VERMONT AGENCY OF AGRICULTURE, FOOD & MARKETS
FOOD SAFETY CONSUMER PROTECTION DIVISION
Meat Inspection Service
MONTPELIER, VT
Anson Tebbetts, Secretary

MIS DIRECTIVE **Adopted from FSIS Directive 8010.1Rev. 6**	8010.1 Revision 6	03/28/2022

METHODOLOGY FOR CONDUCTING IN-COMMERCE SURVEILLANCE ACTIVITIES

CHAPTER I – GENERAL INFORMATION

I. PURPOSE

This directive provides instructions to Compliance and Enforcement Officers and 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), Humane Methods of Slaughter Act (HMSA) (the Acts), and related laws and regulations.

KEY POINTS:

- *States authority for in-commerce surveillance activities, including access to and examination of product, facilities, and records*
- *Describes in-commerce surveillance activities, including prioritizing, preparing for, and conducting surveillance activities*
- *Describes procedures for documenting in-commerce surveillance activities*
- Explains recordkeeping requirements to trace ground beef products at in-commerce retail firms

II. CANCELLATION

VT Directive 8010.1, Revision 5, Methodology for Conducting In-Commerce Surveillance Activities, dated 12/01/16

III. BACKGROUND

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

B. The VT Statutes provide authority for the effective regulation of meat and poultry products and contain provisions pertaining to adulteration, misbranding, prohibited acts, imports, exemptions, access and

examination, recordkeeping, product detention and seizure, and criminal, civil, and administrative sanctions and remedies for addressing violations.

IV. ACCESS AND EXAMINATION

The VT Statutes contain authority to conduct inspections and examinations of the premises, facilities, inventory, records, equipment, and operations of state-inspected establishments and in-commerce facilities, such as warehouses and distribution centers. The VT Statutes contain provisions that require specified persons, firms, and corporations to keep records and provide access for examination of facilities, inventory, and records. Specifically, Chapter 204 of 6 V.S.A 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, use photography, inventory, and records of these businesses; to copy records required to be kept under the Acts; and to take reasonable samples of inventory upon payment of the fair market value. Permission from company management to take photographs during surveillance, investigations, or other activities is not necessary The Statutes also provide for penalties for failure to comply with these requirements.

V. GENERAL

A. The purpose of in-commerce surveillance activities carried out by investigators at warehouses, distributors, transporters, retailers, and other in-commerce businesses within the State of Vermont is to ensure that meat and poultry products are safe, wholesome, and correctly labeled and packaged, and to verify that the persons and firms whose business activities involve meat and poultry products prepare, store, transport, sell, offer for sale or transportation, and import such products in compliance with VAAFM statutory and regulatory requirements.

B. In-commerce surveillance activities include:

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

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

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

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

1. Investigators are to maintain working relationships and personal contacts within the Agency;

with other Federal, State, and local government agencies and officials; and with appropriate outside entities. These contacts may assist Investigators in conducting surveillance or other regulatory activities.

2. These contacts include, but are not limited to, Food and Drug Administration (FDA), Animal and Plant Health Inspection Service (APHIS), Customs and Border Protection (CBP), VT AG, Department of Homeland Security (DHS), VT Agency of Transportation (DOT), FSIS, and other State Meat and Poultry Inspection (MPI) programs.

CHAPTER II – PRIORITIZATION AND PREPARATION

I. PRIORITIZING IN-COMMERCE SURVEILLANCE ACTIVITIES

A. In carrying out VAAFM public health mission, Investigators are to conduct in-commerce surveillance activities based on public health priorities.

B. Prior to conducting in-commerce surveillance activities, Investigators are to:

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

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

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

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

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

6. Be aware of the current threat condition level in the National Terrorism Advisory System (NTAS) and plan surveillance activities accordingly, as outlined in VT Directive 5420.3, *Food Defense Surveillance Procedures and National Terrorism Advisory System Alert Response for the Office of Investigation, Enforcement and Audit.*

II. INVESTIGATOR SURVEILLANCE PRIORITIES

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

B. To focus surveillance resources on in-commerce businesses with the highest risk, VAAFM recognizes different business types and public health risk. There are five risk considerations: food safety hazard, food defense hazard, product volume, consumer susceptibility, and surveillance by other regulatory authorities:

1. Business types with the higher risk generally have significant inherent hazards; handle large volumes of meat, poultry, and egg products; and receive minimal surveillance by other regulatory authorities. These businesses are a high priority. Business types are:
    a. Distributors, Warehouses
    b. 3D/4D Operators, Custom Exempt, Exempt Poultry, Food Banks, Retailers, Salvage, and Transporters;

2. Business types with lower risk generally handle smaller volumes of meat, poultry, and egg products, or receive more significant surveillance from other regulatory authorities. Business types include Abattoir, Animal Food, Bonded Warehouse, Broker, Institutions, Point of Entry, Processor, Renderers, Restaurants, and Miscellaneous;

3. Businesses that are inactive are in those that are either no longer operating but have a compliance history or are operating but do not currently handle VAAFM regulated product.

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

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

2. Conduct follow-up surveillance activities at higher risk businesses, generally, before conducting other surveillance activities, if possible (II. B. 1. a and b above);

3. Conduct surveillance activities at higher risk businesses that have not been surveilled previously before conducting surveillance at the same type of businesses that have been surveilled previously;

4. Conduct surveillance activities at higher risk businesses with greater frequency than at lower risk businesses;

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

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

IV. PREPARING FOR IN-COMMERCE SURVEILLANCE ACTIVITIES

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

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

    a. Laptop computer, printer, and scanner;

    b. Digital camera;

    c. Flashlight;

d. “VT Detained” tags;

e. Freezer coat;

f. Hard hat;

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

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

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

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

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

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

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 Attorney General investigations);

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

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

3. As related to ANet/ICS and USA Herds/USA Plants information, Investigators are to:

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

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

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

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

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

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

d. Determine whether the person or firm to be surveilled is licensed, if applicable, in accordance with 6 V.S. A Chapter 204. If the person or firm has not registered, be prepared to provide a copy Meat and Poultry Program Handlers License application or retail license application;

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

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

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

CHAPTER III – SURVEILLANCE METHODS

I. PROCEDURES FOR IN-COMMERCE SURVEILLANCE ACTIVITIES

A. Introduction and credentials:

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

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

3. Investigators are not to allow their credentials to leave their possession or to allow the credentials to be photocopied. (Title 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 supervisory or management personnel.

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

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

6. If at any time Investigators eel threatened while conducting surveillance activities, they are to leave the situation immediately, go to a secure area, and contact the Meat Inspection Office, or Local Police Department.

B. Determining the business type:

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

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

3. Because the business activities may have changed since the time of the last contact or may be different from the business type licensed, Investigators may need to update the current firm information. If additional information related to the firm, needs to be part of the firm record, Investigators are to attach documents in the File Attachments.

II. FOOD SAFETY

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

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

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

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

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

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 Statutes; 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 Statutes.

B. To accomplish food safety verification activities, 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 products;

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

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

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

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

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

C. To determine whether meat and poultry 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 and poultry products:

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

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

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

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

2. Sanitary conditions:

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

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

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

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

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

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

3. Hazard controls:

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

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

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

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

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

f. Does the firm consider hazards that can occur during mail-order delivery to the consumer?

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

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

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

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

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

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

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

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

1. There are 4 Attachments included with this directive:

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

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

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

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

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

III. FOOD DEFENSE

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

B. To accomplish food defense verification activities:

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

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

IV. NON-FOOD SAFETY CONSUMER PROTECTION

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

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

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

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

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

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

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

C. To determine whether meat, poultry 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?

D. To determine whether meat and poultry 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 relating to meat, poultry, and egg products and specific ingredients or components (e.g., fat, soy, or water) that if substituted, abstracted, or omitted, may cause products to be economically adulterated; and

3. Collect samples for laboratory analysis, as necessary.

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

V. IMPORTED PRODUCTS

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

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

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 inspection (i.e., “U.S. Inspected and Passed”);
    a. Determine if product was imported from Canada; and

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

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

3. Request from the importer of record, product owner, custodian, broker, or other interested party, documents relating to the importation of the product in question. Related documents include, but are not limited to, FSIS Form 9540-1, Import Inspection Application and Report, an inspection certificate issued by the foreign government certifying that the product is eligible for importation into the U.S., U.S. Customs and APHIS paperwork, and bills of lading; and

4. Use PHIS (if available) to verify that products:

    a. Originated from eligible foreign countries;

    b. Originated from certified foreign establishments;

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

    d. Were reinspected and passed by FSIS.

5. Investigators may also use the FSIS website: to verify eligible countries and establishments

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

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

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

VII. ORDER VERIFICATION

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

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

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

3. Contact, if necessary, the probation officer, if one is assigned in the case, to discuss any questions or issues. Contact the Agency's Assistant Attorney general if necessary.

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

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

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

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

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

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

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

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

3. Document his or her findings, as well as any actions taken and the individuals contacted, and;

VIII. PUBLIC HEALTH RESPONSE

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

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

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

D. When conducting activities related to reports of foodborne illness potentially associated with meat, poultry products, Investigators are to follow the instructions of the VT Department of Health;

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

IX. EMERGENCY RESPONSE

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

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

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

CHAPTER IV – SURVEILLANCE FOLLOW-UP

I. FOLLOW-UP SURVEILLANCE

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

1. Compliance with VT statutory and regulatory requirements;

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

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

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

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

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

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

1. The business type;

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

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

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

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

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

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

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

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

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

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

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

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

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

3. Other information subsequently provided (e.g., office).

II FOLLOW-UP REMINDERS

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

B. Outlook will generate reminders to Investigators to conduct follow-up surveillance activities.

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

CHAPTER V – DOCUMENTATION

I. SURVEILLANCE FINDINGS

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

1. Update the firm information record, where needed.

2. Document their findings by completing form MI-C&E- 8010.1 Investigators are to use the surveillance summary page to obtain a signature from a representative of the firm and provide a copy of the surveillance summary page to a representative of the firm either by hand delivery or by email.

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

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

1. Follow, as applicable, the instructions in Directive 5420.3; and

2. Document their findings.

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

II. SURVEILLANCE NOTES

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

B. 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 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 Directives 8010.2 and 8010.3 relevant to investigative notes.

CHAPTER VI – APPARENT VIOLATIONS AND OTHER IRREGULARITIES

I. VIOLATIONS SPECIFIC TO RETAIL VENDORS

A. When Investigators observe apparent violations while conducting surveillance activities at a retailer that involves **failing to maintain ground beef recordkeeping requirements or misbranded retail exempt meat or poultry**, they are to take the following actions:

1. Inform the managing official, designee, or owner of the violation and explain how they can voluntarily comply.

2. Document these findings on the MI-CE-8010.1 Surveillance Record

3. Obtain a signature from the managing official, designee, or owner and provide them with a copy of the surveillance summary page.

4. Schedule a follow-up according to Chapter IV of this directive to determine if corrective actions have been taken to bring the retailer back into compliance.

B. When, during the first scheduled follow-up surveillance , Investigators observe that corrective actions have not been taken and the retail vendor is still In violation, Investigators are to take the following actions:

1. Follow steps 1-4 in part A of this section

2. inform the MSCES of the failure to voluntarily comply and recommend a Letter of Information be sent to the retailer.

C. When, during the second scheduled follow-up, Investigators observe that corrective actions have not been taken and the retail vendor is still In violation, Investigators are to take the following actions:

1. Initiate an investigation;

2. Initiate a product control action or issue a stop sale notice for any misbranded meat or poultry observed;

3. Notify their 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. APPARENT VIOLATIONS

A. When conducting surveillance activities, Investigators may observe apparent food safety violations of the Statutes, Agency regulations, or applicable criminal, civil, or administrative orders or other 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 the product custodian of the apparent violation;

2. Initiate an investigation;

3. Initiate a product control action; or

   Notify their 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 food safety violations or other irregularities involving non-amenable products or facility conditions that, although not subject to VAAFM jurisdiction, are subject to the laws and regulations of other Federal, State, or local agencies.

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

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

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

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

4. Document, the food safety violation or other irregularity observed and the contact and referral to the appropriate Federal, state, or local agency.

Refer questions through supervisory channels.

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

I. INTRODUCTION

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

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

C. MIS 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. MIS Investigators are only to collect raw ground beef samples during a surveillance if the ground beef was prepared using source materials that was slaughtered and/or processed under VT State inspection.

B. 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.

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

1. grinding primals, subprimals, purchased trim, boxed beef, or other components (i.e., mechanically separated beef or partially defatted beef fatty tissue), that are not accompanied by records of negative *E. coli* O157:H7 test results;

2. grinding store generated bench trim derived from its own operations with special emphasis on bench trim generated from non-intact meat cuts such as those that have been mechanically tenderized or enhanced;

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

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

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

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

6. mixing irradiated and non-irradiated beef;

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

8. grinding under insanitary conditions.

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

III. HOW TO COLLECT A SAMPLE OF RAW GROUND BEEF

A. Investigators are to follow the collection instructions below.

1. Randomly select a retail store. Obtain a random 1-pound sample of an unopened (intact), raw ground beef packaged product, if possible; otherwise, have a store employee collect and package (as an intact package) a 1-pound ground beef sample from the grinder head (after grinding). Place the retail packaged sample in a sample bag for this purpose. Close the bag securely. Label the bag with the sample identification label. Follow VT Directive 7355.1, Use of Sample Seals for Laboratory Samples and Other Applications. If there is no unfrozen product available to sample, collect a random 1-pound intact sample of frozen product.

2. Fill out the VT Department of Health Laboratory Sample form. Place the sample request form in a plastic bag and place the plastic bag into the shipping container with the sample.

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

4. Refrigerate unfrozen samples, do not freeze. If the sample was frozen at the time of collection, keep it frozen. Drop off the sample at the laboratory the same or following day of collection. Use sufficient frozen coolant to keep samples cold during transit. Do not drop off samples on the day before a State holiday.

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

IV. WHEN NOT TO COLLECT SAMPLES

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

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

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

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

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

V. SUPPLIES

A. Investigators can get forms and supplies from the Meat Inspection office.

VI. DOCUMENTATION

A. Investigators are to write in “Firm ID” and “Surveillance ID” in the available space. The identification numbers assist with matching the sample form with the surveillance information.

1. If the Investigator knows the Firm ID and Surveillance ID at the time he or she completes the form.

2. If the Investigator has only one of the identification numbers, he or she documents the one available.

C. When a sample is not collected, the Investigator documents the reason .

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

2. If the product is not ground by the retail store but only portioned into retail trays.

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

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

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

6. If there is another reason , the investigator explains in additional comments.

VII. WHAT TO DO IF SAMPLE RESULTS ARE CONFIRMED POSITIVE

A. If a raw ground beef sample tests positive for *E. coli* O157:H7, the meat inspection office is notified.

B. Investigators are to:

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

2. assist with a possible recall;

3. collect follow-up investigative samples, at the discretion of management within a 120-day period; and

ATTACHMENT 4: Definitions of Firm/Business Types

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

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

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

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

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

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

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

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

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

Food Bank: An organization that collects or purchases meat, poultry, shell eggs, and/or egg products from manufacturers, wholesalers, retailers, and/or government agencies to store and donate collected

product to non-profit emergency and community food programs.

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

Institution: An organization founded and united for a specific purpose that prepares meals containing meat, poultry, and/or egg products for resident populations (*e.g.*, hospital, prison).

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

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

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

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

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

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

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

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

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

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

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