These contacts are responsible for communicating relevant information about an investigation to their program area management, EMC representative, and other appropriate personnel.

2. The AES lead investigator is to post the alert information to the IR in FIMS. The alert will provide the name and contact information of the AES lead investigator in addition to the IR number.

3. 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. If there is a need for further dissemination, the AES lead investigator should be contacted first.

4. The AES lead investigator is to send updated e-mail alerts when there are significant developments in a foodborne illness investigation. The updates are to be distributed to the same established network of FSIS program area contacts designated to receive alerts.

C. If an FSIS foodborne illness investigation presents a grave, or potentially grave threat to public health or to the safety of FSIS-regulated product and requires involvement of the EMC, AES will follow the procedures as discussed in FSIS Directive 5500.2. An example includes life-threatening or widespread human illnesses potentially associated with FSIS-regulated product that led to a foodborne illness investigation.

D. 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, *Communicating with the Office of Inspector General (OIG)*.

E. If at any time the AES lead investigator or any other FSIS personnel suspect a potential pre-harvest association to illnesses, they are to notify the AES Director or designee. A determination can be made regarding coordination of root cause assessment with the USDA APHIS as outlined in the MOU between FSIS and APHIS Veterinary Services.

VII. PRODUCT SAMPLING AND LABORATORY ANALYSIS

A. Determining whether to submit product samples for laboratory analysis:

1. AES investigators are to meet with the OPHS SciS and EL 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 products potentially implicated in an FSIS foodborne illness investigation, AES and SciS are to consider the questions presented below in consultation with FSLs:

    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. Does the product that is available for testing meet FSIS criteria for product identity, chain of custody, and product handling as outlined in the decision criteria of FSIS Directive 10,000.1? 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. When applicable, SciS investigators are to consider whether FSIS should analyze non-intact package product samples obtained in commerce or from a case'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? 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 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 FSIS-regulated 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 the FSLs 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 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. Develop an investigative sampling plan: If it is determined that FSIS should conduct investigative sampling at an implicated establishment or retail location, SciS will coordinate development of a sampling plan and work with the Laboratory Quality Assurance Staff (LQAS) to develop alaboratory capacity agreement; 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. When collecting, preparing, and shipping product samples for laboratory analyses as part of a foodborne illness investigation, OIEA/CID investigators are to refer to procedures in FSIS Directive 8010.3.

3. OFO program personnel and OIEA/CID investigators are to contact the SciS 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. District Office (DO) personnel will notify the federal establishment when a product sample is collected for laboratory analysis at a retail setting, another inspected establishment, or from a case's home. OPHS investigators will prepare information to be shared through the DO. Minimally, and as applicable and available, this information is to include:

    i. Talking points regarding the investigation that prompted the sampling event;

    ii. Date and location of the collection;

    iii. Product collected and available packaging information on the product; and

    iv. Intended analyses and tentative timeline for when results will be made available to the establishment.

NOTE: If samples are taken from product that has not moved into commerce, and positive results support that product is adulterated, OFO DO personnel notify the establishment that the sampled lot 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's residence.

7. When samples cannot be collected and shipped by FSIS personnel, the SciS 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 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 FSL 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 investigator and FSL Chief may arrange for testing in a government or university research laboratory that SciS and FSL 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 WGS data derived from FSIS foodborne illness investigations and recall related samples by FSL, 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 efforts.

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 phone or e-mail and upload the information to the IR in FIMS.

4. Information collected during an investigation that contains personal identifiers that can be linked back to cases is to be considered confidential and not released to parties outside of FSIS. The person responsible for entry is to ensure all case personally identifiable information (PII) is 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 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 or exported out of the United States, the OIEA/CID Director or designee will coordinate with the OFO Recall Management and Technical Analysis Division (RMTAD) and OPPD Import and Export Policy Development Staff; OIC will work and communicate with foreign governments; and the International Food Safety Authorities Network (INFOSAN) FSIS representative from OPHS will communicate with INFOSAN as appropriate.

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 is to 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. In the event an IR is approved and an Investigative Plan is not needed, the AES lead investigator will notify OIEA/CID prior to opening the IR and will note this in the IR.

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) or designee.

C. OFO activities during foodborne illness investigations

1. The AES Director or designee is to request assistance from OFO if additional information is needed about product under the control of an FSIS-regulated establishment. The request should include the rationale and how the findings will be used in the investigation. For example, AES may request that OFO obtain available 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, 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 performing a Public Health Risk Evaluation (PHRE) or food safety assessment (FSA), which may yield information relevant to the investigation.

2. The OFO 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, DM, 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, DM or their designee has questions concerning a request for OFO assistance 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, DM, 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 e-mail 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, traceback, 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 during the investigation, 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 that share source materials;

2. Findings from a traceback or traceforward investigation of products consumed by ill persons that provide evidence of a common production source at an FSIS-regulated 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, 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 product is no longer available for sale in commerce, 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 Agency actions that could occur 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 in commerce;

4. Conduct a PHRE as described in FSIS Directive 5100.4, *Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology*; perform 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, *Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces and Environmental Surfaces for Listeria Monocytogenes* (*Lm*)*;* or

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

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, and Federal partners through established channels. FSIS also posts outbreak outcomes on the FSIS Foodborne Outbreak Investigation Outcomes Website. 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 AFTER-ACTION REVIEW

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 partners on a case-by-case basis.

1. The AES lead investigator is to coordinate an FSIS close-out/AAR call with those involved in the investigation. The group is to analyze what occurred to likely cause the human illness and the corrective and preventive actions taken as a result of the investigation.

2. The group is to assess whether there are potential changes that the Agency could make in its inspection or enforcement procedures, policies, 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. The CDC may coordinate close-out calls with public health partners in multistate investigations in which they are the lead agency. AES investigators are to participate on these calls to provide FSIS updates.

4. An AAR with public health partners will be conducted on a case-by-case basis to identify, share, and apply lessons learned with public health and industry partners and consumers to help prevent future illness and improve response.

    a. FSIS applies lessons learned from outbreak investigations to help prevent future illness in various ways, including commodity-specific policy improvements, industry guidance, consumer education, and efforts to strengthen collaborative outbreak response.

    b. The AES Director will designate an AES facilitator to plan and conduct the AAR with public health partners and to develop an AAR report.

    c. FSIS will publish AAR reports, ways in which lessons learned have been applied, and other outbreak investigation outcomes on the FSIS Foodborne Outbreak Investigation Outcomes website.

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. At least twice a year or when the OPPD Risk Management and Innovations Staff (RMIS) determines that it is necessary, OPPD/RMIS 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/RMIS 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/RMIS 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 RMIS 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, including, OFO, OIEA, OPACE, OPARM, OPPD, and SIPRS are invited to share information about new and ongoing FSIS foodborne illness watches, extended watches, and investigations. Representatives from the USDA Food and Nutrition Service (FNS), Agricultural Marketing Service (AMS), APHIS, and Agricultural Research Service (ARS) are also 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 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, extended watches, and investigations to be discussed and will distribute by e-mail to all 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 the weekly meeting participants.

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

B. CDC-FDA-USDA tri-agency meeting

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

C. Recordkeeping

1. AES investigators are to maintain foodborne illness investigation data in the investigation record database

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 cases, 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 are assigned to assist with an investigation; the AES lead investigator should be kept abreast of all activities associated with the investigation.

2. OPACE is the primary point of contact for inquiries about foodborne illness investigations from consumers, media, and other stakeholders

3. The AES Epidemiologist embedded in the CDC ORPB will coordinate a monthly meeting with the FSIS AES Director, Deputy Director, and CDC ORPB Branch Chief, Deputy Branch Chief, and ORPB Foodborne Outbreak Response Team Lead to discuss current outbreaks and identify areas of improvement or to improve response.

4. 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.

    c. OPHS will follow procedures specified in FSIS Directive 2620.5, *Sharing Information with State or Local Agencies, Foreign Government Officials, and International Organizations*, when sharing information concerning FSIS-regulated products.

5. Coordination with CDC

a. The AES Epidemiologist embedded in the CDC ORPB serves as the primary Agency point of contact with the CDC. The AES lead investigator continues to be responsible for the overall coordination of the FSIS foodborne illness investigation.

b. The AES 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 OPHS Epidemiologist or Liaison at CDC and the AES 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. The 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.

6. 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.

7. 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.

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

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, or when establishment produced product has been collected in commerce or from a case, whichever occurs first.

iii. When epidemiologic data is the key evidence linking illness to products produced by the establishment, the AES Epidemiologist embedded at CDC

ORPB and the OPHS Epidemiologist or Liaison at CDC will work with CDC and OFO to coordinate conference calls with industry in addition to ensuring proper FSIS representation at the meeting.

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; and

iii. Isolates collected from products produced at a regulated establishment through FSIS routine sampling or routine sampling by another agency appear closely related genetically to clinical isolates.

E. FSIS personnel are to refer to procedures in FSIS Directive 1450.1, *Freedom of Information and Privacy Act,* if there is a freedom of information act request regarding a foodborne illness investigation. FSIS personnel are to refer to FSIS Directive 2620.5 when sharing information concerning FSIS-regulated products with public health partners.

XIII. EVALUATION

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 FSIS website.

XIV. QUESTIONS

Refer questions regarding this directive to your supervisor or to OPPD/RMIS through askFSIS or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select Sampling for the Inquiry Type.

Assistant Administrator
Office of Policy and Program Development