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

FSIS DIRECTIVE

8010.1, Revision 2

6/25/08

METHODOLOGY FOR CONDUCTING IN-COMMERCE SURVEILLANCE ACTIVITIES

I. PURPOSE

This directive provides instructions to the Food Safety and Inspection Service (FSIS), Office of Program Evaluation, Enforcement and Review (OPEER), Compliance and Investigations Division (CID) Investigators on the methodology that they are to use when conducting in-commerce surveillance activities of persons, firms, or corporations who are subject to the provisions of the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), or the Egg Products Inspection Act (EPIA) (the Acts) and related laws and regulations.

Key Points Covered

- Describes OPEER in-commerce surveillance activities.

- Access, examination, and business types.

- Authority for FSIS personnel to access businesses and to examine product, facilities, and records.

- Preparing for conducting in-commerce surveillance activities.

- Procedures for conducting in-commerce surveillance activities.

- Verification activities for food safety, food defense, court orders, and other surveillance components.

- Documenting the findings of in-commerce surveillance activities.

- Procedures for apparent violations and other irregularities.

II. CANCELLATION

FSIS Directive 8010.1, revision 1, Methodology for Conducting In-Commerce Surveillance Activities, dated 9/4/07

III. REASON FOR REISSUANCE

FSIS is reissuing this directive in its entirety to incorporate instructions related to the In-Commerce System (ICS).

IV. REFERENCES

Federal Meat Inspection Act (FMIA)
Poultry Products Inspection Act (PPIA)
Egg Products Inspection Act (EPIA)
9 CFR Part 300 to end
9 CFR Section 590.10
Title 18 U.S.C. 701
21 U.S.C. Sections 643 and 644
FSIS Directive 4735.4, Reporting Assault, Harassment, Interference, Intimidation or Threat
FSIS Directive 5420.3, Homeland Security Threat Condition Response – Surveillance of Firms and Products in Commerce
FSIS Directive 5500.2, Non-Routine Incident Response
FSIS Directive 5610.1, Procedures to Implement the Consumer Complaint Monitoring System (CCMS)
FSIS Directive 8010.2, Investigative Methodology
FSIS Directive 8010.3, Procedures for Evidence Collection, Safeguarding and Disposal
FSIS Directive 8010.4, Report of Investigation
FSIS Directive 8410.1, Detention and Seizure
FSIS Directive 8080.1, Recall of Meat and Poultry Products

V. BACKGROUND

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

B. The Acts provide authority for the effective regulation of meat, poultry, and egg products. FSIS is responsible for carrying out this statutory authority. Contained within these statutes are provisions pertaining to adulteration, misbranding, prohibited acts, access and examination, and detention and seizure, as well as criminal, civil, and administrative sanctions and remedies for addressing violations.

VI. GENERAL

A. The in-commerce surveillance activities conducted by OPEER and other FSIS personnel protect the health and welfare of consumers by ensuring that meat, poultry, and egg products in commerce are safe, wholesome, correctly labeled and packaged, and secure from intentional acts of contamination. These activities are carried out at in-commerce locations such as warehouses, distribution centers, and retail establishments, as well as ports-of-entry and United States (U.S.) borders, to verify that persons and firms, whose business activities involve FSIS-regulated products, prepare, store, transport, sell, or offer for sale or transportation such products in compliance with FSIS statutory and regulatory requirements.

B. In-commerce surveillance activities include, but are not limited to, the following:

1. Food Safety

2. Food Defense

3. Non-Food Safety Consumer Protection

4. Order Verification

5. Imported Products

6. Public Health Response

7. Emergency Response

C. These activities are conducted collectively, as a whole, and not independent or exclusive of one another. Whenever Investigators conduct in-commerce surveillance activities, they will perform all procedures associated with these activities, when applicable.

VII. ACCESS AND EXAMINATION

Section 202 of the FMIA (21 U.S.C. 642), Section 11 of the PPIA (21 U.S.C. 460), and Sections 5 and 11 of the EPIA (21 U.S.C. 1034 and 1040) provide duly-authorized representatives of the Secretary, with respect to the classes of persons, firms, and corporations set forth in those sections, access to the place of business and opportunity to examine the facilities, inventory of meat, poultry, or egg products, and records thereof, and with authority to copy all such records and to take reasonable samples of the inventory upon payment of the fair market value.

VIII. PREPARATION FOR CONDUCTING IN-COMMERCE SURVEILLANCE ACTIVITIES

A. In carrying out FSIS' public health mission, Investigators are to:

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

2. prioritize and conduct surveillance activities in order of public health importance (e.g., public health response, emergency response);

3. take into account public health tiers and other information for firms in the ICS system;

NOTE: The Agency's ICS system classifies each of the firms (i.e., business types) at which CID Investigators conduct surveillance into "tiers" related to surveillance priorities and provides information to assist Investigators in conducting surveillance activities based on public health priorities. The ICS also records surveillance review findings, provides facility and compliance history information, and assists Investigators in monitoring and initiating follow-up surveillance reviews.

4. take into account other factors, such as travel time and distances relevant to the activities to be conducted, the proximity of the activities to be conducted, the time it takes to conduct surveillance in one type of business versus another, how long it has been since the last surveillance visit, and the findings of the most recent visits; and

5. keep in mind that they may be called away, at any moment, from the activity they are conducting and be re-directed to other activities (e.g., foodborne illness investigations).

B. Before conducting in-commerce surveillance activities, an Investigator is to ensure that he or she has the following standard functioning equipment available and with him or her:

1. Laptop computer and printer

2. Digital camera

3. Flashlight

4. "U.S. Detain" tags

5. Freezer coat

6. Hard hat

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

8. Any other equipment or supplies that are necessary in order to effectively carry out the surveillance activities to be conducted.

C. Before conducting in-commerce surveillance activities, an Investigator needs to:

1. be aware of the current Homeland Security Advisory System threat condition level and plan surveillance activities accordingly;

2. be aware of the nature of the business activity of the person or firm that is the subject of the review and be prepared to explain and discuss how the Acts apply to the person or firm;

3. review, be familiar with, and be prepared to explain and discuss any regulations, directives, notices, and guidelines that have particular application to the firm or person;

4. review and be familiar with previous surveillance review documentation associated with the person or firm, including information available in the ICS system (e.g., firm information, surveillance review information);

5. review and be familiar with previous compliance history, notice of warning letters, Federal court orders, or Agency administrative orders;

NOTE: The firm's business activities may have changed since the time of the last contact or may be different from the business type listed in the ICS system. Investigators may need to update the current firm information in the ICS system. If a firm is not in the ICS system, Investigators will need to add the firm into the Firm Information section of the system.

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

7. be aware of any personal safety concerns and formulate, as necessary, methods and strategies to ensure his or her, and other Agency personnel's, safety during the review.

NOTE: If at any time the Investigator feels threatened while conducting his or her official duties, he or she is 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."

D**.** Before conducting in-commerce surveillance activities, the Investigator may also:

1. contact other Investigators who have knowledge of the subject person or firm;

2. contact any other internal Agency personnel or program areas who have knowledge of the subject person or firm, such as the Evaluation and Enforcement Division (EED)/OPEER, the Office of Field Operations (OFO), or the Office of International Affairs (OIA); and

3. contact any Federal, State, or local agencies that have knowledge of the subject person or firm.

NOTE: Investigators may offer other agency officials the opportunity to participate in the surveillance activity.

IX. PROCEDURES FOR CONDUCTING SURVEILLANCE ACTIVITIES

A. Introduction and credentials:

1. The Investigator will present his or her credentials upon initial introduction with the person or firm management.

2. If initial contact is with reception personnel or an employee in a non-managerial position, the Investigator will again present his or her credentials when he or she is introduced to the firm representative who holds a management or higher position. It may be necessary for the Investigator to present his or her credentials to several individuals during the course of the surveillance review.

3. The Investigator may allow the person or firm to examine his or her credentials in order for the person or firm to document the Investigator's name and badge number. The Investigator is not to allow his or her credentials to leave his or her possession, or allow the credentials to be photocopied.

NOTE: Title 18 U.S.C. 701 prohibits photocopying of official credentials.

4. Investigators may provide a business card in conjunction with presentation of credentials, but a business card is not a substitute for official identification.

5. If the Investigator is reviewing a firm whose activities are open to the public (e.g., retail store or livestock auction), the Investigator is not required to make prior or immediate contact with a firm representative before or upon entering the firm. Therefore, the Investigator does not have to immediately present his or her credentials.

6. Investigators are to request that a management official or designee accompany him or her during the surveillance review. Although not required, the presence of a management official or designee may help facilitate the surveillance activity being conducted. 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 review if he or she finds no reason not to do so.

B. Determining the business type:

1. The Investigator will determine and verify the business type that is the subject of the surveillance review. This determination can only be made by direct observation of activities and discussion with the owner, management official, or designee of the types of activities conducted. Reviewing business licenses and permits may also assist in determining the business type but are never to be relied on solely.

2. Once the business type has been determined, the Investigator can verify that the operations being conducted are in compliance with applicable FMIA, PPIA, and EPIA laws and regulations.

X. INVESTIGATOR'S NOTES

A. Investigators' notes are a contemporaneous record regarding surveillance, investigative, or other activities. These notes are to be accurate, objective, factual, and free of personal feelings or conclusions. Notes are confidential because of the data they may contain (e.g., information pertaining to open investigations, confidential business information, or personal information protected under the Freedom of Information Act (FOIA) or Privacy Act).

B. When Investigators make notes, the notes are to:

1. be handwritten or electronic;

NOTE: Electronic notes are to be stored in a manner that ensures data integrity (e.g., on a CD-R or computer disk).

2. be made in a manner and in a recording medium that will provide continuity and integrity (e.g., bound or loose-leaf notebook or loose paper);

3. be identified with the Investigator's name, title, telephone number, and address;

4. be maintained with the corresponding case investigation or Report of Investigation (ROI); and,

5. be retained in accordance with the retention schedule in FSIS Directive 8010.3;

XI. FOOD SAFETY

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

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

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

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

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

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

B. To accomplish these verification activities, an Investigator is to:

1. walk through the interior of the firm and examine the facilities and equipment used to prepare, store, or otherwise handle amenable products;

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

3. examine records related to the products observed to determine whether those records fully and correctly disclose the transactions involving the products;

4. examine inedible products to determine whether those products are properly identified and denatured as prescribed by the regulations, if appropriate;

5. collect samples for laboratory analysis, as necessary; and

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

C. To determine whether product is adulterated or is being held under insanitary conditions, Investigators are to seek answers to questions such as the following:

1. Meat, poultry, and egg products:

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

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

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

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

2. Sanitary conditions:

a. Do the grounds about 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 those 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 amenable products, and, if so, does the firm verify the products against the accompanying shipping documents?

b. Does the firm visually examine amenable products before receiving them into inventory?

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

e. Are general production practices, as applicable, sufficient to preclude the adulteration of products?

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

g. Does the firm receive returned goods? If so, does the firm have appropriate controls to handle such product, (e.g., identifying why the product was returned)?

h. Does 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?

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

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

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

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

D. For the types of products observed (e.g. raw, ready-to-eat, shelf-stable), determine whether the sanitary conditions and hazard controls are sufficient to preclude those products from becoming adulterated.

E. If Investigators observe apparent violations of the Acts while conducting food safety related surveillance activities, or if the answers to the questions above lead the Investigators to have reason to believe that product may be adulterated or held under insanitary conditions, they are to follow instructions in Section XX. of this directive.

F. Investigators are also to check to see if the Agency has included an appendix in this directive that supplements the general methodology. If there is an appendix that covers the product or type of business that the Investigator is verifying, the Investigator should incorporate that methodology in his/her activities.

XII. FOOD DEFENSE

A. OPEER Investigators and other FSIS personnel conduct on-going food defense surveillance activities in commerce to verify and ensure that FSIS-regulated products are secure from threats and intentional acts of contamination.

B. When conducting food defense surveillance activities, Investigators will follow the instructions set out in FSIS Directive 5420.3, “Homeland Security Threat Condition Response – Surveillance of Firms and Products in Commerce.”

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

XIII. NON-FOOD SAFETY CONSUMER PROTECTION

A. When Investigators conduct surveillance activities, they are to verify that meat, poultry, and egg products are not misbranded, economically-adulterated, or otherwise unacceptable for reasons that do not raise food safety concerns.

1. To accomplish Non-Food Safety Consumer Protection activities, Investigators are to:

a. examine meat, poultry, or egg products to determine whether they are misbranded according to the Acts; and

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

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

B. To determine whether meat, poultry, or egg products are correctly 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, as required?

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

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

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

C. To determine whether meat, poultry, or egg products are economically adulterated, Investigators are to:

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

2. discuss with management or procurement officials any concerns or complaints they may have relating to amenable 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.

D. If Investigators observe apparent violations of the Acts while conducting non-food safety consumer protection surveillance activities, or if answers to the questions above lead the Investigators to have reason to believe that product may be misbranded or economically adulterated, they are to follow the instructions in Section XX. of this directive.

XIV. ORDER VERIFICATION

A. When Investigators conduct surveillance activities, they are to verify that persons or firms are in compliance with the terms and conditions of any applicable administrative orders, court orders, settlement agreements, or other binding case disposition terms (e.g., administrative consent decision, consent decree, injunction, plea agreement).

B. To accomplish these activities, Investigators are to:

1. read and become familiar with any order that applies to the person or firm to be visited and the terms or conditions of the order;

2. contact the EED compliance specialist assigned to the case to discuss any questions or concerns;

3. if there is a probation officer assigned to the case, contact him or her to discuss any questions or concerns; and

4. if the order involves a Federal establishment, contact the Front-line Supervisor to arrange a meeting with OFO personnel to discuss any questions or concerns that OFO personnel may have or that the Investigators believe need to be discussed.

C. To determine whether the person or firm is in compliance with the order, 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.

NOTE: Prior to meeting with the subjects of the order, the Investigators may conduct other activities, such as surveillance reviews of known previous consignees, to verify compliance with the order.

2. discuss each term or condition of the order that is applicable to FSIS jurisdiction; and

3. verify, by direct observation, the subject's compliance with each such term or condition of the order that is applicable to FSIS jurisdiction.

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

1. clearly identify, explain, and discuss the violation with the subjects of the order or with management officials or designees as necessary;

2. for a Federal court order, notify the probation officer and the assigned EED compliance specialist. For an Agency administrative order, the Investigators will notify the EED compliance specialist;

3. document his or her findings in the ICS system, as well as any actions taken and the individuals contacted, such as the probation officer or EED compliance specialist;

4. forward all written documentation related to the violation to the EED compliance specialist; and

5. as applicable, follow the instructions in Section XX. of this directive.

XV. IMPORTED PRODUCTS

A. FSIS is responsible for the re-inspection of imported meat, poultry, and egg products before those products enter U.S. commerce. OPEER Investigators and other FSIS personnel conduct surveillance activities relating to imported products at every point in distribution channels, including U.S. borders, ports-of-entry, distributors, facilities, warehouses, and retail stores. Investigators verify, among other things, that imported products are wholesome, correctly marked and labeled, and are from eligible countries and approved foreign establishments.

B. This section provides the methodology that Investigators and other FSIS personnel are to use when verifying that imported products are from eligible countries and approved foreign establishments. In addition, this section also provides the procedures that are to be followed when surveillance activities reveal meat, poultry, or egg products that have been illegally imported or smuggled into the U.S., and the documentation and distribution of an Import Alert when violative imported product has been located in commerce.

C. Smuggled products are prohibited products that a party fraudulently brings into the U.S. (e.g., chicken from an ineligible country packed into boxes labeled as containing fish). Illegally imported products are products that may be accurately labeled and properly manifested at the border but do not meet all requirements for entry into the U.S. (e.g., beef carcasses from an ineligible country).

D. Ineligible countries are those that do not have an equivalent inspection system to that of the U.S. meat, poultry, and egg products inspection system. Unapproved foreign establishments are those that are in an ineligible country or that have not been certified by an eligible country. Therefore, products from

those countries or those establishments are ineligible to enter U.S. commerce. If such products are found in commerce, and they present an animal health concern, Investigators are to notify the Animal and Plant Health Inspection Service (APHIS).

E. Investigators will coordinate surveillance activities related to imported products with OIA, APHIS, and other Federal, State or local agencies, as appropriate.

F. Investigators will follow the instructions in Section XI., C., 1., 2., and 3. of this directive and, in addition, will follow the procedures below when conducting surveillance activities concerning imported product:

1. Check the shipping container (if available) for the marks of Federal import inspection.

NOTE: Canadian origin product (shipping containers) are not stamped "U.S. Inspected and Passed."

2. Request from the Importer of Record, product owner, custodian, import broker, or other interested party, documents relating to the importation of the product in question. Related documents include, but are not limited to, FSIS Form 9540-1 (Import Inspection Application and Report), a health certificate issued by the foreign government certifying that the product is eligible for importation into the U.S., U.S. Customs and APHIS paperwork, and bills of lading.

3. Check the shipping container for a shipping mark (this is a sequence of alpha-numeric characters also found on the health certificate and import application).

4. Use the Automated Import Information System (AIIS) Web system to verify the products:

   (a) originated from eligible foreign countries;

   (b) originated from eligible foreign establishments;

   (c) were produced while the foreign establishment was listed as eligible; and

   (d) were inspected and passed by FSIS.

G. If Investigators or other FSIS personnel identify meat, poultry, or egg products from a foreign country that have been illegally imported or smuggled

into the U.S., they are to follow the instructions in FSIS Directive 9600.1, “Illegally Imported or Smuggled Products and Reporting in the Alert Tracking System.”

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

XVI. PUBLIC HEALTH RESPONSE

A. As part of its public health mission, FSIS verifies that meat, poultry and egg products are properly recalled as necessary and responds to consumer complaints involving meat, poultry and egg products. Additionally, FSIS has a principal role in working with other Federal, State, and local agencies in investigating illness outbreaks involving FSIS-regulated products. OPEER/CID Investigators may be called upon, at any time, to assist other FSIS program areas in conducting public health response activities, including voluntary recalls, consumer complaints, or illness outbreaks.

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

C. When conducting activities related to consumer complaints, Investigators are to follow instructions set forth 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 FSIS-regulated products, Investigators are to follow instructions set forth in FSIS Directive 8080.3, Foodborne Illness Investigations.

E. If Investigators observe apparent violations of the Acts while conducting these activities, they are to follow the instructions in Section XX. of this directive.

XVII. EMERGENCY RESPONSE

A. FSIS has developed extensive and comprehensive procedures to prevent, prepare for, respond to, and recover from non-routine emergencies resulting from intentional and non-intentional contamination affecting meat, poultry, and egg products. Intentional acts of contamination include tampering or a terrorist attack. Non-intentional acts of contamination include natural disasters such as a hurricane or an earthquake.

B. When conducting Emergency Response surveillance activities, Investigators are to follow the instructions set forth in FSIS Directive 5500.2, Non-Routine Incident Response.

C. If Investigators observe apparent violations of the Acts while conducting these activities, they are to follow the instructions in Section XX. of this directive.

XVIII. DOCUMENTATION OF FINDINGS

A. Upon completion of the surveillance activity, the Investigator is to:

1. Document his or her findings in the ICS system.

2. Update firm information or add a new firm in the Firm Information section of the ICS system, as necessary.

B. In addition, Investigators are to prepare the following documentation as applicable:

1. During a threat condition Elevated (Yellow) level and above, the Investigator will follow the instructions in FSIS Directive 5420.3 and complete FSIS Form 5420-3, Food Defense Surveillance Findings.

2. For non-routine incidents discovered while conducting surveillance activities, Investigators are to follow the instructions in FSIS Directive 5500.2 and complete FSIS Form 5500-4, Non-Routine Incident Report.

XIX. FOLLOW-UP SURVEILLANCE REVIEWS

A. Investigators are to conduct follow-up surveillance reviews as necessary to verify that:

1. persons and firms whose business activities involve FSIS-regulated products are in compliance with FSIS statutory and regulatory requirements;

2. persons or firms are in compliance with applicable administrative orders, court orders, or other binding case disposition terms; and

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

B. The ICS system provides a mechanism for Investigators to identify persons and firms for follow-up surveillance reviews. Generally, Investigators conduct follow-up surveillance reviews, when necessary, within a period of 3-, 6- or 12-months.

NOTE: The ICS system will generate reminders to Investigators for follow-up surveillance reviews. Investigators generally are to complete the follow-up surveillance review within a period of 3-months from the date of the reminder (i.e., 3-6 months, 6-9 months, or 12-15 months).

C. Whenever an Investigator conducts a surveillance review in accordance with this directive, he or she also is to:

1. identify in the ICS system that a follow-up surveillance review is to be conducted within a period of 3-, 6-, or 12-months; or

2. determine that a follow-up surveillance review is not necessary.

NOTE: The ICS system provides Investigators the ability to identify a firm as inactive (e.g., closure of firm or change in firm type or operations such that it no longer engages in activities regulated under the FMIA, PPIA, EPIA, or related laws or regulations).

D. In determining whether to identify a person or firm for a follow-up surveillance review and the period within which to conduct the follow-up review, Investigators are to consider:

1. the firm type (i.e., business type) and ICS tier;

2. whether the person or firm is operating under, and in compliance with, an administrative order, court order, or other binding case disposition terms;

3. surveillance review 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 made inedible; and

e. whether records are being maintained in compliance with agency requirements.

4. whether the Investigator documented an apparent violation(s) of the FMIA, PPIA, EPIA;

5. whether the Investigator initiated a product control action(s); and

6. the person or firm's compliance history.

NOTE: Even where an Investigator does not identify a person or firm in the ICS for a follow-up surveillance review, an Investigator may decide, or may be directed by their supervisor, to conduct a follow-up review based on a referral of an allegation (e.g., other FSIS program area, Federal or State contact, industry, consumer) or other information subsequently received by CID.

E. Investigators may deviate from the criteria for conducting follow-up surveillance reviews when required by public health exigencies (e.g., emergency response activities, food borne illness investigation) or as directed by their supervisor.

XX. APPARENT VIOLATIONS

A. During the course of conducting surveillance activities, an Investigator may observe apparent violations of the FMIA, PPIA, or EPIA , regulations, or applicable court orders or settlement agreements. When an Investigator observes apparent violations he or she is to:

1. initiate an investigation by following the instructions set out in FSIS Directive 8010.2, Investigative Methodology;

2. initiate product control action as set out in FSIS Directive 8410.1, Detention and Seizure;

3. notify his or her supervisor if, in the Investigator's judgment, additional Agency personnel or resources are required to ensure that the health and welfare of consumers are protected; and

4. prepare a Report of Investigation as set out in FSIS Directive 8010.4, Report of Investigation.

XXI. OTHER IRREGULARITIES

A. During the course of conducting surveillance activities, an Investigator may observe 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. When an Investigator

observes irregularities involving non-amenable product or facility conditions, he or she is to:

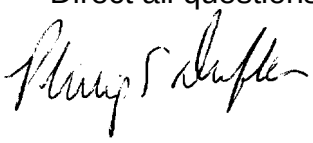
1. inform the management official, designee, owner, or custodian of the irregularity;

2. contact the appropriate Federal, State, or local agency and inform that office of the irregularity observed; and

3. document, in the ICS, the irregularity and that he or she notified the appropriate Federal, State, or local agency.

NOTE: Depending on the irregularity, the Investigator may need immediately to contact the appropriate Federal, State, or local agency.

Direct all questions on this directive through supervisory channels.



Assistant Administrator
Office of Policy and Program Development