FSIS DIRECTIVE	8010.1, Revision 3	9/27/12

METHODOLOGY FOR CONDUCTING IN-COMMERCE SURVEILLANCE ACTIVITIES

CHAPTER I – GENERAL INFORMATION

I. PURPOSE

This directive provides instructions to Office of Program Evaluation, Enforcement and Review (OPEER), Compliance and Investigations Division (CID), Investigators and Office of International Affairs (OIA), Import Inspection Division (IID), Import Surveillance Liaison Officers (ISLOs) on the methods for surveillance of persons, firms, and corporations operating in-commerce who are subject to the provisions of the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), the Egg Products Inspection Act (EPIA), Humane Methods of Slaughter Act (HMSA) (the Acts), and related laws and regulations.

KEY POINTS:

- *States authority for in-commerce surveillance activities, including access to and examination of product, facilities, and records*
- *Describes in-commerce surveillance activities, including prioritizing, preparing for, and conducting surveillance activities*
- *Describes procedures for documenting in-commerce surveillance activities*

II. CANCELLATION

FSIS Directive 8010.1, Revision 2, Methodology for Conducting In-Commerce Surveillance Activities, dated 6/25/08

III. REASON FOR REISSUANCE

FSIS is reissuing this directive in its entirety to incorporate additional instructions related to in-commerce surveillance activities, priorities, and instructions related to the AssuranceNet/In Commerce System (ANet/ICS). FSIS is also reissuing this directive to provide instructions to OIA, IID personnel who conduct surveillance activities.

IV. REFERENCES

FMIA
PPIA
EPIA
(HMSA
9 CFR Part 300 to end
Title 18 U.S.C. 701
FSIS Directive 4735.4, Reporting Assault, Harassment, Interference, Intimidation or Threat

FSIS Directive 5420.3, Food Defense Surveillance Procedures and National Terrorism Advisory System Alert Response for the Office of Program Evaluation, Enforcement and Review
FSIS Directive 5420.4, Food Defense Verification and Surveillance Procedures and National Terrorism Advisory System Alert Response for the Office of International Affairs Import Inspection Division
FSIS Directive 5500.2, Significant Incident Response
FSIS Directive 5610.1, Procedures to Implement the Consumer Complaint Monitoring System (CCMS)
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 8410.1, Detention and Seizure
FSIS Directive 8080.1, Recall of Meat and Poultry Products
FSIS Directive 8080.3, Foodborne Illness Investigations
FSIS Directive 9010.1, United States Exported and Returned Products
FSIS Directive 9030.1, Targeting for High-Risk Imported Product Shipments
FSIS Directive 9600.1, Illegally Imported or Smuggled Products and Reporting in the Import Alert Tracking System.

V. BACKGROUND

A. FSIS protects the health and welfare of consumers by ensuring that meat, poultry, and egg products distributed in commerce are safe, wholesome, not adulterated, and correctly marked, labeled, and packaged; secure from intentional acts of contamination; and legally imported and properly exported.

B. The Acts provide authority for the effective regulation of meat, poultry, and egg products and contain provisions pertaining to adulteration, misbranding, prohibited acts, imports, exports, exemptions, access and examination, recordkeeping, product detention and seizure, and criminal, civil, and administrative sanctions and remedies for addressing violations.

VI. ACCESS AND EXAMINATION

The Acts contain provisions that require specified persons, firms, and corporations to keep records and provide access for examination of facilities, inventory, and records. Specifically, Section 202 of the FMIA (21 U.S.C. 642), Section 11 of the PPIA (21 U.S.C. 460), and Sections 5 and 11 of the EPIA (21 U.S.C. 1034 and 1040) require persons, firms, and corporations that prepare, package, label, buy, sell, store, transport, or engage in other specified activities, to keep records that fully and correctly disclose all transactions involved in their businesses. These provisions also provide authorized program employees authority to access and examine the facilities, inventory, and records of these businesses; to copy records required to be kept under the Acts; and to take reasonable samples of inventory upon payment of the fair market value. The Acts also provide for penalties for failure to comply with these requirements.

VII. GENERAL

A. The purpose of in-commerce surveillance activities carried out by Investigators and ISLOs at warehouses, distributors, transporters, retailers, and other in-commerce businesses is to verify that the persons and firms whose business activities involve FSIS-regulated products prepare, store, transport, sell, offer for sale or transportation, import, and export such products in compliance with FSIS statutory and regulatory requirements.

B. In-commerce surveillance activities include:

1. Food Safety;

2. Food Defense;

3. Non-Food Safety Consumer Protection;

4. Imported Products;

5. Exported Products;

6. Order Verification;

7. Public Health Response; and

8. Emergency Response

C. In-commerce surveillance activities are generally conducted together, as a whole, and not independent or exclusive of one another. When conducting in-commerce surveillance, Investigators or ISLOs are to perform all applicable procedures associated with the surveillance activities they conduct.

D. In-commerce surveillance activities also include, as appropriate, education and outreach to provide in-commerce businesses, owners and operators, employees, and others with regulatory food safety, food defense, and other compliance information.

CHAPTER II – PRIORITIZATION AND PREPARATION

I. PRIORITIZING IN-COMMERCE SURVEILLANCE ACTIVITIES

A. In carrying out FSIS's public health mission, OPEER/CID Investigators and OIA/IID ISLOs are to conduct in-commerce surveillance activities based on public health priorities.

B. FSIS has established management controls and performance measures to ensure that Agency surveillance resources are allocated appropriately and that in-commerce surveillance activities are based on FSIS public health priorities. Supervisors and managers are to use reporting tools in the ANet/ICS, review performance measure data in ANet/ICS, and take other appropriate steps to ensure the organization is actively working toward achieving FSIS surveillance and public health priorities.

C. Prior to conducting in-commerce surveillance activities, Investigators and ISLOs are to:

1. Prioritize surveillance activities based on public health risk and public health impact to achieve Agency public health priorities;

2. Plan activities in a manner that allows for efficient and effective use of Agency personnel and resources;

3. Review and consider firm information, surveillance reports, and other compliance information in ICS, such as how long it has been since the last surveillance activity, the findings of the most recent surveillance activity, and whether the firm is operating under a criminal, civil, or administrative order;

4. Review and consider information, such as violation history, in other Agency databases (e.g., Import Alert Tracking System (IATS)) and available through external sources (e.g., Customs and Border Protection (CBP) Automated Commercial Environment (ACE) Portal access);

5. Take into account logistical factors, such as travel time and distances relevant to the activities to be conducted, the proximity of the activities to be conducted, and the time it takes to conduct surveillance in one type of business versus another; and

6. Be aware of the current threat condition level in the National Terrorism Advisory System (NTAS) and plan surveillance activities accordingly.

II. INVESTIGATOR SURVEILLANCE PRIORITIES

A. Investigators are responsible for conducting surveillance at warehouses, distributors, transporters, and other in-commerce businesses to verify that meat, poultry, and egg products are being handled and held in compliance with the Acts and regulations so to ensure that products are safe, wholesome, and correctly labeled and packaged.

B. To focus surveillance resources on in-commerce businesses with the highest risk, FSIS established a business tier structure based on business type and public health risk. This business tier structure ranks in-commerce business types based on five risk considerations: food safety hazard, food defense hazard, product volume, consumer susceptibility, and surveillance by other regulatory authorities. The tier structure, which is incorporated into the ANet/ICS, ranks in-commerce businesses as follows:

1. Business types with the higher risk are in tiers 1 and 2. These businesses generally have significant inherent hazards; handle large volumes of meat, poultry, and egg products; and receive minimal surveillance by other regulatory authorities. Accordingly, tier 1 and 2 businesses are a high priority. Tier 1 business types in the ANet/ICS are "Distributors, Warehouses, and Transporters. Tier 2 business types are 3D/4D Operators, Salvages, Renderers, Food Banks, and Exempt Poultry;"

2. Business types with lower risk are in tier 3. These businesses generally handle smaller volumes of meat, poultry, and egg products, or receive more significant surveillance from other regulatory authorities. Tier 3 business types in the ANet/ICS are “Restaurants, Retailers, Institutions, Animal Food, Custom Exempt, Abattoir, Processor, Port-of-Entry, Bonded Area, Broker, and Miscellaneous;” and

3. Businesses that are inactive are in tier 4. The inactive business types are those that are either no longer operating but have a compliance history or are operating but do not currently handle FSIS regulated product. These businesses are to be maintained in the ANet/ICS for future reference.

C. To support Agency surveillance priorities, Investigators are to use the following guidance to determine at which in-commerce businesses to conduct surveillance activities. Investigators are to:

1. Take into account the business type and business tier, whether a business has been surveilled previously, how long it has been since the last surveillance activity, the findings of previous surveillance activities, and relevant compliance history;

2. Conduct follow-up surveillance activities (see Chapter V Section I) at tier 1 and tier 2 businesses, generally, before conducting other surveillance activities;

3. Conduct surveillance activities at tier 1 and 2 businesses that have not been surveilled previously before conducting surveillance at tier 1 and tier 2 businesses that have been surveilled previously;

4. Conduct surveillance activities at tier 1 businesses with greater frequency than at tier 2 businesses;

5. Conduct surveillance activities at tier 3 businesses only when there is a need, based on credible information, to conduct surveillance at a particular tier 3 business (e.g., surveillance as part of a foodborne illness investigation, referral from other regulatory agencies, or product sampling required to achieve the public health goals);

6. Conduct surveillance activities at tier 1, 2, and 3 businesses, as necessary, to verify compliance with the terms and conditions of any applicable criminal, civil, or administrative orders or other binding case disposition terms (e.g., pre-trial diversion, civil consent decree, or administrative consent decision); and

7. Conduct surveillance at a particular business, regardless of the business tier, when there is a need to conduct the surveillance (e.g., alleged violations, investigations of foodborne illness, emergency response activities, investigations of consumer complaints, food recall activities, or product sampling).

III. ISLO SURVEILLANCE PRIORITIES

A. ISLOs are responsible for conducting surveillance at U.S. borders, ports of entry, and other in-commerce businesses and of imported meat, poultry, and egg products to ensure that imported products comply with the Acts and the regulations.

NOTE: These activities may occur before or after products enter the U.S.

B. ISLOs are to prioritize in-commerce surveillance activities based on risk to public health from imported meat, poultry, and egg product shipments.

C. To support Agency surveillance priorities, ISLOs are to consider the following factors when determining at which in-commerce businesses to conduct surveillance activities. ISLOs are to:

1. Review and consider the following databases and the information obtained:

    a. Import Alert Tracking System (IATS). The IATS tracks findings of illegally imported or smuggled products, incidents involving failure to present (FTP), potential food defense incidents, or incidents of other concern involving imported meat, poultry, or egg products. Further guidance on the IATS database is in Directive 9600.1;

    b. Automated Commercial Environment (ACE) Portal. The U.S. Customs and Border Protection (CBP) Automated Commercial Environment (ACE) Secure Data Portal provides information with which account holders can identify and evaluate compliance issues and monitor daily operations. ACE allows users to access the reports tool, compile data, and perform national trend analysis versus individual transactions-based analysis; and

    c. Public Health Information System (PHIS). The PHIS import component, which replaces the Automated Import Information System (AIIS) and the Performance Based Inspection System (PBIS), establishes an electronic interface with the U.S. Customs and Border Protection's systems. This interface will enable ACE to provide a prior notification timeframe for import inspection applications that parallels the CBP entry timeframe.

2. Review and consider information obtained from additional resources and documents provided by the Regional Import Field Office (RIFO) or OIA Headquarters (HQ) office, including:

    a. National Targeting Center-Cargo / NTC-C Liaison. FSIS has a representative assigned to the NTC-C. The NTC-C liaison works with CBP personnel to identify high risk imported meat, poultry, and egg shipments from a food defense perspective. The NTC-C liaison provides Investigators or ISLOs with shipment information when warranted. Investigators or ISLOs are further guided from this aspect with instruction provided in Directive 9030.1;

    b. Commercial Targeting and Analysis Center (CTAC). FSIS has a representative assigned to CTAC, which is devoted to supporting the development of strategic and operational plans to address import safety. The CTAC liaison provides Investigators or ISLOs with imported shipment information when warranted;

    c. Notification of Intent (FSIS Form 9540-5) to import meat, poultry, or egg products “Samples for Laboratory Examination, Research, Evaluative Testing or Trade Show Exhibition;”

    d. Shipper Notification – Importation of Undenatured Inedible Meat Product (FSIS Form 9540-4);

    e. Application for the Return of Exported Products to the United States (FSIS Form 9010-1); and

    f. United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors (VS Permit form 16-6A).

3. Conduct liaison activities with internal and external partners and take into account information and referrals obtained, including from:

    a. U.S. Customs and Border Protection (CBP);

    b. Animal and Plant Health Inspection Service (APHIS);

    c. Food and Drug Administration (FDA);

    d. Importers and Brokers; and

    e. Other FSIS Program Areas

IV. PREPARING FOR IN-COMMERCE SURVEILLANCE ACTIVITIES

A. Before conducting in-commerce surveillance activities, Investigators or ISLOs are to ensure that they have the proper tools, equipment, and information and are prepared to conduct surveillance.

1. Investigators or ISLOs are to have the following equipment with them or available to them:

    a. Laptop computer, printer, and scanner;

    b. Digital camera;

    c. Flashlight;

    d. “U.S. Detained” tags;

    e. Freezer coat;

    f. Hard hat;

    g. Related supplies, such as printer paper, batteries, and hard copies of associated forms; and

    h. Any other equipment or supplies that are necessary in order to effectively carry out the surveillance activities to be conducted (e.g., night vision tools, blacklight, ambient temperature thermometer, radiation pager).

2. As related to business type information, Investigators or ISLOs are to:

    a. Be aware of the nature of the business activity of the person or firm that is the subject of the surveillance activity;

    b. Review, be familiar with, and be prepared to explain and discuss how the Acts and regulations apply to the person or firm; and

    c. Review, be familiar with, and be prepared to explain and discuss, as necessary, any directives, notices, compliance guidelines, or other Agency information that have particular application to the person or firm.

3. As related to ANet/ICS information, Investigators or ISLOs are to:

    a. Conduct a search in ANet/ICS to obtain key information in support of the surveillance activity, including Firm Information and any associated surveillance, product control, investigative, or enforcement records. Firm Information contains information such as business name, primary business type, additional business types (if applicable), physical address, location as latitude/longitude, state and county where the business is located, hours of operation, product information, organization structure, and names of business owners and managing officials; and

    b. Review and be familiar with previous surveillance activities documented in ANet/ICS associated with the person, firm, as well as firm information and other associated records.

4. Investigators or ISLOs are to do the following other activities to prepare:

    a. Review and be familiar with previous compliance history of the person or firm to be surveilled (e.g., notice of warning letters, administrative orders, Federal court orders, State actions, Office of Inspector General investigations);

b. Conduct a search of the person or firm to be surveilled using the internet (e.g., Agency recall sites, state and county sites, firm website);

c. Review and be prepared to verify accuracy of the name, address, county, responsible officials, and other information for the person or firm to be surveilled;

d. Determine whether the person or firm to be surveilled is registered, if applicable, in accordance with 21 U.S.C. 460, 643, 644. If the person or firm has not registered, be prepared to provide a copy of FSIS Form 5020-1, Registration of Meat and Poultry Program Handlers;

e. Contact Agency personnel who, or program areas that, have knowledge of the person or firm to be surveilled (e.g., EED, OFO).

f. Contact Federal, state, or local agencies that have knowledge of the person or firm to be surveilled; and

g. Be aware of any personal safety concerns and formulate, as necessary, methods and strategies, including coordination with supervisor, to ensure that Investigators and ISLOs are safe during the surveillance activity.

CHAPTER III – SURVEILLANCE METHODS

I. PROCEDURES FOR IN-COMMERCE SURVEILLANCE ACTIVITIES

A. Introduction and credentials:

1. Investigators or ISLOs are to present their official USDA credentials (i.e., Investigator's badge) upon initial introduction with firm management or responsible person. Investigators or ISLOs may provide a business card in conjunction with presentation of credentials; however, a business card is not a substitute for official identification.

2. If initial contact is with reception personnel or an employee in a non-managerial position, Investigators or ISLOs are to present their credentials again upon introduction to a firm representative who holds a management or higher position. It may be necessary for Investigators or ISLOs to present their credentials to several individuals during the course of the surveillance activity.

3. Investigators or ISLOs are not to allow their credentials to leave their possession or to allow the credentials to be photocopied. (Title 18, U.S.C. 701 prohibits photocopying of official credentials.) Investigators or ISLOs may allow the person to examine their credentials for identification or to document the Investigator's or ISLO's name and badge number.

4. Investigators or ISLOs, if conducting surveillance at a firm whose business is open to the public (e.g., retail store, livestock auction), are not required to make immediate contact with a firm representative upon entering the firm. In these situations, Investigators or ISLOs do not immediately have to present their credentials.

5. Investigators or ISLOs, although not required, may request that a management official, designee, or translator, accompany them during the surveillance activity. The presence of a management official or designee may help facilitate the surveillance activities. In the event that a management official or designee grants access to non-public areas but is unavailable to accompany the Investigator or ISLO, the Investigator or ISLO may proceed with the surveillance activity.

6. If at any time Investigators or ISLOs feel threatened while conducting surveillance activities, they are to leave the situation immediately, go to a secure area, and follow the instructions set out in Directive 4735.4, "Reporting Assault, Harassment, Interference, Intimidation, or Threat."

B. Determining the business type:

1. Investigators or ISLOs are to determine and verify the business type that is the subject of the surveillance activity. This determination is to be made by direct observation of the type of activities being conducted at the firm and discussion with the owner, management official, or employees. Reviewing business licenses and permits may assist Investigators or ISLOs in determining the business type; however, Investigators or ISLOs are not to rely solely on these documents.

2. Once the business type has been determined, Investigators or ISLOs can assess whether the operations being conducted comply with applicable laws and regulations from the Acts.

3. Because the business activities may have changed since the time of the last contact or may be different from the business type listed in ANet/ICS, Investigators or ISLOs may need to update the current firm information in ANet/ICS. If additional information related to the firm, other than the fields available in ANet/ICS, needs to be part of the firm record, Investigators or ISLOs are to attach documents in the File Attachments tab of the Firm Information or Surveillance record.

C. Liaison activities:

1. Investigators or ISLOs are to maintain working relationships and personal contacts within the Agency; with other Federal, state, and local government agencies and officials; and with appropriate outside entities. These contacts may assist Investigators or ISLOs in conducting surveillance or other regulatory activities.

2. These contacts include, but are not limited to, Food and Drug Administration (FDA), Animal and Plant Health Inspection Service (APHIS), Environmental Protection Agency (EPA), Department of Defense (DOD), Department of Homeland Security (DHS), and the Department of Transportation (DOT).

II. FOOD SAFETY

A. When Investigators or ISLOs conduct in-commerce surveillance activities related to food safety, they are to verify that:

1. Meat, poultry, and egg products are wholesome and not adulterated;

2. Sanitary conditions are such that meat, poultry, and egg products will not become contaminated with filth or rendered injurious to health;

3. Hazard controls are adequate to prevent meat, poultry, and egg products from becoming adulterated;

4. Meat, poultry, or egg products not intended for use as human food are properly denatured or otherwise made inedible as prescribed by the regulations; and

5. All records are kept and maintained in a manner that fully and correctly discloses all transactions involved in the business activity that is subject to the provisions of the Acts.

B. To accomplish food safety verification activities, Investigators or ISLOs are, at a minimum, to:

1. Walk through the interior of the firm and examine the facilities and equipment used to prepare, store, or otherwise handle meat, poultry, and egg products;

2. Examine meat, poultry, and egg products and, for the types of products observed (e.g., raw, ready-to-eat, shelf-stable), determine whether the sanitary conditions and hazard controls are adequate to prevent those products from becoming adulterated;

3. Examine records related to the meat, poultry, and egg products observed to determine whether those records fully and correctly disclose the transactions involving the products;

4. Examine, when applicable, inedible meat, poultry, and egg products to determine whether those products are properly identified and denatured as prescribed by the regulations;

5. Collect meat, poultry, and egg product samples for laboratory analysis, as necessary; and

6. Walk the outer perimeter of the firm, when feasible, and observe the exterior structure conditions and the grounds about the firm to determine whether the conditions are adequate to prevent meat, poultry, and egg products from becoming adulterated.

C. To determine whether meat, poultry, and egg products are adulterated or are being held under insanitary conditions, Investigators or ISLOs are to seek answers to questions such as, but not limited to, the following:

1. Meat, poultry, and egg products:

    a. Do the products consist in whole or in part of any filthy, putrid, or decomposed substance, or are they for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food?

    b. Do the products bear or contain any poisonous or deleterious substance that may render them injurious to health?

    c. Are the product containers, (e.g. shipping container, immediate container, or packaging container), composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health?

    d. Have the products been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health?

2. Sanitary conditions:

    a. Do the grounds around the firm provide a harborage or breeding area for rodents or pests?

    b. Does the firm maintain the building structure, both interior and exterior, in a manner to preclude adulteration or environmental contamination?

    c. Are the cleaning practices sufficient to maintain the facility in a sanitary manner?

    d. Are the utensils and equipment used in the processing and handling of edible products and ingredients maintained in a clean and sanitary condition as to not adulterate products?

    e. For firm employees who handle product, are hygienic practices sufficient to preclude products from becoming unwholesome or adulterated?

    f. Does the firm maintain records documenting pest control, sanitation procedures, repairs, and maintenance activities?

3. Hazard controls:

    a. Does the firm receive meat, poultry, and egg products, and if so, does the firm verify products against the accompanying shipping documents?

    b. Does the firm visually examine meat, poultry, and egg products before receiving them into inventory?

    c. Do the firm's receiving procedures limit, to the extent possible, the transfer time from the shipping conveyance to the cooler/freezer or other storage areas?

    d. Do the firm's shipping procedures limit, to the extent possible, the transfer time from the cooler or freezer, or other storage area, to the shipping conveyance?

    e. Does the firm perform temperature monitoring (product or ambient), and if so, by what means (e.g., recording devices and monitoring records)?

f. Are general production practices, as applicable, sufficient to preclude the adulteration of meat, poultry, and egg products?

g. Does the firm thaw or temper frozen meat, poultry, and egg products, and if so, how does the firm monitor and document this process?

h. Does the firm receive returned meat, poultry, and egg products? If so, does the firm have appropriate controls to handle such product, (e.g., identifying why the product was returned)?

i. Does the firm receive non-amenable products and non-food items?

j. Does the firm verify, upon receipt, non-amenable products, and non-food items with the accompanying shipping documents, and if so, does the firm visually examine these products before receiving them into inventory?

k. Does the firm maintain process control programs (e.g., Hazard Analysis and Critical Control Point (HACCP), ISO 9000, or similar type programs)?

l. If the firm does maintain process control programs, is the firm following these programs?

D. If Investigators or ISLOs observe apparent violations of the Acts while conducting food safety surveillance activities, they are to follow the instructions in Chapter VI Section I of this directive.

E. If there is an appendix that covers the activity being conducted, Investigators or ISLOs are to incorporate that methodology into their surveillance activities (See Appendix 1**,** Instructions for Collecting Surveillance Samples of Raw Ground Beef at Retail for E*. coli* O157:H7 Analysis).

NOTE: Investigators and ISLOs are to check on the FSIS webpage to see whether there are updates to Appendix 1 or new appendices have been posted with this directive that address an activity they are investigating.

III. FOOD DEFENSE

A. When Investigators or ISLOs conduct in-commerce surveillance activities related to food defense, they are to verify that meat, poultry, and egg products are secure from threats and intentional acts of contamination.

B. To accomplish food defense verification activities:

1. Investigators are to follow the instructions in FSIS Directive 5420.3; and

2. ISLOs are to follow the instructions in FSIS Directive 5420.4.

C. If Investigators or ISLOs observe apparent violations of the Acts while conducting food defense related surveillance activities, they are to follow the instructions in Chapter VI Section I of this directive.

IV. NON-FOOD SAFETY CONSUMER PROTECTION

A. When Investigators or ISLOs conduct in-commerce surveillance activities related to non-food safety consumer protection, they are to verify that meat, poultry, and egg products are not misbranded, economically adulterated, or otherwise unacceptable for reasons other than food safety.

B. To accomplish non-food safety consumer protection verification activities, Investigators or ISLOs are, at a minimum, to:

1. Examine meat, poultry, and egg products to determine whether they are misbranded according to the Act; and

2. Review records associated with the products to determine whether those products are properly identified in accordance with the Acts.

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NOTE: It is important to remember that, in some situations, misbranding may be a food safety concern or have a significant economic impact on consumers and industry.

C. To determine whether meat, poultry, and egg products are correctly marked, labeled, and packaged, and not misbranded, Investigators or ISLOs are to seek answers to questions including, but not limited to, the following:

1. Do the products observed bear the mark of inspection, as required?

2. Is the labeling false or misleading in any particular way?

3. Are the products observed being offered for sale under the name of another food?

4. Does the firm maintain records that identify the sources of the products observed?

D. To determine whether meat, poultry, and egg products are economically adulterated, Investigators or ISLOs are, at a minimum, to:

1. Review business records, including invoices, labeling, and other information;

2. Discuss with management or procurement officials any concerns or complaints they may have relating to meat, poultry, and egg products and specific ingredients or components (e.g., fat, soy, or water) that if substituted, abstracted, or omitted, may cause products to be economically adulterated; and

3. Collect samples for laboratory analysis, as necessary.

E. If Investigators or ISLOs observe apparent violations of the Acts while conducting non-food safety consumer protection surveillance activities, they are to follow the instructions in Chapter VI Section I of this directive.

V. IMPORTED PRODUCTS

A. When Investigators or ISLOs conduct in-commerce surveillance activities related to imported products, they are to verify that imported products are wholesome, correctly marked and labeled, are from eligible countries and certified foreign establishments, and meet other applicable requirements.

B. To accomplish imported product verification activities, Investigators or ISLOs are, at a minimum, to:

1. Check the shipping container (if available) for the marks of Federal import inspection (i.e., “U.S. Inspected and Passed”); and

2. Check the shipping container for a shipping mark (this is a sequence of alphanumeric characters also found on the inspection certificate and import application).

NOTE: Shipping containers of product imported into the U.S. from Canada are not stamped “U.S. Inspected and Passed.”

3. Request from the importer of record, product owner, custodian, broker, or other interested party, documents relating to the importation of the product in question. Related documents include, but

are not limited to, FSIS Form 9540-1, Import Inspection Application and Report, an inspection certificate issued by the foreign government certifying that the product is eligible for importation into the U.S., U.S. Customs and APHIS paperwork, and bills of lading; and

4. Use PHIS to verify that products:

    a. Originated from eligible foreign countries;

    b. Originated from certified foreign establishments;

    c. Were produced while the foreign establishment was listed as eligible; and

    d. Were reinspected and passed by FSIS.

NOTE: On May 29, 2012, FSIS implemented the import component of PHIS replacing the AIIS; however, Investigators or ISLOs are to continue to use the AIIS web application to verify products that were imported prior to this date.

C. Investigators or ISLOs will coordinate surveillance activities related to imported products with applicable FSIS program areas, APHIS, and other Federal, state or local agencies, as appropriate.

D. If Investigators or ISLOs identify meat, poultry, or egg products from a foreign country that have been illegally imported or smuggled into the U.S., they are to follow the instructions in Directive 9600.1.

E. If Investigators or ISLOs observe apparent violations of the Acts while conducting surveillance activities related to imported products, they are to follow the instructions in Chapter VI Section I of this directive.

VI. EXPORTED PRODUCTS

A. When Investigators or ISLOs conduct in-commerce surveillance activities related to exported products, they are to verify compliance with export requirements.

B. When conducting exported product verification activities, Investigators or ISLOs are to review product, if available, and relevant export documentation to verify that the export process has been properly executed.

C. When performing surveillance activities on returned U.S. exported products, Investigators or ISLOs are to follow the instructions in Directive 9010.1.

D. If Investigators or ISLOs observe apparent violations of the Acts while conducting surveillance activities related to exported products, they are to follow the instructions in Chapter VI Section I of this directive.

VII. ORDER VERIFICATION

A. When Investigators conduct in-commerce surveillance activities related to order verification, they are to verify that persons or firms are in compliance with any criminal, civil, or administrative orders or other binding case disposition terms (e.g., administrative consent decision, civil consent decree, plea agreement, pre-trial diversion agreement).

B. Prior to conducting order verification activities, Investigators are to:

1. Read and become familiar with the terms or conditions of any order or other legally binding case disposition, including compliance with the terms; and

2. Contact EED to coordinate order verification activities, enforcement, or related matters, and to discuss any questions or concerns.

NOTE: EED has Agency- wide responsibility for enforcement of criminal, civil, and administrative orders, and other dispositions and will provide guidance and coordinate verification activities among program areas.

3. Contact, as necessary, OFO District Manager or designee if the order involves a Federal establishment, to discuss any questions or issues; and

4. Contact, if necessary, the probation officer, if one is assigned in the case, to discuss any questions or issues.

C. To accomplish order verification activities, Investigators are to:

1. Meet with the subjects of the order and as necessary, other individuals who may provide information relating to the subject's compliance with the order.

2. Discuss the terms of the order with firm management or officials.

3. Verify, by direct observation, review of records, and other surveillance activities, the subject's compliance with the terms of the order.

4. Conduct, as necessary, surveillance or other activities at consignees to verify compliance with the order.

D. If Investigators find that any term or condition of an order has been violated, they are to:

1. Identify, clearly explain, and discuss the findings, as appropriate, with the subjects of the order;

2. Follow the instructions in Chapter VI Section I of this directive, as necessary, to address food safety issues or other violations;

3. Document his or her findings in the ANet/ICS, as well as any actions taken and the individuals contacted, such as EED; and

4. Notify EED of the verification activity and findings and obtain guidance on additional verification, documentation, or other appropriate actions.

E. When ISLOs conduct in-commerce surveillance activities, they are to review the ANet/ICS, prior to the activity, to determine whether a firm where they are performing surveillance is under a criminal, civil, or administrative order. If ISLOs identify potential violations of an order, they are to contact CID or EED and document the finding and referral in the surveillance record in ANet/ICS.

VIII. PUBLIC HEALTH RESPONSE

A. Investigators or ISLOs may be called upon, at any time, to conduct or to assist other FSIS program areas in conducting public health response activities, including recall, consumer complaint, or foodborne illness outbreak investigations.

B. When conducting activities related to recalls, Investigators or ISLOs are to follow the instructions in FSIS Directive 8080.1.

C. When conducting activities related to consumer complaints, Investigators or ISLOs are to follow the instructions in FSIS Directive 5610.1.

D. When conducting activities related to reports of foodborne illness potentially associated with meat, poultry, and egg products, Investigators or ISLOs are to follow the instructions in FSIS Directive 8080.3.

E. If Investigators or ISLOs observe apparent violations of the Acts while conducting public health response activities, they are to follow the instructions in Chapter VI Section I of this directive.

IX. EMERGENCY RESPONSE

A. Investigators or ISLOs may be called upon, at any time, to conduct or to assist other FSIS program areas or other Federal or state agencies in conducting activities to prevent, prepare for, respond to, or recover from non-routine emergencies resulting from intentional or non-intentional contamination affecting meat, poultry, or egg products (e.g., tampering, natural disaster, terrorist attack).

B. When conducting emergency response activities, Investigators or ISLOs are to follow the instructions in FSIS Directive 5500.2.

C. If Investigators or ISLOs observe apparent violations of the Acts while conducting emergency response activities, they are to follow the instructions in Chapter VI Section I of this directive.

CHAPTER IV – SURVEILLANCE FOLLOW-UP

I. FOLLOW-UP SURVEILLANCE

A. Investigators or ISLOs are to conduct follow-up surveillance activities at in-commerce businesses, as necessary, to verify:

1. Compliance with FSIS statutory and regulatory requirements;

2. That meat, poultry, and egg products prepared, stored, transported, sold, offered for sale or transportation, imported or exported, or in commerce, are safe, wholesome, and correctly labeled and packaged; and

3. Compliance with applicable criminal, civil, or administrative orders or other binding case disposition terms.

B. When Investigators or ISLOs conduct surveillance activities in accordance with this directive, they are to:

1. Determine that follow-up surveillance activities are not required to verify compliance; or

2. Determine that identified violations, food safety findings, or other information requires follow-up surveillance activities and identify, in ANet/ICS, the time frame in which to conduct the follow-up surveillance.

C. To support Agency surveillance priorities, Investigators or ISLOs are to use the following guidance, to determine whether to identify a business for follow-up surveillance activities, and the time frame (e.g., 3-6 month, 6-9 months, 12-15 months) within which to conduct the follow-up surveillance. Investigators or ISLOs are to consider:

1. The business type and tier (Investigators only);

2. The type of order, if any (Investigators only), the person or firm is operating under; the terms of the order; and whether the person or firm is operating in compliance with the order;

3. The surveillance findings including, but not limited to, the following:

    a. Whether products are found to be wholesome and not adulterated;

    b. Whether sanitary conditions are such that products would not become contaminated with filth or rendered injurious to health;

    c. Whether hazard controls are adequate to prevent products from becoming adulterated;

    d. Whether products not intended for use as human food are being properly denatured or otherwise identified as inedible; and

    e. Whether records are being maintained in compliance with agency requirements;

4. The observation of an apparent violation of the Acts; product control action; initiation of an investigation; or, referral of an apparent violation to another agency; and

5. The compliance history of the person or firm that is the subject of the surveillance activity.

D. To accomplish follow-up surveillance activities, Investigators or ISLOs are to use all applicable methodologies (e.g., preparing for surveillance activities, food safety, order verification) in this directive.

E. Generally, when Investigators or ISLOs identify firms for follow-up surveillance activities, the program area (i.e., OPEER, OIA) that identified that need is to perform the follow-up surveillance activity. However, another program area may conduct, where necessary, surveillance activities at the firm prior to the time frame identified for the follow-up surveillance. In these situations, Investigators or ISLOs with the program area that identified the follow-up may determine that the surveillance findings and documentation by the other program area are sufficient and negate the need for the follow-up surveillance.

F. When Investigators or ISLOs do not identify a firm for follow-up surveillance, the Investigator or ISLO may decide, or may be directed by his or her supervisor, to conduct surveillance at the firm based on:

1. A referral of an allegation (e.g., other FSIS program area, Federal or State contact, industry or consumer complaint);

2. Public health exigencies (e.g., emergency response activities, food borne illness investigation); or

3. Other information subsequently provided (e.g., by the Regional or HQ office).

II FOLLOW-UP REMINDERS

A. The ANet/ICS provides a mechanism in surveillance for Investigators or ISLOs to identify firms for follow-up surveillance activities.

B. Investigators or ISLOs are to use the ANet/ICS to set reminders for firms that are identified for follow-up surveillance activities and to identify the time frame for the follow-up surveillance (e.g., 3-6 months, 6-9 months, or 12-15 months).

C. The ANet/ICS will generate reminders to Investigators or ISLOs to conduct follow-up surveillance activities.

D. Investigators or ISLOs generally are to complete the follow-up surveillance within a period of 3-months from the date of the reminder.

CHAPTER V – DOCUMENTATION

I. SURVEILLANCE FINDINGS

A. Upon completion of the surveillance activity, Investigators or ISLOs are to:

1. Update the firm information record, where needed, if a firm is in the ANet/ICS. If a firm is not in the ANet/ICS, add the firm to ANet/ICS by creating a new Firm Information record and entering all required information. Investigators or ISLOs are, where needed, to attach additional information (e.g., floor plan) in the File Attachments tab of the Firm Information record in ANet/ICS;

2. Document their findings in the ANet/ICS by completing all applicable fields in the surveillance record; and

3. Identify, where appropriate, firms for follow-up surveillance activities.

B. When Investigators or ISLOs conduct food defense verification activities during surveillance, they are to:

1. Follow, as applicable, the instructions in Directive 5420.3 (for Investigators) or Directive 5420.4 (for OIA ISLOs); and

2. Document their findings in the surveillance record to complete FSIS Form 5420-3, Food Defense Surveillance Findings.

C. When Investigators or ISLOs identify significant incidents during surveillance activities, they are to follow the instructions in Directive 5500.2 and complete FSIS Form 5500-4, Incident Report (IR).

II. SURVEILLANCE NOTES

A. When conducting surveillance activities in accordance with this directive, Investigators or ISLOs may document, at their discretion, their surveillance activities and findings in notes.

B. Investigators or ISLOs are to be aware that notes may contain information related to open investigations, confidential commercial information, personal information, or other confidential information and are subject to the Freedom of Information Act, the Privacy Act, or other applicable legal requirements.

C. If surveillance activities result in initiation of an investigation and notes of surveillance activities have been documented, Investigators or ISLOs are to maintain the notes with the investigative case file and follow FSIS Directives 8010.2 and 8010.3 relevant to investigative notes.

CHAPTER VI – APPARENT VIOLATIONS AND OTHER IRREGULARITIES

I. APPARENT VIOLATIONS

A. When conducting surveillance activities, Investigators or ISLOs may observe apparent food safety violations of the Acts, Agency regulations, or applicable criminal, civil, or administrative orders or other case dispositions.

B. When Investigators or ISLOs observe apparent violations, they are to take one or more of the following actions as appropriate based on the relevant facts:

1. Inform the management official, designee, owner, or the product custodian of the apparent violation;

2. Initiate an investigation, in accordance with FSIS Directive 8010.2;

3. Initiate a product control action, in accordance with FSIS Directive 8410.1;

4. Initiate an Import Alert in the IATS, in accordance with FSIS Directive 9600.1; or

5. Notify their supervisor if, in the Investigators' or ISLOs' judgment, additional personnel or resources are required to protect the health and welfare of consumers or the safety of Agency personnel.

II. OTHER IRREGULARITIES

A. When conducting surveillance activities, Investigators or ISLOs may observe food safety violations or other irregularities involving non-amenable products or facility conditions that, although not subject to FSIS jurisdiction, are subject to the laws and regulations of other Federal, State, or local agencies.

B. When Investigators or ISLOs observe food safety violations or other irregularities, involving non-amenable products or facilities subject to other authorities, they are, as appropriate, to:

1. Inform the management official, designee, owner, or the product custodian of the irregularity;

2. Contact, immediately if necessary, the appropriate Federal, State, or local agency, to inform that office of the food safety violation or other irregularity observed;

3. Provide support, as necessary, to the agency or office contacted to protect the health and welfare of consumers; and

4. Document, in the ANet/ICS surveillance record, the food safety violation or other irregularity observed and the contact and referral to the appropriate Federal, state, or local agency.

Refer questions through supervisory channels.

Acting Assistant Administrator
Office of Policy and Program Development

APPENDIX 1: INSTRUCTIONS FOR COLLECTING SURVEILLANCE SAMPLES OF RAW GROUND BEEF AT RETAIL FOR *E. coli* O157:H7 ANALYSIS

I. INTRODUCTION

A. Investigators are to follow the directions in this Appendix to determine when to collect a sample of raw ground beef for *E. coli* O157:H7 testing as part of the in-commerce surveillance activities at retail stores per this directive. Following the directions in this Appendix will result in FSIS sampling the raw ground beef products that may present the highest risk to consumers.

B. FSIS samples raw beef (and veal) food products that meet the standards of identity for ground and chopped beef (9 CFR 319.15(a)), hamburger (9 CFR 319.15(b)), and beef patties (9 CFR 319.15(c)). Raw ground beef products include:

1. ground or chopped beef;
2. hamburger;
3. ground or chopped veal;
4. veal or beef patties;
5. veal or beef patty mix; and
6. ground veal or beef product with added seasonings.

NOTE: A raw ground beef product formulated with any amount of beef product derived from Advanced Meat Recovery (AMR) systems is considered "ground beef." Raw product comprised only of beef from AMR systems is not sampled as a raw ground beef product. Raw product comprised only of beef from AMR systems is considered a raw ground beef *component* or raw beef patty *component*.

II. WHEN TO COLLECT A SAMPLE OF RAW GROUND BEEF DURING THE SURVEILLANCE ACTIVITY

A. Advance notice of sampling is not required. Investigators are to collect samples based upon criteria identified below even if the retail facility is not actively grinding at the time of the surveillance activity.

B. Investigators are to follow the collection instructions found in block 18 of FSIS Form 10,210-3, Requested Sample Programs.

C. Investigators are to collect a raw ground beef sample, during operating hours, when the retail store is grinding, or has store-ground product that is still available at the retail store, under one or more of the following circumstances:

1. grinding primals, subprimals, purchased trim, boxed beef, or other components (i.e., mechanically separated beef or partially defatted beef fatty tissue), that are not accompanied by records of negative *E. coli* O157:H7 test results;
2. grinding store generated bench trim derived from its own operations with special emphasis on bench trim generated from non-intact meat cuts such as those that have been mechanically tenderized or enhanced;

3. not cleaning and sanitizing the grinder or other food contact surfaces that are in contact with the product (mixer, conveyor, table, knives, totes, saws, etc.) between the use of different source materials;

NOTE: Source materials are the raw beef components that are used in the finished raw ground beef product (primals, subprimals, beef trim, bench trim, rework, etc.). Same source materials are the same product as labeled, from the same supplier, with the same production codes and other identifiers.

4. using meat cuts (steaks or roasts that the store determines are suitable as an ingredient in raw ground beef) with expired sell-by dates;

5. grinding and failing to keep records sufficient for trace back;

6. mixing irradiated and non-irradiated beef;

7. mixing previously ground beef (regardless of source) from different sources and regrinding it; or

8. grinding under insanitary conditions.

D. Investigators are to attempt to arrive at the retail facility as close to the beginning of the grinding operation as possible to afford the firm the opportunity to hold the product that would be implicated by positive *E. coli* O157:H7 test results.

III. HOW TO COLLECT A SAMPLE OF RAW GROUND BEEF

A. Investigators are to follow the collection instructions below.

1. Randomly select a retail store. Obtain a random 1-pound sample of an unopened (intact), raw ground beef packaged product, if possible; otherwise, have a store employee collect and package (as an intact package) a 1-pound ground beef sample from the grinder head (after grinding). Place the retail packaged sample in the sample bag provided by the lab for this purpose. Close the bag securely. Label the bag with the provided sample identification label. Follow FSIS Directive 7355.1, Use of Sample Seals for Laboratory Samples and Other Applications. (For MT06 samples, also follow guidance in FSIS Directive 8010.3, Procedures for Evidence Collection, Safeguarding and Disposal.)

2. If there is no unfrozen product available to sample, collect a random 1-pound intact sample of frozen product.

3. Fill out the FSIS Form 10,210-3, Requested Sample Programs, according to the instructions. Place the sample request form in a plastic bag and place the plastic bag into the shipping container with the sample.

4. Notify the store management or designee at the time of sampling. Remind the store management or designee of the option to hold the sampled lot. Explain that additional product with the same source materials may be implicated in the event of a positive *E. coli* O157:H7 result.

5. Refrigerate unfrozen samples, do not freeze. If the sample was frozen at the time of collection, keep it frozen. Ship the sample to the laboratory listed in Block 9 of the sample request form and on the pre-addressed label. Ship via overnight courier the same day as collected. Use sufficient frozen coolant to keep samples cold during transit. If samples are collected on a Friday, designate SATURDAY DELIVERY. Do not ship samples on the day before a Federal holiday.

NOTE: If the sample must be held over the weekend to accommodate delivery and lab schedules, the Investigator is to freeze the sample. Sufficient coolant is needed when the sample is shipped.

IV. WHEN NOT TO COLLECT SAMPLES

A. Investigators will not sample the following raw ground beef products that are ground under sanitary conditions and that have sufficient records to allow for trace back:

1. case ready (i.e., consumer-sized packages of ground beef which were packaged at the official establishment);

2. not ground by the retail store but only portioned into retail trays;

3. reground product (i.e., previously ground product from an official establishment which is reground by the retailer into finely ground product without commingling product from other sources); or

4. derived from primals, subprimals, or boxed beef that are accompanied by records of negative *E. coli* O157:H7 test results.

V. SUPPLIES

A. Investigators are to keep a supply of FSIS Forms 10,210-3 with project number MT05 pre-printed in block 14 available at all times. When the supply of forms is low, Investigators are to send an e-mail to the FSIS - SamplingForms-Headquarters@fsis.usda.gov Outlook address to request forms. In the e-mail, the Investigator is to include:

1. his or her name and phone number,

2. his or her OPEER Field Assignment Code number,

3. the address where the forms are to be sent, and

4. the number of MT05 forms requested. Forms will be printed and mailed to the indicated address within three business days.

B. Investigators are to request any needed sample supplies by contacting the appropriate lab via e-mail (below) and include in the e-mail the:

1. sampling project number MT05,

2. Investigator's name and phone number,

3. address where the requested supplies are to be sent, and

4. list of needed supplies.

FSIS- SamplingSupplies-EasternLab@fsis.usda.gov

FSIS- SamplingSupplies-MidwesternLab@fsis.usda.gov

FSIS- SamplingSupplies-WesternLab@fsis.usda.gov

VI. DOCUMENTATION

A. If a sample is collected, Investigators are to complete the following documentation:

1. FSIS Form 8010-1, Retail Ground Beef Sampling Worksheet, which is found on the Forms Intranet Page: http://inside.fsis.usda.gov/fsis/public/static/index.jsp

2. FSIS Form 10,210-3, Requested Sample Programs, with project number MT05 pre-printed in block 14. This form will accompany the sample.

3. ANet/ICS under the Surveillance tab, Investigators enter the requested sampling information and attach a copy of the completed worksheet and a copy of the MT05 Sampling Form under the Surveillance-File Attachment tab.

B. FSIS Form 10,210-3 will be modified to include a place for the Investigator to write the Firm ID and the Surveillance ID from ANet/ICS. Until Investigators receive the modified forms, they are to use the current supply of forms and write in “Firm ID” and “Surveillance ID” in the available space in block 28. The identification numbers assist with matching the sample form with the ICS information.

1. If the Investigator knows the Firm ID and Surveillance ID at the time he or she completes FSIS 10,210-3, he or she is to include them in block 28, below the existing line requesting the non-FSIS contact phone number, by writing “Firm ID” and the number followed by “Surveillance ID” and that number.

2. If the Investigator has only one of the identification numbers, he or she documents the one available in block 28. The missing identification number is to be e-mailed to the lab as instructed in B.3.

3. If the Investigator cannot include both identification numbers at the time the sample is shipped, he or she is to access ANet/ICS soon thereafter to obtain the missing identification numbers. Once the numbers are obtained, the Investigator is to:

    a. e-mail the missing identification numbers to the lab to which the sample was shipped.

    b. Type “In-commerce sample update” in the e-mail subject line.

C. When a sample is not collected, the Investigator selects the reason from the ANet/ICS drop-down menu.

1. If the product is case ready (i.e., consumer-sized packages of ground beef which were packaged at the official establishment), the Investigator selects “Case ready”.

2. If the product is not ground by the retail store but only portioned into retail trays, the Investigator selects “Not ground only portioned”.

3. If the product is reground product (i.e., previously ground product from an official establishment which is reground by the retailer into finely ground product with no additional source materials added), the Investigator selects “Reground product from official Est.”.

4. If the product is derived from primals, subprimals, or boxed beef that are accompanied by records of negative *E. coli* O157:H7 test results, the Investigator selects “Primal subprimal boxed with COA”.

5. If the firm does not grind, either currently or in the foreseeable future, any raw beef to sell as raw ground beef products (raw ground or chopped beef; hamburger; ground or chopped veal; veal or beef patties; veal or beef patty mix; or ground veal or beef product with added seasonings), the Investigator selects “Firm does not grind”.

6. The Investigator should not select “Sufficient grinding records”. This is not a valid option for why a sample was not collected.

7. If there is another reason that is not part of the drop-down menu, the Investigator selects “Other (Explain in Additional Comments).” For example, this is the appropriate option to use if the firm does grind, but is not grinding at the time of the surveillance and has no previously ground product on hand. In such a case, the Investigator explains the reason in the Additional Information tab in the Additional Comments field of the Surveillance record.

VII. WHAT TO DO IF SAMPLE RESULTS ARE CONFIRMED POSITIVE

A. If a raw ground beef sample tests positive for *E. coli* O157:H7, OPEER is notified of the retail positive through the Biological Information Transfer and E-mail System (BITES) and enters the supplier information into the System Tracking *E. coli* O157:H7 – Positive Suppliers (STEPS) system. The OPEER contact person accesses the STEPS system site with the list of suppliers for the sampled product that tested positive and follows the procedures for notifying suppliers.

B. Investigators are to:

1. contact the retail store and follow any supervisory instructions;

2. assist with a possible recall in coordination with the CID Regional Office;

3. collect follow-up MT06 investigative samples (STC-39) at the discretion of OPEER management within a 120-day period; and

4. send all MT06 follow-up samples to the laboratory specified in the MT06 form.

C. The investigative sample collected is to be accompanied by:

1. FSIS Forms 10,210-3, Requested Sample Programs, with project number MT06 in block 14 to indicate that it is an investigative sample. (Since MT06 samples are investigative samples, Investigators are to write “STC-39” in red ink in the upper right-hand corner of the FSIS Form 10,210-3.) The Pathogen Reduction Enforcement Program (PREP) will automatically generate these forms. The forms will be sent to the same address from block 8 of the MT05 form that accompanied the positive sample. If MT06 forms are not received within five business days, they may be requested via e-mail at FSIS -SamplingForms-Headquarters@fsis.usda.gov. Forms will be printed and mailed to the indicated address within three business days. In the e-mail, the Investigator is to include:

   a. his/her name and phone number,

   b. OPEER Field Assignment Code number,

   c. the form number of the positive MT05 sample, and

   d. the address where the MT06 forms are to be sent.

2. FSIS Form 8000-17, Evidence Receipt and Chain of Custody, as set out in FSIS Directive 8010.3, Section V.

NOTE: FSIS Form 10,000-2, Domestic Laboratory Report, is not used with MT06 samples. This is the only exception to the instructions for investigative sampling as stated in FSIS Directive 8010.3, Section VII, C.

D. Investigators are to complete FSIS Form 8010-1, Retail Ground Beef Sampling Worksheet, for each follow-up sample and enter “STC-39” in block 24, Additional Comments.

E. If FSIS management determines that no follow-up MT06 samples are necessary, Investigators are to return the forms to the appropriate lab listed in Block 9 of the FSIS Form 10,210-3. Investigators are to check box 53 – Other, in Block 33, and write, “FSIS management has determined that no MT06 follow-up samples are necessary” as an explanation.

All questions regarding this Appendix are to be directed to the Policy Development Division through askFSIS by selecting General Inspection Policy/Regulations/Agency Issuances or by telephone at 1-800-233-3935. Questions regarding sampling or follow-up sampling should be directed to the Risk Innovations and Management Division through askFSIS by selecting General Inspection Policy/Sampling/E. coli O157:H7 or by telephone at 1-800-233-3935.