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

FSIS DIRECTIVE

8010.1, Revision 5 | 11/14/16

METHODOLOGY FOR CONDUCTING IN-COMMERCE SURVEILLANCE ACTIVITIES

CHAPTER I – GENERAL INFORMATION

I. PURPOSE

A. This directive provides instructions to Office of Investigation, Enforcement and Audit (OIEA), Compliance and Investigations Division (CID) Investigators 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), and the Humane Methods of Slaughter Act (HMSA) collectively referenced as "the Acts", and related laws and regulations.

B. FSIS is reissuing this directive to update information on in-commerce business types and tiers; instructions for the use of the Public Health Information System (PHIS) for sample collection (Attachment 1); in-commerce surveillance of shell eggs (Appendix 2); include the Shell Egg Handling Fact Sheet (Attachment 3) and Firm/Business Definitions (Attachment 4); and clarify other information.

KEY POINTS:

- *Identifies 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*
- *Explains recordkeeping requirements to trace ground beef products at in-commerce retail firms*

II. CANCELLATION

FSIS Directive 8010.1, Revision 4, *Methodology for Conducting In-Commerce Surveillance Activities*, 4/24/14

III. BACKGROUND

A. FSIS protects the health and welfare of consumers by ensuring that meat, poultry, shell eggs, and egg products distributed in commerce are safe, wholesome, not adulterated; properly marked, labeled, and packaged; secure from intentional acts of contamination; 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. The EPIA also provides FSIS authority to ensure shell eggs packed into containers destined for the ultimate consumer meet applicable statutory and regulatory requirements.

IV. ACCESS AND EXAMINATION

A. The FMIA, PPIA, and EPIA provide FSIS personnel broad authority to conduct inspections and examinations of the premises, facilities, inventory, records, equipment, and operations of federally-inspected establishments and in-commerce facilities, such as warehouses and distribution centers, subject to the Acts (21 U.S.C. 460, 604, 609, 642, 1034, and 1040). Specifically, the FMIA (21 U.S.C. 642 (Section 202)), the PPIA (21 U.S.C. 460 (Section 11)), and the EPIA (21 U.S.C. 1034 and 1040 (Sections 5 and 11)) 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; copy records required to be kept under the Acts; and take reasonable samples of inventory upon payment at the fair market value. The Acts also provide for penalties when federally-inspected establishments, in-commerce facilities, or other firms fail to comply with these requirements.

B. Authorized program employees can use photography, under these authorities, as a technique to examine facilities, equipment, operations, inventory, records, and where necessary to copy business records. Permission from company management to take photographs during surveillance, investigations, or other activities is not necessary (FSIS Directive 8010.3, *Procedures for Evidence Collection, Safeguarding and Disposal)*.

V. GENERAL

A. Investigators conduct in-commerce activities at warehouses, distributors, transporters, retailers, ports of entry, and other in-commerce businesses to ensure that meat, poultry, and egg products are safe, wholesome, and correctly labeled and packaged. Investigators conduct in-commerce activities to verify that the persons, firms, and corporations whose business activities involve meat, poultry, and egg products prepare, store, transport, sell, offer for sale or transportation, import, and export such products are in compliance with other FSIS statutory and regulatory requirements.

B. Investigators conduct in-commerce activities at warehouses, distributors, transporters, retailers, and other in-commerce businesses to ensure that shell eggs are properly refrigerated and correctly labeled and that persons, firms, and corporations whose business activities involve shell eggs store, transport, sell, offer for sale or transportation product in compliance with statutory and regulatory requirements. Investigators also verify that domestic shell eggs packed into containers destined for the ultimate consumer are stored or transported at or below 45 degrees Fahrenheit, as well as verifying they are properly labeled and are not adulterated as defined in 21 U.S.C. 1033 (a).

C. 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

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

E. 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.

F. In-commerce surveillance activities also include liaison activities.

1. Investigators 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 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), Customs and Border Protection (CBP), Office of Inspector General (OIG), Environmental Protection Agency (EPA), Department of Defense (DOD), Department of Homeland Security (DHS), Department of Transportation (DOT), and State Meat and Poultry Inspection (MPI) programs.

CHAPTER II – PRIORITIZATION AND PREPARATION

I. PRIORITIZING IN-COMMERCE SURVEILLANCE ACTIVITIES

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

B. In carrying out FSIS's public health mission, Investigators are to conduct in-commerce surveillance activities based on public health priorities. Investigators 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, which may include running a firm report in ANet/ICS and creating an interactive Google map;

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

4. Review and consider information, such as violation history in Agency databases (e.g., Public Health Information System (PHIS) for federally-inspected establishments), and other external sources;

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, as outlined in FSIS Directive 5420.3, *Food Defense Surveillance Procedures and National Terrorism Advisory System Alert Response for the Office of Investigation, Enforcement and Audit.*

II. INVESTIGATOR SURVEILLANCE PRIORITIES

A. To focus surveillance resources on in-commerce businesses with the highest risk, FSIS established a tier structure based on business type and public health risk. This 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 that present higher risk are in tiers 1 and 2. These businesses generally have significant inherent hazards; handle large volumes of meat, poultry, shell eggs, and egg products; and receive minimal surveillance by other regulatory authorities. Accordingly, tier 1 and 2 businesses are considered a high priority.

    a. Tier 1 business types are Distributors and Warehouses.

    b. Tier 2 business types are 3D/4D Operators, Custom Exempt, Exempt Poultry, Food Banks, Retailers, Salvage, and Transporters.

2. Business types with lower risk are in tier 3. These businesses generally handle smaller volumes of product or receive more significant surveillance from other regulatory authorities. Tier 3 business types include Abattoir, Animal Food, Bonded Warehouse, Broker, Institutions, Point of Entry, Processor, Renderers, Restaurants, and Miscellaneous.

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

B. Investigators are to take into consideration the following factors when evaluating which in-commerce businesses surveillance activities should be performed. Investigators are to:

1. Take into account the business type and tier, whether that 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 (Chapter IV Section I) at tier 1 and tier 2 businesses, generally, before conducting other surveillance activities;

3. Conduct surveillance activities at tier 1 and tier 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 activities at a particular tier 3 business (e.g., surveillance as part of a foodborne illness investigation, referral from other regulatory agencies, consumer complaint, or product sampling required to achieve the public health goals);

6. Conduct surveillance activities at tier 1, tier 2, and tier 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. PREPARING FOR IN-COMMERCE SURVEILLANCE ACTIVITIES

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

1. Investigators are to have the following government-issued tools and equipment with them or available to them:

    a. Laptop computer, printer, and scanner;

    b. Digital camera, including smartphone;

    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 to effectively carry out the

surveillance activities to be conducted (e.g., night vision tools, black light, ambient temperature thermometer, or product sample supplies).

2. As related to business type information, Investigators 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 (Investigators can obtain background criminal information/data from the National Crime Information Center and CLEAR databases through local Fusion Centers);

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

   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;

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

   e. Review the person or firm to be surveilled by conducting a search using the internet (e.g., Agency recall sites, State and county sites, or firm website); and

   f. 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.

3. As related to ANet/ICS information, Investigators 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, investigation, or enforcement records. Firm Information includes information such as business name; primary business type; additional business types (if applicable); physical address, including 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;

   b. Create a Firm Information record, if not currently found in ANet/ICS, so that this information will be available for future surveillance activities;

   c. Review and be familiar with previous surveillance activities documented in ANet/ICS, including records documented by applicable State programs, associated with the person and firm, as well as firm information and other associated records; and

   d. Determine whether the person or firm to be surveilled is registered, if applicable, in accordance with 21 U.S.C. 460, 643, and 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.

4. As related to imported products, Investigators are to consider the following:

a. **Automated Commercial Environment (ACE) Portal**. The CBP ACE Secure Data Portal provides information that account holders can use to 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. FSIS has a representative assigned to review data in ACE.

b. **Public Health Information System (PHIS)**. The PHIS import component, which replaced the Automated Import Information System (AIIS) and the Performance Based Inspection System (PBIS), established an electronic interface with the CBP systems. This interface enables PHIS to receive a prior notification timeframe for import inspection applications that parallels the CBP entry timeframe.

c. **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 shipments of FSIS-regulated product from a food defense perspective. The NTC-C liaison provides Investigators with shipment information when warranted (FSIS Directive 9030.1, *Targeting for High-Risk Imported Product Shipments*).

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

e. Relevant **Notifications of Intent** (FSIS Form 9540-5) to import FSIS-regulated products "Samples for Laboratory Examination, Research, Evaluative Testing or Trade Show Exhibition" (FSIS Directive 9500.8, *Importation of Products for Other Than Commercial Purposes*).

f. Relevant **Shipper Notifications** – Importation of Undenatured Inedible Meat Product (FSIS Form 9540-4).

g. Relevant **Applications for the Return of Exported Products to the United States** (FSIS Form 9010-1; FSIS Directive 9010.1, *U.S. Exported and Returned Products*).

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

NOTE: Investigators are to be aware, during surveillance, of the potential for illegally imported or smuggled amenable products. If Investigators observe these types of products, they are to follow FSIS Directive 8010.2, *Investigative Methodology*.

5. Investigators are to do the following other activities to prepare:

   a. Contact Agency personnel who, or program areas that, have knowledge of the person or firm to be surveilled (e.g., Enforcement and Litigation Division (ELD) or Office of Field Operations (OFO));

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

   c. Be aware of any personal safety concerns and formulate, as necessary, methods and

strategies, including coordination with the supervisor, to ensure that Investigators maintain personal safety during the surveillance activity.

CHAPTER III – SURVEILLANCE METHODS

I. PROCEDURES FOR IN-COMMERCE SURVEILLANCE ACTIVITIES

A. Introduction and credentials

1. Investigators are to present their official USDA credentials (i.e., Investigator's government-issued photo identification) upon initial introduction with firm management or a responsible person. Investigators 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 with an employee in a non-managerial position, Investigators 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 to present their credentials to several individuals during the course of the surveillance activity.

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

4. Investigators are not to present any other identification (e.g., State driver's license) or share other personally identifiable information (e.g., personal address or personal phone number) to firm management or employees. If requested, Investigators may provide the name and business phone number of CID supervisory or management personnel.

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

6. Investigators, 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, the Investigator may proceed with the surveillance activity.

7. If at any time Investigators 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 FSIS Directive 4735.4, *Reporting Assault, Harassment, Interference, Intimidation, or Threat*.

NOTE: Only CID personnel and their management team, excluding CID's support staff, will be issued a CID badge and credential. CID badges and credentials are to be used only for official FSIS business. CID personnel are not permitted to use the badge and credential as any other form of identification. CID credentials will have the Investigator's legal name printed on the credential and the signature must match the Investigator's legal name as shown on the credential.

B. Determining the business type

1. Investigators 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 in determining the business type; however, Investigators are not to rely solely on these documents.

2. Once the business type has been determined, Investigators 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 should verify accuracy of firm information on file during the surveillance. If additional information related to the firm, other than the fields available in ANet/ICS, needs to be part of the Firm Information record, Investigators are to attach documents in the File Attachments tab of the Firm Information or Surveillance record.

II. FOOD SAFETY

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

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

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

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

4. Meat, poultry, shell eggs, and egg products that are not intended for use as human food or not fit for human food are properly denatured or otherwise identified as prescribed by the regulations;

5. Shell eggs packed into containers destined for the ultimate consumer are stored and transported in accordance with the EPIA (Attachment 2 of this directive has specific surveillance activities for shell eggs); and

6. 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 determine if the food safety component of the surveillance activity is met, Investigators 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, shell eggs, and egg products;

2. Examine meat, poultry, shell eggs, and egg products to identify the types of products observed (e.g., raw, ready-to-eat, shelf-stable, etc.) and 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, shell eggs, 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, shell eggs, and egg products to determine whether those products are properly identified and denatured as prescribed by the regulations;

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

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, shell eggs, and egg products from becoming adulterated.

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

1. Meat, poultry, shell eggs, 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 that 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?

   e. Were the shell eggs subjected to incubation?

   f. Are the shell eggs restricted eggs? If so, the Investigator is to determine the destination of the restricted eggs for proper use and disposition.

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, shell eggs, or egg products, and if so, does the firm verify products against the accompanying shipping documents?

b. Does the firm visually examine meat, poultry, shell eggs, 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 consider hazards that can occur during mail-order delivery to the consumer?

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

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

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

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

j. Does the firm receive non-amenable products and non-food items and if so, does the firm verify products against the accompanying shipping documents and 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), Recall Plan, ISO 9000, or similar type programs)?

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

D. If there is an Attachment that covers the activity being conducted, Investigators are to incorporate that methodology into their surveillance activities.

1. There are 4 Attachments included with this directive:

a. Attachment 1**,** Instructions for Collecting Surveillance Samples of Raw Ground Beef at Retail;

b. Attachment 2, In-Commerce Surveillance of Shell Eggs;

c. Attachment 3, Shell Egg Handling Fact Sheet; and

d. Attachment 4, Definitions of Firm/Business Types.

2. Investigators are to check the FSIS Website to see if there are updates to the appendices or if new appendices that address surveillance activities have been posted with this directive.

E. If Investigators observe apparent violations of the Acts while conducting food safety activities, they are to follow the instructions in Chapter VI of this directive.

III. FOOD DEFENSE

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

B. To accomplish food defense activities, Investigators are to follow the instructions in FSIS Directive 5420.3, *Food Defense Surveillance Procedures and National Terrorism Advisory System Alert Response for the Office of Investigation, Enforcement and Audit*.

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

IV. NON-FOOD SAFETY CONSUMER PROTECTION

A. When Investigators 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. Additionally, Investigators are to verify that shell eggs are not unacceptable for reasons other than food safety.

B. Investigators are to determine when, in some situations, misbranding may be a food safety concern or have a significant economic impact on consumers and industry. Under the EPIA, the term misbranding only applies to egg products. Shell eggs that are not properly labeled are in violation of the labeling requirements but are not considered misbranded.

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

1. Examine meat, poultry, and egg products to determine whether they are misbranded according to the FMIA, PPIA, or EPIA.

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

3. Verify nutritional labeling per FSIS Directive 7130.1, *Verifying Nutrition Labeling for the Major Cuts of Single-Ingredient, Raw Meat and Poultry Products and Ground or Chopped Meat and Poultry Products*.

4. Verify records kept by in-commerce retail firms that grind raw beef for sale in commerce maintain specific information about their grinding activities (9 CFR 320.1(b)(4); 80 FR 79231, *Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products*). This is necessary to improve FSIS's ability to accurately trace the source of foodborne illness outbreaks involving ground beef and to identify the source materials that need to be recalled. The recordkeeping requirements will greatly assist FSIS in its efforts to trace ground beef products back to a supplier due to the previous lack of documentation identifying all source materials used in their preparation. If CID personnel find noncompliance at an in-commerce firm, the Agency may issue a Notice of Warning letter or request the Department of Justice to initiate a civil proceeding in Federal court to enjoin the defendant from further violations.

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

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

E. To determine whether shell eggs are properly marked, labeled, and packaged, Investigators are to seek answers to questions including, but not limited to, the following:

1. Are consumer-packed shell egg containers labeled to indicate that refrigeration is required?

2. Are consumer-packed shell egg containers stored at an ambient temperature of no greater than 45 degrees Fahrenheit (Attachment 2)?

F. To determine whether meat, poultry, shell eggs, and egg products are economically adulterated, Investigators 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 received relating to meat, poultry, shell eggs, 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.

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

V. IMPORTED PRODUCTS

A. When Investigators conduct in-commerce surveillance activities related to imported products, they are to verify that imported products are wholesome, are correctly marked and labeled, are from eligible countries and certified foreign establishments, and are not adulterated or misbranded.

B. Imported meat, poultry, and egg products are considered "in commerce" when they receive FSIS reinspection and are marked with the official mark of inspection (9 CFR 327.1, *Entry (entered)*). If imported product bypasses FSIS reinspection, FSIS considers such product to be in commerce, a Failure-to-Present (FTP), and in violation of the Acts. An FTP occurs when amenable products produced by a foreign establishment and properly certified by the foreign government are delivered into commerce, further processed, placed into storage, or otherwise distributed to the consumer without the benefit of FSIS import reinspection, as required. Investigators are to investigate all observed FTPs in accordance with FSIS Directive 8010.2.

C. To accomplish imported product verification activities, Investigators are, at a minimum, to:

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

    a. Determine if product was imported from Canada; and

    b. Shipping containers of product imported into the U.S. from Canada are <u>not</u> stamped "U.S. Inspected and Passed;"

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);

3. Request from the importer of record, product owner, custodian, or broker documents relating to the importation of the product in question. Such 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.; and any other shipping documents available;

4. Use PHIS to verify import status, import status by shipping mark, and import facilities directory. Investigators also are to use the FSIS website http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments to verify eligible countries and establishments;

5. Be aware of FTP shipments (FSIS Directive 9900.1, *Imported Product Shipment Presentation)*;

6. Be aware of meat, poultry, and egg products in commerce that are identified as "Refused Entry." The Regional Director (RD) may notify an Investigator when there is potential that refused entry product was removed from the official import inspection establishment and distributed in commerce. Investigators are to follow FSIS Directive 8010.2 for investigations;

7. Refer to FSIS Directive 9010.1, *United States Exported and Returned Products*, for all products that may be U.S. Return;

D. Investigators are to coordinate surveillance activities related to imported products with applicable FSIS program areas, APHIS, and other Federal, State, or local agencies, as appropriate.

E. If Investigators identify meat, poultry, and egg products from a foreign country that have been illegally imported or smuggled into the U.S.; they are to follow the instructions in FSIS Directive 9600.1*, Illegally Imported or Smuggled Products and Reporting in the Import Alert Tracking System*.

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

VI. EXPORTED PRODUCTS

A. When Investigators conduct in-commerce surveillance activities related to product for export, they are to verify compliance with export requirements.

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

C. If Investigators observe apparent violations of the Acts while conducting surveillance activities related to exported products, they are to follow the instructions in Chapter VI 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 (e.g., administrative consent decision, civil consent decree, plea agreement, or pre-trial diversion agreement).

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

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

2. Review any previous activities including investigative, enforcement, or other activities or information associated with compliance with the terms of the order or other binding case disposition;

3. Contact ELD to coordinate order verification activities, enforcement, or related matters and discuss any questions or concerns since ELD 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.

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

5. Contact, as 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 of this directive, as necessary, to address food safety issues or other violations;

3. Notify ELD of the verification activity and findings and obtain guidance on additional verification, investigation, documentation, or other appropriate actions; and

4. Document their findings in the ANet/ICS, as well as any actions taken and the individuals contacted, such as ELD.

VIII. PUBLIC HEALTH RESPONSE

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

B. When conducting activities related to recalls, Investigators are to follow the instructions in FSIS Directive 8080.1, *Recall of Meat and Poultry Products*.

C. When conducting activities related to consumer complaints, Investigators are to follow the instructions in FSIS Directive 5610.1*, Procedures to Implement the Consumer Complaint Monitoring System (CCMS).*

D. When conducting activities related to reports of foodborne illness potentially associated with meat, poultry, shell eggs, or egg products, Investigators are to follow the instructions in FSIS Directive 8080.3, *Foodborne Illness Investigations*.

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

IX. EMERGENCY RESPONSE

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

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

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

CHAPTER IV – SURVEILLANCE FOLLOW-UP

I. FOLLOW-UP SURVEILLANCE

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

1. Compliance with FSIS statutory and regulatory requirements;

2. Meat, poultry, shell eggs, and egg products prepared, stored, transported, sold, offered for sale or transportation, imported, or exported in commerce, are safe, wholesome, and properly labeled and packaged;

3. Shell eggs packed into containers destined for the ultimate consumer are stored and transported at or below 45 degrees Fahrenheit, and bear labeling to indicate that refrigeration is required; and

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

B. When Investigators 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 require follow-up surveillance activities and identify, in ANet/ICS, the time frame in which to conduct the follow-up surveillance.

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

1. The business type and tier;

2. The type of order, if any, 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;

e. Whether records are being maintained in compliance with Agency requirements.

f. Whether the Investigator observed an apparent violation of the Acts, a product control action was initiated, or an investigation was initiated;

g. Whether FSIS referred the apparent violation to another agency; and

4. The additional compliance history of the person who, or firm that, is the subject of the surveillance activity.

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

E. When an Investigator does not identify a firm for follow-up surveillance, the Investigator may decide, or may be directed by his or her supervisor, to conduct subsequent surveillance at the firm based on:

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

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

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

II. FOLLOW-UP REMINDERS

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

B. Investigators are to use the ANet/ICS to set reminders with respect to 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 to conduct follow-up surveillance activities.

D. Investigators 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, including follow-up surveillance, Investigators are to:

1. Update, where needed, the Firm Information record for firms in ANet/ICS. For a firm that is not in the ANet/ICS, Investigators are to add the firm to ANet/ICS by creating a new Firm Information record and entering all required and known information. Investigators are to attach, when needed, 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 conduct food defense verification activities during surveillance, they are to:

1. Follow the instructions in FSIS Directive 5420.3, *Food Defense Surveillance Procedures and National Terrorism Advisory System Alert Response for the Office of Investigation, Enforcement and Audit*; and

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

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

D. When Investigators identify product that has been illegally imported or smuggled, or is considered an FTP, they are to detain and control the product as set out in FSIS Directive 8410.1, *Detention and Seizure*, and initiate an investigation as set out in FSIS Directive 8010.2.

II. SURVEILLANCE NOTES

A. When conducting surveillance activities in accordance with this directive, Investigators may document, at their discretion, their surveillance activities and findings in notes. Surveillance notes are to be maintained in accordance with FSIS Directive 8010.3.

B. If documented, Investigators 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 the initiation of an investigation and notes of surveillance activities have been documented, Investigators are to maintain the notes with the investigative case file and follow FSIS Directive 8010.2 and FSIS Directive 8010.3 relevant to investigative notes.

CHAPTER VI – APPARENT VIOLATIONS AND OTHER IRREGULARITIES

I. APPARENT VIOLATIONS

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

B. When Investigators 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 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. Notify ELD, as per Chapter III of this Directive, of any violations of an order; and

5. Notify the supervisor if, in the Investigators' 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 may observe apparent 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 observe apparent 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 apparent violation or other irregularity;

2. Contact, immediately if necessary, the appropriate Federal, State, or local agency to inform that office of the apparent 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 apparent violation or other irregularity observed and the contact and referral made to the appropriate Federal, State, or local agency.

III. QUESTIONS

Refer questions regarding this directive through supervisory channels.

Assistant Administrator
Office of Policy and Program Development

ATTACHMENT 1: INSTRUCTIONS FOR COLLECTING SURVEILLANCE SAMPLES OF RAW GROUND BEEF AT RETAIL

I. INTRODUCTION

A. Investigators are to follow the directions in this attachment to determine when to collect a sample of raw ground beef for testing as part of the in-commerce surveillance activities at retail stores, per this directive. MT05 ground beef samples are collected by Investigators at retail and tested by FSIS laboratories for *E. coli* O157:H7, *Salmonella,* and in some cases, as selected at random, for nutritional content. MT06 ground beef samples are collected by Investigators as follow-ups to a confirmed *E. coli* O157:H7 positive and are tested by FSIS laboratories for all Shiga toxin-producing *E. coli* (STEC). Following the directions in this Attachment will result in FSIS sampling the raw ground beef products that may present the highest risk to consumers.

B. Investigators are to inform retail facilities that if a sample is confirmed positive for *E. coli* O157:H7, the product, if in commerce, would be subject to a Class I recall. In addition, the lot and all affected products produced using the same source material may be subject to recall. Follow-up samples may be collected at the retail location or the supplier. No follow-up samples will be collected based on *Salmonella* analysis results.

C. 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, and the store is:

1. Grinding primals, subprimals, purchased trim, boxed beef, or other components (e.g., 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 (80 FR 28153, *Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products*);

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

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 (9 CFR 320.1(b)(4));

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

E. 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 randomly select a retail store and:

1. Obtain a random minimum 1-pound sample of an unopened (intact) package of raw ground beef product, if possible; otherwise, have a store employee collect and package (as an intact package) a minimum 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. Investigators are to follow FSIS Directive 7355.1, *Use of Sample Seals for Laboratory Samples and Other Applications*. (For MT06 samples, Investigators also follow FSIS Directive 8010.3).

2. Collect a random minimum 1-pound intact sample of frozen product if there is no unfrozen product available to sample.

3. Log into PHIS and complete the Generate Sample, Sample Collection Data, and Additional Information Tabs.

4. Digitally sign each page of the FSIS Form 8010-1, Sample Analysis Request Form, and save as an electronic file (e.g., pdf).

5. Print and place the sample analysis request form in a plastic bag and place the plastic bag into the shipping container with the sample.

6. Attach electronic copies of the sample analysis request form and results (when available) in the File Attachments tab of the ANet/ICS Surveillance record for this retail firm.

7. Notify the store management or designee at the time of sampling. Investigators are to remind the store management or designee of the option to hold the sampled lot and explain that additional product with the same source materials may be implicated in the event of a positive *E. coli* O157:H7 result. Complete FSIS Form 8010-2, Fact Sheet – Retail Microbiological Test Program for *Escherichia coli* O157:H7 in Raw Ground Beef, and provide it to store management

8. Refrigerate unfrozen samples and do not freeze. If the sample was frozen at the time of collection, Investigators are to keep it frozen.

9. Ship the sample to the laboratory listed in Block 5 of the sample request form and on the pre-addressed label. Investigators are to select the correct FedEx label to match which laboratory is listed in Block 5, and return the Ziploc with the remaining 2 shipping labels in the box with the sample. Investigators are to ship the sample via overnight courier the same day it is collected. Investigators are to use sufficient frozen coolant to keep samples cold during transit. If samples are collected on a Friday, Investigators are to designate SATURDAY DELIVERY. Investigators are not to ship samples on the day before a Federal holiday.

10. 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 are not to 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), provided the grinder is cleaned between different source materials; 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 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 steps in the Public Health Information System (PHIS):

1. Create the Sample Form by selecting the Project Code, Analysis, and Sample Source;

2. Schedule the sample collection and parcel pickup dates;

3. Enter additional information about the sample and complete the sample questionnaire;

4. Print the FSIS Form 8010-1, Retail Ground Beef Sampling Worksheet; and

5. Click Submit to Lab.

B. Investigators are to post the MT05 Sample Form, MT05 Worksheet, MT05 photographs, and (when received) MT05 sample results in the ANet/ICS file Attachment tab of the surveillance for this retail firm.

C. If the Investigator cannot include both the Firm ID and the Surveillance ID 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:

1. E-mail the missing identification numbers to the lab to which the sample was shipped; and

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

D. 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. RESULTS

A. Investigators are to log into the Laboratory Information Management System (LIMS-Direct) within 48 hours of submitting the sample and check back frequently until the sample result is posted.

B. When the sample result is received, Investigators are to edit the surveillance record in ANet/ICS.

C. In the File Attachment tab in ANet/ICS, Investigators select Positive, Negative, or Not Analyzed and attach an electronic copy of the LIMS Direct sample results.

VIII. WHAT TO DO IF SAMPLE RESULTS ARE CONFIRMED POSITIVE

A. If a raw ground beef sample tests positive for *E. coli* O157:H7, OIEA is notified of the retail positive through the LIMS-Direct. The OIEA contact person accesses the LIMS-Direct system site to determine the firm's information 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 OIEA management within a 120-day period; and

4. Send all MT06 follow-up samples to the laboratory specified in the FSIS Form 8010-1.

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

1. FSIS Form 8010-1, generated from PHIS, with project number MT06 in block 2; and

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

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. The COMPLIAN project in PHIS is not used for the MT06 samples. It is used for other investigative samples and preprints STC 39 in the upper right corner of the form.

D. Investigators are to complete FSIS Form 8010-1, Retail Ground Beef Sampling Worksheet, in PHIS.

IX. QUESTIONS

All questions regarding this Attachment are to be directed to the Policy Development Staff 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 Staff through askFSIS by selecting General Inspection Policy/Sampling/*E. coli* O157:H7 or by telephone at 1-800-233-3935.

ATTACHMENT 2: IN-COMMERCE SURVEILLANCE OF SHELL EGGS

I. INTRODUCTION

This Attachment to FSIS Directive 8010.1, *Methodology for Conducting In-Commerce Surveillance Activities*, sets out instructions for OIEA Compliance and Investigations Division (CID) Investigators to follow for food safety, non-food safety, and other in-commerce surveillance activities related to shell eggs packed into containers destined for the ultimate consumer (hereinafter referred to as "shell eggs"). These instructions are in addition to the general instructions for in-commerce surveillance activities in FSIS Directive 8010.1.

II. STATUTORY AUTHORITY

A. The EPIA (21 U.S.C. 1034(e)(1) and (2) and 1037) and FSIS regulations (9 CFR 590.50 and 590.410(a)) require that shell eggs destined for the ultimate consumer be stored or transported under refrigeration at an ambient temperature of no greater than 45 degrees Fahrenheit after packing and contain labeling that indicates that refrigeration of the shell eggs is required.

B. FSIS regulations (9 CFR 590.5) define an "ultimate consumer" as any household consumer, restaurant, institution, or any other party who has purchased or received shell eggs for consumption.

III. SURVEILLANCE OF SHELL EGGS

A. As part of in-commerce surveillance activities under Directive 8010.1, whenever shell eggs are found during surveillance at domestic in-commerce facilities (e.g., warehouses, distributors, or transporters), Investigators are to:

1. Verify that the ambient air temperature of storage facilities and transport vehicles where shell eggs are stored or transported meets statutory and regulatory requirements.

2. Verify that the labeling on shell eggs meets statutory and regulatory requirements.

B. Ambient Air Temperature Verification

3. Investigators determine the ambient air temperature of storage facilities and transport vehicles where shell eggs are stored or transported using calibrated Agency-supplied thermometers specially equipped to obtain ambient air temperatures.

   a. Investigators are to follow the manufacturer's instructions for using and calibrating the thermometers.

   b. The thermometers are accurate to within ±1°F. Therefore, an ambient air temperature reading of 45.0°F on the thermometer could mean an actual ambient air temperature of 44.0°F, 45.0°F, or 46.0°F.

   c. Investigators are to take, record, and average multiple temperature readings in accordance with the instructions in Section III of this Attachment.

d. As set out in this Attachment, to allow for the ±1°F variance in temperature readings of thermometers, an average ambient air temperature of 46.0°F or lower is in compliance with the requirements for shell eggs; an average ambient air temperature of 46.1°F or above is in violation of the requirements.

NOTE: The lack of a refrigeration device or a functioning refrigeration device at a storage facility or in a transport vehicle is not a violation of the statute or regulations. As part of their surveillance activities, Investigators are to evaluate, document, and review with firm management, as needed, any issues identified related to the use, maintenance, or monitoring of refrigeration equipment.

4. Verifying ambient air temperatures of storage facilities

a. In each cooler or other storage unit or storage area where shell eggs are stored, Investigators are to take five (5) temperature readings from five (5) different locations (e.g., different places, areas, positions, or portions of space) within the storage unit or storage area near where the shell eggs are stored.

b. To determine the locations within the storage unit or storage area to take the five (5) temperature readings, Investigators are to consider:

i. The size of the storage unit or storage area,

ii. The locations of any refrigeration or cooling units, devices, or vents within the storage unit or storage area,

iii. The locations of any openings within the storage unit or storage area (e.g., doors),

iv. The locations of the shell eggs within the storage unit or storage area,

v. The amount (in dozens) of shell eggs within the storage unit or storage area, and

vi. Other factors relevant to effectively reflect the ambient temperature where the shell eggs are stored.

c. To determine the ambient air temperature for a storage unit or storage area, Investigators are to average the five (5) temperature readings in accordance with the instructions in Section III.

5. Verifying ambient air temperatures of transport vehicles

a. In each transport vehicle where shell eggs are stored or transported, Investigators are to take three (3) temperature readings.

b. To ensure personal safety, Investigators are to take the temperature readings from locations near the door of the transport vehicle or through an opening in the side of the vehicle (if such an opening exists and is safely accessible).

c. Investigators are to take the three (3) temperature readings from three (3) different

locations within the transport vehicle when possible. If this is not possible, Investigators are to take the readings from the rear of the trailer.

d. To determine the ambient air temperature for a transport vehicle, Investigators are to average the three (3) temperature readings in accordance with the instructions in Section III.

C. Labeling Verification

1. Investigators are to examine shell eggs to verify that shell egg cartons or other shell egg containers are labeled with a statement indicating that refrigeration is required.

2. The EPIA requires that shell eggs contain labeling indicating that refrigeration is required. The EPIA does not require that the label include a statement indicating the temperature at which the shell eggs must be refrigerated. However, if the label does refer to a specific temperature, then the stated temperature must comply with the EPIA.

3. In determining the number of shell egg cartons or containers to examine, Investigators are to consider:

a. The size of the cooler, transport vehicle, or other storage unit or storage area where the shell eggs are stored or transported;

b. The locations of the shell eggs within the cooler, transport vehicle, or other storage unit or storage area;

c. The amount (in dozens) of shell eggs within the cooler, transport vehicle, or other storage unit or storage area; and

d. Other factors relevant to effectively reflect a compliance determination.

IV. DOCUMENTATION

A. Upon completion of surveillance activities, Investigators are to document surveillance findings according to Chapter V of this directive and the specific instructions in this Section.

B. Investigators are to enter shell egg ambient air temperature and labeling findings in the ANet/ICS under the Additional Information tab in the Surveillance record using the “Shell Egg Temperature” drop-down menu, the “Shell Egg Temperatures” box, and the “Are Shell Eggs properly labeled?” drop-down menu.

C. The “Shell Egg Temperature” drop-down menu in the Additional Information tab has two options, “In Compliance” and “In Violation.”

1. For each cooler, storage unit, or storage area, the Investigator is to take and record five (5) temperature readings, then calculate the average temperature by adding the five (5) temperature readings together and dividing the sum by 5.

2. For each transport vehicle, the Investigator is to take and record three (3) temperature readings, then calculate the average temperature by adding the three (3) temperature readings together

and dividing the sum by 3.

3. When necessary, Investigators are to round the calculated average to the nearest tenth according to standard rounding rules. For example, rounding 0.34 to the nearest tenth is 0.3; rounding 0.45 to the nearest tenth is 0.5; rounding 0.843 to the nearest tenth is 0.8; and, rounding 0.866 to the nearest tenth is 0.9.

4. If the average of the ambient air temperature readings for any storage unit, storage area, or transport vehicle is 46.0°F or lower, the Investigator is to select "In Compliance."

5. If the average of the ambient air temperature readings for any storage unit, storage area, or transport vehicle is 46.1°F or higher, the Investigator is to select "In Violation."

6. If the Investigator obtained ambient air temperature readings for more than one cooler, transport vehicle, or other storage unit or storage area, the Investigator is to determine whether the average ambient air temperature for any of the storage units or storage areas is "In Violation" of the EPIA and regulations (i.e., 46.1°F or higher). For example, if the Investigator assessed ambient air temperatures for three storage units and determined the average ambient air temperature for Cooler A was 44.8°F, Cooler B was 45.6°F, and Cooler C was 49.3°F, then the Investigator would select "In Violation" since the average ambient air temperature for Cooler C was 49.3°F. The Investigator would not average the resulting average temperatures of the three coolers.

D. The "Shell Egg Temperatures" box in the Additional Information tab is a free-text field. Investigators are to document the average ambient air temperature and the individual ambient air temperature readings for each cooler, transport vehicle, or other storage unit or storage area for which the Investigator took temperature readings in the "Shell Egg Temperatures" box. Investigators are to document:

1. The temperature information linearly (horizontally), using the following format for indicating temperature, "00.0°F". Using a column (vertical) format takes too many characters and may not fit within the allowed characters in the "Shell Egg Temperatures" box.

2. The average ambient air temperature for each storage unit, storage area, or transport vehicle, using the format, "Cooler X = 00.0 °F". For example, "Cooler A = 44.8°F; Cooler B = 45.6°F; Cooler C = 49.3°F".

3. The individual ambient air temperatures for each storage unit, storage area, or transport vehicle, using the format, "Cooler X – 00.0 °F". For example, "Cooler A – 45.2; 44.3; 44.6; 44.9; 45.0 °F. Cooler B – 47.1; 44.3; 44.6; 44.2; 47.8 °F. Cooler C – 51.2; 46.9; 45.8; 50.9; 51.7 °F." Also, first document the average temperature under each unit and then show each of the separate temperatures taken for each unit.

4. Investigators are always to document the <u>average</u> ambient air temperature in the "Shell Egg Temperatures" box. If there is not sufficient space in the "Shell Egg Temperatures" box to enter the <u>individual</u> temperature readings, Investigators are to document the temperature readings in a Word document and attach it to the surveillance record in ANet/ICS.

E. For labeling findings, Investigators are to select "yes" or "no" from the "Are Shell Eggs properly labeled?" drop-down menu to document whether shell eggs observed during surveillance

contained required labeling indicating that refrigeration is required.

1. If the shell eggs are labeled with a statement indicating that refrigeration is required, the Investigator is to select “yes.”

2. If the shell eggs are not labeled with a statement indicating that refrigeration is required, the Investigator is to select “no.”

V. APPARENT VIOLATIONS AND OTHER IRREGULARITIES

A. Shell eggs packed into containers destined for the ultimate consumer that are found in violation of temperature requirements of the EPIA are not considered adulterated. Shell eggs may be considered adulterated for other reasons supported by the statute. The actions for temperature violations are identified below.

B. The EPIA (21 U.S.C. 1041, 1048, 1049, 1050) authorizes product detention, administrative civil penalties, criminal penalties, and other enforcement actions for violations, including violations of the requirements that shell eggs destined for the ultimate consumer be stored or transported under refrigeration at an ambient temperature of no greater than 45°F after packing and contain labeling that indicates that refrigeration of the shell eggs is required.

C. When Investigators observe apparent ambient air temperature, labeling, or other violations involving shell eggs, they are to follow FSIS Directive 8410.1 and FSIS Directive 8010.2.

D. CID will refer all shell egg cases to ELD.

ATTACHMENT 3:

Shell Egg Handling Fact Sheet

Refrigeration and Labeling Requirements for Shell Eggs Packed into Containers Destined for the Ultimate Consumer

What are the requirements?

An egg handler is any person, excluding the consumer, who engages in any business in commerce that involves buying or selling any eggs from the domesticated chicken, turkey, duck, goose, or guinea. The Egg Products Inspection Act (21 U.S.C. 1037(c)) and regulations (9 Code of Federal Regulations 590.50 and 590.410) prohibit any egg handler from possessing any shell eggs packed into containers destined for the ultimate consumer unless they are

- stored and transported under refrigeration at an ambient temperature not to exceed 45°F (7.2°C), and
- labeled to indicate that refrigeration is required.

Any producer-packer with a flock of 3,000 or fewer layers is exempt from these requirements.

Why must these requirements be enforced?

Shell eggs are a perishable food product. Unbroken shell eggs could contain *Salmonella Enteritidis,* bacteria that can cause foodborne illness. Refrigeration slows the growth of *Salmonella*, and cooking destroys the bacteria. Like all perishable foods, shell eggs should be safely handled, refrigerated, and properly cooked. For the raw shell eggs intended for the ultimate consumer, by law, the shell eggs must be stored or transported at temperatures of 45°F (7.2°C) or less and labeled to indicate refrigeration is required.

Who enforces the requirements and where?

The United States Department of Agriculture's Food Safety and Inspection Service (FSIS) is responsible for ensuring industry's compliance with shell egg temperature and labeling requirements at in-commerce locations (e.g., public warehouse, distributor) and on transport vehicles at these firms. FSIS will initiate enforcement actions when a violation occurs.

What happens if a violation is found?

When FSIS finds a violation, FSIS documents the temperature or labeling violation, notifies the firm's management, and may detain the shell eggs pending proper disposition. FSIS will take other appropriate enforcement action. This action may include administrative notices of warning, civil penalties, or civil or criminal sanctions in accordance with the Egg Products Inspection Act (21 U.S.C. 1041 and 1042).

Is there further information about these requirements?

Further information about shell eggs is on FSIS' website: http://www.fsis.usda.gov/wps/portal/fsis/home. Specific information is found by entering "Shell Eggs from Farm to Table" in the search field. Additionally, FSIS Directive 8010.1, *In-Commerce Surveillance Methodology*, Attachment 2; FSIS Directive 8410.1, *Detention and Seizure*; and FSIS Directive 8010.5, *Case Referral and Disposition*, set out FSIS' policy on shell egg surveillance and enforcement.

ATTACHMENT 4: Definitions of Firm/Business Types

NOTE: The business types marked with an (*****) asterisk; (3D/4D, Animal Food, Broker, Distributor/Wholesaler, Renderer, Warehouse (*public warehouse*)) are required to register with FSIS (21 U.S.C. 643 and 21 U.S.C. 460).

***3D/4D:** A facility that handles dead, dying, disabled, or diseased animals (amenable meat/poultry species). This type of facility cannot legally put the products into commerce for human consumption.

Abattoir: A facility operating under a federal, state, or Talmadge-Aiken grant of inspection where animals are slaughtered for consumption as food products.

***Animal Food:** Any person, firm, or corporation engaged in the business of manufacturing or processing animal food derived wholly or in part from carcasses, or parts of products of the carcasses, of cattle, sheep, swine, goats, or poultry; 9 CFR 301.2, 381.1(b)**.**

Bonded Warehouse: A facility that handles meat, poultry, shell eggs, and/or egg products from multiple overseas suppliers and temporarily stores said product in cold storage or freezers without processing or breaking down the product in any way. A bonded warehouse is a facility authorized by Customs and Border Patrol for the storage of dutiable goods. Payment of duties is deferred until the goods are removed from the warehouse; however, the warehouse is responsible for the safekeeping of the products at the facility.

***Broker:** Any person, firm, or corporation engaged in the business of buying or selling meat, poultry, shell eggs, and egg products, or parts of amenable species on commission, or otherwise negotiating purchases or sales of such articles other than for his own account or as an employee of another person, firm, or corporation; 9 CFR 301.2, 381.1(b).

Custom Exempt: A facility that provides slaughter and/or processing services for the owner of the livestock, poultry, or meat/poultry product, for a fee. Product prepared under the custom exemption is for the exclusive use of the owner, and is not eligible for sale or donation; 9 CFR 303.1(a)(2), 381.10(a)(4).

***Distributor:** A facility that handles meat, poultry, shell eggs, and/or egg products from multiple domestic and/or overseas suppliers, stores said products in cold storage or freezers, and supplies said products to multiple customers without processing or breaking down the product in any way.

Exempt Poultry: A facility that slaughters and/or processes poultry exempt from federal or state inspection. This type of facility, (other than custom exempt poultry operators that do not engage in the buying/selling of any poultry product capable of use as human food), can sell to household or non-household consumers.

Food Bank: An organization that collects or purchases meat, poultry, shell eggs, and/or egg products from manufacturers, wholesalers, retailers, and/or government agencies to store and donate collected product to non-profit emergency and community food programs.

Inactive: A business that is not currently operating (or permanently closed) and is not periodically surveilled.

Institution: An organization founded and united for a specific purpose that prepares meals containing

meat, poultry, and/or egg products for resident populations (*e.g.*, hospital, prison).

Point of Entry: A location where eligible meat, poultry, shell eggs, and/or egg products are re-inspected prior to entering into U.S. Commerce.

Processor: A facility operating under a federal, state, or Talmadge-Aiken grant of inspection that receives bulk meat, poultry, and/or egg products and breaks down and further processes the bulk product into a further processed product (e.g., ready-to-eat, ready-to-cook packaged product).

***Renderer:** Any person, firm, or corporation engaged in the business of rendering carcasses or parts or products of meat or poultry except rendering conducted under inspection or exemption; 9 CFR 301.2, 381.1(b).

Restaurant: A business that prepares and serves food and drink to customers. Meals are generally served and eaten on premises, but many restaurants also offer take-out and food delivery services. Restaurants vary greatly in appearance and offerings, including a wide variety of cuisines and service models; 9 CFR 303.1(d)(2)(iv), 381.10(d)(2)(iv).

Retailer: A facility that sells meat, poultry, shell eggs, and/or egg products directly to consumers for consumption off-premises; 9 CFR 303.1(d)(1), 381.10(d)(1).

Salvage: A facility that purchases, sorts and sells "distressed" meat, poultry, shell eggs, and/or egg products that other businesses have been unable to sell.

Transporter: A business that provides transportation services of meat, poultry, shell eggs, and/or egg products for fees. They do not buy, sell, process, label, or store products in any way.

Warehouse: A facility that handles meat, poultry, shell eggs, and/or egg products from multiple domestic and/or overseas suppliers and may be public (leases space to product owners) or private (stores its own products for its own retail stores).

A warehouse may operate under voluntary identification and/or certification service where it could repackage/label, certify for export, or other programs; 9 CFR 350.3, 362.2.

If a warehouse is owned by a retail store and stores only meat, poultry, or shell eggs products that are the property of that retail store, the warehouse is a private warehouse and is <u>not required to register</u> with FSIS.

However, if the warehouse stores any meat or poultry products that are not owned by the retail store that owns the warehouse, that warehouse would be considered a ***public warehouse** and <u>would be required to register with FSIS</u>. (*i.e.*, If a retail store has consigned meat products to a hotel, restaurant, institution, or other retailer, and the product is stored in the warehouse owned by the retail store, the warehouse is functioning as a public warehouse, because the retail store no longer owns the products, and would be required to register).