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

FSIS DIRECTIVE

8010.1
Rev. 6

6/3/22

METHODOLOGY FOR CONDUCTING IN-COMMERCE SURVEILLANCE ACTIVITIES

CHAPTER I – GENERAL INFORMATION

I. PURPOSE

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. FSIS is reissuing this directive to update the methods for prioritizing, conducting, and documenting surveillance activities, reorder the Attachments, update the business types (Attachment 1), update the surveillance activities and fact sheet for shell eggs (Attachments 2 and 3), update the instructions for surveillance samples (Attachment 4), incorporate a quick reference guide of Siluriformes fish requirements (Attachment 5), 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*

II. CANCELLATION

FSIS Directive 8010.1, Revision 5, *Methodology for Conducting In-Commerce Surveillance Activities*, 11/14/16

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; 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. 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), the PPIA (21 U.S.C. 460), and 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; copy records required to be kept under the Acts; and take reasonable samples of inventory upon payment at the fair market value. The FMIA, PPIA, and EPIA 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 surveillance activities at warehouses, distributors, transporters, retailers, ports-of-entry, and other in-commerce businesses to ensure that regulated products are safe, wholesome, and correctly labeled and packaged. Investigators verify that the persons, firms, and corporations whose business activities involve regulated products comply with FSIS statutory and regulatory requirements when preparing, storing, transporting, selling, offering for sale or transportation, importing, and exporting such products.

B. In-commerce surveillance activities are grouped into categories. When conducting in-commerce surveillance activities at a business, Investigators are to perform the necessary activities for all applicable categories. These categories include:

1. Food Safety;
2. Food Defense;
3. Non-Food Safety Consumer Protection;
4. Imported Products;
5. Exported Products;
6. Custom Exempt Reviews;
7. Order Verification;
8. Public Health Response; and
9. Emergency Response.

NOTE: 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 OF SURVEILLANCE ACTIVITIES

I. PRIORITIZING IN-COMMERCE SURVEILLANCE ACTIVITIES

Investigators are to:

1. Prioritize surveillance activities based on public health risk and impact in accordance with Agency goals;

2. Review and consider information in AssuranceNet (ANet), 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;

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

4. Plan activities in a manner that allows for efficient and effective use of their time, including the use of resources available within ANet such as the interactive map and list of firms from the standard reports;

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. TIER STRUCTURE OF FACILITY (BUSINESS) TYPES

A. To focus surveillance resources on in-commerce facilities that pose a greater risk to public health, FSIS established a 3-tier structure based on business type and public health impact. This tier structure is based on five risk considerations: inherent food safety hazards, inherent food defense hazards, product volume, consumer susceptibility, and monitoring by other regulatory authorities. ANet assigns firms to the appropriate tier based on relevant data captured by Investigators during the performance of surveillance activities.

1. **TIER 1:** These businesses have the potential to significantly impact public health. They are characterized by risk considerations such as large volumes of amenable products and significant inherent food safety or food defense hazards. Businesses in Tier 1 are generally subject to minimal monitoring by other regulatory authorities.

2. **TIER 2:** Based on their specific combination of risk considerations, these businesses have less potential to significantly impact public health than businesses in Tier 1.

3. **TIER 3:** These businesses have less potential to significantly impact public health than businesses in Tiers 1 and 2 because they handle little to no amenable products, lack significant inherent food safety or food defense hazards, or are subject to routine monitoring by other regulatory authorities.

B. Certain considerations may vary greatly among like businesses. For example, some distributors deal with very large volumes of meat, poultry, and egg products while others primarily handle low volumes of amenable product and a few cases of shell eggs. Further, some states have cooperative agreements with FSIS to provide regulatory oversight of meat, poultry, and egg products in intrastate commerce while other states do not.

NOTE: Investigators are to refer to Attachment 1, *Definitions of Business Types*, for a complete list of the business types, including definitions.

III. FACTORS USED TO DETERMINE SURVEILLANCE ACTIVITIES

When determining where to conduct surveillance activities, Investigators are to ensure they:

1. Conduct surveillance activities at Tier 1 facilities a minimum of once every 18 months;

2. Conduct surveillance activities at Tier 2 facilities as workload permits, with an emphasis on firms where surveillance activities have not been previously conducted;

3. Conduct surveillance activities, regardless of tier, when there is a need to conduct surveillance. For example, investigation of alleged violations, foodborne illness, or consumer complaints; emergency response activities; and recall activities;

4. Conduct surveillance activities, as necessary, to achieve FSIS goals for product sampling, special projects, or education and outreach;

5. Conduct follow-up surveillance activities at facilities where prior surveillances revealed violations or other conditions that warrant follow-up (see Section IV of this chapter); and

6. Conduct surveillance activities at facilities, 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).

NOTE: Investigators are to consult with the OIEA, Enforcement Operations Staff (EOS) prior to verifying compliance with orders or other binding case dispositions.

IV. SURVEILLANCE FOLLOW-UP AND REMINDERS

A. Investigators schedule and conduct follow-up surveillance activities at in-commerce businesses where prior surveillances revealed violations or other conditions that warrant follow-up. Investigators are to use the following guidance to determine the timeframe for conducting the follow-up surveillance:

1. If a violation is found during a surveillance activity, the Investigator is to follow-up within three months of the resulting enforcement action.

2. If the first follow-up results in another violation, the Investigator is to follow-up within three months

of the resulting enforcement action.

3. If the first follow-up after any violation results in compliance, the Investigator is to follow-up again within six months.

4. If the second follow-up results in compliance, additional surveillance activities are to be scheduled and conducted in accordance with Section III of this chapter.

5. If a firm is operating under an order, the Investigator is to follow-up based on the terms of the order. The Investigator is to consult with EOS regarding order verification, including any follow-up activities and any time new violations by a firm operating under an order are identified.

NOTE: If the Investigator identifies other conditions that warrant follow-up during the performance of surveillance activities (e.g., sanitation or product handling concerns), they are to consult with their supervisor to determine the appropriate timeframe for follow-up.

B. ANet provides a mechanism in the Surveillance Module to remind Investigators to conduct follow-up surveillance activities. Investigators are to set reminders and identify the appropriate timeframes based on the information in this chapter.

1. When Investigators document a violation, they are to set a follow-up reminder once they are notified an enforcement action has been taken. Investigators are to set subsequent follow-up reminders, as necessary, when they document findings from follow-up surveillance activities.

2. Investigators are to, in consultation with their supervisor, set reminders for facilities where other conditions warrant follow-up.

3. ANet generates reminders for Investigators to conduct follow-up surveillance activities. These are displayed on the home page of ANet with the expected follow-up date.

4. Investigators are to complete the follow-up surveillance by the due date of the reminder.

5. Once an Investigator conducts the follow-up surveillance, ANet will automatically clear the reminder from the system.

CHAPTER III – SURVEILLANCE METHODS

I. 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 necessary to conduct their planned activities.

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, personal protective equipment, or product sample supplies).

2. Prior to conducting surveillance activities, Investigators are to:

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

b. Understand and be prepared to explain how the Acts and regulations apply to the person or firm;

c. Review, be familiar with, and be prepared to explain, as necessary, any directives, notices, compliance guidelines, or other Agency information that are relevant 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. Contact FSIS personnel (e.g., EOS or Office of Field Operations (OFO)) or other Federal, State, or local agencies that have knowledge of the person or firm to be surveilled;

f. Research the person or firm to be surveilled using the internet (e.g., Agency recall sites, State and county sites, firm website); and

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

3. Using ANet, Investigators are to:

a. Obtain key information in support of the surveillance activity by reviewing firm information and any associated surveillance, product control, investigation, or enforcement records, including any records documented by applicable State programs. Firm information includes information such as business name; primary business type; additional business types (if applicable); physical address; 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, so that this information will be available for future surveillance activities; and

c. 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. Investigators are also to be aware of potential safety concerns and coordinate with their supervisor, as necessary, to develop strategies to ensure their personal safety during the surveillance activity.

II. PROCEDURES FOR CONDUCTING 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 along 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 position. It may be necessary for Investigators to present their credentials to several individuals during 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 activity. If 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 the surveillance activity, 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*.

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 are to 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, Investigators are to verify accuracy of firm information on file during the surveillance. Investigators are to collect the data necessary to complete and update the Firm Information in ANet.

III. FOOD SAFETY

A. When Investigators conduct in-commerce surveillance activities, 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, 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 perform the food safety component of the surveillance activity, 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) 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, 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; and

6. Walk the outer perimeter of the firm, when feasible, and observe the exterior structure 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, 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 maintains process control programs, is the firm following these programs?

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

1. There are five Attachments included with this directive:

   a. Attachment 1, *Definitions of Business Types*;

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

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

   d. Attachment 4, *Instructions for Collecting Surveillance Samples of Raw Ground Beef at Retail*; and

   e. Attachment 5, *Fish FAQs and Activities – Siluriformes* (Farmed and Wild-Caught).

2. Investigators are to check the FSIS Website to see if there are updates to the attachments or if new attachments 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 V of this directive.

IV. 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.

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

V. 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.

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 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*).

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 evaluate whether consumer-packed shell egg containers are labeled with safe handling instructions (Attachment 2).

NOTE: 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.

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 V of this directive.

VI. IMPORTED PRODUCTS

A. When Investigators conduct in-commerce surveillance activities related to imported products, they are to verify that imported products are wholesome, correctly marked and labeled, from eligible countries and certified foreign establishments, and not otherwise 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. A FTP occurs when amenable products produced by a foreign establishment and properly certified by the foreign government are delivered into commerce, further processed in an official establishment, 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, *Investigative Methodology*.

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").

NOTE: Shipping containers of product imported into the U.S. from Canada are not 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 the shipping mark to verify the product's eligibility and import status using PHIS and information available on the FSIS Website.

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, the Animal and Plant Health Inspection Service, 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 United States; they are to follow the instructions in FSIS Directive 8010.2 .

1. "Illegally imported products" are products that may be accurately labeled and properly manifested but do not meet all FSIS requirements for entry into the United States (e.g., beef carcasses from an ineligible country).

2. "Smuggled products" are prohibited meat, poultry, or egg products that enter the United States by a covert or clandestine act or acts intended to conceal the prohibited products in order to avoid completely or circumvent the regulatory process of entry (e.g., chicken from an ineligible country packed into boxes labeled as containing fish).

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 V of this directive.

VII. EXPORTED PRODUCTS

A. While conducting in-commerce surveillance activities, Investigators may observe product for export.

B. Investigators may examine product for export, if available, and review relevant export documentation.

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 V of this directive.

VIII. CUSTOM EXEMPT REVIEWS

When Investigators conduct in-commerce surveillance activities related to meat and poultry products produced under the custom exemption or other similar exemptions (21 U.S.C. 464(c) and 623(a)), they are to follow FSIS Directive 8160.1, *Custom Exempt Review Process*.

IX. 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 EOS to coordinate order verification activities, enforcement, or related matters and discuss any questions or concerns since EOS has Agency-wide responsibility for enforcement of criminal, civil, and administrative orders and other dispositions and is to 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 subjects' 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 V of this directive, as necessary, to address food safety or other violations;

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

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

EOS.

X. 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 V of this directive.

XI. 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, *Significant Incident Response*.

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

CHAPTER IV – DOCUMENTATION

I. SELECTING THE APPROPRIATE SURVEILLANCE REASONS

Investigators are to document the reason they are conducting the surveillance activity at the firm in ANet.

1. Investigators are to use the definitions provided below to select the most appropriate reason for the surveillance activity.

    a. **Allegation** – Receipt of information alleging a violation involving FSIS regulated products and it does not meet the definition of a Consumer Complaint, Industry Complaint, or Referral by Government Agency.

    b. **Consumer Complaint** – A complaint received via the Consumer Complaint Monitoring System (CCMS) or directly from a consumer.

    c. **Custom Exempt Review** – Activities conducted to determine if firms producing custom exempt

products are complying with the Acts and applicable regulations.

d. **Enforcement Follow-up** – Activities conducted to monitor/verify compliance related to FSIS' issuance of a Notice of Warning (NOW), or order verification such as a Consent Decree, Consent Order, Plea Agreement, or Pre-Trial Diversion.

e. **Foodborne Illness** – Activities conducted related to a foodborne illness. Examples include, but are not limited to, trace-forward and trace-back activities.

f. **Industry Complaint** – A complaint received from a business who handles FSIS regulated products.

g. **Investigation** – Activities conducted related to an open investigation.

h. **Office of Inspector General (OIG) Hotline Complaint** – Activities conducted in response to receipt of an OIG hotline complaint.

i. **Random** – Surveillance activity that is unplanned. Example is discovery of a new business that handles FSIS regulated products.

j. **Recall Effectiveness** – Activities conducted to verify the effectiveness of a firm's voluntary recall of FSIS regulated product.

k. **Referral by Government Agency** – Receipt of information or allegation involving FSIS regulated products from any Federal, State, or local agency.

l. **Retail Project** – Use one of the choices in the drop-down list.

m. **Routine** – Activities conducted as a routine surveillance based on tier (i.e., the firm is not subject to follow-up based on previous enforcement).

n. **Special Project** – Use one of the choices in the drop-down list.

o. **Other** – Use one of the choices in the drop-down list.

2. For any retail project, special project or other activities, Investigators are to use the additional reasons listed below to properly attribute and account for those activities. As noted, the Retail/Special/Other Project list allows for multi-selection, which can occur frequently, especially at a retail facility.

   a. **Ground Beef Sample Collected** – Collecting an MT05/06 ground beef sample.

   b. **Grinding Log Verification** – Activities conducted to verify compliance with 9 CFR 320.1(b).

   c. **Retail Deli Checklist or Tool Completed** – Completing a retail deli checklist/tool in PHIS.

   d. **Special Project** – Defined by Headquarters (HQ), when necessary (e.g., National School Lunch Program Project). This will bring up a separate text box that Investigators are to use to include the name of the project, as provided by HQ.

   e. **Other** – For use when no other reason is applicable. Consult with supervisor before use. This

will bring up a separate text box that Investigators are to use to explain the reason for going to the firm.

II. SURVEILLANCE FINDINGS

A. Upon completion of the surveillance activity, including follow-up surveillance, Investigators are to:

1. Document their findings in ANet by completing all applicable fields in the Surveillance record. When food defense activities are performed as a part of the surveillance, the Investigator is to document any findings in the Surveillance record to complete FSIS Form 5420-3, *Food Defense Surveillance Findings*;

2. Identify, where appropriate, firms for follow-up surveillance activities; and

3. Update, where needed, the Firm Information record for firms in ANet. For a firm that is not in ANet, Investigators are to add the firm to ANet 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.

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

C. When Investigators identify product that has been illegally imported or smuggled, or is considered a 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.

III. 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.

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 V – 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 and collect evidence in accordance with FSIS Directive 8010.3;

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

4. Notify EOS, as per Chapter III, Section IX 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 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: DEFINITIONS OF BUSINESS TYPES

3D/4D: A person, firm, or corporation 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. A 3D/4D business is required to register as a meat and poultry handler (21 U.S.C. 643 and 460).

Abattoir: A person, firm, or corporation operating under a Federal, State, or Talmadge-Aiken grant of inspection where animals are slaughtered for consumption as food products.

Animal Food Manufacturer: A 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 amenable animals (9 CFR 301.2, 381.1(b)). An animal food manufacturer is required to register as a meat and poultry handler (21 U.S.C. 643 and 460).

Bonded Area: A facility or designated area within a facility (authorized by the U.S. Customs and Border Patrol) that handles meat, poultry, shell eggs, or egg products from suppliers outside the United States and temporarily stores said product in cold storage or freezers without processing or breaking down the product.

Broker: A 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)). A broker is required to register as a meat and poultry handler (21 U.S.C. 643 and 460).

Custom Exempt Operator: A person, firm, or corporation that provides slaughter 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 animal's owner, and is not eligible for sale or donation (9 CFR 303.1(a)(2), 381.10(a)(4)).

Distributor: A person, firm, or corporation that receives and handles meat, poultry, shell eggs, or egg products typically from multiple domestic or overseas suppliers, stores said products in cold storage or freezers, and then redistributes said products to multiple customers without processing or breaking down the product. A distributor is required to register as a meat and poultry handler (21 U.S.C. 643 and 460).

Exempt Poultry Operator: A person, firm, or corporation that slaughters or processes poultry exempt from Federal or State inspection. This type of operation (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 (9 CFR 381.10(a)(5-7), 381.10(b), and 381.10(c)).

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

Inactive: A business that is not currently operating (or permanently closed) and is not periodically surveilled. These businesses are to remain in ANet for historical reference.

Institution: An entity or organization typically founded and united for a specific purpose (e.g., hospital, daycare center, prison, or military base) that prepares food containing meat, poultry, or egg products for resident populations.

Port-of-Entry: Any place designated by law or order at which a U.S. Customs and Border Protection

officer is authorized to accept entries of merchandise, i.e., meat, poultry, shell eggs, or egg products, to collect duties, and to enforce the various provisions of the customs and navigation laws before entering into U.S. Commerce.

Processor: A person, firm, or corporation operating under a Federal, State, or Talmadge-Aiken grant of inspection that receives meat, poultry, or egg products and further processes the bulk product into a further processed product (e.g., ready-to-eat, ready-to-cook packaged product).

Renderer: A 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)). A renderer is required to register as a meat and poultry handler (21 U.S.C. 643 and 460).

Restaurant: A business that prepares and serves food and drink to customers. Food is generally served and eaten on premises, though 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 person, firm, or corporation that sells meat, poultry, shell eggs, or egg products directly to consumers for consumption, generally off-premises. Retail operations may include cutting up, slicing, trimming, grinding, freezing, curing, cooking, smoking, breaking bulk, or wrapping or rewrapping amenable food products (9 CFR 303.1(d)(1), 381.10(d)(1)).

Salvage: A person, firm, or corporation that purchases, sorts and sells "distressed" meat, poultry, shell eggs, or egg products that other businesses have been unable to sell (e.g., wholesome and properly labeled products that have quality issues or do not meet purchase specifications).

Siluriformes Fish Pond: A person, firm, or corporation operating and maintaining ponds that raise Siluriformes fish that are slaughtered or further processed for consumption as Siluriformes fish or fish product. A Siluriformes fish pond is required to register as a meat handler (21 U.S.C. 643).

Transporter: A person, firm, or corporation that provides transportation services of meat, poultry, shell eggs, or egg products for fees. A transporter does not buy, sell, process, or label, but may temporarily store products (e.g., FedEx, UPS).

Warehouse: A person, firm, or corporation that handles meat, poultry, shell eggs, or egg products from multiple domestic or overseas suppliers and may be public (leases space to product owners) or private (stores its own products for its own retail stores). A public warehouse is required to register as a meat and poultry handler; a private warehouse is not required to register (21 U.S.C. 643 and 460). A warehouse also may operate under voluntary identification or certification service where it could repackage/label, certify for export, or perform other activities (9 CFR 350.3, 362.2).

ATTACHMENT 2: IN-COMMERCE SURVEILLANCE OF SHELL EGGS

I. INTRODUCTION

This Attachment 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 this directive.

II. STATUTORY AUTHORITY

A. The EPIA (21 U.S.C. 1034(e)(1)(A) and (B) and 1037) 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 and contain labeling that indicates that refrigeration of the shell eggs is required.

B. In addition to the statutory requirements of the EPIA, the regulations (9 CFR 590.50(a)) require that shell eggs be labeled with safe handling instructions in accordance with 21 CFR 101.17(h).

C. 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 this directive, 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

1. 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 IV of this Attachment.

    d. As described 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.

2. 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 temperature readings from five 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 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 temperature readings in accordance with the instructions in Section IV of this Attachment.

3. Verifying ambient air temperatures of transport vehicles

    a. In each transport vehicle where shell eggs are stored or transported, Investigators are to take three 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 temperature readings from three 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 temperature readings in accordance with the instructions in Section IV of this Attachment.

C. Labeling Verification

1. Investigators are to examine shell eggs to verify that shell egg cartons or other shell egg containers

are labeled with safe handling instructions in accordance with 21 CFR 101.17(h), including:

a. The label of all shell eggs must bear the following statement:

SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly.

b. The label statement must appear prominently and conspicuously, with the words "SAFE HANDLING INSTRUCTIONS" in bold type, on the principal display panel, the information panel, or on the inside of the lid of egg cartons. If this statement appears on the inside of the lid, the words "Keep Refrigerated" must appear on the principal display panel or information panel; and

c. The label statement shall be set off in a box by use of hairlines.

NOTE: Though 21 CFR 101.17(h)(4) and (5) provide exemptions and alternatives to the labeling requirements for safe handling instructions, these exemptions or alternatives do not supersede the statutory requirements of the EPIA. In accordance with 21 U.S.C. 1034(e)(1)(B), Investigators are to ensure that, at a minimum, shell eggs destined for the ultimate consumer contain labeling that indicates refrigeration is required if 21 CFR 101.17(h)(1-3) is not applicable for the reasons cited in 21 CFR 101.17(h)(4) and (5).

2. 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 IV of this directive and the specific instructions in this Section.

B. Investigators are to enter shell egg ambient air temperature and labeling findings in ANet 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 temperature readings, then calculate the average temperature by adding the five temperature readings together and dividing the sum by five.

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

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.

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 the required safe handling instructions or, if exempt from the safe handling requirements, met the statutory requirements of the EPIA.

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. This includes 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 otherviolations involving shell eggs, they are to follow FSIS Directive 8410.1 and FSIS Directive 8010.2.

D. CID is to refer all shell egg cases to EOS.

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 (EPIA) (21 U.S.C. 1037(c)) and regulations (9 CFR 590.50(a)) 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 with safe handling instructions.[1]

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 with safe handling instructions.[1]

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 EPIA (21 U.S.C. 1041 and 1042).

Is there further information about these requirements?

Further information about shell eggs is on FSIS' Website. Specific information is found by entering "Shell Eggs from Farm to Table" in the search field. Additionally, this directive's Attachment 2; FSIS Directive 8410.1; and FSIS Directive 8010.5, *Case Referral and Disposition*, set out FSIS' policy on shell egg surveillance and enforcement.

[1] The EPIA (21 U.S.C. 1034(e)(1)(B)) requires that shell eggs contain labeling that indicates that refrigeration is required. Under 9 CFR 590.50(a), shell eggs are also required to bear safe handling instructions in accordance with 21 CFR 101.17(h).

ATTACHMENT 4: INSTRUCTIONS FOR COLLECTING SURVEILLANCE SAMPLES OF RAW GROUND BEEF PRODUCTS 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 *E. coli* O157:H7 and *Salmonella*. 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 are to 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 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., head meat, cheek meat, heart meat);

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. Regrinding 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);

4. 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;

5. Using meat cuts (e.g., steaks or roasts that the store determines are suitable as an ingredient in raw ground beef) that have been pulled back from the retail case regardless of the sell-by date;

6. Grinding and failing to keep records sufficient for trace back (9 CFR 320.1(b)(4));

7. Mixing irradiated and non-irradiated beef;

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

9. Grinding under insanitary conditions.

C. 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.

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 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). If there is no fresh product available to sample, collect a random minimum 1-pound intact sample of frozen product. Place the retail packaged sample in the sample bag provided by the lab for this purpose. Close the bag securely.

2. 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.

3. Log into the Public Health Information System (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. Attach electronic copies of the FSIS Form 8010-1 and results (when available) in the File Attachments tab of the ANet Surveillance record for this retail firm.

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

NOTE: If the sample is 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.

7. Ensure integrity of the sample in accordance with FSIS Directive 7355.1, *Use of Sample Seals for Laboratory Samples and Other Applications*, by:

    a. Printing the signed FSIS Form 8010-1 and affixing one small-sized bar-coded label to the top of the form ensuring that the bar code does not obstruct any printed information (other than the title of the form);

    b. Placing the FSIS Form 8010-1 into the provided plastic sleeve to protect it during shipping and including the form with the collected sample;

    c. Sealing the sample bag with the medium-sized bar-coded label (FSIS Form 7355-2B); and

    d. Packaging the sample in the shipping container with sufficient coolant and sealing the shipping container by placing the large-sized bar-coded label (FSIS Form 7355-2A) across the flap.

8. Ship the sample to the laboratory listed in Block 5 of FSIS Form 8010-1 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 shipping labels in the box with the sample. Investigators are to ship the sample via overnight courier the same day it is collected. 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.

IV. WHEN NOT TO COLLECT SAMPLES

Investigators are not to sample the following raw ground beef products that are:

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

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

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@usda.gov

FSIS- SamplingSupplies-MidwesternLab@usda.gov

FSIS- SamplingSupplies-WesternLab@usda.gov

VI. DOCUMENTATION

A. If a sample is collected, Investigators are to complete the following steps in 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; and
5. Click "Submit to Lab."

B. Investigators are to post the FSIS Form 8010-1 and (when received) MT05 sample results in the ANet Surveillance record under the File Attachments tab.

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 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 is to select the reason from the ANet drop-down menu.

1. If the product is case ready (i.e., consumer-sized packages of ground beef which werepackaged at the official establishment), the Investigator selects "Case ready."
2. 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 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."

4. 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.

NOTE: If the Investigator is unable to collect a sample based on one of these reasons, they are to collect a sample, as described in Section II of this attachment, at another retail store.

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.

NOTE: If the sample is not analyzed, Investigators are to contact their supervisor for further instruction.

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

C. In the Additional Info tab in ANet, Investigators select Positive, Negative, or Not Analyzed and attach an electronic copy of the LIMS Direct sample results under the File Attachments tab.

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 MT06 follow-up samples 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 follow-up 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: 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 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 are to be directed to the Risk Management and Innovations Staff through askFSIS by selecting General Inspection Policy/Sampling/*E. coli* O157:H7 or by telephone at 1-800-233-3935.

Attachment 5: Fish FAQs and Activities - Siluriformes (Farmed and Wild-Caught)

Criteria	Personal Use[1]	Restaurant 9 C.F.R 532.3 and 303.1(d)	Retail 9 C.F.R 532.3 and 303.1(d)	Wholesale, Distributor ("Box-In, Box-Out")	Federal Establishment[2]
Slaughter Limit	N/A - Sales Not Permitted	No Limit (e.g., Live Tank)	No Limit (e.g., Live Tank)	Not Permitted FMIA 21 U.S.C. 610	No Limit - Whole[3] fish sourced from farmers, Anglers, etc. Activities conducted under Federal Inspection Services
Processing	N/A - Sales Not Permitted	Fish sourced from an Angler must be whole[3], non-eviscerated and not otherwise cut, knifed or processed	Fish sourced from an Angler must be whole[3], non-eviscerated and not otherwise cut, knifed or processed	Not Permitted FMIA 21 U.S.C. 610	Yes - Whole[3] fish sourced from farmers, Anglers, other Federally inspected source, etc. Activities conducted under Federal Inspection Services
75 lb. Limit to Consumer (Normal Retail Quantity)	N/A	Yes	Yes	N/A	No Limit
150 lb. Limit to HRI	N/A	N/A	Yes	N/A	No Limit
25%-75% HRI Sale	N/A	N/A	Yes	N/A	No Limit
HRI Dollar Limitation	N/A	N/A	Yes	N/A	No Limit
Can Sell to Any Buyer[4] (9 C.F.R. 532.3)	No	No	No	Yes	Yes
Can Sell to HRI (HRI Product must originate from federally or state inspected)	No	Yes - Federally inspected and/or State inspected for intra-state.	Yes - Federally inspected and/or State inspected for intra-state.	Yes	Yes
Sells Fish They Slaughter or Process to Distributors for Resale	No	No	No	N/A FMIA 21 U.S.C. 610	Yes
May Sell to Retail Stores	No	No - FMIA 21 U.S.C. 610	No - FMIA 21 U.S.C. 610	Yes - Federally Inspected Product	Yes
Processed Fish Sold & Distributed to *Intra* state Consumers	No	Yes	Yes	Yes - Federally Inspected Product	Yes
Processed Fish Sold at Store & Distributed to *Inter* state Consumers	No	No	Yes - Retail sales to households and HRI derived from Federally inspected & passed fish product	Yes - Federally Inspected Product	Yes
Safe Handling Instructions	N/A	Yes	Yes	Yes, and other labeling	Yes, and other labeling

[1] Personal Use (as a disposition) does not apply for Fish and/or Fish Products under the FMIA (No provision in the FMIA. 21 U.S.C. 625 precludes 623)

[2] Imported products subjected to reinspection services are considered Federally inspected and passed.

[3] Whole/Round/Head On (Whole Fish, Fish in the Round, Heads On) are non-eviscerated and not otherwise cut, knifed or processed whether wild-caught or farmed.

[4] Any Buyer: Includes, but is not limited to, any persons, firms, corporations that may engage in the act of buying fish products (e.g., consumer, HRI, retailer, wholesalers, distributors, manufacturers, resellers, salvage)